

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

Drug	isotretinoin
Brand Name	Epuris™
Dosage Form(s)	10 mg, 20 mg, 30 mg and 40 mg capsules
Manufacturer	Cipher Pharmaceuticals Inc.
Submission Review	Line Extension
Use Reviewed	For severe nodular and/or inflammatory acne, acne conglobata and recalcitrant acne
Common Drug Review (CDR)	Isotretinoin was not reviewed by the CDR
Drug Benefit Council (DBC)	Isotretinoin was not reviewed by the DBC because this product is considered a line extension as isotretinoin capsules were previously reviewed by PharmaCare.
Drug Coverage Decision	Non-Benefit
Date	October 10, 2013
Reason(s)	- Epuris™ is a new formulation of isotretinoin that is bioequivalent to two other formulations of isotretinoin, Accutane® and Clarus™ under fed conditions and has improved bioavailability under fasted conditions. - Epuris™ clinical efficacy appears to be similar to Accutane® in terms of reductions in acne lesion counts. - Based on the submitted product price, the drug is more costly than the isotretinoin products Accutane® and Clarus™ which are regular PharmaCare benefits.
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](#) gives advice to the Ministry. The Council looks at:

- advice from a national group called the Common Drug Review
- whether the drug is safe and effective
- whether it is a good value for the people of B.C. and the drugs cost
- the ethics of covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a decision based on many factors, including:

- advice from the Council
- drugs used to treat similar medical conditions that B.C. PharmaCare already covers
- the overall cost of covering the drug

For more information about the B.C. Drug Review Process, please visit
<http://www.health.gov.bc.ca/pharmacare/outgoing/drugrevproc2.pdf>.

To find out more about the Pharmaceutical Services Division and the PharmaCare program, visit
www.health.gov.bc.ca/pharmacare.

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