An Important Message from

The Texas Health and Human Services Commission (HHSC)

Prior Authorization Criteria for High-Cost Clinician Administered Drug (HCCAD) Aucatzyl Effective July 1, 2025

Background:

On July 1, 2025, Aucatzyl will become a benefit of Medicaid and CHIP. HHSC requires prior authorization for Aucatzyl (procedure code Q2058) for Medicaid and CHIP, effective for dates of service on or after Aug. 1, 2025.

Key Details:

Aucatzyl (obecabtagene autoleucel) is a CD19-directed genetically modified autologous T cell immunotherapy indicated to treat adult clients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

HHSC will reimburse Aucatzyl as non-risk and designated as a high-cost clinician-administered drug (HCCAD). The HHSC-approved clinical prior authorization is mandatory for MCOs.

Prior Authorization Requirements

Prior authorization approval for a one-time, split dose Aucatzyl (obecabtagene autoleucel) Q2058 infusion therapy will be considered when all the following criteria are met:

- The client is 18 years and older;
- There is a confirmed diagnosis of relapsed or refractory B-cell precursor ALL (diagnosis code: C91.00, C91.02);
- The client has adequate cardiac, hepatic, pulmonary, and renal function;
- A bone marrow blast assessment was conducted and result from a sample obtained to start lymphodepleting chemotherapy;
- The client does not have a clinically significant active infection or inflammatory disorder:
- The client has been screened and does not have active/latent Hepatitis B virus, active Hepatitis C virus, or human immunodeficiency virus (HIV); and
- The client has not received prior CAR-T therapy.

Aucatzyl (obecabtagene autoleucel), Q2058 is limited to one transfusion treatment per lifetime.

Required Monitoring Parameters

MCOs must require providers to monitor the client for the parameters listed below following Aucatzyl (obecabtagene autoleucel) treatment:

- Signs and symptoms of cytokine release syndrome (CRS);
- Signs and symptoms of immune effector cell-associated neurotoxicity syndrome (ICANS) and other acute toxicities; and
- Signs of cytopenias (e.g., anemia, neutropenia, thrombocytopenia) and secondary malignancies.

Action:

VDP will implement the fee-for-service Medicaid criteria on Aug. 1, 2025. MCOs do not need to wait for publication in the TMPPM before implementation.

Refer to the <u>Outpatient Drug Services Handbook Chapter</u> of the Texas Medicaid Provider Procedure Manual for the current HCCADs list and more details on the clinical policy and prior authorization requirements. TMHP will publish the Aucatzyl maximum allowable rate on the Online Fee Lookup portion of the <u>fee schedule</u> soon.

Questions?

Please contact UnitedHealthcare Customer Service at 888-887-9003, 8 a.m.–6 p.m. CT, Monday–Friday.