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ForwardHealth UPDATE

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CHANGES FOR CASGEVY AND LYFGENIA AND OTHER POLICIES IN THE NEW CELL AND GENE THERAPY ACCESS MODEL FOR MEMBERS WITH SICKLE CELL DISEASE

The Wisconsin Department of Health Services (DHS) is participating in the Centers for Medicare & Medicaid Services' (CMS) Cell and Gene Therapy (CGT) Access Model. This model allows DHS to enter into enhanced rebate agreements with the manufacturers of two State-Selected Model Drugs, Casgevy and Lyfgenia. Wisconsin's participation in the CGT Access Model begins January 1, 2026, and will continue through December 31, 2030.

This ForwardHealth Update details:

- Member qualifications for participation in the CGT Access Model.
- Prior authorization (PA) changes for Casgevy and Lyfgenia, the State-Selected Model Drugs used to treat sickle cell disease (SCD).
- Changes to non-emergency medical transportation (NEMT) and managed care policy in connection with the CGT Access Model.

AFFECTED PROGRAMS
BadgerCare Plus, Medicaid

TO
Community Health Centers, Hospital Providers, Nurse Practitioners, Pharmacies, Pharmacists, Physician Assistants, Physician Clinics, Physicians, Rural Health Clinics, Tribal Federally Qualified Health Centers, HMOs and Other Managed Care Programs

CONTACT INFORMATION
Provider Services, 800-947-9627

The information provided in this ForwardHealth Update is published in accordance with Wis. Stat. § 49.45(49) and Wis. Admin. Code § DHS 107.10.

WISCONSIN DEPARTMENT of HEALTH SERVICES

All PA and other policy changes are effective January 1, 2026.

Refer to the following sections for more information about:

- The CGT Access Model
- Qualifications for BadgerCare Plus and Medicaid members' participation
- Fertility preservation
- Managed care exemption
- NEMT
- Mental health services
- Pharmacy policy changes for Casgevy and Lyfgenia

Cell and Gene Therapy Access Model

CMS's CGT Access Model supports outcome-based agreements between states and manufacturers that will provide treatments within a framework that lowers prices for states and ties payments to outcomes. The model aims to improve health outcomes through increasing people's access to CGTs. The model's initial focus is on people living with SCD.

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DHS joined this model and entered into a multi-year agreement with drug manufacturers that allows DHS to establish an enhanced rebate structure for two State-Selected Model Drugs: Casgevy and Lyfgenia. Participation in this model enables DHS to recoup expenses from the drug manufacturer if a treatment is unsuccessful.

Qualifications for BadgerCare Plus and Medicaid Members' Participation

Certain BadgerCare Plus and Medicaid members' treatment with these drugs will qualify for receiving it through the CGT Access Model. The model cannot include members of the Children's Health Insurance Program portion of BadgerCare Plus.

To qualify under this model, members must:

- Have a documented medical diagnosis of SCD.
- Have Wisconsin Medicaid as the primary payer for a State-Selected Model Drug.
- Have received an infusion of a State-Selected Model Drug.
- Have received that infusion while the CGT Access Model outcome-based agreements between DHS and the drug manufacturers are in effect.

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Fertility Preservation

Fertility preservation is **not** a covered BadgerCare Plus or Medicaid benefit. It is **only** available to members who qualify to receive care through the CGT Access Model as it is offered through the manufacturers of Casgevy and Lyfgenia. Free fertility preservation services are not available to members with SCD whose treatment does not qualify for participation in the CGT Access Model. Providers should follow the drug manufacturers' guidance regarding referrals for fertility preservation for interested members receiving care under the model.

Managed Care Exemption

Effective January 1, 2026, BadgerCare Plus and Medicaid members who participate in the CGT Access Model will be permanently exempted from having to be in an HMO once an infusion date has been scheduled after successful apheresis, beginning on the first of the month of the first round of apheresis.

