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Prior Authorization Criteria Update: Gene Therapy for Sickle Cell Disease

Plain Language Summary:

- The Centers for Medicare and Medicaid Services is working with two drug companies and state Medicaid agencies to make two gene therapies approved for sickle cell disease more affordable.
- To participate in this program, the current prior authorization criteria must be changed.

Purpose of Update:

The Centers for Medicare & Medicaid Services has developed the Cell and Gene Therapy (CGT) Access Model with the manufacturers of LYFGENIA™ and CASGEVY®. This model allows for outcomes-based supplemental rebate arrangements and includes other features, such as manufacturer coverage of fertility preservation for patients receiving these myeloablative gene therapies. Participation requires modifications to currently approved prior authorization criteria for participation. Both agents will be "carved-out" of the Coordinated Care Organizations to be obtained from Fee-for-Service for the sickle cell disease indications. The carve-out does not extend to other Food and Drug Administration (FDA) approved indications or off-label uses.

Recommendation:

- Modify prior authorization criteria to allow the state to participate in the Cell and Gene Therapy Access Model for sickle cell disease gene therapies.
- Make exagamglogene autotemcel (CASGEVY®) and lovotibeglogene autotemcel (LYFGENIA™) preferred.

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August 2025

Appendix 1. Proposed Edits

Sickle Cell Disease, Gene Therapy

Goal(s):

- Approve Exagamglogene autotemcel (CASGEVY) and Lovotibeglogene autotemcel (LYFGENIA) for conditions supported by evidence of benefit

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)

Note: Any requests on behalf of a patient enrolled in a coordinated care organization (CCO) for an indication *other than* sickle cell disease should be sent to CCO.

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. • If for sickle cell disease, continue to question #2; • If for beta thalassemia and patient is enrolled in fee-for-service, go to “Approval Criteria for Beta Thalassemia” section below; • If for beta thalassemia and patient is enrolled in a coordinated care organization (CCO), request should be directed to that CCO.

Approval Criteria for Sickle Cell Disease		
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
5. Does the patient have Sickle Cell Disease with recurrent vaso-occlusive crisis (VOC)? Note: Recurrent VOC defined as at least 4 or moreVOC 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.	**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

Approval Criteria for Sickle Cell Disease		
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?	**Yes**: Approve for one-time infusion treatment for lifetime of the patient. Approval is valid for 12 months and will be extended if needed to cover treatment journey. Notify DMAP of approval.	**No:** Pass to RPh. Deny; medical appropriateness Notify DMAP of denial.

Approval Criteria for Beta Thalassemia		
1. Is this an FDA approved indication?	**Yes**: Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
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: • 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 #8	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria for Beta Thalassemia		
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
13. Is there documentation that the provider and patient have discussed risks of myeloablative treatment on future fertility and options for fertility-preservation?	**Yes:** Approve for one-time infusion treatment for lifetime of the patient. Approval is valid for 12 months and will be extended if needed to cover treatment journey.	**No:** Pass to RPh. Deny; medical appropriateness

Lovotibeglogene Autotemcel - Retire

Goal(s):

- Approve lovotibeglogene autotemcel (LYFGENIA) for conditions supported by evidence of benefit

Length of Authorization:

- Once in a lifetime dose.

Requires PA:

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

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		
1. What diagnosis is being treated?	Record ICD10 code.	
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		
5. Does the patient have Sickle Cell Disease with recurrent vaso-occlusive crisis (VOC)? Note: Recurrent VOC defined as at least 2 VOC events/year for more than one year. Examples of VOC include acute chest syndrome, priapism lasting > 2 hours and requiring visit to medical facility, acute pain event requiring visit to medical facility and pain medications (e.g. opioids, injectable non-steroidal anti-inflammatory drugs) or red blood transfusion, acute splenic sequestration, or acute hepatic sequestration.	**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 α-thalassemia trait (-α3.7/-α3.7) or more than two α-globin gene deletions?	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. 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 #10	**No:** Pass to RPh. Deny; medical appropriateness
10. 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 #11	**No:** Pass to RPh. Deny; medical appropriateness
11. Has the patient (and/or guardian, if applicable) been educated on the risk of insertional oncogenesis and need for lifelong monitoring (bloodwork) at every 6 months?	**Yes**: Go to #12	**No**: Pass to RPh. Deny; medical appropriateness
12. Is the patient of childbearing potential OR capable of fathering a child?	**Yes:** Go to #13	**No:** Go to #15

Approval Criteria		
13. Is the patient pregnant, actively trying to conceive, or trying to father a child?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #14
14. 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 #15	**No**: Pass to RPh. Deny; medical appropriateness
15. Is there documentation that the provider and patient have discussed risks of myeloablative treatment on future fertility and options for fertility-preservation?	**Yes:** Approve for one-time infusion treatment for lifetime of the patient.	**No:** Pass to RPh. Deny; medical appropriateness

P&T/DUR Review: 6/24 (SF)
Implementation: 7/1/24