

Drug Coverage Decision for B.C. PharmaCare

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.

Details of Drug Reviewed

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| Drug | fluorouracil-salicylic acid |
| Brand Name | Actikerall™ |
| Dosage Form(s) | 5-Fluorouracil 0.5%/salicylic acid 10% 25 mL bottle |
| Manufacturer | Cipher Pharmaceuticals Inc. |
| Submission Type | New Submission |
| Use Reviewed | For the treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (Grade I/II) of the face, forehead, and balding scalp in immunocompetent adult patients. |
| Common Drug Review (CDR) | Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions . Visit the CDR website for more details: https://www.cadth.ca/sites/default/files/cdr/complete/SR0498_complete_Actikerall-Mar-24-17.pdf |
| Provincial Review | <p>DBC now screens drug submissions under review by the CDR to determine whether or not a full DBC review is necessary, based on past DBC reviews, recommendations, and existing PharmaCare coverage. If a full DBC review is determined to not be required, the Ministry's drug coverage decision will be based on the CDEC recommendation and an internal review only. The DBC screened Actikerall on March 2, 2015.</p> <p>The DBC advised that because 5-fluorouracil-salicylic acid is similar to some of the other drugs used for the treatment of actinic keratosis, the Ministry may accept the CDEC's recommendation.</p> |
| Drug Coverage Decision | Non-Benefit |
| Date | March 20, 2018 |
| Reason(s) | <p>The CDEC recommended that the drug be listed for the topical treatment of actinic keratosis with a condition that the drug plan cost of treatment with 5-fluorouracil/salicylic acid should not exceed the drug plan cost of treatment with less costly alternative topical medications. Based on British Columbia's provincial review of 5-fluorouracil/salicylic acid, the drug does not meet any unmet clinical need and the cost of 5-fluorouracil alone; as such, PharmaCare decided that 5-fluorouracil/salicylic acid should not be listed as an eligible PharmaCare benefit.</p> <ul style="list-style-type: none"> In clinical trials, Actikerall was compared to placebo, not to the standard of care (cryotherapy) or to other topically administered drugs for treatment of actinic keratosis, such as fluorouracil alone, ingenol mebutate, or imiquimod. Based on the clinical trial, Actikerall is superior to placebo with regard to complete clearance of actinic keratosis lesions, but there is no data comparing Actikerall to other topical treatments for actinic keratosis lesions. As a result, the place in therapy for Actikerall is unclear. |

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| | <ul style="list-style-type: none"> • Fluorouracil (Efudex) is a PharmaCare Regular Benefit. • At the submitted price, Actikerall costs more per course of treatment than fluorouracil alone. |
| Other Information | None |

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the [Drug Benefit Council \(DBC\)](#) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the [Common Drug Review \(CDR\)](#)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit [The Drug Review Process in B.C. - Overview](#) and [Ministry of Health - PharmaCare](#) for more information.

This document is intended for information only.

It does not take the place of advice from a physician or other qualified health care provider.