**Appendix B**

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## Proposed Health Technology Appraisal

## Mirabegron for the treatment of overactive bladder

## Draft scope (Pre-referral)

### Draft remit/appraisal objective

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

### Background

Overactive bladder is typically caused by spasms of the muscles of the bladder resulting in a sudden and unstoppable urge to urinate, even though the bladder may only contain a small amount of urine. Causes of overactive bladder are unclear 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 in comparison with placebo or tolterodine (an antimuscarinic drug) in adults with symptoms of overactive bladder for at least 12 weeks.

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| **Intervention** | Mirabegron |
| **Population** | Adults with symptoms of overactive bladder |
| **Comparators** | Antimuscarinic drugs including:<br>• oxybutynin (including modified-release preparations)<br>• tolterodine<br>• darifenacin<br>• fesoterodine<br>• propiverine<br>• solifenacin<br>• trospium |
| **Outcomes** | The outcome measures to be considered include:<br>• symptoms of urgency<br>• urinary frequency<br>• frequency of urge urinary incontinence<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>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. |
| **Other considerations** | Guidance will only be issued in accordance with the marketing authorisation. |
| **Related NICE recommendations** | Related Guidelines:<br>Clinical Guideline No. 97, May 2010, 'Lower urinary tract symptoms in men'. Review decision date May 2013.<br>Clinical Guideline No. 40, October 2006, 'Urinary incontinence: the management of urinary incontinence in women'. Currently under review.<br>Related Interventional Procedures: |

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| | Interventional Procedure Guidance No. 362, October 2010, 'Percutaneous posterior tibial nerve stimulation for overactive bladder syndrome'.<br><br>Interventional Procedure Guidance No. 64, June 2004, 'Sacral nerve stimulation for urge incontinence and urgency-frequency'. |

**Questions for consultation**

Is mirabegron likely to be used to treat people with overactive bladder who:

- are treatment naive **or**
- have previously received treatment with an antimuscarinic drug **or**
- both populations?

Have the most appropriate comparators for mirabegron for the treatment of overactive bladder been included in the scope?

- Are all the comparators listed routinely used in clinical practice?
- Are other antimuscarinic treatments, such as flavoxate, propantheline or duloxetine also used routinely for overactive bladder?
- Is botulinum toxin type A (bladder injection) an appropriate comparator?

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

Please consider whether in the remit or the scope there are any issues relevant to equality. Please pay particular attention to whether changes need to be made to the remit or scope in order to promote equality, eliminate unlawful discrimination, or foster good relations between people who share a characteristic protected by the equalities legislation and those who do not share it, or if there is information that could be collected during the assessment process which would enable NICE to take account of equalities issues when developing guidance.

Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of the technology can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)