

14.02 Aciclovir
30mg/g (3%) eye ointment, 4.5g
AciVision[®], Medsurge Healthcare Pty Ltd

1 Purpose of application

1.1 The submission requested the temporary Restrict Benefit listing of aciclovir (AciVision) on the Pharmaceutical Benefits Schedule (PBS) as an alternative to currently listed, aciclovir (Zovirax), to ensure access to a treatment for Herpes simplex keratitis.

2 Requested Listing

| Name, Restriction, Manner of administration and form | Max. Qty (Packs) | Max. Qty (Units) | No. of Rpts | Proprietary Name and Manufacturer | |
|--|------------------|------------------|-------------|-----------------------------------|-------------------------|
| ACICLOVIR 3mg/g (3%) eye ointment, 4.5g | 1 | 1 | 0 | AciVision | TBC (code for Medsurge) |

| | |
|------------------------------------|--|
| Category / Program | GENERAL – General Schedule (Code GE) |
| Prescriber type: | <input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives |
| Condition: | Herpes simplex keratitis |
| PBS Indication: | Herpes simplex keratitis |
| Restriction Level / Method: | <input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined |
| Administrative Advice | Note: Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. |

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3 Background

- 3.1 On 24 October 2014, the Therapeutic Goods Administration (TGA) announced that consumers and health professionals were advised that GSK, in consultation with the TGA, was undertaking a recall of unsold Zovirax Ophthalmic ointment (3% aciclovir), after metal particles were found in three different lots of the active pharmaceutical ingredient, aciclovir. This recall resulted in a product shortage for this medicine.
- 3.2 On 25 February 2015, the TGA advised that aciclovir 30mg/g (3%) eye ointment (AciVision), 4.5g was alternative ophthalmic (eye) treatment. On 20 April 2015, Virgan 0.15% w/w ganciclovir eye gel was announced as an additional alternative product.
- 3.3 The TGA approved the importation and supply of an unregistered product in Australia, namely aciclovir 30mg/g (3%) eye ointment (AciVision), 4.5g, under Section 19A of the Therapeutic Goods Act 1989, from 25 February to 31 October 2015. This approval was extended to 30 June 2016.
- 3.4 This was the first consideration by the PBAC of ACICLOVIR AciVision 3mg/ml (3%, 4.5 g) for the treatment for Herpes simplex keratitis.

4 Pricing considerations

- 4.1 The sponsor proposed the same price as currently listed product, Zovirax (DPMQ \$37.41).

5 Other relevant factors

- 5.1 The sponsor proposed that listing is under the same conditions as Zovirax.
- 5.2 The listing of ACICLOVIR AciVision 3mg/ml (3%, 4.5 g), as proposed would replace the use of ACICLOVIR Zovirax 3% (4.5 g), resulting in no additional cost to the Commonwealth.

6 PBAC Outcome

- 6.1 The PBAC recommend the temporary Restrict Benefit listing of ACICLOVIR AciVision 3mg/ml (3%, 4.5 g) on the Pharmaceutical Benefits Schedule (PBS) as an alternative to currently listed, ACICLOVIR Zovirax (3%, 4.5 g), to ensure access to a treatment for Herpes simplex keratitis.
- 6.2 The PBAC considered that there is a clinical need for the supply of an aciclovir ointment to be maintained on the PBS. The PBAC considered that the listing should remain during the validity of the Section 19A approval by the TGA. For a longer term listing of the product, a submission to the PBAC would be required.
- 6.3 The PBAC considered that listing should be the same Restricted benefit conditions

as Zovirax, namely suitable for inclusion for prescribing by nurse practitioners and optometrists, and the Safety Net 20 Day Rule should not apply

- 6.4 The PBAC advised, at this time and due to the circumstances of this temporary listing, under Section 101 (3BA) of the National Health Act, ACICLOVIR AciVision should be not treated as interchangeable on an individual patient basis with any other drug, and ACICLOVIR AciVision and ACICLOVIR Zovirax should be not be considered equivalent for the purposes of substitution.

Outcome:

Recommended

7 Recommended listing

Add new item:

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8 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.

9 Sponsor’s Comment

The sponsor had no comment.