Paper: PB.21.07.2017/05

NHS ENGLAND – BOARD PAPER

Title: Items which should not routinely be prescribed in primary care
Lead Director: Professor Sir Bruce Keogh, Medical Director Paul Baumann, Chief Financial Officer
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-prescribed products of low clinical value and/or available to the public over the counter (OTC). • The NHS England Commissioning Committee has approved a set of proposals which, subject to support from the NHS England Board, will now be consulted on. • These propose initially limiting prescribing of 18 “low value” products costing £141million pa and potentially medicines that are available over the counter for generally time-limited/short term conditions suitable for self-care, costing a further £50-100million. In addition, the Department of Health (DH) is consulting on limits on £26million of expenditure on Gluten Free foods. Our consultation will also seek views on other opportunities for prescribing efficiency.
The Board is invited to: • Approve formal public consultation on products which are considered to be relatively ineffective, unnecessary, inappropriate or unsafe for prescription on the NHS.

Items which should not routinely be prescribed in primary care

A. Background

1. Last year, 1.1billion prescription items were dispensed in primary care at a cost of £9.2billion. Over 90% of prescriptions currently issued are exempt from a prescription charge. It is vital that the NHS achieves the greatest value from the money that it spends, and we know that across England there is significant variation on what is being prescribed and to whom. Often patients are receiving medicines which have been proven to be ineffective or for which there are other more effective and/or cheaper alternatives, and products which it may no longer be appropriate to prescribe on the NHS.

2. NHS England has partnered with NHS Clinical Commissioners (NHSCC) to support Clinical Commissioning Groups (CCGs) in ensuring that they can use their prescribing resources effectively and get the best value from the medicines that their local population uses. CCGs asked for a nationally coordinated approach to the development of commissioning guidance developed with and by CCGs. The aim is that this will lead to more equitable and consistent local decisions

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

4. NHSCC engaged with NHS England to secure support for their work, which aligns with the objectives of the Medicines Value Programme that we are establishing to pursue savings from the rapidly rising drugs bill whilst improving outcomes for patients. Any savings from implementing the proposals will be reinvested in improving patient care.

5. Together, NHS England and NHSCC established a clinical working group, chaired by representatives of these two organisations, with membership including GPs and pharmacists, CCGs, Royal College of General Practitioners, National Institute for Health and Care Excellence (NICE), Department of Health, the Royal Pharmaceutical Society and others.

6. Initial work has focused on developing guidelines for a list of eighteen products which are relatively ineffective, unnecessary, inappropriate or unsafe for prescription on the NHS. The Department of Health is consulting separately on access to Gluten Free foods.

7. Consideration has also been given to a wider list of medicines which, in addition to being available on prescription, are available over the counter and some of those are either clinically ineffective or used to treat short term conditions which are suitable for self-care.

8. The NHS England Commissioning Committee, on 28 June 2017, received and supported proposals to limit use of medicine in these categories, and agreed that a public consultation should be launched, subject to approval by the full Board.

9. The commissioning guidance upon which we are consulting will be addressed to CCGs to support them to fulfil their duties around appropriate use of resources. This will need to be taken into account by the CCGs in adopting or amending their own local guidance to their clinicians in primary care. Those clinicians will be expected to have regard to the local and national guidance, but retain their clinical discretion in treating individual patients.

10. It is proposed that the final guidance will be statutory guidance issued under S14ZG of the NHS Act 2006.

B. Proposed action on medicines which are relatively ineffective, unnecessary, inappropriate or unsafe for prescription on the NHS (initial work: eighteen products)

11. Guidelines have been developed for eighteen products which are relatively ineffective, unnecessary, inappropriate or unsafe for prescription on the NHS.

12. These eighteen products comprise a list of ten products originally compiled by NHSCC, working in conjunction with their member CCGs. To it, we have added a further eight items identified following further discussion within the NHSE/NHSCC clinical working group (denoted by * in the tables below).

13. The eighteen products, which cost the NHS an estimated £141million a year, have been included on the list for at least one of three reasons:

- 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 some 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.

14. Having identified the eighteen items, the clinical working group has met on three occasions to review each product against the following criteria:

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

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

o **Unintended consequences**

15. The list of eighteen products is as outlined below. The specific recommendations attached to each, and the rationale for the recommendations, are as outlined in the accompanying consultation document.

