An Important Message from

The Texas Health and Human Services Commission (HHSC)

Prior Authorization Criteria for Niktimvo Effective July 1, 2025

Background:
On July 1, 2025, Niktimvo, will become a benefit of Medicaid and CHIP. HHSC requires prior authorization for Niktimvo (procedure code J9038) for Medicaid and CHIP, effective for dates of service on or after Aug. 1, 2025.

Key Details:
Niktimvo (axatilimab-csfr) is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

Prior Authorization Requirements
Prior authorization approval for Niktimvo (axatilimab-csfr) J9038 infusion therapy will be considered when the following criteria are met:

- Client weighs at least 40 kg (88 lbs);
- Client has a confirmed diagnosis of cGVHD (diagnosis code: D89.811 or D89.812);
- Client has undergone allogenic stem cell transplantation;
- Client has a failure history with at least two prior systemic therapies for cGVHD; and
- The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment of Niktimvo and 30 days after the last dose of therapy.

Required Monitoring Parameters
MCOs must require providers to monitor the client's aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase prior to starting therapy, every 2 weeks for the first month, and one or two months after Niktimvo treatment.

Continuation Therapy
For continuation of Niktimvo therapy, MCOs must require providers to monitor the client for the parameters listed below:

- Client met initial requirements to prior authorization and is currently treated with Niktimvo with absence of unacceptable toxicity (e.g., severe infusion related reactions); and
- Client experienced positive clinical response to therapy.

Action:
Fee-for-service Medicaid will implement the criteria on Aug. 1, 2025. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive. Refer to the Outpatient Drug Services Handbook Chapter of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

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