RX.PA.002.MPC *Adagen® (Pegademase Bovine) & Revcovi (elapegademase-lvlr)*

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 adenosine deaminase (ADA) deficiency in patients with severe combined immunodeficiency disease (SCID) who are not suitable candidates for – or who have failed – bone marrow transplantation. Adagen® (pegademase bovine) is recommended for use in infants and children of any age at the time of diagnosis. Adagen® (pegademase bovine) injection is not intended as a replacement for human leukocyte antigen (HLA) identical bone marrow transplant therapy. Adagen® (pegademase bovine) 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.

Revcovi *(elapegademase-lvlr)* is indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

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

The drugs, Adagen® (pegademase bovine) and Revcovi (elapegademase-lvlr), are subject to the prior authorization process.

PROCEDURE

A. <u>Initial Authorization Criteria:</u>

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 ADA with SCID and have failed or not be a candidate for bone marrow transplantation

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Adagen and Revcovi will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

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, if required for the plan and level of request.

HCPCS Codes:

Code	Description
J2504	Injection, pegademase bovine, 25 IU
J3490	Unclassified drugs
J3590	Unclassified biologics

REFERENCES

1. Adagen [package insert]. Enzon Pharmaceuticals. Bridgewater NJ, January 2009.
2. Leadiant Biosciences Inc. Revcovi Prescribing Information. 2018, www.accessdata.fda.gov/drugsatfda_docs/label/2018/761092s000lbl.pdf

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*