Mass General Brigham
Health Plan

Enzyme and Metabolic Disorder Therapies
Avlayah (tividenofusp alfa-eknm)
Effective 01/04/2027

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Avlayah (tividenofusp alfa-eknm) is a hydrolytic lysosomal glycosaminoglycan (GAG)-specific enzyme indicated for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment.

Coverage Guidelines
If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs
OR
Authorization may be granted when all of the following criteria are met:

1. Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II)
2. Prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided
3. Medical records or a copy of testing to support **ONE** of the following:
    a. Genetic testing confirming mutation in IDS gene
    b. Iduronate-2-sulfatase assay test confirming reduced or absent activity in the serum, white blood cells, or fibroblasts
4. Member weight is ≥ 5 kg
5. Avlayah and Elaprase will NOT be used in combination
6. **ONE** of the following:
    a. Inadequate response, adverse reaction or contraindication to Elaprase
    b. **BOTH** of the following:
        i. **ONE** of the following:
            1. Neurologic manifestations associated with MPS II
            2. Risk for neurologic manifestations and presymptomatic
        ii. No advanced neurologic impairment (e.g., severe cognitive decline, minimal ability to communicate or interact meaningfully, or profound functional dependence)
7. Appropriate dosing

Continuation of Therapy
Resubmission by prescriber will infer a positive response to therapy.

Limitations
1. Initial approvals will be granted for 12 months
2. Reauthorizations will be granted for 12 months

References

1. Avlayah [package insert]. South San Francisco (CA):Denali Therapeutics Inc.; 2026 Mar.
2. Kaplan SL. Mucopolysaccharidoses: Clinical features and diagnosis. In: Stapleton BF (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2026 [cited 2026 Jun 7]. Available from: http://www.utdol.com/utd/index.do

Review History
9/9/26 – Created for P&T. New drug has been added requiring PA under medical benefit. Effective 10/1/26
11/4/26 – Reviewed and updated for P&T. Updated formatting. Effective 1/4/27