Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Taliglucerase alfa

INITIATION
Re-assessment required after 12 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION
Re-assessment required after 3 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a metabolic physician or any relevant practitioner on the recommendation of a metabolic physician, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

- ○ RRadiological (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 that the above details are correct:

Signed: ..... Date: .....