PUBLIC SUMMARY DOCUMENT

Product: Levonorgestrel, intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours), Mirena®

Sporsor: Schering Pty Ltd

Date of PBAC Consideration: March 2007

1. Purpose of Application

The submission sought extension of the current listing to include menorrhagia.

2. Background

This drug has not previously been considered by the PBAC for this indication. Mirena was listed for contraception on 1 February 2003.

3. Registration Status

Mirena is TGA-approved for contraception, treatment of idiopathic menorrhagia and prevention of endometrial hyperplasia during oestrogen replacement therapy.

4. Listing Requested and PBAC's View

Restricted benefit
Treatment of idiopathic menorrhagia when oral medical therapies for menorrhagia have been ineffective or are contraindicated.

See Recommendation and Reasons for PBAC's view

5. Clinical Place for the Proposed Therapy

Mirena would provide an alternative treatment strategy to surgery in women where oral treatments have been ineffective or are contraindicated.

6. Comparator

The submission nominated hysterectomy as the main comparator to levonorgestrel intrauterine delivery system (LNG-IUS). The comparator was considered appropriate.

7. Clinical Trials

The submission provided a single head to head randomised trial over five years comparing LNG-IUS with hysterectomy, in menstruating women aged 35-49 who had completed their family.

The trial had been published at the time of submission, as follows:

Trial/First Author	Protocol title/Publication title	Publication citation
Hurskainen R et al	Clinical outcomes and costs with the LNG-IUS-	JAMA 2004, 291:1456-1463.

	releasing intrauterine system or hysterectomy for treatment of menorrhagia: randomized trial 5-year follow-up.	
Hurskainen R et al	Quality of life and cost-effectiveness of LNG-IUS-releasing intrauterine system versus hysterectomy for treatment of menorrhagia: a randomised trial.	Lancet 2001, 357:273-277

8. Results of Trials

The results showed that five years after insertion of LNG-IUS, 48% of the women in the LNG-IUS group still had a LNG-IUS in situ, and 42% had undergone hysterectomy. The main reasons for discontinuation with LNG-IUS were bleeding problems. At the 5-year follow-up, 94% of the women in the LNG-IUS group and 93% of women in the hysterectomy group were satisfied with treatment.

9. Clinical Claim

The submission claimed that LNG-IUS is an effective alternative to initial hysterectomy and in contrast to hysterectomy, LNG-IUS is reversible.

10. Economic Analysis

A preliminary economic evaluation was presented using a cost-minimisation approach. The trial based incremental cost (LNG-IUS compared to hysterectomy) was estimated to provide savings to the health care system.

The submission did not present a modelled economic evaluation.

11. Estimated PBS Usage and Financial Implications

The submission estimated the financial cost/year to the PBS to be < $10 million in Year 2 of listing. The submission estimated the likely number of patients/year to be < 10,000 in Year 2.

12. Recommendation and Reasons

The PBAC considered that levonorgestrel IUD has a place in the treatment of menorrhagia and accepted that a number of patients would progress to have a hysterectomy despite its use.

The PBAC recommended listing as a restricted benefit on a cost-minimisation basis compared to hysterectomy and on the basis that over a five year period, overall savings in the order of <$5,000 per patient on average would result for cases where hysterectomy had not been undertaken during that time period.

Recommendation

LEVONORGESTREL, intrauterine drug delivery system 52 mg (releasing approximately 20 micrograms per 24 hours)

Add the following to the restriction:

Restricted benefit
Idiopathic menorrhagia where oral treatments are ineffective;
Idiopathic menorrhagia where oral treatments are contra-indicated.

Maximum Quantity: 1
Repeats: nil

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