

STANDARD MEDICARE PART B 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 Indications

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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions: enzyme assay or genetic testing results supporting diagnosis of ADA deficiency.

III. CRITERIA FOR INITIAL APPROVAL

Severe combined immunodeficiency disease (SCID) associated with adenosine deaminase (ADA) deficiency

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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Adagen
- B. Adagen is being used to treat an indication enumerated in Section III
- C. The member is experiencing benefit from therapy. Benefit is defined as disease stability or disease improvement.

V. REFERENCES

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