~~APPROVED~~ DRAFT PA Criteria

Initial Approval: July 9, 2014
Revised Date: January 19, 2022; October 20, 2021
October 10, 2018; October 8, 2014

CRITERIA FOR PRIOR AUTHORIZATION

Enzyme Replacement Therapy

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES The following drug requires prior authorization:
Agalsidase beta (Fabrazyme®)
Alglucosidase alfa (Lumizyme®)
Eliglustat (Cerdelga®)
Idursulfase (Elaprase®)
Imiglucerase (Cerezyme®)
Migalastat (Galafold™)
Avalglucosidase alfa-ngpt (Nexviazyme®)
Taliglucerase Alfa (Elelyso®)
Velaglucerase Alfa (VPRIV®)

CRITERIA FOR ENZYME REPLACEMENT THERAPY Must meet one of the following:

- For use of Cerdelga, Cerezyme, Elelyso, or VPRIV:
  - Patient must have a diagnosis of Type 1 Gaucher disease
- For use of Elaprase:
  - Patient must have a diagnosis of Hunter Syndrome
- For use of Fabrazyme or Galafold:
  - Patient must have a diagnosis of Fabry disease
- For use of Lumizyme or Nexviazyme:
  - Patient must have a diagnosis of Pompe disease (GAA deficiency)

LENGTH OF APPROVAL Does not require annual PA renewal

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months