Board Meetings held in Common

Date: 28 June 2019

Agenda item: 7

Paper Title: Items which should not be routinely prescribed in primary care: an update and a consultation on further guidance for CCGs

Report by: Professor Stephen Powis, National Medical Director

---

Making Responsibility:

NHS England	☐
NHS Improvement	☐
NHS England and NHS Improvement	☒
N/A - joint discussion	☐

Introduction

1. In November 2018, the NHS England Board approved publication of a set of proposals to update Clinical Commissioning Group's (CCGs) guidance on items which should not be routinely prescribed in primary care. NHS England and NHS Clinical Commissioners (NHSCC) consulted publicly on these proposals between November 2018 and February 2019.

2. This paper sets out the findings of the consultation and seeks the Board's agreement on the proposed next steps.

The Board is invited to:

3. Consider and note the findings of the public consultation in relation to the one updated and eight new items considered to be relatively ineffective or for which there are other more effective and/or cheaper alternatives; there are also products which are no longer appropriate to be prescribed on the NHS.

4. Approve the final recommendations and the publication and dissemination of updated guidance to CCGs.

Context

5. Last year 1.1 billion prescription items were dispensed in primary care at a cost of £8.8 billion (source: NHS Digital Prescription Cost Analysis 2018). However, there is significant variation in what is being prescribed and to whom. Often patients are

receiving medicines which are relatively ineffective or for which there are other more effective and/or cheaper alternatives; there are also products which are no longer appropriate to be prescribed on the NHS.

6. In response to calls from GPs and CCGs who were having to take individual decisions about their local formularies, NHSCC surveyed their members to assess views on whether a range of medicines and other products should be routinely available for prescription on the NHS.

7. CCGs asked for a nationally co-ordinated approach to commissioning guidance developed by NHS England and NHSCC. The aim was a more equitable basis on which CCGs could take individual and local implementation decisions.

8. NHS England and NHSCC established a jointly-chaired clinical working group, with membership including GPs and pharmacists, CCGs, Royal College of General Practitioners, National Institute for Health and Care Excellence (NICE), Department of Health and Social Care, the Royal Pharmaceutical Society and others. This clinical working group was tasked with identifying which products should no longer be routinely prescribed in primary care.

9. Work focused on developing guidelines for an initial list of eighteen products which fell into one or more of the following categories:

    - Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns;
    - Products which are clinically effective but where more cost-effective products are available, including some products that have been subject to excessive price inflation; and
    - Products which are clinically effective but due to the nature of the product are deemed a low priority for NHS funding.

10. The NHS England Board agreed to a public consultation on specific proposals for the eighteen products, to seek views on the proposed recommendations on the routine prescribing of eighteen products.

11. In November 2017 following NHS England Board approval, CCG guidance on items which should not routinely be prescribed in primary care, including recommendations for these eighteen products was published.

12. Progress against forecasted primary care spend reduction in 2019/20 is broadly on track, although further CCG implementation is required to expediate reduction of unwarranted variation.

13. NHS England and NHSCC committed to a 12-month post publication review of this guidance. In Autumn 2018 the clinical working group reviewed the CCG guidance recommendations and identified one proposed update to the recommendations on rubefacients and eight new items including:
    a. Aliskiren;
    b. Amiodarone;

c. Bath and shower preparations for dry and pruritic skin conditions;
d. Blood glucose testing strips for type 2 diabetes;
e. Dronedarone;
f. Minocycline for acne;
g. Needles for Pre-Filled and Reusable Insulin Pens; and
h. Silk garments.

14. Proposals were subject to a three-month consultation from 28 November 2018 to 28 February 2019. The consultation sought views on the proposed recommendations on the routine prescribing of one updated and eight new products, on which we published draft guidance to CCGs and an Equalities and Health Inequalities Impact Assessment for consultation.

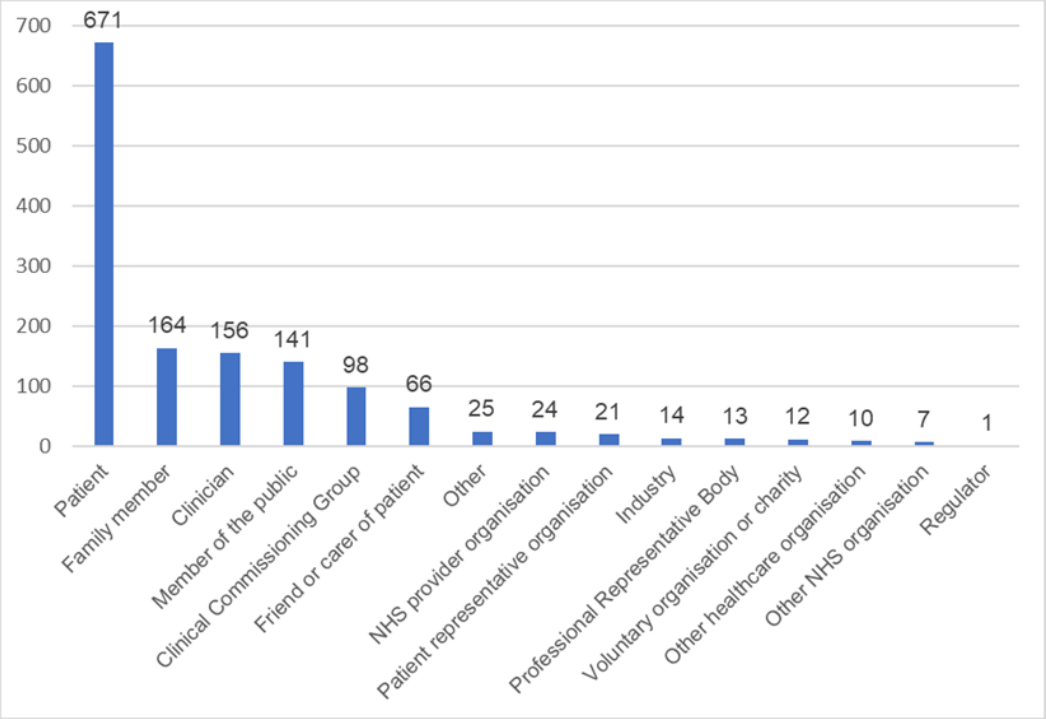
Consultation Responses

15. A full analysis and report on the consultation responses is attached at **Annex A**.

16. 1461 responses were received through the online consultation survey and 54 submissions by post or email. In addition, we held seven webinars for stakeholders, and two face-to-face public and patient stakeholder events in London and Birmingham, alongside three individual meetings with key stakeholder groups including industry and the Royal Colleges.

17. Chart 1 below shows responses for the 1423 respondents who told us in what capacity they were responding. 38 respondents did not tell us in what capacity they were responding. Nearly half the responses were from patients.

Chart 1. Number of responses by respondent type (Total 1423)



18. The draft guidance has been reviewed in light of the responses, discussion through the webinars and the engagement exercises, as well as recommendations from the joint clinical working group. Most aspects of the final guidance remain unchanged from the draft guidance shared with the Board in November 2018.

19. However, in light of the consultation and following further advice, one significant change has been to remove blood glucose strips from the guidance. It was recommended that blood glucose testing strips were not included while further work is being undertaken on the features of different testing meters, the quality of different testing strips and how these factors may impact on the choice of blood glucose testing strip. The guidance to CCGs therefore makes no recommendations on blood glucose testing strips for type 2 diabetes.

20. The total primary care spend for the seven new items included in the final updated guidance (not including blood glucose testing strips) is £41.6m (BSA, 2018/19). If NHS prescribing were in line with the top performing CCGs, the estimated saving from the guidance would be £22.4m (Source: OpenPrescribing.net, 2018/19). These figures and methodology will require some further refinement before they can be used for monitoring purposes.

Changes to the Guidance

21. Based on the consultation findings there have also been some further reviews and important refinements and clarifications as follows:

Aliskiren

22. Based on the consultation, the clinical working group did not feel it necessary to amend the proposed recommendations for aliskiren. Of the 130 respondents, 89% agreed and 8% disagreed that CCGs should advise prescribers in primary care not to initiate aliskiren for any new patient. 82% agreed and 12% disagreed that CCGs should support deprescribing of aliskiren in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Amiodarone

23. Based on the consultation, the clinical working group did not feel it necessary to amend the proposed recommendations for amiodarone. Of the 171 respondents, 79% agreed and 16% disagreed that CCGs should advise prescribers in primary care not to initiate amiodarone for any new patient. 85% agreed and 8% disagreed that CCGs should support prescribing in exceptional circumstances, if there is a clinical need, in a cooperation arrangement with a multi-disciplinary team.

Bath and shower preparations for dry and pruritic skin conditions

24. Based on the consultation and Specialist Pharmacist Service (SPS) evidence review (**Annex B**), the clinical working group did not feel it necessary to amend the recommendations significantly. The group acknowledged that whilst feedback from patients indicated that bath and shower products should be available as a

treatment option, there is an absence of good quality clinical evidence to support this. The group also recognises that the clinical evidence relied upon in reaching the recommendations refers primarily to children but again felt that in the absence of other good quality evidence (e.g. randomised controlled trials), it is acceptable to extrapolate the evidence pertaining to children to adults until better quality evidence emerges for adults.

25. Of the 581 respondents 31% agreed and 65% disagreed that CCGs should advise prescribers in primary care not to initiate bath and shower preparations for any new patients. 42% agreed and 52% disagreed that CCGs should support deprescribing of bath and shower preparations and support substitution with 'leave-on' emollients and, where appropriate, to ensure the availability of relevant services to facilitate this change.

Blood glucose testing strips for type 2 diabetes

26. Although consultation results are reported, on advice of the NHS England and NHS Improvement Diabetes team, further work is being undertaken on the features of different testing meters available, the quality of different testing strips and how this may impact on the choice of blood glucose testing strip. It is proposed that the clinical working group await and review the outcome of this work before making any final CCG recommendations on blood glucose testing strips. The guidance to CCGs therefore makes no recommendations on blood glucose testing strips for type 2 diabetes.

Dronedarone

27. Based on the consultation, the clinical working group did not feel it necessary to amend the proposed recommendations for dronedarone. Of the 140 respondents 82% agreed and 14% disagreed that CCGs should advise prescribers in primary care not to initiate dronedarone for any new patient. 83% agreed and 9% disagreed that CCGs should support prescribing in exceptional circumstances, if there is a clinical need, in a cooperation arrangement with a multi-disciplinary team.

Minocycline for acne

28. Based on the consultation, the clinical working group did not feel it necessary to amend the proposed recommendations for minocycline. Of the 159 respondents 82% agreed and 13% disagreed that CCGs should advise prescribers in primary care not to initiate minocycline for any new patient. 84% agreed and 4% disagreed that CCGs should support deprescribing minocycline in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Needles for pre-filled and reusable insulin pens

29. The clinical working group proposed that the recommendations remain unchanged but with clarification for the use of safety needles in particular settings. Of the 454

respondents, 41% agreed and 50% disagreed that CCGs should support prescribers in primary care to not initiate insulin pen needles that cost more than £5 per 100 needles for any new patient. 49% agreed and 41% disagreed that CCGs should support deprescribing of insulin pen needles that cost more than £5 per 100 needles and, where appropriate ensure the availability of relevant services to facilitate this change.

Silk garments

30. Based on the consultation and SPS evidence review (**Annex C**) the clinical working group did not feel it necessary to amend the recommendations significantly. The SPS review presented no clear or robust evidence base to support the routine use of silk garments in the NHS. Of the 355 respondents 48% agreed and 48% disagreed that CCGs should advise prescribers in primary care not to initiate silk garments for any new patient. 58% agreed and 36% disagreed that CCGs should be advised to support the deprescribing of silk garments in all patients and, where appropriate, to ensure the availability of relevant services to facilitate this change.

Rubefacients

31. The recommendations consulted on for this item was an update to the 2017 guidance. NICE guidance advises that capsaicin cream can be prescribed and so the updated proposal was to exclude capsaicin cream from the recommendation to deprescribe. Based on the consultation, the clinical working group did not feel it necessary to amend the updated recommendations for rubefacients. Of the 727 respondents 41% agreed and 23% disagreed that CCGs should advise prescribers in primary care not to initiate rubefacients (excluding topical NSAIDs and capsaicin) for any new patient. 44% agreed and 18% disagreed that CCGs should support deprescribing rubefacients in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

Additional recommendations

32. In relation to a number of products, the consultation included feedback about patients with exceptional circumstances where no other medicine or intervention is clinically appropriate and available for the individual. Because of what we heard in the consultation the definition of *routine* was slightly amended to reflect that the recommendations apply to the routine prescribing of items in primary care and not to patients where there is a **clinically** exceptional reason for a prescription.

Next steps

33. The final proposed guidance for CCGs is attached at **Annex D** for the Board's consideration and approval to publish. This is accompanied by an Equalities Impact Assessment, attached at **Annex E**.

34. CCGs will be expected to take this guidance into account in formulating local policies, and prescribers should reflect these local policies in their prescribing

practice. This guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

35. A number of resources have been made available to CCGs to support local implementation including: quick reference guides, patient information leaflets and data visualisation dashboards and tools.

Recommendations

36. The Board is invited to:

- Consider and note the findings of the public consultation in relation to the one updated and eight new items considered to be relatively ineffective or for which there are other more effective and/or cheaper alternatives; there are also products which are no longer appropriate to be prescribed on the NHS.

- Approve the final recommendations and the publication and dissemination of updated guidance to CCGs.

Report of findings: Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs

NHS England

Items which should not routinely be prescribed in primary care: Consultation Report of Findings

Version number: 1

First published: TBC

Prepared by: Midlands and Lancashire Commissioning Support Unit

Classification: OFFICIAL

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages upon request. Please contact england.medicines@nhs.net

DRAFT

Contents

DRAFT

1 Background

1.1 The issue to tackle

It is important that the NHS achieves the greatest value from the money that it spends. Last year 1.1 billion prescription items were dispensed in primary care at a cost of £8.8 billion and across England there is significant variation in what is being prescribed and to whom. In addition, patients continue to receive medicines which have been proven to be ineffective or in some cases dangerous, and/or for which there are other more effective, safer and/or cheaper alternatives.

Clinical Commissioning Groups (CCGs) therefore asked for a nationally-coordinated approach to the development of commissioning guidance to ensure consistency and address unwarranted variation. As part of the review of medicines which could be considered to be of a 'low clinical priority', NHS England has continued to partner with NHS Clinical Commissioners to support CCGs in ensuring that they use their prescribing resources effectively and deliver the best patient outcomes from the medicines their local population uses. To lead the work, NHS England hosted a clinical working group in partnership with NHS Clinical Commissioners, with prescriber and pharmacy representatives and relevant national stakeholders.

The aim is that guidance will help support a more equitable process for making decisions about medicines; but CCGs will need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reduce health inequalities.

1.2 Developing the proposals

The 'low priority prescribing project' (previously the 'low value medicines project') and working group are led jointly by NHS England and NHS Clinical Commissioners (NHSCC). They were established in April 2017 as CCGs asked for a nationally co-ordinated approach to the creation of commissioning guidance. The aim was to reduce unwarranted variation and introduce a more equitable framework from which CCGs can take an individual and local implementation decision.

During 2017/18, CCG guidance was published by NHS England and NHSCC after a three-month public consultation. The guidance was for:

- Items which should not be routinely prescribed in primary care (November 2017)
- Conditions for which over the counter items should not routinely be prescribed in primary care (March 2018).

In the joint clinical working group, items were considered for inclusion if they were:

- Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
- Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation
- Items which are clinically effective but, due to the nature of the product, are deemed a low priority for NHS funding.

The items included in the most recent consultation include one updated item: rubefacients (excluding topical NSAIDs and capsaicin) and proposals for eight new items including:

a) Aliskiren
b) Amiodarone
c) Bath and shower preparations for dry and pruritic skin conditions
d) Blood glucose testing strips for type 2 diabetes

e) Dronedarone
f) Minocycline for acne
g) Needles for pre-filled and reusable insulin pens
h) Silk garments.

The joint Clinical working group assigned one or more of the following recommendations to the items considered:

- Advise CCGs that prescribers in primary care should not initiate {item} for any new patient
- Advise CCGs that prescribers in primary care should not initiate {item} that cost {price} for any new patient
- Advise CCGs to support prescribers in deprescribing {item} in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change
- Advise CCGs to support prescribers in deprescribing {item} that cost {price} in all patients and where appropriate ensure the availability of relevant services to facilitate this
- Advise CCGs that if, in exceptional circumstances, there is a clinical need for {item} to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional
- Advise CCGs that all prescribing should be carried out by a specialist
- Advise CCGs that {item} should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {circumstance}.

1.3 Overview of the consultation and this report

The consultation ran from 28 November 2018 until 28 February 2019. Following the close of the consultation period, NHS England and NHS Clinical Commissioners analysed and considered all responses received with a summary of the responses published on the NHS England website.

NHS England and NHS Clinical Commissioners, via the joint clinical working group, reviewed the responses received and developed finalised commissioning guidance. The finalised commissioning guidance will then be published with the expectation that CCGs should have regard to it, in accordance with the NHS Act 2006.

Individual CCGs will then need to make a local decision on whether to implement the national commissioning guidance, with due regard to both local circumstances and their own impact assessments.

All the feedback from the consultation is presented in this consultation report of findings.

1.4 Report authors

NHS England commissioned NHS Midlands and Lancashire Commissioning Support Unit (MLCSU) to collate and analyse the feedback from the consultation and produce this report. **The report has been produced by the Communications and Engagement and the Medicines Management Optimisation teams at MLCSU.**

DRAFT

2 Engagement methodology and feedback

This section provides an overview of the feedback channels used for the consultation engagement, the analysis process, the methodology and a profile of the consultation survey respondents.

2.1 Engagement methodology

The consultation engagement activity is outlined in Table 1 and includes the number of responses and events for each activity.

Table 1. Breakdown of responses according to feedback method

Feedback methods	No. responses / events, webinars conducted	Analysis and reporting information
Online survey (31 closed questions and 14 open questions)	1,461	Closed questions are tabulated by respondent type. Open questions are coded, key quotes are identified and tabulated by respondent type. In total, 2,671 open responses to individual questions across the 1461 responses were received and analysed.
Patient and public correspondence (emails and letters)	22	Each item was read and coded against the online survey coding frame and the key findings included in the report.
Specialist and organisational correspondence (emails, letters and formal correspondence)	32	Each item was read and coded against the online survey coding frame. The feedback was then coded by a pharmacist and included in the report.
Face-to-face consultation meetings in London and Birmingham	2	The notes from each event were read and coded against the online survey coding frame and key findings included in the report.
Webinars (general)	3	The recordings and notes from each event were coded against the online survey coding frame and key findings included in the report.
Webinars (targeted to GPs and pharmacists)	2	The recordings and notes from each event were coded against the online survey coding frame and key findings included in the report.
Webinars (targeted to CCGs)	2	The recordings and notes from each event were coded against the online survey coding frame and key findings included in the report.
Events and meetings (professional and industry)	3	The notes from each meeting were read and coded against the online survey coding frame and key findings included in the report.
Easy read survey	119	The responses to the open questions have been coded and key themes incorporated into the report of findings.

DRAFT

2.2 Analysing the engagement feedback

The consultation survey included a combination of 'open text' questions where respondents could write their views and opinions and closed questions where respondents 'ticked' their response to a set of preset responses (for example, 'to what extent to do you agree with [proposal]' with the options: agree, disagree, neither or unsure). The closed questions were tabulated, and responses shown by respondent type.

The open questions were handled differently. A random sample of responses from each open question were read and the key themes (codes) discussed by respondents were listed. This was undertaken for every question. Some codes were replicable across more than one response, while others were specific to a single question. This means that every comment was coded, because the list of themes/codes were not predetermined, but instead emerged from the responses received. The most frequently mentioned themes raised in these open questions are presented in this report; therefore, some questions with high numbers of themes do not have all their themes listed, just the most frequently cited. Themes not included in this report would typically only have one to six mentions. The themes mentioned in this report cover the majority of the comments raised. Tables listing every theme and the frequency they were mentioned have been provided to NHS England and all responses were considered in finalising the CCG guidance.

The base figure refers to the number of survey participants providing an answer to each question. This number varies as involvement in this consultation was voluntary, therefore, participants were able to skip past questions in the survey they did not wish to answer. So for example in the tables broken down by respondent type, some respondents did not tell us in what capacity they were responding.

The coding frames created from the survey were also used to read, code and analyse the correspondence received. The key themes raised in these correspondences are presented in this report.

Notes and recordings from webinars, meetings and events were also read, coded and analysed. Again, the key themes raised in these engagement events are presented in this report.

This report of findings takes into account the feedback from all of the organisations participating in the consultation.

Some organisations have included the views of patients, healthcare professionals and other key stakeholders in their response to this consultation.

During some of these webinars, meetings and events, items from guidance previously consulted upon were discussed. There were also comments regarding previous consultations in correspondence and the online survey. Themes raised relating to previous consultations have been analysed and considered as part of the ongoing monitoring of published guidance.

Supporting evidence, reports, academic papers and other documents which were submitted by organisations were reviewed by NHS England separately.

DRAFT

2.3 Respondent profiling

Table 2 provides an overview of the respondent types for those who completed the questions on demographic characteristics. The base number in the table below therefore refers to the number of respondents who answered the questions on demographic characteristics.

Table 2. Demographic characteristics of consultation respondents

Respondent type			Gender		
Patient	671	47%	Female	991	69%
Member of the public	141	10%	Male	401	28%
Clinician	156	11%	Non-binary	2	0.1%
Family member	164	12%	Trans	1	0.1%
Clinical Commissioning Group	98	7%	Intersex	0	-
Friend or carer of patient	66	5%	Prefer not to say	44	3%
NHS provider organisation	24	2%	***Base***	***1,439***	
Patient representative organisation	21	1%	**Sexual orientation**		
Voluntary organisation or charity	12	1%	Heterosexual	1,184	83%
Other healthcare organisation	10	1%	Gay	29	2%
Other NHS organisation	7	0.5%	Lesbian	5	0.4%
Professional Representative Body	13	0.9%	Bisexual	26	2%
Industry	14	1%	Prefer not to say	182	13%
Regulator	1	0.1%	***Base***	***1,426***	
Other	25	2%	**Age**		
Base	***1,423***		Under 18	16	1%
Ethnicity			19 – 29	102	7%
White: Welsh/English/Scottish/Northern Irish/British	1,207	85%	30 – 39	284	20%
White: Irish	20	1%	40 – 49	348	24%
White: Gypsy or Irish Traveller	0	0%	50 – 59	328	23%
White: Any other White background	38	3%	60 – 69	201	14%
Mixed: White and Black Caribbean	7	0.5%	70 – 79	95	7%
Mixed: White and Black African	1	0.1%	80+	20	1%
Mixed: White and Asian	2	0.1%	Prefer not to say	35	2%
Mixed: Any other mixed background	9	1%	***Base***	***1,429***	
Asian/Asian British: Indian	50	4%	**Religion/beliefs**		
Asian/Asian British: Pakistani	22	2%	Christian	601	42%
Asian/Asian British: Bangladeshi	5	0.4%	No religion	512	36%
Asian/Asian British: Any other Asian background	10	1%	Atheist	59	4%
Black or Black British: Black – Caribbean	5	0.4%	Muslim	30	2%
Black or Black British: Black – African	9	1%	Hindu	31	2%
Black or Black British: Any other Black background	1	0.1%	Jewish	16	1%
Other ethnic background: Chinese	10	1%	Buddhist	7	0.5%
Other ethnic background: Any other ethnic group	23	2%	Sikh	6	0.4%
Base	***1,419***		Any other religion	34	2%
Disability			Prefer not to say	134	9%
Yes	336	23%	***Base***	***1,430***	
No	1,010	70%	**Read the consultation document**		
Prefer not to say	90	6%	Yes	1,351	93%
Base	***1,436***		No	100	7%
			Base	***1,451***	

DRAFT

Table 3 provides an overview of the demographic characteristics of those for those who completed questions on demographic characteristics. The base number in the table below therefore refers to the number of respondents who answered the questions on demographic characteristics.

Table 3. Demographic characteristics of consultation survey respondents

Age			**Gender**		
Under 18	2	2%	Male	19	18%
Between 19 and 30	17	15%	Female	86	80%
Between 30 and 50	49	45%	Prefer not to say	3	3%
Between 50 and 65	30	27%	***Base***	***108***	
Over 65	11	10%	**Disability**		
Prefer not to say	1	1%	Yes	22	20%
Base	***110***		No	81	74%
Read the consultation document			Prefer not to say	6	6%
Yes	96	88%	***Base***	***109***	
No	13	12%			
Base	***109***				

DRAFT

3 Proposals for new commissioning guidance

This section presents the feedback for the items where new commissioning guidance proposals have been created.

3.1 Aliskiren

Table 4 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate aliskiren for any new patient in primary care.

The largest proportion of respondents (89%) agree with the proposal, although support is lowest amongst industry and professional representative bodies and highest amongst NHS provider organisations and other healthcare and NHS organisations.

Table 4. Advise CCGs that prescribers in primary care should not initiate aliskiren for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**89%**	**2%**	**8%**	**2%**	**130**
Patient	64%	0%	29%	7%	14
Member of the public / family member / friend or carer of patient	86%	0%	14%	0%	14
Clinician	90%	5%	5%	0%	21
CCG	97%	2%	2%	0%	63
NHS provider organisation / other healthcare organisation / other NHS organisation	100%	0%	0%	0%	8
Industry / professional representative body	33%	0%	33%	33%	3
Patient representative organisation / voluntary organisation or charity	50%	0%	50%	0%	2
Other	100%	0%	0%	0%	3

Table 5 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to support prescribers in deprescribing aliskiren in all patients, and where appropriate, ensure the availability of relevant services to facilitate this change.

The largest proportion of respondents agree with the proposal (82%), although support is lower among industry and professional representative bodies and patient representative, voluntary organisations and charities.

Table 54. Advise CCGs to support prescribers in deprescribing aliskiren in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**82%**	**4%**	**12%**	**2%**	**131**
Patient	73%	0%	27%	0%	15
Member of the public / family member / friend or carer of patient	87%	7%	7%	0%	15
Clinician	76%	5%	14%	5%	21
CCG	87%	5%	6%	2%	62
NHS provider organisation / other healthcare organisation / other NHS organisation	75%	0%	25%	0%	8
Industry / professional representative body	67%	0%	0%	33%	3
Patient representative organisation / voluntary organisation or charity	50%	0%	50%	0%	2
Other	67%	0%	33%	0%	3

DRAFT

The key themes raised about this proposal in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Patients

Although there are other more effective treatments available, patients should still be given access to aliskiren, if it is shown to work for them. For instance, aliskiren is noted as being an effective treatment for some forms of renal failure.

Members of the public / family members, friends or carers of patients

Comments in support of the proposal include: aliskiren is of limited benefit and not cost-effective, when compared to alternatives and there is a lack of clinical evidence showing the effectiveness of aliskiren, therefore, other more effective treatments should be utilised.

Comments against the proposal include: aliskiren is an effective treatment for some forms of renal failure; it is a suitable alternative for patients who are unable to tolerate other anti-hypertensives and deprescribing aliskiren may not be straight forward in some patient groups.

If this proposal is implemented, there will be a need to educate patients.

Clinicians

Comments in support of the proposal include: there is a lack of clinical evidence showing the effectiveness of aliskiren; it is not a widely used treatment and it should be blacklisted.

Comments against the proposal include: patients should have access to aliskiren, if it is shown to work for them; there are no safety issues to consider with aliskiren prescribing in primary care. However, the proposal should review the shared responsibility of prescribing and monitoring aliskiren between primary and secondary care (such as shared care agreements, guidance on dose titration for primary care and specialist initiation).

Considerations raised by this group include: the cost and impact on the services required to facilitate this change (e.g. GP appointments, referrals and advice from secondary care); that deprescribing aliskiren may not be straight forward in some patient groups; although it is not a widely-used treatment, it is an alternative for patients who are unable to tolerate other anti-hypertensives; and patients should have access to aliskiren if it works for them.

If the proposals were to be implemented, these respondents state: although most healthcare professionals will prescribe aliskiren appropriately, changes should only be made by those who are specialists in this area; the idea of patients currently on aliskiren being transferred back into the care of the hospital specialist should be supported and NHS England should make a decision on the proposal.

CCGs

Comments in support of the proposal include: aliskiren should be blacklisted; there are well-known safety concerns with aliskiren and other more effective drugs should be utilised.

Comments against the proposal include: patients should have access to aliskiren if it works for them.

Similarly to clinicians, other considerations that are raised include: the cost and impact on the services required to facilitate this change (e.g. GP appointments, referrals and advice from secondary care); the need for greater patient education on the implementation of the proposal and that GPs and CCGs should be given adequate support to implement the proposals.

Although this proposal will have little or no effect on local prescribing, due to the small number of patients being prescribed aliskiren, changes should only be made by those who are specialists in this area. However, NHS England should decide on the proposal.

DRAFT

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

There was support raised for the proposal from professional representative bodies. Comments in support of the proposal include: aliskiren should be blacklisted and support for patients who are currently on aliskiren being transferred back into the care of the hospital specialist. However, it was also commented that the unintended consequences of deprescribing need to be monitored and the role of the community pharmacy considered.

Comments against the proposal include: the deprescribing of aliskiren may not be straight forward in some patient groups and aliskiren is an alternative for patients who are unable to tolerate other anti-hypertensives.

Other comments include: NHS England should make a decision on the proposal; changes should only be made by those who are specialists in this area and the proposal should review the shared responsibility of prescribing and monitoring aliskiren between primary and secondary care (e.g. shared care agreement, guidance on dose titration for primary care, specialist initiation).

It was also commented that aliskiren is not a widely-used treatment but may be useful in a small number of patients.

Patient representative organisations / voluntary organisations or charities

The proposal was questioned and it was argued that patients should have access to aliskiren, if it works for them.

3.2 Amiodarone

Table 6 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate amiodarone for any new patient in primary care.

The largest proportion of respondents (79%) agree with the proposal, although support is lowest amongst industry and professional representative bodies and highest amongst CCGs.

Table 6. Advise CCGs that prescribers in primary care should not initiate amiodarone for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**79%**	**2%**	**16%**	**3%**	**171**
Patient	52%	4%	39%	4%	23
Member of the public / family member / friend or carer of patient	74%	0%	21%	5%	19
Clinician	86%	3%	11%	0%	35
CCG	95%	2%	3%	0%	63
NHS provider organisation / other healthcare organisation / other NHS organisation	69%	8%	23%	0%	13
Industry / professional representative body	20%	0%	60%	20%	5
Patient representative organisation / voluntary organisation or charity	33%	0%	33%	33%	6
Other	100%	0%	0%	0%	4

Table 7 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised that if, in exceptional circumstances, there is a clinical need for amiodarone to be prescribed in primary care, this should be undertaken in cooperation with a multi-disciplinary team or other healthcare professional.

DRAFT

The largest proportion of respondents agree with the proposal (85%), although support is lowest amongst patient representative organisations, voluntary organisations and charities and highest amongst CCGs and other respondent types.

Table 7. Advise CCGs that if, in exceptional circumstances, there is a clinical need for amiodarone to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**85%**	**4%**	**8%**	**3%**	**171**
Patient	74%	0%	22%	4%	23
Member of the public / family member / friend or carer of patient	89%	5%	5%	0%	19
Clinician	83%	6%	9%	3%	35
CCG	94%	3%	2%	2%	63
NHS provider organisation / other healthcare organisation / other NHS organisation	85%	8%	8%	0%	13
Industry / professional representative body	60%	0%	20%	20%	5
Patient representative organisation / voluntary organisation or charity	50%	0%	33%	17%	6
Other	100%	0%	0%	0%	4

The key themes raised about this proposal in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Patients

Comments against the proposal include: amiodarone is an effective treatment and the proposal may lead to adverse patient outcomes and quality of life.

