Coordinated Care Organization Guidance for Cell and Gene Therapy Access Model and High-Cost Drug Carve-Out

The Oregon Health Authority (OHA) is implementing both the Cell and Gene Therapy (CGT) Access Model to treat sickle cell disease and the High-Cost Drug Carve-Out (HCDCO) effective January 1, 2026.

The CGT Access Model and HCDCO are described in Exh. B, Part 2, Sec. 9, Para. a, Sub.Paras. (5) and (4) of the 2026 Coordinated Care Organization (CCO) Medicaid, Non-Medicaid, and Oregon Health Plan Bridge – Basic Health Program Contracts.

Capitalized terms not defined in this guidance have the meanings assigned to them in the CCO contracts.

Background

The Centers for Medicare & Medicaid Services (CMS) establishes the terms for state participation in the CGT Access Model. Oregon's approach to satisfy the CMS terms is to carve-out the costs of CGT Access Model products from CCO capitation payments. Additionally, OHA is carving out other high-cost, low-utilization pharmaceutical products from CCO capitation payments.

OAR 410-141-3855 will be amended effective January 1, 2026, to add the High Cost, Rarely Used Carve-Out Drug List, which includes the CGT Access Model products and the additional carved-out products.

OHA and CCO Responsibilities

Under both the CGT Access Model and HCDCO, OHA is responsible for determining medical necessity, issuing Prior Authorizations (PAs), and paying Providers for approved therapies. CCOs are responsible for all other Covered Services associated with the approved therapies, including but not limited to, inpatient and outpatient services, transportation, and Care Coordination.

Care Coordination Contacts:

For the CGT Access Model, CMS requires each CCO to designate primary and secondary care coordinators. OHA encourages CCOs to do the same for the HCDCO. OHA obtained CCO care coordinator contact information as part of implementation planning for the January 1, 2026, effective date. CCOs should promptly notify OHA about any change in the name, email, title, and/or phone number of their care coordinators by emailing Deborah ("Dee") Weston at deborah.g.weston@oha.oregon.gov.

For HCDCO products (other than CGT Access Model products):

1. To facilitate Care Coordination and minimize Provider burden, CCOs should notify OHA of approved PAs for HCDCO products that are expected to be dispensed or administered on or after January 1, 2026. To do so, email DMAP.RXQuestions@odhsoha.oregon.gov to request the HCDCO PA template. Complete and return the Template according to the directions contained in the template.

2. For new PA requests, refer prescribers to the FFS PA request form. The form includes the fax and phone number to request PA.

3. When OHA approves a PA request for a CCO Member, OHA staff will send a secure email to the relevant CCO care coordinators to notify them of the PA decision. OHA will notify CCOs of approved therapies as soon as practicable.

4. To prevent duplicate reimbursement, CCOs must direct Providers to exclude the cost of HCDCO products from inpatient claims, single case agreements, and all other billing transactions.

5. Reimbursement and billing requirements for approved therapies will be according to fee-for-service (FFS) rules.

For CGT Access Model products to treat sickle cell disease:

Oregon will participate in the CMS-led Access Model for the "State-Selected Model Drugs" identified below:

- Lyfgenia, produced by Genetix Therapeutics (previously produced by bluebird bio, Incorporated); and

- Casgevy, produced by Vertex Pharmaceuticals Incorporated.

Oregon intends to rely on Oregon Health & Science University (OHSU) as the sole contracted qualified Access Model therapy provider for Access Model therapies. OHSU is currently a qualified treatment center for Lyfgenia and is working toward certification for Casgevy.

Oregon must only cover Access Model products that are administered by a hospital participating in the Center for International Blood & Marrow Transplant Research (CIBMTR) CMS-specified study. OHSU intends to participate in this study. OHA will notify CCOs when OHSU completes enrollment in this study and is able to serve as the sole contracted provider for CGT to treat sickle cell disease for Oregon Health Plan (OHP) Members. If OHSU is unable to provide treatment through the Access Model, a referral will be made to an alternate hospital that is participating in the Model.

Each CCO must:

1. For Access Model therapy approved by OHA, ensure access to gene therapy care (including preparation and follow-up care) with a Provider qualified to administer the State-Selected Model Drug. OHA will provide Administrative Notice to inform CCOs of status changes.
2. Direct patients exclusively to a qualified treatment center that confirms they are participating in the CIBMTR CMS-specified study. Qualified Providers must be a member of the CMS-designated patient registry for the Model. OHA will provide Administrative Notice to inform CCOs of status changes.
3. Withhold payment for all costs associated with an Access Model product delivered by a Provider that is not meeting requirements to participate in the Model. OHA will notify CCOs promptly of any status changes.
4. For CCO members transitioning from a predecessor plan or FFS, honor PAs for administration of Access Model products and any other associated services.
5. Allow continued access to the same Access Model Provider until at least one year after receiving the gene therapy infusion.
6. Provide and update primary and secondary contacts for Access Model Care Coordination. OHA will notify the qualified Access Model therapy provider of any changes. The purpose of these contacts is to facilitate care coordination of CGT to treat sickle cell disease, including but not limited to, inpatient services, administration and follow-up care.
7. If the qualified Access Model therapy Provider is not a Network Provider, cover associated gene therapy care by the out-of-network Provider (Non-Participating Provider).

8. Comply with timeframes for responding to requests for associated medical services in accordance with OAR 410-141-3835(12)(a) and (12)(b)(A), as amended effective January 1, 2026.

9. Provide to OHA, upon request, documentation including, but not limited to, chart notes and other records that OHA determines are necessary for OHA to meet its reporting obligations to CMS.

Technical Assistance

Please contact Dee Weston at 971-283-8818 or deborah.g.weston@oha.oregon.gov for technical assistance related to the CGT Access Model and HCDCO.