Cigna Healthcare Gene Therapy Prior Auth Request Form

This therapy requires supportive documentation (chart notes, genetic test results, etc.).

****Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) fields on this form are completed****

Gene Therapy Prior Authorization

To allow more efficient and accurate processing of your medication request, please complete this form and fax it back along with copies of all supporting clinical documentation. Fax completed form to Fax# 833-910-1625.

Notice: Failure to complete this form in its entirety may result in delayed processing or an adverse determination for insufficient information.

Gene Therapy Product Name **Skysona**

Cigna has designated the above product to be a gene therapy product, which is included in the Cigna Gene Therapy Provider Network.

Questions pertaining to gene therapy may be directed to the dedicated Gene Therapy Program team at 855.678.0051 or email to GeneTherapyProgram@Cigna.com

PHYSICIAN INFORMATION			PATIENT INFORMATION		
* Physician Name:			*Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.*		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Customer Name:		
Office Phone:			* Cigna ID:	*Customer Date of Birth:	
Office Fax: *Is your fax machine kept in a secure location? ☐ Yes ☐ No *May we fax our response to your office? ☐ Yes ☐ No			* Customer/Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		

Urgency:
☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

Where will this medication be obtained?
☐ CVS Specialty Pharmacy
☐ Other (please specify):

ICD10:

Name of Facility administering medication:
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

Clinical Information – Skysona

Does your patient have a documented diagnosis of Cerebral Adrenoleukodystrophy?
☐ Yes
☐ No
☐ Unknown

Is your patient 4 years of age to 17 years of age?
☐ Yes
☐ No

Is there documentation of adrenoleukodystrophy as demonstrated by meeting BOTH of the following? (Please include copy of these results)
☐ Genetic confirmation of a pathogenic variant, or likely pathogenic variant, in the adenosine triphosphate binding cassette, sub family D member 1 (ABCD1) gene
☐ Elevated very long chain fatty acid levels according to the standard reference values of the performing laboratory

Is there documentation of early, active cerebral adrenoleukodystrophy as demonstrated by meeting ALL of the following? (Please include copy of these results)
☐ Neurologic function score (NFS) less than or equal to 1
☐ Gadolinium enhancement (GdE+) on brain magnetic resonance imaging (MRI)
☐ Loes score between 0.5 and 9

Is there Documentation of ALL of the following? (Please include copy of these results)
☐ Aspartate aminotransferase values are no greater than 2.5 times the upper limit of normal
☐ Alanine aminotransferase values are no greater than 2.5 times the upper limit of normal
☐ Total bilirubin values are no greater than 3.0 mg/dL
☐ Peripheral blood absolute neutrophil count of at least 1,500 cells/mm3
☐ Platelet count of at least 100,000 cells/mm3
☐ Hemoglobin of at least 10 g/dL
☐ No uncorrected bleeding disorder
☐ Estimated creatinine clearance is at least 50 mL/min OR Estimated glomerular filtration rate is at least 70 mL/minute/1.73 m2
☐ Adequate cardiac function as evidenced by a left ventricular ejection fraction greater than 40%
☐ Prior to collection of cells for manufacturing, your patient is negative for Hepatitis B virus
☐ Prior to collection of cells for manufacturing, your patient is negative for Hepatitis C virus
☐ Prior to collection of cells for manufacturing, your patient is negative for Human T-lymphotropic virus 1 and 2
☐ Prior to collection of cells for manufacturing, your patient is negative for Human immunodeficiency virus 1 and 2

According to the prescriber, the patient does NOT have ANY of the following:
☐ No active bacterial, viral, fungal or parasitic infection
☐ No prior or current malignancy or myeloproliferative disorder
☐ No familial cancer syndrome or a history of such in their immediate family

According to prescriber, patient is unable to receive stem cell transplant due to ONE of the following:
☐ Patient is without a matched HLA family donor
☐ A matched family donor is unwilling to donate

According to the prescriber, hematopoietic stem cell transplantation procedure is appropriate for the individual
☐ Yes
☐ No
☐ Unknown

Medication is prescribed by a hematologist, a neurologist, and/or a stem cell transplant specialist?
☐ Yes
☐ No
☐ Unknown

Does the patient have a prior history of having a hematopoietic stem cell transplant?
☐ Yes
☐ No
☐ Unknown

Does the patient have prior history of receiving a gene therapy?
☐ Yes
☐ No
☐ Unknown

If any of the requirements listed above are not met and provider feels administration of Skysona is medically necessary please provide clinical support and rationale for the use of Skysona.

Additional pertinent information: *(including disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)*

Additional CPT and Administration Codes for Consideration Following Medical Necessity Determination

Cell Collection

☐ 96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
☐ 38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
☐ Other

Select applicable G-CSF (Cigna preferencing may apply)

☐ J2562 Injection, plerixafor, 1 mg (Mozobil) Plus
Directions for use: Dose: Quantity: Duration of therapy:
☐ J1442 Injection, filgrastim (G-CSF), excludes biosimilar, 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ J1447 Injection, tbo-filgrastim, 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Q5101 Injection, filgrastim-sndz, biosimilar, (Zarxio), 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Q5110 Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 mcg
Directions for use: Dose: Quantity: Duration of therapy:
☐ Other
Directions for use: Dose: Quantity: Duration of therapy:

Conditioning Regimen

☐ J0594 Injection, busulfan, 1 mg
☐ Other

Please indicate any other CPT codes that will be billed for administration

☐ Other

Additional Attestation required for Embarc Benefit Protection* Criteria when applicable

According to the prescribing physician:
☐ Your patient is able to undergo monitoring by magnetic resonance imaging
☐ Your patient plans to undergo mobilization, apheresis, myeloablative conditioning and lymphodepletion
☐ A granulocyte-colony stimulating factor product and Mozobil (plerixafor subcutaneous injection) will be utilized for mobilization
☐ Busulfan will be used for myeloablative conditioning
☐ Cyclophosphamide or fludarabine will be used for lymphodepletion
☐ Your patient has received or is planning to receive prophylaxis for hepatic veno-occlusive disease/hepatic sinusoidal obstruction syndrome before conditioning
☐ If your patient (or their partner) is of childbearing potential, will be using an effective method of contraception from the start of mobilization through at least 6 months after administration of Skysona

**For additional information on Embarc Benefit Protection refer to the Cigna Reference Guide of physicians, physicians, hospitals, ancillaries, and other health care providers. This guide is available at CignaforHCP.com > Resources > Reference Guides > Medical Reference Guides: View Documents > Health Care Professional Reference Guides. Providers must log in to access.*

Additional Attestation required for Embarc Benefit Protection* Criteria when applicable.
Has your patient received the requested gene therapy in the past?

☐ Yes
☐ No
☐ Unknown

**For additional information on Embarc Benefit Protection refer to the Cigna Reference Guide of physicians, physicians, hospitals, ancillaries, and other health care providers. This guide is available at CignaforHCP.com > Resources > Reference Guides > Medical Reference Guides: View Documents > Health Care Professional Reference Guides. Providers must log in to access.*

Agreement and Attestation

Do you and your patient agree to share any required plan specific outcome measures?
☐ Yes
☐ No

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature:_____ Date:_____

v032824

 Address: Cigna Pharmacy Services, PO Box 42005, Phoenix AZ 85080-2005