Single Technology Appraisal (STA)

Mirabegron for the treatment of symptoms associated with overactive bladder

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you
Your name: June Rogers MBE
Name of your organisation: PromoCon, Disabled Living
Are you (tick all that apply):
- a patient with the condition for which NICE is considering this technology?
 a carer of a patient with the condition for which NICE is considering this technology?
 an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc) PromoCon Team Director

- other? (please specify)

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What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

Currently, as a result of side effects, such as dry mouth with traditional antimuscarinics, there is a relatively high drop out rate.

A medication, such as Mirabegron, which potentially may provide an alternative treatment of OAB for individuals who are either unable to tolerate the side effects or who have suboptimal response, would be welcomed

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition

- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above

Potential benefits

Improved treatment outcomes Improved quality of life Reduced need for further invasive treatments – such as botox injections

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2. Disadvantages

Please list any problems with or concerns you have about the technology. Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or thier family (for example cost of travel needed to access the technology, or the cost of paying a carer)

Potential disadvantages

Side effects – although level of tolerance to side effects can vary greatly between individuals

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

I am not aware of this medication being in full clinical use in UK so cannot answer

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

Patients who are intolerant to routine anti-muscarinics or who have sub –optimal improvement in their symptoms may well benefit from this new medication

Cannot think of anyone who would not benefit other than those unable/unwilling to take oral medication

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Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Current comparable treatment would be anti-muscarinics although they work slightly differently

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement of the condition overall
- improvement in certain aspects of the condition

- ease of use (for example tablets rather than injection)

- where the technology has to be used (for example at home rather than in hospital) - side effects (please describe nature and number of problems, frequency, duration, severity etc)

Potential advantages

Currently, as a result of side effects, such as dry mouth with traditional antimuscarinics, there is a relatively high drop out rate.

A medication, such as Mirabegron, which is said to have reduced side effects may potentially provide an alternative treatment of OAB for individuals who are either unable to tolerate the side effects or who have suboptimal response, would be welcomed

By increasing the storage capacity of the bladder while not reducing the strength of contractions the risk of post void residual urine would potentially be reduced

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 (iii) If you think that the new technology has any disadvantages for patients compared with current standard practice, please describe them. Disadvantages might include: worsening of the condition overall worsening of specific aspects of the condition difficulty in use (for example injection rather than tablets) where the technology has to be used (for example in hospital rather than at home) side effects (for example nature or number of problems, how often, for how long, how severe).
Potential disadvantages
Side effects – although level of tolerance to side effects can vary greatly between individuals
Research evidence on patient or carer views of the technology If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.
Cannot comment as not aware of this medication being currently used
Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?
Cannot comment as not aware of this medication being currently used

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Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

I presume you have these but have listed them anyway

How dry is "**OAB**-dry"? Perspectives from **patients** and physician experts.

Anger JT, Le TX, Nissim HA, Rogo-Gupta L, Rashid R, Behniwal A, Smith AL, Litwin MS, Rodriguez LV, Wein AJ, Maliski SL.

J Urol. 2012 Nov;188(5):1811-5. doi: 10.1016/j.juro.2012.07.044. Epub 2012 Sep 19.

Women's perspective of botulinum toxin treatment for overactive bladder symptoms.

Digesu GA, Panayi D, Hendricken C, Camarata M, Fernando R, Khullar V.

Int Urogynecol J. 2011 Apr;22(4):425-31. doi: 10.1007/s00192-010-1315-x. Epub 2010 Nov 24.

<u>Neurourol Urodyn.</u> 2011 Sep;30(7):1295-9. doi: 10.1002/nau.21004. Epub 2011 Apr 28.

Women's experience with severe overactive bladder symptoms and treatment: insight revealed from patient focus groups.

<u>Anger JT</u>, <u>Nissim HA</u>, <u>Le TX</u>, <u>Smith AL</u>, <u>Lee U</u>, <u>Sarkisian C</u>, <u>Litwin MS</u>, <u>Raz S</u>, <u>Rodriguez LV</u>, <u>Maliski SL</u>. <u>Urology</u>. 2006 Aug;68(2 Suppl):29-37.

Patient-reported outcomes in overactive bladder: the influence of perception of condition and expectation for treatment benefit.

Marschall-Kehrel D, Roberts RG, Brubaker L.

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Availability of this technology to patients in the NHS What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?
Would potentially reduce the drop out rate for oral medication
What implications would it have for patients and/or carers if the technology was not made available to patients on the NHS?
May potentially increase the number of patients seeking further invasive treatments
May decrease quality of life for women with OAB who are unwilling/unable to go on to further invasive treatment if standard anti-muscarinic treatments fail
Are there groups of patients that have difficulties using the technology?
None that I am aware of
Equality

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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 this appraisal:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/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 lead to recommendations that 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.

Not aware of any issues

Other Issues

Please consider here any other issues you would like the Appraisal Committee to consider when appraising this technology.

Cost compared to current anti-muscarinic treatments