Comments in support of the proposal include: amiodarone is of limited benefit to patients; it is associated with many adverse side effects and there are other more effective alternatives that could be used.

Considerations raised by this group include: the need for clearer guidance and explanation on the proposal; changes should only be made by those who are specialists in this area; and the proposal should review the shared responsibility of prescribing and monitoring amiodarone between primary and secondary care (e.g. shared care agreement, guidance on dose titration for primary care, specialist initiation).

Members of the public / family members, friends or carers of patients

Comments in support of the proposal include: amiodarone is associated with many adverse side effects and is of limited benefit to patients and other more effective drugs should be utilised.

Comments against the proposal include: amiodarone is an effective treatment; implementing the proposal may lead to adverse outcomes on the quality of life of some patients and the impact of increased workload on the NHS should be considered.

This respondent group also said national guidance should be implemented, rather than individual CCGs implementing their own. A number of questions around the proposal were raised, therefore clearer guidance and explanation is required.

Clinicians and CCGs

Both respondent groups said clearer guidance and explanation is required about the proposal. In particular, the proposal should review the shared responsibility of prescribing and monitoring amiodarone between primary and secondary care (e.g. shared care agreement, guidance on dose titration for primary care, specialist initiation), because the

DRAFT

proposal may lead to inequality of treatments for patients (e.g. a two-tiered system where patients already on amiodarone will continue to be supported by just primary care, whilst newly initiated patients will be under a shared care service).

Additionally, changes should only be made by those who are specialists in this area, and therefore there is a need to consider the impact of increased workloads on staff.

Clinicians

This respondent group said NHS England should decide on the proposals and national guidance should be implemented, rather than individual CCGs implementing their own.

CCGs

In support of the proposal, this respondent group said amiodarone is an effective treatment. However, they were concerned the proposal may lead to adverse patient outcomes and quality of life. Also, the cost of this item has increased.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

Several organisations expressed support for the proposals for amiodarone. However, clearer guidance and explanation is required.

Considerations raised by this respondent group include: the proposal should review the shared responsibility of prescribing and monitoring amiodarone between primary and secondary care; changes should only be made by those who are specialists in this area; the impact of increased workload on NHS staff and the impact on vulnerable groups, high risk groups, BME, elderly and pregnant women. Finally, this respondent group comment NHS England should decide on the proposal.

Patient representative organisations / voluntary organisations or charities

In support of the proposal this respondent group said amiodarone is associated with many adverse side effects.

However, comments raised against this proposal include: amiodarone is an effective treatment and the proposal may lead to adverse patient outcomes and quality of life.

DRAFT

3.3 Bath and shower preparations for dry and pruritic skin conditions

Table 8 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate bath and shower preparations for dry and pruritic skin conditions for any new patient in primary care.

The largest proportion of respondents (65%) disagree with the proposal, with disagreement highest among patient and public respondents. However, a large proportion of CCGs agree with the proposal.

Table 8. Advise CCGs that prescribers in primary care should not initiate bath and shower preparations for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**31%**	**2%**	**65%**	**2%**	**581**
Patient	12%	1%	84%	3%	231
Member of the public / family member / friend or carer of patient	18%	1%	81%	1%	165
Clinician	57%	5%	38%	0%	63
CCG	96%	0%	3%	1%	72
NHS provider organisation / other healthcare organisation / other NHS organisation	64%	0%	36%	0%	14
Industry / professional representative body	15%	0%	77%	8%	13
Patient representative organisation / voluntary organisation or charity	11%	0%	78%	11%	9
Other	33%	33%	33%	0%	6

Table 9 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to support prescribers in the deprescribing of bath and shower preparations and substitute them with 'leave-on' emollients, and, where appropriate, ensure the availability of relevant services to facilitate this change.

The largest proportion of respondents disagree with the proposal (52%), with high levels of disagreement among patient representative and voluntary organisations or charities. However, a large proportion of CCGs agree with the proposals.

Table 9. Advise CCGs to support prescribers in deprescribing bath and shower preparations in this category and substitute with 'leave-on' emollients and, where appropriate, to ensure the availability of relevant services to facilitate this change.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**42%**	**3%**	**52%**	**4%**	**582**
Patient	25%	4%	65%	6%	230
Member of the public / family member / friend or carer of patient	29%	2%	66%	3%	166
Clinician	70%	3%	27%	0%	63
CCG	93%	1%	3%	3%	73
NHS provider organisation / other healthcare organisation / other NHS organisation	71%	0%	21%	7%	14
Industry / professional representative body	31%	0%	62%	8%	13
Patient representative organisation / voluntary organisation or charity	11%	0%	78%	11%	9
Other	67%	0%	33%	0%	6

DRAFT

The key themes raised about this proposal in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Patients and members of the public / family members, friends or carers of patients

Comments against the proposal include: the proposal takes a blanket approach, which does not consider the needs of individual patients; bath and shower preparations are an effective treatment and patients should have access to them as an option; there is concern that the research used to inform the proposal is inadequate and should be considered not valid; effective bath and shower preparations may not be widely available over the counter; the proposal may lead to adverse outcomes on patient quality of life (e.g. pain, infections) and the adverse effects on patients could ultimately cost the NHS more money.

Considerations raised by this respondent group include: the impact on vulnerable age groups (young children, elderly); the impact on low income groups or those from a lower socioeconomic background and exempting specific groups of people and ensuring these exemptions are clear to avoid deprescribing across the board.

Focusing on leave-on emollients, this respondent group said these items also present a risk of falls.

Clinicians

Comments in support of the proposal include: these items should be blacklisted and there is a lack of clinical evidence showing the effectiveness of bath and shower products.

Comments against the proposal include: there is concern that the research used to inform the proposal is inadequate and should be considered not valid; the proposal is a blanket approach, which does not consider the needs of individual patients; patients should have access to these items as a treatment option; these items are an effective treatment and the proposal may lead to adverse patient outcomes and quality of life (e.g. pain, infections, worsening of conditions).

This respondent group said NHS England should decide on the proposals, taking into consideration the impact on NHS resources (e.g. dealing with complaints and difficult patients).

CCGs

Comments in support of the proposal include: these items should be blacklisted; these items are available to buy over the counter; there is a lack of clinical evidence to support their use and there is an increase in the risk of falls when using these items.

Comments against the proposal include: there is concern that the research used to inform the proposal is inadequate and should be considered not valid; and these items are an effective treatment.

Considerations raised by this respondent type include: the impact on vulnerable age groups (e.g. children; elderly, low income groups); exempting specific groups of people (e.g. children, those with genital dermatoses or hand dermatitis); the impact on NHS resources (e.g. time-consuming dealing with complaints or difficult patients for GPs and other NHS staff); the need to ensure alternative treatments are available and the need to include the views of health visitors.

This respondent group also express a need for greater public education, specifically, on the cost and lack of clinical effectiveness of these items. There is also a lack of understanding around the correct use of emollients which needs to be tackled because incorrect use can lead to a reduction in treatment efficacy.

Finally, this respondent group suggest that NHS England should decide on the proposal.

DRAFT

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

Comments were raised both in support and against the proposal from this respondent group.

Comments raised in support of the proposal include: more expensive items should be blacklisted; there is a lack of clinical evidence for the effectiveness of bath and shower preparations; patients should be counselled on the risks and benefits of using these products and the need to include additional evidence to support the proposal.

An organisation supporting the proposal raised questions and said there should be specific groups of people that are exempt, such as: children, those with genital dermatoses, hand dermatitis, eczema, ichthyosis and psoriasis.

Comments against the proposal were raised by several organisations; these include: patients should have access to bath and shower preparations as a treatment option; these items are an effective treatment; the proposal opposes the current NICE guidance; the proposal limits access to treatments and does not consider patient choice; the proposal will disproportionately affect ethnic minorities; the proposal takes a blanket approach and does not consider the needs of individual patients; the proposal may lead to adverse outcomes on patient quality of life (e.g. pain, infections) which could ultimately cost the NHS more money; and there is concern that the research used to inform the proposal is inadequate and should be considered not valid.

A pharmaceutical company highlighted additional studies supporting the use of bath and shower preparations, while it was commented that further research into soap substitutes is required before the proposal is implemented. A pharmaceutical company explained the clinical efficacy of licensed medications will already have been determined by the Medicines and Healthcare products Regulatory Agency (MHRA).

Considerations raised by this respondent group include: the impact on vulnerable age groups (e.g. young children and the elderly); the impact on those with a low income and from a lower socioeconomic background; the advantages of using this item in specific groups (primarily children and those with a disability) over other bath products; the impact on NHS resources and exempting antimicrobial bath and shower preparations.

An organisation also commented that leave-on emollients being used as soap substitutes may be impractical (e.g. in areas of hard water).

Focusing on the financial implications, concern was raised that substituting bath and shower preparations for leave-on emollients is not a cost saving.

Patient representative organisations / voluntary organisations or charities

Comments against the proposal were raised by a number of patient representative and voluntary organisations / charities.

Comments against the proposal include: the proposal takes a blanket approach and does not consider the needs of individual patients; bath and shower preparations are an effective treatment; patients should have access to these items as a treatment option; bath and shower preparations should continue to be prescribed for eczema patients.

There is concern that the research used to inform the proposal is inadequate and should be considered not valid; the proposal may lead to adverse patient outcomes and quality of life; and the adverse effects on patients could ultimately cost the NHS more money.

Considerations made by this respondent group include: the impact on vulnerable age groups such as young children and the elderly; the impact on those with a low income or from a lower socioeconomic background; the exemptions to the proposals for these items should be made clear to avoid deprescribing across the board.

Other

Comments raised in support of the proposal include: bath and shower preparations should be blacklisted.

Comments against the proposal include: patients should have access to bath and shower preparations as a treatment option and there is concern that the research used to inform the proposal is inadequate and should be considered not valid.

This respondent group also suggests that NHS England should decide on the proposals.

Further themes emerged from the public events and general webinars that are not attributable to specific respondent groups.

Comments raised in support of the proposal include: bath and shower preparations should be blacklisted.

Comments against the proposal include: the proposal is a blanket approach, which does not consider the needs of individual patients; bath and shower preparations are an effective treatment; the proposal may lead to adverse outcomes on patient quality of life; substituting bath and shower preparations for leave-on emollients is not a cost saving; there is a lack of clinical evidence for the effectiveness of leave-on emollients; and leave-on emollients increase the risk of falls and express disagreement that this is an issue with bath and shower preparations.

Considerations raised by this respondent group include: the proposal should consider exempting specific groups of people such as children with genital dermatoses or hand dermatitis; the impact on vulnerable age groups, those with a low income or from a lower socioeconomic background, ethnic minorities; and the impact on NHS resources.

It was commented that bath and shower preparations are available over the counter, however, patients should have access to these items as a treatment option. NHS England should ensure alternative treatments are available and engage with suppliers, retailers and pharmacies to make over the counter alternatives cheaper.

DRAFT

3.4 Blood glucose testing strips for type 2 diabetes

Table 10 shows the proportion of consultation respondents who agree or disagree that CCGs should be advised to not initiate blood glucose testing strips that cost more than £10 for 50 strips for any new patient.

The largest proportion of respondents (49%) agree with the proposal, although support is low amongst patient representative and voluntary organisations or charities and highest amongst CCGs.

Table 10. Advise CCGs that prescribers in primary care should not initiate blood glucose testing strips that cost more than £10 for 50 strips for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**49%**	**6%**	**42%**	**3%**	**458**
Patient	27%	6%	63%	4%	209
Member of the public / family member / friend or carer of patient	51%	8%	38%	3%	63
Clinician	82%	5%	9%	4%	55
CCG	95%	1%	4%	0%	73
NHS provider organisation / other healthcare organisation / other NHS organisation	44%	11%	44%	0%	18
Industry / professional representative body	36%	0%	55%	9%	11
Patient representative organisation / voluntary organisation or charity	9%	18%	55%	18%	11
Other	50%	13%	38%	0%	8

Table 11 shows the proportion of consultation respondents who agree or disagree that CCGs should be advised to support prescribers in deprescribing blood glucose testing strips that cost more than £10 for 50 strips in all patients, and where appropriate, ensure the availability of relevant services to facilitate this change.

The largest proportion of respondents agree with the proposal (54%), although support is lowest amongst patient representative and voluntary organisations or charities and highest amongst CCGs.

Table 5. Advise CCGs to support prescribers in deprescribing blood glucose testing strips that cost more than £10 for 50 strips and where appropriate, ensure the availability of relevant services to facilitate this change.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**54%**	**6%**	**35%**	**5%**	**454**
Patient	37%	5%	53%	5%	207
Member of the public / family member / friend or carer of patient	54%	8%	33%	5%	63
Clinician	72%	6%	15%	7%	54
CCG	90%	3%	5%	1%	73
NHS provider organisation / other healthcare organisation / other NHS organisation	61%	17%	22%	0%	18
Industry / professional representative body	55%	0%	36%	9%	11
Patient representative organisation / voluntary organisation or charity	10%	0%	70%	20%	10
Other	50%	13%	25%	13%	8

DRAFT

The key themes raised about this proposal in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Key themes mentioned by all the respondent groups include: the proposal is a blanket approach which does not consider the needs of individual patients or specific groups of patients, such as type 1 diabetics and insulin-dependent diabetics; patient care should be the main priority when making these decisions and the proposal may lead to adverse outcomes on patient quality of life.

Patients

Comments in support of the proposal include: it reduces unnecessary costs to the NHS through the use of more cost-effective alternatives and NHS England should engage with manufacturers to reduce costs.

Comments against the proposal include: the proposal may lead to adverse patient outcomes impacting quality of life (e.g. worsening of condition); the adverse effects as a result of the proposal could ultimately cost the NHS more money and patient care should be the main priority when making these decisions.

Considerations raised by this respondent group include: the implications of product quality when choosing cheaper alternatives; patient choice; the impact on vulnerable groups, specifically those with a low income, high risk groups, BME, elderly, pregnant women and children; and whether the proposal could outline a specification on meters and blood glucose testing strips, rather than a maximum cost.

It was also commented that type 2 insulin-dependent diabetics should be treated the same as type 1 insulin-dependent diabetics.

Members of the public / family members, friends or carers of patients

In support of the proposal respondents said that the proposal reduces unnecessary costs to the NHS and patients can self-fund testing strips if required. However, against the proposal respondents said: the possible adverse effects as a result of the proposal could ultimately cost the NHS more money.

This respondent group highlight the need to consider the implications of product quality when choosing cheaper alternatives and the impact on vulnerable groups (specifically: those with a low income, high risk groups, BME, elderly, pregnant women and children).

It is also felt clearer guidance and explanation around the proposal is required on the proposal.

Clinicians

Comments in support of the proposal include it reduces unnecessary costs to the NHS using more cost-effective alternatives. However, clearer guidance and explanation is required.

Comments against the proposal include: patient choice should be considered and healthcare professionals need to have flexibility when prescribing.

Considerations raised by this respondent group include: that some groups of patients will require more expensive testing strips and consider reviewing the maximum cost stipulated.

CCGs

In support of the proposal, this group comment that work in primary care around blood glucose testing strips has already been implemented. However, clearer guidance and explanation of the proposal is required, and NHS England should make a clear decision on the proposal (e.g. allow GPs to prescribe items or blacklist them).

Comments against the proposal include: the proposal takes a blanket approach which does not consider the needs of individual patients or specific groups of patients, for instance type 1

DRAFT

diabetics and insulin-dependent diabetics and patient care should be the main priority when making decisions.

Considerations raised by this group include: greater education around blood glucose meters and testing strips is required; the requirement for face-to-face consultations with patients and healthcare professionals, when implementing changes to their treatment; the maximum cost stipulated for these items should be reviewed and some groups of patients will require more expensive testing strips.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

Comments raised in support of the proposal include: the proposal reduces unnecessary costs to the NHS using more cost-effective alternatives and more expensive items should be blacklisted. However, the proposal requires clearer guidance and stronger wording.

Comments against the proposal include: there is concern that the research used to inform the proposal is inadequate and should be considered not valid; healthcare professionals need to have flexibility when prescribing; the proposal takes a blanket approach, which does not consider individual patient needs or specific groups of patients; work in primary care around blood glucose testing strips has already been implemented; specifying a maximum price may have a negative public reaction (i.e. a cheap product means a less effective product).

Patient care should be the main priority, when making these decisions and the proposal may lead to adverse patient outcomes and impact quality of life - which could ultimately cost the NHS more.

Considerations raised by this respondent group, include: the implications of product quality when choosing cheaper alternatives; the impact on vulnerable groups; support should be provided to healthcare providers when switching patients to alternatives and some groups will require more expensive testing strips.

A number of organisations argued that the costs associated with microvascular complications could be avoided with better glycaemic control, which could be achieved with meters that use advanced technology which require more expensive strips.

They also said that the cost of prescribing strips costing more than £10 per pack accounts for between 0.3% and 0.45% of the total NHS spend, and many of the strips above £10 have a CCG rebate associated with them – therefore the actual cost difference between these and those under £10 would be less.

Focusing on implementation, there is a need to consider drug tariff reviews, to aid implementation of the proposal, to ensure CCGs do not misinterpret the recommendation. For instance, they suggest patients purchase these privately, and recommend face-to-face consultations and education for patients and healthcare professionals. This is important when changing testing strips because patients are likely to need a new blood glucose meter.

Focusing on the quality of blood glucose testing strips, a manufacturer commented: it cannot be assumed that all strips are equivalent and therefore will have the same effect on patient care; better quality products can attract higher prices (i.e. research and development investment and manufacturing processes) and an in-depth product assessment needs to be carried out. Examples and evidence of the importance of accurate blood glucose testing and the validity of their products were also shared.

Comments focusing on the financial implications of the proposal include: the need to consider the impact of price alterations on the implementation of the proposal (i.e. monitoring and changing cut-off price); the proposal should consider that price alterations could lead to multiple changes for patients to manage and prescribers will need up-to-date information on pricing.

DRAFT

Patient representative organisations / voluntary organisations or charities

Comments against the proposal include: the proposal takes a blanket approach and does not consider individual patient needs or the needs of specific patient groups; patient care should be the main priority when making these decisions and the proposal may lead to adverse outcomes on patient quality of life, through the worsening of the condition (therefore the psychological and emotional impact of deprescribing should be considered).

Concerns were also raised over the impact of the proposals on the management of diabetes, for instance: restrictions on access to blood glucose testing strips has a negative impact on the management of diabetes; a better understanding of diabetes helps patients to manage their condition more effectively and deprescribing risks undermining an individual's self-management of their condition. It was also commented that clearer guidance and explanation is required.

Considerations raised by this respondent group include: the proposal should consider that some groups of patients will require more expensive testing strips; re-prescribing of cheaper testing strips should be aimed at new patients only; the impact on vulnerable groups such as those with a low income, high risk groups, BME, elderly, pregnant women and children should also be considered; patient choice should be considered; any changes to treatment should involve a shared decision-making process between the clinician and the patient and healthcare professionals need to have flexibility when prescribing.

Additionally, type 2 insulin-dependent diabetics should be treated the same as type 1 insulin-dependent diabetics. It was also commented that the proposal could be seen to discriminate against those with type 2 diabetes.

Others

Comments in support of the proposal include: cheaper blood glucose testing strips are effective; patients can self-fund testing strips if required; and work around blood glucose testing strips has already been implemented in some parts. However, clearer guidance and explanation is required.

Comments against the proposal include: patient care should be the main priority when making these decisions and the proposal takes a blanket approach, which does not consider the needs of individual patients or groups of patients.

Considerations raised by this respondent group include: some patient groups will require more expensive testing strips; the impact on vulnerable groups (such as those with a low income, high risk groups, BME, elderly, pregnant women and children); and the need to consider the implications of product quality when choosing cheaper alternatives.

Further themes emerged from the public events and general webinars that are not attributable to specific respondent groups

Comments in support of the proposal include: cheaper testing strips are effective and greater education around blood glucose meters and testing strips is required.

Comments against the proposal include: the proposal takes a blanket approach which does not consider the needs of individual patients or specific groups of patients.

It was also suggested that: the specification of meters and glucose testing strips could be made, rather than a maximum cost; the proposal needs stronger statements and wording; patient choice needs to be considered and type 2 insulin-dependent diabetics should be treated the same as type 1 insulin-dependent diabetics. Also, a number of questions were raised around the proposals for these items.

DRAFT

3.5 Dronedarone

Table 12 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate dronedarone for any new patient in primary care.

The largest proportion of respondents (82%) agree with the proposal, although support is lowest among industry and professional representative bodies and highest amongst CCGs.

Table 12. Advise CCGs that prescribers should not initiate dronedarone in primary care for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**82%**	**2%**	**14%**	**1%**	**140**
Patient	44%	0%	50%	6%	16
Member of the public / family member / friend or carer of patient	85%	0%	15%	0%	13
Clinician	77%	9%	14%	0%	22
CCG	98%	0%	2%	0%	64
NHS provider organisation / other healthcare organisation / other NHS organisation	83%	8%	8%	0%	12
Industry / professional representative body	25%	0%	50%	25%	4
Patient representative organisation / voluntary organisation or charity	33%	0%	67%	0%	3
Other	100%	0%	0%	0%	3

Table 13 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised that if, in exceptional circumstances, there is a clinical need for dronedarone to be prescribed in cooperation with a multi-disciplinary team or other healthcare professional.

The largest proportion of respondents agree with the proposal (83%), although support is lowest amongst patient representative and voluntary organisations or charities and highest amongst CCGs.

Table 13. Advise CCGs that if, in exceptional circumstances, there is a clinical need for dronedarone to be prescribed, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**83%**	**6%**	**9%**	**1%**	**139**
Patient	75%	0%	19%	6%	16
Member of the public / family member / friend or carer of patient	77%	15%	8%	0%	13
Clinician	73%	18%	9%	0%	22
CCG	95%	3%	2%	0%	63
NHS provider organisation / other healthcare organisation / other NHS organisation	83%	8%	8%	0%	12
Industry / professional representative body	50%	0%	25%	25%	4
Patient representative organisation / voluntary organisation or charity	33%	0%	67%	0%	3
Other	67%	0%	33%	0%	3

The key themes raised about this question in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

DRAFT

Patients

Comments in support of the proposal include: Dronedarone should only be used if other options have been exhausted and only initiated or recommended by specialists and then continued in primary care. The decision to prescribe dronedarone should be left to individual healthcare professionals.

Comments against the proposal include: dronedarone is associated with many adverse side effects; it is an effective treatment, meaning the proposal may lead to adverse outcomes on patient quality of life. Also, the impact of increased workload on the NHS should also be considered.

Members of the public / family members, friends or carers of patients

Comments in support of this proposal include: dronedarone should only be initiated or recommended by specialists and clearer guidance and explanation is required on the proposal.

Against the proposal, this respondent group said the proposal may lead to adverse patient outcomes and quality of life.

Clinicians, CCGs and Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

Comments were in support of the proposal and include: dronedarone should only be prescribed / initiated by specialists; clearer guidance and explanation is required; NHS England should decide on the proposal; the proposal should review the shared responsibility of prescribing and monitoring dronedarone between primary and secondary care (e.g. shared care agreement and guidance on dose titration for primary care).

Clinicians

Comments against the proposal include: dronedarone is an effective treatment; the proposal may lead to adverse outcomes on patient quality of life and the proposal will increase costs for CCGs (e.g. service payments for shared care).

The impact of increased workloads on the NHS should also be considered.

CCGs

CCGs said that dronedarone is associated with many adverse side effects, however they voiced concerns that the proposals may lead to inequality of treatment for patients (e.g. a two-tiered system).

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

A number of organisations expressed support for the proposal. However, they suggested that clearer guidance and explanation is required.

Comments against the proposal include: the proposal may lead to inequality of treatment for patients (e.g. two-tiered system) as well as adverse outcomes on patient quality of life.

Considerations raised by this group include: dronedarone should only be used if other options have been exhausted and should only be initiated or recommended by specialists but continued in primary care.

Patient representative organisations / voluntary organisations or charities

This respondent group said the need to consider the impact on the NHS through increased workload (e.g. shared care, secondary and tertiary care).

DRAFT

3.6 Minocycline for acne

Table 14 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate minocycline for any new patient in primary care.

The largest proportion of respondents (82%) agree with the proposal, although support is lower among patients and highest amongst CCGs.

Table 14. Advise CCGs that prescribers in primary care should not initiate minocycline for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**82%**	**3%**	**13%**	**2%**	**159**
Patient	55%	0%	41%	5%	22
Member of the public / family member / friend or carer of patient	72%	0%	20%	8%	25
Clinician	83%	17%	0%	0%	24
CCG	98%	2%	0%	0%	64
NHS provider organisation / other healthcare organisation / other NHS organisation	73%	0%	27%	0%	11
Industry / professional representative body	80%	0%	20%	0%	5
Patient representative organisation / voluntary organisation or charity	0%	0%	100%	0%	1
Other	67%	0%	33%	0%	3

Table 15 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to support prescribers in deprescribing minocycline in all patients, and where appropriate, ensure the availability of relevant services to facilitate this change.

The largest proportion of respondents agree with the proposal (84%), although support is lowest amongst patients and highest among industry and professional representative bodies and other respondent types.

Table 15. Advise CCGs to support prescribers in deprescribing minocycline in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**84%**	**3%**	**9%**	**4%**	**158**
Patient	68%	0%	23%	9%	22
Member of the public / family member / friend or carer of patient	71%	4%	21%	4%	24
Clinician	79%	13%	4%	4%	24
CCG	95%	2%	2%	2%	64
NHS provider organisation / other healthcare organisation / other NHS organisation	73%	0%	18%	9%	11
Industry / professional representative body	100%	0%	0%	0%	5
Patient representative organisation / voluntary organisation or charity	0%	0%	100%	0%	1
Other	100%	0%	0%	0%	3

The key themes raised about this proposal in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

DRAFT

Patients

Comments in support of the proposal include: minocycline is associated with many adverse side effects and the risks of prescribing it outweigh the benefits.

Considerations raised by this respondent group include: patient choice; the social and mental health impacts of acne need to be considered and private prescriptions for those who wish to be prescribed minocycline.

Members of the public / family members, friends or carers of patients

Comments in support of the proposal include: minocycline is associated with many adverse side effects and the risks of prescribing it outweigh the benefits. This respondent group said clearer guidance and explanation is required, and GPs and CCGs should be given adequate support to implement the proposals.

Considerations raised by this group include: patient choice; the impact on patient mental health; referring patients to dermatologists, minocycline should only be prescribed in severe cases and minocycline alternatives should be provided.

Clinicians

There is support for the proposal; however, minocycline should only be prescribed in severe cases and the recommendations should exclude indications other than acne and where minocycline is an effective treatment.

CCGs

There is support for the proposals. Furthermore, the national guidance would support existing recommendations and the proposal would only affect a small number of patients. However, clearer guidance and explanation is required, and the recommendations should exclude other indications where minocycline is an effective treatment.

Minocycline should only be initiated or recommended by specialists but continued in primary care.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

A number of organisations expressed support for the proposal. However, there is need for clearer guidance and explanation.

Comments were raised stating minocycline is an effective treatment.

It was commented that minocycline is used for indications other than acne, which should be considered for exclusion from the proposal. Also, minocycline should only be initiated or recommended by specialists, but continued in primary care, and alternatives provided.

Additionally, the need to consider the impact of acne on mental health was highlighted.

Patient representative organisations / voluntary organisations or charities

Support was expressed for the proposal from a patient organisation, stating this item is associated with many adverse side effects and the proposal would only affect a small number of patients.

It also recommends the exclusion of minocycline where it is used as a treatment for other indications.

Others

There is support for the proposal. However, where minocycline is used for other indications, these should be removed from the proposal.

On the other hand, minocycline is an effective treatment, and should only be initiated or recommended by specialists but continued in primary care.

DRAFT

3.7 Needles for pre-filled and reusable insulin pens

Table 16 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate insulin pen needles that cost more than £5 per 100 needles for any new diabetes patient in primary care.

The largest proportion of respondents (50%) disagree with the proposal, although there are high levels of support from CCGs.

Table 16. Advise CCGs that prescribers in primary care should not initiate insulin pen needles that cost more than £5 per 100 needles for any new diabetes patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**41%**	**4%**	**50%**	**4%**	**454**
Patient	24%	5%	66%	5%	209
Member of the public / family member / friend or carer of patient	39%	6%	54%	1%	67
Clinician	53%	2%	40%	4%	45
CCG	92%	1%	4%	3%	73
NHS provider organisation / other healthcare organisation / other NHS organisation	50%	5%	45%	0%	20
Industry / professional representative body	30%	0%	50%	20%	10
Patient representative organisation / voluntary organisation or charity	8%	8%	75%	8%	12
Other	22%	11%	67%	0%	9

Table 17 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to support prescribers in deprescribing insulin pen needles that cost more than £5 per 100 needles, and where appropriate, ensure the availability of relevant services to facilitate this change.

The largest proportion of respondents agree with the proposal (49%), although support is lowest amongst patient representative and voluntary organisations or charities and highest amongst CCGs.

Table 17. Advise CCGs to support prescribers in deprescribing insulin pen needles that cost more than £5 per 100 needles and, where appropriate ensure the availability of relevant services to facilitate this change.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**49%**	**5%**	**41%**	**5%**	**456**
Patient	35%	6%	53%	6%	209
Member of the public / family member / friend or carer of patient	42%	4%	51%	3%	67
Clinician	60%	6%	27%	6%	48
CCG	89%	5%	3%	3%	73
NHS provider organisation / other healthcare organisation / other NHS organisation	58%	5%	37%	0%	19
Industry / professional representative body	40%	0%	40%	20%	10
Patient representative organisation / voluntary organisation or charity	25%	8%	58%	8%	12
Other	22%	11%	67%	0%	9

DRAFT

The key themes raised about this proposal in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Patients and members of the public / family members, friends or carers of patients

Comments against the proposal include: the proposal takes a blanket approach which does not consider the needs of individual patients; the proposal may lead to adverse outcomes on patient quality of life (injuries, bleeding, bruising, anxiety, decreased insulin), which could ultimately cost the NHS more money; patient care should be the main priority when making these decisions and patients should have a choice of insulin pen needles.

There is a need to consider the implications of using cheaper items on product quality (e.g. breakages and product efficacy).

Patients

In support of the proposal, this respondent group said cheaper insulin pen needles are just as effective.

Comments against the proposal include: the proposals disproportionately affect certain groups, such as the disabled, women and ethnic minorities and there is concern that the research used to inform the proposal is inadequate and should be considered not valid.

Additionally, NHS England should consult with specialists (e.g. Diabetes UK) and include patient views and feedback in decision making.

Members of the public / family members, friends or carers of patients

Comments in support of the proposal include: lower cost products should be used and the proposal reduces unnecessary costs to the NHS.

Considerations raised by this respondent group include: children should be exempt from the proposal; healthcare professionals need to have the flexibility to prescribe as needed and patient views and feedback regarding insulin pen needles needs to be considered in decision making.

Clinicians

In support of the proposal respondents said cheaper insulin pen needles are just as effective.

Comments against the proposal include: the proposal takes a blanket approach which does not consider the needs of individual patients; patient care should be the main priority when making these decisions, as the proposal may lead to adverse outcomes on patient quality of life (e.g. reusing needles, injuries, bruising, bleeding, decreased insulin levels, anxiety) and the proposal may negatively impact patients financially.

Considerations raised by this respondent group include: the implications on product quality when using cheaper insulin pen needles (e.g. breakages and level of efficacy); the increased risk of needlestick injuries to NHS staff and carers; making children exempt and the need to consider the views of patients on insulin pen needles.

