

# Revcovi (elapegademase-lvlr)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Revcovi (elapegademase-lvlr) intramuscular injection

## **APPROVAL CRITERIA**

Initial requests Revcovi (elapegademase-lvlr)] may be approved if the following criteria are met:

- I. Individual has a diagnosis of adenosine deaminase deficient severe combined immunodeficiency (ADA-SCID);

### **AND**

- II. Documentation is provided that diagnosis is confirmed by any of the following:
  - A. Genetic testing revealing biallelic mutations in the ADA1 gene; **OR**
  - B. Positive newborn screening via T cell receptor excision circles (TRECs); **OR**
  - C. Characteristic laboratory findings including but not limited to decreased or absent ADA activity and increase in erythrocyte deoxyadenosine nucleotide (dATP/dAXP) levels;

### **AND**

- III. Revcovi (elapegademase-lvlr) will be used only until definitive therapy with hematopoietic stem cell transplantation (HSCT); **OR**
- IV. Individual is not a suitable candidate for HSCT (including but not limited to matched sibling or family donor not available); **OR**
- V. Individual has failed HSCT (Label; Kohn 2019).

Continuation requests for Revcovi (elapegademase-lvlr)] may be approved for the following:

- I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease (Including but not limited to improved or stabilized plasma ADA activity, dAXP levels, total lymphocyte counts, and/or immune function).

Requests for Revcovi (elapegademase-lvlr) may not be approved for the following:

- II. Individual has severe thrombocytopenia; **OR**
- III. When the above criteria are not met and for all other indications.

### **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 2, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Kohn DB, Hershfield MS, Puck JM, Aiuti A, Blincoe A, Gaspar HB, Notarangelo LD, Grunebaum E. Consensus approach for the management of severe combined immune deficiency caused by adenosine deaminase deficiency. *J Allergy Clin Immunol*. 2019 Mar;143(3):852-863.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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