

## 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 a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

Authorization of 24 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.

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCE

1. Adagen [package insert]. Gaithersburg, MD: Sigma-Tau Pharmaceuticals, Inc.; June 2014.