Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Adagen (pegademase bovine)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***September 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Adagen (pegademase bovine).

Adagen (pegademase bovine) is a modified enzyme injection indicated for enzyme replacement therapy for ADA deficiency in patients with SCID who are not suitable candidates for – or who have failed – bone marrow transplantation. Pegademase bovine (Adagen) is recommended for use in infants and children of any age at the time of diagnosis. Pegademase bovine (Adagen) injection is not intended as a replacement for HLA identical bone marrow transplant therapy. Pegademase bovine (Adagen) is also not intended to replace continued close medical supervision and the initiation of appropriate diagnostic tests and therapy (e.g. antibiotics, nutrition, oxygen, gammaglobulin) as indicated for intercurrent diseases.

DEFINITIONS

Adenosine deaminase (ADA) – an enzyme that catalyzes the conversion of adenosine and deoxyadenosine to inosine and deoxyinosine
HLA – human leukocyte antigen

Severe Combined Immunodeficiency Disease (SCID) – a rare primary immune deficiency usually characterized by a severe defect in both the T and B lymphocyte systems resulting in serious infections

POLICY

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, Adagen (pegademase bovine), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Must have confirmed diagnosis of adenosine deaminase deficiency (ADA) with Severe Combined Immunodeficiency (SCID) and have failed or not be a candidate for bone marrow transplantation

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:

Length of Authorization (if above criteria met)	
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. Adagen [package insert]. Enzon Pharmaceuticals. Bridgewater NJ, January 2009.

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

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*