SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Avlayah™ (tividenofusp alfa-eknm) **(C9399/J3590) MEDICAL**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage (pediatric patients weighing ≥ 5 kg):

Dosing Week	Dosage Level
Week 1 to Week 4	3 mg/kg once weekly
Week 5 to Week 8	7.5 mg/kg once weekly
Week 9 and beyond	15 mg/kg once weekly (maintenance dosage)

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NDC and/or Billable Units:

- NDC 84976-001-01: supplied as a sterile, preservative-free, white to off-white lyophilized powder with a cake-like appearance in a single-dose vial; 150 mg of tividenofusp alfa-eknm

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months. **NOTE: Max approved dose will be 15 mg/kg every 7 days**

- ❑ Member is a pediatric patient ≤ 18 years of age and weighs at least 5 kg
- ❑ Provider is a specialist in genetics or metabolic disorders
- ❑ Member has a diagnosis of Hunter disease (also referred to as Mucopolysaccharidosis II; MPS II) confirmed by **ONE** of the following **(submit documentation)**:
  - ❑ Deficient iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase
  - ❑ Detection of pathogenic mutations in the IDS gene by molecular genetic testing
- ❑ Member's condition meets **ONE** of the following **(submit documentation)**:
  - ❑ Clinical documentation of neurologic manifestations associated with MPS II (e.g., hearing loss, cardiovascular conditions, delayed growth/development, joint stiffness)
  - ❑ No symptomology or neurological manifestations are present, but the member is at high risk for neurologic manifestations (high risk includes known genotypes with inversions or recombinations associated neuronopathic MPS II such as c.1004A>G, c.262C>T, c.257C>G, c.700_703dup, c.709del) **[NOTE: if not provided as part of the criterion above for the confirmation of Mucopolysaccharidosis II, a genetic panel documenting a high risk genotype MUST be submitted]**
- ❑ Provider will **NOT** use tividenofusp alfa-eknm in combination with other enzyme replacement therapy for the treatment of MPSII
- ❑ Provider must submit documentation of pretreatment baseline value for urinary glycosaminoglycan (uGAG)

  _____ mg/mmol creatinine (or mg/g creatinine) Date: _____
- ❑ Provider must submit documentation of pretreatment baseline value for cerebrospinal fluid (CSF) of heparan sulfate

  _____ng/mL Date: _____
- ❑ Provider must submit documentation of pretreatment cognitive, behavioral, or developmental status using a validated patient-reported outcomes scale (e.g., Vineland Adaptive Behavior Scale, Bayley Scales of Infant and Toddler Development, Kaufman Assessment Battery for Children, etc.)

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Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Provider has conducted a measurement and submitted documentation demonstrating the member has experienced a reduction or stabilization in urinary glycosaminoglycan (uGAG) since starting tividenofusp alfa-eknm

  _____ mg/mmol creatinine (or mg/g creatinine) Date: _____
- ❑ Provider has conducted a measurement and submitted documentation demonstrating the member has experienced a reduction or stabilization in cerebrospinal fluid (CSF) of heparan sulfate since starting tividenofusp alfa-eknm

  _____ng/mL Date: _____
- ❑ Member has demonstrated beneficial response to therapy evidenced by disease stability, or mild progression, documented using a validated patient-reported outcomes scale that can identify cognitive, behavioral, or developmental improvement (e.g., Vineland Adaptive Behavior Scale, Bayley Scales of Infant and Toddler Development, Kaufman Assessment Battery for Children, etc.) **(submit documentation)**
- ❑ Member has **NOT** experienced any unacceptable toxicity from the drug (e.g., severe hypersensitivity including anaphylactic and anaphylactoid reactions, intolerable infusion-related reactions, anemia, nephropathy)

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR
- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: **5/29/2026**
REVISED/UPDATED/REFORMATTED: ~~6/15/2026,~~ **7/22/2026**