

**CONSULTATION ON ITEMS WHICH SHOULD NOT BE ROUTINELY PRESCRIBED
IN PRIMARY CARE**

FREQUENTLY ASKED QUESTIONS

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- Gluten-free foods

Consultation content: proposed action on medicines which are relatively ineffective, unnecessary, inappropriate or unsafe for prescription on the NHS (18 products)

1. Which 18 medicines are included?

Items of relatively low clinical effectiveness or which are unsafe:

Item
Co-proxamol
Omega 3 Fatty Acid Compounds
Lidocaine Plasters
Rubefacients (excluding topical NSAIDs)
Dosulepin
Glucosamine and Chondroitin
Lutein and antioxidants
Oxycodone and Naloxone Combination Product
Homeopathy items
Herbal medicines

Items which are clinically effective but where more cost-effective items are available in most cases (this includes items that have been subject to excessive price inflation):

Item
Liothyronine
Prolonged Release Doxazosin
Perindopril Arginine
Immediate Release Fentanyl
Once Daily Tadalafil
Trimipramine
Paracetamol and Tramadol Combination product*

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)

The travel vaccines included in the consultation are:

- Hepatitis B
- Japanese Encephalitis
- Meningitis ACWY
- Yellow Fever
- Tick-borne Encephalitis
- Rabies
- BCG.

This consultation only considers when these vaccines are given for the purposes of travel. For example, Meningitis ACWY is offered routinely to young teenagers and 'fresher' students going to university for the first time.

These vaccines are not available on the NHS for the purposes of travel but due to confusion on vaccine eligibility some people are administered these on the NHS. This consultation restates the current position of the NHS and aims to reduce confusion.

The travel vaccines which are not included in the consultation:

- Cholera
- Diphtheria/Tetanus/Polio
- Hepatitis A
- Typhoid.

These vaccines are available on the NHS for the purposes of travel and any proposed changes will require a change of regulations and an assessment of public health impact.

For details of the evidence and recommendations [please see the consultation document](#)

For further information: [NHS Business Services Authority Prescribing Data](#)

Patient experience

2. What will happen if I want to keep taking my medicine? Will I have to switch?

This is a consultation so there will be no change until any commissioning guidance is issued. This would be late Autumn 2017 at the earliest. Subject to the outcome of the consultation, and subsequent decision by NHS England, the commissioning guidance would be addressed to CCGs to support them to fulfil their duties around appropriate use of resources. Clinicians would be expected to have regard to the guidance, but retain their clinical discretion in treatment patients in accordance with their professional obligations.

In the guidance each medicine would be assigned one or more of the following recommendations:

- Advise CCGs that prescribers in primary care should not initiate {item} for any new patient.
- Advise CCGs to support prescribers in de-prescribing {item} in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
- Advise CCGs that if, in exceptional circumstances, there is a clinical need for the 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 this item should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {item}.

Those people who felt a particular prescription drugs was appropriate for them as an individual may be asked by their GP to try a clinically proven alternative.

Patient safety will remain the top priority for prescribers and if you have any questions or concerns about items you are currently receiving, please speak to a healthcare professional such as a doctor, nurse or pharmacist.

3. Surely this is about rationing and not about improving patient care?

It is about making the best use of precious NHS resources. We cannot afford to:

- Take medicines when we don't need to take them, when there is no benefit, or when they can cause harm
- Use medicines which are not cost-effective.

The NHS is here to help people to get the best results from their medicines – and to ensure we get the best possible value for the taxpayer at the same time.

We are asking everyone who works in or uses the NHS to contribute to and support our consultation on low value medicines – so we improve people's health and increase safety.

It is important to reduce any unnecessary waste from the £141 million currently spent on these 18 products. Every unnecessary medicine that is prescribed means someone else doesn't get the help they need when they need it.

Savings

4. Are these savings real - how did we arrive at them?

The amounts quoted in consultation document for each individual medicine are the 'net ingredient cost' for 2016 from the Prescription Costs Analysis published by NHS Digital. The figure quoted does not include any dispensing costs and fees, or the costs to the NHS of providing an appointment with your doctor.

5. Where will the savings be reinvested?

The savings mean the NHS will be able to invest more in new drugs and treatments that have been shown to be safe and effective, and provide better patient care.

