

Adagen® (pegademase bovine)

When requesting Adagen® (pegademase bovine), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication¹

- Adagen® (pegademase bovine) is indicated for the treatment of adenosine deaminase deficiency in individuals having severe combined immunodeficiency disease.

Approved Off-label Compendial use²

- No off-label uses meet evidence standards.

Coverage Guidelines

Adenosine Deaminase Deficiency in Severe Combined Immunodeficiency Disease

The individual must meet **all** of the following criteria for approval:

- Diagnosis of severe combined immunodeficiency disease
- Condition due to adenosine deaminase deficiency as confirmed by enzyme assay demonstrating a deficiency of adenosine deaminase enzyme activity or by genetic testing^{1,3}
- **Not** a suitable candidate for bone marrow transplantation or has failed bone marrow transplantation¹
- **Not** to be used as preparatory or support therapy for bone marrow transplantation¹
- Does **not** have severe thrombocytopenia¹

Approval duration: 12 months

Additional Information for Prescribers¹

None

References

1. Adagen® prescribing information. Gaithersburg, MD: Sigma-Tau Pharmaceuticals, Inc.: Revised June 2014. http://adagen.com/pdf/AdagenPI_Jun2014.pdf. Accessed February 21, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 21, 2017. <https://www.micromedexsolutions.com>.
3. American Academy of Allergy, Asthma, & Immunology. Severe Combined Immunodeficiency (SCID): Symptoms and diagnosis. Accessed February 21, 2017. <http://www.aaaai.org/conditions-and-treatments/primary-immunodeficiency-disease/severe-combined-immunodeficiency>.