

NHS ENGLAND BOARD PAPER

Title: Low Priority Prescribing Consultation and Gluten-Free Food Guidance – for decision

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Purpose of Paper:

- The Next Steps document, published on 31 March 2017, included as part of the NHS 10 Point Efficiency Plan a commitment to review the appropriateness of aspects of NHS prescribing, including products deemed to be of ‘low clinical value’ and/or available to the public over the counter (OTC)
- During 2017/18 CCG guidance was published by NHS England and NHS Clinical Commissioners (NHSCC) for:
 - Items that should not be routinely prescribed in primary care (Nov 2017); and
 - Conditions for which over the counter items should not routinely be prescribed in primary care (March 2018)
- It was agreed that NHS England should continue to work with NHSCC to identify further low priority items that should not routinely be prescribed in primary care. A further eight items have been identified. Subject to support from the NHS England Board, we propose to commence a three-month public consultation on restrictions to these items
- In addition, following a Department of Health and Social Care (DHSC) consultation on the prescribing of gluten-free (GF) foods in primary care, regulations are being laid in Parliament which would allow for no GF products to be prescribed at NHS expense, other than GF bread and GF mixes
- NHS England has developed supporting guidance for CCGs, which is intended to communicate the changes in regulations, and to support CCGs with the development of local GF food prescribing policies. Subject to support from the NHS England Board, this guidance document will be published after the regulations come into force on 4 December 2018

The Board is invited to:

- Approve formal public consultation on further low priority items that should not routinely be prescribed in primary care as they are considered to be relatively ineffective, unnecessary, inappropriate or unsafe for prescription in the NHS; and
- Approve publication of guidance for CCGs, and an accompanying Equality and Health Inequalities Impact Assessment, on prescribing of Gluten-Free Foods in primary care.

Low Priority Prescribing Consultation and Gluten-Free Food Guidance

Context and Background

1. It is important that the NHS achieves the greatest value from the money that it spends. In 2017, the cost of prescriptions dispensed in the community was £9.17billion, and we know that across England there is significant variation in what is being prescribed and to whom.
2. 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.
3. CCGs need to take difficult decisions about their local drug formularies and are seeking wider national level support for their actions. The low priority prescribing project and a clinical working group led jointly by NHS England and NHS Clinical Commissioners (NHSCC) were established in April 2017 in response to CCGs asking for a nationally co-ordinated approach to the development of commissioning guidance. The aim was to reduce unwarranted variation and introduce a more equitable framework from which CCGs can take individual and local implementation decisions.
4. During 2017/18, the Board approved a public consultation, and the subsequent publication of CCG guidance on:
 - Items that should not be routinely prescribed in primary care (November 2017); and
 - Conditions for which over the counter items should not routinely be prescribed in primary care (March 2018).
5. Feedback from CCGs through NHSCC has indicated that this national co-ordinated approach and CCG guidance, outlining national recommendations, has been an important lever to initiate and support local decision making and to implement changes.
6. It was agreed that NHS England should continue to work jointly with NHSCC to address further low priority items that should not routinely be prescribed. A further eight items have been identified, which are considered to be of low priority for NHS funding. Subject to support from the Board, these items will be consulted upon, along with a proposed update to the November 2017 guidance in respect of a previously reviewed item ie rubefaciants.

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7. In parallel with the low priority prescribing work, DHSC has undertaken two national consultations on the NHS prescribing of Gluten-Free (GF) foods in primary care.
8. The first consultation (March 2017) proposed changes to prescribing arrangements and resulted in the Government's decision (published February 2018) to restrict such foods to bread and mixes. The second consultation (August - October 2018) shared revised draft regulations, and asked stakeholders how well these would work in practice. There were 932 responses; 71% agreed that the revised regulations would be understood by the service, and 44% agreed that they would provide a staple list of gluten-free bread and mix products.
9. Regulations were laid in Parliament on 6 November 2018, and, subject to annulment by either House of Parliament, they will come into force on 4 December 2018.
10. NHS England has developed supporting guidance for CCGs, which is intended to communicate the changes in regulations, and to support CCGs with their development of their local GF food prescribing policies. Subject to support from the Board, this guidance document will be published after the regulations come into force.
11. The Board is invited to:
 - Approve formal public consultation on further low priority items that should not routinely be prescribed in primary care, as they are considered to be relatively ineffective, unnecessary, inappropriate or unsafe for prescription in the NHS;
 - Approve publication of guidance for CCGs, and an accompanying Equality and Health Inequalities Impact Assessment, on prescribing of Gluten-Free Foods in primary care.