Additionally, there needs to be a clear distinction between standard pen needles and safety needles within the proposal; the proposal should specifically refer to screw-on needles as ‘click’ or ‘twist’ needles do not have cost-effective alternatives and the proposal should review the recommendation around needle length.

DRAFT

CCGs

This respondent group raised questions around this proposal; therefore, it was commented that clearer guidance and explanation is required along with stronger statements and clearer wording. This respondent group also said NHS England should decide on the proposal.

Comments in support of the proposal include: blacklisting items which are not cost effective; the proposal reduces unnecessary cost to the NHS and the proposals are already being implemented locally in some areas, however national guidance would be useful to encourage further implementation.

Considerations raised by this respondent group include: the increased risk of needlestick injuries to NHS staff and carers; the maximum cost stipulated in the proposal; utilising a more holistic approach to reduce costs of diabetic items and conducting a review of the drug tariff process, to aid implementation of the proposal.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

A number of organisations commented in support of the proposal, while others agree that lower cost products should be used.

It was commented that more expensive items should be blacklisted and several comments were made in relation to price alterations, including: the impact of price alterations on the implementation of the proposal should be considered (i.e. monitoring and changing cut-off price); the proposal should consider that price alterations could lead to multiple changes for patients to manage and prescribers will need up-to-date information on pricing.

Additionally, it was commented that there is a need to consider the impact on children, possibly exempting them from the proposal. Also, the proposal should consider including additional evidence supporting equivalent efficacy of originator products versus cheaper, generics.

Comments against the proposal include: patient care should be the main priority when making these decisions; the proposal may restrict treatment options; healthcare professionals need to have flexibility to prescribe as needed; the proposal may negatively affect certain groups, such as disabled, women and ethnic minorities; the proposal may lead to adverse patient outcomes and quality of life (e.g. reusing needles, injuries, bruising, decreased insulin, anxiety); the proposal may restrict treatment options; it takes a blanket approach that does not consider individual patient needs and patients should have a choice of insulin pen needles.

Other considerations raised by this respondent group include: increased risk of needlestick injuries to NHS staff and carers; the implications of using cheaper items on product quality (e.g. breakages and product effectiveness) and the need to consider the views of patient views during decision making. This respondent group said NHS England should provide relevant guidance to aid the implementation of the proposal.

The need to consider the health and safety of pharmacy staff when insulin pen needles are purchased privately via the community pharmacy was highlighted. It was also commented that it should be ensured that CCGs do not misinterpret the recommendation, by suggesting that patients purchase these privately.

Furthermore, comments were raised that there is a need to review the maximum cost stipulated. And that there should be a review of the recommended needle length.

Themes raised around needle safety include: the proposal limits the accessibility of safety needles, which are needed for specific groups of people (e.g. needle phobic, visual disability); there needs to be a clear distinction between standard pen needles and safety needles within the proposal and the increased risk of needlestick injuries to NHS staff and carers should be considered. A manufacturer commented that the proposal should consider

DRAFT

exempting needles that have specific advantages for vulnerable groups (e.g. patients with dexterity issues and children) and ensure that changes, as a result of the guidance, are reflected in local formularies.

Focusing on financing and self-funding insulin pen needles, there is polarisation amongst this respondent group, with some saying patients should self-fund if they wish to use more expensive insulin pen needles, whilst others said the proposals will have a negative financial impact on patients who may try to self-fund these items.

Patient representative organisations / voluntary organisations or charities

Comments in support of the proposal include: cheaper insulin pen needles are just as effective.

Comments made against this proposal include: patient care should be the main priority when making these decisions; patients should have a choice of insulin pen needles; healthcare professionals need to have the flexibility to prescribe as needed; the proposal may lead to adverse patient outcomes and quality of life (e.g. reusing needles, injuries, bruising, decreased insulin, anxiety) and the proposal does not reduce unnecessary costs to the NHS.

Other considerations raised by this respondent group include: the need to consider the implications of using cheaper items on product quality (e.g. breakages and effectiveness); patient views and feedback should be considered in decision making; any changes should involve a shared decision-making process between the clinician and patient and the impact on children (issues around familiarity and supporting effective usage), therefore consider exempting children from the proposal.

Additionally, concerns were raised over safety needles; the proposal limits access to safety needles which are needed for specific groups of people (e.g. needle phobic, visual disability). There needs to be a clear distinction between standard pen needles and safety needles within the proposal.

It was also commented that NHS England should provide relevant guidance to aid in the implementation of the proposal as well as an in-depth product assessment needs to be carried out.

Others

Comments in support of the proposal include: cheaper insulin pen needles are just as effective.

Considerations raised by this group include: the implications on product quality when using cheaper insulin pen needles, specifically the greater chance of breakages and decrease in effectiveness; consider patient views and feedback in decision making; this proposal may restrict treatment options and consider the increased risk of needlestick injuries to NHS staff and carers.

Further themes emerged from the public events and general webinars that are not attributable to specific respondent groups

Comments in support of the proposal include: more expensive items should be blacklisted.

Comments against the proposal include: the proposal takes a blanket approach, which does not consider the needs of individual patients; the proposal may lead to adverse outcomes on patient quality of life; the proposal limits the accessibility of safety needles, which are required for specific groups of people (e.g. needle phobic, visually impaired) and patients should have a choice of insulin pen needles.

Considerations highlighted include: the implications on product quality when using cheaper insulin pen needles (e.g. breakages and lower efficacy); consider the increased risk of needlestick injuries to NHS staff and carers; consider FIT recommendations such as needle

diameter and penetration force; consider the impact on children and possibly make them exempt.

In both the webinars and public events questions were raised around the proposals for insulin pen needles. Therefore, clearer guidance and explanation on the proposal is proposal.

DRAFT

3.8 Silk garments

Table 18 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate silk garments for any new patient in primary care.

An equal proportion of respondents (48%) agree and disagree with the proposal with low levels of agreement from patient and public respondents and high levels of agreement amongst CCGs.

Table 18. Advise CCGs that prescribers in primary care should not initiate silk garments for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**48%**	**2%**	**48%**	**2%**	**355**
Patient	28%	1%	67%	4%	82
Member of the public / family member / friend or carer of patient	25%	1%	74%	1%	126
Clinician	68%	5%	24%	2%	41
CCG	97%	0%	3%	0%	70
NHS provider organisation / other healthcare organisation / other NHS organisation	70%	0%	20%	10%	10
Industry / professional representative body	33%	17%	33%	17%	6
Patient representative organisation / voluntary organisation or charity	40%	0%	60%	0%	5
Other	57%	0%	43%	0%	7

Table 19 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to support prescribers in deprescribing silk garments in all patients, and where appropriate, ensure the availability of relevant services to facilitate this change.

The largest proportion of respondents agree with the proposal (58%), although support is lowest amongst industry and professional representative bodies and highest amongst CCGs.

Table 19. Advise CCGs to support prescribers in deprescribing silk garments in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**58%**	**3%**	**36%**	**3%**	**356**
Patient	41%	1%	53%	5%	83
Member of the public / family member / friend or carer of patient	43%	4%	50%	2%	125
Clinician	68%	5%	24%	2%	41
CCG	97%	1%	1%	0%	70
NHS provider organisation / other healthcare organisation / other NHS organisation	73%	9%	9%	9%	11
Industry / professional representative body	33%	17%	33%	17%	6
Patient representative organisation / voluntary organisation or charity	60%	0%	40%	0%	5
Other	57%	14%	29%	0%	7

The key themes raised about this question in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

DRAFT

Patients

Comments in support of the proposal include: there is a lack of clinical evidence showing the effectiveness of silk garments and patients should self-fund if they wish to use silk garments.

Comments against the proposal include: the proposal takes a blanket approach, which does not consider the needs of individual patients and the adverse effects of the proposal on patients could ultimately cost the NHS more money.

Considerations raised by this respondent group include: the impact on patient quality of life and the impact on vulnerable groups such as those with a low income or from a lower socioeconomic background, high risk groups, BME, elderly and pregnant women. Additionally, rather than deprescribing these items, limiting the number or frequency is suggested.

Members of the public / family members, friends or carers of patients

Comments in support of the proposal include: blacklist all silk garments.

Comments against the proposal include: healthcare professionals need to have flexibility when prescribing; the proposal takes a blanket approach, which does not consider the needs of individual patients; there is concern that the research used to inform the proposal is inadequate and should be considered not valid and the adverse effects on patients could ultimately cost the NHS more money.

Rather than deprescribing these items, limiting the number or frequency is suggested, particularly when there is a lack of alternatives to these items and alternatives to silk garments are less effective.

Considerations raised by this respondent group include: the impact on patient quality of life; the impact on vulnerable groups such as those with a low income or from a lower socioeconomic background, high risk groups, BME, elderly and pregnant women; the proposal should consider exempting specific severe cases and those with chronic conditions, and these exemptions should be made clear, to avoid deprescribing across the board.

Clinicians

Comments in support of the proposal include: blacklisting all silk garments; there is a lack of clinical evidence showing the effectiveness of these items and patients should self-fund their use of these items.

Comments against the proposal include: the need to consider the impact on patient quality of life; the impact on vulnerable groups; the ultimate cost of these adverse effects to the NHS and the proposal is a blanket approach which does not consider the needs of individual patients. Also, an academic raised a concern that the research used to inform the proposal is inadequate and should be considered not valid.

CCGs

This respondent group said silk garments should be blacklisted as conditions requiring these items could mostly be treated better with other products. They also suggest that NHS England should make a clear decision on the proposal.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

Comments raised by this respondent group in support of the proposal include: conditions requiring silk garments could mostly be treated with other products; more expensive items should be blacklisted and there is a lack of clinical evidence for the effectiveness of silk garments.

A healthcare provider commented that they no longer recommend silk garments.

DRAFT

Comments against the proposal were received from representative and industry organisations. Their comments include: the proposal takes a blanket approach which does not consider the needs of individual patients; the adverse effects on patients could ultimately cost the NHS more money; there is concern that the research used to inform the proposal is inadequate and should be considered not valid and healthcare professionals need to have flexibility when prescribing.

Considerations were raised by several organisations. Their considerations include: the proposal should consider exempting specific severe cases or chronic conditions; the impact on those with a low income or lower socioeconomic background; the negative impact on patients' quality of life and the need for NHS England to consult with specialists such as paediatric dermatologists.

As an alternative option limiting the number or frequency of prescriptions was suggested rather than their deprescription. For example, silk garments should not be put onto repeat prescription but only re-prescribed when they have been outgrown or worn out.

A manufacturer proposed collaborative working with the NHS to support patient outcomes. Another manufacturer explains the validity of their product and why it should not be blacklisted, stating changes should only be made by those who are specialists in this area. The prescription of silk garments should only be initiated by specialists when GP management fails to control the condition.

It was also commented that prescribing certain silk garments should continue, highlighting the disparity between cost and value of silk garments within the NHS, and different brands of silk garments are not comparable and should not be reviewed as such in the consultation process.

Patient representative organisations / voluntary organisations or charities

Comments against the proposal raised by this group include: there is concern that the research used to inform the proposal is inadequate and should be considered not valid; silk garments should continue to be prescribed and the adverse effects on patients could ultimately cost the NHS more money.

A number of patient organisations outlined considerations, including: the impact on those with a low income or from a lower socioeconomic background; the impact on patient quality of life; the impact on vulnerable groups; the proposal should consider exempting specific groups of people (e.g. severe cases, chronic conditions) and these exemptions should be made clear to avoid deprescribing across the board and the prescribing of silk garments should be initiated by specialists when GP management fails to control the condition.

Finally, different brands of silk garments are not comparable and should not be reviewed as such in the consultation process.

Other

Comments against the proposal include: there is concern that the research used to inform the proposal is inadequate and should be considered not valid and the proposal takes a blanket approach and does not consider the needs of individual patients.
Also, different brands of silk garments are not comparable and should not be reviewed as such in the consultation process.

DRAFT

4 Equality and health inequalities

This section presents the feedback from the consultation on the equality and health inequality questions. These questions explored respondents' views on whether the proposals may disproportionately impact specific groups, which groups may be impacted and any other evidence that should be considered when finalising the proposals.

4.1 Patients who may be disproportionately impacted

Table 20 shows the proportion of consultation survey respondents who feel there are specific groups that are likely to be disproportionately affected.

Table 20. Do you feel there are any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?

	Total	Patient	Members of the public / family member / friend or carer of patient	Clinician	CCG	NHS provider / other NHS / other healthcare organisations	Industry / professional representative body	Patient representative / voluntary / charity organisation	Other
Yes	**31%**	35%	36%	25%	5%	20%	36%	39%	31%
No	**41%**	32%	35%	56%	85%	54%	46%	33%	41%
Unsure	**29%**	33%	30%	19%	10%	27%	18%	27%	29%
Base:	1,459	671	371	156	98	41	28	33	25

Table 21 shows which groups, protected by the Equality Act 2010, respondents believe are likely to be disproportionately affected by these proposals.

Table 21. Which groups, protected by the Equality Act 2010, do you feel are likely to be disproportionately affected by this work?

	Total	Patient	Members of the public / family member / friend or carer of patient	Clinician	CCG	NHS provider / other NHS / other healthcare organisations	Industry / professional representative body	Patient representative / voluntary / charity organisation	Other
Age	**55%**	51%	52%	70%	100%	75%	90%	77%	40%
Disability	**80%**	86%	79%	61%	25%	75%	70%	62%	100%
Gender reassignment	**5%**	5%	5%	9%	0%	0%	10%	0%	0%
Race	**10%**	11%	10%	0%	0%	0%	20%	23%	20%
Religion or belief	**5%**	6%	3%	0%	0%	0%	10%	8%	0%
Sex	**9%**	11%	9%	3%	0%	0%	20%	0%	0%
Sexual orientation	**5%**	6%	4%	0%	0%	0%	10%	0%	0%
Marriage and civil partnership	**4%**	4%	4%	3%	0%	0%	10%	0%	0%

Pregnancy and maternity	**13%**	16%	12%	12%	0%	0%	20%	0%	0%
Base:	**402**	209	116	33	4	8	10	13	5

The key themes raised about this question in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Patients

Respondents listed several groups who they feel would be adversely affected by the proposals. This includes those who require considerable care (e.g. disabled, elderly), diabetic patients and those with a low income or from a lower socioeconomic background (concerns that a lack of affordability could lead to adverse patient outcomes).

Focusing on the diabetic items, respondents felt that the proposals could restrict access to insulin pen needles and blood glucose testing strips. It should also be considered that effective blood glucose testing prevents adverse patient outcomes.

Other themes raised by this respondent group include: the proposals are taking a blanket approach which is not suitable when treating individual conditions and the adverse effects, which follow implementation of the proposed guidance, could ultimately cost the NHS more money.

Members of the public / family members, friends or carers of patients

This respondent group lists several groups who could be adversely affected by the proposals. This includes those who require considerable care (e.g. disabled, elderly), diabetic patients, those with rare illnesses, children suffering from eczema and those with a low income or from a lower socioeconomic background. There were concerns that the proposal will make it harder for some to access treatment and that a lack of affordability could lead to negative patient outcomes.

Concerns were also raised that the proposals are taking a blanket approach, and the adverse effects, following the implementation of the proposed guidance, could ultimately cost the NHS more money.

Focusing on the diabetic items, respondents felt that these proposals could restrict access to insulin pen needles and blood glucose testing strips. It should also be considered that effective blood glucose testing prevents adverse patient outcomes.

There are also concerns around the impact of reducing access to silk garments leading to adverse patient outcomes and social implications on patients and their carers.

Clinicians

Respondents listed several groups who they feel would be adversely affected by the proposals. This includes those who require considerable care (e.g. disabled, elderly), diabetic patients, those with a low income or from a lower socioeconomic background and children with eczema.

Other concerns include: the proposals are taking a blanket approach which will make it harder for some patients to access suitable treatment; the lack of treatment affordability could lead to adverse patient outcomes; the adverse effects on patients could ultimately cost the NHS more money and that the proposals limit access to safety needles, which are needed for specific groups of people (e.g. needle phobic, visual disability).

CCGs

Respondents argued that the proposals adversely affect those who require considerable care (e.g. disabled, elderly) and raised concerns that the lack of affordability could lead to adverse patient outcomes. They also urged consideration of the impact on carers who manage treatments.

DRAFT

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

Respondents listed several groups who they feel would be adversely affected by the proposals. This includes: those who require considerable care (e.g. disabled, elderly), those with a low income or from a lower socioeconomic background, children with eczema, elderly patients who are more likely to be prescribed amiodarone and dronedarone and diabetic patients.

Other concerns about the proposals include: it may make it harder for some to access appropriate treatment; it will lead to an increased administrative burden on the NHS; it could result in limited access to safety needles, which are needed for specific groups (e.g. needle phobic, visually impaired) and it will lead to patients having to attend more hospital appointments.

Patient representative organisations / voluntary organisations or charities

Respondents list several groups who they feel would be adversely affected by the proposals. This includes those who require considerable care (e.g. disabled, elderly), diabetic patients and ethnic minorities for whom diabetes prevalence is higher, those on low incomes or from a lower socioeconomic background and patients requiring amiodarone and dronedarone.

Other concerns about the proposals include: they take a blanket approach; they may lead to patients having to attend more hospital appointments and the adverse effects on patients could ultimately cost the NHS more money.

Other

Concerns were raised that the proposals will make it harder for some patients to access treatment and may adversely affects those who require considerable care (e.g. disabled, elderly).

DRAFT

4.2 Other evidence which should be considered on the potential impact on health inequalities experienced by certain groups

Table 22 shows the proportion of consultation survey respondents who feel there is further evidence that should be considered on the potential impact on health inequalities experienced by certain groups.

Table 22. Do you feel there is any further evidence we should consider in our proposals on the potential impact on health inequalities experience by certain groups e.g. people on low incomes; people from black and minority ethnic (BME) communities?

	Total	Patient	Members of the public / family member / friend or carer of patient	Clinician	CCG	NHS provider / other NHS / other healthcare organisations	Industry / professional representative body	Patient representative / voluntary / charity organisation	Other
Yes	34%	40%	37%	22%	7%	27%	54%	45%	9%
No	39%	32%	31%	56%	84%	56%	32%	42%	48%
Unsure	26%	28%	32%	22%	9%	17%	14%	12%	43%
Base:	**663**	**361**	**153**	**97**	**41**	**28**	**33**	**23**	**663**

The key themes raised about this question in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Patients, members of the public / family members / friends / carers of patients and patient representative organisations / voluntary organisations or charities

There was broad agreement in the themes raised by these respondent groups. A set of themes were raised around the impact on specific patient groups. This includes: those who require considerable care (e.g. disabled, elderly), those with atrial fibrillation who require amiodarone and dronedarone and those who require access to silk garments (specifically the social implications should these items no longer be available). The impact on carers was also highlighted.

Other concerns raised by this respondent group include: the proposals are taking a blanket approach which does not work for all patients when treating individual's conditions; the proposals may mean items will be universally deprescribed (making it harder for patients to access them, which could encourage self-funding of treatments) and a lack of evidence does not mean treatments are ineffective.

This respondent group also highlight several areas which need to be taken into consideration. They include: the requirement for everyone to be treated equally; patient discrimination; reviewing who is eligible for free prescriptions and the impact on children with eczema; the need for more education on the treatments available (especially when some can be purchased over the counter) and the possible negative impact on the level of service offered to patients due to the additional workload placed on the NHS.

A set of themes focused on financial issues, including: the impact on those with a low income or from a lower socioeconomic background and their ability to purchase the medication and concerns that the lack of affordability could lead to adverse patient outcomes. Also, the removal of these items by prescribers may ultimately cost the NHS more money.

Focusing on the silk garment proposal concerns were raised including: the impact on patient outcomes following limited access to silk garments (if the proposals are implemented) and the social implications on carers (parents of young children) as well as patients.

Clinicians

There is a concern that the implementation of this guidance will result in an increase in the demand for appointments with primary care health professionals. This may result in an increased workload which must be considered.

Groups who they feel would be adversely affected by the proposals include: those with a low income or from a lower socioeconomic background (because a lack of affordability could lead to adverse patient outcomes); those who require high levels of care (e.g. disabled, elderly) and those who require silk garments (because of the negative impact on patient outcomes should these items not be available).

There is also a need for greater education to raise awareness of alternative treatments. The proposals are taking a blanket approach and the discrimination that some patients may face as a result should be considered. Finally, the removal of access to treatments may ultimately cost the NHS more money.

CCGs

There is concern that these proposals will impact specific groups. They include: those with a low income or from a lower socioeconomic background; diabetic patients from ethnic minorities and patients and carers (parents of young children). CCGs mentioned the proposals may potentially promote non-compliance or incorrect use of items such as insulin pen needles (multiple use of needles).

Other areas for consideration include: the requirement for everyone to be treated equally; some of these treatments are available over the counter; the potential for increased demand for appointments with primary care professionals and the variation in treatment options available by geographical area.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

A set of themes were raised around the impact on specific patient groups. This includes: those from a low income or lower socioeconomic background; those who require considerable care (e.g. disabled and elderly); carers who manage treatments; diabetic patients from ethnic minorities and female patients.

There is concern that: variable uptake of the guidance could lead to inconsistency in GP prescribing; additional health inequalities may arise from items not being available on prescription; the proposals will make it harder for some to access treatment or medication and the proposal adversely affects patients with diabetes

There is a need to take into consideration those who are exempt from prescription charges and the impact on BME communities because they are more likely to be affected by the proposal.

A set of themes focus on financial issues and the potential burden on the NHS. They include: concern that the lack of affordability may lead to adverse patient outcomes; removal of access to treatment may ultimately cost the NHS more money and the possible negative impact on the services provided to patients due to additional staff workload.

Concerns were raised about the bath and shower preparation proposal. There was a concern that the proposal would: disproportionately affect certain groups (e.g. elderly, children and families with young children); have a life-long impact on patients who presently use these items; have financial implications on patients who will have to purchase these items and for those who cannot afford these items, it will lead to adverse patient outcomes.

DRAFT

Others

There is a need to consider the impact on: those who require considerable care (e.g. disabled, elderly) and those with a low income or from a lower socioeconomic background (because there is concern a lack of affordability could lead to adverse patient outcomes).

DRAFT

5 Updating and reviewing the process for identifying items for inclusion or removal from the guidance

This section presents the feedback from the consultation survey on the proposed process for the identification of items for possible addition or removal from the guidance.

Table 23 shows the proportion of consultation survey respondents who agree or disagree with the proposed process for the identification of items for possible inclusion in the guidance.

The largest proportion of respondents (33%) agree with the proposal, although support is lowest amongst patients and highest amongst CCGs.

Table 23. How do you feel about the proposed process for identification of items for possible addition to the guidance or indeed possible removal, from the guidance?

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**33%**	**19%**	**32%**	**16%**	**1,439**
Patient	21%	21%	40%	18%	**665**
Member of the public / family member / friend or carer of patient	27%	18%	35%	20%	**366**
Clinician	54%	18%	17%	11%	**153**
CCG	83%	9%	2%	6%	**98**
NHS provider organisation / other healthcare organisation / other NHS organisation	51%	24%	15%	10%	**41**
Industry / professional representative body	29%	7%	50%	14%	**28**
Patient representative organisation / voluntary organisation or charity	33%	27%	30%	9%	**33**
Other	57%	14%	24%	5%	**21**

The key themes raised about this question in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

All respondent groups said that further scrutiny and review of the proposals is required.

Patients

Several comments highlight the need to consider the impact on vulnerable groups, specifically: those with a low income, high risk groups, BME, elderly, pregnant women and children. There should also be greater input from patients in working groups.

Patients are concerned that the blanket approach of the proposals will not work when treating for individual conditions. Consequently, medications and items should be available to all patients. There is concern that the research used to inform the proposals are inadequate and should be considered not valid. Finally, the impact on quality of life of patients, families and carers should be considered.

Focusing on the financial implications, the adverse effects of the proposals on patients could ultimately cost the NHS more money and cost saving measures should be sought elsewhere.

Members of the public / family members, friends or carers of patients

Comments against the proposals include: if required, these items should be available to all patients; the proposals take a blanket approach, which does not work when treating individual's conditions; there is concern that the research used to inform the proposals are inadequate and should be considered not valid and further scrutiny and review of the

DRAFT

proposals are required (this could include the involvement of specialists and patients in clinical working groups).

There is a need to consider the impact on the quality of life of patients, families and carers, vulnerable groups, those with a low income, high risk groups, BME, the elderly, children, pregnant women and young children with eczema. It is felt the adverse effects on patients could ultimately cost the NHS more money and therefore cost saving measures should be sought from elsewhere.

If the proposals are implemented the impact on the relationship between primary and secondary care should be considered. Also, Local Pharmaceutical Committees (LPCs) should work with CCGs and other organisations to plan the implementation of the proposals.

Clinicians

Most clinicians support the proposed process with many stating the proposals had already been implemented at local levels.

However, concern is expressed around how the guidance would be implemented. This respondent group raise a series of points, including: CCGs are already informally adopting the guidance before the consultation period has ended and the guidance is being misinterpreted by some clinicians to mean a complete ban on the prescription of these items. Therefore, clearer guidance and explanation on the proposals is required, as well as the involvement and input of specialists (e.g. cardiologists, British Diabetic Association) and further scrutiny and review.

Other key considerations raised by this respondent group include: the impact on the demand for healthcare professionals if these changes are made; the need for greater patient education and awareness and the impact on the quality of life for patients, families and carers.

They also said that the expected cost savings are not likely to be achievable because of local variation in prescribing.

Focusing on the diabetic items, there is a need to consider: the effect of the proposal on specific groups of diabetic patients (e.g. type 1 diabetics) and the implications of product quality when using cheaper insulin pen needles.

CCGs

Although questions were raised, this respondent group support the proposed process, commenting that many of the proposals are already being implemented at local levels. However, clearer guidance and explanation is required, as well as input from patients and specialists (e.g. cardiologists, British Diabetic Association, paediatricians and dermatologists).

Expressing a note of caution, this respondent group said that variable uptake of the guidance could lead to inequality and inconsistency in prescribing. To address this, alternative items should be made available on prescription. Finally, there is concern that the expected savings from the proposed guidance are not achievable.

Other comments discussed how the proposed guidance could be implemented. Suggestions include: Local Pharmaceutical Committees working with CCGs and other organisations to plan the implementation process; regular and timely review of the NHS drug tariff and associated processes for listing and removing products as well as use of “the blacklist”; collaborative working with NHS England; face-to-face consultations with patients and healthcare professionals; uniform communications and messaging, utilised by all healthcare professionals to maintain consistency; patient education and awareness raising and carefully managing stock levels of the affected items, so pharmacy contractors have adequate notice of local prescribing changes.

DRAFT

This respondent group also argue that insulin pen needles and glucose testing strips should be removed from the proposals.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

A series of questions and concerns about the proposals were raised by these respondents. They include: the expected cost savings are not achievable, because local variation in prescribing may have an impact on budgets; the validity of the research used to develop the proposals is questionable; the proposals take a blanket approach, which is not suitable when treating individual conditions; the availability of an item over the counter should not be the rationale for prescribers not issuing prescriptions and variable uptake of the guidance could lead to inequality and inconsistency in prescribing. There is concern that CCGs are already informally adopting the guidance, before the consultation period has ended and the proposals being at odds with NHS key principles.

Therefore, further scrutiny and review of the proposals are required, and clearer guidance provided.

Themes also raised by organisations include: careful consideration and planning is required if the proposals are implemented; standardised communications and messages for all healthcare professionals; face-to-face consultations with patients and healthcare professionals will be required; a review of drug tariff processes and there is a need for greater collaboration with NHS England or at least being part of the working group.

Focusing on the implementation of the guidance, it is suggested that Local Pharmaceutical Committees (LPCs) work with CCGs and other organisations to plan the implementation of the proposals.

Other considerations include: the demand placed on healthcare professionals following these changes; the impact on the quality of life of patients, families and carers, vulnerable groups, those with a low income, high risk groups, BME, the elderly, pregnant women and young children with eczema; the impact on community pharmacies; limiting patient choice; the risks of patients buying their medication online, if not available on prescription; the proposal will make it more difficult to track patient journeys, if they purchase over the counter; checking and managing the stock levels of the affected products appropriately; giving pharmacy contractors adequate notice of changes and ensuring community pharmacies have access to resources, aiding the implementation of the guidance (e.g. leaflets).

Other organisations note that consideration must be taken over the position of treatments, in relation to national guidance; question how best to engage stakeholders and comment that there are established existing mechanisms for ensuring the prices of generic medicines are affordable for the NHS. Furthermore, careful consideration and planning is required as to how the proposals will be implemented. For example, consider conducting a risk / benefit assessment on the impact of restricting prescribing of pharmacy (P) and general sales list (GSL) medicines and reviewing the list of unintended consequences further.

Focusing on the proposals around the diabetic items, these respondents argue there is a need to consider the implication of product quality, when using cheaper variants and patient and healthcare professional education around the guidance.

Patient representative organisations / voluntary organisations or charities:

Themes arising from this group were: the proposals are taking a blanket approach, which is not suitable when treating individual conditions; there is concern that the research used to inform the proposal is inadequate and should be considered not valid; clearer guidance and explanation is required and a greater level of patient and clinical involvement is required with patients living with the condition, at the centre of any decisions made. Additionally, medications should be made available to patients if they require them, or alternative items should be available on prescription.

DRAFT

It was commented that there is a need for further scrutiny of the proposals and regular reviews of the items, subject to the guidance. They also said that the relationship between primary and secondary care needs to be considered, as well as the need to address issues caused by the implementation of the previous guidance, before implementing further guidance.

Financially, there is concern there will be adverse effects on patients following the implementation of this guidance, which could ultimately cost the NHS more money. If cost savings are sought, this should happen elsewhere. A patient representative organisation also said increased NHS efficiency should not reduce the NHS's offer to patients.

Others

There is concern that the research used to inform the proposal is inadequate and should be considered not valid, therefore further scrutiny and review of the proposals are required.

Themes from the public events that are not attributable to specific respondent groups include: a need for further scrutiny and review of the proposals; clearer guidance and explanation and the variable uptake of the guidance, could lead to inequality and inconsistency in prescribing (therefore the relationship between primary and secondary care may need to be considered).

Other considerations raised in the public events include: the need for greater patient education and awareness; the impact of the proposals on patients', families' and carers' quality of life and the impact on vulnerable groups, such as those with a low income, high risk groups, BME, elderly, pregnant women and children. There is also a need to consider; the impact on the demand for healthcare professionals as a result of changes; the financial impact on CCGs, after implementing the changes and a review and consideration of issues arising from implementation of the proposals from previous guidance.

Respondents at public events also questioned the consultation process. Specifically, they said: the consultation requires the input of specialists; the proposals are already being implemented at local levels; uniform communications and messages regarding the proposal should be utilised by all healthcare professionals, to maintain consistency and support implementation and stock levels of the affected products should be managed appropriately, so that pharmacy contractors are given adequate notice of local changes to prescribing.

DRAFT

6 Proposals for updated CCG commissioning guidance

This section presents the feedback on the proposal for rubefacients (excluding topical NSAIDs and capsaicin) to update the November 2017 CCG commissioning guidance.

6.1 Rubefacients (excluding topical NSAIDs and capsaicin)

Table 24 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to not initiate rubefacients (excluding topical NSAIDs and capsaicin) for any new patient in primary care.

The largest proportion of respondents (41%) agree with the proposal, although support is lowest amongst patients and highest amongst CCGs.

