

# 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

<b>Drug</b>	<b>abobotulinumtoxinA</b>
Brand Name	<b>Dysport Therapeutic™</b>
Dosage Form(s)	300 units and 500 units vials with sterile lyophilized powder for solution for injection
Manufacturer	Ipsen Biopharmaceuticals Canada Inc.
<b>Submission Type</b>	<b>New Submission</b>
Use Reviewed	Cervical dystonia (CD), lower limb spasticity (LLS) in pediatric patients two years of age and older and upper limb spasticity (ULS) in adults.
Common Drug Review (CDR)	Yes, CDR recommended: <b>to Reimburse with clinical criteria and/or conditions.</b> Visit the CDR website for more details: <b>CD :</b> <a href="http://www.cadth.ca/sites/default/files/cdr/complete/SR0512_complete_Dysport_Therapeutic_Jul_28_17_e.pdf">www.cadth.ca/sites/default/files/cdr/complete/SR0512_complete_Dysport_Therapeutic_Jul_28_17_e.pdf</a> <b>ULS :</b> <a href="http://www.cadth.ca/sites/default/files/cdr/complete/SR0517_complete_Dysport_Therapeutic_ULS_Oct_26-17_e.pdf">www.cadth.ca/sites/default/files/cdr/complete/SR0517_complete_Dysport_Therapeutic_ULS_Oct_26-17_e.pdf</a> <b>LLS :</b> <a href="http://www.cadth.ca/sites/default/files/cdr/complete/SR0556_Dysport_Therapeutic_Aug_23_18.pdf">www.cadth.ca/sites/default/files/cdr/complete/SR0556_Dysport_Therapeutic_Aug_23_18.pdf</a>
Provincial Review	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 Dysport Therapeutic (aboBoNTA) on March 6, 2017, on November 6, 2017 and on April 9, 2018 for the CD, the ULS and the LLS indications, respectively. The DBC advised that because aboBoNTA is similar to other botulinum neurotoxin A (BoNTA) products already listed as Limited Coverage benefits for the aforementioned indications, the Ministry may accept the CDEC's recommendations.
<b>Drug Coverage Decision</b>	<b>Limited Coverage Benefit.</b> Access the aboBoNTA criteria from: <a href="http://www.gov.bc.ca/pharmacarespecialauthority">www.gov.bc.ca/pharmacarespecialauthority</a>
Date	February 26, 2019
Reason(s)	<ul style="list-style-type: none"> <li>CDR reviews for the three above indications included two double-blind, randomized controlled trials (RCTs) for the CD indication, one RCT for the ULS indication and one RCT for the LLS indication, all comparing the product to placebo. Significant benefits or improvements on respective disease scales or validated tools for assessing response to the treatment were observed.</li> <li>There are currently no data to suggest clinical superiority of aboBoNTA in comparison with the two other BoNTA drugs available in Canada. AboBoNTA does not address any unmet need that</li> </ul>

	<p>is not currently met by other BoNTA drugs.</p> <ul style="list-style-type: none"> <li>• The CDEC recommended covering aboBoNTA with criteria and on the condition that the cost of aboBoNTA does not exceed that of competing products (other BoNTA drugs).</li> <li>• The Ministry participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer of aboBoNTA and the participating jurisdictions were able to reach an agreement with the manufacturer. The decision to list aboBoNTA as a Limited Coverage benefit for the three above indications was made.</li> <li>• The Ministry’s drug coverage decision is consistent with the CDEC recommendations for the three indications.</li> </ul>
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.