Pharmacy Drug Policy & Procedure

Policy Name:	Revcovi (elapegademase)	Policy #:	2706P

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 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 thrombocyctopenia (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 (elapegademase-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 elapegademase 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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