

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
.....	Address:	
.....		
Fax Number:		Fax Number:

Taliglucerase alfa

Initial application

Applications only from a metabolic physician. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has a diagnosis of symptomatic type 1 or type 3* Gaucher disease confirmed by the demonstration of specific deficiency of glucocerebrosidase in leukocytes or cultured skin fibroblasts, and genotypic analysis
- and
- ☐ Patient does not have another life-threatening or severe disease where the prognosis is unlikely to be influenced by enzyme replacement therapy (ERT) or the disease might be reasonably expected to compromise a response to ERT
- and
- ☐ Patient has haematological complications of Gaucher disease

or

☐ Patient has skeletal complications of Gaucher disease

or

☐ Patient has significant liver dysfunction or hepatomegaly attributable to Gaucher disease

or

☐ Patient has reduced vital capacity from clinically significant or progressive pulmonary disease due to Gaucher disease

or

☐ Patient is a child and has experienced growth failure with significant decrease in percentile linear growth over a 6-12 month period
- and
- ☐ Taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units)

Note: Indication marked with * is an unapproved indication

Renewal

Current approval Number (if known):.....

Applications only from a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician. Approvals valid for 3 years.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has demonstrated a symptomatic improvement and has maintained improvements in the main symptom or symptoms for which therapy was started
- and
- ☐ Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size
- and
- ☐ Radiological (MRI) signs of bone activity performed at two years since initiation of treatment, and five yearly thereafter, demonstrate no deterioration shown by the MRI, compared with MRI taken immediately prior to commencement of therapy or adjusted dose
- and
- ☐ Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT
- and
- ☐ Patient is adherent with regular treatment and taliglucerase alfa is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest whole vial (200 units)

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz