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?

☐ Buy and Bill / Office Stock
☐ Contracted SRx Name]
☐ Other (please specify):

What location will this medication be administered?

☐ Outpatient Hospital ☐ Inpatient Hospital ☐ MD Office / Clinic

☐ Home ☐ Other

ICD 10 Associated with the Indication of this request:

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

Skysona is considered medically necessary when the following criteria are met, check all that apply:

☐ Patient is male*; AND

☐ Patient is ≥ 4 and < 18 years of age; AND

☐ Patient has not received Skysona in the past [verification in claims history required]; AND
Note: If no claim for Skysona is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Skysona.

☐ Patient has early, active cerebral adrenoleukodystrophy as demonstrated by meeting **ALL** of the following (i, ii, and iii):
- ☐ i. Patient has a neurologic function score ≤ 1 **[documentation required]**; AND
- ☐ ii. Patient has gadolinium enhancement on brain magnetic resonance imaging (MRI) **[documentation required]**; AND
- ☐ iii. Patient has a Loes score between 0.5 and 9 **[documentation required]**; AND

☐ Patient has a pathogenic variantin the adenosine triphosphate binding cassette, sub family D member 1 (*ABCD1*) gene **[documentation required]**; AND

☐ Patient has elevated very long chain fatty acid levels according to the standard reference values of the laboratory **[documentation required]**; AND

☐ Patient meets ONE of the following (i or ii):
- ☐ i. Patient does not have a Human Leukocyte Antigen (HLA)-matched donor; OR
- ☐ ii. Patient has an HLA-matched donor, but the individual is not able or is not willing to donate; AND

☐ Patient does not currently have an active bacterial, viral, fungal, or parasitic infection; AND

☐ Patient **does not** have any of the following (i and ii):
- ☐ i. Prior or current hematologic malignancy or myeloproliferative disorder; AND
- ☐ ii. Familial cancer syndrome or a history of such in his immediate family; AND

☐ According to the prescribing physician, hematopoietic stem cell transplantation is appropriate for the patient; AND

☐ Patient has undergone liver function testing within the past 30 days and meets **ALL** the following (i, ii, and iii):
- ☐ i. Aspartate aminotransferase level is ≤ 2.5 times the upper limit of normal **[documentation required]**; AND
- ☐ ii. Alanine aminotransferase level is ≤ 2.5 times the upper limit of normal **[documentation required]**; AND
- ☐ iii. Total bilirubin level is ≤ 3.0 mg/dL **[documentation required]**; AND

☐ Within the past 30 days, the patient meets **ONE** of the following (i or ii):
- ☐ i. Estimated creatinine clearance ≥ 50 mL/minute **[documentation required]**; AND
- ☐ ii. Estimated glomerular filtration rate ≥ 70 mL/minute/1.73 m^2 **[documentation required]**; AND

☐ According to the prescribing physician, patient does not have evidence of cardiac compromise; AND

☐ Prior to collection of cells for manufacturing, screening is negative for **ALL** of the following (i, ii, iii, and iv):
- ☐ i. Hepatitis B virus **[documentation required]**; AND
- ☐ ii. Hepatitis C virus **[documentation required]**; AND
- ☐ iii. Human T-lymphotropic virus 1 and 2 **[documentation required]**; AND
- ☐ iv. Human immunodeficiency virus 1 and 2 **[documentation required]**; AND

☐ Within the past 30 days, the patient meets **ALL** the following (i, ii, and iii):
- ☐ i. Peripheral blood absolute neutrophil count ≥ 1,500 cells/mm^3 **[documentation required]**; AND
- ☐ ii. Platelet count ≥ 100,000 cells/mm^3 **[documentation required]**; AND
- ☐ iii. Hemoglobin ≥ 10 g/dL **[documentation required]**; AND

☐ Patient meets **ALL** of the following (i, ii, iii, and iv):
- ☐ i. Patient will undergo mobilization, apheresis, myeloablative conditioning, and lymphodepletion; AND
- ☐ ii. A granulocyte-colony stimulating factor product will be used for mobilization; AND
- ☐ iii. Busulfan will be used for myeloablative conditioning; AND
- ☐ iv. Cyclophosphamide or fludarabine will be used for lymphodepletion; AND

☐ Medication is prescribed by a hematologist, a neurologist, and/or a stem cell transplant specialist

☐ Current patient body weight has been obtained within the past 30 days **[documentation required]**

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 recent history and physical, recent lab work, disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)

Any other use is considered experimental, investigational, or unproven, including the following, check all that apply:

☐ **Patient has a Full *ABCD1* Gene Deletion.** In one patient involved in the Skysona clinical trials who had a full *ABCD1* gene deletion, disease progression occurred.[1,9] The patient experienced radiologic disease progression, along with declining peripheral blood vector copy number, suggesting a loss of product efficacy which may have been immune mediated. The patient eventually underwent allogeneic HSCT for treatment. A noted limitation of use is that an immune response to Skysona may limit the persistence of descendent cells of Skysona, causing rapid loss of efficacy of Skysona in patients with full deletions of the *ABCD1* transgene.

☐ **Prior Hematopoietic Stem Cell Transplantation**.
Note:Prescribing physician must confirm that the patient has not received a prior hematopoietic stem cell transplantation. Prior allogeneic hematopoietic stem cell transplant was an exclusion criterion in the pivotal studies.

☐ **Prior Receipt of Gene Therapy**. This was an exclusion criterion in the pivotal studies.

If any of the above apply to your customer, please provide clinical support and rationale for the use of this gene therapy

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

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:_____

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