

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Revcovi (elapegademase-lvlr)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Revcovi (elapegademase-lvlr) intramuscular injection

APPROVAL CRITERIA

Requests for enzyme replacement therapy (ERT) for Adenosine Deaminase Deficiency [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. Diagnosis is confirmed by any of the following:
 - A. Genetic testing revealing mutations in the ADA1 gene; **OR**
 - B. Positive newborn screening via T cell receptor excision circles (TREC); **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. ERT 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).

Requests for Enzyme Replacement Therapy for Adenosine Deaminase Deficiency [Revcovi (elapegademase-lvlr)] may **not** be approved for the following:

- I. All other indications not included above; **OR**
- II. Individual has severe thrombocytopenia.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: January 4, 2020.
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.; 2020; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.