

# Ministry of Health and Long-Term Care

## Ontario Public Drug Programs

### Drug Submission Status

<b>Generic Name:</b>	alpha1-proteinase inhibitor (human)
<b>Brand Name:</b>	Prolastin
<b>Strength:</b>	1000mg/vial powder for solution
<b>Manufacturer:</b>	Talecris Biotherapeutics Inc.
<b>Indication:</b>	Chronic replacement therapy of individuals having congenital alpha1-antitrypsin deficiency with clinically demonstrable panacinar emphysema
<b>Rapid Review:</b>	Not requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Decision:
First Review (Initial Submission)	24/03/2009	21/07/2009	CED review completed	N/A
Second Review (Resubmission #1)	13/10/2009	20/10/2009	EO decision rendered	Funding not available through the Exceptional Access Program (EAP)

**Rapid Review:**

Details of the Rapid Review process can be found at:

[www.health.gov.on.ca/english/providers/program/drugs/drug\\_submissions/rapid\\_review\\_process.html](http://www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html)

**Review Status:**

- Screening – Ministry is screening the manufacturer's submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.
- Submission incomplete – Manufacturer did not meet the necessary requirements to allow review to proceed.
- Submission complete & under review – Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.
- Committee to Evaluate Drugs (CED) review completed, manufacturer requesting reconsideration – A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.
- Committee to Evaluate Drugs (CED) review completed – A recommendation was made by the CED.
- Executive Officer (EO) decision rendered.

**Funding Decision:**

*The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision can be found at: [www.health.gov.on.ca/english/providers/program/drugs/ced\\_rec\\_table.html](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)*

Updated: September 15, 2011