Betibeglogene Autotemcel

Goal(s):

- Approve Betibeglogene Autotemcel (ZYNTEGLO) 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:

- Betibeglogene 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		
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 for any diagnosis?	**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 genotype documented?	**Yes:** Go to #6 Genotype_____	**No:** Pass to RPh. Deny; medical appropriateness
6. 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 (patients 12 years and older)	**Yes**: Go to #7	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
7. Is the patient 5 years old or older?	**Yes**: Go to #9	**No:** Go to #8
8. Does the patient weigh at least 6 kg?	**Yes**: Go to #9	**No:** Pass to RPh. Deny; medical appropriateness
9. Does the patient have cirrhosis or advanced liver disease?	**Yes**: Pass to RPh. Deny; medical appropriateness	**No:** Go to #10
10. Is there documentation that the patient does not have active or chronic infections of HIV, hepatitis B, or hepatitis C?	**Yes**: Go to #11	**No:** Pass to RPh. Deny; medical appropriateness
11. 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 #12	**No:** Pass to RPh. Deny; medical appropriateness
12. Has the patient (and/or guardian, if applicable) been educated on the risk of insertional oncogenesis and need for lifelong monitoring (bloodwork) at least annually?	**Yes**: Go to #13	**No**: Pass to RPh. Deny; medical appropriateness
13. Is the patient of childbearing potential OR capable of fathering a child?	**Yes:** Go to #14	**No:** Approve one lifetime dose.
14. Is the patient pregnant, actively trying to conceive, or trying to father a child?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #15
15. 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:** Pass to RPh. Pend; Refer to DMAP for secondary review. Duration: Approvals cover one lifetime dose. Approval are valid for 12 months and will be extended if needed to cover treatment journey.	**No**: Pass to RPh. Deny; medical appropriateness