

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 | estradiol/progesterone |
|-----------------|----------------------------------------------------------------------------------------------------------------------------|
| Brand Name | Bijuva™ |
| Dosage Forms | 0.5 mg estradiol /100 mg progesterone and |
| | 1 mg estradiol /100 mg progesterone oral capsules |
| Manufacturer | Knight Therapeutics Inc. |
| Submission Type | New Submission |
| Use Reviewed | For the treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause in women with an intact uterus. |
| Canadian | Yes, the CRR recommended: Reimburse . Visit the CRR website for more details: |
| Agency for | www.cadth.ca/sites/default/files/DRR/2022/SR0697%20Bijuva%20-%20CADTH%20Final%20Rec- |
| Drugs and | meta.pdf . |
| Technologies in | |
| Health (CADTH) | |
| Reimbursement | |
| Reviews (CRR) | |
| Drug Benefit | The DBC now screens drug submissions under review by the CRR to determine whether or not a |
| Council (DBC) | 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 estradiol/progesterone (Bijuva) and advised that because estradiol/progesterone |
| | (Bijuva) is similar to some of the other drugs used for the treatment of menopausal symptoms, |
| | the Ministry may accept the CDEC's recommendation. |
| Drug Coverage | Non-Benefit |
| Decision | |
| Date | July 6, 2023. |
| Reasons | Drug coverage decision is consistent with the CDEC recommendation: |
| | • Estradiol/progesterone (Bijuva) was demonstrated advantage over placebo with respect to |
| | efficacy. However, there was a lack of comparison to already available therapies. |

Ministry of Health

Therapeutic Assessment and Access Branch Pharmaceutical, Laboratory & Blood Services Division

| | • Estradiol/progesterone (Bijuva) does not provide cost-savings for this indication relative to the cost of treatment of estradiol and progesterone as individual components reimbursed for the treatment of moderate to severe VMS with menopause in patients with intact uterus. |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Other | None |
| Information | |

The Drug Review Process in B.C.

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

An independent group called the <u>Drug Benefit Council (DBC)</u> gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the <u>Canadian Agency for Drugs and Technologies in Health</u> (CADTH) Reimbursement Reviews(CRR)
- 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 <u>The Drug Review Process in B.C. - Overview</u> and <u>Ministry of Health - PharmaCare</u> 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.