

Policy Name:	Revcovi (elapegademase)	Policy #:	2706P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Revcovi (elapegademase).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Revcovi (elapegademase) under the specialty medical benefit when the following criteria has been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of severe combined immunodeficiency disease (SCID) with a definitive diagnosis of adenosine deaminase deficiency as determined by one of the following:
 - Deficient ADA catalytic activity (<1% of normal) in hemolysates (in untransfused individuals) or in extracts of other cells (e.g., blood mononuclear cells, fibroblasts); OR
 - Detection of pathogenic mutations in the ADA gene by molecular genetic testing
- 1.2 Documentation that the patient has a marked elevation of the metabolite of dATP or total dAdo nucleotides (the sum of dAMP, dADP, and dATP) in erythrocytes
- 1.3 Documentation that the patient is not a candidate for or has failed bone marrow transplantation (BMT)
- 1.4 Baseline values for plasma ADA activity, red blood cell deoxyadenosine triphosphate (dATP), trough deoxyadenosine nucleotide (dAXP) levels and/or total lymphocyte counts have been obtained
- 1.5 Review of chart notes and labs documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Revcovi by both a pharmacist and medical director

2. Exclusion Criteria

- 2.1 Patient has severe thrombocytopenia (low platelets defined as <50,000/micoL)

3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Reapproval: 12 months with documentation that the patient has experienced a positive clinical response to Revcovi marked by one of the following:
 - Increase in plasma ADA activity (target trough level 15 mmol/hr/L)
 - Red blood cell dATP level decreased (target 0.005 to 0.015 mmol/L)
 - Improvement in immune function with diminished frequency/complications of infection as evidenced in improvement in the ability to produce antibodies
 - Improvement in red blood cell dAXP levels (target trough level 0.02mmol/L)
- 3.3 Health Alliance will only approve medical claims for Revcovi from a contracted vendor and will not allow provider offices to buy and bill.

CPT Codes	

HCPCS Codes	

References

1. Revcovi (elapegamase-lvlr) [prescribing information]. Cary, NC: Chiesi USA Inc; August 2022.
2. Booth C, Gaspar HB. Pegademase bovine (PEG-ADA) for the treatment of infants and children with severe combined immunodeficiency (SCID). *Biologics* 2009; 3:349.
3. 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; 143:852.
4. Bradford KL, Moretti FA, Carbonaro-Sarracino DA, et al. Adenosine Deaminase (ADA)-Deficient Severe Combined Immune Deficiency (SCID): Molecular Pathogenesis and Clinical Manifestations. *J Clin Immunol* 2017; 37:626.
5. Ariga T, Uchiyama T, Onodera M, et al. Safety and efficacy of elapegamase in patients with adenosine deaminase deficiency: A multicenter, open-label, single-arm, phase 3, and postmarketing clinical study. *Immun Inflamm Dis.* 2023 Jul;11(7):e917.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.