(i) Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns – ANNUAL COST ESTIMATED AT £49MILLION

Item
Co-proxamol
Omega 3 Fatty Acid Compounds
Lidocaine Plasters
Rubefacients*
Dosulepin*
Glucosamine and Chondroiton*
Lutein and antioxidants*
Oxycodone and Naloxone*
Homeopathy items (see Appendix A)
Herbal medicines

(ii) Items which are clinically effective but where more cost-effective items are available (this includes items that have been subject to excessive price inflation) – ANNUAL COST ESTIMATED AT £89MILLION

Item
Liothyronine
Doxazosin Modified Release (MR)
Perindopril Arginine*
Fentanyl Immediate Release
Tadalafil Once Daily
Trimipramine*
Paracetamol and Tramadol Combination product*

(iii) Items which are clinically effective but, due to the nature of the item, are deemed a low priority for NHS funding

Item
Some travel vaccines already not permitted on the NHS (see note below)

16. Please note that for Travel Vaccines, this only applies to seven vaccines *which are not currently available on the NHS for the purposes of travel* but are sometimes prescribed and administered in error due to confusion over vaccine eligibility. Public Health England has agreed to undertake a joint assessment of a further four travel

vaccines which are eligible for prescription currently, with a view to whether they should be removed from NHS availability without unintended public health consequences. At present, there is considerable confusion at prescriber level as to what is or is not allowed to be prescribed at NHS expense in this area.

17. Based on a review of the criteria in paragraph 14, NHS England proposes to make one or more of the following recommendations to CCGs for each product:
    - Advise CCGs that prescribers should not initiate **[item]** in primary care for any new patient;
    - Advise CCGs to support prescribers in de-prescribing **[item]** for all patients and ensure the availability of relevant services to facilitate this change;
    - 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 for **[item]** should be carried out by a specialist; and
    - Advise CCGs that **[item]** should not be routinely prescribed in primary care but may be prescribed in specific circumstances.

18. Subject to NHS England Board approval, we intend to put these recommendations to national consultation with CCGs, patients, clinicians, professional and other stakeholder bodies, from July to October 2017. This consultation is intended to provide a consistent, national framework in the context of which, local CCGs will be able to decide to implement the national clinical commissioning guidance, with due regard to both local circumstances and their own impact assessments.

C. Action on over the counter medicines

19. As part of this review of medicines which could be considered to be of a low clinical value, NHS Clinical Commissioners and NHS England have identified a number of products and conditions which fall into wider categories that need to be considered. The NHS in England spends approximately £645million on medicines which can otherwise be purchased over the counter from a pharmacy and/or other outlets such as petrol stations or convenience stores.

20. These include products that:
    - Can be purchased over the counter, and sometimes at a lower cost than that that would be incurred by the NHS;
    - Treat a condition that is considered to be self-limiting and so does not need treatment as it will heal/be cured of its own accord; and/or
    - Treat a condition which lends itself to self-care, ie that the person suffering does not normally need to seek medical care and/or treatment for the condition.

21. These conditions include the following, which in most cases are minor and/or self-limiting conditions:

Diarrhoea	Cold sores
Constipation	Teething
Acute Pain	Nappy rash

Athlete's foot	Mouth ulcers
Fever	Haemorrhoids
Oral and vaginal thrush	Ear wax
Head lice	Warts and verrucae
Insect bites and stings	Soft tissue injury/musculoskeletal joint injury
Conjunctivitis	Viral upper respiratory tract infections
Contact dermatitis	Scabies
Sore throat	Ring worm
Headache	Mild acne
Indigestion and heartburn (Dyspepsia)	Minor burns and scalds

22. Approximately 3200 different products, which can be purchased over the counter, are prescribed on the NHS for the above conditions. Examples include:

Painkillers (analgesics) and medicines for fever (antipyretics), such as paracetamol and ibuprofen	Laxatives
Antifungal creams	Lubricating eye drops
Nasal sprays	Eczema creams and ointments
Coughs and cold remedies	Antiviral creams
Sunscreens	Ear wax removal liquid

23. These product categories include:
    - Medicines which are relatively clinically ineffective;
    - Medicines which are clinically effective but suitable for self-care and used to treat acute conditions;

(i) <u>Medicines which are relatively clinically ineffective</u>

24. Some medicines which are available both on prescription and OTC are recognised as being relatively clinically ineffective. There are likely to be a significant number of individual products within the 3,200 which fit within this category. Our consultation document will consult on the criteria to be used in identifying which of the 3,200 products should be recommended as generally not prescribed, and give respondents the opportunity to comment on any individual products.

(ii) <u>Medicines which are clinically effective but suitable for self-care and used to treat generally short term/time-limited conditions;</u>

25. A broader list of medicines which are available both on prescription and OTC are regarded as being clinically effective but used to treat conditions which are suitable for self-care and are episodic and which do not require ongoing or long term treatment. We have estimated NHS expenditure of up to £100m p.a. on those prescribing instances where a medicine has only been prescribed once within a six month period

for an individual patient. Within that, **over £50m pa is accounted for by spending on medicines used to treat minor and/or self-limiting conditions**. By self-limiting, we mean conditions which without treatment to alleviate symptoms, would heal of their own accord, for example the common cold. Whilst many conditions suitable for self-care are self-limiting, some are not. Some examples of self-care conditions which are not self-limiting and which would not resolve without treatment include hayfever (antihistamine used to treat) or vitamin D insufficiency (vitamin D used to treat). The draft consultation document consults on restricting in this category of prescribing too.

