

Prior Authorization Criteria

CASGEVY® (exagamglogene autotemcel) PA CRITERIA for Sickle Cell Disease:

CASGEVY® (exagamglogene autotemcel) is an autologous genome edited hematopoietic stem cell-based gene therapy indicated for the treatment of patients aged 12 years and older with sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) or transfusion-dependent β -thalassemia (TDT).

Prior authorization is required for CASGEVY® (exagamglogene autotemcel) in sickle cell disease (SCD). Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

<u>Initial Authorization</u>: 12 Months. One single dose per lifetime.

- 1. Age of the patient is 12 years and older; **AND**
- 2. Patient has a diagnosis of sickle cell disease confirmed by genetic testing; AND
- 3. Patient has one of the following based on provider attestation:
 - a. Experienced recurrent vaso-occlusive crises (VOCs), defined as 2 or more documented VOCs per year in the previous 24 months; **or**
 - b. Currently receiving chronic transfusion therapy for recurrent VOCs; AND
- 4. Patient has prior use of or intolerance to hydroxyurea (as determined by healthcare professional judgement) at any point in the past; **AND**
- 5. Prescribed by or in consultation with a board-certified hematologist with sickle cell disease expertise; **AND**
- 6. Prescriber attests that patient is clinically stable and fit for transplantation.

CASGEVY® Dosing:

Dosing is based on body weight. The minimum recommended dose is 3 x 10⁶ CD34+ cells/kg. CASGEVY® is for autologous use only. Please see the full prescribing information for further details.

Formulation:

• CASGEVY® is a cell suspension for intravenous infusion.