Either the member or the HMO may request exemption through a DHS nurse consultant. Appropriate documentation showing an approved PA and scheduled infusion date must accompany the exemption request. Refer to ForwardHealth Online Handbook Disenrollment and Exemptions topic #392 for more information.

Non-Emergency Medical Transportation

NEMT is a free service that helps members get to and from health care appointments if they have no other transportation options. Federal law requires NEMT to provide the least expensive type of ride to get a member to their appointments based on their needs. The rides through NEMT may be on public buses, specialized medical vehicles, or common carriers (for example, sedans or minivans). It may also cover:

- Gas mileage reimbursement for members or family members who can drive to appointments.
- Out-of-state travel, meals, and lodging associated with Medicaid-covered appointments.

Transportation for any SCD-related appointment is considered a **critical care** ride. Critical care rides can be scheduled up to the same day as the appointment, and they are eligible for additional support from NEMT call

QUICK LINKS

- Disenrollment and Exemptions topic #392
- Covered Outpatient Mental Health Services topic #6037
- Covered Outpatient Drug Reimbursement topic #1351
- Pharmacy Resources page

center representatives who can help schedule and coordinate rides. These representatives can:

- Work with members to set up same day rides and recurring rides up to three months in advance.
- Coordinate consistent transportation providers.
- Troubleshoot issues in real time.
- Address other special needs.

Members may choose to have other people travel with them to their appointments, including children, attendants, people under a member's care, or riders requested by a health care provider. When members schedule a ride, they should let NEMT representatives or managers know if they are planning to bring someone with them to an appointment.

> **"Transportation for any SCD-related appointment is considered a critical care ride. Critical care rides can be scheduled up to the same day as the appointment, and they are eligible for additional support from NEMT call center representatives who can help schedule and coordinate rides.**

When members schedule rides, they must tell the agent that the ride is to an SCD-related appointment so the agent can document it as critical. Members may qualify for meals and overnight stays depending on how far they need to travel for SCD-related appointments. Refer to the Medicaid: Non-Emergency Medical Transportation page on the DHS website for more information and instructions on scheduling rides. At the bottom of that webpage, there are several fact sheets that can help members better understand and use this benefit.

Mental Health Services

Members who have an existing mental or behavioral health diagnosis or who are suffering from depression or anxiety related to CGT treatment may benefit from a referral to mental health services. ForwardHealth provides broad coverage for:

- Outpatient mental health services such as strength-based assessments (including differential diagnostic evaluations).
- Psychotherapy services.
- Mental health clinical consultations.
- Other psychiatric services.

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ForwardHealth also provides coverage for inpatient mental health services. Refer to the Covered Outpatient Mental Health Services topic #6037 for more information.

Pharmacy Policy Changes for Casgevy and Lyfgenia

Effective January 1, 2026, ForwardHealth has revised the clinical criteria and pharmacy policies for Casgevy and Lyfgenia to align with requirements for participation in the CGT Access Model.

Casgevy and Lyfgenia will remain on the Select High Cost, Orphan, and Accelerated Approval Drugs data table on the Pharmacy Resources page of the Portal.

For information about reimbursement for drugs covered under the pharmacy benefit, providers may refer to the Covered Outpatient Drug Reimbursement topic #1351.

For specific questions about the billing or coverage of high cost, orphan, and accelerated approval drugs, providers may contact Provider Services or email DHSOrphanDrugs@dhs.wisconsin.gov.

Casgevy

Clinical PA is required for Casgevy.

If a PA request for Casgevy is approved, Casgevy will be covered under the pharmacy benefit. To bill ForwardHealth for Casgevy, pharmacy providers must submit a pharmacy noncompound drug claim and include the member's diagnosis code on the pharmacy claim submitted for Casgevy. The date of service (DOS) submitted on the pharmacy claim must be the date the member received the infusion of Casgevy.

