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 and NHS Improvement

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

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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.**

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.

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.

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***	

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***				

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 5. 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

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.

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.

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 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.

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

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.

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.

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 11. 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

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 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.

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.

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.

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).

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.

Table15. 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.

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.

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

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.

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 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.

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.

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.

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.

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.

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).

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.

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).

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 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.

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.

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.

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.

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.

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.

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

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.