

4 July 2008

Proposal to subsidise imiquimod (Aldara)

Proposal summary

PHARMAC is seeking public feedback on a proposal to subsidise imiquimod 5% cream for patients with either superficial basal cell carcinoma (non-melanoma skin cancer) or genital warts under Special Authority from 1 September 2008.

Further details of this proposal to subsidise an additional medicine can be found on the following pages.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **5 pm, Friday 18 July 2008** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

The details of the proposal

PHARMAC has entered into a provisional agreement with Douglas Pharmaceuticals Limited to list imiquimod 5% cream (Aldara) in the Dermatologicals Therapeutic Group of Section B, and in Part II of Section H, of the Pharmaceutical Schedule from 1 September 2008 at a price and subsidy of \$110.40 per 12 sachets (ex-manufacturer, excluding GST).

The provisional agreement contains a confidential risk sharing arrangement, including rebates, for community and hospital expenditure. In addition, Aldara would have protection from delisting and subsidy reduction until 1 September 2011.

Patients would be required to meet the following Special Authority criteria to receive a subsidy for Aldara:

Initial application from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Either:

- 1 The patient has external anogenital warts and podophyllotoxin has been tried and failed (or is contraindicated); or
- 2 The patient has confirmed superficial basal cell carcinoma where other standard treatments, including surgical excision, are contraindicated or inappropriate.

Note

Surgical excision remains first-line treatment for superficial basal cell carcinoma as it has a higher cure rate than imiquimod and allows histological assessment of tumour clearance.

Imiquimod has not been evaluated for the treatment of superficial basal cell carcinoma within 1 cm of the hairline, eyes, nose, mouth or ears.

Imiquimod is not indicated for recurrent, invasive, infiltrating, or nodular basal cell carcinoma.

Renewal from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 Inadequate response to initial treatment for anogenital warts; or
- 2 New confirmed superficial basal cell carcinoma where other standard treatments, including surgical excision, are contraindicated or inappropriate; or
- 3 Inadequate response to initial treatment for superficial basal cell carcinoma.

Note

Confirmation that the lesion is a superficial basal cell carcinoma should be obtained using a biopsy

The use of imiquimod 5% cream (Aldara) for the treatment of actinic keratosis or any other indication besides those above are not included in this proposal and would not be subsidised.

Background to the proposal for imiquimod

Imiquimod 5% cream has been reviewed on a number of occasions by the Pharmacology and Therapeutics Advisory Committee (PTAC).

PTAC recommended that imiquimod 5% cream be listed on the Pharmaceutical Schedule for patients with confirmed superficial basal cell carcinoma where other standard treatments, including surgical excision, are contraindicated or inappropriate.

PTAC also recommended that imiquimod 5% cream be listed on the Pharmaceutical Schedule for patients with external anogenital warts, where podophyllotoxin has been tried and failed (or is contraindicated).