Protocol for Casgevy® (exagamglogene autotemcel) for Sickle Cell Disease

January 2025

Background:

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

Criteria for approval:

1. Diagnosis of sickle cell disease has been confirmed by genetic testing
2. Patient has prior use of, or intolerance to, hydroxyurea (per health care professional judgement) at any point in the past.
3. Patient is ≥ twelve (12) years of age at the expected time of gene therapy administration.
4. Patient is clinically stable for transplantation
5. Medication is prescribed by or in consultation with a board-certified hematologist with SCD expertise
6. Member's treatment center is a Qualified Treatment Center for the product
7. Patient has experienced recurrent vasooclusive crisis (VOCs), defined as more than or equal to two (2) documented VOCs per year in the previous twenty-four (24) months, based on provider attestation
8. Any prior authorization, once approved, will be valid for at least twelve (12) months

Approval Duration: Approve, once per lifetime (one single dose intravenously)

References:

1. Casgevy® [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; January 2024