



**Adenosine Deaminase Deficiency
Adagen (pegademase bovine) J2504
Prior Authorization Request
Medicare Part B Form**

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

| | | | |
|--|-------------------------------------|--------------------------|--|
| <input type="checkbox"/> | Standard Request– (72 Hours) | <input type="checkbox"/> | Urgent Request (standard time frame could place the member's life, health or ability in serious jeopardy) |
| Date Requested _____ | | | |
| Requestor _____ Clinic name: _____ Phone _____ / Fax _____ | | | |

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

| HCPC Code | Name of Drug | Dose (Wt: _____ kg Ht: _____) | Frequency | End Date if known |
|-----------|--------------|--------------------------------|-----------|-------------------|
| | | | | |

Initial: 10 units/kg for first dose, 15 units/kg for second dose, 20 units/kg for third dose
 Maintenance: 20 units/kg/wk IM, increase by 5 units/kg/wk if necessary; MAX single dose 30 units/kg
 Other Regimen _____

Self-administered Provider-administered Home Infusion

Chart notes attached. Other important information: _____

Diagnosis: ICD10: _____ **Description:** _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Adenosine deaminase deficiency - Severe combined immunodeficiency disease

- Patient is less than or equal to 18 years of age **AND**
- Patient requires enzyme replacement therapy for adenosine deaminase (ADA) deficiency?
- Patient is not a suitable candidate for, or has failed bone marrow transplantation
 - Documentation bone marrow transplant failure / unsuitability attached.

If not, please provide **clinical rationale** for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Patient had an **adequate response** or **significant improvement** while on this medication.

Red cell dATP levels have decreased to a range of ≤ 0.005 to $0.015 \mu\text{mol/mL}$.

Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ **Date:** ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Adagen Prior Authorization

Drug Name(s):

ADAGEN

PEGADEMASE BOVINE

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.
 - Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:

N/A

Prescriber Restrictions:

Hematologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Adagen

- Adenosine deaminase deficiency - Severe combined immunodeficiency disease

Off-Label Uses:

N/A

Age Restrictions:

Indicated for patients 6-weeks to 12 years old.

Other Clinical Consideration:

N/A

Resources:

<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Adagen&UserSearchTerm=Adagen&SearchFilter=filterNone&navitem=searchGlobal#>