Ontario

Ministry of Health
Ontario Public Drug Programs (OPDP)
Drug Programs Delivery Branch
5700 Yonge Street, 3rd floor
Toronto ON M2M 4K5

Fabry Disease Enzyme Replacement Therapy (Agalsidase) Assessment

Fax completed form to the Canadian Fabry Disease Initiative (CFDI) Ontario office at 416-340-3226.

- Patients must be residents of Ontario with valid Ontario Health Insurance (OHIP) who do not have private or employer sponsored insurance coverage for agalsidase.
- Reimbursement of agalsidase will be considered for new patients who meet the current Canadian Fabry Disease Treatment Guidelines for ERT. All requests for funding will be reviewed by the Canadian Fabry Disease Initiative (CFDI) Scientific Committee.
- Upon receipt and review of the application, the CFDI will contact the prescriber to discuss appropriate ERT therapy and opportunities to participate in the ongoing CFDI study.
- The CFDI will also manage monthly ordering and shipping of agalsidase to an infusion centre.
- For additional information or to contact the Canadian Fabry Disease Initiative (CFDI), call 416-340-3721.

Section 1 – Prescriber Information

Last Name	First Name	Middle Initial

Mailing Address

Unit Number	Street Number	Street Name	PO Box

City	Province	Postal Code

Site

Fax Number	Telephone Number	Email Address

Section 2 – Patient Information

Last Name	First Name	Middle Initial

Ontario Health Insurance Number	Gender

Body Weight (kg)	Date of Birth (yyyy/mm/dd)

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Section 3 – Guidelines and Criteria

Canadian Fabry Disease Treatment Guidelines for Enzyme Replacement Therapy. Check all criteria that apply.

☐Renal ☐Cardiac ☐Neurological ☐Gastrointestinal ☐Pain

System	Criteria
Renal (check minimum 1 major criterion or 2 minor criteria)	**Major** ☐GFR < 60 ml/min/1.73m^2 (2 consistent estimates or measures over 2 months) ☐GFR 60 – 90 ml/min/1.73m^2 (3 consistent estimates or measures over 4 months with GFR slope greater than age-related normal) ☐GFR > 135 ml/min/1.73m^2 (15% decrease in GFR or GFR slope greater than age-related normal. Must be measured GFR) ☐Persisting proteinuria of 500 mg/day/1.73m^2 ☐Renal pathology (Males only) **Minor** ☐Hyperfiltration (GFR ≥ 135 ml/min/1.73m^2, 2 consistent measured GFR at least 1 month apart) ☐Isolated proteinuria of 300 mg/day/1.73m^2 or greater without cause ☐Renal tubular dysfunction (Nephrogenic diabetes insipidus and/or Fanconi syndrome) ☐Hypertension ☐Renal pathology (Females only)
Cardiac (check minimum 2 criteria)	☐LV wall thickness >12 mm in males and >11 mm in females ☐LVH by ECG; Estes ECG score must be > 5 ☐LVMI by 2D echocardiogram 20% above normal for age. ☐Diastolic filling abnormalities by 2D echo. Grade 2 or 3 diastolic dysfunction and/or presence of speckle tracking abnormalities ☐Increase of LV mass of at least 5 g/m^2/year (3 measurements over a minimum 12 months) ☐Abnormal base to apex circumferential strain gradient ☐Increase of LA size on 2D echocardiogram. In parasternal long axis view (PLAX) >40 mm; Left Atrial volume index >34ml/m^2 ☐Cardiac conduction and rhythm abnormalities: AV block, short PR interval, LBBB, ventricular or atrial tachyarrhythmias, sinus bradycardia (in the absence of drugs with negative chronotropic activity or other causes) ☐Moderate to severe mitral or aortic insufficiency ☐Late enhancement of LV wall on MRI ☐T1 values using 1.5 Tesla magnet : below 901 ms in Males; below 916 ms in Females ☐Increase of N-terminal pro-natriuretic brain peptide (NT-proBNP) OR increase in high sensitivity troponin more than two times the upper limit of normal range
Neuro (check minimum 1 criterion)	☐Stroke or TIA < age of 55 documented by a neurologist ☐Acute onset unilateral hearing loss without other cause ☐Acute monocular visual loss without other cause
Gastrointestinal	☐Chronic, intractable diarrhea and/or abdominal pain/cramps, refractory to standard management for at least 6 months
Pain	☐Chronic, intractable neuropathic pain, refractory to analgesics and standard pain management for at least 6 months

Please provide any additional relevant patient details

Please provide a de-identified copy of any supporting investigations.

Section 4 – Signature

Collection and Use of Personal Information

The information on this form is collected under the authority of the *Personal Health Information Protection Act, 2004*, S.O. 2004, c.3, Sched. A (PHIPA) and Section 13 of the *Ontario Drug Benefit Act*, R.S.O. 1990c.O.10 and will be used in accordance with PHIPA, as set out in the Ministry of Health "Statement of Information Practices", which may be accessed at www.health.gov.on.ca. If you have any questions about the collection or use of this information, call Ontario Public Drug Programs at 1-866-811-9893 or contact the Director, Exceptional Access Program, 5700 Yonge Street, 3rd Floor, Toronto ON M2M 4K5.

Physician Last Name	Physician First Name
Signature	Date (yyyy/mm/dd)

CFDI Use Only

☐ Approved ☐ Not Approved

Reviewer Last Name	Reviewer First Name
Signature	Date (yyyy/mm/dd)