Table 24. Advise CCGs that prescribers in primary care should not initiate rubefacients (excluding topical NSAIDs and capsaicin) for any new patient.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**41%**	**18%**	**23%**	**18%**	**727**
Patient	27%	23%	29%	22%	319
Member of the public / family member / friend or carer of patient	32%	15%	33%	20%	168
Clinician	57%	18%	12%	12%	89
CCG	97%	0%	3%	0%	79
NHS provider organisation / other healthcare organisation / other NHS organisation	80%	10%	5%	5%	20
Industry / professional representative body	31%	25%	25%	19%	16
Patient representative organisation / voluntary organisation or charity	8%	33%	33%	25%	12
Other	42%	25%	8%	25%	12

Table 25 shows the proportion of consultation survey respondents who agree or disagree that CCGs should be advised to support prescribers in deprescribing rubefacients (excluding topical NSAIDs and capsaicin) in all patients, and where appropriate, ensure the availability of relevant services to facilitate this change.

The largest proportion of respondents agree with the proposal (44%), although support is lowest amongst patients and highest amongst CCGs.

DRAFT

Table 25. Advise CCGs to support prescribers in deprescribing rubefacients (excluding topical NSAIDs and capsaicin) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

	Agree	Neither agree or disagree	Disagree	Unsure	*Base*
Total	**44%**	**20%**	**18%**	**18%**	**725**
Patient	31%	25%	21%	22%	318
Member of the public / family member / friend or carer of patient	38%	16%	26%	20%	167
Clinician	57%	22%	9%	11%	89
CCG	95%	1%	0%	4%	79
NHS provider organisation / other healthcare organisation / other NHS organisation	80%	10%	5%	5%	20
Industry / professional representative body	38%	25%	19%	19%	16
Patient representative organisation / voluntary organisation or charity	8%	33%	33%	25%	12
Other	42%	25%	8%	25%	12

The key themes raised about these proposals in the online survey, easy read survey, correspondence, webinars and meetings are now presented by respondent type.

Patients

In support of the proposal, this respondent group states rubefacients are widely available to purchase at a low cost.

Comments against the proposal include: patient care should be the main priority when these decisions are made; the proposal is taking a blanket approach, which does not consider the needs of individual patients; CCGs should not make decisions on what medications are provided; rubefacients are an effective treatment and the proposal may lead to adverse patient outcomes.

Members of the public / family members, friends or carers of patients

Comments against the proposal include: patient care should be the main priority when making these decisions; the proposal is a blanket approach, which does not consider the needs of individual patients; rubefacients are an effective treatment so there is a need to ensure alternative treatments are available and the proposal may lead to adverse patient outcomes.

There is a need to consider the impact on those with a low income and their ability to purchase rubefacients.

Clinicians

Comments in support of the proposal include: rubefacients should be blacklisted as they are widely available to purchase over the counter at a low cost; and national guidance would be welcomed as it would encourage further implementation.

Comments against the proposal include: patient care should be the main priority when making these decisions; the proposal represents a blanket approach, which does not consider the needs of individual patients; and rubefacients may be the only treatment option for some (e.g. patients with allergies).

Consideration raised by this group include: the impact on the services required to facilitate this change (e.g. GP appointments) and the need for public education.

DRAFT

CCGs

This group express their support for the proposal with comments including: there is a lack of clinical evidence showing the effectiveness of rubefacients; their prescribing is not an effective use of NHS resources and rubefacients should be blacklisted (as they are widely available over the counter at a low cost).

Comments against the proposal include: rubefacients are an effective treatment and the proposal may ultimately cost the NHS more money (through the prescribing of costlier alternatives).

It was also commented that the proposal is already being implemented successfully in some areas, but national guidance would be useful as it would encourage further implementation. Focusing on the proposed guidance, it is felt it could be made clearer and supported by public education to communicate the rationale for the proposal.

Other NHS organisations / NHS provider organisations / professional representative bodies / regulator / industry

Comments both in support and against the proposals were raised by this respondent group.

Comments in support of the proposal include: there is a lack of clinical evidence showing the effectiveness of rubefacients; and these items should be blacklisted. Another comment is that the proposal is already being implemented successfully in some areas.

Comments against the proposal include: there is concern that the research used to inform the proposal is inadequate and should be considered not valid; the proposal takes a blanket approach and does not consider individual patients' needs as rubefacients may be the only treatment option for some (e.g. patients with allergies) and the proposal may lead to adverse patient outcomes, so there is a need to ensure alternative treatments are available.

Considerations raised by this group include: the impact on the services required to facilitate this change (e.g. GPs); the impact on patients in rural areas (who may lack access to over the counter alternatives); the impact on the elderly, disabled and women (as these groups may be disproportionately affected).

It was also commented that patients should be made aware of prescribing changes and there is a need to ensure community pharmacies have access to resources aiding implementation of the guidance (e.g. leaflets).

Patient representative organisation / voluntary organisation or charity

Comments against the proposal include: patient care should be the main priority when making decisions as rubefacients may be the only treatment option for some (e.g. due to allergies); there is concern that the research used to inform the proposal is inadequate and should be considered not valid and the proposal may lead to adverse patient outcomes.

Additionally, the level of impact on those with a low income and their ability to purchase rubefacients should be taken into consideration.

DRAFT

7 Additional comments

Respondents were given the opportunity to raise any additional comments at the end of the consultation survey. The key themes are now presented by respondent type.

Patients / members of the public / family members, friends or carers of patients

In support of the proposals, it was commented that the proposals should be extended to include other medications.

Comments against the proposals include: the proposals take a blanket approach, which may lead to adverse patient outcome, which could ultimately cost the NHS more money; there is concern that the research used to inform the proposal is inadequate and should be considered not valid and the proposal may disproportionately affect women or ethnic minorities.

Focusing on the specific items in the consultation, this respondent group comment that bath and shower preparations are an effective treatment and patients should have access to them. Also, amiodarone should be prescribed if alternatives cannot be used.

Considerations raised by this group include: the need for greater patient education on the implementation of the proposals and the impact on quality of life and on low income groups.

Clinicians

Comments in support of the proposals include that they should be extended to include other medications. There is also a need to consider the impact on low income groups.

Focusing on minocycline, it was commented that it is associated with many adverse side effects and should be blacklisted.

CCGs

Comments in support of the proposals include that they should be extended to include other medications.

Comments raised against the proposals include: there is concern that the research used to inform the proposal is inadequate and should be considered not valid and that the proposal is taking a blanket approach which does not work when treating individual conditions.

Also, there is a need to consider the need for greater patient education on the implementation of the proposals.

Professional representative bodies / regulator / industry

Additional comments raised against the proposals include: the proposal may lead to adverse patient outcomes and quality of life (e.g. pain, infections, worsening of conditions); adverse effects on patients could ultimately cost the NHS more money and there is concern that the research used to inform the proposal is inadequate and should be considered not valid.

Considerations raised by this respondent group include the need for greater patient education on the implementation of the proposals and the impact on those with a low income or from a lower socioeconomic background.

In relation to bath and shower preparations, it was commented that a lack of understanding around the correct use of emollients leads to inappropriate use and a reduction in treatment efficacy.

Patient representative organisations / voluntary organisations or charities

DRAFT

Additional comments raised against the proposal include: it takes a blanket approach which does not work when treating individual conditions and there is concern that the research used to inform the proposal is inadequate and should be considered not valid.

DRAFT

Clinical evidence for emollient bath and shower preparations

Brief

Emollient bath and shower preparations for dry and pruritic skin conditions are included in the NHS England consultation document published in November 2018: "Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs". These items are classified as being of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

This evidence review has been prepared in response to concerns about including emollient bath and shower preparations in the NHS England consultation, and following a request for a full review of the evidence base. This review focuses on the literature available for emollient bath and shower preparations, i.e. an emollient product designed specifically for washing with in the bath or shower, and will assess its quality.

Summary of clinical evidence

- Emollient bath and shower preparations are used in patients with atopic eczema/dermatitis and a variety of other dry skin conditions. A large number of proprietary preparations are available, all of which may be prescribed on an NHS prescription. See Appendix 1 for definition of emollient preparations.
- A literature search was undertaken by SPS of Medline, Embase, CINAHL, BNI, Cochrane Library, GREAT database, NICE Evidence and Google Scholar. Search strategy is shown in Appendix 2. The search was limited to randomised controlled trials (RCTs), systematic reviews or reviews. It was not limited by clinical indication. RCTs of leave-on emollients and soap substitutes were excluded; further exclusion criteria are listed in Appendix 3.
- We identified a single RCT assessing the efficacy of emollient bath additives – the BATHE study. We also identified three systematic reviews (conducted before BATHE was published) that assessed efficacy of emollients but identified no RCTs of emollient bath or shower preparations. The lack of evidence in support of emollient bath additives (prior to publication of the BATHE study) has been confirmed numerous times by authors of guideline development groups and narrative reviews.
- The BATHE study is a high-quality, UK general practice-based study that compared efficacy and safety of commonly used emollient bath additives plus standard eczema care with standard care alone in children aged 1 to 11 years with atopic eczema. It showed that using emollient bath additives, in addition to other leave-on emollients and emollient soap substitutes, does not result in a clinically significant improvement in eczema symptoms compared with standard care alone. The trial provides sufficient assurance that there is evidence to support not routinely using emollient bath additives in children with mild-to-moderate atopic eczema being managed in primary care.
- The BATHE study did not include adolescents or adults, but it would seem appropriate to extrapolate the study findings to older patients with atopic eczema being managed in primary care, in the absence of any conflicting trial data (of which there are currently none). Although it only included patients with atopic eczema, the findings are probably also applicable to patients with other dry skin conditions being managed by their GPs.
- Few patients with severe eczema were included in the BATHE study, and the findings may not be so directly applicable to patients with severe dry skin conditions being managed by secondary care specialists who are likely to require a combination of treatment modalities because of the severity of their disease.

Place in national/ international guidance

Guidance on use of emollients, including emollient bath and shower preparations, has been published by national and international organisations.

National guidance

- **National Institute for Health and Care Excellence (NICE) 2007**
  NICE guideline CG57 on treatment of atopic eczema in children aged under 12 years (2007) recommends that health professionals should offer children with atopic eczema a choice of unperfumed emollients to use every day for moisturising, washing and bathing.[1] This may include a combination of products or one product for all purposes.

The full NICE evidence review did not identify any controlled studies comparing emollients to placebo or active intervention, so it was not possible to quantify benefits and harms of emollient therapy.[2] The literature search found two uncontrolled studies using emollient bath additives (and two additional studies using emollient bath additives containing antimicrobials) but were judged by the guideline development group to be inadequate to inform the guideline.

- One study was a case series reporting on use of a bath oil preparation containing soya oil plus lauromacrogols in children and young people with dry, itchy dermatoses (n=3,566). Mean duration of treatment and follow-up was six weeks. The diagnosis was atopic eczema in 86% of the cases, and most (94%) of those included were aged under 15 years. Overall, 78% received other treatment for their skin condition, but because details of these treatments were not reported it is not known whether improvements in the children's global condition were due to the bath oil preparation or to other treatments.

- The second study assessed the effects of using *Oilatum*® bath emollient daily (by soaking one arm in a basin of water with added emollient) in a within-patient (left–right side) comparison (n=9). All children had standardised treatment consisting of weekly whole-body bathing in a bath containing the same emollient, twice-daily application of an emollient and a topical corticosteroid, and use of emulsifying wax as soap substitute. The treated (daily treatment) and untreated (routine care) arms were evaluated by an assessor blind to treatment allocation. Mean difference in clinical score at four weeks (a measure of extent and severity of atopic eczema) was not significant, although the difference in mean change in score over the duration of the four-week study was reported to be significantly different.

The NICE guideline development group concluded that a complete emollient regimen provides optimum benefit. Emollient bath oils and other emollient wash products provide an essential method to clean the skin without the damaging effect of soap and detergents. They note some children may need additional products that can be applied indirectly to the skin, such as in the bath, to ensure that adequate amounts of emollient are absorbed into their skin. Healthcare professionals should offer a range of different products; the correct emollient is the one that the child will use.

Following publication of the BATHE study in 2018 (see below), NICE announced in February 2019 that it plans to update its guideline.[3]

- **Scottish Intercollegiate Guidelines Network (SIGN) 2011**
  In its guideline on management of atopic eczema in children and adults in primary care, SIGN notes that a systematic review in 2000 did not identify any high quality clinically relevant evidence in support of emollient monotherapy.[4] However, SIGN acknowledged that expert opinion (from NICE guideline CG57 in children, but applicable to adults) supports use of emollients. Emollient bath oils are included in their list of available types of emollients.

- **British Association of Dermatologists (BAD) *undated***
  BAD published a position statement on the place of bath emollients in treatment of atopic dermatitis.[5] They recommend that people with atopic dermatitis use a very mild wash product with some emollient ingredients – use an emollient cream as a soap substitute or, as an alternative, an emollient bath oil or shower product. BAD notes NICE advises patients, or their parents, should be allowed to choose either an emollient or a bath/shower product, as there is no evidence to separate the two choices. They also note that results from the then ongoing BATHE study will allow a more evidence-based approach to be used when developing prescribing policies.

- **Primary Care Dermatology Society (PCDS) 2018**
  PCDS clinical guidance on atopic eczema recommends complete emollient therapy to the whole skin every day – the correct use of moisturisers, bath or shower emollients, and soap substitutes.[6] Supporting evidence is not described.

- **Clinical Knowledge Summaries (CKS) 2018**
  CKS notes that emollient bath additives and shower products are an option for people with extensive areas of dry skin, although evidence to support their use is limited and there is no universal consensus as to their benefit.[7] The guidance cautions that if emollient bath additives are to be used, it is essential they do not replace standard emollients, but are used in addition to leave-on emollients.

- **Royal College of Nursing (RCN) 2013**
  The RCN, in its 2013 guidance for nurses, recommends that first-line treatment of atopic eczema should be complete emollient therapy (use of a bath or shower product, soap substitutes and leave-on emollients).[8] It refers to the NICE guideline on atopic eczema in support of this statement.

- **UK Emollient Consensus Group 2013** *(sponsored by Almirall)*
  As use of emollient therapy in dry skin conditions is supported only by limited or atopic dermatitis-specific guidelines and a best practice statement, an Emollient Consensus Group was set up to review current data and practice.[9] In 2013, they advised that patients should be given the opportunity to consider a variety of emollients from the whole spectrum of products available, and to identify the most suitable products for their skin. Emollient bath additives should be used in conjunction with leave-on emollients. No evidence in support of this recommendation is provided.

- **British Dermatological Nursing Group (BDNG) 2012** *(sponsored by Almirall)*
  In a best practice statement published in 2012 by BDNG with support from the International Skin care Nursing Group (ISNG), use of bath additives is advocated.[10] It notes there are also wash products designed for use in the shower. It states there is little evidence as to the efficacy of emollient bath additives, but that for patients they can be a useful way to get moisturisers onto the skin.

Research published on local guidance

A cross-sectional study designed to identify and compare emollient formularies across all clinical commissioning groups in England and local health boards in Wales (total n=216) identified 102 formularies.[11] Of the 82% that recommended an emollient bath additive (24 different ones), 75% (64/84) gave no rationale, six noted evidence to support use was lacking, eight recommended use in specific circumstances, and six cited 'possible benefit for some patients'. There was no mention of emollient bath additives in 7% of formularies, and 11% did not recommend routine use of emollient bath additives.

International guidance

- **European Consensus Group 2018**
  In an update to its 2012 guidance on atopic dermatitis, this consensus-based guideline developed as a joint interdisciplinary European project, recommends use of emollient bath oils and soap substitutes in addition to leave-on emollients.[12] It notes that bath oils are a valuable addition for skin care, especially in babies and children. It does not present any evidence in support of the recommendation to use emollient bath additives.

- **American Academy of Dermatology 2014**
  The American Academy of Dermatology, in its 2014 evidence-based guideline for management of atopic dermatitis in adults and children, states that the addition of oils and emollients to bath water cannot be recommended at this time, because of insufficient evidence.[13] The quantity of emollient deposited on the skin via a bath additive is likely to be lower than that from direct application. Bathing with water can hydrate the skin and remove scale, crust, irritants and allergens, which can be helpful for patients with atopic dermatitis. However, if the water is left to evaporate from the skin, greater trans-epidermal water loss occurs. Therefore, application of moisturisers soon after bathing is necessary to maintain good hydration status.

Evidence for this SPS review

A literature search for emollient bath and shower preparations identified a single RCT[14] that assessed the efficacy of emollient bath additives (see Appendix 2).

Prior to publication of this study,[14] several narrative reviews have concluded there is no published evidence from RCTs evaluating the efficacy of emollient bath additives in atopic eczema and other dry skin conditions.[2,13,15-18] This lack of evidence, until recently, has been common to leave-on emollients and emollient bath additives.[15] However, whereas there is consensus among clinicians and long-standing clinical experience that leave-on emollients are effective, it is not the case with emollient bath additives.[7,15,18] There is also no evidence that complete emollient therapy is effective.[16]

Despite the lack of evidence and consensus of opinion, use of emollient bath and shower preparations in England is significant.[18,19] In 2015, total spend on these products in England was nearly £23.1 million.[18] A cross-sectional study published online in December 2018, involving 13,618 children with atopic eczema in England, found that 34% of children with active atopic eczema were prescribed an emollient bath additive by their GP during the 1-year study period (29% received both bath additive and leave-on emollient, and 5% received a bath additive but no leave-on emollient).[19] Overall, 75% received a leave-on emollient and 20% received neither a leave-on emollient or an emollient bath additive.

Systematic reviews

Four systematic reviews have assessed the efficacy of emollients.[20-23] However, a Cochrane review of emollients and moisturisers for eczema focussed only on leave-on moisturisers.[23]

- **Nankervis *et al*. 2017**
  A systematic scoping review of all systematic reviews and RCTs for atopic eczema treatments (designed to map existing evidence and identify gaps in the literature) found no RCTs on non-antiseptic emollient bath additives or shower emollients.[20] This review was commissioned by the National Institute for Health Research (NIHR) to update a previous review published in 2000.[22]

- **Hoare *et al*. 2000**
  This initial NIHR-commissioned systematic scoping review of treatments for atopic eczema identified only five published RCTs for emollients, none for emollient bath or shower preparations.[21]

- **Jacobi *et al*. 2015**
  A systematic review of keratolytics and emollients in patients with psoriasis found no RCTs for emollient bath or shower preparations.[22]

Published randomised controlled trials

- **Santer M *et al.* (BATHE study)**
  A UK-based, open-label, pragmatic RCT (n=482) compared emollient bath additives plus standard eczema care with standard care alone in children aged 1 to 11 years (mean age 5.3 years; 51% female) with a diagnosis of atopic dermatitis (according to UK diagnostic criteria).[14] Children with very mild (score ≤5 on Nottingham eczema severity scale) or inactive eczema (over last 12 months) and those who bathed less than once weekly were excluded.

  Children were randomised in a 1:1 ratio to their group using an automated on-line software package (with a back-up phone option). From the detail available it appears that allocation concealment was achieved and the investigator would have had no opportunity to influence whether the patient was allocated to the emollient bath additive (intervention) group or the control group. Overall, randomisation resulted in two groups similar at baseline. However, there is an unexplained disparity in numbers allocated – 264 patients were allocated to the intervention group and 218 to the control group. This does not materially affect the validity of trial design but it would be useful to understand how this arose. The authors suggest their use of a simple randomisation technique may have been the cause, as the technique can result in imbalances in numbers recruited to each group.[24]

  Patients, carers, clinical study officers and research nurses were not blind to treatment allocation, but statisticians carrying out the analyses were. This was a pragmatic trial and the authors said it is not possible to create a credible “placebo” emollient bath additive. This is a valid argument and does not significantly compromise the validity of findings.

  Children in the intervention group were prescribed emollient bath additives (ideally one of the three most widely prescribed in the UK) and asked to use them regularly for 12 months, while children in the control group were not prescribed emollient bath additives and were asked not to use any emollient bath additives for 12 months. *Oilatum*® was used by 45% of the intervention group, *Aveeno*® by 26% and *Balneum*® by 4.5%, with 30% of children prescribed another brand of emollient bath additive. Emollient bath additives containing antimicrobials were not permitted as they may cause irritation. Both groups received written information on how to wash, including use of leave-on emollients as a soap substitute. No data presented suggested that there was any differential approach to management between the two groups.

The primary outcome was eczema severity, measured by the validated Patient Oriented Eczema Measure (POEM) score over 16 weeks. POEM is a patient/carer-reported outcome measure which consists of seven questions to provide a score of between 0 and 28; minimal clinically important difference (MCID) is 3 points. At baseline, 62 children (13%) had severe eczema, 233 (48%) had moderate eczema and 187 (39%) had mild eczema. Although baseline mean POEM scores are similar between the intervention and control groups (9.5 vs. 10.1, respectively), it would appear that more patients with mild eczema were randomised to emollient bath additives (43%) than the control group (33%) – it could be argued that this reduced the scope to achieve significant reductions in POEM score from baseline in the intervention group.

The study was adequately powered for the primary outcome to have a 90% chance of detecting a mean difference of 2.0 points on the POEM scale at $p<0.05$ level in the intention-to-treat (ITT) population, if such a difference existed. It was slightly underpowered to undertake a per-protocol (PP) analysis but only by a few patients.

Results

In the intervention group, mean POEM score over 16 weeks was 7.5 points (SD 6.0) from a baseline score of 9.5; in the control group, mean POEM score was 8.4 points (SD 6.0) from a baseline score of 10.1. There was no statistically significant difference in POEM score between the two groups over 16 weeks. After adjusting for baseline severity, confounders (including topical corticosteroid and soap substitute use), and allowing for clustering within practices and responses within participants over time, the POEM score in the control group was 0.41 points higher (95% confidence interval [CI] -0.27 to 1.1) compared with the intervention group. The upper limit of the CI (1.1 points) falls well below the MCID of 3 points, so the authors feel that this rules out the possibility of a clinically significant effect within the credible range of results seen.

These findings were reinforced in the PP analysis (which increases the likelihood of demonstrating a positive difference in that it selects the population that actually complied with the allocated treatments) in which mean difference in POEM score was a statistically insignificant difference of 0.32 (95% CI: -0.37 to 1.02).

There was no significant difference between groups according to baseline disease severity. Adjusted difference in mean POEM score was -0.07 (95% CI: -1.08 to 0.95) in the mild eczema group, 0.65 (95% CI: -0.45 to 1.74) in the moderate eczema group, and -1.16 (95% CI: -3.62 to 1.32) in the severe group.

No significant differences were observed between groups for any of the secondary outcomes. These included POEM scores measured every four weeks over 52 weeks, disease-specific quality of life at 16 weeks and one year (measured using dermatitis family impact), generic quality of life at 16 weeks and one year (measured using child health utility-9D), number of disease exacerbations requiring primary care consultation over one year, type and quantity of topical corticosteroid/topical calcineurin inhibitor prescribed over one year, resource use, adherence to treatment allocation, and adverse effects.

The authors also assessed the economic impact of using emollient bath additives and found no benefits that could be used to consider them to be cost-effective.

- Overall mean annual cost to the NHS was £180.50 in the intervention group vs. £166.12 in the control group, a non-significant difference of £14.38 (95% CI: -£33.45 to £62.21).
- For costs borne by families, there was a non-significant difference between groups, with a higher spend of £51.37 in the control group (95%CI: -£15.74 to £118.49); the adjusted difference was £47.56 (-£18.07 to £113.19).
- There was no significant difference in quality adjusted life years (QALYs) between groups, with 0.91 QALYs in the intervention group vs. 0.90 in the control group, mean difference 0.00 (-0.01 to 0.02).

Adverse events were similar across groups. Over the first 16 weeks, 35% of children in each group reported at least one adverse event, with no significant difference between groups (odds ratio 1.4, 95% CI: 0.79 to 2.47). Adverse events reported at 16 weeks across the intervention and control groups, respectively, were slipping in bath (17% vs. 25%), redness (14% vs. 23%), refusal to bathe (8% vs. 12%) and stinging (2% vs. 2%). At 52 weeks, these figures had mostly increased – slipping in bath (22% vs. 30%), redness (17% vs. 29%), refusal to bathe (12% vs. 15%) and stinging (3% vs. 2%).

Discussion

This is a pragmatic study conducted in primary care centres in the UK – so clearly applicable to practice, particularly in children. There may be some debate as to whether it is appropriate to extrapolate findings to adolescents, adults and patients with more severe disease who require specialist care (as only 13% had severe disease).

The open-label design of the study may have introduced bias, as parents knew which group their child was randomised to. This knowledge may have affected how they managed their child's eczema, for example the volume of soap substitute emollient used. In addition, all participants in the study received information on use of emollients as soap substitutes. However, both of these factors would be expected to improve the patients' skin in both groups. It would have been interesting to have been presented with an analysis of proportion of patients in each group that achieved a 3-point reduction in baseline POEM score – as this would have supported a more intuitive NNT-type (number needed to treat) analysis of the results.

The authors analysed the results using both ITT and PP principles. ITT is the preferred approach in superiority trials. The researchers showed no significant difference in the ITT population (which is the population that more closely reflects clinical practice). Analysis of the PP population takes account of the fact that some patients in the intervention group used additives less than 50% of the time and some patients in the control group used emollient bath additives more than 50% of the time. This potentially reduces the chances of showing a difference in favour of emollient bath additives if one exists. However, in taking the "non-compliant" patients out of the PP analysis, there was still no significant beneficial effect seen from using emollient bath additives.

There were low rates of loss to follow-up in both arms of the study – 13/265 in the intervention group and 9/218 in the control group. As no significant differences were found in terms of primary or secondary outcomes it seems unlikely that loss to follow-up significantly impacted on the results described. However, without a dichotomous outcome (such as proportion of patients that achieved a fall of 3 points or more on POEM score), it is not possible to explore this in any more detail.

In the absence of any robust evidence to contradict the findings of this RCT, this study provides sufficient assurance that there is good evidence to support not routinely using emollient bath additives in children with mild-to-moderate atopic dermatitis that are managed in primary care. It would seem appropriate to extrapolate the findings to older patients and those with other dry skin conditions, in the absence of any conflicting trial data. However, it is less clear whether it is appropriate to extrapolate the findings to patients with severe disease who may require a combination of treatment modalities.

Note: The BATHE study has also been published as a health technology assessment report.[24]

References

1. NICE. Clinical guideline [CG57] Atopic eczema in under 12s: diagnosis and management. Dec 2007. Available at www.nice.org.uk/guidance/cg57, accessed 1/3/19.
2. National Collaborating Centre for Women's and Children's Health. Atopic eczema in children: management of atopic eczema in children from birth up to the age of 12 years. Dec 2007. Available at https://www.nice.org.uk/guidance/cg57/evidence/full-guideline-pdf-196612237, accessed 8/3/19.
3. NICE Surveillance report. 2019 exceptional surveillance of atopic eczema in under 12s: diagnosis and management (NICE guideline CG 57). 15 Feb 2019. Available at www.nice.org.uk/guidance/cg57/resources/2019-exceptional-surveillance-of-atopic-eczema-in-under-12s-diagnosis-and-management-nice-guideline-cg57-pdf-8639785095109, accessed 1/3/19.
4. Scottish Intercollegiate Guidelines Network (SIGN). Management of atopic eczema in primary care. Edinburgh: SIGN; 2011. (SIGN publication no. 125). [Mar 2011]. Available at www.sign.ac.uk/assets/sign125.pdf, accessed 1/3/19.
5. British Association of Dermatologists. Position statement on the place of bath emollients in the treatment of atopic dermatitis (AD). Undated. Available at www.bad.org.uk/shared/get-file.ashx?itemtype=document&id=4163, accessed 22/2/19.
6. Primary Care Dermatology Society. Atopic eczema. Last updated 25 Jul 2018. Available at www.pcds.org.uk/clinical-guidance/atopic-eczema#management accessed 8/3/19.
7. NICE Clinical Knowledge Summaries. Eczema – atopic. Last revised Jan 2018. Available at https://cks.nice.org.uk/eczema-atopic, accessed 22/2/19.
8. Royal College of Nursing. Caring for children and young people with atopic eczema. Guidance for nurses. Apr 2013. Available at www.rcn.org.uk/-/media/royal-college-of-nursing/documents/publications/2013/august/pub-003228.pdf, accessed 1/3/19.
9. Moncrieff G, Cork M, Lawton S *et al*. Use of emollients in dry-skin conditions: consensus statement. Clin Exp Dermatol 2013; 38(3): 231-8. Available at https://doi.org/10.1111/ced.12104, accessed 6/3/19.
10. Penzer R. Best practice in emollient therapy: A statement for healthcare professionals. Dermatological Nurs 2012; 11(4): 60-79. Available at www.ingentaconnect.com/contentone/bdng/dn/2012/00000011/00000004/art00008, accessed 27/3/19.
11. Chan JP, Boyd G, Quinn PA and Ridd MJ. Emollient prescribing formularies in England and Wales: a cross-sectional study. BMJ Open 2018; 8: e022009. Available at http://dx.doi.org/10.1136/bmjopen-2018-022009, accessed 5/3/19.
12. Wollenberg A, Barbarot S, Bieber T, *et al*. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part I. J Eur Acad Dermatol Venereol. 2018; 32(5): 657-82. Available at https://doi.org/10.1111/jdv.14891, accessed 26/3/19.
13. Work Group: Eichenfield LF, Tom WL, Berger TG *et al*. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014; 71: 116-32. Available at http://dx.doi.org/10.1016/j.jaad.2014.03.023, accessed 5/3/19.
14. Santer M, Ridd MJ, Francis NA *et al*. Emollient bath additives for the treatment of childhood eczema (BATHE): multicentre pragmatic parallel group randomised controlled trial of clinical and cost effectiveness. BMJ 2018; 361: k1332. Available at www.bmj.com/content/361/bmj.k1332/rapid-responses, accessed 5/3/19.
15. Anon. Bath emollients for atopic eczema: why use them? Drug Ther Bulletin 2007; 45(10): 73-5. Available at http://dx.doi.org/10.1136/dtb.2007.09.0015, accessed 22/2/19.
16. Tarr A and Iheanacho I. Should we use bath emollients for atopic eczema? BMJ 2009; 339: b4273. Available at http://doi.org/10.1136/bmj.b4273, accessed 5/3/19.
17. Gittler JK, Wang JF and Orlow SJ. Bathing and associated treatments in atopic dermatitis. Am J Clin Dermatol 2017; 18: 45-57. Available at http://doi.org/10.1007/s40257-016-0240-2, accessed 5/3/19.
18. PrescQIPP. Cost effective prescribing of emollients. Bulletin 76. May 2015. Available at www.prescqipp.info/our-resources/bulletins/bulletin-76-emollients/, accessed 6/3/19.
19. Ganatra N, Ban L, Harman K and Thomas K. How often are bath emollients prescribed to children with atopic eczema in primary care in England? A cross-sectional study. Br J Dermatol 2019; published early 10 Dec 2018. Available at https://doi.org/10.1111/bjd.17514, accessed 5/3/19.
20. Nankervis H, Thomas KS, Delamere FM *et al*. What is the evidence base for atopic eczema treatments? A summary of published randomized controlled trials. Br J Dermatol 2017; 176: 910-27. Available at https://doi.org/10.1111/bjd.14999, accessed 5/3/19.
21. Hoare C, Li Wan Po A and Williams H. Systematic review of treatments for atopic eczema. Health Technology Assessment 2000; Vol 4: No. 37. Available at https://doi.org/10.3310/hta4370, accessed 5/3/19.
22. Jacobi A, Mayer A and Augustin M. Keratolytics and emollients and their role in the therapy of psoriasis: a systematic review. Dermatol Ther 2015; 5(1): 1-18. Available at https://dx.doi.org/10.1007%2Fs13555-015-0068-3, accessed 8/3/19.
23. van Zuuren EJ, Fedorowicz Z, Christensen R *et al*. Emollients and moisturisers for eczema. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD012119. Available at https://doi.org//10.1002/14651858.CD012119.pub2, accessed 5/3/19.
24. Santer M, Rumsby K, Ridd MJ *et al*. Adding emollient bath additives to standard eczema management for children with eczema: the BATHE RCT. Health Technology Assessment 2018; Vol 22: Issue 57. Available at http://dx.doi.org/10.3310/hta22570, accessed 5/3/19.