Casgevy Cell and Gene Therapy Access Model Requirements for Treatment Centers

Casgevy is a State-Selected Model Drug in the CGT Access Model when used for the treatment of SCD. Casgevy used for β-thalassemia is **not** included in the CGT Access Model at this time.

RESOURCES

- Medicaid: Non-Emergency Medical Transportation page
- Medicaid: Cell and Gene Therapy for Sickle Cell Disease page
- DHS Orphan Drugs email, DHSOrphanDrugs@dhs.wisconsin.gov
- CMS-Designated Patient Registry for the CMS CGT Access Model email, CGTModel@mcw.edu

The treatment center must agree to **all** of the following for members determined to be eligible for treatment in the CGT Access Model:

- Treatment center providers administering Casgevy for SCD must enroll and participate in the CMS-Designated Patient Registry through the Center for International Blood and Marrow Transplant Research (CIBMTR).
- Treatment center providers must be enrolled in CIBMTR before administering Casgevy to Wisconsin Medicaid members.
- Treatment center providers must also obtain member consent to participate in the CIBMTR Research Database Protocol under which this study will be governed and are responsible for submitting data to CIBMTR, per the CGT Access Model study requirements.
- Treatment center providers administering Casgevy for SCD must ensure Casgevy is not purchased through the 340B Drug Pricing Program (340B Program) when administered to eligible CGT Access Model members.

For assistance with enrollment in the CMS-Designated Patient Registry for the CMS CGT Access Model, contact CIBMTR at CGTModel@mcw.edu.

Requirements for Casgevy

Requirements for Casgevy treatment include **all** of the following:

- Casgevy will be reimbursed separately from physician and clinical services associated with the administration of Casgevy. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that the physician-administered Casgevy is delivered directly to the administering treatment center.
- Pharmacy providers may only submit a claim to ForwardHealth for Casgevy that has been administered to a member. If Casgevy has been dispensed for a member but the dose is not administered to the member, the prescriber is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Casgevy that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
- Casgevy must be prescribed at a minimum recommended dose of 3.0×10^6 CD34+ cells/kg of body weight.
- The member must have full myeloablative conditioning administered before infusion of Casgevy. Full myeloablative conditioning must be

administered between 48 hours and seven days before infusion of Casgevy.
- Standard procedures for patient management after hematopoietic stem cell (HSC) transplantation should be followed after Casgevy infusion.
- The prescriber must manage other concomitant medications (as applicable) consistent with Food and Drug Administration (FDA) product labeling.
- The member must not take disease-modifying therapies (for example, crizanlizumab, hydroxyurea, L-glutamine, voxelotor) for at least two months prior to mobilization.
- The member must not take iron chelation therapy at least seven days prior to myeloablative conditioning. The member must not take non-myelosuppressive iron chelators for at least three months and myelosuppressive iron chelators for at least six months after Casgevy infusion.

Additional Requirement for Sickle Cell Disease Treatment

Granulocyte-Colony Stimulating Factor (G-CSF) must not be used prior to or with mobilization and conditioning.

PA Information for Casgevy

Conditions for Which PA Requests for Casgevy Will Be Considered for Review

ForwardHealth will only consider PA requests for Casgevy for the following clinical conditions:
- β-thalassemia
- SCD

Clinical Criteria for Casgevy for β-Thalassemia

The clinical criteria that must be documented for approval of a PA request for Casgevy for β-thalassemia are all of the following:
- Casgevy must be prescribed and administered by a physician and treatment center with expertise in treating β-thalassemia with Casgevy.
- The member has β-thalassemia, which requires regular red blood cell (RBC) transfusions. The member has a history of transfusions for the past two years of at least 100 mL/kg/year of packed RBCs or at least 10 units/year of RBC transfusions in the previous two years.

