NHS

Evidence Review for Prescribing Clinical Network

Treatment: Aralax Suppositories

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Topic Submitted by:

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Summary page

- How strong is the evidence for claimed efficacy?
  (Grade A = > 1 RCT or meta-analysis; Grade B = 1 RCT or descriptive study;
  Grade C = expert committee report/opinion)
  None

- Potential advantages in terms of: efficacy, compliance, pharmacokinetics, drug interactions and adverse effects?

Anecdotally faster acting

- Is there a clear place in therapy / treatment pathway?
  (E.g. patient type / characteristics, and relationship to other therapies)
  No

- Is monitoring for efficacy required?

No

- Is monitoring for toxicity required?

No

- Is dose titration required?
  No
- Traffic light status (ie who will prescribe the drug and any restrictions required)?

Black

- Role of the specialist (if applicable)?

- Role of GP (if applicable)?

- Financial implications?

Estimated cost or saving per 100 000 population: Saving £1700

- Other issues

- National Guidance available

No

Recommendations: BLACK

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
1	16/10/13	Amy Scott	Draft	
2	06/10/13	Amy Scott	Final	

1. Purpose of the Review

MS nurses in Surrey have been requesting that GPs prescribe unlicensed Aralax (bisacodyl 7.5mg) suppositories for patients. Bisacodyl 5mg and 10mg suppositories are available as a licensed product. This review is to ascertain whether Aralax should be prescribed on FP10.

2. Appropriateness

Aralax is being prescribed for MS patients for constipation within Surrey. Bisacodyl is a stimulant laxative which increases intestinal motility and is indicated for constipation[1].

People with MS are more likely to suffer with constipation than the rest of the population, it is not known exactly why this[2].

Many patients report that Aralax suppositories work more quickly than the licensed product. This is thought to be because of the water solubility of the excipient (Propylene glycol, Polyethylene glycols (PEGs) 1500, 1000 and 400, disodium edetate and purified water[3]). There is no evidence to prove this is the case. Dulcolax suppositories are usually effective in 20 mins (range 10 to 30 mins)[4].

NICE CG8 Multiple sclerosis: Management of multiple sclerosis in primary and secondary care discusses bowel problems. The guidance states that any person with MS who has apparent constipation (pain on or difficulty with defecation, bowels open less than twice a week) should be offered advice on fluid intake and dietary changes that might help, and then be considered for oral laxatives. If oral laxatives are ineffective the patient should be considered for the routine use of suppositories or enemas. NICE does not give a preference for the type of suppository[5].

Alternative treatments

Bisacodyl suppositories are also available as licensed products in 5mg and 10mg strengths (Dulcolax®)[2]. Excipient hard fat (adeps solidus).

Budget

Aralax suppositories £428.17 per item (based on data from epact October 2013)
Bisacodyl 5mg suppository x 5 £0.99 (Drug Tariff October 2013)
Bisacodyl 10mg suppository x 12 £3.55 (Drug Tariff October 2013)

Evidence

None

Impact

In the past year there have 4 prescriptions for bisacodyl 7.5mg suppositories from one practice costing a total of £1712.67[6].

Conclusion

Aralax is an unlicensed stimulant laxative often used for patients with MS and spinal injuries. There is a lack of robust evidence supporting the use of this product and no national guidelines recommending this product. Brighton and Hove, High Weald

Lewes Havens and Buckinghampshire formulary have all recommended that Aralax is not for routine prescribing.

Recommendation
Aralax Suppositories to be a BLACK drug

Appendix 1: Evidence search

Search terms used: Bisacodyl suppository 7.5mg, Aralax, Magic bullet

Resource	Used in this review?
National Library for Health (NHL) http://www.library.nhs.uk/Default.aspx A gateway site with access to other resources such as Reviews (Bandolier, Cochrane, CRD etc), Guidelines (e.g. NICE), Clinical Knowledge Summaries (CKS) and Journals including AMED, British Nursing Index, CINAHL, E-books, EMBASE, HMIC, MEDLINE, My Journals, PsycINFO, PubMed, Databases from Dialog.	✓
National Institute of Health and Clinical Excellence (NICE) http://www.nice.org.uk/ NICE produces national guidance in three areas of health: 1. Public health - guidance on the promotion of good health and the prevention of ill health 2. Health technologies - guidance on the use of new and existing medicines, treatments and procedures within the NHS 3. Clinical practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.	✓ (through NHL)
Bandolier http://www.medicine.ox.ac.uk/bandolier/index.html Bandolier is a website about the use of evidence in health, healthcare, and medicine. Information comes from systematic reviews, meta-analyses, randomised trials, and from high quality observational studies.	✓(through NHL)
Centre for Reviews and Dissemination http://www.york.ac.uk/inst/crd/ CRD undertakes high quality systematic reviews that evaluate the effects of health and social care interventions and the delivery and	✓(through NHL)

organisation of health care. Databases maintained by CRD include Database of Abstracts of Reviews of Effects (DARE), NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA) Database	
Scottish Intercollegiate Guidelines Network (SIGN) http://www.sign.ac.uk/ Scottish equivalent of NICE	✓
Medical Services Advisory Committee (Australia) http://www.msac.gov.au/internet/msac/publishing.nsf/Content/home-1 The principal role of the Medical Services Advisory Committee (MSAC) is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures.	✓
Canadian Agency for Drugs and Technologies in Health (CADTH) http://www.cadth.ca/index.php/en/home The Canadian Agency for Drugs and Technologies in Health (CADTH) is a national body that provides Canada's federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies.	✓

Evidence retrieved

Guidelines
None

Reviews:
None

Journals

None

Study	Design	Number of participants	Results
Title: **Citation:** **Author(s):**			

Appendix 2: Grading of evidence

- Ia: systematic review or meta-analysis of randomised controlled trials
- Ib: at least one randomised controlled trial
- IIa: at least one well-designed controlled study without randomisation
- IIb: at least one well-designed quasi-experimental study, such as a cohort study
- III: well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, case–control studies and case series
- IV: expert committee reports, opinions and/or clinical experience of respected authorities

Appendix 3: References

1. BNF 66. Pharmaceutical Press. September 2013
2. MS Society. Managing the bowel in MS. Accessed 29.10.13. http://www.mssociety.org.uk/sites/default/files/Documents/Essentials/Managing%20the%20bowel%20in%20MS%20(MS%20Essentials%2025)%20ES25.1110(2)%20-%20web.pdf
3. Aralax. Technical Information Leaflet. Mitovie. Obtained October 2013.
4. www.medicines.org.uk Summary of product characteristics. Dulcolax suppositories. Updated September 2012. Accessed 29.10.13
5. NICE CG8 Multiple sclerosis: Management of multiple sclerosis in primary and secondary care. November 2003.
6. Epact data. Bisacodyl 7.5mg suppositories. Accessed 29.10.13.