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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. 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



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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. Reauthorization Criteria:

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
 - o Provider has documented clinical response of the member to treatment

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	
J3490	Unclassified drugs	
J3590	Unclassified biologics	



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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
Annual Review	02/2023
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

