



It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Fabrazyme (agalsidase beta), is subject to the prior authorization process.

## **PROCEDURE**

### **Initial Authorization Criteria:**

*Must meet all of the criteria listed under the respective gender:*

#### **1. For members who are male:**

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Must have a diagnosis of Fabry disease based on clinical symptoms or by genetic testing

#### **2. For members who are female:**

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Must have presumed symptoms of Fabry disease (heterozygous carriers) based on family history and/or genetic testing

### **Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

### **Limitations:**



<b>Length of Authorization (if above criteria met)</b>	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

## REFERENCES

1. Fabrazyme [package insert]. Genzyme Corporation. Cambridge MA, December 2008.

## RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

## REVIEW HISTORY

<b>DESCRIPTION OF REVIEW / REVISION</b>	<b>DATE APPROVED</b>
<i>Annual review</i>	<i>02/17, 02/18</i>

