# AVLAYAH™ (tividenofusp alfa-eknm) Start Form

**Phone:** 1-844-DNLI365 (1-844-365-4365) | **Fax:** 1-650-456-1875 | www.AVLAYAH.com | patientservices@care.dnli.com

DENALI Patient Services

## How to Get Started for Patients and Caregivers

### About Denali Patient Services

Denali Patient Services provides support to help patients and caregivers navigate access to treatment. By completing this form, you authorize our team to provide assistance with understanding insurance coverage, exploring financial assistance options, and treatment coordination. Our team can also answer questions and, if requested, provide educational materials related to treatment and opportunities to connect with the Denali Patient Services team.

### To Receive Support

You must first **complete and sign this form on page 2** before Denali Patient Services can provide access support. Your healthcare provider will also need to complete their portion of the form. If you have questions about these services or this form, please call us at **1-844-DNLI365 (1-844-365-4365)**.

You can choose not to sign this form. Without your signature on page 2, Denali cannot provide the access services outlined. Enrollment in this program does not impact your ability to obtain your Denali product from your healthcare provider or health insurance plan.

## Please Follow These Steps

### 1. Review

Read pages 1 and 2

### 2. Sign

Fill in your information and sign where indicated on page 2

### 3. Submit Your Form

**Fax:** Complete and fax it to **1-650-456-1875**

**Online Submission:** Contact Denali Patient Services for online submission options

**Please note:** Your healthcare provider has to complete the prescriber section of their form before we can begin helping with access support, such as understanding insurance coverage, exploring financial assistance options, and treatment coordination. Your authorization is also required to allow Denali to provide core services and any additional optional services you request.

**If you and your healthcare provider complete and submit your sections separately, that's okay. Denali Patient Services will combine both parts once received.**

### Core Services (receive automatically): Once this form is completed and signed, Denali Patient Services will assign you a dedicated representative who will support you with:

- Work with your health insurance company to understand or verify coverage for Denali products and administration benefits
- Determine your eligibility for financial assistance programs and facilitate enrollment if eligible (e.g., copay card)
- If eligibility criteria are met, help coordinate temporary product access to keep treatment on track while insurance coverage is being verified or re-established. This support is available for up to 2 months and provided at no cost to eligible patients
- Provide logistics support and coordinate with your healthcare provider's office, infusion site, and pharmacy
- Contact you using the information provided to discuss insurance coverage, treatment costs, and available assistance for core services

**Additional Services (at your request):** If you would like, Denali Patient Services may also provide additional services. These services are optional and do not affect your ability to receive help with insurance, financial assistance, or treatment coordination. At your request, we may:

- Provide additional education and materials about your condition or Denali product
- Connect you with the Denali Patient Services team for virtual or in-person support
- Send you communications at the contact information provided to share additional product-related information or other requested educational materials. By providing your mobile number, you agree to receive recurring messages from Denali. Message frequency may vary, and messaging and data rates may apply. You can opt out any time by texting STOP or clicking the unsubscribe link on email messages

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## Authorization to Use and Disclose Personal Health Information

### Please review and complete to enroll in Denali Patient Services

I authorize my doctors, their staff, pharmacies, and health insurance plan (together, my "healthcare providers") to share my personal information with Denali Patient Services. This may include contact, financial, medical, treatment, and health insurance and benefits information. My healthcare providers and Denali Patient Services (including its partners, affiliates, subcontractors, and agents) may use and share this information only as needed and only with the parties listed to provide the services described on this form. This may also include optional educational or product-related materials and support if I request them.

I understand that I do not have to sign this authorization. Denali Patient Services cannot provide services without it. My healthcare providers cannot deny me treatment, payment, enrollment, or insurance coverage if I do not sign.

### I also understand and agree that:

- This authorization is valid for six (6) years from the date I sign, or the date I last enrolled, whichever comes first, unless I cancel it sooner or the law requires a shorter period. If I choose, I may re-enroll in Denali Patient Services by completing a new authorization form
- The information shared under this authorization may include sensitive health information, used only to check if I qualify for and to provide me with the services outlined in this form
- Denali Patient Services may share my information with my healthcare providers, program partners, and any alternate contact I choose
- Denali Patient Services may contact me using the information I provide on this form, to provide the core access services described in this form, such as coverage updates, financial assistance information, and help with my access questions. Denali may also use this contact information to share additional educational and product-related materials, or optional opportunities to provide feedback, but only if I choose to receive these additional services
- My pharmacy may be paid for providing my information to Denali Patient Services and for using my information as required for Denali Patient Services to provide the services in this form
- My information may be combined with other patients' information and used in a de-identified way for program reporting, quality improvement, analytics, and to improve Denali's patient services and communications
- I may cancel this authorization anytime by writing to Denali Therapeutics at: **Denali Therapeutics | 161 Oyster Point Blvd. South San Francisco, CA 94080**
  - If I cancel, Denali will stop services, and my providers will stop regular disclosures once notified. Revocation won't affect information already used or shared before Denali receives my notice
- I also have a right to receive a copy of this authorization
- Once shared, my information may no longer be protected by HIPAA or other privacy laws. Denali will only use it as described here or as allowed by law
- Enrollment does not guarantee coverage or access to any benefit or service
- Denali reserves the right to discontinue or change services at any time
- More information about my privacy rights, including state-specific rights, is available in Denali Therapeutics' Privacy Policy at **https://www.denalitherapeutics.com/privacy-policy**

### Please Complete This Section (to be signed by patient or their legally authorized representative) (*required)

*Name (First, Middle Initial, Last) .....

Patient's Date of Birth (MM/DD/YYYY) ..... / ..... / .....

Preferred Language: ☐ English ☐ Spanish ☐ Other .....

Alternate Contact (optional): Full Name .....

Relationship to Patient .....

Email .....

Home Phone .....

Cell Phone .....

**Note: The following information is optional and may help us better support you.**

Patient's State

Patient's ZIP

☐ **Consent to Stay Informed**

**By checking this box,** I agree to receive information such as product education, resources, event details, and other support materials at the contact information I provide. These may include, but are not limited to, materials to support you through your treatment journey. Participation is voluntary and not required for enrollment or treatment. Message frequency may vary, and messaging and data rates may apply. I can opt out anytime by texting STOP or clicking the unsubscribe link on email messages.

**REQUIRED:** By signing below, I confirm that I have read and understand this authorization, and I agree to the use and disclosure of my information as described.

SIGN HERE .....

*Signature of Patient/Legally Authorized Representative
(A parent or guardian must sign for patients under 18 years of age)

..... / ..... / .....

*Date Signed (MM/DD/YYYY)

**Person signing** (if not patient)

Print first name .....

Print last name .....

Relationship to patient .....

**If you have any questions, talk to your healthcare provider or call us at 1-844-DNLI365 (1-844-365-4365) Monday-Friday 8:30 AM – 8 PM ET**



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## Healthcare Provider Section (to be completed by the provider)

Healthcare providers should review and complete page 3, then submit the form by fax. Please do not include any patient medical records with the submission. Ensure that the patient/caregiver reads pages 1 and 2, and completes page 2 to provide the required authorizations.

### 1. Prescribing Physician Information

**Items marked with * are required.**

| | | | |
|---|---|---|---|
| *Name (First, Middle Initial, Last) | | Practice Name | |
| *Street | *City | *State | *ZIP |
| NPI† | Tax ID | State License | |
| Office Contact | Telephone | Fax | Email |

### 2. Site-of-Care Information

| | | | | |
|---|---|---|---|---|
| Site-of-Care Name | ☐ Home Infusion (if checked, provide address of the Home Infusion Company below) | | | |
| Street | City | State | ZIP | |
| Office Contact | Telephone | Fax | Email | NPI† |

### 3. Patient Information

| | | | |
|---|---|---|---|
| *Name (First, Middle Initial, Last) | | | |
| ☐ Male ☐ Female Patient Weight (Kg) | | *DOB (MM/DD/YYYY) / / | |
| *Street | *City | *State | *ZIP |
| Home Phone | Cell Phone | Email | |
| Caregiver Name (First, Last) | | Caregiver Email | |
| Caregiver Telephone | | Relationship to Patient | |

### 4. Diagnosis and Clinical Information

| | | | |
|---|---|---|---|
| *Diagnosis Code | ☐ E76.1 (MPS II) | ☐ Other | |
| Prior/Current Therapy | ☐ Elaprase | ☐ AVLAYAH (tividenofusp alfa-eknm) | ☐ Other |
| Expected AVLAYAH Start Date (if known) / / | | Other Last Date of Treatment (if known) / / | |

### 5. Insurance Information

Please complete the information below or attach copies of both sides of the patient's insurance card(s).

☐ Check if the patient does *not* have insurance

| | Primary Insurance | Secondary Insurance |
|---|---|---|
| Insurance Name | | |
| Policy/Member ID | | |
| Group # | | |
| Policyholder Name (First, Last) | | |
| Relationship to Patient (if policyholder is not the patient) | | |
| Insurance Telephone | | |

| | | |
|---|---|---|
| Pharmacy Plan Name | Policy/Member ID | Pharmacy Plan Telephone |
| Rx BIN # | Rx PCN | Group # |

By signing this form, I certify that the Denali product is medically necessary for the patient identified in this application ("Patient"). I have reviewed the current product Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to Denali Product, including its agents or contractors, for the purpose of seeking information related to coverage and/or assisting in initiating or continuing Denali Product. I authorize Denali Patient Services to transmit this prescription to the appropriate pharmacy as designated by the Patient's health plan and/or Denali's dispensing network. I agree that any product provided through the Program shall only be used for this Patient, is provided at no cost, and must not be billed, resold, offered for sale or trade, or returned for credit. I understand that Patient's enrollment does not guarantee coverage or reimbursement, and it is my responsibility to complete and submit all forms and paperwork necessary for reimbursement.

**SIGN HERE**

***Prescriber Signature (required; stamps not acceptable)**

***Date Signed (MM/DD/YYYY)** / /

†National Provider Identifier.



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