Written by: London & South East Medicines Information Service & North West Medicines Information Service.
Date: March 2019
Contact: nwmedinfo@nhs.net

Appendix 1: Definition of emollient preparations

NHS England requested a review of the evidence base for emollient bath and shower preparations, as defined in the BATHE study.[14] The definition is:

> "Emollients are applied in one of three ways:
> - leave-on, where emollients are directly applied to the skin;
> - soap substitutes, where emollients are used instead of soap or other wash products; and
> - bath additives, comprising oil or emulsifiers, or both designed to be added to bath water and thought to leave a film of oil over the skin.
>
> Some emollients can be used in more than one way. We therefore use the term "emollient bath additives" or "bath additives" rather than bath emollients to emphasise the differences between the three methods of application in recognition that products may have more than one method of application."

We have used the term 'emollient bath additives' when discussing bath emollients within this evidence review.

Appendix 2: Search strategy

Database	Search term	Results
EMBASE – 25/3/19	("EMOLLIENT AGENT"/ AND (BATH/ OR (bath).af OR (shower).af)) AND (exp "CONTROLLED CLINICAL TRIAL"/ OR exp REVIEW/)	88
Medline – 25/3/19	(exp EMOLLIENTS/ AND (BATHS/ OR (bath).af OR (shower).af)) [Document type Meta-analysis OR Randomized Controlled Trial OR Review]	38
CINAHL – 15/3/19	(exp EMOLLIENTS/ AND ("BATHING AND BATHS"/ OR (shower).af)) [Publication types Meta Analysis OR Randomized Controlled Trial OR Systematic Review]	5
BNI – 15/3/19	((bath).af OR (shower).af AND (emollient).af))	18
Cochrane Library via www.thecochranelibrary.com – 15/3/19	Search: Moisuturi* AND (bath* OR shower*) Emollient* AND (bath* OR shower*)	 36 53
NICE Evidence – 4/3/19	Search: bath emollient Limit to guidance and policy; remove prescribing and technical information	34
Google Scholar – 5/3/19	Advanced search: Search exact phrase = bath emollient AND Search = trial OR study OR adult OR child	143
GREAT database via www.greatdatabase.org.uk – 15/3/19	Search: (Bath [any field] OR shower [any field]) AND emollient* [any field]	24

Appendix 3: Exclusion criteria

- leave-on emollients
- soap substitutes
- healthy volunteers
- neonates
- prevention of dry skin, e.g. routine skin care in healthy infants
- tar-containing preparations
- antibiotic-containing preparations
- antiseptic-containing preparations
- studies evaluating cellular or biochemical responses, or blood tests
- conference abstracts

Clinical evidence for silk garments

Brief

Silk garments are included in the NHS England consultation document published in November 2018: "Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs". These items are classified as being of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns. This evidence review has been prepared in response to concerns raised by the manufacturers of Dermasilk® regarding inclusion of silk garments in the NHS England consultation. This review aims to focus on the literature available and will assess the quality of this literature.

Summary of clinical evidence

- Silk garments are classified as medical devices. Currently, manufacturers need to ensure that their devices are safe and fit for their intended purpose to gain the CE mark; there is no requirement for clinical trials of efficacy
- Silk garments are primarily used in patients with atopic eczema although they have been used in a variety of other conditions including vulvar conditions, epidermolysis bullosa and burns. A range of garments are available including eye masks, socks, gloves, vests, pyjamas and body suits.
- The manufacturers of Dermasilk® provided a bibliography of 48 papers relating to the use of silk garments in a variety of clinical conditions.
- In addition to this, a literature search was undertaken by SPS of Medline, Embase, CINAHL, Cochrane Library and NHS Evidence. Search strategy is shown in Appendix 1. The search was limited to randomised controlled trials (RCTs), systematic reviews or reviews. It was not limited by clinical indication.
- Through this process we identified one systematic review published in 2013. We further included five RCTs of $\geq$ 30 patients, which were either not included in the systematic review (primarily due to different indications) or that were published subsequent to the systematic review.
- Trials of silk garments have generally included very small numbers of participants (range 11 to 300). Only one identified study has included more than 100 patients.
- It is widely recognised that treatment effect estimates are significantly larger in smaller trials, regardless of sample size[1]. Compared with trials of 1000 patients or more, treatment effects were, on average, 48% larger in trials with fewer than 50 patients (ratio of odds ratios 0.52, 0.41 to 0.66), 34% larger in trials with 50-99 patients (0.66, 0.56 to 0.79), 30% larger in trials with 100-199 patients (0.70, 0.61 to 0.80), 19% larger in trials with 200-499 patients (0.81, 0.73 to 0.88), and 10% larger in trials with 500-999 patients (0.90, 0.82 to 1.00).
- The GRADE handbook (*GRADE – the international standard for assessing clinical evidence*) suggests downgrading evidence for imprecision whenever sample sizes of less than 400 are used.
- Whilst we have included trials with small sample sizes in this review, clinical trials with such numbers of participants would never be an acceptable threshold for conventional medicines.
- We used the AMSTAR tool for scoring methodological quality of the systematic review. This scores a systematic review on a scale 0-11. We considered a score of 8-11 as a high quality systematic review; 4-7 moderate quality and 0-3 a low quality systematic review.
- Details and critique of these studies are reported below.

Place in national/ International guidance

- We have not identified any NICE or other UK guidance which recommends the use of silk garments for any clinical condition.
- NICE guidance on treatment of atopic eczema in children (2007) made no recommendations about the use of such garments in the management of eczema, though they included one of the largest studies in their review[2].

Evidence

Systematic reviews

Lopes et al[3]

A systematic review and meta-analysis of trials of functional textiles for atopic dermatitis. The review included 13 studies, six of which involved silk garments. Four studies included children whereas two included children and adults. Patient numbers ranged from 15 to 46. Only two studies of silk garments (tubular sleeves) were considered suitable for inclusion in a meta-analysis. From this the odds ratio of reduction of Eczema Area and

Severity Index (EASI) of atopic dermatitis symptoms in favour of silk was 1.74 (95% CI 2.19 to 1.30). The authors concluded that the quality of evidence for functional textiles for atopic eczema was low or very low.
The systematic review was considered moderate quality (AMSTAR score 7/11).

Published randomised controlled trials cited by Dermasilk® bibliography but not included in the systematic review:

D'Antuono et al (2011)[4]
A small (n=42), double-blind randomised controlled trial looking at the use of silk fabric (Dermasilk®) (treatment arm) compared to cotton briefs (control arm) in women (aged >18 years) with vulvar lichen sclerosus. The study looked at a range of subjective outcomes based on the signs and symptoms of vulvar lichen sclerosus.
The authors reported a lower rate of burning sensation in the treatment arm (9/21 patients) compared to the control arm (21/21 patients, p<0.0001) after six months treatment. Similarly, soreness was reported less often in the treatment arm (0/21 patients) than in the control arm (17/21 patients, p<0.0001) at six months. All other symptoms were numerically less frequent in the intervention arm than in the control arm, but p-values were not provided. A more mixed picture was presented for differences in rates of clinical signs at six months; only erythema was presented with a p-value (p<0.05) for a difference in rates between intervention (9/21 patients) versus control (19/21 patients). All patients in the treatment arm experienced either "complete response" or "good/partial response" in terms of symptoms and clinical signs, with none experiencing "poor response". Whereas 4/21 patients in the control arm had "poor response" for symptoms and 9/21 patients had poor response for clinical signs.
There are a number of methodological limitations of this study, which need to be considered. The study was not powered to provide assurance of statistical significance, and 17 different outcomes were compared for the two groups. It was not described how randomisation was carried out. Patient blinding will have been difficult to maintain due to the inherent differences between silk and cotton underwear. Adherence to use of this treatment underwear was not measured. The study relied on subjective outcomes, yet no information was provided on who was assessing the subjectivity (though logic suggests that patients will have reported the symptoms and a clinician will have been involved in assessing the signs). Use of subjective outcomes in trials where blinding may have been difficult to maintain presents a methodological limitation.
There was a large "placebo" response seen in this study, which may in part be due to patients in both control and intervention arms being directed to administer once daily "very potent" steroid cream and once daily moisturiser. Baseline severity was insufficiently described because data were not presented on prior use of steroid creams (which were noted as the standard of care used).

D'Antuono et al (2012)[5]
A double-blind, randomised controlled trial (n=96) comparing silk briefs (intervention) compared to cotton briefs (control) in adult women with recurrent vulvovaginal candidosis (at least 1 year history) and failure of fluconazole oral treatment. The study aimed to show a difference in signs and symptoms of recurrent vulvovaginal candidosis over a six month period.
The reduction in rate of recurrence between the treatment arm (11/48 without recurrence) and control arm (4/48 without recurrence) was an interesting outcome, but the study was not powered for this. Itching and burning symptoms were reduced more in the treatment arm than in the control arm at six months (6 patients vs. 28 patients reporting itching, p<0.0001; 1 patient vs. 8 patients reporting burning, p<0.01). Caution is advised when interpreting these patient-reported, subjective outcomes as blinding in this study will have been difficult to maintain thus introducing risk of bias. Erythema was lower in the treatment arm (6 patients) than the control arm (38 patients, p<0.0001) at six months. The change in severity of symptoms and signs was discussed in the paper, but results were not presented. Erythema severity was reported to have improved for more of the treatment arm (25/48 patients, 52%) vs. control arm (7/48 patients, 15%; p<0.0001) between three and six months. A higher proportion of the treatment arm did not experience a recurrence during the study (11/48 patients, 22.9%) compared to the control arm (4/48 patients, 8.3%; p=0.036). Although interesting findings, it should be noted that the study was not powered for these outcomes, so caution is needed when interpreting them.
The randomisation process was not described, and baseline data were not provided to allow comparison of the intervention and control arms. This study was not powered for any of the outcomes chosen. The outcomes were all subjective, with an unvalidated score used to compare severity of the symptoms measured. It was again not clear how blinding could be maintained in this study, as women were issued with either silk briefs or cotton briefs. As all women were concomitantly treated with oral weekly fluconazole, it is of concern that baseline data on extent of prior treatment with fluconazole was not provided. Lack of data on adherence to treatment means there is less certainty about where a failure in blinding may have contributed to the result.

D'Antuono et al (2013)[6]
A small (n=30) randomised controlled trial comparing silk briefs (treatment arm) to cotton briefs (control arm) to improve the signs and symptoms of recurrent vulvovaginal candidosis. Patients recruited to this study were adult

women (not menopausal) with a history of recurrent vulvovaginal candidosis (mean duration not stated). Unlike in D'Antuono *et al* (2011)[4] described above, women in this study were specifically instructed not to apply any topical creams or pessaries. Women recruited to this study had refused to take a course of fluconazole, though there were differing reasons for this, including having received a previous course or because they feared side effects (numbers in each group not provided). This adds a potential difference in initial disease severity that is not controlled through stratification.

The primary outcome considered was to evaluate impact on vulvovaginal symptoms and signs in recurrent vulvovaginal candidosis, with a secondary outcome looking at the impact of exacerbations of symptoms. Patients in the treatment arm were statistically significantly more likely to have an improvement in symptoms and signs compared to the control arm ($p<0.001$ for three out of three symptoms and three out of four signs). There was no difference in impact on the rarer symptom of excoriations/fissures. There was a statistically significantly lower overall rate of flares in the treatment arm compared to the control arm (24 episodes vs. 68 episodes, $p<0.001$). It is notable that only two women in the treatment arm and zero in the control arm were completely free from flares at 6 months.

As with the studies discussed above, there were a number of methodological limitations of this trial, which impact on confidence in the results. There is no power calculation, the sample size was small, and there is concern about the ability to maintain patient blinding. The primary outcome, improvement of signs and symptoms, relies in part on subjective patient response, hence the importance of maintaining blinding.

Fabbrocini et al. [Abstract][7]

An English abstract of an Italian-language paper was reviewed, but provided very little detail about either effectiveness of tolerability of the intervention. It is not possible to critically appraise this abstract alone, and therefore no comment can be made about its conclusions.

Other published randomised controlled trials identified by SPS:

Thomas et al 2017[8]

A pragmatic, randomised- controlled trial recruited 300 children aged 1-15 with moderate to severe eczema (the CLOTHES trial). Participants were randomised to standard care plus silk garments or standard care alone. The trial was funded by the National Institute for Health Research (NIHR) HTA programme. Two different brands of silk garments were used (DermaSilk® and DreamSkin®) and patients were instructed to wear them as often as possible during the day and at night. Given the design of the trial patients were not blinded to treatment although observers were. The primary outcome was eczema severity at 6 months, using the validated Eczema Area and Severity Index (EASI). A safety outcome was skin infections. The study was powered to show a 3 point difference in mean EASI scores between the groups. A minimally clinically important difference for EASI in adults receiving systemic therapy is 6 points.

Overall 282 patients were included in the outcome assessment. The garments were mostly worn at night (81% of nights vs 34% of days). The groups were generally well matched at baseline although the EASI was slightly higher in the intervention group. At 6 months mean EASI score had reduced from 9.2 to 5.4 in the intervention group and 8.4 to 5.4 in standard care group (ratio of geometric mean 0.95 (95%CI 0.85-1.07, p=0.43 NS). There were no differences between treatment group for any outcomes assessed by the observers or percentage of days on which topical steroids or calcineurin inhibitors were used. Skin infection occurred in 25% of the intervention group and 28% of the standard care group (p=0.66 NS). Two secondary measures (Patient Orientated Eczema Measure - POEM) and participant global assessment (PGA) showed statistically significant improvement in the silk group.

Limitations: The study was limited due to the lack of blinding of patients and did not reach the participant numbers according to the power calculation. It is also worth noting that, whilst the authors considered adherence was good, patients wore the clothing only on 34% of days. This may have impacted on the results although may also show the 'real-world' usage of such products.

References

1. Dechartres A, Trinquart L, Boutron I et al Influence of trial sample size on treatment effect estimates: meta-epidemiological study BMJ 2013;346:f2304 https://www.bmj.com/content/346/bmj.f2304
2. NICE Clinical guideline [CG57] Atopic eczema in under 12s: diagnosis and management December 2007 (Available at https://www.nice.org.uk/guidance/cg57, accessed 14/2/19)
3. Lopes C, Silva D, Delgado L, Correia O, Moreira A. Functional textiles for atopic dermatitis: a systematic review and meta-analysis. Pediatr Allergy Immunol 2013: 24: 603–613
4. D'Antuono A, Bellavista S, Negosanti F *et al*. Dermasilk briefs in vulvar lichen sclerosus: an adjuvant tool. Journal of Lower Genital Tract Disease 2011; 15(4): 287 – 291 https://www.ncbi.nlm.nih.gov/pubmed/21959572
5. D'Antuono A, Baldi E, Bellavista S *et al.* Use of Dermasilk briefs in recurrent vulvovaginal candidosis: safety and effectiveness. Mycoses 2012; 55:e85 - e89. https://www.ncbi.nlm.nih.gov/pubmed/21895786
6. D'Antuono A, Bellavista S, Gaspari V *et al*. Dermasilk® briefs in recurrent vulvovaginal candidosis. An alternative option in long-lasting disease. Minerva Ginecol 2013; 65: 697 - 705.
7. Fabbrocini G, Panariello L, Russo G and Romano M. Effectiveness and tolerability of clothing made of silk fabric (Dermasilk®) in patients undergoing chemotherapy. Esperienze Dermatologiche 2015; 17(3): 123 - 127.
8. Thomas KS, Bradshaw LE, Sach TH, et al. Silk garments plus standard care compared with standard care for treating eczema in children: A randomised, controlled, observer-blind, pragmatic trial (CLOTHES Trial). PLoS Med 2017; 14(4): e1002280. https://doi.org/10.1371/journal.pmed.1002280

Written by Trent Medicines Information, Leicester and London Medicines Information Service.
Contact: medicines.info@uhl-tr.nhs.uk

February 2019.

Appendix: search strategy

Database	Search term	Results
EMBASE	((exp SILK/ OR (silk).af) AND (exp CLOTHING/ OR (clothing).af OR (garment).af)) AND (exp "CONTROLLED CLINICAL TRIAL"/ OR exp REVIEW/)	44
Medline	((exp SILK/ OR (silk).af) AND (exp CLOTHING/ OR (clothing).af OR (garment).af)) [Document type Meta-analysis OR Randomized Controlled Trial OR Review]	17
CINAHL	((silk).af AND (exp CLOTHING/ OR (clothing).af OR (garment).af)) [Publication types Meta Analysis OR Randomized Controlled Trial OR Systematic Review]	7
Cochrane Library via http://www.thecochranelibrary.com/view/0/index.html - 4/2/19	Search: Silk garments Silk clothing	 7 20
NICE Evidence – 04/02/19	Search: silk garments or clothing limited to systematic reviews	34

NHS Clinical Commissioners
The independent collective voice of clinical commissioning groups

NHS England

Items which should not routinely be prescribed in primary care: Guidance for CCGs

Version 2, June 2019

DRAFT

NHS England Publication XXXX

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the recommendations set out in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

DRAFT

CONTENTS

DRAFT

1 Background

This guidance was first published in November 2017 and included recommendations on 18 items which were consulted on from July – Oct 2017. In the Autumn of 2018 the guidance was reviewed, and further consultation was undertaken from Nov 2018 – Feb 2019 on an update to one of the 18 items (rubefacients) and 8 new items.

This updated CCG guidance therefore includes original recommendations for 17 items, an update to the recommendations for 1 of the original items and recommendations for 7 new items. Proposed recommendations for one of the new items (blood glucose testing strips) as outlined in the consultation document are not included in this version of the guidance and will be considered for addition at a later date.

Updated or new items are highlighted as [Updated 2019] or [New 2019]. Previous items are highlighted as [2017].

1.1 Who is this guidance for?

This guidance is addressed to Clinical Commissioning Groups (CCGs) to support them to fulfil their duties around appropriate use of their resources. We expect CCGs to take this guidance into account in formulating local polices, and prescribers to reflect local policies in their prescribing practice. Where appropriate there should be shared responsibility of prescribing and monitoring between primary and secondary care. Local areas should also take account of the NHS England guidance: Responsibility for prescribing between primary and secondary/tertiary care.

This guidance is issued as general guidance under s14Z10 and S2 of the NHS Act 2006 and is addressed to CCGs to support them to fulfil their duties around appropriate use of prescribing resources. The objective of this guidance is to support CCGs in their decision-making, to address unwarranted variation, and to provide clear national advice to make local prescribing practices more effective.

The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

1.2 Why have we developed this guidance?

Last year 1.1 billion prescription items[1] were dispensed in primary care at a cost of £8.8 billion[2]. This cost coupled with finite resources means it is important that the NHS achieves the greatest value from the money that it spends. We know that across England there is significant variation in what is being prescribed and to whom. Some patients are receiving medicines which have been proven to be relatively ineffective or in some cases potentially harmful, and/or for which there are other more effective, safer and/or cheaper alternatives; there are also products which are no longer appropriate to be prescribed on the NHS.

[1] An item is anything which can be prescribed on an NHS prescription. More information on what is prescribed on an NHS prescription is available in the Drug Tariff.
[2] NHS Digital Prescription Cost Analysis 2018

NHS England has partnered with NHS Clinical Commissioners to support Clinical Commissioning Groups (CCGs) in ensuring that they can use their prescribing resources effectively and deliver best patient outcomes from the medicines that their local population uses. CCGs asked for a nationally co-ordinated approach to the creation of commissioning guidance, developed with and by CCGs. The aim was a more equitable basis on which CCGs can take an individual and local implementation decisions. CCGs will still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

1.3 How have the recommendations in this guidance been developed?

In response to calls from General Practitioners (GPs) and CCGs who were having to take individual decisions about their local formularies, NHSCC, surveyed their members during February and March 2017 to assess views as to whether a range of medicines and other products should be routinely available for prescription on the NHS.

NHS Clinical Commissioners asked NHS England to work with them to produce commissioning guidance to support their member organisations in taking decisions about prescribing of these products in primary care.

Together, NHS England and NHSCC established a clinical working group, chaired by representatives of these two organisations, with membership including GPs and pharmacists, CCGs, Royal College of General Practitioners, National Institute for Health and Care Excellence (NICE), Department of Health and Social Care, the Royal Pharmaceutical Society and others (full membership listed at appendix A). This clinical working group was tasked with identifying which products should no longer be routinely prescribed in primary care.

Work focused on developing guidelines for products which fall into one or more of the following categories:

In the joint clinical working group, items were considered for inclusion if they were:

- Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns;

- Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation; and/or

- Items which are clinically effective but, due to the nature of the product, are deemed a low priority for NHS funding.

The group assigned one or more of the following recommendations to items considered:

- Advise CCGs that prescribers in primary care should not initiate {item} for any new patient;

DRAFT

- Advise CCGs that prescribers in primary care should not initiate {item} that cost {price} for any new patient.
- Advise CCGs to support prescribers in deprescribing {item} in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change;
- Advise CCGs to support prescribers in deprescribing {item} that cost {price} in all patients and where appropriate ensure the availability of relevant services to facilitate this.
- Advise CCGs that if, in exceptional[3] circumstances, there is a clinical need for {item} to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional;
- Advise CCGs that all prescribing should be carried out by a specialist; and/or
- Advise CCGs that {item} should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {circumstance}.

Subsequently NHS England's Board considered the proposals prior to them being formally consulted upon publicly.

In reaching its recommendations for the 25 products listed in this guidance document, the group considered recommendations from NICE, where relevant, in order to support CCGs in implementing NICE guidance across the country; in particular it identified items which NICE consider to be "Do not do's[4]".

Where NICE guidance was not available, the group considered evidence from a range of sources, for example; the Medicines and Healthcare products Regulatory Agency (MHRA), the British National Formulary, the Specialist Pharmacist Service and PrescQIPP Community Interest Company (CIC) evidence reviews.

The group reviewed each product against the following criteria:

- **Legal Status** i.e. is it prescription only, or is it available over the counter in pharmacies and/or any retail outlet?
- **Indication** i.e. what condition is it used to treat?
- **Background** i.e. a general narrative on the drug including. pack size, tablet size, whether administered orally etc.
- **Patent Protection** i.e. is the drug still subject to a patent?
- **Efficacy** i.e. is it clinically effective?
- **Safety** i.e. is the drug safe?
- **Alternative treatments and exceptionality for individuals** i.e. do alternatives exist and if so, who would they be used for?
- **Equalities and Health Inequalities** i.e. are there groups of people who would be disproportionately affected?
- **Financial implications, comprising:**
    - **Commissioning/funding pathway** i.e. how does the NHS pay for the drug?
    - **Medicine Cost** i.e. how much does the drug cost per item?

[3] In this context, "exceptional circumstances" should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual.
[4] Practices NICE recommend should be discontinued completely or should not be used routinely

- **Healthcare Resource Utilisation** i.e. what NHS resources would be required to implement a change?
- **Annual Spend** i.e. what is the annual spend of the NHS on this item?

- **Unintended consequences**

The group's recommendations on the original 18 items within this guidance were publicly consulted on for a period of 3 months, from 21st July 2017 – 21st October 2017 for the first iteration and 28th November 2018 – 28th February 2019 for the second iteration. This latter iteration included an update to one item from the 2017 guidance and recommendations on eight new items.

During both consultations, we heard from members of the public, patients and their representative groups, NHS staff, various Royal Colleges and the pharmaceutical industry, amongst others. Section 1.4 details the main findings from the consultations and the changes that have been made because of what we have heard. More detailed reports on both consultations can be found in *Items which should not routinely be prescribed in primary care: consultation report of findings (Nov 2017 and June 2019)*, published alongside this guidance. The final recommendations set out in this guidance document reflect the outcome of both consultations. Final guidance includes eighteen original items published in 2017, one of which was updated in 2019, along with the addition of seven new items. The potential impact of these recommendations on equality and health inequalities has also been considered and is outlined in the Equality and Health Inequalities Impact Assessment documents (Nov 2017 and June 2019) published alongside this guidance.

1.4 How have the recommendations in this guidance been developed following the results of the consultation?

We listened to what our stakeholders told us through the consultations and refined our draft guidance considering the written and survey responses, discussion through webinars and engagement exercises, as well as recommendations from the joint clinical working group which considered the feedback in detail.

There have been some important refinements and clarifications made in respect of several products because of the consultations. Details of each product are as follows:

July 2017 – October 2017 consultation:

Co-proxamol – We received a significant number of responses during the consultation around co-proxamol and the safety of continuing to prescribe this treatment emerged as the main theme. Because of what we heard, the joint clinical working group recommended that we keep our original recommendations.

Dosulepin – Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for dosulepin.

Prolonged-release Doxazosin - Because of what we heard the joint clinical working group did not feel it necessary to amend the proposed recommendations on deprescribing for prolonged-release doxazosin; however, the group felt that there would not be cases of exceptionality that would warrant referral to a multidisciplinary team so removed that recommendation.

DRAFT

Immediate release Fentanyl – During the consultation we heard from patients, healthcare professionals and others that it is important that immediate-release fentanyl is available for use in palliative care. The joint clinical working group therefore decided that the three original proposed recommendations should remain but that a defined exemption and clarification should be provided for use as outlined in NICE guidance for palliative care.

Glucosamine and Chondroitin - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for glucosamine and chondroitin.

Herbal Treatments - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for Herbal treatments.

Homeopathy – During the consultation we heard a range of views both agreeing and disagreeing with our proposals on homeopathy. Due to the volume of evidence submitted a further review of the evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The SPS review found that there was no clear or robust evidence base to support the use of homeopathy in the NHS and therefore, also considering responses received from medical and scientific bodies, the joint clinical working group did not feel it necessary to amend the proposed recommendations for homeopathy.

Lidocaine Plasters - During the consultation we heard from patients, healthcare professionals and others that there may be some specialist uses for this item which may be outside the terms of its license. We also received further submissions of evidence and a review of this evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The joint clinical working group considered the consultation feedback and the SPS evidence review and decided that the three recommendations should remain, but that a defined exemption and clarification should be provided for the use of lidocaine plasters in Post Herpetic Neuralgia (PHN) only, for which it is licensed in adults and for which there is some evidence of efficacy.

Liothyronine - We received a significant number of responses during the consultation around liothyronine. The main recurring theme – particularly from patients and organisational bodies - is that liothyronine is an effective treatment which is invaluable to patient wellbeing, quality of life and condition management. We also heard that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction. The joint clinical working group considered the consultation feedback and therefore decided that liothyronine should still be prescribed for a small cohort of patients. The joint clinical working group changed the recommendations so that initiation of prescribing of liothyronine in appropriate patients should be initiated by a consultant endocrinologist in the NHS, and that deprescribing in ‘all’ patients is not appropriate as there are recognised exceptions.

Lutein and Antioxidants – Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for lutein and antioxidants.

DRAFT

Omega-3 Fatty Acid Compounds - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for omega-3 fatty acid compounds.

Oxycodone and Naloxone combination product - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for oxycodone and naloxone combination product.

Paracetamol and Tramadol combination product - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for paracetamol and tramadol Combination Product.

Perindopril Arginine - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for perindopril arginine.

Rubefacients (excluding topical NSAIDs) - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for rubefacients (excluding topical NSAIDs).

Once daily Tadalafil - Because of what we heard the joint clinical working group did not feel it necessary to amend the proposed recommendations for once daily tadalafil.

Vaccines administered exclusively for the purposes of travel - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for vaccines administered *exclusively for the purposes of travel*. However, we did hear that confusion persists around travel vaccines and we have amended the wording of our guidance to reduce confusion.

Trimipramine - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for deprescribing trimipramine however the group felt that there would not be cases of exceptionality that would warrant referral to a multidisciplinary team so removed that recommendation.

Whilst not a part of this consultation, the Department of Health consulted on the availability of Gluten free foods in primary care from August – October 2018. The Department of Health made recommendations in November 2018 and we removed references to Gluten free foods from this commissioning guidance. NHS England also published CCG guidance on Prescribing Gluten Free Food in Primary Care in November 2018.

November 2018 – February 2019 consultation:

Aliskiren - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for aliskiren.

Amiodarone - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for amiodarone.

DRAFT

Bath and shower preparations for dry and pruritic skin conditions - During the consultation we heard a range of views both agreeing and disagreeing with our proposals on bath and shower preparations. We also received further submissions of evidence and a review of this evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The SPS review found that there was no clear or robust evidence base to support the use of bath and shower preparations for dry and pruritic skin conditions in the NHS. Having considered responses received from medical and scientific bodies, the joint clinical working group did not feel it necessary to amend the proposed recommendations significantly but did make minor changes to the wording. The group recognises that the clinical evidence relied upon in reaching the recommendations refers primarily to children but the working group felt that in the absence of other good quality evidence (e.g. randomised controlled trials), it is acceptable to extrapolate the evidence pertaining to children to adults until good quality evidence emerges for adults.

Blood glucose testing strips for type 2 diabetes – Although the consultation was on the whole positive with regards to the recommendations, on advice of the NHS England & NHS Improvement Diabetes team, further work is being undertaken on the features of different testing meters available and how this may impact on the choice of blood glucose testing strip. It is therefore decided that the joint clinical working group await the outcome of this work before making any final CCG recommendations on blood glucose testing strips. The guidance therefore makes no recommendations on blood glucose testing strips for type 2 diabetes.

Dronedarone - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for dronedarone.

Minocycline for acne - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for minocycline.

Needles for pre-filled and reusable insulin pens - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for needles for pre-filled and reusable insulin pens. The joint clinical working group therefore decided that the two original proposed recommendations should remain but clarification should be provided for use of safety needles in particular settings.

Rubefacients (excluding topical NSAIDs and capsaicin) - Recommendations on rubefacients were issued in November 2017. The recommendation was updated to highlight that capsaicin cream can be prescribed in line with NICE guidance and would therefore be excluded from the recommendations for rubefacients. We consulted on this change only. Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed updated recommendation for rubefacients.

Silk garments - During the consultation we heard a range of views both agreeing and disagreeing with our proposals on silk garments. We also received further submissions of evidence and a review of this evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The SPS review found that there was no clear or robust evidence base to support the routine use of silk

DRAFT

garments in the NHS and therefore, also considering responses received from medical and scientific bodies, the joint clinical working group did not feel it necessary to amend the proposed recommendations.

DRAFT

2 How will this guidance be updated and reviewed?

To ensure that the NHS continues to allocate its resources effectively, the joint clinical working group will review the guidance at least annually (or more frequently if required) to identify potential items to be retained, retired, updated or added to the current guidance. There will be three stages:

Item identification
Organisations represented on the joint clinical working group will, considering previous feedback, identify items from the wide range of items that can be prescribed on NHS prescription in primary care in the categories defined in section 1.3.

Item prioritisation
The joint clinical working group will prioritise items based on the following criteria:

- Safety Issue
- Evidence of efficacy
- Degree of variation in prescribing
- Cost to the NHS
- Clinician or patient feedback

To seek initial views from interested parties, a draft list of items will be shared with the organisations detailed in Appendix 1 and others where appropriate. A consultation document will be made available and a public consultation will be undertaken. Feedback will be collated and then published on the NHS England website.

Item selection for inclusion or removal from the guidance
The joint clinical working group will consider the feedback and produce the updated list of recommendations for consideration by NHS England and NHS Clinical Commissioners to update the proposed commissioning guidance for items which should not be routinely prescribed in primary care.