Working group

6. Who has developed the consultation?

NHS England and NHS Clinical Commissioners established an expert joint clinical working group to develop these proposals. An extended stakeholder meeting was held in June 2017 to discuss the developed proposals. Full lists of the organisations represented at these meetings are outlined in the consultation document.

7. How was the consultation developed?

NHS Clinical Commissioners, working on behalf of their CCG members, developed a list of items that they consider need not be routinely prescribed in primary care in order to ensure that CCG resources are used most appropriately. This process was supported by PrescQIPP, who provide support on medicines optimisation to 90% of CCGs in England.

NHS Clinical Commissioners asked NHS England to work with them to produce commissioning guidance to support CCGs in addressing these issues on a consistent national basis in order to reduce duplication and reduce unwarranted variation. NHS England established a joint clinical working group in partnership with NHS Clinical Commissioners, to produce these recommendations. Medicines were considered for inclusion in the consultation if they were considered to be;

- Items of relatively 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.
- Items which are available over the counter.

8. Where did the working group obtain its evidence?

The joint clinical working group considered information from various sources and organisations. The group considered recommendations from NICE in order to support CCGs in implementing NICE guidance across the country and in particular it identified items which NICE consider to be 'Do not do', i.e. should not be prescribed.

Where NICE guidance was not available the group considered evidence from a range of sources, for example; the Medicines and Healthcare products Regulatory Agency, the British National Formulary and PrescQIPP evidence reviews. The group also considered alternative treatments, listed prices and costs, patent expiry and unintended consequences.

9. What do you mean by excessive price inflation?

Where there is a rise in the price of a medicine which is greater than the usual levels of price inflation observed in similar types of medicine and/or where a price increase is not easily justified by unavoidable increases in costs for the supplier.

10. What causes excessive price inflation?

There may be a number of reasons why the price of a medicine appears to rise excessively. Ultimately this is a matter for the suppliers. The relevance here is that we are including drugs in the consultation where more cost effective products are available.

Over-the-counter medicines

11. What proposals are we making for over-the-counter medicines?

NHS England and NHS Clinical Commissioners propose as a next phase of this review to look at over 3,200 products which could otherwise be purchased over the counter from a pharmacy and/or other outlets such as petrol stations or convenience stores. The NHS in England spends approximately £645 million p.a. on such medicines.

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, i.e. that the person suffering does not normally need to seek medical care and/or treatment for the condition.

These conditions include but are not limited to 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

NHS England and NHS Clinical Commissioners have identified three separate categories of product which are available over the counter and may be considered appropriate for restriction in primary care:

- Further medicines additional to the 18 already identified which are relatively clinically ineffective;
- Medicines which are used to treat generally time-limited/short term conditions suitable for self-care (this will include many conditions which are self-limiting). Medicines within this category account for approx. £50m - £100m p.a. of NHS spend. In this category, we mean conditions which are episodic and which do

not require ongoing or long term treatment. By self-limiting, we mean conditions which without treatment to alleviate symptoms, would normally heal of their own accord, for example the common cold; and

- Medicines which are used for longer term, chronic conditions but which are being prescribed at an estimated cost of approx. £545m p.a. For example, some but not all of the £70m spent annually on paracetamol might fall into this category, as may antihistamines on which the NHS spends £14m p.a.

Using defined criteria, the NHS England and NHS Clinical Commissioners joint clinical working group will consider items available for purchase over the counter in the coming months and where appropriate will develop detailed guidance for further consultation. At this stage we are seeking views generally on this area and evidence that will inform our future programme of work.

12. How would the public be engaged in discussions regarding future proposals?

This is a consultation in principle at this stage and any proposals which are developed will be subject to further full public consultation. We would encourage everyone who is interested to respond to this part of the current consultation.

This consultation will run from 21 July to 21 October 2017 after which commissioning guidance on the other items is likely to be published by NHS England and CCGs will be asked to consider its implementation with prescribers in primary care (GPs, pharmacists, nurses), ensuring they take into account their legal duties to advance equality and have regard to reduce health inequalities. Over the counter medicines will not be included in that guidance at this stage, as we intend to consult further about specific proposals.

Gluten free foods

13. What is being proposed?

Gluten free foods, costing £26 million a year, are subject to a separate consultation which was run by the Department of Health from April-June 2017, and we are awaiting the outcome. Subject to the outcome of the NHS England consultation, this will be included in the final guidance that is issued to CCGs.