**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Health Technology Evaluation**

# Vibegron for treating symptoms of overactive bladder

**Draft scope**

## Draft 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 (brand name unknown, 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.

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| **Intervention(s)** | Vibegron |
| **Population(s)** | Adults with symptoms of overactive bladder |
| **Subgroups** | If the evidence allows the following subgroups will be considered:<br>• men and women<br>• previously untreated and previously treated overactive bladder |

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| **Comparators** | • Mirabegron<br>• Antimuscarinic drugs including:<br>  ○ oxybutynin (including modified-release preparations)<br>  ○ tolterodine<br>  ○ fesoterodine<br>  ○ solifenacin<br>  ○ trospium<br>  ○ darifenacin<br>  ○ propiverine |
| **Outcomes** | The outcome measures to be considered include:<br>• symptoms of urgency<br>• urinary frequency<br>• frequency of urge urinary incontinence<br>• nocturia<br>• adverse effects of treatment<br>• health-related quality of life. |
| **Economic analysis** | The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.<br>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.<br>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.<br>Costs will be considered from an NHS and Personal Social Services perspective.<br>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.<br>The availability and cost of biosimilar and generic products should be taken into account. |

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| **Other considerations** | 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. |
| **Related NICE recommendations** | **Related technology appraisals:**<br>Mirabegron for treating symptoms of overactive bladder (2013) NICE technology appraisal guidance 290.<br>**Related NICE guidelines:**<br>Pelvic floor dysfunction: prevention and non-surgical management (2021) NICE guideline NG210.<br>Urinary incontinence and pelvic organ prolapse in women: management (2019) NICE guideline NG123.<br>Urinary incontinence in neurological disease: assessment and management (2012) NICE guideline CG148.<br>Lower urinary tract symptoms in men: management (2010, last updated June 2015) NICE guideline CG97.<br>Axonics sacral neuromodulation system for treating refractory overactive bladder (2020) NICE guideline MTG50.<br>**Related interventional procedures:**<br>Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome (2010) NICE interventional procedures guidance 362<br>Laparoscopic augmentation cystoplasty (including clam cystoplasty) (2009) NICE interventional procedures guidance 326<br>Sacral nerve stimulation for urge incontinence and urgency-frequency (2004) NICE interventional procedures guidance 64<br>**Related quality standards:**<br>Urinary incontinence in women (2015, last updated December 2021) NICE quality standard 77<br>Lower urinary tract symptoms in men (2013) NICE quality standard 45 |
| **Related National Policy** | Service specification: Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse (16 years and above) (2021) Reference 1758.<br>NHS England (2020) Service specification: Specialised complex surgery for urinary incontinence and vaginal and uterine prolapse (16 years and above). Reference 1649.<br>The NHS Long Term Plan (2019) NHS Long Term Plan |

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| | NHS England (2017, updated 2023) Prescribed Specialised Services Manual (version 6). Chapter 58: specialist adult gynaecological surgery and urinary surgery services for females<br><br>NHS England (2015) Clinical Commissioning Policy: sacral nerve stimulation for overactive bladder. Reference: E10/P/b.<br><br>NHS England (2013) NHS standard contract for complex gynaecology : recurrent prolapse and urinary incontinence. Reference: E10/S/d. |

**Questions for consultation**

Where do you consider vibegron will fit into the existing care pathway for overactive bladder?

Are invasive treatment options (such as botulinum toxin type A, percutaneous sacral nerve stimulation, urinary diversion and laparoscopic augmentation cystoplasty [including clam cystoplasty]) expected to be considered comparators to vibegron?

Would Axonics sacral neuromodulation system be considered as a comparator to vibegron?

Does the treatment pathway for treating symptoms of overactive bladder differ for men and women?

Are there any subgroups of people in whom vibegron is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Would vibegron be a candidate for managed access?

Do you consider that the use of vibegron can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which vibegron will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE is considering evaluating this technology through its cost comparison evaluation process.
Please provide comments on the appropriateness of appraising this topic through this process.
(Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?
- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway since NICE technology appraisal 290 (2013) was published? If so, please describe.
- Will the intervention be used to treat the same population as the comparator(s)?
- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?
- Would it be appropriate to use the cost-comparison methodology for this topic?

**References**

1. Royal United Hospitals Bath NHS Foundation Trust (2017) Overactive Bladder Syndrome (OAB). Accessed August 2023