Reference number(s)
2118-A

SPECIALTY GUIDELINE MANAGEMENT

ADAGEN (pegademase bovine) injection

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Adagen is indicated for enzyme replacement therapy for adenosine deaminase (ADA) deficiency in patients with severe combined immunodeficiency disease (SCID) who are not suitable candidates for—or who have failed—bone marrow transplantation. Adagen is recommended for use in infants from birth or in children of any age at the time of diagnosis.

All other indications are considered experimental/investigational and are not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: enzyme assay or genetic testing results supporting diagnosis of ADA deficiency.

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of severe combined immunodeficiency disease (SCID) associated with adenosine deaminase (ADA) deficiency when the condition has failed to respond to a bone marrow transplant (BMT) or the member is not currently a suitable candidate for BMT.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for SCID associated with ADA deficiency who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

V. REFERENCE

1. Adagen [package insert]. Gaithersburg, MD: Leadiant Biosciences, Inc.; November 2017.