

# B.C. Ministry of Health Services Drug Coverage Decisions

## About PharmaCare

B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

## PharmaCare Coverage

The Ministry of Health Services (Ministry) decides which drugs should be covered. The Drug Benefit Council (DBC) gives the Ministry its independent advice. The DBC has members from the health care professions and the public. The DBC looks at whether the drug is safe and effective, and whether it is a good value for the people of B.C. The Ministry looks at the drugs used to treat similar medical conditions that B.C. PharmaCare already covers and at the overall cost of covering the drug.

## Inside

**Page 1** explains the Ministry's decision in simple words. **Page 2** gives more detailed information about the DBC recommendation, the Ministry's decision, and the reasons for the Ministry's decision.

## Imiquimod (Aldara®) for actinic keratosis on the face or balding scalp

### Understanding the DBC Recommendation and PharmaCare Coverage Decision

#### Background

- **Actinic keratosis** is a skin condition in which several small red, brown or skin-coloured patches form on areas of the skin exposed to the sun. These patches occur mostly on the face, hands, neck and upper arms, and do not go away. The patches may feel rough and they may itch or sting. Actinic keratosis is treated with medicated skin creams (e.g., imiquimod, 5-fluorouracil), **cryotherapy** (applying extreme cold to the affected area), or in other ways. Treatment may lower the chance of the patches changing into skin cancer.
- **Imiquimod** is a medicated skin cream with the trade name **Aldara®**. It is used to treat actinic keratosis. It is not known how imiquimod works for this skin condition.

#### Why was this drug reviewed?

- Drug company request.

#### What did the review find?

- The DBC recommended that imiquimod be listed as a **Limited Coverage** benefit for the treatment of actinic keratosis in adults with certain criteria. This was based on a review of studies in which topical imiquimod was compared to dummy drug (placebo), topical 5-fluorouracil or cryotherapy.

#### Reasons for the Ministry of Health Services Decision

- After the DBC recommendation, the Ministry received more information from physicians who are experts on skin conditions.
- Imiquimod will not be listed because:
  - it has less value for money compared to 5-fluorouracil and cryotherapy.
  - there is a concern that imiquimod will be used instead of treatments that are less expensive.
  - 5-fluorouracil and cryotherapy are meeting patients' needs

#### What decision was made?

- Imiquimod will not be covered.

#### Key Term(s)

- **Limited Coverage** drugs are not normally considered the first choice in treatment, or other drugs may offer better value. To receive coverage, the patient's physician must submit a Special Authority request to PharmaCare. If the request is approved, the drug is covered up to the usual PharmaCare coverage limits. Actual reimbursement depends on the rules of a patient's PharmaCare plan including any annual deductible requirement.

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Please visit us online to find out more about the Pharmaceutical Services Division and the PharmaCare program at [www.health.gov.bc.ca/pharmacare](http://www.health.gov.bc.ca/pharmacare). To find out more about how drugs are considered for PharmaCare coverage, visit [www.health.gov.bc.ca/pharmacare/formulary](http://www.health.gov.bc.ca/pharmacare/formulary).



## Imiquimod (Aldara®) for actinic keratosis on the face or balding scalp

### Drug Class

- Immune Response Modifier

### Available Dosage Forms

- 5% topical cream as 250mg single-use packet

### Sponsor/Requestor

- Graceway Pharmaceuticals

### Submission (Request) to PharmaCare

- Request to obtain coverage for the treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratosis on the face or balding scalp in adults.

### Drug Benefit Council (DBC) Recommendations

- The Drug Benefit Council (DBC) recommended that imiquimod (Aldara®) be listed as a Limited Coverage benefit with criteria.
- The DBC recommendation was based on a review of studies in which topical imiquimod was compared to placebo, 5-fluorouracil cream or cryotherapy for the treatment of actinic keratosis .

### Reasons for the Ministry of Health Services Decision

- After the DBC recommendation, the Ministry received additional input from physician dermatology specialists who reviewed and provided a clinical practice perspective review.
- The Ministry has determined to not list imiquimod due to:
  - Concerns about the cost-effectiveness of imiquimod for the treatment of actinic keratosis compared to 5-fluorouracil and cryotherapy;
  - Concerns about the potential risk of inappropriate utilization when less expensive alternatives are available;
  - Available therapies of 5-fluorouracil and cryotherapy apparently meeting patient therapeutic needs.

### Decision and Status

- Imiquimod (Aldara®) will not be listed – Non Benefit
- Effective June 28, 2010

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