Ontario

Ministry of Health and Long-Term Care

Ontario Public Drug Programs (OPDP)
Drug Programs Delivery Branch
5700 Yonge St., 3rd floor
Toronto ON M2M 4K5

Request for Aldurazyme®

Please fax completed form and/or any additional relevant information to 416 327-7526 or toll-free 1 866 811-9908; or send to the Ontario Public Drug Programs (OPDP), 3rd floor, 5700 Yonge Street, Toronto ON M2M 4K5.
For copies of this and other forms, please visit http://www.health.gov.on.ca/en/public/forms/odb_fm.aspx

This form is intended to facilitate the submission of requests for funding consideration. Additional documentation to support the request may be required.
Please ensure that all appropriate information for each section is provided to avoid delays.

Section 1 – Prescriber Information

First Name | Initial | Last Name

Mailing Address
Street No. | Street Name

City | Postal Code

Treatment Centre

Fax No. ( ) | Telephone No. ( )

Section 2 – Patient Information

First Name | Initial | Last Name

Ontario Health Insurance Number

Gender
☐ Male ☐ Female

Body Weight *(kg)*

Date of Birth *(yyyy/mm/dd)*

☐ **New Request**

☐ **Renewal of existing EAP Approval** *(specify EAP #)* _____ — _____

Section 3 – Drug, Dosage and Regimen

☑ Aldurazyme® (laronidase) 0.58mg/ml

Regimen and Dosage:

Section 4 – Clinical Information – New Request

☐ Confirmed diagnosis of Hurler-Scheie Disease

☐ Confirmed diagnosis of Hurler Disease

Please provide enzymology testing report *AND* mutation analysis report.

Age at diagnosis:

Hurler-Scheie *(require **1 or more** clinical features of MPS I below to be eligible for reimbursement)*:

☐ Sleep disordered breathing: patients with an apnea/hypopnea incidence of > 5 events/hour of total sleep time or more than 2 severe episodes of desaturation *(oxygen saturation < 80%)* in an overnight sleep study

☐ Respiratory function tests: patients with **persistent** FVC < 80% of predicted value for height *(require 2 measures of FVC < 80% measured within 6 months, at least 1 month apart)*

☐ Cardiac: myocardial dysfunction as indicated by a reduction in ejection fraction to less than 56% *(normal range 56% - 78%)* OR a reduction in fraction shortening to < 25% *(normal range 25%-46%)*

☐ Joint contractures: patients developing restricted range of movement of joints of greater than 15 degrees from normal in shoulders, neck, hips, knees, elbows, or hands

Please provide overnight sleep study, respiratory function tests, cardiac tests, and joint contracture tests

If there is joint contracture involvement, please indicate the number of joints affected: _____

Hurler *(For patients with less than 2 severe mutations identified, require **1 or more** clinical features of MPS I below to be eligible for reimbursement)*:

☐ Sleep disordered breathing: patients with an apnea/hypopnea incidence of > 5 events/hour of total sleep time or more than 2 severe episodes of desaturation *(oxygen saturation < 80%)* in an overnight sleep study

☐ Respiratory function tests: patients with **persistent** FVC < 80% of predicted value for height *(require 2 measures of FVC < 80% measured within 6 months, at least 1 month apart)*

☐ Cardiac: myocardial dysfunction as indicated by a reduction in ejection fraction to less than 56% *(normal range 56% - 78%)* OR a reduction in fraction shortening to < 25% *(normal range 25%-46%)*

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Section 4 – Clinical Information – New Request *(cont'd)*

☐ Joint contractures: patients developing restricted range of movement of joints of greater than 15 degrees from normal in shoulders, neck, hips, knees, elbows, or hands

AND

☐ Patient will be undergoing hematopoietic stem cell transplantation *(HSCT)* ***and*** shows evidence of significant airway or other cardiopulmonary complications or these complications are anticipated to arise prior to HSCT.

Estimated Date of HSCT: _____

AND

☐ Patient less than 2 years of age

Section 5 – Clinical Information – Renewal Request

Hurler-Scheie:

An improvement or stabilization/no progression of disease activity in ***ALL*** of the following clinical features:

- Sleep disordered breathing
- Respiratory function tests:
  - Patients < 7 years old: FVC or 6MWT *(if available)*
  - Patients ≥ 7 years old: FVC or 6MWT *(required)*
- Cardiac: ejection fraction OR fraction shortening
- Joint contractures *(require stability or reduction in the number of joints affected as well as signs of stability / improvement in joint contractures based on traditional measures)*

Please provide overnight sleep study, respiratory function tests, cardiac tests, and joint contracture tests

If joint contracture involvement, please indicate the number of joints affected: _____

Hurler:

No renewal requests will be accepted, as HSCT should be completed.

Section 6 – Current Medication Use and Co-Morbid Conditions

List of current medication use ***AND*** document serious co-morbid conditions, if any.

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 and Long-Term Care "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, Drug Programs Delivery Branch, 5700 Yonge St., 3rd Floor, Toronto ON M2M 4K5.

Prescriber Signature *(mandatory)*	CPSO Number	Date *(yyyy/mm/dd)*