March 2018

Arthritis Research UK incorporating Arthritis Care response to 'Conditions for which over the counter items should not routinely be prescribed in primary care: A Consultation on guidance for CCGs.'

1. Arthritis Research UK incorporating Arthritis Care welcomes the opportunity to respond to NHS-England's 'Conditions for which over the counter items should not routinely be prescribed in primary care: A Consultation on guidance for CCGs.'[1] We also contributed at the face-to-face engagement event in London on Monday 5 March 2018.

2. We understand the purpose of this consultation is to contribute to the development of national guidance for Clinical Commissioning Groups (CCGs) on the prescribing of over the counter (OTC) products for 35 'minor or self-limiting conditions'. This work is intended to support CCGs in their decision-making when formulating local prescribing policies, to address unwarranted variation and to provide clear national guidelines on local prescribing practices for the conditions identified. It builds on the previous consultation 'Items which should not be routinely prescribed in primary care'.[2]

3. Arthritis Research UK and Arthritis Care have joined together so that we can do more to help people with arthritis to live full and active lives.[3] We invest in breakthrough treatments, the best information and vital support for everyone affected by arthritis. We combine cutting edge research and the expertise of people with arthritis to make everyday life better for 17.8 million people with arthritis and related conditions in the UK.[4]

4. This response includes:
   - Prevalence of musculoskeletal conditions and their impact in primary care
   - Potential impact on health inequalities
   - Proposals for CCG commissioning guidance
   - Section 1: Drugs with limited evidence of clinical effectiveness
   - Section 3: Minor ailments suitable for self-care

Prevalence of musculoskeletal conditions and their impact in primary care

5. Arthritis and other musculoskeletal conditions are the most common cause of disability in adults in the UK, and accounted for a third (30.5 %) of all years lived with disability (YLDs) in in the UK in 2010.[5]

1 NHS England (December 2017). Conditions for which over the counter items should not routinely be prescribed in primary care: A consultation on guidance for CCGs. https://www.engage.england.nhs.uk/consultation/over-the-counter-items-not-routinely-prescribed/

2 NHS England (July – October 2017). Items which should not be routinely prescribed in primary care'. https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-consultation-report-of-findings/

3 For further information see arthritisresearchuk.org/merger.

4 Institute for Health Metrics and Evaluation (IHME) (2017). Global Burden of Disease Collaborative Network, "Global Burden of Disease Study 2016 (GBD 2016) Results.

5 Murray C et al. (2013). UK health performance: findings of the Global Burden of Disease Study 2010, Lancet 381, 9871, 997-1020.

6. These conditions have a significant impact on primary care. One in five people consult a GP about a musculoskeletal problem each year.[6] Treatment and support for people with chronic pain (such as back pain or osteoarthritis) in primary care in the UK has been estimated to account for 4.6 million appointments per year, comparable to 793 whole time GPs.[7]

Potential impact on health inequalities

7. See section 20 below for our views on the proposed restriction of Vitamin D for maintenance and its potential impact on health inequalities.

Proposals for CCG commissioning guidance

8. The proposed guidance identifies 35 minor or self-limiting conditions, in two categories (self-limiting conditions, minor illnesses suitable for self-care) and proposes that CCGs would be advised to support prescribers in advising patients that prescriptions for these conditions should not be routinely offered in primary care.

9. The proposed guidance sets out **general exceptions** that could apply to the recommendations on prescription of OTC items for conditions identified as being appropriate for self-care.

10. It states that clinicians should continue to prescribe, taking account of National Institute for Health and Care Excellence (NICE) guidance ... for the treatment of:
    - Long term conditions (e.g. regular pain relief for chronic arthritis or treatments for inflammatory bowel disease);
    - More complex forms of minor illnesses (e.g. severe migraines that are unresponsive to OTC medicines);
    - Patients that have symptoms that suggest the condition is not minor (i.e. those with red flag symptoms such as cough lasting longer than three weeks);
    - Complex patients (e.g. immunosuppressed patients);
    - Patients on treatments that are only available on prescription;
    - Patients prescribed OTC products to treat an adverse effect or symptom of a more complex illness.

    Prescriptions should also continue to be issued for:
    - Circumstances where the product licence doesn't allow for the product to be sold OTC to certain groups (e.g. babies, children, pregnant or breast-feeding women);
    - Patients with a minor condition suitable for self-care that has not responded sufficiently to treatment with an OTC product;
    - Patients where the clinician considers that the presenting symptom is due to a condition that would not be considered a minor ailment;
    - Circumstances where the prescriber believes that in their clinical judgement, exceptional circumstances exist that warrant deviation from the recommendation to self-care;
    - 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.

11. **We welcome the general exception that clinicians should continue to prescribe for long-term conditions, including pain relief for chronic arthritis. However, we query how 'long-term conditions' will be defined, and whether this definition will include**

6 Arthritis Research UK National Primary Care Centre, Keele University (2009). Musculoskeletal Matters.
7 Belsey, J. (2002). Primary care workload in the management of chronic pain. A retrospective cohort study using a GP database to identify resource implications for UK primary care. Journal of Medical Economics, 5(1‑4), 39‑50. doi:10.3111/200205039050.

musculoskeletal conditions that have symptoms of fluctuating severity or that are episodic in nature (e.g. back pain; gout).

Section 1: Drugs with limited evidence of clinical effectiveness

12. The proposed guidance identifies probiotics, vitamins and minerals as 'items of low clinical effectiveness, where there is a lack of robust evidence for clinical effectiveness'. Under the proposed guidance CCGs would be advised to support prescribers in advising patients that items in this group should not be routinely prescribed in primary care.

13. Section 4.1.2 of the proposed guidance includes some exceptions which would apply within this category, including:
    - Iron deficiency anaemia;
    - Demonstrated Vitamin D deficiency (NB not maintenance);
    - Calcium and Vitamin D for osteoporosis;
    - Malnutrition including alcoholism.

14. **We welcome the exception that clinicians should continue to prescribe calcium and Vitamin D for osteoporosis.**

15. **We also welcome the exception that clinicians should continue to prescribe Vitamin D for demonstrated Vitamin D deficiency. However, in our view that Vitamin D maintenance should also be included in the exceptions.**

16. Vitamin D is essential for skeletal growth and bone health. Severe deficiency can result in rickets[8] (among children) and osteomalacia[9] (among children and adults).

17. NICE Public Health Guideline 56 states that 'the Department of Health should work with manufacturers to ensure vitamin D supplements providing the reference nutrient intake … are widely available for the following specific population groups:
    - infants and children aged under 4;
    - pregnant and breastfeeding women, particularly teenagers and young women;
    - people over 65;
    - people who have low or no exposure to the sun, for example, those who cover their skin for cultural reasons, who are housebound or confined indoors for long periods people with darker skin, for example, people of African, African-Caribbean or South Asian family origin.' [10]

18. If, as the proposed guidance suggests, the maintenance dose for vitamin D deficient patients become no longer routinely available by prescription, availability for these at-risk groups and for those who need to maintain vitamin D treatment to continue to avoid deficiency, may be compromised.

19. NICE Public Health Guideline 56 also states that 'suitable supplements should also be available for people with particular dietary needs (for example, people who avoid nuts, are vegan or have a halal or kosher diet). If appropriate products were no longer routinely available by prescription availability for these groups may be compromised.

8 A disease of children caused by vitamin D deficiency, characterized by imperfect calcification, softening, and distortion of the bones typically resulting in bow legs.
9 Softening of the bones, typically through a deficiency of vitamin D or calcium.
10 National Institute for Health and Care Excellence (November 2014). Public health guideline 56. Vitamin D: supplement use in specific population groups.

20. The consultation seeks views on the potential impact of the proposed guidance on equality and health inequalities. In addition to the protected groups included in section 17 above,[11] people with low incomes who routinely receive free prescription medications may not to purchase the OTC maintenance dose of vitamin D and so compromise their musculoskeletal health.

Section 3: Minor Ailments Suitable for Self-Care

21. The proposed guidance includes 'minor conditions associated with pain, discomfort and/fever (e.g. aches and sprains, headache, period pain, back pain') in the list of minor ailments suitable for self-care'.

22. Back pain affects around a third of the UK adult population each year.[12] While most cases of back pain resolve regardless of the course of therapy, a significant number of people do not get the right treatment and go on to suffer long term pain and disability.[13] Low back pain was the leading cause of years lived with disability (YLDs) in the UK in both 1990 and 2015 with a 17% increase over this time. [14] It is also a leading cause of sickness absence in the UK.[15]

23. The challenge for practitioners, patients and policy-makers is to be able to classify back pain patients according to their risk of persistent pain, and to target them to appropriate treatments.[16] Treatment for back pain is usually in primary care and includes remaining active, appropriate exercise and treatment with pain-relieving medication. In more severe cases, physiotherapy, occupational therapy, addition medication or surgery may be helpful.

24. Risk stratification can be used to identify a person's risk of poor functional outcome or long-term problems from low back pain. Risk stratification tools can also help to determine the complexity and intensity of support that a person may need.[17] The STarT Back tool provides an example of stratified care for low back pain, where patients are screened for risk of chronicity.[18] The NICE quality standard for low back pain and sciatica in over 16s (QS155) statement 1 is that: 'Primary care services have an approach to risk stratification for young people and adults presenting with a new episode of low back pain with or without sciatica.'[19]

25. **NHS England should consider whether it is appropriate to include all types of back pain within 'minor ailment suitable for self-care'. The description/definition of back pain in the guidance should be clarified. NHS England should fully assess the consequences, particularly among the working age population, that may result from people not seeking support for persistent back pain within primary care.**

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11 Protected characteristics under the Equality Act (2010) include: age, disability, pregnancy and maternity, race and religion or belief.
12 Macfarlane G et al (2006). Managing low back pain presenting to primary care: where do we go from here? Pain 122(3):219-222.
13 See http://atlas.ahsnnetwork.com/start-back/
14 Global Burden of Disease Study 2015. Institute for Health Metrics and Evaluation. GBD Compare Tool. Link: http://vizhub.healthdata.org/gbd- compare/
15 Chartered Institute for Professional Development (2014). Absence management. Annual survey report 2014.
16 See http://atlas.ahsnnetwork.com/start-back/
17 National Institute for Health and Care Excellence (July 2017). Quality standard 155. Low back pain and sciatica in over 16s.
18 http://atlas.ahsnnetwork.com/start-back/
19 National Institute for Health and Care Excellence (July 2017). Quality standard 155. Low back pain and sciatica in over 16s.