PUBLIC SUMMARY DOCUMENT
Product: Oxybutynin, transdermal patches, 36 mg (releasing approximately 3.9 mg per 24 hours), 8, Oxytrol®
Sponsor: Hospira Australia Pty Ltd
Date of PBAC Consideration: March 2009

1. Purpose of Application
The submission sought a Restricted Benefit listing for the treatment of urge urinary incontinence or urgency due to detrusor instability in a patient who cannot tolerate or swallow oral oxybutynin.

2. Background
The PBAC had rejected submissions to list transdermal oxybutynin on two previous occasions, at its meetings in March and November 2008, on the basis of uncertain comparative clinical effectiveness and the resulting uncertain cost-effectiveness.

A copy of the Public Summary Document (PSD) for the March and November 2008 PBAC consideration of oxybutynin is available from the web site at: http://www.health.gov.au/internet/main/publishing.nsf/Content/public-summary-documents-by-meeting

3. Registration Status
Oxybutynin transdermal patch was TGA registered on 10 May 2007 for the treatment of overactive bladder with symptoms of urinary frequency, urgency or incontinence or any combination of these symptoms.

4. Listing Requested and PBAC's View
Restricted Benefit
Urge urinary incontinence or urgency due to detrusor instability in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin.

For PBAC's view see Recommendation and Reasons.

5. Clinical Place for the Proposed Therapy
Transdermal oxybutynin represents a treatment option for patients with urge urinary incontinence or urgency, in patients who are unable to tolerate the oral dose form.

6. Comparator
As previously, the submission nominated placebo as the main comparator.

7. Clinical Trials
No new clinical data were presented in this resubmission compared with the November 2008 submission.

Please see November 2008 Public Summary Document.

8. Results of Trials
Please see November 2008 Public Summary Document.

9. Clinical Claim

As previously, the submission claimed that transdermal oxybutynin was more effective than placebo, but was associated with more adverse events (application site reactions).

10. Economic Analysis

The submission presented the effect of a price reduction on the modelled cost-effectiveness of transdermal oxybutynin.

The main concern with the previous economic analysis was not the incremental cost-effectiveness ratio (ICER) *per se*. Based on the clinical data, the ICER was calculated as < $15,000 per quality-adjusted life year (QALY). The primary source of concern was the large uncertainty associated with the point estimates.

The price reduction proposed by the re-submission reduced the uncertainty. The chance that transdermal oxybutynin resulted in worse outcomes had reduced from 40.7% to 27%.

The incremental cost per extra QALY gained of < $15,000 based on the revised price was considered acceptable by the PBAC.

11. Estimated PBS Usage and Financial Implications

The resubmission estimated the likely net cost to the PBS of < $10 million in Year 5.

The PBAC noted that there is potential for use outside the requested restriction.

12. Recommendation and Reasons

The PBAC recommended the listing of oxybutynin transdermal patches on the PBS for treatment of detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin on the basis of acceptable cost effectiveness over placebo.

The PBAC noted that the primary cause of concern from the previous submission was the large uncertainty associated with the relative risk point estimate for achieving complete continence. The Committee agreed that the price reduction offered by the sponsor reduced the associated uncertainty around this point estimate, with the chance that transdermal oxybutynin is more effective and less costly over placebo (i.e., results in cost-saving and better outcomes) increasing, and the chance that transdermal oxybutynin results in worse outcomes reducing from 40.7% to 27%. The incremental cost per extra QALY gained of < $15,000 based on the revised price was considered acceptable by the PBAC.

The PBAC noted that there is potential for use outside the requested restriction.

Recommendation

OXYBUTYNIN, transdermal patches, 36 mg (releasing approximately 3.9 mg per 24 hours), 8

Restriction: <u>Restricted Benefit</u>
Detrusor overactivity in a patient who cannot tolerate oral oxybutynin, or who cannot swallow oral oxybutynin.

Max. Qty: 1

Repeats: 5

13. Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

14. Sponsor's Comment

Hospira welcomes the PBAC's decision to recommend PBS listing for Oxytrol, and increase the reimbursed options available to patients suffering urge urinary incontinence and urgency.