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

12. When the guidance for CCGs on *Items that should not be routinely prescribed in primary care* was published in November 2017, the clinical working group committed to reviewing the guidance at least annually, and identifying potential items to be retained, removed or added to it.
13. Over the summer, the clinical working group undertook a review of existing item recommendations from the November 2017 guidance. Of those recommendations, it is proposed that guidance on rubefacients (excluding topical NSAIDs) be updated to consider exclusion of capsaicin cream, in line with NICE guidance.

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14. The clinical working group also undertook an exercise to identify additional items for inclusion. Items were considered for inclusion if they were:

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

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

- Advise CCGs that prescribers in primary care should not initiate {item} for any new patient;
- 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 exceptional¹ circumstances, there is a clinical need for {item} to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional;
- Advise CCGs that all prescribing should be carried out by a specialist; and/or
- Advise CCGs that {item} should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {circumstance}.

16. The clinical working group propose that the following items be included in the draft CCG guidance for consultation:

- a) Aliskiren
- b) Amiodarone
- c) Emollient bath & shower preparations for dry and pruritic skin conditions
- d) Dronedarone
- e) Minocycline for acne
- f) Silk garments
- g) Blood glucose testing strips
- h) Needles for pre-filled and reusable Insulin pens

¹ In this context, “exceptional circumstances” should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual

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17. The actual cost of products a) to f) above is **£19.9m** (BSA data 2017/18), most of which we expect to be realisable as savings; although further work is required to refine this estimate to take account of clinical exceptions and the degree of optimisation that could be achieved.
18. The actual cost of blood glucose testing strips and needles for pre-filled and reusable insulin pens is £191.3m (BSA 2017/18). Analysis of spend variation between CCGs would suggest an opportunity for a possible **£48.9m** of savings, if all CCGs were to prescribe the strips and needles that cost no more than recommended upper limit of £10 per 50 strips and £5 per 100 needles. Again, further work is required to refine this estimate to take account of clinical exceptions and the degree of optimisation that could be achieved.
19. The initial estimate of the potential efficiency saving, per annum, is therefore **£68.8m** against actual expenditure in 2017/18.
20. This is predicated on universal uptake of the guidance as envisaged in the consultation document. This is detailed to give a sense of scale of the opportunity presented and not identification of a realisable target. Both during and post consultation, the following adjustments may need to be made to this estimate, to refine expected realisable savings:
 - Any adjustment to criteria for exceptions agreed during the consultation.
 - Any intelligence from current implementation of existing guidance, to assess the potential for all CCGs to implementation from day 1 of the policy.
 - The impact of retained margin on the overall realisable value to the NHS.
 - Any impact of prescription charge revenue to NHS England as a whole.
21. Until the consultation is complete, it is not possible to determine for certain the overall realisable savings that may be delivered, although it is considered at this point that the majority, if not all of the £68.8m will be realised.
22. It is also important to note that the consultation document cites Net Ingredient Cost (NIC) as a conventional way of displaying spend in the NHS. However, to estimate savings we need to make adjustments to NIC to account for discounts and other adjustments to reflect actual spend.
23. The draft CCG guidance for consultation is attached at **Annex A** for the Board's approval to publish, along with a draft Equality and Health Inequalities Impact Assessment, attached at **Annex B**.
24. Subject to Board approval, the draft guidance and Equality and Health Inequalities Impact Assessment would be published on 28th November 2018,

and the public consultation would run from 28th November 2018-28th February 2019.

