Elapegademase-lvir (Revcovi®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA Approved Indications

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

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:
Adenosine Deaminase Severe Combined Immune Deficiency
Initial requests:

- Genetic or molecular test results or medical records confirming the diagnosis.
- Baseline values for plasma adenosine deaminase (ADA) activity, red blood cell deoxyadenosine triphosphate (dATP), trough deoxyadenosine nucleotide (dAXP) levels, and/or total lymphocyte counts.
- Hematologic assessment (e.g., complete blood count) demonstrating absence of severe thrombocytopenia (platelets <50,000/microL).

Continuation requests:
Chart notes, lab values, or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by an or in consultation with an immunologist or a physician who specializes in the treatment of metabolic disease and/or lysosomal storage disorders.

COVERAGE CRITERIA

Adenosine Deaminase Severe Combined Immune Deficiency

Authorization of 12 months may be granted for treatment of ADA-SCID when all of the following criteria are met:

- The diagnosis is confirmed by one of the following:
  - Increased red blood cell deoxyadenosine triphosphate (dATP) or trough deoxyadenosine nucleotide (dAXP) concentrations and ONE of the following:
    - Absent or very low (<1% of normal) adenosine deaminase (ADA) activity in red blood cells
    - Genetically confirmed, biallelic variant in the ADA gene.
- Baseline values for plasma ADA activity, red blood cell dATP, dAXP levels, and/or total lymphocyte counts have been obtained.
- Member meets one of the following:
  - The requested medication will only be used until definitive therapy with hematopoietic stem cell transplantation (HSCT) .
  - Member is not a suitable candidate for HSCT (e.g., matched sibling or family donor not available).
  - Member has failed HSCT.
- Member does not have severe thrombocytopenia (platelets <50,000/microL).
- Member does not have autoimmune disease requiring immunosuppressive therapy.
- Member will be monitored for evidence of treatment efficacy per protocol outlined in the prescribing information during treatment with Revcovi.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when all of the following criteria are met:

- Member meets the criteria for initial approval.
- Member does not have unacceptable toxicity (e.g., severe injection site reactions/bleeding, severe thrombocytopenia).
- Member is experiencing benefit from therapy (e.g., maintenance of target trough plasma ADA activity ≥30 mmol/L, trough erythrocyte dAXP levels below 0.02 mmol/L, improved or stabilized total lymphocyte counts and/or immune function).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Revcovi [package insert]. Cary, NC; Chiesi USA, Inc.; 2020.

2. Grunebaum E, Booth C, Cuvelier GDE, Loves R, Aiuti A, Kohn DB. Updated Management Guidelines for Adenosine Deaminase Deficiency. J Allergy Clin Immunol Pract. 2023;11(6):1665-1675. doi:10.1016/j.jaip.2023.01.032
3. Kohn DB, Hershfield MS, Puck JM, et al. Consensus approach for the management of severe combined immune deficiency caused by adenosine deaminase deficiency. J Allergy Clin Immunol. 2019;143(3):852-863. doi:10.1016/j.jaci.2018.08.024

EFFECTIVE DATE 5/31/2025

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