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- The member's age at the time of planned infusion is consistent with the FDA-approved product labeling for Casgevy.
- The prescriber will provide documentation of completed negative screening for active infectious diseases, including hepatitis B virus (HBV), hepatitis C virus (HCV), HIV 1 and 2 (HIV-1/HIV-2) and human T-lymphotropic virus (HTLV) 1 and 2 (HTLV-1/HTLV-2), in accordance with clinical guidelines before collection of cells for manufacturing.
- The prescriber has attested that the member is clinically stable and fit for transplantation.

Clinical Criteria for Casgevy for Sickle Cell Disease

The clinical criteria that must be documented for approval of a PA request for Casgevy for SCD are **all** of the following:

- Casgevy must be prescribed and administered by a physician and treatment center with expertise in treating SCD with Casgevy.
- The prescribing provider attests that at least one of the following is true:
  - The member has experienced an unsatisfactory therapeutic response with hydroxyurea.
  - The member has experienced a clinically significant adverse drug reaction with hydroxyurea.
  - There is a clinically significant drug interaction between another drug(s) the member is taking and hydroxyurea.
  - The member has a medical condition(s) that prevents the use of hydroxyurea.
- The prescribing provider attests that the member has SCD with a history of two or more vaso-occlusive crises (VOCs) per year within the previous 24 months or is currently receiving chronic transfusion therapy for recurrent VOCs (based on provider attestation).
- The member's age at the time of planned infusion is consistent with the FDA-approved product labeling for Casgevy.
- The prescriber will provide documentation of completed negative screening for active infectious diseases, including HBV, HCV, HIV 1 and 2 (HIV-1/HIV-2), and HTLV 1 and 2 (HTLV-1/HTLV-2), in accordance with clinical guidelines before collection of cells for manufacturing.
- The prescriber has attested that the member is clinically stable and fit for transplantation.

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Conditions Not Approved for PA Requests for Casgevy

PA requests for Casgevy for β-thalassemia or SCD will **not** be approved if the member has any of the following conditions:

- Advanced liver disease that, in the opinion of the prescriber, renders the member not clinically fit and stable for transplantation
- A history of untreated Moyamoya disease or the presence of Moyamoya disease that, in the opinion of the prescriber, puts the member at risk of bleeding
- Current malignancy, myeloproliferative disorder, or significant immunodeficiency disorder, unless the prescribing provider attests that the member's condition would not deem the member ineligible for treatment
- Prior allogenic or autologous HSC transplant

Submitting PA Requests for Casgevy

PA requests for Casgevy must be completed, signed, and dated by the prescriber. PA requests for Casgevy must be submitted using Section VI (Clinical Information for Drugs With Specific Criteria Addressed in the ForwardHealth Online Handbook) of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (01/2024). Clinical documentation supporting the use of Casgevy must be submitted with the PA request.

The PA form must be sent to the pharmacy where the prescription will be filled. The prescriber may send the PA form to the pharmacy, or the member may carry the PA form with the prescription to the pharmacy. The pharmacy provider will use the completed PA form to submit a PA request to ForwardHealth. Prescribers should **not** submit the PA form to ForwardHealth.

Pharmacy providers are required to submit the completed PA/DGA form and a completed Prior Authorization Request Form (PA/RF), F-11018 (05/2013), to ForwardHealth.

When initially accessing Online Handbook topic links available throughout this Update, providers need to click the "I Accept" button at the bottom of the licensure agreement page of the Online Handbook. After 30 minutes of inactivity, providers will need to click "I Accept" again before going to their intended topic.

QUICK LINKS

Forms page

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PA requests for Casgevy may be submitted on the ForwardHealth Portal (the Portal), by fax, or by mail (but **not** using the Specialized Transmission Approval Technology-Prior Authorization [STAT-PA] system).

PA requests for Casgevy will be approved for 365 days.

Lyfgenia

Clinical PA is required for Lyfgenia.

If a PA request for Lyfgenia is approved, Lyfgenia will be covered under the pharmacy benefit. To bill ForwardHealth for Lyfgenia, pharmacy providers should submit a pharmacy noncompound drug claim and must include the member's diagnosis code on the pharmacy claim submitted for Lyfgenia. The DOS submitted on the pharmacy claim must be the date the member receives the infusion of Lyfgenia.

