

Revcovi™ (elapegademase-lvlr)

When requesting Revcovi™ (elapegademase-lvlr), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

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

Coverage Guidelines

The individual must meet **all** of the following criteria for authorization:

- Has a diagnosis of adenosine deaminase severe combined immune deficiency (ADA-SCID) confirmed by one of the following:
 - o Molecular genetic testing confirming bi-allelic mutations in the *ADA* gene; OR
 - o Absent or very low (less than 1% of normal) adenosine deaminase catalytic activity at baseline
- Revcovi is prescribed by or in consultation with an immunologist, hematologist/ oncologist, or physician who specializes in ADA-SCID or related disorders.

Approval duration: 12 months

Dosing Recommendations

Individuals transitioning from Adagen to Revcovi:

If a patient's weekly Adagen dose is unknown, or a patient's weekly Adagen dose is at or lower than 30 U/kg, the recommended minimum starting dose of Revcovi is 0.2 mg/kg administered intramuscularly, once a week.

If a patient's weekly Adagen dose is above 30 U/kg, an equivalent weekly Revcovi dose (mg/kg) should be calculated using the following conversion formula:

$$\text{Revcovi dose in mg/kg} = \frac{\text{Adagen dose in U/kg}}{150}$$

The subsequent doses may be increased by increments of 0.033 mg/kg weekly. The total weekly dose may be divided into multiple intramuscular administrations during a week.

Adagen-naïve individuals

The starting weekly dose of Revcovi is 0.4 mg/kg based on ideal body weight or actual weight whichever is greater, divided into two doses (0.2 mg/kg twice a week), intramuscularly, for a minimum of 12 to 24 weeks until immune reconstitution is achieved.

References

1. Revcovi® [prescribing information]. Gaithersburg, MD: Leadiant Biosciences; December 2020.
2. Hershfield M. GeneReviews [Internet]. Updated March 16, 2017. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK1483/>. Accessed on November 17, 2023.
3. Gaspar HB, Aiuti A, Porta F, et al. How I treat ADA deficiency. *Blood*. 2009;114:3524-3532.
4. 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.