DRAFT

3 Definitions

Annual Spend: This is the primary care spend from NHS Prescription Services at the NHS Business Services Authority. Prescriptions written by General Medical Practitioners and non-medical prescribers (nurses, pharmacists etc.) in England represent the clear majority of prescriptions included. Prescriptions written by dentists and hospital doctors which are dispensed in the community are not included. Prescriptions written and dispensed in Prisons or Hospitals, and Private prescriptions are not included. Prescriptions written in England but dispensed in Wales, Scotland, Guernsey/ Alderney, Jersey and Isle of Man are included. Prescriptions written in the rest of the UK but dispensed in England are not included. The figure quoted is the Actual Cost which is the basic price of the drug adjusted for the discount pharmacists receive and including container costs. It does not include any adjustment for income obtained where a prescription charge is paid at the time the prescription is dispensed or where the patient has purchased a prepayment certificate.

BNF: British National Formulary provides healthcare professionals with authoritative and practical information on the selection and clinical use of medicines.

Deprescribing: A collaborative process with the patient (or their carer) used to ensure the safe and effective withdrawal of medicines that are no longer appropriate, beneficial or wanted, which is guided by a person-centred approach and shared decision making.

Exceptional Circumstances: In the context of this guidance, “exceptional circumstances” should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual.

Item: An item is anything which can be prescribed on an NHS prescription. More information on what is prescribed on an NHS prescription is available in the Drug Tariff.

New patient: This refers to any patient newly initiated on an item listed in the guidance.

NICE: The National Institute for Health and Care Excellence. They provide the NHS with clinical guidance on how to improve healthcare.

MHRA: Medicines and Healthcare Products Regulatory Agency. They regulate medicines, medical devices and blood components for transfusion in the UK.

NHS Clinical Commissioners: NHSCC are the independent membership organisation for CCGs, providing their collective voice, facilitating shared learning and delivering networking opportunities for CCG members.

PHE: Public Health England. They protect and improve the nation's health and wellbeing, and reduce health inequalities.

DRAFT

PrescQIPP CIC (Community Interest Company): PrescQIPP are an NHS funded not-for-profit organisation that supports quality, optimised prescribing for patients. They produce evidence-based resources and tools for primary care commissioners, and provide a platform to share innovation across the NHS.

Routinely: The term routine can be defined as 'regularly, as part of the usual way of doing things rather than for any clinically exceptional reason.

4 Implementation

CCGs will still need to take individual decisions on implementation locally, ensuring they consider their legal duties to advance equality and have regard to reducing health inequalities. Effective implementation will involve engagement with secondary care and use of shared care arrangements where appropriate. Provision of support for patients who may review a change to their current prescription is recommended. Various resources are available to support implementation and monitoring of the guidance including patient leaflets.

There are dashboards illustrating current prescribing patterns available to CCGs to monitor prescribing data for the items included in this guidance. These are available from NHS BSA in ePACT 2, PrescQIPP and OpenPrescribing.net. Data on spend and volume is summarised by item and is available at regional, area team, STP, CCG and practice level. When monitoring, clinical exceptions defined in the guidance should be taken account of and care should be taken to ensure that targets of zero prescribing are not used inappropriately.

A Low Priority Prescribing (LPP) indicator will form part of the 2019/20 CCG Improvement and Assessment Framework (IAF). The CCG IAF technical specification will outline the methodology for this indicator. As part of the IAF process each CCG will be given a score based on their prescribing rates and this will contribute to the IAF CCG overall assessment. CCGs are encouraged to monitor prescribing data and demonstrate where appropriate, reduced prescribing over time.

Working closely with Integrated Care Systems (ICS) and Primary Care Networks (PCN), the Regional Medicines Optimisation Committees (RMOC) will monitor variance at each meeting, this will enable them to support CCGs with any challenges with local implementation.

DRAFT

5 Recommendations

5.1 Aliskiren [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate aliskiren for any new patient. • Advise CCGs to support prescribers in deprescribing aliskiren in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been defined.
Category	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.
Annual Spend	£776,000 (BSA, 2018/19)
Background and Rationale	Aliskiren is a renin inhibitor which inhibits renin directly; renin converts angiotensinogen to angiotensin. It is indicated for essential hypertension either alone or in combination with other antihypertensives. NICE state there is insufficient evidence of its effectiveness to determine its suitability for use in resistant hypertension. Whilst aliskiren has shown comparable efficacy to other antihypertensive agents in terms of blood pressure reduction, its effects on mortality and long-term morbidity are currently unknown.
Further Resources and Guidance for CCGs	Patient information leaflets

DRAFT

5.2 Amiodarone [New 2019]

Recommendation	• Advise CCGs that prescribers should not initiate amiodarone in primary care for any new patient. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for amiodarone to be prescribed, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	Must be initiated by a specialist and only continued under a shared care arrangement for patients where other treatments cannot be used, have failed or is in line with NICE Guidance CG180. It may also be suitable in patients prior and post cardioversion or in specific patients who also have heart failure or left ventricular impairment.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£1,427,000 (BSA, 2018/19)
Background and Rationale	Treatment of arrhythmias, particularly when other drugs are ineffective or contra-indicated, including paroxysmal supraventricular, nodal and ventricular tachycardias, atrial fibrillation and flutter, ventricular fibrillation, and tachyarrhythmias associated with Wolff-Parkinson-White syndrome (initiated in hospital or under specialist supervision). Amiodarone has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. It has potential major toxicity and its use requires monitoring both clinically and via laboratory testing. NICE clinical guideline on Atrial Fibrillation (AF) CG 180 puts greater emphasis on rate rather than rhythm control and has clarified the place of amiodarone in the treatment pathway: NICE have issued the following “Do not do” recommendation: **Do not offer amiodarone for long-term rate control.**
Further Resources and Guidance for CCGs	NICE CG180 Atrial fibrillation: management Patient information leaflets NHS England, Responsibility for prescribing between Primary & Secondary/Tertiary Care

DRAFT

5.3 Bath and shower preparations for dry and pruritic skin conditions [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate bath and shower preparations for any new patient. • Advise CCGs to support prescribers in deprescribing bath and shower preparations in this category and substitute with "leave-on" emollients and, where appropriate, to ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been defined.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£11,708,000 (BSA, 2018/19)
Background and Rationale	Emollient bath and shower preparations are routinely prescribed for dry and pruritic skin conditions including eczema and dermatitis. A multicentre pragmatic parallel group RCT looking at emollient bath additives for the treatment of childhood eczema (BATHE) showed that there was no evidence of clinical benefit for including emollient bath additives in the standard management of childhood eczema. Soap avoidance and 'Leave-on' emollient moisturisers can still be used for treating eczema. These emollients can also be used as a soap substitute. Patients should be counselled on the use of any emollients as soap substitutes and the risk of using bath and shower emollients should be fully explained. It is recognised that BATHE trial looked at use in children however in the absence of other good quality evidence it was agreed that it is acceptable to extrapolate this to apply to adults until good quality evidence emerges.
Further Resources and Guidance for CCGs	Specialist Pharmacy Service bath and shower preparations evidence review: Patient information leaflets

DRAFT

5.4 Co-proxamol [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate co-proxamol for any new patient. • Advise CCGs to support prescribers in deprescribing co-proxamol in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£8,272,000 (BSA, 2016/17)
Annual Spend (current)	£3,237,000 (BSA, 2018/19)
Background and Rationale	Co-proxamol was a pain-killer which was previously licensed in the UK until being fully withdrawn from the market in 2007 due to safety concerns. All use in the UK is now on an unlicensed basis. Since 1985 advice aimed at the reduction of co-proxamol toxicity and fatal overdose has been provided, but this was not effective and resulted in withdrawal of co-proxamol by the MHRA. Since the withdrawal, further safety concerns have been raised which have resulted in co-proxamol being withdrawn in other countries. Due to the significant safety concerns, the joint clinical working group considered co-proxamol suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs	MHRA Drug Safety Update: November 2007, January 2011 PrescQIPP CIC Drugs to Review for Optimised Prescribing - Co-proxamol Patient information leaflets

5.5 Dosulepin [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate dosulepin for any new patient. • Advise CCGs to support prescribers in deprescribing dosulepin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for dosulepin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.

DRAFT

Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£2,342,000 (BSA, 2016/17)
Annual Spend (current)	£3,706,000 (BSA, 2018/19)
Background and Rationale	Dosulepin, formerly known as dothiepin, is a tricyclic antidepressant. NICE CG90: Depression in Adults has a "do not do" recommendation: "*Do not switch to, or start, dosulepin because evidence supporting its tolerability relative to other antidepressants is outweighed by the increased cardiac risk and toxicity in overdose.*" Due to the significant safety concerns advised by NICE, the joint clinical working group considered dosulepin suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs	NICE CG90: Depression in Adults PrescQIPP CIC Drugs to Review for Optimised Prescribing - Dosulepin Patient information leaflets

5.6 Prolonged-release Doxazosin (also known as Doxazosin Modified Release) [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate prolonged-release doxazosin for any new patient. • Advise CCGs to support prescribers in deprescribing Prolonged-release doxazosin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£6,828,000 (BSA, 2016/17)
Annual Spend (current)	£5,009,000 (BSA, 2018/19)
Background and Rationale	Doxazosin is an alpha-adrenoceptor blocking drug that can be used to treat hypertension and benign prostatic hyperplasia. There are two oral forms of the medication (immediate release

DRAFT

	and prolonged-release) and both are taken once daily. Prolonged-release Doxazosin is approximately six times the cost of doxazosin immediate release (NHS Drug Tariff). NICE CG127 Hypertension in adults: diagnosis and management recognises that doxazosin should be used in treatment but does not identify benefits of prolonged-release above immediate release. NICE CG97 Lower urinary tract symptoms in men: management recommends Doxazosin as an option in men with moderate to severe lower urinary tract symptoms. It does not identify benefits of Prolonged-release above immediate release. Due to the significant extra cost of prolonged-release doxazosin and the availability of once daily immediate release doxazosin, the joint clinical working group considered prolonged-release doxazosin suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs	NICE CG127 Hypertension in adults: diagnosis and management NICE CG97 Lower urinary tract symptoms in men PrescQIPP CIC Drugs to Review for Optimised Prescribing - Prolonged Release Doxazosin BNF - Doxazosin Patient information leaflets

5.7 Dronedarone [New 2019]

Recommendation	• Advise CCGs that prescribers should not initiate dronedarone in primary care for any new patient. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for dronedarone to be prescribed, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions	Must be initiated by a specialist and only continued under a shared care arrangement for patients where other treatments cannot be used, have failed or is in line with NICE Guidance CG180.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£1,519,000 (BSA 2018/19)
Background and Rationale	Dronedarone is used for the maintenance of sinus heart rhythm after cardioversion in clinically stable patients with paroxysmal or persistent atrial fibrillation, when alternative treatments are unsuitable (initiated under specialist supervision).

DRAFT

	Dronedarone was originally approved to prevent atrial fibrillation from coming back or to lower the heart rate in adults who have had or have non-permanent atrial fibrillation. In September 2011 this indication was restricted to the maintenance of normal heart rhythm in 'persistent' or 'paroxysmal' atrial fibrillation after normal heart rhythm has been restored. This followed a review of data that became available since its authorisation including data from the PALLAS study. NICE clinical guideline on Atrial Fibrillation (AF) CG 180 puts greater emphasis on rate rather than rhythm control and has clarified the place of dronedarone in the treatment pathway:
Further Resources and Guidance for CCGs	NICE CG180 Atrial fibrillation: management Patient information leaflets NHS England, Responsibility for prescribing between Primary & Secondary/Tertiary Care

5.8 Immediate Release Fentanyl [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate immediate release fentanyl for any new patient. • Advise CCGs to support prescribers in deprescribing immediate release fentanyl in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for immediate release fentanyl to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	**These recommendations do not apply to patients undergoing palliative care treatment** and where the recommendation to use immediate release fentanyl in line with NICE guidance (see below), has been made by a multi-disciplinary team and/or other healthcare professional with a recognised specialism in palliative care.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£10,185,000 (BSA, 2016/17)
Annual Spend (current)	£8,592,000 (BSA, 2018/19)

DRAFT

Background and Rationale	Fentanyl is a strong opioid analgesic. It is available as an immediate release substance in various dosage forms; tablets, lozenges, films and nasal spray. Immediate release fentanyl is licensed for the treatment of breakthrough pain in adults with cancer who are already receiving at least 60mg oral morphine daily or equivalent. NICE CG140 Opioids in Palliative Care states *Do not offer fast-acting fentanyl as first-line rescue medication.* This recommendation does not apply to longer sustained release versions of fentanyl which come in patch form. Due to the recommendations from NICE and immediate release fentanyl being only licensed for use in cancer, the joint clinical working group considered immediate release fentanyl was suitable for inclusion in this guidance with specific exceptions for people receiving palliative care reflecting NICE and the terms of the product licence.
Further Resources and Guidance for CCGs	Opioids Aware: A resource for patients and healthcare professionals to support prescribing of opioid medicines for pain PrescQIPP CIC Drugs to Review for Optimised Prescribing - Immediate Release Fentanyl Faye's story: good practice when prescribing opioids for chronic pain Patient information leaflets

5.9 Glucosamine and Chondroitin [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate Glucosamine and Chondroitin for any new patient. • Advise CCGs to support prescribers in deprescribing glucosamine and chondroitin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£405,000 (BSA, 2016/17)
Annual Spend (current)	£174,000 (BSA, 2018/19)
Background and	Glucosamine and Chondroitin are nutraceuticals which used to

DRAFT

Rationale	improve pain associated with osteoarthritis. The BNF states the following about glucosamine, "*The mechanism of action is not understood and there is limited evidence to show it is effective."* NICE CG177: Osteoarthritis care and management has the following "do not do" recommendation: *Do not offer glucosamine or chondroitin products for the management of osteoarthritis* Due to the recommendation from NICE and due to the lack of evidence as advised by the BNF, the joint clinical working group considered glucosamine and chondroitin suitable for inclusion in this guidance
Further Resources and Guidance for CCGs and prescribers	BNF NICE CG177: Osteoarthritis care and management PrescQIPP CIC Drugs to Review for Optimised Prescribing - Glucosamine Patient information leaflets

5.10 Herbal Treatments [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate herbal items for any new patient. • Advise CCGs to support prescribers in deprescribing herbal items in all patients and where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£111,000 (BSA, 2016/17)
Annual Spend (current)	£57,000 (BSA, 2018/19)
Background and Rationale	Under a Traditional Herbal Registration there is no requirement to prove scientifically that a product works, the registration is based on longstanding use of the product as a traditional medicine. Due to the lack of scientific evidence required to register these products with the MHRA, the joint clinical working group felt that they were suitable for inclusion in this guidance.
Further Resources and	GOV.UK Traditional herbal medicines: registration form and guidance

DRAFT

Guidance for CCGs and prescribers	GOV.UK Herbal medicines granted a traditional herbal registration (THR) Patient information leaflets

5.11 Homeopathy [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate homeopathic items for any new patient. • Advise CCGs to support prescribers in deprescribing homeopathic items in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£85,000 (BSA, 2016/17)
Annual Spend (current)	£47,000 (BSA, 2018/19)
Background and Rationale	Homeopathy seeks to treat patients with highly diluted substances that are administered orally. During the consultation we received a range of submissions pertaining to homeopathy and it was deemed necessary to have a further, up to date review of the evidence which was conducted by the Specialist Pharmacy Service. The review found that there was no clear or robust evidence to support the use of homeopathy on the NHS.
Further Resources and Guidance for CCGs and prescribers	Specialist Pharmacy Service homeopathy evidence review GOV.UK Register a homeopathic medicine or remedy Patient information leaflets

DRAFT

5.12 Lidocaine Plasters [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate lidocaine plasters for any new patient (apart from exceptions below). • Advise CCGs to support prescribers in deprescribing lidocaine plasters in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for lidocaine plasters to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	These recommendations do not apply to patients who have been treated in line with NICE CG173 *Neuropathic pain in adults: pharmacological management in non-specialist settings* but are still experiencing neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia).
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Annual Spend (baseline)	£17,888,000 (BSA, 2016/17)
Annual Spend (current)	£16,206,000 (BSA, 2018/19)
Background and Rationale	Lidocaine plasters can be applied for pain relief and are licensed for symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults. NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings does not recommend lidocaine plasters for treating neuropathic pain. The joint clinical working group also considered a PrescQIPP CIC review, and during the consultation more evidence was provided and an up to date evidence summary was deemed necessary and prepared by the Specialist Pharmacy Service to inform the joint clinical working group's recommendations. Based on this review and non-inclusion, the lidocaine plasters are included with defined exceptions.
Further Resources and Guidance for CCGs and prescribers	NICE Clinical Knowledge Summaries - Post-herpetic neuralgia Patient information leaflets Specialist Pharmacy Service lidocaine plasters evidence review

DRAFT

5.13 Liothyronine (including Armour Thyroid and liothyronine combination products) [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate liothyronine for any new patient. • Advise CCGs that individuals currently prescribed liothyronine should be reviewed by a consultant NHS endocrinologist with consideration given to switching to levothyroxine where clinically appropriate. • Advise CCGs that a local decision, involving the Area Prescribing Committee (or equivalent) informed by National guidance (e.g. from NICE or the Regional Medicines Optimisation Committee), should be made regarding arrangements for on-going prescribing of liothyronine. This should be for individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist.
Exceptions and further recommendations	The British Thyroid Association (BTA) advise that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction. In these circumstances, where levothyroxine has failed and in line with BTA guidance, endocrinologists providing NHS services may recommend liothyronine for individual patients after a carefully audited trial of at least 3 months duration of liothyronine. Liothyronine is used for patients with thyroid cancer, in preparation for radioiodine ablation, iodine scanning, or stimulated thyroglobulin test. In these situations, it is appropriate for patients to obtain their prescriptions from the centre undertaking the treatment and not be routinely obtained from primary care prescribers.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£31,390,000 (BSA, 2016/17)
Annual Spend (current)	£23,184,000 (BSA, 2018/19)
Background and Rationale	Liothyronine (sometimes known as T3) is used to treat hypothyroidism. It has a similar action to levothyroxine but is more rapidly metabolised and has a more rapid effect. It is sometimes used in combination with levothyroxine in products. The price (NHS Drug Tariff) of liothyronine has risen significantly and there is limited evidence for efficacy above Levothyroxine.

DRAFT

	The British Thyroid Association, in their 2015 position statement, state "*There is no convincing evidence to support routine use of thyroid extracts, L-T3 monotherapy, compounded thyroid hormones, iodine containing preparations, dietary supplementation and over the counter preparations in the management of hypothyroidism".* Due to the significant costs associated with liothyronine and the limited evidence to support its routine prescribing in preference to levothyroxine, the joint clinical working group considered liothyronine suitable for inclusion in this guidance. However, during the consultation, we heard and received evidence about a cohort of patients who require liothyronine and the clinical working group felt it necessary to include some exceptions based on guidance from the British Thyroid Association.
Further Resources and Guidance for CCGs and prescribers	British Thyroid Association Guidelines UKMI Medicines Q&A - What is the rationale for using a combination of levothyroxine and liothyronine (such as Armour® Thyroid) to treat hypothyroidism? Patient information leaflets Regional Medicines Optimisation Committee guidance

5.14 Lutein and Antioxidants [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate lutein and antioxidants for any new patient. • Advise CCGs to support prescribers in deprescribing lutein and antioxidants in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£1,779,000 (BSA, 2016/17)
Annual Spend (current)	£723,000 (BSA, 2018/19)
Background and Rationale	Lutein and antioxidants (e.g. vitamin A, C E and zinc) are supplements which are sometimes recommended for Age Related Macular Degeneration. A variety of supplements are available to purchase in health food stores and other outlets where they are promoted to assist with "eye health".

DRAFT

	Two Cochrane Reviews have been conducted on this topic **Antioxidant vitamin and mineral supplements for preventing age-related macular degeneration** http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000253.pub3/full The authors conclude *"There is accumulating evidence that taking vitamin E or beta-carotene supplements will not prevent or delay the onset of AMD. There is no evidence with respect to other antioxidant supplements, such as vitamin C, lutein and zeaxanthin, or any of the commonly marketed multivitamin combinations".* **Antioxidant vitamin and mineral supplements for slowing the progression of age-related macular degeneration** http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000254.pub3/full The authors conclude *"People with AMD may experience delay in progression of the disease with antioxidant vitamin and mineral supplementation. This finding is drawn from one large trial conducted in a relatively well-nourished American population. The generalisability of these findings to other populations is not known."* PrescQIPP CIC has issued a bulletin which did not find evidence to support prescribing of lutein and antioxidants routinely on the NHS. NICE have published draft consultation guidance on Age-Related Macular Degeneration and proposed that the effectiveness and cost-effectiveness of the use of lutein and antioxidants is currently a research recommendation.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Lutein and Antioxidants NICE - Macular Degeneration Patient information leaflets

5.15 Minocycline for acne [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate minocycline for any new patient with acne. • Advise CCGs to support prescribers in deprescribing minocycline in all patients with acne and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.

DRAFT

Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£503,000 (BSA 2018/19)
Background and Rationale	Minocycline is a tetracycline antibiotic that can be used for many indications but is mainly used in primary care for acne. Minocycline is mainly used for acne however there are various safety risks associated with its use. NICE CKS advises *Minocycline is not recommended for use in acne as it is associated with an increased risk of adverse effects such as drug induced lupus, skin pigmentation and hepatitis.* A PrescQIPP CIC review found there is no evidence to support the use of one tetracycline over another in terms of efficacy for the treatment of acne vulgaris and alternative once daily products are available.
Further Resources and Guidance for CCGs and prescribers	NICE Clinical Knowledge Summaries - Acne vulgaris PrescQIPP CIC Drugs to Review for Optimised Prescribing - Minocycline Patient information leaflets

5.16 Needles for Pre-Filled and Reusable Insulin Pens [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate insulin pen needles that cost >£5 per 100 needles for any diabetes patient. • Advise CCGs to support prescribers in deprescribing insulin pen needles that cost >£5 per 100 needles and, where appropriate ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.
Annual Spend	£24,802,000 (BSA, 2018/19)
Background and Rationale	Pen needles are available in a complete range of sizes from 4mm to 12mm; different needles will fit different pens; however, some pen needles will fit all major insulin delivery pen devices currently available.

DRAFT

	There are many different types of insulin pen needles available at a varying cost from £2.75 to £30.08 for 100[5]. Rationalising use ensures that the most cost-effective options are used first line. In addition, the Forum for Injection Technique (FIT) UK considers the **4mm needle to be the *safest* pen needle** for adults and children regardless of age, gender and Body Mass Index (BMI). Using needles of a shorter length helps to prevent intramuscular injection of insulin. (IM injection of insulin should be avoided as it can result in unpredictable blood glucose levels). Therefore, needle choice should be the most cost effective 4mm needle. For patients currently using longer pen needle lengths (8mm, 12mm), it is advisable to change to a shorter needle length (6mm or less) but only after discussion with a healthcare professional, to ensure they receive advice on the correct injection technique. For patients that are not able to self-administer it may be appropriate that a safety needle is used by the health care professional, however this would not need to be prescribed on prescription.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Needles for Pre-Filled and Reusable Insulin Pens Patient information leaflets

5.17 Omega-3 Fatty Acid Compounds [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate omega-3 Fatty Acids for any new patient. • Advise CCGs to support prescribers in deprescribing omega-3 Fatty acids in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Annual Spend (baseline)	£5,718,000 (BSA, 2016/17)

[5] NHS Drug Tariff

DRAFT

Annual Spend (current)	£3,813,000 (BSA, 2018/19)
Background and Rationale	Omega-3 fatty acid compounds are essential fatty acids which can be obtained from the diet. They are licensed for adjunct to diet and statin in type IIb or III hypertriglyceridemia; adjunct to diet in type IV hypertriglyceridemia; adjunct in secondary prevention in those who have had a myocardial infarction in the preceding 3 months. NICE have reviewed the evidence and advised they are not suitable for prescribing by making "Do not do" recommendations Do not offer or advise people to use omega-3 fatty acid capsules or omega-3 fatty acid supplemented foods to prevent another myocardial infarction. If people choose to take omega-3 fatty acid capsules or eat omega-3 fatty acid supplemented foods, be aware that there is no evidence of harm. Do not offer omega-3 fatty acid compounds for the prevention of cardiovascular disease to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with chronic kidney disease, people with type 1 diabetes, people with type 2 diabetes. Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD. Do not offer omega-3 fatty acids to adults with non-alcoholic fatty liver disease because there is not enough evidence to recommend their use. Initiation of omega-3-acid ethyl esters supplements is not routinely recommended for patients who have had a myocardial infarction (MI) more than 3 months earlier. Do not use omega-3 fatty acids to manage sleep problems in children and young people with autism. People with familial hypercholesterolemia (FH) should not routinely be recommended to take omega-3 fatty acid supplements. Do not offer omega-3 or omega-6 fatty acid compounds to treat multiple sclerosis (MS). Explain that there is no evidence that they affect relapse frequency or progression of MS. The joint clinical working group agreed with NICE recommendations and considered omega-3 fatty acid compounds suitable for inclusion in this guidance.
Further	PrescQIPP CIC Drugs to Review for Optimised Prescribing -

DRAFT

Resources and Guidance for CCGs and prescribers	Omega 3 Fatty Acids Patient information leaflets

5.18 Oxycodone and Naloxone Combination Product [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate oxycodone and naloxone combination product for any new patient. • Advise CCGs to support prescribers in deprescribing oxycodone and naloxone combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for oxycodone and naloxone combination product to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£4,589,000 (BSA, 2016/17)
Annual Spend (current)	£3,348,000 (BSA, 2018/19)
Background and Rationale	Oxycodone and naloxone combination product is used to treat severe pain and can also be used second line in restless legs syndrome. The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors locally in the gut. PrescQIPP CIC have issued a bulletin and did not identify a benefit of oxycodone and naloxone in a single product over other analgesia (with laxatives if necessary). Due to the significant cost of the oxycodone and naloxone combination product and the unclear role of the combination product in therapy compared with individual products, the joint clinical working group considered oxycodone and naloxone suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	Opioids Aware: A resource for patients and healthcare professionals to support prescribing of opioid medicines for pain Faye's story: good practice when prescribing opioids for

DRAFT

	chronic pain PrescQIPP CIC Drugs to Review for Optimised Prescribing - Oxycodocne and Naloxone Combination Product Patient information leaflets

5.19 Paracetamol and Tramadol Combination Product [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate paracetamol and tramadol combination product for any new patient. • Advise CCGs to support prescribers in deprescribing paracetamol and tramadol combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£1,766,000 (BSA, 2016/17)
Annual Spend (current)	£487,000 (BSA, 2018/19)
Background and Rationale	Paracetamol and tramadol combination products are more expensive than the products with the individual components (Drug Tariff). PrescQIPP CIC also issued a bulletin which did not identify any significant advantages over individual products, however it does recognise that some people may prefer to take one product instead of two. There are also different strengths of tramadol (37.5mg) and paracetamol (325mg) in the combination product compared to commonly available individual preparations of tramadol (50mg) and paracetamol (500mg), although the PrescQIPP CIC review found no evidence that combination product is more effective or safer than the individual preparations. Due to the significant extra cost of a combination product, the joint clinical working group considered paracetamol and tramadol combination products suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Paracetamol and Tramadol Combination Product Patient information leaflets

DRAFT

5.20 Perindopril Arginine [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate perindopril arginine for any new patient. • Advise CCGs to support prescribers in deprescribing perindopril arginine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£1,441,000 (BSA, 2016/17)
Annual Spend (current)	£1,059,000 (BSA, 2018/19)
Background and Rationale	Perindopril is an ACE inhibitor used in heart failure, hypertension, diabetic nephropathy and prophylaxis of cardiovascular events. The perindopril arginine salt version was developed as it is more stable in extremes of climate than the perindopril erbumine salt, which results in a longer shelf-life. perindopril arginine is significantly more expensive than perindopril erbumine and a PrescQIPP CIC review of the topic found there was no clinical advantage of the arginine salt. NICE CG127: Hypertension in adults: diagnosis and management recommends that prescribing costs are minimised. Due to the significant extra costs with the arginine salt and the availability of the erbumine salt, the joint clinical working group considered perindopril arginine suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	NICE CG127: Hypertension in adults: diagnosis and management PrescQIPP CIC Drugs to Review for Optimised Prescribing - Perindopril Argininehttps://www.prescqipp.info/-perindopril-arginine/category/89-perindopril-arginine Patient information leaflets

DRAFT

DRAFT

5.21 Rubefacients (excluding topical NSAIDs[6] and capsaicin) [Updated 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate rubefacients (excluding topical NSAIDs and capsaicin) for any new patient. • Advise CCGs to support prescribers in deprescribing rubefacients (excluding topical NSAIDs and capsaicin) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
2019 update	Capsaicin cream is now excluded as well as topical NSAIDs. i.e. capsaicin can now be prescribed as per NICE guidance. Capsaicin cream falls within **NICE guidance** • Neuropathic Pain: Consider capsaicin cream for people with localised neuropathic pain who wish to avoid, or who cannot tolerate oral treatments. • Osteoarthritis: Topical capsaicin should be considered as an adjunct to core treatments for knee or hand osteoarthritis.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£6,247,000 (BSA, 2016/17)
Annual Spend (current)	£3,887,000 (BSA, 2018/19)
Background and Rationale	Rubefacients are topical preparations that cause irritation and reddening of the skin due to increased blood flow. They are believed to relieve pain in various musculoskeletal conditions and are available on prescription and in over-the-counter remedies. They may contain nicotinate compounds, salicylate compounds, essential oils and camphor. The BNF states *"The evidence available does not support the use of topical rubefacients in acute or chronic musculoskeletal pain."* NICE have issued the following "Do not do" recommendation: Do not offer rubefacients for treating osteoarthritis. Due to limited evidence and NICE recommendations the joint clinical working group considered rubefacients (excluding topical NSAIDS) suitable for inclusion in this guidance.

[6] This does not relate to topical non-steroidal anti-inflammatory drug (NSAID) items such as Ibuprofen and Diclofenac.

DRAFT

Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing – Rubefacients BNF: Soft-tissue disorders Patient information leaflets

5.22 Silk Garments [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate silk garments for any patient. • Advise CCGs to support prescribers in deprescribing silk garments in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£912,000 (BSA, 2018/19)
Background and Rationale	Silk garments are typically prescribed for eczema or dermatitis. These products are knitted, medical grade silk clothing which can be used as an adjunct to normal treatment for severe eczema and allergic skin conditions. Four brands of knitted silk garments are currently listed as an appliance in part IX A in the Drug Tariff and are relatively expensive. The PrescQIPP document on silk garments states that the evidence relating to their use is weak and is of low quality. In addition, due to limited evidence supporting the efficacy of silk clothing for the relief of eczema, the NIHR HTA programme commissioned the CLOTHES trial, which aimed to examine whether adding silk garments to standard eczema care could reduce eczema severity in children with moderate to severe eczema, compared to use of standard eczema treatment alone: The CLOTHing for the relief of Eczema Symptoms trial (CLOTHES trial). Overall the trial concluded that using silk garments for the management of eczema is unlikely to be cost-effective for the NHS.
Further Resources and Guidance for CCGs and	Specialist Pharmacy Service silk garments evidence review PrescQIPP CIC Drugs to Review for Optimised Prescribing – silk garments

DRAFT

prescribers	Patient information leaflets

5.23 Once Daily Tadalafil [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate once daily tadalafil for any new patient. • Advise CCGs to support prescribers in deprescribing once daily tadalafil in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.
Annual Spend (baseline)	£10,644,000 (BSA, 2016/17)
Annual Spend (current)	£6,311,000 (BSA, 2018/19)
Background and Rationale	Tadalafil is a phosphodiesterase-5-inhibitor and is available in strengths of 2.5mg, 5mg, 10mg and 20mg used to treat erectile dysfunction. In addition, 2.5mg and 5mg can be used to treat benign prostatic hyperplasia. Only 2.5mg and 5mg should be used once daily. 10mg and 20mg[7] are used in a "when required fashion". Tadalafil can be prescribed for erectile dysfunction in circumstances as set out in part XVIIIB of the Drug Tariff. Benign Prostatic Hyperplasia: NICE terminated their technology appraisal (TA273) due to receiving no evidence from the manufacturer. In NICE CG97: Lower Urinary Tract Symptoms in Men NICE state that there is not enough evidence to recommend phosphodiesterase inhibitors in routine clinical practice. Erectile Dysfunction: PrescQIPP CIC have reviewed the evidence for Tadalfil and although tadalafil is effective in treating erectile dysfunction, there is not enough evidence to routinely recommend once daily preparations in preference to "when required" preparations particularly as when required preparations are now available as a generic. Due to recommendations from NICE and that alternative tadalafil preparations are available, the joint clinical working group felt once daily tadalafil was suitable for inclusion in this guidance.

[7] There is also a 20mg once daily preparation, branded *Adcirca*, which is used to treat pulmonary hypertension. This recommendation does not apply to this product, however it should only be prescribed by specialist centres and not routinely prescribed in primary care.

DRAFT

Further Resources and Guidance for CCGs and prescribers	NICE CG97: Lower Urinary Tract Symptoms in Men NICE Clinical Knowledge Summaries - Erectile Dysfunction PrescQIPP CIC Drugs to Review for Optimised Prescribing - Once Daily Tadalafil Patient information leaflets

5.24 Travel Vaccines (vaccines administered exclusively for the purposes of travel) [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate the stated vaccines exclusively for the purposes of travel for any new patient. **N.B This is a restatement of existing regulations and no changes have been made.**
Exceptions and further recommendations	The vaccines in this proposal are listed below and they may continue to be administered for purposes other than travel, if clinically appropriate. NHS England and NHS Clinical Commissioners recognise that the availability of vaccinations on the NHS for the purposes of travel can be confusing for prescribers and the public. The working group has recommended that Public Health England and Department of Health, working collaboratively with NHS England and NHS Clinical Commissioners, conduct a review of travel vaccination and publish the findings in Spring 2018.
Category	Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding.
Annual Spend (baseline)	£3,801,000 (BSA, 2016/17) Only some of this total will be administered for the purposes of travel.
Annual Spend (current)	£1,837,000 (BSA, 2018/19) Only some of this total will be administered for the purposes of travel.
Background and Rationale	To note the following vaccines may still be administered on the NHS exclusively for the purposes of travel, if clinically appropriate, pending any future review: • Cholera • Diphtheria/Tetanus/Polio • Hepatitis A • Typhoid This guidance covers the following vaccinations which should

DRAFT

	not be prescribed on the NHS exclusively for the purposes of travel: • Hepatitis B • Japanese Encephalitis • Meningitis ACWY • Yellow Fever • Tick-borne encephalitis • Rabies • BCG These vaccines should continue to be recommended for travel but the individual traveller will need to bear the cost of the vaccination. For all other indications, as outlined in Immunisation Against Infectious Disease – the green book – the vaccine remains free on the NHS.
Further Resources and Guidance for CCGs and prescribers	The Green Book Travel Health Pro (NaTHNaC) PrescQIPP CIC Drugs to Review for Optimised Prescribing - Travel Guidance Patient information leaflets

5.25 Trimipramine [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate trimipramine for any new patient. • Advise CCGs to support prescribers in deprescribing trimipramine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£19,961,000 (BSA, 2016/17)
Annual Spend (current)	£12,773,000 (BSA, 2018/19)
Background and Rationale	Trimipramine is a tricyclic antidepressant (TCA) however the price of trimipramine is significantly more expensive than other antidepressants. NICE CG90: Depression in Adults recommends selective serotonin reuptake inhibitor (SSRI) antidepressants first line if

DRAFT

	medicines are indicated as they have a more favourable risk to benefit ratio compared to TCA. However, if a TCA is required there are more cost-effective TCAs than trimipramine available. Due to the significant cost associated with trimipramine and the availability of alternative treatments, the joint clinical working group considered trimipramine suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	NICE CG90: Depression in Adults NICE Clinical Knowledge Summaries – Depression Patient information leaflets

DRAFT

Appendix 1

Membership of the Joint Clinical Working group

Dr Graham Jackson (Co-chair)	NHSCC Co-chair	NHSCC
Dr Bruce Warner (Co-chair)	Deputy Chief Pharmaceutical officer	NHS England
Raj Patel	Deputy Director of Primary Care	NHS England
Julie Wood	Chief Executive	NHSCC
Michele Cossey	Regional Pharmacist	NHS England/NHS Improvement
David Geddes	Director of Primary Care Commissioning	NHS England
Jonathan Underhill	Medicines Clinical Adviser	NICE
Claire Potter	Medicines Regulation & Prescribing	Department of Health and Social Care
Carol Roberts	Chief Executive	PrescQIPP
Margaret Dockey	Information Services Manager	NHS BSA
Manir Hussain	Deputy Director of Primary Care & Medicines Optimisation & Chair of Pharmacy Local Professional Network	Staffordshire CCGs & NHS England
Clair Huckerby	Consultant Pharmacist Primary Care MO	Dudley CCG
Jane Freeguard	Head of Medicines Commissioning	Redditch and Bromsgrove South Worcestershire and Wyre Forest CCGs
Paul Gouldstone	Head of Medicines Management	Enfield CCG
Steve Pike	GP Medicines Optimisation Lead	Coastal West Sussex CCG
Jonathan Leach	Joint Honorary Secretary Royal College of GPs	Royal College of GPs
Ravi Sharma	Director for England	Royal Pharmaceutical Society
Andrew Green	Clinical and Prescribing Policy Lead.	GPC
Alex Williams	Deputy Director of Medicines Policy Team	NHS England
Margaret Williams	Chief Nurse	Morecambe Bay CCG
Jan MacDonald	Group Manager, Access & Information for Medicines & Standards	MHRA

DRAFT

Stakeholder Organisations

Association of the British Pharmaceutical Industry (ABPI)	NHS Clinical Commissioners
British Generic Manufacturers Association	NHS England
British Medical Association (General Practitioners Committee)	NHS Improvement
Care Quality Commission	NICE
Department of Health and Social Care	Patients Association
Enfield CCG	Pharmaceutical Services Negotiating Committee (PSNC)
General Medical Council	PrescQIPP
Healthwatch England	Public Health England
National Voices	Royal Pharmaceutical Society

DRAFT

Appendix 2

The working group considered the potential unintended consequences of its recommendations. These are set out in the table below. The group will be monitoring these on a regular basis, however these may also need to be considered locally when implementing this guidance.

Potential unintended consequences of issuing the proposed guidance	**Response**
Interactions with secondary care and consequent costs	This will need monitoring but is not inevitable. For some products, joint local guidance with secondary care providers may be appropriate.
Use of appointments in primary care	The group recognised that there could initially be increased use of appointments in primary care however this is not expected to be sustained.
Some alternative treatments may not be clinically identical, such as side-effect profile	Prescribers should make a shared decision with patients and CCGs should provide appropriate resources (e.g. decision-support tools) to facilitate this.
Alternative treatments could, in some cases, be prescribed with cost consequences.	This is an opportunity to review medication, and if appropriate to de-prescribe. Although alternatives may need to be considered including their cost impact. Guidance on suitable alternatives and the indication for use will be provided. In the implementation plan for the proposed guidance, monitoring of prescribing patterns would be undertaken and mitigations instigated if appropriate.
Individual prescribers' decision making.	Prescribers must recognise and work within the limits of their competence, as recommended by the GMC and other professional regulators/bodies. Nationally accessible resources (e.g. patient information leaflets) and local professional support should be provided to prescribers. The proposed guidance does dot remove the clinical discretion of the prescriber in deciding what is in accordance with their professional duties.
People currently on treatment stopping or altering their treatments	Prescribers should endeavour to explain the rationale for any proposed changes in treatments to come to a shared decision.
Complaints about general practice and associated administration time	The group discussed the potential for numbers of complaints to rise and the impact this would have on general practice workload and parts of the NHS. Therefore to support communication of the changes proposed in the guidance,

DRAFT

	educational aids will be produced.
Effect on medicines supply	The group recognised that by proposing guidance on individual items there is potential for alternative items to see increased demand. NHS England will work with Department of Health colleagues to ensure that pharmaceutical companies are aware of the proposed guidance and potential need for increased supply in some other products.

DRAFT

NHS England

Equality and Health Inequalities – Full Analysis - Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs

Document Title: Equalities and Health Inequalities Full Analysis - Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs

Version number: V2

First published: June 2019

To be read in conjunction with the Equalities and Health Inequalities Analysis Guidance, Equality and Health Inequalities Unit, NHS England, July 2016

Classification: OFFICIAL-SENSITIVE: COMMERCIAL

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please contact NHS England on england.medicines@nhs.net

DRAFT

PART A: General Information

1. Title of project, programme or work:
Items which should not routinely be prescribed in primary care: updated guidance for CCGs

2. What are the intended outcomes?
Production of commissioning guidance, in partnership with NHS Clinical Commissioners, to advise CCGs on items which should not be routinely prescribed in primary care. This guidance updates original CCG guidance published in November 2017 for one item only (rubefacients) and includes recommendations for 8 further items which have not previously been included in guidance.

Recommendations categorise items as one of the following;

- Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns;
- Items which are clinically effective but where more cost-effective products are available, this includes products that have been subject to excessive price inflation; and/or
- Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding.

An equality and health inequalities – full analysis is also available for the original 18 items which can be accessed here.

3. Who will be affected by this project, programme or work?

- Staff – primarily primary care prescribers (e.g. GPs) who prescribe items identified within the commissioning guidance. Other staff groups (e.g. community pharmacy staff, secondary care clinicians) will also be impacted and will have a role to support patients in changes to their therapies.
- Patients – those who receive the prescription for items listed in the guidance.
- Partner organisations (e.g. NICE, MHRA etc.). We are using recommendations from partner organisations and they will have a role to play in implementation.

4. Which groups protected by the Equality Act 2010 and/ or groups that face health inequalities are very likely to be affected by this work?

The nine defined items within the review could potentially be prescribed to anyone in the population requiring them to treat a medical condition, therefore covering all characteristics. The profile of people who are currently being prescribed each item can only be interrogated accurately for age and gender as national prescribing data available from the NHS Business Services Authority (NHS BSA) is only available for these two characteristics. We are therefore only able to demonstrate an accurate patient profile for individual items for these two characteristics. However, we have also used data and responses collected from this consultation to further inform development of the final guidance.

Overall this prescribing data for 2017/18 indicates that all items in the review are prescribed almost equally for males and females.

DRAFT

Looking at the age profiles of patients prescribed medications in 2017/18 (see 5.1) the items prescribed for cardiovascular conditions and diabetes are more commonly prescribed in patients over the age of 65 years. Bath and shower emollient preparations and silk garments were prescribed most frequently to under 18 year olds, although bath and shower emollient preparations were prescribed in an almost equal proportion to the over 65 year age group.

A literature review was also undertaken to explore the research evidence on patient characteristics within disease areas rather than by individual item. The aim of this exercise was to explore whether particular groups of patients may be affected by the proposals in a more general sense. Full results can be seen in Appendix A. Overall the evidence reflects patterns seen in the prescribing data with no additional indication that specific groups of the population would be adversely impacted by the recommendations.

Some of the items in the review are shown to be unsafe, ineffective or have a more cost-effective alternative. Without review and implementation by CCGs, inequalities to the wider population are likely due to unnecessary variation in prescribing and use of NHS funding on items which are shown to be of low clinical effectiveness. Money used on these products may displace funding on more evidence based and cost-effective treatments. Not undertaking this work could result in inequality for the wider population by not making most effective use of the NHS prescribing budget and NHS budgets more generally.

Consultation results

A 3 month consultation was undertaken from November 2018 – February 2019. This consultation provided an opportunity for views to be provided on the proposals for the update to the recommendations on rubefacients and the 8 new items. Appendix C includes an overview of key themes from the consultation for the 1 update and 8 new items proposed for inclusion in the updated CCG guidance. Relevant themes and results have also been reflected throughout the remainder of this document. The analysis undertaken as part of this equality and health inequalities impact assessment was taken account of when considering the content of the final CCG guidance. It should be noted that the themes highlighted in appendix C should be considered within the wider context of the consultation results and report (see Items which should not routinely be prescribed in primary care consultation report, June 2019).

All consultation results were considered and the clinical working group felt there were no changes required to the proposals to mitigate risk of inequality, although some changes were made to the proposed guidance following the consultation and these are detailed in the final CCG guidance.

PART B: Equalities Groups and Health Inequalities Groups

5. Impact of this work for the equality groups listed below.

Focusing on each equality group listed below (sections 5.1. to 5.9), please answer the following questions:

a) Does the equality group face discrimination in this work area?
b) Could the work tackle this discrimination and/or advance equality or good relations?
c) Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
d) Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?

DRAFT

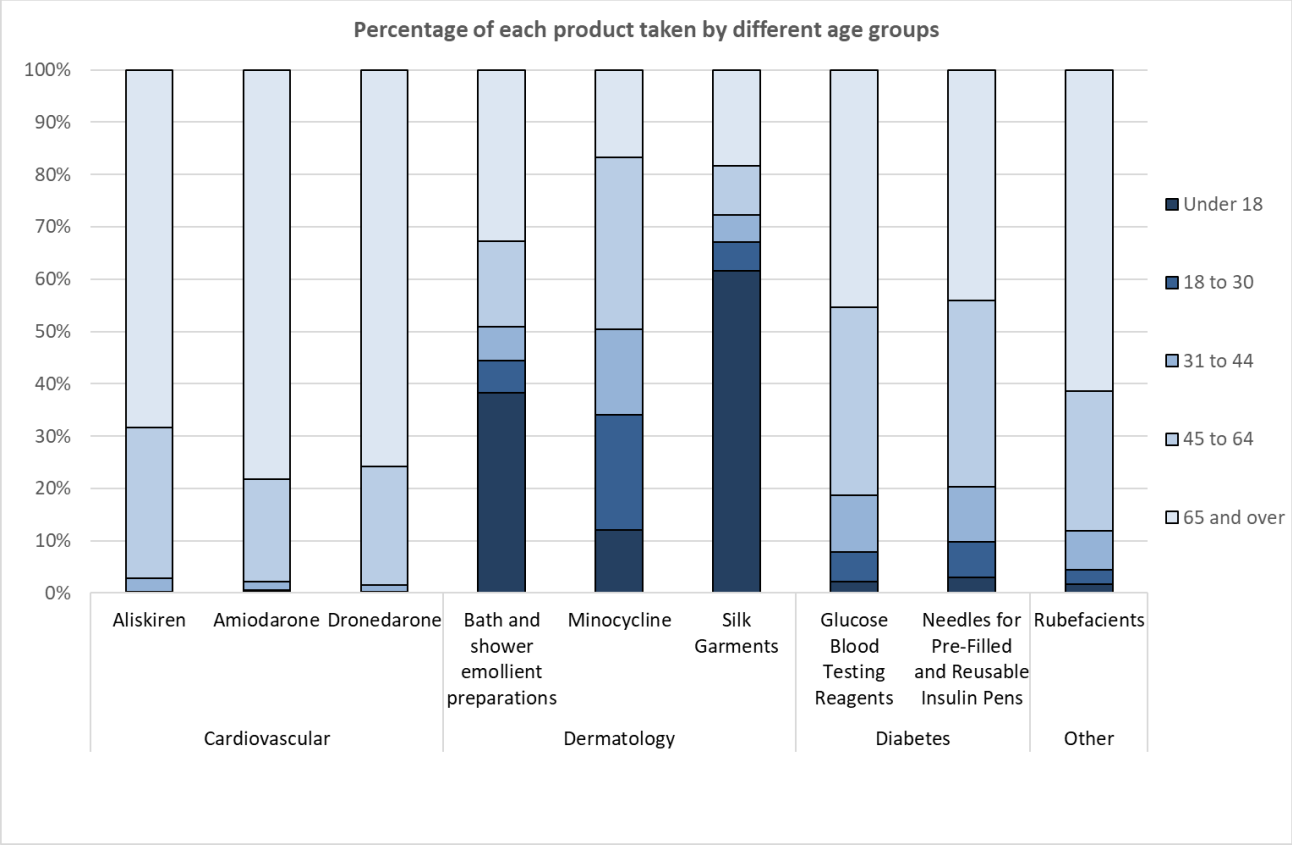
e) If you cannot answer these questions what action will be taken and when?

5.1. Age

Does the equality group face discrimination in this work area?
As people get older they are more likely to be taking prescribed medications, however there is no evidence to suggest that this prescribing is due to discrimination and is more likely due to increasing prevalence of various diseases related to increasing age.

Supporting Reference:
http://content.digital.nhs.uk/catalogue/PUB16076/HSE2013-Ch5-pres-meds.pdf

Figure 1. NHS BSA prescribing data 2017/18 by age (see appendix B for source data)



Could the work tackle this discrimination and/or advance equality or good relations?
Looking at the age profiles of patients prescribed the defined items in 2017/18, the items related to cardiovascular issues, diabetes and the rubefacients were most frequently prescribed to adults aged 45 and over. For the cardiovascular medications, in over 65% of cases, they were prescribed to the 65 year and over age group and no patients aged 30 or lower were prescribed these items.

Bath and shower preparations were prescribed most frequently to the under 18 year old (38%) and the 65 and over age groups (33%). Silk garments were prescribed most frequently to the under 18 year old group (62%). Minocycline prescriptions were also prescribed in an even distribution across all age bands.

As people of increasing age take more prescribed medicines, older people are likely to receive more items included within our proposed guidance on *Items of low clinical effectiveness, where*

there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns. This guidance, if adopted by CCGs, should prompt review of these patients' treatments to optimise their treatment with more effective medicines.

During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic, see appendix C for results. For those who responded to the online consultation, the demographic analysis of patient age, didn't show a particular difference or stronger view between age groups, with regards to agreeing or disagreeing with the recommendations

When looking at the themes for individual items from the consultation, the following themes relating to age were reported by respondents:

- Elderly patients who are more likely to be prescribed amiodarone and dronedarone.
- Impact of the recommendations for bath and shower preparations for dry and pruritic skin conditions on children with eczema.
- Bath and shower preparations for dry and pruritic skin conditions – consider impact on vulnerable age groups (e.g. young children and the elderly).

There was no indication from the wider consultation results that the proposals would result in people of particular ages experiencing inequalities in access to healthcare or health outcomes.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
This work could assist in potentially reducing harm caused to patients by certain prescribed items which older and younger people are more likely to receive. The recommendations for bath and shower preparations recommend an alternative product where appropriate.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
During the 3 month consultation, communications and engagement activities were undertaken with specific patient groups and charities to ensure that people of age groups who may be more widely represented were adequately able to respond to the consultation. During the consultation, responses were monitored to ascertain if there were any unintended consequences on the protected characteristic.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the proposed guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

5.2. Disability

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and disability so we cannot definitively assess fully at a national level.

DRAFT

During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic, see appendix C for results. For those who responded to the online consultation, a higher proportion of patients who reported having a disability disagreed with our recommendations for specific items, compared to those who did not have a disability. These items included: Bath and shower preparations for dry and pruritic skin conditions, blood glucose testing strips, dronedarone, needles for pre-filled insulin pens and rubefacients.

There was no indication from the wider consultation results that the proposals would result in people with disabilities experiencing inequalities in access to healthcare or health outcomes.

Could the work tackle this discrimination and/or advance equality or good relations?
Medication reviews could be used as an opportunity to optimise medical treatment for people with disabilities.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
These medication reviews could assist in potentially reducing harm caused to patients by certain medicines (not necessarily included in this guidance) which people with a disability are more likely to receive.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?

During the 3 month consultation communications and engagement activities were undertaken with specific patient groups and charities to ensure that people with and without disabilities, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

5.3. Gender reassignment

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and gender reassignment so we cannot definitively assess, at a national level, how many people will be affected.

Could the work tackle this discrimination and/or advance equality or good relations?
Medication reviews could be used as an opportunity to optimise medical treatment for people who have undergone gender reassignment.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
This work could assist in potentially reducing harm caused to patients by certain prescribed items which people who have undergone gender reassignment are more likely to receive.

DRAFT

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?

During the 3 month consultation communications and engagement activities were undertaken with specific patient groups and charities to ensure that people with this protected characteristic, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

5.4. Marriage and civil partnership

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and marriage/civil partnership so we cannot definitively assess, at a national level, how many people in a marriage/civil partnership will be affected. No link between prescribing and marriage/civil partnership has been identified.

Could the work tackle this discrimination and/or advance equality or good relations?
Medication reviews could be used as an opportunity to optimise medical treatment for people who are married or in a civil partnership.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
This work could assist in potentially reducing harm caused to patients by certain prescribed items which people who are married or in a civil partnership are more likely to receive.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
During the 3 month consultation, communications and engagement activities were undertaken with specific patient groups and charities to ensure that people with this protected characteristic, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

5.5. Pregnancy and maternity

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and pregnancy/maternity so we cannot definitively assess, at a national level, how many people who are pregnant or who have had a baby will be affected.

DRAFT

None of the items proposed in the guidance are used for conditions that are closely related to pregnancy or maternity. We expect prescribers will use medications *Summary of Product Characteristics* to inform treatment if any of these medicines are going to be used and prescribe accordingly.

Could the work tackle this discrimination and/or advance equality or good relations?
Medication reviews could be used as an opportunity to optimise medical treatment for people who are pregnant or who have had a baby.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
This work could assist in potentially reducing harm caused to patients by certain prescribed items which people who are pregnant or who have had a baby are more likely to receive.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
During the 3 month consultation, communications and engagement activities were undertaken with specific patient groups and charities to ensure that people with this protected characteristic, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

5.6. Race

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and race so we cannot definitively assess, at a national level, how many people will be affected. Although there is an indication that the prevalence of type 2 diabetes is more prevalent for particular ethnic groups, the draft recommendation for these items is that a prescriber should offer a more cost-effective substitution rather than deprescribe.

Could the work tackle this discrimination and/or advance equality or good relations?
Medication reviews could be used as an opportunity to optimise medical treatment for people of all races.

During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic, see appendix C for results. For those who responded to the online consultation, the demographic analysis of race for those who had reported this, didn't show a particular difference or stronger view between different races.

When looking at the themes for individual items from the consultation, the following themes relating to race were reported by respondents:

- Need to consider the impact on groups with increased prevalence of diabetes (e.g. ethnic minorities).

DRAFT

- Bath and shower preparations - proposal will disproportionately affect ethnic minorities.

There was no indication from the wider consultation results that the proposals would result in any particular race experiencing inequalities in access to healthcare or health outcomes.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
This work could assist in potentially reducing harm caused by prescribed items to patients of all races.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?

During the 3 month consultation, communications and engagement activities were undertaken with specific patient groups and charities to ensure that people of all races, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

5.7. Religion or belief

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and religious belief so we cannot definitively assess, at a national level, how many people will be affected. We have not identified any religious belief that would make a patient more or less likely to receive the items included in the guidance.

Could the work tackle this discrimination and/or advance equality or good relations?
Medication reviews could be used as an opportunity to optimise medical treatment for people of all religious beliefs.

During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic, see appendix C for results. For those who responded to the online consultation, the demographic analysis of religion and belief for those who had reported this, didn't show a particular difference or stronger view between those with different relions of beliefs.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
This work could assist in potentially reducing harm caused by prescribed items to patients of all religious beliefs.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?

DRAFT

During the 3 month consultation, communications and engagement activities were undertaken with specific patient groups and charities to ensure that people of all religions and beliefs, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

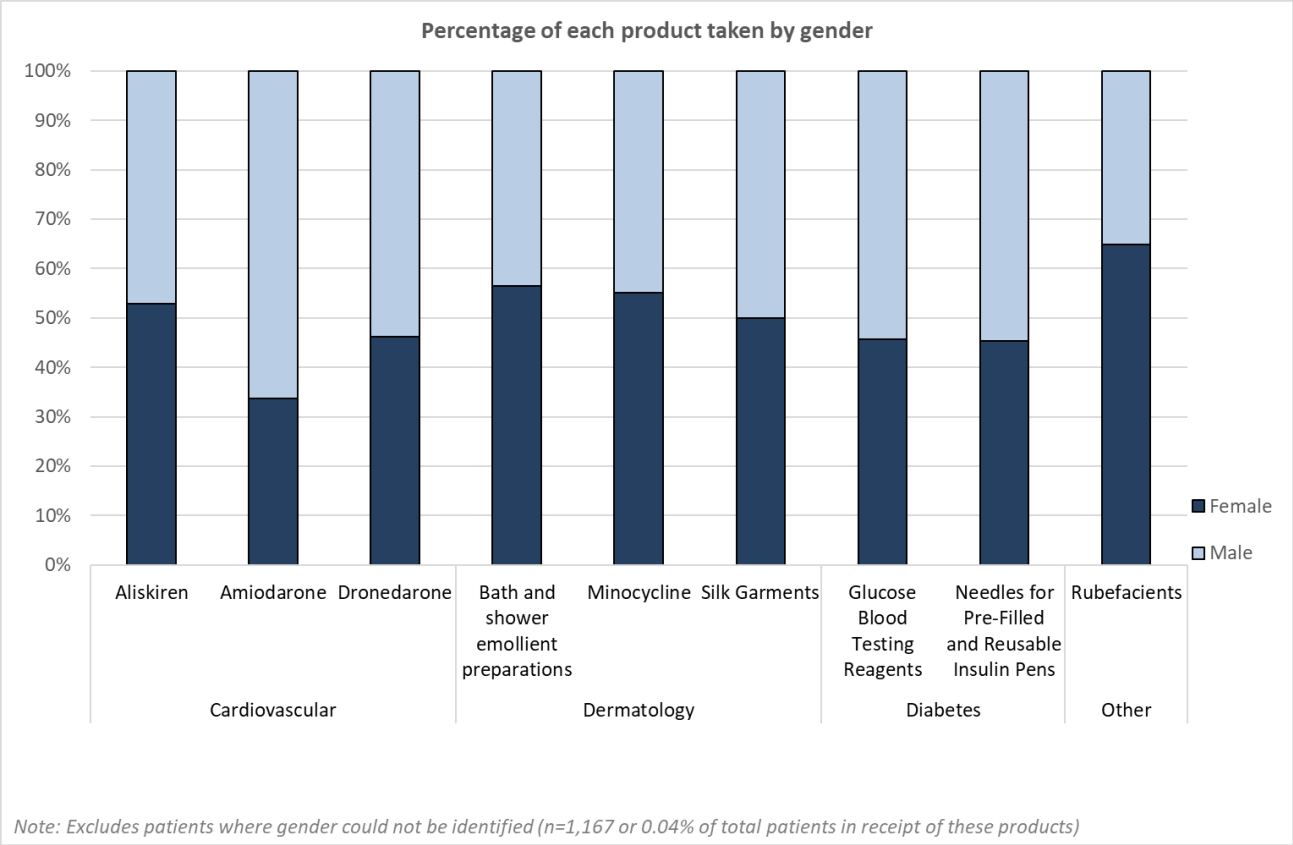
DRAFT

5.8. Sex or gender

Does the equality group face discrimination in this work area?
Nationally approximately 43% of men and 50% of women take at least one prescribed medicine. This proportion is higher among young women than young men, but increases more sharply with age in men than women. Overall 22% of men and 24% of women report that they take at least three prescribed medicines; although this proportion increases with age it does not vary by sex.

Source:
http://content.digital.nhs.uk/catalogue/PUB16076/HSE2013-Ch5-pres-meds.pdf

Figure 2. NHS BSA prescribing data 2017/18 by gender (see appendix B for source data)



Could the work tackle this discrimination and/or advance equality or good relations?
Overall this prescribing data for 2017/18 indicates approximately the same amount of females (50.4%) and males (49.6%) were prescribed the items. This indicates that medication reviews and potential deprescribing may be required equally for males and females.

This guidance, if adopted by CCGs, should prompt review of treatments meaning more people will receive reviews to optimise their treatment from the groups above.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
During the consultation, responses were monitored to ascertain if there are any unintended consequences on this protected characteristic, see appendix C for results. For those who responded to the online consultation, the demographic analysis for those who had reported their gender didn't show a particular difference or stronger view between different genders.

When looking at the themes for individual items from the consultation, the following themes relating to gender were reported by respondents:

- Blood glucose testing strips - proposal will affect women more than men.

There was no indication from the wider consultation results that the proposals would result in any particular gender experiencing inequalities in access to healthcare or health outcomes. There is the potential that it could assist in potentially reducing harm caused by certain prescribed items which particular genders are more likely to receive.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?

During the 3 month consultation, communications and engagement activities were undertaken with specific patient groups and charities to ensure that people of all genders, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

5.9. Sexual orientation

Does the equality group face discrimination in this work area?
There is no routinely collected data on prescribing and sexual orientation so we cannot definitively assess, at a national level, how many people will be affected. There is no established link between the prescribing of items proposed in this guidance and sexual orientation.

Could the work tackle this discrimination and/or advance equality or good relations?
Medication reviews could be used as an opportunity to optimise medical treatment for people of all sexual orientations.

Could the work assist or undermine compliance with the Public Sector Equality Duty (PSED)?
This work could assist in potentially reducing harm caused by prescribed items to patients of all sexual orientations.

Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?

During the 3 month consultation, communications and engagement activities were undertaken with specific patient groups and charities to ensure that people of all sexual orientations, were adequately able to respond to the consultation.

CCGs will also be required to assess the impact on their population with regard to the particular demographics of the population they serve. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice.

DRAFT

The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

6. Implications of our work for the health inclusion groups listed below.

Focusing on the work described in sections 1 and 2, in relation to each health inclusion group listed below (Sections 6.1. To 6.12), and any others relevant to your work[1], please answer the following questions:

f) Does the health inclusion group experience inequalities in access to healthcare?
g) Does the health inclusion group experience inequalities in health outcomes?
h) Could the work be used to tackle any identified inequalities in access to healthcare or health outcomes?
i) Could the work assist or undermine compliance with the duties to reduce health inequalities?
j) Does any action need to be taken to address any important adverse impact? If yes, what action should be taken?
k) As some of the health inclusion groups overlap with equalities groups you may prefer to also respond to these questions about a health inclusion group when responding to 5.1 to 5.9. That is fine; please just say below if that is what you have done.
l) If you cannot answer these questions what action will be taken and when?

6.1. Alcohol and / or drug misusers

None of the items in the review are specifically used to support the treatment of patients suffering alcohol or drug misuse. There is no data available on the prevalence of alcohol or drug users who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.2. Asylum seekers and /or refugees

There is no data available on the prevalence of asylum seekers and/or refugees who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes

6.3. Carers

There is no data available on the prevalence of carers who are currently prescribed the items in the review. There was a theme from the consultation highlighting the need to consider the impact on carers in managing treatment. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.4. Ex-service personnel / veterans

There is no data available on the prevalence of ex-service personnel / veterans who are currently prescribed the items in the review. There was no indication from the consultation results that the

[1] Our guidance document explains the meaning of these terms if you are not familiar with the language.

proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.5. Those who have experienced Female Genital Mutilation (FGM)

There is no data available on the prevalence of those who have experienced Female Genital Mutilation (FGM) who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.6. Gypsies, Roma and travellers

There is no data available on the prevalence of Gypsies, Roma and travellers who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.7. Homeless people and rough sleepers

There is no data available on the prevalence of homeless people and rough sleepers who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.8. Those who have experienced human trafficking or modern slavery

There is no data available on the prevalence of those who have experienced human trafficking or modern slavery who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.9. Those living with mental health issues

None of the medicines in the review are specifically used in the treatment of mental health conditions. There is no data available on the prevalence of people with mental health conditions who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.10.Sex workers

There is no data available on the prevalence of sex workers who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.11.Trans people or other members of the non-binary community

There is no data available on trans people or other members of the non-binary community who are currently prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

6.12.The overlapping impact on different groups who face health inequalities

There is no data available on different groups who face health inequalities who are currently

DRAFT

prescribed the items in the review. There was no indication from the consultation results that the proposals would result in this health inclusion group experiencing inequalities in access to healthcare or health outcomes.

