

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	vancomycin
Brand Name	Vancocin® and generics
Dosage Forms	125 mg and 250 mg capsules
Manufacturer	Fresenius Kabi, Jamp Pharma Co, Merus Labs Inc.
Submission Type	Modification of Criteria
Use Reviewed	Treatment of Clostridium Difficile infection.
Common Drug Review (CDR)	CDR did not review.
Drug Benefit Council (DBC)	DBC met on November 5, 2018. DBC considered various inputs including: a Drug Evaluation Report on Oral Vancomycin issued December 1, 2016 by the Atlantic Common Drug Review; the Association of Medical Microbiology and Infectious Disease Canada 2018 treatment practice guidelines for Clostridium difficile infection; the 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) to the Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children; Clinical Practice Reviews from two specialists; and a Budget Impact Assessment.
Drug Coverage Decision	Limited Coverage Benefit. Access the vancomycin criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	December 18, 2018
Reasons	<p>Drug coverage decision is consistent with the DBC recommendation.</p> <ul style="list-style-type: none"> Recent clinical evidence, updated clinical practice guidelines and current clinical practice in British Columbia support the use of oral vancomycin as a first-line treatment option in selected patients. To assist with continuity of care and ease of access to the drug, the Limited Coverage criteria was amended to include patients who were initiated on oral vancomycin as an inpatient (in settings such as a hospital, nursing home or long-term care facility) and to remove a requirement that the drug be prescribed by an infectious disease or gastro-intestinal specialist.
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 [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.

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Vancomycin capsules (Vancocin® and generics)

Merus Labs International Inc. (Vancocin®) and various generic manufacturers

Description

Drug review of **vancomycin capsules (Vancocin® and generics)** for the following Health Canada approved indications:

For the treatment of *Clostridium difficile* (*C. difficile*) infection.

The DBC was asked to consider the following questions:

1. Based on the evidence provided, should the British Columbia Ministry of Health (the Ministry) provide first-line coverage for vancomycin capsules (Vancocin®, generics) for the treatment of *Clostridium difficile* (*C. difficile*)?
2. If first-line coverage for vancomycin capsules for the treatment of *C. difficile* is recommended, what amendments to the existing PharmaCare Limited Coverage criteria for vancomycin capsules are recommended?

In their review, the DBC considered the following: a Statement from the BC Provincial Antimicrobial Clinical Experts issued June 21, 2018; a Drug Evaluation Report on Oral Vancomycin issued December 1, 2016 by the Atlantic Common Drug Review; the Association of Medical Microbiology and Infectious Disease Canada 2018 treatment practice guidelines for *Clostridium difficile* infection; the 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) to the Clinical Practice Guidelines for *Clostridium difficile* Infection in Adults and Children; Clinical Practice Reviews from two specialists; and a Budget Impact Assessment.

Dosage Forms

Vancomycin is available as 125 mg and 250 mg capsules.

Recommendations

1. The Drug Benefit Council (DBC) recommends that vancomycin capsules (Vancocin® and generics) should be listed as a first-line benefit for the treatment of *C. difficile* but only for specific patient populations.
2. The DBC recommends that existing PharmaCare criteria for coverage of vancomycin capsules be changed to the following or similar:
For the treatment of patients diagnosed with symptomatic *C. difficile* infection who:
 1. Are allergic, resistant or intolerant to metronidazole;
 2. Have failed to respond to 4-6 days of oral metronidazole at doses of 500 mg three times a day; and
 3. Have moderate or severe disease or a second recurrence.
 4. For the treatment of patients diagnosed with symptomatic *C. difficile* infection who have been initiated on vancomycin in hospital or other health-care associated facility.

Reasons for the Recommendation

1. Summary

- Clinical practice guidelines and systematic reviews have indicated that oral vancomycin is superior to metronidazole in treating *C. difficile* infection regardless of disease severity.
- Oral vancomycin is better tolerated than oral metronidazole, but inappropriate use of vancomycin may favour the development of multiple drug resistant organisms.
- At manufacturer listed prices, oral vancomycin is significantly more expensive than metronidazole but significantly less expensive than fidaxomycin.

2. Clinical Efficacy

- Current clinical practice guidelines for treatment of *C. difficile* infection recommend that oral vancomycin be used as a first-line treatment for first and second episodes of *C. difficile* infection regardless of severity of illness.
- Guidelines recommend fidaxomycin (and sometimes metronidazole) as alternative choices in patients who are unable to tolerate vancomycin.

3. Safety

- Oral vancomycin is reportedly better tolerated and has fewer associated adverse events than oral metronidazole.
- The inappropriate use of vancomycin for the treatment of *C. difficile* infection may favour the development of multiple drug resistant organisms such as MRSA.
- Metronidazole is the preferred first line therapy of non-severe *C. difficile* infection from an antimicrobial stewardship point of view.

4. Economic Considerations

- At manufacturer list prices, the average annual average cost per patient for vancomycin is significantly higher than metronidazole but significantly lower than fidaxomycin.
- Amending the existing PharmaCare Limited Coverage criteria for oral vancomycin to allow first-line coverage in specific circumstances is expected to incur a moderate budget impact.