elapegademase-lvlr (Revcovi)

Commercial Medical Benefit Drug Policy

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT
Mechanism of Action: Recombinant adenosine deaminase
HCPCS:
C9399:Unclassified drugs or biologicals
J3590:Unclassified biologics
How Supplied:
NDC:
57665-0002-01: 2.4 mg/1.5 mL (1.6 mg/mL) single dose vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Adenosine Deaminase Severe Combined Immune Deficiency (ADA-SCID)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Adenosine Deaminase Severe Combined Immune Deficiency (ADA-SCID)
Meets medical necessity if all the following are met:
Initial:
1. Patient has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by ONE of the following:
   a. Molecular genetic confirmation of mutations in both alleles of the ADA1 gene
   b. Deficiency or absence of ADA in lysed erythrocytes, fibroblasts (cultured from amniotic fluid), or chorionic villus
   c. Positive screening by T cell receptor excision circles (TRECs)
   d. Increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates over the testing laboratory's upper limit of the normal range
2. Dose does not exceed FDA-approved maximum

Reauthorization:

1. Patient is responding to therapy

Covered Doses:
Switching from Adagen:
- If previous Adagen dose ≤30 U/kg or unknow: Up to 0.2 mg/kg given intramuscularly weekly
- If previous Adagen dose >30 U/kg: Revcovi weekly dose in mg/kg = Adagen weekly dose in U/kg divided by 150

Adagen-naïve patients:
- Up to 0.2 mg/kg given intramuscularly twice a week

Per prescribing information, the total weekly dose may be divided into multiple intramuscular (IM) administrations during a week. Doses may be increased and/or decreased based on trough ADA activity, trough deoxyadenosine nucleotides (dAXP) level, and/or inadequate immune reconstitution based on the clinical assessment of the patient. Subsequent doses may be increased by increments of 0.033 mg/kg weekly if trough ADA activity is under 30 mmol/hr/L, trough deoxyadenosine nucleotides (dAXP) are above 0.02 mmol/L, and/or the immune reconstitution is inadequate based on the clinical assessment of the patient.

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
D81.3

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Revcovi (elapegademase-lvlr) Prescribing Information. Chiesi USA, Inc., Cary, NC: 8/2022.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:
- P&T (3Q2025): clinical update: Clarify coverage for adenosine deaminase severe combined immune deficiency (ADA-SCID). Rationale: ensure appropriate use

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee