Lovotibeglogene Autotemcel

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 physician 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
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

Approval Criteria		
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
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