

Exceptions application form for renewal of imiglucerase (Cerezyme) for people with Gaucher disease

Return completed form to:
Exceptional Circumstances
Pharmac
PO Box 10-254
WELLINGTON
Phone: 0800 660 050 option 2
Email: nppa@pharmac.govt.nz

Note that this form should only be used to apply for renewal of funding for patients who already have an exceptional circumstances (EXCP) approval. Applications for all other people with Gaucher disease should be made through the on-line Special Authority system for taliglucerase alfa.

In 2019, the funded first-line enzyme replacement therapy (ERT) for the treatment of Gaucher disease changed from imiglucerase (Cerezyme) to taliglucerase alfa (Elelyso).

For the small group of people who currently receive funded access to imiglucerase via our Exceptional Circumstances Framework, we have created a renewal form with criteria that are consistent with that of the taliglucerase alfa Special Authority renewal. The Exceptional Circumstances framework provides a mechanism for individual patients to receive funding consideration for medicines not listed in the Pharmaceutical Schedule (either at all or for their clinical circumstances).

An EXCP Special Authority number will be generated for all approvals to enable pharmacies with community contracts to claim for the medicines dispensed.

Any new initial applications for funded access to imiglucerase will need to be assessed using the [Named Patient Pharmaceutical Application \(NPPA\) Policy](#) and will require supporting clinical information as to why the person is unable to receive treatment with taliglucerase alfa.

To submit a renewal application for funding of imiglucerase (Cerezyme) in the community for your patient, please complete the application form below.

| Patient Details | | Details of Applying Practitioner | |
|-----------------|--|----------------------------------|--|
| Last name: | | Last name: | |
| First Name: | | First nameK | |
| Address: | | AddressK | |
| | | | |
| Gender: | | PhoneK | |
| NHI No: | | NZMC#: | |
| Date of Birth: | | Email addressK | |

Application (check boxes where appropriate)

| | | |
|--|---|--------------------------|
| Renewal – from a metabolic physician or any relevant practitioners on the recommendation of a metabolic physician. Approvals valid for 3 years for applications meeting the following criteria: | | |
| All of the following: | | |
| 1 | Patient has demonstrated a symptomatic improvement or has maintained improvements in the main symptom or symptoms for which therapy was started; and | <input type="checkbox"/> |
| 2 | Patient has demonstrated a clinically objective improvement or no deterioration in haemoglobin levels, platelet counts and liver and spleen size; and | <input type="checkbox"/> |
| 3 | 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 | <input type="checkbox"/> |
| 4 | Patient has not developed another medical condition that might reasonably be expected to compromise a response to ERT; and | <input type="checkbox"/> |
| 5 | Patient is adherent with regular treatment and imiglucerase is to be administered at a dose no greater than 30 unit/kg every other week rounded to the nearest 400 units. | <input type="checkbox"/> |

Applicant's Declaration

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

Signature: _____

Date: _____