B.C. Ministry of Health Services Drug Coverage Decisions

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.
PharmaCare Coverage	The Ministry of Health Services (Ministry) decides which drugs should be covered. The Drug Benefit Council (DBC) gives the Ministry its independent advice. The DBC has members from the health care professions and the public. The DBC looks at whether the drug is safe and effective, and whether it is a good value for the people of B.C. The Ministry looks at the drugs used to treat similar medical conditions that B.C. PharmaCare already covers and at the overall cost of covering the drug.
Inside	**Page 1** explains the Ministry's decision in simple words. **Page 2** gives more detailed information about the DBC recommendation, the Ministry's decision, and the reasons for the Ministry's decision.

Clostridium botulinum neurotoxin type A (Xeomin®) for muscle spasticity

Understanding the DBC Recommendation and PharmaCare Coverage Decision

Background

- Botulinum toxin is produced by bacteria. It blocks the nerves involved in muscle contraction.
- **Clostridium botulinum neurotoxin type A** has the trade name **Xeomin®**. It is used to treat conditions caused by constant muscle contraction (**spasticity**). It is used for treating **blepharospasm**, in which spasticity of a muscle around the eye causes abnormal eyelid closure. It is also used to treat **cervical dystonia**, which causes spasticity of the neck muscles. In people who have had a stroke, it is used to treat arm spasticity. It is given by injection into a muscle.

Why was this drug reviewed?

- Drug company request.

What did the review find?

- For blepharospasm and cervical dystonia, Clostridium botulinum neurotoxin type A (Xeomin®) works better than **placebo** (inactive dummy pill) and it works as well as a similar product called botulinum neurotoxin type A complex (Botox®). For these conditions, the Xeomin® product is at least as safe as the Botox® product. The information on safety and how well it works comes from studies that compare single doses of the Xeomin® product to single doses of placebo or the Botox® product. It is not known how the drugs compare when more than one dose is given.
- For arm spasticity after a stroke, Clostridium botulinum neurotoxin type A (Xeomin®) works better than placebo for decreasing the amount of muscle spasticity. Other measures of how well it works to improve day-to-day activities were either not tested or they did not show that it works better than placebo.
- Clostridium botulinum neurotoxin type A (Xeomin®) is less costly than botulinum neurotoxin type A complex (Botox®).

What decision was made?

- Clostridium botulinum neurotoxin type A (Xeomin®) will have **limited coverage** for:
  - Blepharospasm
  - Cervical dystonia
  - Arm spasticity after a stroke

Key Term(s)

- **Limited Coverage drugs** are not normally considered the first choice in treatment, or other drugs may offer better value. To receive coverage, the patient's physician must submit a Special Authority request to PharmaCare. If the request is approved, the drug is covered up to the usual PharmaCare coverage limits. Actual reimbursement depends on the rules of a patient's PharmaCare plan including any annual deductible requirement.

Please visit us online to find out more about the Pharmaceutical Services Division and the PharmaCare program at www.health.gov.bc.ca/pharmacare. To find out more about how drugs are considered for PharmaCare coverage, visit www.health.gov.bc.ca/pharmacare/formulary.

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Clostridium botulinum neurotoxin type A (Xeomin®) for muscle spasticity

Drug Class

- Muscle relaxant, peripherally acting agent

Available Dosage Forms

- Single use 100 unit vial

Sponsor/Requestor

- Merz Pharma Canada Ltd.

Submission (Request) to PharmaCare

- Request to obtain coverage for the following Health Canada approved indication(s):
  - Blepharospasm
  - Cervical dystonia of a predominantly rotational form (spasmodic torticollis)
  - Post-stroke spasticity of the upper limb

Drug Benefit Council (DBC) Recommendations

- The Drug Benefit Council (DBC) recommended that Clostridium botulinum neurotoxin type A (Xeomin®) be listed as **Limited Coverage** with criteria similar to the indications it shares with botulinum neurotoxin type A complex (Botox®) which are:
  - Blepharospasm
  - Cervical dystonia of a predominantly rotational form (spasmodic torticollis)
  - Post-stroke spasticity of the upper limb

Reasons for the Ministry of Health Services Decision

- For the indications of blepharospasm and cervical dystonia, Clostridium botulinum neurotoxin type A (Xeomin®) was found to be more effective than placebo and non-inferior to botulinum neurotoxin type A complex (Botox®). No safety differences were found, though both this and the efficacy conclusion are limited by the single-dose design.
- For post-stroke spasticity of the upper limb, Clostridium botulinum neurotoxin type A (Xeomin®) was more effective than placebo on the Ashworth scale which measures spasticity, but other important functional outcomes were either not evaluated or not improved.
- Clostridium botulinum neurotoxin type A (Xeomin®) is less costly than Clostridium botulinum neurotoxin type A complex (botulinum neurotoxin).

Decision and Status

- **Limited Coverage** benefit with criteria effective June 15, 2010
- Limited Coverage criteria and approval period:
  - Blepharospasm - one year
  - Cervical dystonia of a predominantly rotational form (spasmodic torticollis) - one year
  - Post-stroke spasticity of the upper limb - one year

Key Term(s)

- **Limited Coverage** drugs are not normally considered the first choice in treatment, or other drugs may offer better value. To receive coverage, the patient's physician must submit a Special Authority request to PharmaCare. If the request is approved, the drug is covered up to the usual PharmaCare coverage limits. Actual reimbursement depends on the rules of a patient's PharmaCare plan, including any annual deductible requirement.