

Hematopoietic Agents – Sickle Cell Disease Cell and Gene Therapies

Medical policy no. 82.80.40-1

Effective Date: 1/1/2026

Related medical policies:

Policy Name
82.80.10 Hematopoietic Agents – Sickle Cell Anemia L-glutamine (Endari)
82.80.50.AA Hematopoietic Agents – Sickle Cell Anemia voxelotor (Oxbryta)
82.80.70.20 Hematopoietic Agents – Sickle Cell Anemia crizanlizumab (Adakveo)

Apple Health participates in the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) Cell and Gene Therapy Access Model. Under this model, treatment centers that provide gene therapies for sickle cell disease (gene therapies for beta-thalassemia are not included at this time) must be members of the CMS Designated Registry through the Center for International Blood and Marrow Transplant Research (CIBMTR). Treatment centers must be enrolled in CIBMTR before administering gene therapies for sickle cell disease to Apple Health clients.

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: <https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

Medical necessity

Drug	Medical Necessity
Exagamglogene autotemcel (Casgevy) Lovotibeglogene autotemcel (Lyfgenia)	<p>Hematopoietic Agents – Sickle Cell Disease Cell and Gene Therapies may be considered medically necessary in patients who meet the criteria described in the clinical policy below.</p> <ul style="list-style-type: none"> Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in Non-Clinical Policy No 0001 (NC-001).

	If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.
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Clinical policy:

Clinical Criteria	
<p>Sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOC) Exagamglogene autotemcel (Casgevy)</p>	<p>Exagamglogene autotemcel (Casgevy) may be approved when all of the following documented criteria are met:</p> <ol style="list-style-type: none"> 1. Patient is 12 years of age or older at expected time of gene therapy administration, AND 2. Prescribed by, or in consultation with a board-certified hematologist with SCD experience at a qualified treatment center; AND 3. Diagnosis of sickle cell disease as confirmed by genetic testing; AND 4. Prescriber attests that the patient is clinically stable and fit for hematopoietic stem cell transplantation; AND 5. Patient is not a prior recipient of gene therapy or an allogenic hematopoietic stem cell transplant; AND 6. Patient has prior use of hydroxyurea and, per health care professional judgment, hydroxyurea resulted in treatment failure, is contraindicated, or patient is intolerant; AND 7. Patient has experienced recurrent vaso-occlusive crises (VOCs), as defined by ONE of the following: <ol style="list-style-type: none"> a. Patient has experienced recurrent VOCs, defined as more than or equal to two (2) documented VOCs per year in the previous twenty-four (24) months, based on provider attestation; OR b. Patient is currently receiving chronic transfusion therapy for recurrent VOCs, based on provider attestation. <p>If ALL criteria are met, the request will be authorized for 12 months for a single, one time dose.</p>
Criteria (Reauthorization)	
	<p>Exagamglogene autotemcel (Casgevy) is a one-time gene therapy and should not receive reauthorization unless the previous prior authorization has expired AND the patient did not receive the gene therapy.</p>
<p>Sickle cell disease (SCD) with recurrent vaso-occlusive events (VOE)</p>	<p>Lovotibeglogene autotemcel (Lyfgenia) may be approved when all of the following documented criteria are met:</p> <ol style="list-style-type: none"> 1. Patient is 12 years of age or older at expected time of gene therapy administration, AND

<p>Lovotibeglogene autotemcel (Lyfgenia)</p>	<ol style="list-style-type: none"> 2. Prescribed by, or in consultation with a board-certified hematologist with SCD experience at a qualified treatment center; AND 3. Diagnosis of sickle cell disease as confirmed by genetic testing; AND 4. Prescriber attests that the patient is clinically stable and fit for hematopoietic stem cell transplantation; AND 5. Patient is not a prior recipient of gene therapy or an allogenic hematopoietic stem cell transplant; AND 6. Patient has prior use of hydroxyurea and, per health care professional judgment, hydroxyurea resulted in treatment failure, is contraindicated, or patient is intolerant; AND 7. Either ONE of the following: <ol style="list-style-type: none"> a. Patient is currently receiving chronic transfusion therapy for recurrent vaso-occlusive event (VOEs); OR b. Experienced four or more VOEs requiring medical treatment in the previous 24 months, based on provider attestation <p>If ALL criteria are met, the request will be authorized for 12 months for a single, one time dose.</p>
<p>Criteria (Reauthorization)</p>	
<p>Lovotibeglogene autotemcel (Lyfgenia) is a one-time gene therapy and should not receive reauthorization unless the previous prior authorization has expired AND the patient did not receive the gene therapy.</p>	

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Casgevy	Sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOC)	A single, one-time dose	<ul style="list-style-type: none"> • minimum dose of 3.0×10^6 CD34+ cells/kg
Lyfgenia	Sickle cell disease (SCD) with recurrent vaso-occlusive events (VOE)	A single, one-time dose	<ul style="list-style-type: none"> • minimum dose of 3.0×10^6 CD34+ cells/kg

Coding:

HCPCS Code	Description
J3392	Injection, exagamlogene autotemcel, per treatment
J3394	Injection, lovotibeglogene autotemcel, per treatment

Background:

Sickle cell disease (SCD) is a genetic disease caused by a mutation in the gene responsible for producing hemoglobin. The result of this mutation is that the body produces sickle hemoglobin, an abnormal type of hemoglobin which leads to anemia, resulting in serious complications, such as organ failure, severe pain, infections, and other complications.

Certain medications can be used to help alleviate symptoms and prevent complications. Among the newest options available are gene therapies which aim to replace the deficient gene with a functional copy that can produce normal, functioning hemoglobin. This clinical policy helps patients and providers determine when such gene therapies may be medically necessary and appropriate for specific patients.

History:

Approved Date	Effective Date	Version	Action and Summary of Changes
11/19/2025	01/01/2026	82.80.40-1	-New policy created -Approved by HCA

Appendix

Definitions	
Vaso-occlusive crises (VOC) or vaso-occlusive event (VOE)	<ul style="list-style-type: none"> An episode of sickle cell disease exacerbation that (1) may manifest as acute pain crises, acute chest syndrome, acute splenic sequestration, priapism, or splenic sequestration and (2) is diagnosed as such by a qualified medical professional within their scope of practice, and (3) requires treatment at a medical facility (e.g., emergency department, hospital)