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| HIGH COST DRUGS | imiquimod | 1 of 2 | | |
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BACKGROUND:

Imiquimod is an immune response modulator indicated to treat actinic keratosis, superficial basal cell carcinoma, and genital and perianal warts. Imiquimod is on the Alberta Drug Benefit Restricted List.

PREAMBLE

Imiquimod cream is indicated for the following conditions:

- Treatment of typical non hyperkeratotic, non hypertrophic actinic keratosis on the face or balding scalp.

When choosing among the available topical therapies for actinic keratoses, consideration should be given to the extent of the actinic keratoses lesions, patient tolerance, ability to comply with treatment and cost of treatment¹.

The most common treatment method for actinic keratoses is cryosurgery with liquid nitrogen¹.

- Treatment of biopsy confirmed primary superficial basal cell carcinoma (sBCC) with a maximum tumor diameter of 2.0 cm located on the trunk or extremities (excluding hands and feet).

The National Cancer Institute recommends that imiquimod only be used to treat superficial basal cell carcinoma when the patient is not a candidate for surgery as, surgical treatments have been demonstrated to have greater efficacy⁵.

- Treatment of external genital and perianal warts in adults.

Limited efficacy data on imiquimod for this treatment is available and studies comparing imiquimod with other therapies are not available³.

PROTOCOL

HCD authorization and funding requires annual submission, from the date of original drug provision. Funding is provided for use under the following conditions:

Protocol 1 – Actinic Keratosis

Treatment of actinic keratoses when there is documented evidence that reasonable trials of the following usual treatment options have resulted in intolerance, treatment failure or are not feasible or reasonable.

- Physical removal of lesions: cryosurgery, curettage, dermabrasion, chemical peels, laser therapy
- 5-fluorouracil, applied daily to twice daily x 6 weeks

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Protocol 2 – Superficial Basal Cell Carcinoma (sBCC)

Treatment of biopsy confirmed primary sBCC with a maximum tumor diameter of 2.0 cm located on the trunk or extremities (excluding hands and feet) when, the patient is not a candidate for surgery

AND,

There is documented evidence of treatment failure or intolerance to 5- fluorouracil, applied twice daily for 3-6 weeks.

Dosing

| Treatment | Dosing for actinic keratosis | Dosing for sBCC |
|----------------|--|---|
| 5-fluorouracil | Apply every day-twice daily for 2-6 weeks | Apply twice daily for 3-6 weeks |
| Imiquimod | Apply once daily two times per week for 16 weeks | Apply once daily 5 times weekly for 6 weeks |

Reference /

Protocol 3 – Genital and Perianal Warts

Treatment of actinic keratoses when there is documented evidence that reasonable trials of the following usual treatment options have resulted in intolerance, treatment failure or are not feasible or reasonable.

- Cryotherapy with liquid nitrogen and podophyllin
- Laser or surgical treatment

AND

prescribed by a dermatologist.

References

1. Pharmacist’s Letter: Aldara (Imiquimod) Approved for Actinic Keratoses, May 2004, Volume 20, No. 200507.
2. 3M pharmaceuticals. Aldara Product monograph. December 24, 2004:1-38.
3. Pharmacist’s Letter: New Drug, Imiquimod 5% Cream (Aldara), October 199, Volume 15, No. 151021.
4. Compendium of Pharmaceutical and Specialties: The Canadian Drug Reference for Health Professionals. Canadian Pharmacists Association 2006.
5. Carewest, Pharmacy Department, Formulary Evaluation, March 2006.
6. Alberta Health and Wellness, Interactive Drug Benefit List, April 22nd, 2007.
7. McGraw Hill’s Access Medicine Drug Monographs 2005.

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