NICE National Institute for Health and Care Excellence

NICE guidance

Vibegron for treating symptoms of overactive bladder syndrome

Technology appraisal guidance
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www.nice.org.uk/guidance/ta999

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Vibegron is recommended as an option for treating the symptoms of overactive bladder syndrome in adults. It is only recommended if antimuscarinic medicines are not suitable, do not work well enough or have unacceptable side effects.

1.2 If people with the condition and their healthcare professional consider vibegron to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, the least expensive should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

1.3 This recommendation is not intended to affect treatment with vibegron that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

Why these recommendations were made

Usual treatment for symptoms of overactive bladder syndrome is antimuscarinic medicines. If these are not suitable, do not work well enough or have unacceptable side effects, mirabegron is recommended as a treatment option. Vibegron works in a similar way to mirabegron. This evaluation only looked at vibegron for the same people who would be offered mirabegron.

Clinical trial evidence shows that vibegron is more effective than placebo for treating the symptoms of overactive bladder syndrome. The evidence is limited because most people in the trial had not had antimuscarinic medicines. But the reduction in symptoms was similar for people who had had antimuscarinic medicines and people who had not. The licensed dose of vibegron (75 mg) has not been directly compared in a clinical trial with mirabegron, but an indirect treatment comparison suggests it is likely to work as well.

Cost-comparison results suggest vibegron is likely to be cost saving compared with mirabegron. So, vibegron is recommended.

For all evidence see the committee papers. For more information on NICE's evaluation of

mirabegron, see the committee discussion section in NICE's technology appraisal guidance on mirabegron for treating symptoms of overactive bladder.

2 Information about vibegron

Marketing authorisation indication

2.1 Vibegron (Obgemsa, Pierre Fabre) is indicated 'in symptomatic treatment of adult patients with overactive bladder (OAB) syndrome'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for vibegron.

Price

2.3 The list price of vibegron is £26.68 per pack of 30 tablets (excluding VAT; company submission July 2024).

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication. Because vibegron has been recommended through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.

3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has overactive bladder syndrome and the healthcare professional responsible for their care thinks that vibegron is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the lead team of the highly specialised technologies evaluation committee, which includes the chair and vice chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Paul Arundel
Chair, highly specialised technologies evaluations committee

Iolo Doull
Vice chair, highly specialised technologies evaluations committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser and a project manager.

Raphael Egbu and Alice Bell
Technical leads

Caron Jones
Technical adviser

Jeremy Powell
Project manager

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