OPTIMA HEALTH PLAN

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: Skysona® (elivaldogene autotemcel) **(J3590/C9399) (Medical)**

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

❑ 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.

Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:
- **Skysona up to 2 infusion bags, 20 mL/infusion bag, overwrap, and metal cassette: 73554-2111-xx**
- **A single dose of Skysona containing a minimum of 5.0 × 10^6 CD34+ cells/kg of body weight, in one or more infusion bags**

B. Max Units (per dose and over time) [HCPCS Unit]:
- **A single dose of Skysona containing a minimum of 5.0 × 10^6 CD34+ cells/kg of body weight, in one or more infusion bags**

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.

Authorization Criteria: Coverage will be provided for one treatment course (1 dose of Skysona) and may not be renewed.

❑ Member is a male at least 4 years of age and less than 18 years of age

❑ Member has a documented diagnosis of cerebral adrenoleukodystrophy (CALD) as defined by at least **ONE** the following **(laboratory results MUST be submitted)**:

(Continued on next page)

- ❑ Elevated very long chain fatty acids (VLCFA) value for **ALL** the following:
  - ❑ Concentration of C26:0
  - ❑ Ratio of C24:0 to C22:0
  - ❑ Ratio of C26:0 to C22:0
- ❑ Pathogenic variants in the ABCD1 gene detected by molecular genetic testing

❑ Member has active central nervous system (CNS) disease established by central radiographic review of brain magnetic resonance imaging (MRI) demonstrating **BOTH** of the following **(current MRI results MUST be submitted)**:
- ❑ Loes score between 0.5 and 9 (inclusive) on the 34-point scale
- ❑ Gadolinium enhancement on MRI of demyelinating lesions

❑ Member does **NOT** have a full ABCD1-gene deletion **(Note: Rapid loss of efficacy due to immune response may result)**

❑ Neurologic Function Score (NFS) ≤ 1 (asymptomatic or mildly symptomatic disease) **[assessment must be current; completed in the past 30 days]**

❑ Member has been screened for hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotrophic virus 1 & 2 (HTLV-1/HTLV-2), and human immunodeficiency virus 1 &2 (HIV-1/HIV-2) in accordance with clinical guidelines prior to collection of cells (leukapheresis)

❑ Member does **NOT** have an active infection, including clinically important localized infections

❑ Prophylaxis for infection will be followed according to standard institutional guidelines

❑ Vaccinations will **NOT** be administered within the 6-weeks prior to the start of therapy and will **NOT** be administered concurrently while on therapy **AND** member is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy

❑ Requested medication will be used as single agent therapy (not applicable to lymphodepleting or bridging therapy while awaiting manufacture)

❑ Member will receive periodic life-long monitoring for hematological malignancies (Myelodysplastic syndrome [MDS] has developed in patients treated in clinical studies with a varied clinical presentation)

❑ Member will avoid concomitant therapy with anti-retroviral medications for at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are completed **(Note: if a member requires anti-retroviral for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization)**

❑ Member does **NOT** have head trauma induced disease

❑ Medication will **NOT** be used to prevent the development of or treat adrenal insufficiency due to adrenoleukodystrophy

❑ Member is eligible to undergo hematopoietic stem cell transplant (HSCT) and has **NOT** had a prior allogeneic-HSCT

❑ Males capable of fathering a child and their female partners of childbearing potential should use an effective method of contraception (e.g., intra-uterine device or combination of hormonal and barrier contraception) from start of mobilization through at least 6 months after administration of Skysona

❑ Provider attests a human leukocyte antigen matched related HSC donor is **NOT** available

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(Please ensure signature page is attached to form.)

Medication being provided by a Specialty Pharmacy - PropriumRx

- ❑ **Location/site of drug administration:** _____
- ❑ **NPI or DEA # of administering location**: _____

OR

- ❑ **Specialty Pharmacy - PropriumRx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima'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.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR /NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 11/18/2022
REVISED/UPDATED: 11/29/2022;