

Response ID ANON-788X-RE1F-D

Submitted to **Conditions for which over the counter items should not routinely be prescribed in primary care: A consultation on guidance for CCGs**
Submitted on 2018-03-14 11:38:03

Introduction

1 In what capacity are you responding?

In what capacity are you responding?:

Other

If 'other' please specify::

As a campaigning organisation for children with bladder and bowel problems

2 Name or organisation (optional):

Name or organisation:

Paediatric Continence Forum

3 Email address (optional):

Email address (optional):

paediatriccontinenceforum@whitehouseconsulting.co.uk

4 Have you read the document 'Conditions for which over the counter items should not routinely be prescribed in primary care: A consultation on guidance for CCGs'?

Yes

Equality and Health Inequalities

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

Yes

Age, Disability, Sex

Please provide further information on why you think this might be the case::

This work raises questions under the provisions of the Equality Act around age, disability and sex. While the Paediatric Continence Forum (PCF) campaigns for the appropriate treatment of continence (bladder and bowel) problems in children, and this will be the focus of this response, it would be a concern if exceptions were made to these prescribing regulations for children that are not also offered to adults where clinically appropriate.

Continence problems that begin in childhood can persist into adulthood, particularly if appropriate treatment is not sought or offered. If young people with constipation were prescribed laxatives which were then not available on prescription as soon as they became adults, this could be a form of age discrimination, as well as being a clinically inappropriate course of action.

People of all ages with disabilities and women are disproportionately affected by constipation and therefore it could be argued that for this condition these guidelines are potentially discriminatory.

6 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?

Unsure

Please provide further information on why you think this might be the case::

Research indicates that children and young people with physical and learning disabilities are more likely to suffer chronic constipation than the rest of the paediatric population. These children are more likely to be living in families on a restricted income and so be entitled to free prescriptions, which may be an issue with respect to equality. Children with congenital anomalies of the bowel are also more likely to need medication for constipation over the long term. People with financial hardship are more likely to be negatively affected than those who have spare income.

Proposals for CCG commissioning guidance

7 Do you agree with the three proposed categories for [items] or [conditions] as follows:

How do you feel about the three proposed categories for [items] or [conditions] as follows: - An item of low clinical effectiveness, where there is a lack of robust evidence for clinical effectiveness.:

Unsure

How do you feel about the three proposed categories for [items] or [conditions] as follows: - A condition that is self-limiting and does not require medical advice or treatment as it will clear up on its own.:

Unsure

How do you feel about the three proposed categories for [items] or [conditions] as follows: - A condition that is a minor illness and is suitable for self-care and treatment with items that can easily be purchased over the counter from a pharmacy.:

Unsure

Please provide further information.:

The Paediatric Continence Forum is concerned about a blanket approach to conditions that may be considered self-limiting, or minor and 'suitable for self-care and treatment with items that can easily be purchased over the counter from a pharmacy'. The key issue with respect to bladder and bowel problems, including constipation, is assessment. If constipation is considered minor, self-limiting or suitable for self-care, assessment by a suitable healthcare professional may not be offered. It also needs to be remembered that this condition is often under-reported due to embarrassment as well as lack of recognition. Refusal of treatment may compound under-reporting.

Critically these proposals, with respect to constipation, contradict NICE guidance (CG99, 2010) which states that first line treatment for constipation in children (i.e. those under 18 years) should be macrogol laxatives. Macrogol laxatives are prescription only medicines for children under the age of 12 years. Furthermore, dietary and fluid interventions are not first line treatment for constipation in children (NICE 2010, p.32). While we appreciate that the consultation document refers to infrequent constipation, there is research evidence that parents and carers are often unaware of constipation in children and young people and so could not distinguish between infrequent and chronic constipation. 34% of British children aged 4-11 years are estimated to suffer from constipation at any one time and it becomes chronic in about one third of these cases. Those with learning and physical disabilities are disproportionately affected and there have been much publicized deaths of young adults with learning disabilities (e.g. Richard Handley) as a result of constipation.

If parents or carers are unable to afford over-the-counter treatments, or do not appreciate the potential impact of neglecting to treat constipation early and effectively, it becomes more severe, with associated reduction in school attendance, accident and emergency visits and admissions for faecal impaction. Hospital Episodes Statistics data demonstrates that constipation already presents a significant cost to the NHS in terms of cost of admission to hospital for all age groups, and that this reduces where there are robust services with appropriate assessment and prescribing. This is likely to deteriorate with restriction to prescribing of laxatives in primary care and therefore increase NHS costs.

General exceptions

8 Do you agree with the general exceptions proposed?

How do you feel about the general exceptions proposed? - Circumstances where the product licence doesn't allow the product to be sold over the counter to certain groups of patients.:

Unsure

How do you feel about the general exceptions proposed? - Patients with a minor condition suitable for self-care that has not responded sufficiently to treatment with an OTC product.:

Unsure

How do you feel about the general exceptions proposed? - Patients where the clinician considers that the presenting symptom is due to a condition that would not be considered a minor ailment.:

Unsure

How do you feel about the general exceptions proposed? - Circumstances where the prescriber believes that in their clinical judgement, exceptional circumstances exist that warrant deviation from the recommendation to self-care.:

Unsure

How do you feel about the general exceptions proposed? - Patients where the clinician considers that their ability to self-manage is compromised as a consequence of social, medical or mental health vulnerability to the extent that their health and/or wellbeing could be adversely affected if left to self-care.:

Unsure

Please provide further information.:

Please see our previous responses. We are concerned about constipation, which is often not recognised or is dismissed as a minor condition, and is therefore not treated appropriately with significant consequences to the patient and the NHS.

