UTAH MEDICAID PHARMACY PRIOR AUTHORIZATION REQUEST FORM

Skysona (elivaldogene autotemcel)

Member and Medication Information * indicates required field	
*Member ID:	*Member Name:
*DOB:	*Weight:
*Medication Name/ Strength:	
☐ Do Not Substitute. Authorizations will be processed for the preferred Generic/Brand equivalent unless specified.	
*Directions for use:	
Provider Information * indicates required field	
*Requesting Provider Name:	*Requesting Prescriber NPI:
Address:	
*Contact Person:	*Office Phone:
*Office Fax:	*Office Email:
Medically Billed Information * indicates required field for all medically billed products	
*Diagnosis Code:	*HCPCS Code:
*Dosing Frequency:	*HCPCS Units per Dose:
Servicing Provider Name:	NPI:
Servicing Provider Address:	
Facility/Clinic Name:	NPI:
Facility/Clinic Address:	
Fax form and relevant documentation including: laboratory results, chart notes and/or updated provider letter to Pharmacy PA at **855-828-4992**, to prevent processing delays.	

Criteria for Approval: (*All* of the following criteria must be met)

1. Is the requested therapy for a patient 4-17 years of age? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of the following:? ❑ **Yes** ❑ **No**
   - ☐ Early (asymptomatic or mildly symptomatic), active cerebral adrenoleukodystrophy (CALD) and **ALL** of the following are met:
     - ☐ With neurologic function score, NFS ≤ 1 **AND**
     - ☐ Gadolinium enhancement (GdE+) on brain magnetic resonance imaging (MRI) **AND**
     - ☐ Loes scores of 0.5-9 (inclusive) on the 34-point scale **AND**
     - ☐ Confirmed mutation(s) in the *ABCD1* gene, and elevated very-long chain fatty acids (VLCFAs)
3. Is the medication being prescribed by or in consultation with a provider specializing in the treatment of CALD (i.e. hematologist, neurologist, or a stem cell transplant specialist)? ❑ **Yes** ❑ **No**
4. Is a human leukocyte antigen (HLA)-matched related donor unavailable for allogeneic hematopoietic cell transplantation (allo-HCT)? ❑ **Yes** ❑ **No**
5. Does the patient have normal blood counts without signs and symptoms of bleeding prior to collection of cells for manufacturing? ❑ **Yes** ❑ **No**
6. Is the patient negative for active infection, including the following, prior to collection of cells for manufacturing? ❑ **Yes** ❑ **No**

- ☐ Patient has negative serology tests for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2), and Human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2)

7. Does the provider attest that the patient does **NOT** have any of the following? ❑ **Yes** ❑ **No**
   - ☐ A full *ABCD1* gene deletion
   - ☐ Prior hematopoietic stem cell transplantation
   - ☐ Prior receipt of gene therapy
   - ☐ CALD secondary to head trauma
8. Does the provider attest to the following recommendations for monitoring and counseling:? ❑ **Yes** ❑ **No**
   - ☐ Monitoring for the development of malignancy:
     - ☐ Complete blood count checks at least every 3 months
     - ☐ Have thorough assessments for evidence of clonal expansion or predominance at least twice in the first year following Skysona administration and annually thereafter
   - ☐ Monitoring for the development of serious infections, cytopenia, and other hematologic disorders
   - ☐ Counseling to ensure use of adequate contraception methods for fertile patients and their partners

Initial Authorization: Once for a one (1) time treatment

Note:

- ❖ Hematologic malignancies, including life-threatening cases of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), have occurred in 10 of 67 (15%) Skysona trial participants.
- ❖ Monitor patients closely for evidence of malignancy through complete blood counts at least every 3 months for at least the first 15 years after treatment and through assessments for evidence for clonal expansion or predominance at least twice in the first year and annually thereafter; consider bone marrow evaluations as clinically indicated.
- ❖ Provider shall review and submit additional Ultra High Cost Drug Forms below at: https://medicaid.utah.gov/pharmacy/resource-library/
  - ➢ UHCD Written Claim of Business Confidentiality Form
  - ➢ Ultra High Cost Drug Invoice Submission Form

PROVIDER CERTIFICATION

I hereby certify this treatment is indicated, necessary and meets the guidelines for use.

_____ _____

Prescriber's Signature Date