

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Mirabegron for the treatment of symptoms associated with overactive bladder

Final scope

**Remit/appraisal objective**

To appraise the clinical and cost effectiveness of mirabegron within its licensed indication for the treatment of symptoms associated with overactive bladder.

**Background**

Overactive bladder typically results from spasms of the muscles of the bladder that produce a compelling urge to urinate, even though the bladder may only contain a small amount of urine. Causes of overactive bladder are often unclear (idiopathic) but the condition is linked to urinary tract infections, some types of drugs, benign prostatic hyperplasia and certain conditions that affect nerves, including Parkinson's disease, multiple sclerosis or stroke. It affects approximately 17% of men and women aged 40 years and over, and prevalence increases with age.

NICE clinical guideline 40 'Urinary incontinence: the management of urinary incontinence in women' and NICE clinical guideline 97 'Lower urinary tract symptoms in men' recommend that bladder training and lifestyle advice should be offered as first-line treatments. An antimuscarinic drug should be offered second line. NICE clinical guideline 40 specifies that non-proprietary oxybutynin should be offered first. If this is not effective, alternatives are darifenacin, solifenacin, tolterodine, trospium, or different oxybutynin formulations.

**The technology**

Mirabegron (brand name unknown, Astellas Pharma) is a  $\beta_3$ -adrenoceptor agonist, which activates  $\beta_3$ -adrenoceptors causing the bladder to relax, which helps it to fill and also to store urine. It is administered orally.

Mirabegron does not currently have a UK marketing authorisation for the treatment of overactive bladder. It has been studied in clinical trials compared with placebo or tolterodine (an antimuscarinic drug) in adults with symptoms of overactive bladder for at least 12 weeks.

<b>Intervention</b>	Mirabegron
<b>Population</b>	Adults with symptoms of overactive bladder
<b>Comparators</b>	Antimuscarinic drugs including: <ul style="list-style-type: none"> <li>• oxybutynin (including modified-release preparations)</li> <li>• tolterodine</li> <li>• fesoterodine</li> <li>• solifenacin</li> <li>• trospium</li> </ul>
<b>Outcomes</b>	The outcome measures to be considered include: <ul style="list-style-type: none"> <li>• symptoms of urgency</li> <li>• urinary frequency</li> <li>• frequency of urge urinary incontinence</li> <li>• nocturia</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<b>Other considerations</b>	<p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• men and women</li> <li>• previously untreated and previously treated overactive bladder</li> </ul>

<p><b>Related NICE recommendations</b></p>	<p>Related Guidelines:</p> <p>Clinical Guideline No. 97, May 2010, 'Lower urinary tract symptoms in men'. Review decision date May 2013</p> <p>Clinical Guideline No. 40, October 2006, 'Urinary incontinence: the management of urinary incontinence in women'. Currently under review</p> <p>Related Interventional Procedures:</p> <p>Interventional Procedure Guidance No. 362, October 2010, 'Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome'</p> <p>Interventional Procedure Guidance No. 64, June 2004, 'Sacral nerve stimulation for urge incontinence and urgency-frequency'</p>
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