Lyfgenia Cell and Gene Therapy Access Model Requirements for Treatment Centers

Lyfgenia is a State-Selected Model Drug in the CGT Access Model when used for the treatment of SCD.

The treatment center must agree to **all** of the following for members determined to be eligible for treatment in the CGT Access Model:

- Treatment center providers administering Lyfgenia for SCD must enroll and participate in the CMS-Designated Patient Registry through CIBMTR.
- Treatment center providers must be enrolled in CIBMTR before administering Lyfgenia to Wisconsin Medicaid members.
- Treatment center providers must also obtain member consent to participate in the CIBMTR Research Database Protocol under which this study will be governed and are responsible for submitting data to CIBMTR, per the CGT Access Model study requirements.
- Treatment center providers administering Lyfgenia for SCD must ensure Lyfgenia is not purchased through the 340B Program when administered to eligible CGT Access Model members.

For assistance with enrollment in the CMS-Designated Patient Registry for the CMS CGT Access Model, contact CIBMTR at CGTModel@mcw.edu.

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Requirements for Lyfgenia

Requirements for Lyfgenia include all of the following:

- Lyfgenia will be reimbursed separately from physician and clinical services associated with the administration of Lyfgenia. The pharmacy provider is required to establish a delivery process with the prescriber to ensure that the physician-administered Lyfgenia is delivered directly to the administering treatment center.
- Pharmacy providers may only submit a claim to ForwardHealth for Lyfgenia that has been administered to a member. If Lyfgenia has been dispensed for a member but the dose is not administered to the member, the prescriber is responsible for notifying the dispensing pharmacy. If ForwardHealth has paid the dispensing pharmacy for any portion of the dispensing of Lyfgenia that is not administered to the member, the dispensing pharmacy is responsible for reversing any claims submitted to ForwardHealth.
- Lyfgenia must be prescribed at a minimum recommended dose of 3×10^6 CD34+ cells/kg of body weight.
- The member must have full myeloablative conditioning administered before infusion of Lyfgenia. Full myeloablative conditioning must be administered a minimum of 48 hours before infusion of Lyfgenia.
- Standard procedures for patient management after HSC transplantation should be followed after Lyfgenia infusion.
- The prescriber must manage other concomitant medications (as applicable) consistent with FDA-approved product labeling.
- The member must not take disease-modifying therapies for SCD (for example, crizanlizumab, L-glutamine, voxelotor) for at least two months prior to mobilization.
- The member must not take iron chelation therapy at least seven days prior to mobilization and conditioning. If the member takes iron chelation after apheresis, the member must discontinue iron chelation at least seven days prior to myeloablative conditioning. Myelosuppressive iron chelators are not recommended for six months after Lyfgenia infusion.
- The member must not take erythropoietin for at least two months prior to mobilization.
- The member must not take hydroxyurea at least two months prior to mobilization and two days prior to conditioning and will not resume until all cycles of apheresis are completed.

- The member must not take prophylactic HIV anti-retroviral medications for at least one month prior to mobilization and until all cycles of apheresis are completed. Adjust time appropriately for long-acting anti-retroviral medications.
- G-CSF must not be used prior to or with mobilization and conditioning. G-CSF is not recommended for at least 21 days after Lyfgenia infusion.

PA Information for Lyfgenia

Clinical Criteria for Lyfgenia

The clinical criteria that must be documented for approval of a PA request for Lyfgenia for SCD are **all** of the following:

- Lyfgenia must be prescribed and administered by a physician and treatment center with expertise in treating SCD with Lyfgenia.
- The prescribing provider attests that at least one of the following is true:
  - The member has experienced an unsatisfactory therapeutic response with hydroxyurea.
  - The member has experienced a clinically significant adverse drug reaction with hydroxyurea.
  - There is a clinically significant drug interaction between another drug(s) the member is taking and hydroxyurea.
  - The member has a medical condition(s) that prevents the use of hydroxyurea.
- The prescribing provider attests that the member is currently receiving chronic transfusion therapy for recurrent vaso-occlusive events (VOEs), or the member has experienced four or more VOEs in the previous 24 months.
- The member's age at the time of planned infusion is consistent with the FDA-approved product labeling for Lyfgenia.
- The prescriber will provide documentation of completed negative screening for active infectious diseases, including HBV, HCV, HIV 1 and 2 (HIV-1/HIV-2) and HTLV 1 and 2 (HTLV-1/HTLV-2), in accordance with clinical guidelines before collection of cells for manufacturing.
- The prescriber has attested that the member is clinically stable and fit for transplantation.

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Conditions Not Approved for PA Requests for Lyfgenia

PA requests for Lyfgenia **will not** be approved if the member has any of the following conditions:

- Advanced liver disease (for example, alanine transaminases greater than three times the upper limit of normal, direct bilirubin value greater than three times the upper limit of normal, baseline prothrombin time [INR] greater than 1.5 times the upper limit of normal, cirrhosis, bridging fibrosis, or active hepatitis)
- A history of untreated Moyamoya disease or the presence of Moyamoya disease that, in the opinion of the prescriber, puts the member at risk of bleeding
- Current malignancy, myeloproliferative disorder, or significant immunodeficiency disorder, unless the prescribing provider attests that the member's condition would not deem the member ineligible for treatment
- Prior allogenic or autologous HSC transplant

Submitting PA Requests for Lyfgenia

PA requests for Lyfgenia must be completed, signed, and dated by the prescriber. PA requests for Lyfgenia must be submitted using Section VI (Clinical Information for Drugs With Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form. Clinical documentation supporting the use of Lyfgenia must be submitted with the PA request.

The PA form must be sent to the pharmacy where the prescription will be filled. The prescriber may send the PA form to the pharmacy, or the member may carry the PA form with the prescription to the pharmacy. The pharmacy provider will use the completed PA form to submit a PA request to ForwardHealth. Prescribers should **not** submit the PA form to ForwardHealth.

Pharmacy providers are required to submit the completed PA/DGA form and a completed PA/RF to ForwardHealth.

PA requests for Lyfgenia may be submitted on the Portal, by fax, or by mail (but not using the STAT-PA system).

PA requests for Lyfgenia will be approved for 365 days.

QUICK LINKS

Forms page

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No Additional Billing Changes to Clinical Services

Clinical services associated with the administration of Casgevy or Lyfgenia will be reimbursed according to current policy. Refer to the Online Handbook for details.

Documentation Retention

Providers are reminded that they must follow the documentation retention requirements per Wis. Admin. Code § DHS 106.02(9). Providers are required to produce or submit documentation, or both, to DHS upon request. Per Wis. Stat. § 49.45(3)(f), providers of services shall maintain records as required by DHS for verification of provider claims for reimbursement. DHS may audit such records to verify the actual provision of services and the appropriateness and accuracy of claims. DHS may deny or recoup payment for services that fail to meet these requirements. Refusal to produce documentation may result in denial of submitted claims, recoupment of paid claims, application of intermediate sanctions, or termination from the Medicaid program.

Information Regarding Managed Care Organizations

This Update applies to Family Care, Family Care Partnership, BadgerCare Plus, and SSI Medicaid managed care program members because pharmacy services for members of these programs are provided on a fee-for-service basis. Pharmacy services for Medicaid members enrolled in the Program of All-Inclusive Care for the Elderly (PACE) are provided by the member's managed care organization.

This Update also applies to changes for clinical services that members receive on a fee-for-service basis.

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This Update was issued on 12/19/2025 and information contained in this Update was incorporated into the Online Handbook on 01/02/2026.