MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**176**	
Subject:	**Cell and Gene Therapy**	
Section:	**Utilization Management**	
Initial Effective Date:	**1/1/2026**	
Revision Effective Date(s):	**07/26**	
Review Effective Date(s):		
Responsible Parties:	**AVP Clinical Operations, Manager of Utilization Management**	
Responsible Department(s):	**Clinical Operations, Pharmacy, Compliance**	
Regulatory References:	**MDH transmittal PT 43-26, MDH HealthChoice MCO Agreement - Appendix O**	
Approved:	**AVP Clinical Operations**	**Chief Medical Officer**

Purpose: To successfully implement the Cell and Gene Therapy (CGT) Access Model for members with Sickle Cell Disease

Scope: Medstar Family Choice, Maryland

Policy: Ensure eligible members with Sickle Cell Disease receive access to the appropriate medications, treatments, and allied services as defined by Maryland Department of Health CGT Access Model

Procedure:

1. Requests for CGT will be entered into the clinical software system.
2. The nurse or pharmacy technician will verify that clinical information to support the CGT request is complete and being requested from an approved authorized treatment center (ATC). The two approved ATCs are Children's National Medical Center who offers and University of Maryland Medical Center who offer both Casgevy and Lyfgenia.
3. The nurse or pharmacy technician will then send the request to a medical director or health plan pharmacist to review.
4. The medical director or health plan pharmacist will utilize the criteria provided by MDH (See Appendix A) and request additional information if needed.
5. The nurse or pharmacy technician will follow the Pre-Service (non-urgent) turnaround times as noted in Table A.

Table A

Review Type	Timeline for UM Decision Making	Timeline for Notification from Receipt of Request	Notification Method	Who Must Be Notified
Pre-Service (Non-Urgent)	Within 2 business days of the receipt of the information necessary to make a determination, but no longer than 7 calendar days from the date of the initial request.	Within 72 hours from the date of the determination, not to exceed 7 calendar days from the receipt of Request for Authorization	Verbal (optional) Electronic or written (required for denials*)	Verbal (optional): - Requesting practitioner or provider Written (required for denials)**:** - Requesting facility - Requesting physician or clinician - PCP -Member or member's authorized representative Quarterly Pre-service Denial: Report sent to Maryland EQRO (see Policy 144A; Denial or Action Notice) Denials only

6. MedStar Family Choice will not impose step therapy.
7. Manufacturers of the medications are responsible for covering fertility preservation under the CGT Model.
8. If approved, the authorization covers initial consultation to determine eligibility, chemotherapy, infusion of Casgevy or Lyfgenia and the associated inpatient stay, ancillary care, and return visits for long term follow-up care. The authorization is valid for a period of 12 months from the decision date.
9. Members are entitled to on-going disease management; collection of the patient's stem cells, through a process known as apheresis; creation of the gene therapy using the patient's stem cells; infusion of the gene therapy and recovery; and ongoing monitoring of the patient's condition after infusion.
10. The nurse, medical director or pharmacy technician will refer all members to Case Management.
11. Case Management and Utilization Management will collaborate to ensure continuity of care should members move to fee for service (FFS), change to another Managed Care Organization (MCO), or experience any change in Medicaid status.
12. The duration of the care journey through the conclusion of the therapy infusion is approximately 12 months. After infusion, the patient will have an initial six-week follow-up, and then monthly visits for the first year. After the first year, the patient shifts to annual follow-up visits.
13. Case Management will ensure members have access to and keep post infusion visits by coordinating with the local health department of members for the provision of timely non-emergency medical transportation services and related travel for members and their

caregivers, as applicable. If members are unable to receive non-emergency medical transportation, MedStar Family Choice may either cover these costs optionally as a value-added service or coordinate with the ATCs for wraparound resources and support. MedStar Family Choice will also work with the ATCs to coordinate members' access to housing and childcare support.

Appeals:
If coverage is denied, the member retains full appeal rights, and MDH will coordinate with MedStar Family Choice for appeals and state fair hearings related to denials.

Payment Process:

1. Within 30 days of the coverage decision, MedStar Family Choice is responsible for submitting the complete documentation used for the coverage decision to the Department for retrospective review.
2. The Department will notify MedStar Family Choice within 30 days of whether MDH will reimburse MedStar Family Choice for the actual acquisition cost of the Model drug and the inpatient stay for the infusion through the invoice process. The basis of this determination is on the documentation MedStar Family Choice received to make its decision and its adherence to the Model clinical criteria for each medication.
3. MedStar Family Choice will reimburse ATCs for all components of the care journey—including apheresis and disease management. MDH reimbursement for CASGEVY or LYFGENIA, as well as the inpatient stay during which the infusion takes place at the ATC, will follow the procedure for the High-Cost Low Volume Inpatient and Outpatient Drug Policies, meaning that the costs for these medications and the infusion are excluded from the capitation rate base data, and MFC is still responsible for managing and paying all claims related to the CGT Model medications.
4. The only difference is MedStar Family Choice must follow the CGT Model clinical criteria set by MDH.
5. MedStar Family Choice is required to reimburse the ATCs for the actual acquisition costs for the CGT Model medications to receive reimbursement. In cases where the participant is discharged and later readmitted, MedStar Family Choice remains responsible for payment.
6. If MDH approves MedStar Family Choice coverage decision for the Model medications, Medstar Family Choice may invoice MDH for expenses incurred for the actual acquisition cost of CASGEVY or LYFGENIA, and the inpatient stay for their infusion. MFC may submit the invoices on a quarterly basis.

Reporting:
1. MedStar Family Choice will cooperate with MDH, CMS, and/or CMS' designee(s) and provide all data needed by MDH and CMS to evaluate and monitor the CGT Model, including individually identifying information, claims data and payment information.

2. MedStar Family Choice will maintain records for CGT Model participants for 10 years.

Appendix A: Criteria

Clinical Criteria
Coverage of these therapies is limited to Medicaid participants with sickle cell disease who meet the Maryland Medicaid clinical criteria. Both MCOs and Medicaid fee-for-service participants must follow the same clinical criteria under the Model. Step therapy is not permitted as a requirement before accessing the covered therapies. HealthChoice MCOs also may not impose clinical criteria that are more expansive or restrictive than what Maryland Medicaid requires. To access the clinical criteria, see the links below.

- **LYFGENIA: https://bit.ly/3LvfTz4**

- **CASGEVY: https://bit.ly/3Lz0v4J**

Model Drug	**HCPCS Code**	**Description**	**Cost**
Casgevy	J3392	Injection, exagamglogene autotemcel	**Payable by invoice**
Lyfgenia	J3394	Injection, lovotibeglogene autotemcel	**Payable by invoice**

Summary of Changes:	**07/26:** • Procedure #2 updated language as University of Maryland is approved to provide Casgevy. 1/1/26 • New Policy