

# PRIOR AUTHORIZATION CHECKLIST for AVLAYAH (tvidenofusp alfa-eknm)

Prior authorization (PA) is required by most health plans to determine medical necessity before coverage. This checklist highlights documentation commonly requested for PA submissions. Because requirements vary by health plan and may change over time, always confirm the specific criteria with each patient's plan.

**Doctors and patients are responsible for completing and submitting all required PA paperwork to the health plan. Denali Therapeutics cannot guarantee reimbursement or coverage for a drug product even if you follow all tips listed below.**

If you have any questions on PA processes for AVLAYAH, please reach out to your Denali Therapeutics representative or call our Denali Patient Services at **1-844-DNLI365 (1-844-365-4365)**, Monday-Friday, 8:30 AM - 8 PM ET (except holidays).

## 1. Identify plan PA requirements and gather documentation

Each health plan has specific documentation requirements. Submit all required and relevant records per payer policy, along with the PA request, to avoid delays or denials

## 2. Initial PAs may require the following documentation

Lab results confirming MPS II diagnosis, such as:

- Iduronate-2-sulfatase (I2S) enzyme deficiency, or
- Molecular genetic testing showing a mutation/deletion in the I2S gene

Confirmation of dosing per product label

Related laboratory findings (eg, urinary glycosaminoglycans)

Documentation of neurologic manifestations consistent with MPS II. These can include\*\*:

- Cognitive impairment or developmental delay (eg, neuropsychological or developmental assessment)
- Behavioral problems, including hyperactivity, impulsivity, attention deficit, aggression (eg, specialist evaluation documenting behavioral impairment)
- Brain structural abnormalities, including hydrocephalus, white matter, corpus callosum (eg, brain MRI/CT report)
- Seizures (eg, neurology consult note and/or EEG report)
- Other relevant neurologic examination findings (eg, abnormal reflexes)

Other clinical signs & symptoms

Imaging and specialist evaluations (eg, EKG/ECHO, MRI, PFTs)

Documentation of prior therapy

Baseline hemoglobin level

Lack of efficacy from prior/current treatments

## 3. PA Submission

Review the PA form — confirm all required fields and plan-specific criteria are complete (incomplete forms are the main reason for denials)

Verify submission method — check with the health plan (via phone, fax, email, website, or portal)

Submit the PA form with all required documentation

- Consider including a Letter of Medical Necessity to support clinical rationale and a more efficient review process

## 4. PA Approvals

Orsini is Denali's commercial specialty pharmacy partner for AVLAYAH. If you are using Orsini, please fax the PA approval letter from the patient's health plan to 1-847-879-9551 or provide approval details by phone at **1-800-410-8575**

If your institution's pharmacy acquires the drug product directly, please follow your organization's standard process for PA documentation

## 5. PA Denials

If a PA is denied, consider an Appeal Letter to justify clinical rationale for treatment

## 6. Reauthorizations

Document evidence of positive clinical response compared with baseline using methods required and/or permitted by the payer's reauthorization policy

\*These examples are illustrative and non-exhaustive; other evidence of neurologic manifestation consistent with MPS II may also be submitted.

\*\*Neurologic manifestations in MPS II are described in Lau H, et al. *Mol Genet Metab Rep.* 2023;37:101005, and Yund B, et al. *Mol Genet Metab.* 2015;114(2):170-177. These may be referenced to support documentation as needed.