Gluten-Free Food Guidance

25. DHSC has undertaken two national consultations on the prescribing of Gluten-Free (GF) foods in primary care. The first of these proposed changes to prescribing arrangements and resulted in the Government's decision to restrict such foods to bread and mixes. The second consultation shared the draft regulations and asked stakeholders how well these would work in practice.
26. In March 2017, DHSC published a consultation proposing changes to the availability of GF foods at NHS expense. This presented three options for changing the availability of GF foods so that savings could be achieved and funds used elsewhere in the NHS. The options in question were to **make no changes**, to **restrict all GF foods** or to **restrict to certain products**.
27. The DHSC consultation received 7941 responses from a range of stakeholders including general practitioners and other approved prescribers, dietitians, pharmacists, patients, members of the public, national charities and manufacturers of GF foods. 70% of respondents were in favour of restricting prescribing to certain products as this struck a balance between achieving savings for the NHS and maintaining availability of GF foods for patients.
28. Following an analysis of responses, DHSC decided to restrict GF prescriptions to GF bread and mixes. This was intended to both deliver savings to the NHS and to help mitigate the risk that those on lower incomes would not be able to purchase their own GF foods.
29. In August 2018, DHSC carried out a second consultation which shared a draft copy of the Amendment Regulations and invited scrutiny of these to ensure that they would work in practice. The consultation received 932 responses from a range of stakeholders including patients and carers of patients, members of the public, dietitians, pharmacists and NHS CCGs. Altogether, 71% of respondents said that the proposed Amendment Regulations would be understood by prescribers, patients and suppliers; 44% of respondents thought that the changes would achieve the desired outcome; and 56% of respondents stated that there would be some unintended consequences because of the changes. The full government response to the consultation can be found at the following web address ([Response to consultation](#))
30. Regulations were laid in Parliament on 6th November 2018, and, subject to annulment by either House of Parliament, they will come into force on 4th December 2018. Part XV (Borderline Substances) and Part XVIII A (Schedule

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1) of the Drug Tariff will be updated for the edition for December to reflect the changes.

31. It is expected that the annual financial saving to the NHS of restricting GF prescriptions to GF bread and mixes will be **£0.7 million per year**. This reduction in spend is adjusted for lost income from prescription charges.
32. We have developed a guidance document for CCGs, setting out national recommendations on the prescribing of GF foods in primary care. This is intended to communicate the changes in regulations to CCGs, and to support them with their development of their local GF food prescribing policies.
33. The recommendations in the guidance have been clinically reviewed by the Low Priority Prescribing (LPP) clinical working group. The guidance document takes the same form as previously published CCG guidance on routine prescribing in primary care.
34. The guidance makes the following recommendations:
 - Advise CCGs to support prescribers to prescribe in line with the revised regulations which allow for no gluten-free products to be prescribed at NHS expense, other than gluten-free bread and/or gluten-free mixes.
 - Advise CCGs that patients in receipt of NHS prescriptions for gluten-free bread and/or mixes should be those diagnosed by their doctor as suffering from established gluten-sensitive enteropathies, including dermatitis herpetiformis and coeliac disease.
35. The GF Food guidance is attached at **Annex C** for the Board's approval to publish, along with an Equality and Health Inequalities Impact Assessment, attached at **Annex D**.
36. Subject to Board approval, both documents would be published following the regulations coming into force on 4th December 2018.

Recommendations

37. The Board is invited to:
 - Approve formal public consultation on further low priority items that should not routinely be prescribed in primary care, as they are considered to be relatively ineffective, unnecessary, inappropriate or unsafe for prescription in the NHS; and
 - Approve publication of guidance for CCGs, and an accompanying Equality and Health Inequalities Impact Assessment, on prescribing of Gluten-Free Foods in primary care.