

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Fabrazyme</u>
<u>Drugs</u>	<u>Fabrazyme (agalsidase beta)</u>
<u>Covered Uses</u>	<u>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</u>
<u>Exclusion Criteria</u>	<u>N/A</u>
<u>Required Medical Information</u>	<u>See “other criteria”</u>
<u>Age Restrictions</u>	<u>Members should be greater than or equal to 8 years of age</u>
<u>Prescriber Restrictions</u>	<u>Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease</u>
<u>Coverage Duration</u>	<u>Initial Authorization: If the criteria are met, the request will be approved for a 6-month duration.</u> <u>Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</u>
<u>Other Criteria</u>	<p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • <u>Male members must have a documented diagnosis of Fabry disease confirmed by one of the following:</u> <ol style="list-style-type: none"> 1. <u>An undetectable (<3%) alpha galactosidase A (alpha-Gal-A) activity level OR</u> 2. <u>A deficient (3-35%) alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (GLA) gene by molecular genetic testing</u> • <u>Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the GLA gene by molecular genetic testing</u> • <u>Member must not be using concurrently with Galafold (migalastat)</u> • <u>Documentation of the member’s current weight</u> • <u>Request is for an FDA-approved dose</u> <p><u>Re-Authorization:</u></p>

Revision/Review Date:
6/2021

- **Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic**
- **Member must not be using concurrently with Galafold (migalastat)**
- **Documentation of the member's current weight**
- **Request is for an FDA-approved dose**

If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.

Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.