RX.PA.002.MPC *Revcovi (elapegademase-lvlr)*

The purpose of this policy is to define the prior authorization process for Recovi® (elapegademase-lvlr).

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 drug, Revcovi (elapegademase-lvlr), is 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 documented diagnosis of ADA with SCID and have failed or not be a candidate for bone marrow transplantation
- Member does not have severe thrombocytopenia (<50,000/microL)

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. 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 to determine medical necessity for continuation of therapy. Authorizations may be extended based upon:
- MPC Renewal:
  - Chart documentation from the prescriber showing the member has continued to respond to therapy
  - Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Non-MPC Renewal:
  - Members who have previously been taking Adagen or Revcovi and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria); AND
  - Member has not been receiving medication samples for Revcovi; AND
  - Provider has documented clinical response of the member to treatment

<u>Limitations:</u>

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
J3490	Unclassified drugs

J3590	Unclassified biologics

REFERENCES

1. 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
Update to reauthorization criteria with MPC vs Non-MPC renewal and removal of discontinued medication, Adagen	*09/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*