ALBERTA BLUE CROSS®

# MIGALASTAT
# SPECIAL AUTHORIZATION REQUEST FORM

**Patients may or may not meet eligibility requirements as established by Alberta government-sponsored drug programs.**



**PATIENT INFORMATION**

| PATIENT LAST NAME | FIRST NAME | INITIAL | ☐ Alberta Blue Cross<br>☐ Alberta Human Services<br>☐ Other |
|---|---|---|---|
| BIRTH DATE (YYYY-MM-DD) / GENDER (M/F) | ALBERTA PERSONAL HEALTH NUMBER | | |
| STREET ADDRESS | CITY / PROV / POSTAL CODE | | ID, CLIENT/COVERAGE NUMBER |

**NOTIFICATION**

You may be eligible to receive migalastat drug benefits. Information from your prescriber is collected for the sole purpose of determining eligibility for drug coverage. Your consent is required: (A) for your prescriber to release necessary and relevant information to Alberta Blue Cross, to Alberta Health, to Alberta Human Services (if requested) and to the Canadian Fabry Disease Initiative; and (B) for Alberta Blue Cross to release that to Alberta Health and the Canadian Fabry Disease Initiative. The information will be shared with Canadian Fabry Disease Initiative which reviews the request for coverage. In addition, related usage information may be released to Alberta Health.

**PATIENT CONSENT**

I hereby authorize: (A) my prescriber to release to Alberta Blue Cross, Alberta Health, Alberta Human Services (if they request it) and to the Canadian Fabry Disease Initiative (the aforesaid being the "designated recipients"); and (B) Alberta Blue Cross to release to Alberta Health and the Canadian Fabry Disease Initiative, the information on this form and information relating to my usage of and experience with the drug and treatment results, and I consent to the designated recipients collecting such information.

Date (YYYY-MM-DD) Patient's signature

**PRESCRIBER INFORMATION**

| PRESCRIBER LAST NAME / FIRST NAME / INITIAL | PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION |
|---|---|
| | ☐ CPSA ☐ ACO ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other — REGISTRATION NUMBER |
| STREET ADDRESS | |
| CITY, PROVINCE | PHONE / FAX |
| POSTAL CODE | FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED |

## Please provide the following information for ALL requests

| | |
|---|---|
| ☐ Migalastat (e.g. Galafold)<br>☐ **Other** _____ | Dosage and frequency requested |

☐ **New request (please see Section 1a – page 1 and Section 1b – page 2)** ☐ **Renewal request (please see Section 2 – page 2)**

## Section 1a – New requests

**α-galactosidase levels (copy of test report must be provided)** _____ **Reference range** _____

**DNA mutation (copy of test report must be provided)** _____

**Please check all that apply**

| System | Criteria |
|---|---|
| ☐ **Renal (1 major OR 2 minor)** | **Major**<br>☐ GFR <60 ml/min/1.73m$^2$ (2 consistent estimates or measures over 2 months)<br>☐ GFR 60-90 ml/min/1.73m$^2$ (3 consistent estimates or measures over 4 months with GFR slope greater than age-related normal)<br>☐ GFR >135 ml/min/1.73m$^2$ (15% decrease in GFR or GFR slope greater than age-related normal. Must be measured in GFR)<br>☐ Persisting Proteinuria of 500 mg/day/1.73m$^2$ without any other causes<br>☐ Renal pathology (males only) |
| | **Minor**<br>☐ Hyperfiltration (GFR ≥135 ml.min/1.73m$^2$, 2 consistent measured GFR at least 1 month apart)<br>☐ Isolated proteinuria of 300 mg/day/1.73m$^2$ or greater without cause<br>☐ Renal tubular dysfunction (Nephrogenic diabetes insipidus and/or Fanconi syndrome)<br>☐ Hypertension<br>☐ Renal pathology (females) |

**For new requests, please continue to section 1b for new requests on page 2.**

**For renewal requests, please continue to section 2 for renewal requests on page 2.**

The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. The information will be shared with Canadian Fabry Disease Initiative which reviews the request for coverage. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009 - 108 Street, Edmonton AB T5J 3C5.

ALBERTA BLUE CROSS®

# MIGALASTAT
# SPECIAL AUTHORIZATION REQUEST FORM

**Patients may or may not meet eligibility requirements as established by Alberta government-sponsored drug programs**

## Section 1b for new requests



| System | Criteria |
|---|---|
| ☐ **Cardiac (2)** | ☐ LV wall thickness >12 mm in males and >11 mm in females<br>☐ LVH by ECG; Estes ECG score must be > 5.<br>☐ LVMI by 2D echocardiogram 20% above normal for age<br>☐ Diastolic filling abnormalities by 2D echo. Grade 2 or 3 diastolic dysfunction and or presence of speckle tracking abnormalities<br>☐ Increase of LV mass of at least 5 g/m$^2$/year (3 measurements over a minimum 12 months)<br>☐ Abnormal base to apex circumferential strain gradient<br>☐ Increase of LA size on 2D echo.In parasternal long axis view (PLAX) >40 mm; Left atrial volume index > 34 ml/m$^2$<br>☐ 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)<br>☐ Moderate to severe mitral or aortic insufficiency<br>☐ Late enhancement of LV wall on MRI<br>☐ T1 values using a 1.5 Tesla magnet in males below 901 ms and females below 916 ms<br>☐ 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 (1)** | ☐ Stroke or TIA documented by a neurologist<br>☐ Acute onset unilateral hearing loss without other cause.<br>☐ 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 |

## Section 2 – Renewal requests

According to the Canadian Fabry Disease Treatment Guidelines, does the patient meet any of the following criteria for consideration of discontinuation of disease specific therapy?

☐ Yes – please check all that apply

- ☐ Patient request
- ☐ Life expectancy < 1 year
- ☐ Permanent severe neurocognitive decline
- ☐ Severe reduction of quality of life and functional status despite disease specific therapy
- ☐ Lack of response to disease specific therapy for one year in which the sole indication for disease specific therapy was neuropathic pain or severe gastrointestinal symptoms
- ☐ Lack of response to disease specific therapy that initially mandated treatment start
- ☐ Lack of compliance
- ☐ Persistent life threatening reactions that do not respond to prophylaxis e.g. anaphylaxis

☐ No

**Additional information relating to request:**

| PRESCRIBER'S SIGNATURE | DATE (YYYY-MM-DD) | Please forward this request to<br>▪ **Alberta Blue Cross, Clinical Drug Services**<br>**10009 108 Street NW, Edmonton, Alberta T5J 3C5**<br>▪ **FAX**: **780-498-8384** in Edmonton • **1-877-828-4106** toll free all other areas |
|---|---|---|

**ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE-FAX YOUR REQUEST**