Further exceptions

9 Should we include any other patient groups in the general exceptions?

Yes

Please provide further information.:

Children (i.e. those under 18 years of age) should be included in general exceptions as they do not have the ability to decide for themselves whether a condition is such that it warrants financial investment, but are dependent on their parents and carers. Parents and carers' decisions may be influenced by other priorities, including demand on limited financial resources, or a belief that if the GP is not prescribing the condition is not important enough to warrant immediate expenditure on over-the-counter medication. This will increase the likelihood of constipation becoming chronic with associated decreases in quality of life, an increase in symptoms and increase in costs to the NHS.

Drugs with limited evidence of clinical effectiveness

10 Do you agree with the recommendation to: Advise CCGs to support prescribers in advising patients that [item] should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness?

How do you feel about the recommendation to: Advise CCGs to support prescribers that the following items should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness? - Probiotics.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that the following items should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness? - Vitamins and minerals.:

Unsure

Please provide further information.:

There is some emerging evidence that probiotics are beneficial for children with bowel problems. If the decision is taken to advise prescribers that probiotics, vitamins and minerals should not routinely be prescribed in primary care, there should be a robust structure for revisiting and rescinding this should evidence of clinical effectiveness emerge.

Self-limiting conditions

11 Do you agree with the recommendation to: Advise CCGs to support prescribers in advising patients that a prescription for treatment of [condition] should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment?

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Acute sore throat.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Cold sores.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Conjunctivitis.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Coughs and colds and nasal congestion.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Cradle cap (Seborrhoeic dermatitis – infants).:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Haemorrhoids.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Infant colic.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment? - Mild cystitis.:

Unsure

Please provide further information.:

Minor ailments suitable for self-care

12 Do you agree with the recommendation to: Advise CCGs to support prescribers in advising patients that a prescription for treatment of [condition] should not routinely be offered in primary care as the condition is appropriate for self-care?

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Contact dermatitis.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Dandruff.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Diarrhoea (Adults).:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Dry eyes/sore (tired) eyes.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Earwax.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Excessive sweating (Hyperhidrosis).:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Head lice.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Indigestion and heartburn.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Infrequent constipation.:

Disagree

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Infrequent migraine.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Insect bites and stings.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mild acne.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mild dry skin/sunburn.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mild to moderate hay fever/seasonal rhinitis.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Minor burns and scalds.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Minor conditions associated with pain, discomfort and/fever. (e.g. aches and sprains, headache, period pain, back pain):

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Mouth ulcers.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Nappy rash.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Oral thrush.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Prevention of dental caries.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Ringworm/athletes foot.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Teething/mild toothache.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Threadworms.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Travel sickness.:

Unsure

How do you feel about the recommendation to: Advise CCGs to support prescribers and patients that a prescription for treatment of the following conditions, should not routinely be offered in primary care as the condition is appropriate for self-care, unless general exemptions apply? - Warts and verrucae.:

Unsure

Please provide further information.:

We do not agree that CCGs should be advised not to prescribe treatments for infrequent constipation in primary care as a matter of routine. We do not agree with the assertion that the condition is entirely self-limiting and "can be effectively managed with a change in diet or lifestyle and short term use of over the counter laxatives."

As stated previously, we are concerned that NHS England's proposal contradicts NICE guidance (CG99, 2010), which states:

"Do not use dietary interventions alone as first-line treatment for idiopathic constipation. Treat constipation with laxatives and a combination of: negotiated and non-punitive behavioural interventions suited to the child or young person's stage of development [...]; dietary modifications to ensure a balanced diet and sufficient fluids are consumed." (NICE constipation in children and young people: diagnosis and management (CG99), p.32).

As macrogols are not available over the counter for children under 12 years, it will no longer be possible to be compliant with NICE guidance in this age group if macrogols are not used for what is considered to be infrequent constipation. Furthermore, parents and carers of children with constipation may struggle to use over the counter laxatives effectively, either through a lack of understanding, or incorrect advice from healthcare professionals, which can result in the constipation continuing and becoming chronic with increased costs to the NHS and decreased quality of life.

While we note the exception "Patients with a minor condition suitable for self-care that has not responded sufficiently to treatment with an OTC product", we have concerns that the guidance given under point 4.3.9 of the consultation document does not specify timescales or severities of the condition after which a patient would be considered to have not responded sufficiently to treatment. In addition, how can severity or impact of a condition that is often under-reported and is under-recognised by parents and carers be decided without assessment by a GP or suitably qualified paediatric continence nurse adviser?

Constipation can be linked to underlying co-morbidities which may be missed if the parent or carer bypasses a healthcare professional and buys a laxative over the counter without the child undergoing a comprehensive assessment. In addition, treating constipation in children often requires higher doses of laxatives (to overcome withholding) than are normally recommended and needs to be combined with lifestyle adjustments and behaviour modification programmes to ensure complete resolution.

Children and young people with constipation need to be prescribed an appropriate course of treatment following an assessment by a healthcare professional to ensure that there is no underlying comorbidity and that constipation is being effectively treated.

Condition specific exceptions

13 Are there any item or condition specific exceptions you feel should be included, in addition to those already proposed and the general exceptions covered earlier?

No

Please provide further information::