26. It also seeks views on the appropriateness of prescribing in the far bigger category of £545million pa, which it is estimated is spent on two or more prescriptions for the same condition in a six month period that could have been purchased over the counter.

27. The draft consultation document is attached as an Annex to this Board paper.

Recommendations

28. The Board is asked to:
    - Approve formal public consultation on the proposals outlined in this paper.

APPENDIX A

Homeopathy

1. NHS England's view is that, at best, homeopathy is a placebo and a misuse of scarce NHS funds which could better be devoted to treatments that work.

2. Data on the residual use and cost of homeopathy on the NHS are hard to come by. A recent Freedom of Information request by a third party suggested that at least £578,000 has been spent on prescribed homeopathy over the past five years, with the total cost being higher than that when the cost of consultations was factored in.

3. As well as primary care prescribing, there are two homeopathic hospitals affiliated to NHS Trusts in Bristol and at University College London Hospitals (UCLH). In both cases, CCGs have sought to restrict provision.

4. Bristol CCG is the lead commissioner for homeopathy for 13 CCGs, and University Hospitals Bristol is the lead secondary care provider (but subcontracts the service). Homeopathy referrals are now subject to Individual Prior Approval, which have reduced volumes significantly but not completely.

5. A recent NHS England London review sought clarity on commissioning of homeopathy services in the region. This found that no CCG commissions homeopathic treatments; however the Royal London Hospital for Integrated Medicine (RLHIM) may be providing homeopathy as part of a wider package of treatment. CCGs commission a range of treatment pathways from UCLH provided from the RLHIM site.

6. There are a number of complexities that limit UCLH's ability to identify the total system cost of providing homeopathy:
    - RLHIM provides an outpatient service with a standard outpatient tariff that covers a number of different treatments and therapies, one of which is homeopathy;
    - In the majority of cases, homeopathy is provided as part of a wider package of treatment rather than in isolation; and
    - Currently this means UCLH are unable to accurately say how many patients have received homeopathy alone.

7. In addition to consulting on initiatives in primary care prescribing of homeopathy, it is therefore also proposed that we explore including a ban on reimbursing homeopathic treatments in the NHS Standard Contract.

APPENDIX B

Gluten Free Foods

1. Gluten Free (GF) foods, costing £26 million a year, are subject to a separate consultation which was run by the Department of Health, concluding in June 2017. DH has still to respond to this consultation.

2. Staple GF foods, e.g. bread, flour, pasta, oats etc, are available on prescription to patients diagnosed with gluten sensitivity enteropathies. A limited number of non-staple foods are also available, including crackers, biscuits and pizza bases.

3. Unlike other foodstuffs, gluten containing products are not necessary for a healthy diet and patients with gluten sensitivity can safely exclude it from their diet and still eat healthily without purchasing special foods. Patients can safely eat meat, fish, vegetables, fruit, rice and most dairy products, and there are a wide variety of products now on the market, eg rice cakes, crackers etc to allow patients to complement their GF diets safely and obtain all their nutritional requirements.

4. GF foods were made available on prescription in the late 1960s when the availability of such foods on general sale was extremely limited. GF foods are now readily available in large supermarkets and therefore the ability of patients to obtain these foods without a prescription has greatly increased. However, some GF foods, in particular bread, are still more expensive than non-GF foods.

5. Research into the prescribing position in England, as at March 2016, has shown that out of 209 CCGs in England, 112 have adopted policies to restrict the provision of GF foods. This includes 18 CCGs that have stopped the prescribing of all GF foods, and a further 12 that are considering or consulting on changes to GF prescribing. Of the CCGs that have made restrictions to the type of GF food available, most have restricted to either bread and flour, or bread, flour and pasta.

<u>Types of GF food prescribed in 2015 – Cost and Items</u>

Type	Net Ingredient Cost (NIC)	Items dispensed
Biscuits	£1,086,400	174,300
Bread	£16,710,900	844,900
Cakes/Pastries	£300	100
Cereals	£912,700	160,800
Cooking Aids	£1000	200
Grains/Flours	£132,100	23,500
Mixes (flour/bread)	£4,328,900	221,300
Pasta	£2,554,900	262,100
TOTALS	£25,727,200	1,678,200

6. NHS England supports this consultation.