

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 request is for treatment of severe combined immunodeficiency disease (SCID) due to adenosine deaminase deficiency (ADA)
- The diagnosis has been confirmed by molecular genetic testing confirming bi-allelic mutations in the ADA gene OR the individual has had 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 that specializes in ADA-SCID or related disorders

Approval duration: 12 months

Dosing Recommendations

Revcovi is for intramuscular injection only.

Patients 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 is 0.2 mg/kg weekly.

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

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

Adagen-naïve patients:

The starting dose is 0.4 mg/kg weekly based on ideal body weight, divided into two doses (0.2 mg/kg twice a week).

References

1. Revcovi™ [prescribing information]. Gaithersburg, MD: Leadiant Biosciences, Inc; October 2018.
2. Hershfield M. GeneReviews [Internet]. Updated March 16, 2017. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK1483/>. Accessed on October 15, 2018.
3. Gaspar HB, Aiuti A, Porta F, et al. How I treat ADA deficiency. *Blood*. 2009;114:3524-3532. Available at: <http://www.bloodjournal.org/content/114/17/3524?sso-checked=true>. Accessed on October 16, 2018.
4. National Center for Environmental Health. Severe Combined Immunodeficiency (SCID). Centers for Disease Control and Prevention. Updated October 12, 2017. Available at <https://www.cdc.gov/nceh/dls/scid.html>. Accessed on October 15, 2018.
5. Kwan A, Abraham RS, Currier R, et al. Newborn screening for severe combined immunodeficiency in 11 screening programs in the United States. *JAMA*. 2014;312(7):729-738.
6. 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*. 2018 September 5 [Epub ahead of print].
7. Booth C and Gaspar HB. Pegademase bovine (PEG-ADA) for the treatment of infants and children with severe combined immunodeficiency. *Biologics*. 2009;3:349-58.