

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA164; Febuxostat for the management of hyperuricaemia in people with gout**

This guidance was issued December 2008 with a review date of August 2011.

**Background**

At the GE meeting of 26 July 2011 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<b>Proposal put to consultees:</b>	The guidance should be transferred to the 'static guidance list'. <sup>1</sup>
<b>Rationale for selecting this proposal</b>	The new clinical evidence that has been published since TA164 was issued is consistent with the conclusions by the Appraisal Committee on the clinical effectiveness of febuxostat. There has been no change to the price of febuxostat, and no information is available about any changes to the marketing authorisation or any new or ongoing trials of the effectiveness of febuxostat. Based on this information it is proposed that the guidance is placed on the static list.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

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<sup>1</sup> Guidance is placed on the static list when it is clear that there is no new research available that would have any material effect on the current guidance. Topics on the static list may be transferred back to the active list for further appraisal if new evidence becomes available that is likely to have a material effect on the last guidance issued.

<b>Recommendation post consultation:</b>	The guidance should be transferred to the 'static guidance list'.
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<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
Healthcare Improvement Scotland	No comment	Healthcare Improvement Scotland has no comment to make on the proposal to move this guidance to the static list.	Comment noted
British Health Professionals in Rheumatology	No comment	Nothing new to add.	Comment noted
British Society for Rheumatology	Agree	The British Society for Rheumatology fully agree with the suggestion by NICE to move Guidance 164 on febuxostat to the Static list - since the initial review and subsequent appeal by Ipsen there has been no new evidence to alter the current guidance on use of febuxostat.	Comment noted
Royal College of Nursing	No comment	Nurses working in this area of health have reviewed the technology appraisal guidance on Febuxostat for the management of hyperuricaemia in people with gout.  There are no comments or evidence to submit at this stage on behalf of the Royal College of Nursing.	Comment noted

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Physicians	Agree	Please take this email as confirmation that the Royal College of Physicians agrees with the proposal for the above guidance to be moved to the static list.  In reaching this conclusion, we have liaised with the British Society for Rheumatology and expert renal physicians.	Comment noted
Department of Health	No comment	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Comment noted
Medicines and Healthcare products Regulatory Agency	No comment	Our experts in the Vigilance Risk Management of Medicines division confirm that we are not aware of any evidence that affects the recommendations of TA164 on febuxostat.	Comment noted

**No response received from:**

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none"> <li>Menarini Pharma (Febuxostat)</li> </ul> <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> <li>Action on Pain</li> <li>Afiya Trust</li> <li>Arthritic Association</li> <li>Arthritis and Musculoskeletal Alliance (ARMA)</li> <li>Arthritis Care</li> <li>Black Health Agency</li> </ul>	<p><u>General</u></p> <ul style="list-style-type: none"> <li>Board of Community Health Councils in Wales</li> <li>British National Formulary</li> <li>Care Quality Commission</li> <li>Commissioning Support Appraisals Service</li> <li>Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>National Association of Primary Care</li> <li>National Pharmacy Association</li> <li>NHS Alliance</li> </ul>
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- British Kidney Patient Association
- Chinese National Healthy Living Centre
- Counsel and Care
- Equalities National Council
- Kidney Alliance
- Kidney Research UK
- Muslim Council of Britain
- Muslim Health Network
- National Kidney Federation
- National Rheumatoid Arthritis Society
- Pain Concern
- Pain Relief Foundation
- South Asian Health Foundation
- Specialised Healthcare Alliance
- UK Gout Society

Professional groups

- Association of Renal Industries
- Association of Renal Technologists
- British Association for Services to the Elderly
- British Dietetic Association
- British Geriatrics Society
- British Institute of Musculoskeletal Medicine
- British Orthopaedic Association
- British Pain Society
- British Renal Society
- Chartered Society of Physiotherapy
- College of Occupational Therapists
- Physiotherapy Pain Association
- Primary Care Rheumatology Society

- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium
- Welsh Kidney Patients Association

Possible comparator manufacturer(s)

- AAH Pharmaceuticals (Allopurinol)
- Accord Healthcare (Allopurinol)
- Actavis (Allopurinol)
- Almus Pharmaceuticals (Allopurinol)
- Arrow Generics (Allopurinol)
- Aspen (Allopurinol)
- Barts and the London NHS Trust (Benzbromarone, Probenecid)
- Bristol Laboratories (Allopurinol)
- Burton Hospitals NHS Trust (Benzbromarone, Probenecid)
- Calderdale and Huddersfield NHS Foundation Trust (Benzbromarone, Probenecid)
- Colchester Hospital University NHS Foundation Trust (Benzbromarone, Probenecid)
- Co-Pharma (Allopurinol)
- Dowelhurst (Allopurinol)
- East Sussex Hospitals NHS Trust (Benzbromarone, Probenecid)
- GlaxoSmithKline(Allopurinol)
- Guy's and St. Thomas' NHS Foundation Trust (Benzbromarone, Probenecid )
- Ipswich Hospital NHS Trust Benzbromarone, Probenecid)
- Kent Pharmaceuticals (Allopurinol)

- Renal Association
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal Pharmaceutical Society
- Royal Society of Medicine
- Society for DGH Nephrologists
- Society for Endocrinology
- United Kingdom Clinical Pharmacy Association

Others

- NHS Calderdale
- NHS Cambridgeshire
- Welsh Government

- Moorfields Pharmaceuticals (Benzbromarone, Probenecid)
- Newcastle upon Tyne Hospitals NHS Foundation Trust (Benzbromarone, Probenecid)
- North West London Hospitals NHS Trust (Benzbromarone, Probenecid)
- Nottingham University Hospitals NHS Trust (Benzbromarone, Probenecid)
- Portsmouth Hospitals NHS Trust (Benzbromarone, Probenecid)
- Preston Pharmaceuticals (Benzbromarone, Probenecid)
- Ranbaxy (Allopurinol)
- Royal Free Hampstead NHS Trust (Benzbromarone, Probenecid)
- Sandoz (Allopurinol)
- St George's Healthcare NHS Trust (Benzbromarone, Probenecid)
- Stockport Pharmaceuticals (Benzbromarone, Probenecid)
- Teva (Allopurinol)
- Torbay PMU (Benzbromarone, Probenecid)
- University College Hospital NHS Foundation Trust (Benzbromarone, Probenecid)
- University Hospital of North Staffordshire NHS Trust (Benzbromarone, Probenecid)
- Wockhardt (Allopurinol)

Relevant research groups

- Arthritis Research UK
- Chronic Pain Policy Coalition
- Cochrane Musculoskeletal Group

	<ul style="list-style-type: none"><li>• MRC Clinical Trials Unit</li><li>• National Institute for Health Research</li><li>• Research Institute for the Care of Older People</li></ul> <p><u>Assessment Group</u></p> <ul style="list-style-type: none"><li>• Assessment Group tbc</li><li>• National Institute for Health Research Health Technology Assessment Programme</li></ul> <p><u>Associated Public Health Groups</u></p> <ul style="list-style-type: none"><li>• Tbc</li></ul> <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"><li>• Tbc</li></ul>
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**GE paper sign-off:** Elisabeth George, Associate Director – Technology Appraisals Programme

**Contributors to this paper:**

Technical Lead: Helen Tucker

Project Manager: Andrew Kenyon

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