

Sickle Cell Disease, Gene Therapy

Goal(s):

- Approve exagamglogene autotemcel (CASGEVY) and lovetibeglogene autotemcel (LYFGENIA) for conditions supported by evidence of benefit
- Incorporate 2-step review process for drugs on the high-cost drug carve-out list.

Length of Authorization:

- Once in a lifetime dose.

Requires PA:

- Exagamglogene autotemcel (billed as pharmacy or provider administered claim)
- Lovotibeglogene autotemcel (billed as pharmacy or provider administered claim)

Covered Populations:

- FFS and CCO enrolled populations beginning 1/1/26

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria for Sickle Cell Disease		
1. What diagnosis is being treated?	Record ICD10 code. <ul style="list-style-type: none"> • For sickle cell disease, continue to question #2; • For beta thalassemia and patient is enrolled in fee-for-service, go to “Approval Criteria for Beta Thalassemia” section below 	
2. Is this an FDA approved indication?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is there documentation that the patient has never received another gene therapy or hematopoietic stem cell transplant for any diagnosis?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Is the medication being ordered by, or in consultation with, a hematologist?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria for Sickle Cell Disease

<p>5. Does the patient have Sickle Cell Disease with recurrent vaso-occlusive crisis (VOC)?</p> <p>Note: Recurrent VOC defined as at least 4 or more VOC events in previous 24 months or receiving chronic transfusion therapy for recurrent VOC based on provider attestation. If lacking provider attestation, documentation of VOCs could include, but are not limited to, acute chest syndrome, priapism lasting > 2 hours and requiring visit to medical facility, acute pain event requiring visit to medical facility (with pain medications [e.g. opioids, injectable non-steroidal anti-inflammatory drugs] or red blood transfusion), acute splenic sequestration, or acute hepatic sequestration.</p>	<p>Yes: Go to #6</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>6. Is the patient 12 years old or older?</p>	<p>Yes: Go to #7</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>7. Does the prescriber attest that the patient's general health and comorbidities have been assessed and that the patient is expected to safely tolerate myeloablation?</p>	<p>Yes: Go to #8</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>8. Will the drug be administered at an authorized treatment center in Oregon who is participating in the CMMI Access Model?</p> <p>Note: As of 1/1/26, Oregon Health and Science University is the only participating and authorized treatment center in Oregon.</p>	<p>Yes: Pass to RPh. Pend; Refer to DMAP for secondary review.</p> <p>Note: Approvals cover one-time infusion for the lifetime of the patient. Approval are valid for 12 months and will be extended if needed to cover treatment journey.</p>	<p>No: Go to #9</p>
<p>9. Is there documentation that gene therapies available at participating treatment centers are clinically inappropriate based on individual patient circumstances?</p>	<p>Yes: Pass to RPh. Pend; Refer to DMAP for secondary review.</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

Approval Criteria for Beta Thalassemia

<p>1. Is this an FDA approved indication?</p>	<p>Yes: Go to #2</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
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Approval Criteria for Beta Thalassemia

2. Is there documentation that the patient has never received another gene therapy or hematopoietic stem cell transplant for any diagnosis?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is the medication being ordered by, or in consultation with, a hematologist?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Does patient have confirmed beta thalassemia?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness
5. Is the patient transfusion dependent, defined as requiring in each of the past 2 years: <ul style="list-style-type: none"> • 100 mL/kg/year or more of packed red blood cells (any patient age) OR • 8 transfusions or more of packed red blood cells per year 	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness
6. Is the patient 12 years old or older?	Yes: Go to #7	No: Pass to RPh. Deny; medical appropriateness
7. Is there documentation that the patient does not have cirrhosis or advanced liver disease?	Yes: Go to #8	No: Pass to RPh. Deny; medical appropriateness
8. Is there documentation that the patient does not have HIV or active infections (acute or chronic) of either hepatitis B or hepatitis C?	Yes: Go to #9	No: Pass to RPh. Deny; medical appropriateness
9. Does the prescriber attest that the patient's general health and comorbidities have been assessed and that the patient is expected to safely tolerate myeloablation?	Yes: Go to #10	No: Pass to RPh. Deny; medical appropriateness
10. Is the patient of childbearing potential OR capable of fathering a child?	Yes: Go to #11	No: Go to #13
11. Is the patient pregnant, actively trying to conceive, or trying to father a child?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #12
12. Is there documentation that the provider and patient have discussed the teratogenic risks of the drug if the patient were to become pregnant or father a child during treatment and for at least 6 months after administration of the gene therapy?	Yes: Go to #13	No: Pass to RPh. Deny; medical appropriateness

Approval Criteria for Beta Thalassemia

13. Is there documentation that the provider and patient have discussed risks of myeloablative treatment on future fertility and options for fertility-preservation?

Yes: Pass to RPh. Pend; Refer to DMAP for secondary review.

Note: Approvals cover one-time infusion for the lifetime of the patient. Approvals are valid for 12 months and will be extended if needed to cover treatment journey.

No: Pass to RPh. Deny; medical appropriateness

*P&T/DUR Review: 8/25; 6/24 (SF)
Implementation: 9/15/25; 7/1/24*