Clinical Oversight Review Board (CORB) Criteria for Prescribing

lovotibeglogene autotemcel (Lyfgenia)

Notes:

- Quantity Limits: Yes (one time dose)

Non-Formulary **lovotibeglogene autotemcel (Lyfgenia)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria:

- Prescribed by Hematology provider
- Patient has a diagnosis of sickle cell anemia
- Patient must be 12-40 years old
- Patient must meet **ALL** the following criteria to be eligible:
  - Experienced hydroxyurea failure at any point in the past (defined as >1 VOC or ≥1 acute coronary syndromes [ACS] after taking hydroxyurea for at least three months) or must have intolerance to hydroxyurea (defined as inability to be maintained on an adequate dose of hydroxyurea due to marrow suppression or severe drug-induced toxicity [e.g. gastrointestinal distress, fatigue])
  - Severe SCD (defined as ≥2 of the following events per year during the two-year period before treatment initiation):
    - Acute pain requiring medical facility visit and administration of pain medications (opioids or IV non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions
    - Acute chest syndrome, as indicated by the presence of a new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever
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    - Splenic sequestration
  - Have a Karnofsky performance status of ≥80 or Lansky performance status ≥80 (if less than 16 years old)
  - Must have either failed or unable to find a matched related donor for allogenic stem cell transplant
  - Be medically eligible to undergo HSC transplant
  - Agrees to use effective contraception from start of mobilization through at least six months after gene therapy infusion
  - Consider a trial of L-glutamine for at least three to six months before considering gene therapy

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- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel with the recommendation to use medication