

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 7, 2022

Revcovi[®] (elapegamase-ivlr)

LENGTH OF AUTHORIZATION: Up to one year

INITIAL REVIEW CRITERIA:

- Patient has a diagnosis of severe combined immunodeficiency disease (SCID) with a definitive diagnosis of adenosine deaminase deficiency (ADA) as determined by one of the following:
 - 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; **AND**
- Patient has a marked elevation of the metabolite deoxyadenosine triphosphate (dATP) or total dAdo nucleotides (the sum of dAMP, dADP, and dATP) in erythrocytes; **AND**
- Patient is not a candidate for or has failed bone marrow transplantation (BMT); **AND**
- Patient does not have severe thrombocytopenia (platelets < 50,000/microL); **AND**
- 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.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 2.4 mg/1.5 mL (1.6 mg/mL) single-dose vial.