



## RI Executive Office of Health & Human Services

### Medicaid Fee for Service (FFS) and Managed Care Sickle Cell Disease Cell and Gene Therapy Clinical Access Policy

#### Drug Category: Blood disorder

#### Medication Class/Individual Agents: Hematopoietic

The following cell and gene therapy agents have been approved by the FDA for the treatment or management of sickle cell disease.

1. Exagamglogene autotemcel (Casgevy)
2. Lovotibeglogene autotemcel (Lyfgenia)

GENERIC NAME	BRAND NAME(S)	INDICATION	DOSING	NOTES	PA STATUS
Exagamglogene autotemcel	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: <ul style="list-style-type: none"> <li>• sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs)</li> <li>• Transfusion-dependent <math>\beta</math>-thalassemia (TDT)</li> </ul>	Weight based dosing; minimum recommended dose is $3 \times 10^6$ CD34+ cells/kg.	Exagamglogene autotemcel is a cell suspension for intravenous infusion.	PA required

For SCD: Prior to apheresis it is recommended that patients be transfused with a goal to maintain hemoglobin S (HbS) levels < 30% of total hemoglobin (Hb) while keeping total Hb concentration  $\leq 11\text{g/dL}$ .

Coverage criteria includes:

1. Documented diagnosis of SCD with confirmatory genetic testing.
2. Age twelve (12) years and older.
3. Prior use of or intolerance to hydroxyurea (per health care professional judgement) at any point in the past.
4. Clinically stable and fit for transplantation.
5. Prescribed in consultation with a board-certified hematologist with SCD experience.
6. Experienced recurrent VOCs (defined as more than or equal to two (2) document VOCs per year in the previous twenty-four (24) months, based on provider attestation).
7. No contraindication to the prescribed medication.

Any prior authorization, once approved, will be valid for at least twelve (12) months.

GENERIC NAME	BRAND NAME(S)	INDICATION	DOSING	NOTES	PA STATUS
Lovotibeglogene autotemcel	Lyfgenia	Lovotibeglogene autotemcel is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age and older with sickle cell disease and a history of vaso-occlusive events.	Weight based dosing; minimum recommended dose is $3 \times 10^6$ CD34+ cells/kg.	Lovotibeglogene autotemcel is a cell suspension for intravenous infusion.	PA required

Coverage criteria includes:

1. Documented diagnosis of SCD with confirmatory genetic testing.
2. Age twelve (12) years and older at the expected time of gene therapy administration.
3. Failure or intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgement) at any point in the past.
4. Clinically stable and fit for transplantation.
5. Prescribed Manufacturer CGT Product by or in consultation with a board-certified hematologist with SCD expertise.
6. Eligible Beneficiary's Treatment Center has a Sickle Cell Center.
7. Either a or b (based on provider attestation):
  - a. Currently receiving chronic transfusion therapy for recurrent Vaso-Occlusive Events (VOEs); or
  - b. Experienced four (4) or more VOEs in previous twenty-four (24) months as determined by the Eligible Beneficiary's treating clinician.
8. No contradiction to the prescribed medication.

Any prior authorization, once approved, will be valid for at least twelve (12) months.

\*Please note that this may be subject to change as new therapies are approved by the FDA.