ALBERTA BLUE CROSS®

VELAGLUCERASE ALFA/ TALIGLUCERASE ALFA for Gaucher Disease
SPECIAL AUTHORIZATION REQUEST FORM

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

Please complete all required sections to allow your request to be processed.

PATIENT INFORMATION				**COVERAGE TYPE**
PATIENT LAST NAME	FIRST NAME		INITIAL	☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other
BIRTH DATE (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER			
STREET ADDRESS	CITY	PROV.	POSTAL CODE	ID/CLIENT/COVERAGE NUMBER

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 INITIAL requests

1) Drug requested

☐ VPRIV

☐ Elelyso: if requesting Elelyso, please indicate the reasons that the patient is unable to receive therapy with velaglucerase alfa, including

- ☐ Rare cases of severe allergic reactions or hypersensitivity to velaglucerase alfa, please elaborate on the nature of reaction*_____
- ☐ Patients who are sub-optimally responsive despite maximum doses of velaglucerase alfa for at least 12 months, please elaborate*_____
- ☐ Patients unable to receive velaglucerase alfa for medical reasons, please elaborate*_____

Supporting documentation may be required

Please indicate if this patient is

☐ starting drug upon approval

☐ new to coverage but currently maintained on drug

☐ submitting renewal request

2a) Weight (kg) **2b) Dosage and frequency**

3) Diagnosis

☐ **Type 1 Gaucher Disease** ☐ Other (specify) _____

4) Confirmation of Diagnosis	
☐ Specific deficiency of glucocerebrosidase in tissue or cultured skin fibroblasts.	Date
☐ Presence, in tissue or peripheral blood leukocytes, of mutations in the glucocerebrosidase gene known to result in severe enzyme deficiency.	Date
☐ Other potentially confounding diagnoses, such as Hodgkin's disease or other storage disorders must have been ruled out	Date:

Please provide the following information for ALL requests

5) Exclusion criteria (does patient meet any of the following?)	
The presence of any Gaucher disease-related condition that might reasonably be expected to compromise a response to therapy	☐Yes ☐No
The presence of another medical condition that might reasonably be expected to compromise a response to therapy	☐Yes ☐No
Asymptomatic Gaucher disease	☐Yes ☐No
The presence of primary neurological disease due to Gaucher disease	☐Yes ☐No

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6) Clinical Measures monitored for the patient:

Baseline parameters	Baseline Measures	Response measures for renewals and for patients already on drug but new to coverage
Hemoglobin	<85% of lower limit of age- and sex-appropriate normal ☐Yes ☐No	Hb level (g/L): _____ Date:
Platelet count	<50 x 10^9/L on two separate occasions at least one month apart ☐Yes ☐No	☐ Increase platelet count to level sufficient to prevent spontaneous bleeding ☐ Normalization of platelet count in splenectomized patients ☐ In patients with intact spleen, an increase of at least 1.5X in baseline platelet count
Splenic infarction	☐Yes ☐No	☐ Spleen volume reduction: _____(%) ☐ Prevention of further splenic infarcts ☐ Evidence of splenic infarcts
Bone crises	☐Yes ☐No	☐ Prevention of bone crises ☐ Evidence of bone crises
Radiographic or MRI evidence of incipient destruction of any major joint at baseline	☐Yes ☐No	☐ Improvement in imaging parameters (either MRI, QCSI2, or BMD) ☐ Evidence of further joint destruction
Spontaneous fractures	☐Yes ☐No	☐ Prevention of spontaneous fractures ☐ Evidence of further fractures
Chronic bone pain	☐Yes ☐No	☐ Reduced bone pain ☐ Increased bone pain
Major Joint Replacement	☐Yes ☐No	☐ Optimize surgical outcome for major joint replacement surgery where required at baseline. ☐ Need for new major joint replacement surgery where it was not required at baseline.
Liver synthetic dysfunction	☐Yes ☐No	☐ Improvement in liver function ☐ Decline in liver function
Symptomatic hepatosplenomegaly	☐Yes ☐No	☐ Spleen volume reduction: _____(%) ☐ Liver volume reduction: _____ (%
Progressive pulmonary disease due to Gaucher disease	Pulmonary hypertension (PH) ☐Yes ☐No Need for oxygenation ☐Yes ☐No Hepatopulmonary syndrome ☐Yes ☐No	☐ pulmonary hypertension (PH) ☐improvement ☐ evidence of worsening PH ☐ oxygenation ☐improvement ☐ decrease ☐ hepatopulmonary syndrome ☐reversal ☐ continuation
Growth failure in children	☐Yes ☐No	☐ Return to normal range on height percentiles ☐ less than normal range on height percentiles

Additional information relating to request

PRESCRIBER'S SIGNATURE	DATE	Please forward this request to **Alberta Blue Cross, Clinical Drug Services** **10009 108 Street NW, Edmonton, Alberta T5J 3C5** **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