7. Other groups that face health inequalities that we have identified.

Have you have identified other groups that face inequalities in access to healthcare?
No other groups have not been identified from the consultation responses.

Does the group experience inequalities in access to healthcare and/or inequalities in health outcomes?
N/A as above.

Short explanatory notes - other groups that face health exclusion.

As we research and gather more data, we learn more about which groups may be facing health inequalities.

If your work has identified more groups that face important health inequalities please answer questions 7 and 8. Please circle as appropriate.

Yes Complete section 8	**No** Go to section 9	N/A

N/A

8. Other groups that face health inequalities that we have identified.
Could the work be used to tackle any identified inequalities in access to healthcare or health outcomes in relation to these other groups that face health inequalities?

Could the work undermine compliance with the duties to reduce health inequalities and, if so, what action should be taken to reduce any adverse impact?

Is the work going to help NHS England to comply with the duties to reduce health inequalities?
If you have identified other groups that face health inequalities please answer the questions below. You will only answer this question if you have identified additional groups facing important health inequalities

N/A

PART C: Promoting integrated services and working with partners

Short explanatory notes: Integrated services and reducing health inequalities.

Our detailed guidance explains the duties in relation to integrated services and reducing health inequalities. Please answer the questions listed below.

9. Opportunities to reduce health inequalities through integrated services.

Does the work offer opportunities to encourage integrated services that could reduce health

inequalities? If yes please also answer 10.

Yes Go to section 10	**No** Go to section 11	Do not know

No

10. How can this work increase integrated services and reduce health inequalities?

Please explain below, in a few short sentences, how the work will encourage more integrated services that reduce health inequalities and which partners we will be working with.

N/A

PART D: Engagement and involvement

11. Engagement and involvement activities already undertaken.

How were stakeholders, who could comment on equalities and health inequalities engaged, or involved with this work? For example in gathering evidence, commenting on evidence, commenting on proposals or in other ways? And what were the key outputs?

NHS England established a clinical working group in partnership with NHS Clinical Commissioners with membership from their own organisations plus partner organisations. During November 2018 stakeholder engagement was undertaken with national patient organisations to contribute their views on the proposals including:

- National Voices
- Healthwatch
- Patient Association

Comments and suggestions were received on how to consult and reach further group affected by the proposals.

A 3 month public consultation was undertaken from November 2018 – February 2019. This consultation provided an opportunity for views to be provided on the proposals for the 1 updated item and 8 new items. As part of this consultation 1461 online responses and almost 54 written responses were received. A programme of engagement was also undertaken including webinars and engagement events with key stakeholder groups e.g. patients, professionals, CCGs etc.

12. Which stakeholders and equalities and health inclusion groups were involved?

NHS England, NHS Clinical Commissioners, Royal Pharmaceutical Society, NICE, Department of Health and Social Care, PrescQIPP, NHS Business Services Authority, Royal College of GPs, National Voices, Patients Association, Healthwatch.

The consultation had involvement of a number of stakeholders and equalities and health inclusion groups (see Items that should not be routinely prescribed in primary care consultation report, June

DRAFT

2019).

13. Key information from the engagement and involvement activities undertaken.

Were key issues, concerns or questions expressed by stakeholders and if so what were these and how were they addressed? Were stakeholders broadly supportive of this work?

Stakeholders are broadly supportive of the work on the proposals for 1 updated and 8 new items. Results and themes relating to equalities and health inequalities raised by stakeholders are reflected in appendix C and throughout this review. Full consultation results as outlined in the report 'Items that should not be routinely prescribed in primary care consultation report' (June 2019).

14. Stakeholders were not broadly supportive but we need to go ahead.

If stakeholders were not broadly supportive of the work but you are recommending progressing with the work anyway, why are you making this recommendation?

For some of the additional items in the update guidance there are groups that are not broadly supportive of the recommendations. Further details can be found in appendix C and the 'Items that should not be routinely prescribed in primary care consultation report (June 2019).

15. Further engagement and involvement activities planned.

Are further engagement and involvement activities planned? If so what is planned, when and why?

Publication of the final CCG guidance alongside the results from the consultation.

PART E: Monitoring and Evaluation

16. In relation to equalities and reducing health inequalities, please summarise the most important monitoring and evaluation activities undertaken in relation to this work

Evaluation plan is being developed and consideration will be given to inequalities monitoring. For example we can monitor age and sex of all people on these items.

17. Please identify the main data sets and sources that you have drawn on in relation to this work. Which key reports or data sets have you drawn on?

NHS Business Services Authority (BSA) community pharmacy reimbursement data 2017/18.

Please see appendix A for further evidence and literature references and sources.

DRAFT

Items that should not be routinely be prescribed in primary care consultation report (June 2019).

18. Important equalities or health inequalities data gaps or gaps in relation to evaluation.

In relation to this work have you identified any:

- important equalities or health inequalities data gaps or
- gaps in relation to monitoring and evaluation?

Yes	No

There is currently no nationally collected data for 7 of the 9 characteristics and additional health improvement groups for the individual medications in this review.

19. Planned action to address important equalities or health inequalities data gaps or gaps in relation to evaluation.

If you have identified important gaps and you have identified action to be taken, what action are you planning to take, when and why?

This is something that individual CCGs may have more insight on when looking at their local population data and will be encouraged to consider this as part of local consultation and impact assessment. We expect CCGs to take the guidance into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties. CCGs still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

DRAFT

PART F: Summary analysis and recommended action		
20. Contributing to the first PSED equality aim. Can this work contribute to eliminating discrimination, harassment or victimisation?		
Yes	**No**	Do not know
If yes please explain how, in a few short sentences		
N/A		
21. Contributing to the second PSED equality aim. Can this policy or piece of work contribute to advancing equality of opportunity? Please circle as appropriate.		
Yes	No	Do not know
Currently patients could be prescribed items that are unsafe, ineffective or where there is a more cost effective alternative available. By setting a national direction on a set of defined items, this project encourages CCGs to implement policy that encourages review of patients taking these items to ensure that their treatment is optimised, it can also reduce variation across the country. This enables patients to have access to the most effective products to achieve the best outcomes. If more cost-effective options are utilised this frees up funding for other care and treatment to optimise wider population benefit and outcomes.		
22. Contributing to the third PSED equality aim. Can this policy or piece of work contribute to fostering good relations between groups? Please circle as appropriate.		
Yes	No	Do not know
The Low Priority Prescribing clinical working group includes representatives from NHSCC, CCG medicines optimisation teams, NICE etc. We are also working with other stakeholders as described in question 12. The common aim to ensure that the CCG guidance developed supports CCGs in effective medicines optimisation for the population they serve. Fostering of good relationships will also be enhanced through engagement with a number of other stakeholders including charities and patient groups. The consultation also provided an opportunity for organisations, health professionals, patients and the public to be considered in the development of the CCG guidance.		
23. Contributing to reducing inequalities in access to health services. Can this policy or piece of work contribute to reducing inequalities in access to health services?		
Yes	No	Do not know

DRAFT

Currently patients could be prescribed items that are unsafe, ineffective or where there is a more cost effective alternative available. By setting a national direction on a set of defined items this project encourages CCGs to implement policy that encourages review of patients taking these items to ensure that their treatment is optimised. This enables patients to have access to the most effective products to achieve the best outcomes. If more cost effective options are utilised this frees up funding for other care and treatment to optimise wider population benefit and outcomes. Patients currently taking the items will benefit. If CCGs implement the guidance once finalised, all patients being prescribed the included items should be considered for medication reviews aimed to optimise their treatment and outcomes. There are also wider population gains than those who may benefit from the more efficient use of the money currently spent on low value medicines. CCGs will need to consider this national impact assessment and the report from the national consultation when making individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities. This will help ensure that specific groups locally are not impacted adversely.		
24. Contributing to reducing inequalities in health outcomes. Can this work contribute to reducing inequalities in health outcomes?		
Yes	No	Do not know
See section 23.		
25. Contributing to the PSED and reducing health inequalities. How will the policy or piece of work contribute to the achieving the PSED and reducing health inequalities in access and outcomes? Please describe below in a few short sentences.		
As section 23.		
26. Agreed or recommended actions. What actions are proposed to address any key concerns identified in this Equality and Health Inequalities Analysis (EHIA) and / or to ensure that the work contributes to the reducing unlawful discrimination / acts, advancing equality of opportunity, fostering good relations and / or reducing health inequalities? Is there a need to review the EHI analysis at a later stage?		

Action	Public Sector Equality Duty	Health Inequality	By when	By whom
Ensure that CCGs are encouraged to consider their local demographic and prescribing data available to ensure	Yes	Yes	Post guidance publication	CCGs

that local implementation decisions are effective and in line with legislation.				
Support implementation with resources referenced in the guidance to support prescribers with deprescribing and offer of alternative prescribed items where appropriate.	Yes	Yes	Post guidance publication	Project team

DRAFT

Appendix A

Equalities and Health Inequalities Evidence Search

Cardiovascular conditions

The following evidence indicates that cardiovascular conditions such as hypertension are more prevalent with some of the protected characteristics (see below for details). The draft recommendations for these drugs ensure that patients would be offered a suitable alternative. Where required this would involve an MDT of other health professionals. There are no recommendations that result in patients being disadvantaged by offering no alternative or one that was not agreed collaboratively by the patient and clinician.

Prevalence
2015/2016 QOF recorded prevalence for hypertension Report hypertension prevalence rate as 13.8 per cent.

National CVD Intelligence network (2014) estimate expected prevalence per total population = 23.6% (includes undiagnosed estimates).

Age/sex
The relationship between age and the prevalence of hypertension differed between the sexes. The prevalence of survey-defined hypertension was significantly higher in men than women across each age group apart from those aged 65 and over.

Deprivation
Mirroring the trends found with equivalised household income, the age-standardised prevalence of hypertension was highest among those living in areas of high deprivation. Prevalence rose from 26% of men and 23% of women in the least deprived quintile to 34% of men and 30% of women in the most deprived quintile.
Knott C, Mindell J. Health Survey for England - 2011: Chapter 3, Hypertension. Leeds, UK: Health and Social Care Information Centre, 2012.

Dermatology

The following evidence does indicate that eczema is more prevalent depending on age. Atopic eczema affects more children than adults, this is estimated at 15 - 20% of children and 1 - 3% of adults worldwide.
Asher MI, Montefort S, Bjorksten B, Lai CK, Strachan DP, Weiland SK, Williams H: Worldwide time trends in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and eczema in childhood: ISAAC Phases One and Three repeat multicountry cross-sectional surveys. Lancet 2006;368:733-743.

The following evidence from the Global Burden of Disease Project estimates the prevalence of acne at 9.4%. Studies evaluating sex differences have shown that acne is more prevalent in girls at younger age ranges, with increasing prevalence in boys as they reach puberty. Following the teenage years, the prevalence in women again tends to be higher than in men.

DRAFT

https://onlinelibrary.wiley.com/doi/full/10.1111/bjd.13462

Type 2 Diabetes

Public Health England data indicates that the prevalence of diabetes in England is 6.7% (QOF, 2016/17). The highest percentage of people with type 2 diabetes are aged between 40 – 79 years. Data indicates that type 2 diabetes is slightly more prevalent in males than females.
https://fingertips.phe.org.uk/profile/diabetes-ft/data#page/0/gid/1938133138/pat/46/par/E39000030/ati/153/are/E38000010

Type 2 diabetes is much more common in ethnic minorities groups residing in developed countries; South Asian and African-Caribbean groups in the UK in particular have a high prevalence. Poverty has also been recognised as a contributor to prevalence of type 2 diabetes.
Riste L, Khan F, Cruickshank K. High prevalence of type 2 diabetes in all ethnic groups, including Europeans, in a British inner city: relative poverty, history, inactivity, or 21st century Europe? Diabetes Care2001;24:1377–83.

Chronic pain conditions – rubefacients

The following evidence indicates that the prevalence of chronic pain increases with age and was higher among females, and in people with disabilities, low incomes and low educational levels. The evidence also suggests that females may be more likely to report pain and that there are lots of other influencing factors which would affect the epidemiology of different types of chronic pain.

The draft recommendations for rubefacients ensure that patients would be offered a suitable alternative and where required, this would involve other relevant services. Recommendations do not result in patients being disadvantaged by offering no pain relief or an alternative that was not agreed collaboratively by the patient and clinician.

The estimated prevalence of chronic pain in the UK, derived from 7 studies, ranged from 35.0% to 51.3% (pooled estimate 43.5%, 95% CIs 38.4% to 48.6%). The prevalence of moderate-severely disabling chronic pain (Von Korff grades III/IV), based on 4 studies, ranged from 10.4% to 14.3%. 12 studies stratified chronic pain prevalence by age group, demonstrating a trend towards increasing prevalence with increasing age from 14.3% in 18–25 years old, to 62% in the over 75 age group, although the prevalence of chronic pain in young people (18–39 years old) may be as high as 30%. Reported prevalence estimates were summarised for chronic widespread pain (pooled estimate 14.2%, 95% CI 12.3% to 16.1%; 5 studies), chronic neuropathic pain (8.2% to 8.9%; 2 studies) and fibromyalgia (5.4%; 1 study). Chronic pain was more common in female than male participants, across all measured phenotypes.
Prevalence of chronic pain in the UK: a systematic review and meta-analysis of population studies (Fayaz, 2016)

National pain audit (2013)
The prevalence of chronic pain is estimated at 8-60% of the population, depending on the definition. Severe pain is estimated at 11% for adults and 8% for children.

Older age, sex, poor housing and type of employment (for example heavy manual work) are significant predictors of chronic pain in the community.
The epidemiology of chronic pain in the community (1999, Elliott et al)

A survey in Scotland (n = 3605) identified age, sex, housing tenure, and employment status as significant predictors of the presence of chronic pain in the community.
https://www.ncbi.nlm.nih.gov/pubmed/11166468

Chronic pain in Australia: a prevalence study (Blyth et al, 2001)
This study reports chronic pain prevalence in a randomly selected sample of the adult Australian population. Data were collected by Computer-Assisted Telephone Interview (CATI) (n = 17,543) Having chronic pain was significantly associated with older age, female gender, lower levels of completed education, and not having private health insurance. It was also strongly associated with receiving a disability benefit (adjusted OR=3.89, P<0.001) or unemployment benefit (adjusted OR=1.99, P<0.001); being unemployed for health reasons (adjusted OR=6.41, P<0.001); having poor self-rated health (adjusted OR=7.24, P<0.001); and high levels of psychological distress (adjusted OR=3.16, P<0.001).
http://ovidsp.uk.ovid.com/sp-3.25.0a/ovidweb.cgi?&S=HBIEPDNJPPHFFLLOFNGKOHEGHGHAAA00&Abstract=S.sh.91%7c99%7c1

Chronic pain: One year prevalence and associated characteristics, the HUNT pain study (Elsevier, 2013)
The total prevalence of chronic pain was 36% (95% CI 34-38) among women and 25% (95% CI 22-26) among men. The prevalence increased with age, was higher among people with high BMI, and in people with low income and low educational level.
http://ovidsp.uk.ovid.com/sp-3.25.0a/ovidweb.cgi?&S=HBIEPDNJPPHFFLLOFNGKOHEGHGHAAA00&Complete+Reference=S.sh.91%7c405%7c1

The prevalence of chronic pain in united states adults: Results of an internet-based survey (Johannas, 2010)
A cross-sectional, Internet-based survey was conducted in a nationally representative sample of United States (US) adults to estimate the point prevalence of chronic pain and to describe sociodemographic correlates and characteristics of chronic pain (n = 27,035). The weighted point-prevalence of chronic pain (defined as chronic, recurrent, or long-lasting pain lasting for at least 6 months) was 30.7% (95% CI, 29.8-31.7). Prevalence was higher for females (34.3%) than males (26.7%) and increased with age. Multiple logistic regression analysis identified low household income and unemployment as significant socioeconomic correlates of chronic pain. Chronic pain is prevalent among US adults and is related to indicators of poorer socioeconomic status

Gender considerations in the epidemiology of chronic pain (LeResche, 1999)
Indicates age and sex differences for different types of chronic pain conditions. Some indication that women may be more likely to report chronic pain, although this may not be a true indication of cases in the population.

DRAFT

Appendix B

Patients prescribed products by gender

(April 2017 - March 2018) *Source: NHS Business Services Authority*

	Number of identifiable patients				Percentage of identifiable patients			
	Female	**Male**	**Unknown**	**Total**	**Female**	**Male**	**Unknown**	**Total**
Aliskiren	1,410	1,253		**2,663**	52.9%	47.1%	0.0%	**100.0%**
Amiodarone	19,867	39,081	9	**58,957**	33.7%	66.3%	0.0%	**100.0%**
Bath and shower emollient preparations	486,695	374,071	792	**861,558**	56.5%	43.4%	0.1%	**100.0%**
Dronedarone	1,277	1,482		**2,759**	46.3%	53.7%	0.0%	**100.0%**
Glucose Blood Testing Reagents	568,143	673,188	204	**1,241,535**	45.8%	54.2%	0.0%	**100.0%**
Minocycline	5,385	4,399	7	**9,791**	55.0%	44.9%	0.1%	**100.0%**
Needles for Pre-Filled and Reusable Insulin Pens	297,006	357,465	80	**654,551**	45.4%	54.6%	0.0%	**100.0%**
Rubefacients	207,819	112,279	138	**320,236**	64.9%	35.1%	0.0%	**100.0%**
Silk Garments	3,752	3,745	6	**7,503**	50.0%	49.9%	0.1%	**100.0%**
Total	**1,591,354**	**1,566,963**	**1,236**	**3,159,553**	**50.4%**	**49.6%**	**0.0%**	**100.0%**

Notes: Patient counts are not unique across products. A patient is counted once per product but if they are prescribed multiple products then they will be counted multiple times. Patient gender will be unknown where the information could not be identified via the Personal Demographics Service (PDS) for an individual patient

Patients prescribed products by age band

(April 2017 - March 2018) *Source: NHS Business Services Authority*

	Number of identifiable patients						Percentage of identifiable patients					
	Under 18	**18 to 30**	**31 to 44**	**45 to 64**	**65 and over**	**Total**	**Under 18**	**18 to 30**	**31 to 44**	**45 to 64**	**65 and over**	**Total**
Aliskiren		6	69	769	1,819	**2,663**	0.0%	0.2%	2.6%	28.9%	68.3%	**100.0%**
Amiodarone	135	197	907	11,547	46,171	**58,957**	0.2%	0.3%	1.5%	19.6%	78.3%	**100.0%**
Bath and shower emollient preparations	329,075	53,774	55,852	140,075	282,782	**861,558**	38.2%	6.2%	6.5%	16.3%	32.8%	**100.0%**
Dronedarone		5	39	622	2,093	**2,759**	0.0%	0.2%	1.4%	22.5%	75.9%	**100.0%**
Glucose Blood Testing Reagents	28,000	69,659	135,318	446,059	562,499	**1,241,535**	2.3%	5.6%	10.9%	35.9%	45.3%	**100.0%**
Minocycline	1,182	2,155	1,606	3,217	1,631	**9,791**	12.1%	22.0%	16.4%	32.9%	16.7%	**100.0%**
Needles for Pre-Filled and Reusable Insulin Pens	19,429	44,816	68,549	233,218	288,539	**654,551**	3.0%	6.8%	10.5%	35.6%	44.1%	**100.0%**
Rubefacients	5,386	8,688	24,233	85,418	196,511	**320,236**	1.7%	2.7%	7.6%	26.7%	61.4%	**100.0%**
Silk Garments	4,620	413	395	697	1,378	**7,503**	61.6%	5.5%	5.3%	9.3%	18.4%	**100.0%**
Total	**387,827**	**179,713**	**286,968**	**921,622**	**1,383,423**	**3,159,553**	**12.3%**	**5.7%**	**9.1%**	**29.2%**	**43.8%**	**100.0%**

Notes: Patient counts are not unique across products. A patient is counted once per product but if they are prescribed multiple products then they will be counted multiple times. The patients age is based on the maximum age of the patient, at the time of prescribing, during the financial year. Therefore a single patient will only appear in the results for one age group for a particular drug category

DRAFT

Appendix C

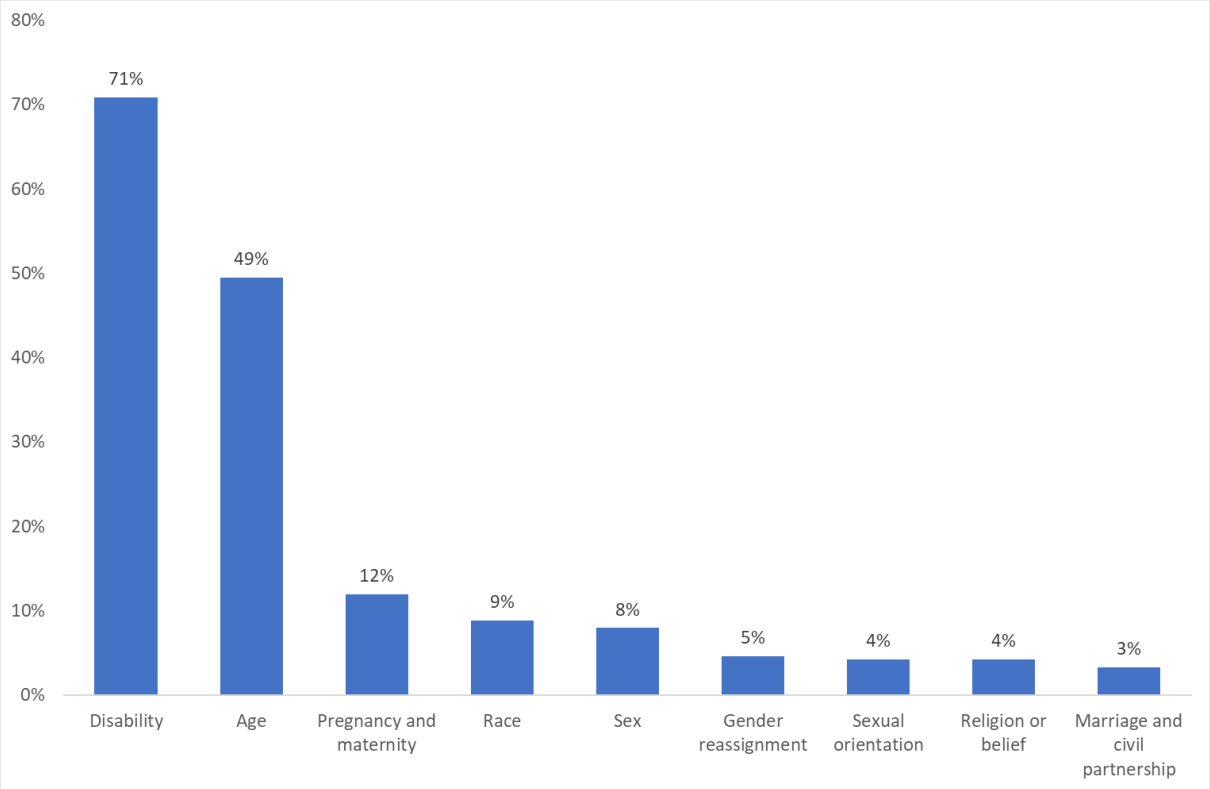
As part of the online consultation survey there were two questions that focused on the impact of the work on equalities and health inequalities as follows. Key results for these questions are also reported.

1. Do you feel there any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?

Table 1 – Responses to consultation question 'Do you feel there any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?' (n = 1,461)

Response	Percentage
Yes	31%
No	41%
Unsure	28%

Figure 1 – Responses to consultation question 'Which groups do you think will be effected' (n = 453)



2. Do you feel there is any further evidence we should consider in our proposals on the potential impact on health inequalities experience by certain groups e.g. people on low incomes; people from BME communities?

Table 2 – Responses to consultation question 'Do you feel there is any further evidence we should consider in our proposals on the potential impact on health inequalities experience by certain groups' (n = 1,434)

Response	Percentage
Yes	34%
No	39%
Unsure	26%

Themes relating to equalities and health inequalities reported from the further information. It should be noted that the themes highlighted here should be considered within the wider context of the consultation results and report (see Items which should not routinely be prescribed in primary care consultation report, June 2019). The following themes were reported:

- Adversely affects those who require considerable care (e.g. disabled, elderly).
- Impact on those on low income/lower socioeconomic background.
- Make it harder for some to access treatment or medication.
- Impact on children with eczema.
- Adversely affect patients with diabetes.
- Need to consider the impact on groups with increased prevalence of diabetes (e.g. ethnic minorities).
- Need to consider the requirements of patients with rare illnesses.
- Need to consider the impact on carers in managing treatment.
- CCGs should be seeking the most cost-effective medications for all.

The consultation also provided an opportunity for respondents to say if they agreed or disagreed with the proposals for each of the updated and new items and to provide further information. It should be noted that the themes highlighted here should be considered within the wider context of the consultation results and report (see Items which should not routinely be prescribed in primary care consultation report, June 2019). The following item specific themes relating to equalities and health inequalities were reported:

Aliskiren

- Consider that deprescribing of aliskiren may not be straight forward in some patient groups.

Amiodarone

- Consider the impact on elderly patients who are more likely to be prescribed amiodarone and dronedarone.
- Consider the impact on vulnerable groups (e.g. high risk groups, BME, elderly).

DRAFT

Bath and shower preparations for dry and pruritic skin conditions

- Consider the impact on children with eczema.
- Consider the impact on vulnerable age groups (e.g. young children and the elderly).
- Consider the impact on those on low income / lower socioeconomic background.
- The proposal should consider exempting specific groups of people (e.g. children, those with genital dermatoses or hand dermatitis).
- Proposal will disproportionately affect ethnic minorities.

Blood glucose testing strips for type 2 diabetes

- Consider that effective blood glucose testing prevents adverse patient outcomes
- Proposal could restrict access to insulin pen needles and blood glucose testing strips for patients with type 1 diabetes
- Type 2 insulin-dependent diabetics should be treated the same as type 1 insulin-dependent diabetics
- Consider impact on vulnerable groups (e.g. low income, high risk groups, BME, elderly, pregnant patients, children).
- Proposal will affect women more than men.
- The proposal should consider that some groups of patients will require more expensive testing strips

Needles for pre-filled and reusable insulin pens

- Proposal disproportionately affects certain groups (e.g. disabled people, women, ethnic minorities)
- Proposal limits the accessibility of safety needles which are needed for specific groups of people (e.g. needle phobic, visual disability)
- Consider the impact on diabetes patients with poor dexterity
- Children should be exempt from the proposal

Silk garments

- Consider the impact of accessibility to silk garments on patient outcomes
- Consider impact on vulnerable groups (e.g. high-risk groups, BME, elderly, pregnant patients)
- The proposal should consider exempting specific groups of people (e.g. severe cases, chronic conditions)
- Consider the impact on those on low income / lower socioeconomic background

Rubefacients

- Consider the impact on those with low incomes and their ability to purchase rubefacients

Analysis of responses from patients, by protected characteristics

Responses from the 673 patients[2] were analysed by the protected characteristics captured in the online survey. Where a patient group responded with a particularly different or stronger view to other patients within the same protected characteristic then this is reported here. That does not however mean that patients with other protected characteristics do not disagree with the proposals. Where patients overall disagree with proposals then it will be the case that this will be reflected across the

[2] In the survey 667 respondents ticked the box that identified them as a patient but six other respondents identified themselves as a patient in the free text box so these were recoded as patients in the dataset.

patient characteristics unless noted here. For example, only where males and females disagree to a different extent with a proposal will this be reported here.

Bath and shower preparations for dry and pruritic skin conditions

Patients considering themselves to have a disability disagreed more strongly with the proposals.

		Disability	
Proposal	**Response**	**Yes**	**No**
Advise CCGs to support prescribers in deprescribing bath and shower preparations in this category and substitute with "leave-on" emollients and, where appropriate, to ensure the availability of relevant services to facilitate this change	Agree	17	41
	Disagree	57	89
	Neither agree or disagree	4	6
	Unsure	7	6
	Percent disagree	**67%**	**63%**
Advise CCGs that prescribers in primary care should not initiate bath and shower preparations for any new patient.	Agree	4	27
	Disagree	74	113
	Neither agree or disagree	0	1
	Unsure	7	2
	Percent disagree	**87%**	**79%**

Blood glucose testing strips

Patients considering themselves to have a disability disagreed more strongly with the proposals.

		Disability	
Proposal	**Response**	**Yes**	**No**
Advise CCGs to support prescribers in deprescribing blood glucose testing strips that cost more than £10 for 50 strips and where appropriate, ensure the availability of relevant services to facilitate this change	Agree	39	45
	Disagree	62	41
	Neither agree or disagree	4	5
	Unsure	4	5
	Percent disagree	**57%**	**43%**
Advise CCGs that prescribers in primary care should not initiate blood glucose testing strips that cost more than £10 for 50 strips for any new patient.	Agree	27	35
	Disagree	74	51
	Neither agree or disagree	6	6
	Unsure	4	4
	Percent disagree	**67%**	**53%**

DRAFT

Dronedarone

Patients considering themselves to have a disability felt more strongly about the proposals, though this may be due to small numbers of respondents.

		Disability	
Proposal	**Response**	**Yes**	**No**
Advise CCGs that prescribers should not initiate dronedarone in primary care for any new patient	Agree	0	9
	Disagree	4	5
	Unsure	0	1
	Percent disagree	**100%**	**33%**
Advise CCGs that if, in exceptional circumstances, there is a clinical need for dronedarone to be prescribed, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.	Agree	4	10
	Disagree	0	4
	Unsure	0	1
	Percent disagree	**0%**	**27%**

Needles for pre-filled insulin pens

Patients considering themselves to have a disability disagreed more strongly with the proposal on advising not to initiate patients. They disagreed to the same extent as those not considering themselves to have a disability with the other proposal.

		Disability	
Proposal	**Response**	**Yes**	**No**
Advise CCGs to support prescribers in deprescribing insulin pen needles that cost more than £5 per 100 needles and, where appropriate ensure the availability of relevant services to facilitate this change.	Agree	35	42
	Disagree	51	54
	Neither agree nor disagree	6	5
	Unsure	8	4
	Percent disagree	**51%**	**51%**
Advise CCGs that prescribers in primary care should not initiate insulin pen needles that cost more than £5 per 100 needles for any new diabetes patient.	Agree	17	35
	Disagree	71	62
	Neither agree nor disagree	6	3
	Unsure	6	5
	Percent disagree	**71%**	**59%**

DRAFT

Rubefacients

Patients considering themselves to have a disability disagreed more strongly with the proposals.

		Disability	
Proposal	**Response**	**Yes**	**No**
Advise CCGs to support prescribers in deprescribing insulin pen needles that cost more than £5 per 100 needles and, where appropriate ensure the availability of relevant services to facilitate this change.	Agree	33	69
	Disagree	34	30
	Neither agree nor disagree	44	37
	Unsure	29	36
	Percent disagree	**24%**	**17%**
Advise CCGs that prescribers in primary care should not initiate insulin pen needles that cost more than £5 per 100 needles for any new diabetes patient.	Agree	25	64
	Disagree	46	40
	Neither agree nor disagree	40	32
	Unsure	30	35
	Percent disagree	**33%**	**23%**

DRAFT