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

<table>
<thead>
<tr>
<th>Drug</th>
<th>somatropin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name</td>
<td>Omnitrope*</td>
</tr>
<tr>
<td>Dosage Form</td>
<td>15 mg/1.5 mL solution for injection (cartridge)</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Sandoz Canada Inc.</td>
</tr>
</tbody>
</table>

**Submission Type**

Line Extension

Use Reviewed

True growth hormone deficiency or chronic renal insufficiency in children 20 years of age and younger

Common Drug Review (CDR)

No, CDR did not review.

Provincial Review

Omnitrope was reviewed internally and was not reviewed by the Drug Benefit Council (DBC) because this product is a line extension of existing Omnitrope strengths.

**Drug Coverage Decision**

Limited Coverage Benefit. Access the somatropin criteria from: [www.gov.bc.ca/pharmacarespecialauthority](http://www.gov.bc.ca/pharmacarespecialauthority)

**Date**

April 10, 2018

**Reasons**

- This line extension is bioequivalent to some of the currently listed somatropin formulations based on the results of a bioequivalence study.
- There were no observable differences in the number, intensity, or nature of treatment-emergent adverse events between the studied formulations.
- This new higher strength will reduce the volume of liquid required per injection.
- The manufacturer’s submitted price per unit for this product is proportional to the price per unit of the existing strengths of Omnitrope cartridges.

**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.