



Avlayah

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ **Date:** _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ☐ Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ☐ Same as Referring Provider ☐ Same as Requesting Provider

Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ *kg*

Patient Height: _____ *cm*

Please indicate the place of service for the requested drug:

- | | | |
|--|---------------------------------|---|
| ☐ Ambulatory Surgical | ☐ Home | ☐ Off Campus Outpatient Hospital |
| ☐ On Campus Outpatient Hospital | ☐ Office | ☐ Pharmacy |

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

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Criteria Questions:

1. What is the diagnosis?

☐ Mucopolysaccharidosis II (MPS II, Hunter syndrome), *Continue to 2*

☐ Other, please specify. _____, *Continue to 2*

2. Will the requested drug be prescribed by or in consultation with a physician who specializes in the treatment of metabolic disease and/or lysosomal storage disorders?

☐ Yes, *Continue to 3*

☐ No, *Continue to 3*

3. Is this a request for continuation of therapy with the requested drug?

☐ Yes, *Continue to 4*

☐ No, *Continue to 7*

4. Has the patient experienced a clinically positive response to therapy, which shall include improvement, stabilization, or slowing of disease progression (e.g., improvement, stabilization, or slowing of disease progression for cerebrospinal fluid, blood, or urine heparan sulfate levels, Vineland Adaptive Behavior Scale Adaptive Score Composite, liver volume, 6-minute walk test (6MWT), cognitive and language-and-motor domain age-equivalent score (AES), Bayley scales of infant and toddler development, third edition (BSID-III); or nonverbal index (NVI) of the Kaufman assessment battery for children, second edition (KABC-II))? **ACTION REQUIRED:** If Yes, attach chart notes, medical records, or lab results documenting a clinically positive response to therapy, which shall include improvement, stabilization, or slowing of disease progression (e.g., improvement, stabilization, or slowing of disease progression for cerebrospinal fluid, blood, or urine heparan sulfate levels, Vineland Adaptive Behavior Scale Adaptive Score Composite, liver volume, 6-minute walk test (6MWT), cognitive and language-and-motor domain age-equivalent score (AES), Bayley scales of infant and toddler development, third edition (BSID-III); or nonverbal index (NVI) of the Kaufman assessment battery for children, second edition (KABC-II)).

☐ Yes, *Continue to 5*

☐ No, *Continue to 5*

5. Will the requested drug be used in combination with other enzyme replacement therapies for the treatment of Hunter syndrome (e.g., Elaprase)?

☐ Yes, *Continue to 6*

☐ No, *Continue to 6*

6. Does the requested dose exceed 15 mg/kg once weekly?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

7. What is the patient's age?

_____ years of age, *Continue to 8*

8. What is the patient's weight?

_____ kilograms, *Continue to 9*

9. Was the diagnosis confirmed by enzyme assay demonstrating a deficiency of iduronate-2-sulfatase (I2S) enzyme activity (i.e., less than or equal to 10% of the lower limit of the normal range, per laboratory performing the test) in plasma, white blood cells, and/or skin fibroblasts? **ACTION REQUIRED:** If Yes, attach chart notes, medical records, or lab results documenting enzyme assay demonstrating deficiency of iduronate-2-sulfatase (I2S) enzyme activity (i.e., less than or equal to 10% of the lower limit of the normal range, per laboratory performing the test) in plasma, white blood cells, and/or skin fibroblasts.

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- ☐ Yes, *Continue to 10*
☐ No, *Continue to 10*

10. Was the diagnosis confirmed by pathogenic (or likely pathogenic) variant in the IDS gene? **ACTION REQUIRED:** If Yes, attach chart notes, medical records, or lab results documenting pathogenic (or likely pathogenic) variant in the IDS gene.

- ☐ Yes, *Continue to 11*
☐ No, *Continue to 11*

11. Does the patient have neuronopathic mucopolysaccharidosis type II (nMPS II) (e.g., developmental delay, cognitive impairment, behavioral issues, seizures, ataxia, gait disturbances)?

- ☐ Yes, *Continue to 12*
☐ No, *Continue to 12*

12. Does the patient have advanced neurologic impairment?

- ☐ Yes, *Continue to 13*
☐ No, *Continue to 13*

13. Will cerebrospinal fluid, blood, or urinary heparan sulfate, hemoglobin, serum creatinine, and urinary protein to creatinine ratio be assessed at baseline and monitored as clinically appropriate? **ACTION REQUIRED:** If Yes, attach chart notes, medical records, or lab results documenting baseline cerebrospinal fluid, blood, or urinary heparan sulfate, hemoglobin, serum creatinine, and urinary protein to creatinine ratio assessments.

- ☐ Yes, *Continue to 14*
☐ No, *Continue to 14*

14. Does the patient have a documented loss of activity of sulfatases other than iduronate-2-sulfatase (I2S), indicating multiple sulfatase deficiency?

- ☐ Yes, *Continue to 15*
☐ No, *Continue to 15*

15. Does the patient have a documented mutation of other genes, including loci adjacent to the IDS gene (e.g., fragile X mental retardation 1 [FMR1] or AF4/FMR2 family member 2 [i.e., AFF2 or FMR2]) that are known to be associated with developmental delay, seizures, or other significant central nervous system disorders?

- ☐ Yes, *Continue to 16*
☐ No, *Continue to 16*

16. Does the patient have clinically significant thrombocytopenia (i.e., platelets less than 100,000/mm³), other clinically significant coagulation abnormality, or significant active bleeding?

- ☐ Yes, *Continue to 17*
☐ No, *Continue to 17*

17. Does the patient have clinically significant anemia, defined as a hemoglobin level less than 10.0 g/dL?

- ☐ Yes, *Continue to 18*
☐ No, *Continue to 18*

18. Does the patient have contraindication(s) to lumbar puncture procedure?

- ☐ Yes, *Continue to 19*
☐ No, *Continue to 19*

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19. Does the patient have any clinically significant CNS trauma or disorder, including severe untreated intracranial hypertension, that, in the opinion of the provider, may make treatment with the requested drug unsafe for the patient?

☐ Yes, *Continue to 20*

☐ No, *Continue to 20*

20. Does the patient have a history of serious adverse reaction to the I2S enzyme or any component of the requested drug (e.g., hypersensitivity or anaphylaxis requiring hospitalization)?

☐ Yes, *Continue to 21*

☐ No, *Continue to 21*

21. Will the requested drug be used in combination with other enzyme replacement therapies for the treatment of Hunter syndrome (e.g., Elaprase)?

☐ Yes, *Continue to 22*

☐ No, *Continue to 22*

22. Will the initial and subsequent doses of the requested drug exceed 15 mg/kg once weekly?

☐ Yes, *No Further Questions*

☐ No, *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature

Date (mm/dd/yy)

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