

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Vibegron for treating symptoms of overactive bladder

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of vibegron within its marketing authorisation for treating symptoms of overactive bladder.

Background

Overactive bladder typically results from involuntary contractions of the bladder that produce an urge to urinate, even though the bladder may only contain a small amount of urine. Overactive bladder may be associated with Parkinson's disease, spinal cord injury, diabetic neuropathy, multiple sclerosis, dementia or stroke; however most cases have no specific cause. Approximately 12% of the total adult population have symptoms of overactive bladder.¹

[NICE guideline 123](#) and [NICE clinical guideline 97](#) recommend that bladder training and lifestyle advice should be offered as first-line treatments. An antimuscarinic (also known as anticholinergics) should be offered at second-line. NICE guideline 123 recommends that the anticholinergic treatment with the lowest acquisition cost is offered. If the first anticholinergic treatment is not effective or well-tolerated, another treatment with a low acquisition cost may be offered. [NICE technology appraisal TA290](#) recommends mirabegron as an option for treating the symptoms of overactive bladder only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects. NICE guideline 123 advises that for people with overactive bladder that has not responded to non-surgical management or pharmacological treatment, more invasive procedures may be considered.

The technology

Vibegron (Obgemsa, Pierre Fabre) does not currently have a marketing authorisation in the UK for treating symptoms of overactive bladder. It has been studied in clinical trials alone compared with tolterodine and placebo in adults with symptoms of overactive bladder.

Intervention	Vibegron
Population	Adults with symptoms of overactive bladder
Subgroups	If the evidence allows the following subgroups will be considered: <ul style="list-style-type: none"> • men and women • previously untreated and previously treated overactive bladder

<p>Comparator</p>	<p>For people who have not had previous treatment for symptoms of overactive bladder:</p> <ul style="list-style-type: none"> • Bladder training and lifestyle advice <p>For people who have not achieved satisfactory benefit from bladder training and lifestyle advice:</p> <ul style="list-style-type: none"> • Antimuscarinic treatments, including: <ul style="list-style-type: none"> ○ oxybutynin (including modified-release preparations) ○ tolterodine ○ fesoterodine ○ solifenacin ○ trospium ○ darifenacin ○ propiverine <p>For people in whom antimuscarinic drugs are contraindicated, clinically ineffective, or have unacceptable side effects:</p> <ul style="list-style-type: none"> • Mirabegron
<p>Outcomes</p>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • symptoms of urgency • urinary frequency • frequency of urge urinary incontinence • nocturia • adverse effects of treatment • health-related quality of life.
<p>Economic analysis</p>	<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>If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out.</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>

<p>Other considerations</p>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<p>Related NICE recommendations</p>	<p>Related technology appraisals:</p> <p>Mirabegron for treating symptoms of overactive bladder (2013) NICE technology appraisal guidance 290.</p> <p>Related NICE guidelines:</p> <p>Pelvic floor dysfunction: prevention and non-surgical management (2021) NICE guideline NG210.</p> <p>Urinary incontinence and pelvic organ prolapse in women: management (2019) NICE guideline NG123.</p> <p>Urinary incontinence in neurological disease: assessment and management (2012) NICE guideline CG148.</p> <p>Lower urinary tract symptoms in men: management (2010, last updated June 2015) NICE guideline CG97.</p> <p>Axonics sacral neuromodulation system for treating refractory overactive bladder (2020) NICE guideline MTG50.</p> <p>Related interventional procedures:</p> <p>Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome (2010) NICE interventional procedures guidance 362</p> <p>Laparoscopic augmentation cystoplasty (including clam cystoplasty) (2009) NICE interventional procedures guidance 326</p> <p>Sacral nerve stimulation for urge incontinence and urgency-frequency (2004) NICE interventional procedures guidance 64</p> <p>Related quality standards:</p> <p>Urinary incontinence in women (2015, last updated December 2021) NICE quality standard 77</p> <p>Lower urinary tract symptoms in men (2013) NICE quality standard 45</p>
<p>Related National Policy</p>	<p>Service specification: Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse (16 years and above) (2021) Reference 1758.</p> <p>NHS England (2020) Service specification: Specialised complex surgery for urinary incontinence and vaginal and uterine prolapse (16 years and above). Reference 1649.</p> <p>The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2017, updated 2023)</p>

	<p>Prescribed Specialised Services Manual (version 6). Chapter 58: specialist adult gynaecological surgery and urinary surgery services for females</p> <p>NHS England (2015) Clinical Commissioning Policy: sacral nerve stimulation for overactive bladder. Reference: E10/P/b.</p> <p>NHS England (2013) NHS standard contract for complex gynaecology : recurrent prolapse and urinary incontinence. Reference: E10/S/d.</p>
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References

1. Royal United Hospitals Bath NHS Foundation Trust (2023) [Overactive Bladder Syndrome \(OAB\)](#). Accessed February 2024