Elapegademase-lvlr (Revcovi®)	<u>Place of Service</u> Home Infusion Administration Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: J3590 NDC: 57665-0002-01: 2.4 mg/1.5 mL (1.6 mg/mL) single dose vial

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

- Adenosine deaminase severe combined immune deficiency (ADA-SCID)

AHFS therapeutic class: Enzymes
Mechanism of action: Recombinant adenosine deaminase

(1) Special Instructions and Pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for elapegademase-lvlr (Revcovi®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Adenosine deaminase severe combined immune deficiency (ADA-SCID)

- Being used as monotherapy for ADA-SCID

Covered Doses

Switching from Adagen:

- If previous Adagen dose ≤30 u/kg, minimum starting dose of 0.2 mg/kg IM weekly
- If previous Adagen dose >30 u/kg, Revcovi weekly dose in mg/kg is calculated as: Adagen weekly dose in u/kg divided by 150

Adagen-naïve patients:

- Initial dose is up to 0.2 mg/kg IM 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.

Coverage period

Indefinite

ICD-10:

D81.3

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for elapegademase-lvlr (Revcovi®) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

2.4 mg/1.5 mL (1.6 mg/mL) single-dose vial

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Revcovi® (elapegademase-lvlr) [Prescribing Information]. Cary, NC: Chiesi USA, Inc.; 12/2020.

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee