Fabrazyme (agalsidase beta)  
CG-DRUG-54

Override(s)  
Prior Authorization  
Approval Duration  
1 year

Medications  
Fabrazyme (agalsidase beta)  
Quantity Limit  
N/A

APPROVAL CRITERIA

Fabrazyme (agalsidase beta) is considered medically necessary for the treatment of an individual with Fabry disease when the following criteria are met:

I. Diagnosis of Fabry disease is confirmed with either of the following:
   A. Documentation of complete deficiency or less than 5% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity in leukocytes, dried blood spots, or serum (plasma) analysis; OR
   B. Documented galactosidase alpha gene mutation by gene sequencing; AND

II. The individual to be treated has one or more symptoms or physical findings attributable to Fabry disease, such as:
   A. Acroparesthesias; OR
   B. Angiokeratomas; OR
   C. Corneal verticillata (whorls); OR
   D. Decreased sweating (anhidrosis or hypohidrosis); OR
   E. Personal or family history of exercise, heat, or cold intolerance; OR
   F. Personal or family history of kidney failure.

Fabrazyme (agalsidase beta) is considered not medically necessary when the criteria above are not met and for all other indications.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
WEB-PEC-0539-16
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