etuvetidigene autotemcel (Waskyra)

Commercial Medical Benefit Drug Policy

Place of Service

Hospital Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: Autologous hematopoietic stem cell-based gene therapy

HCPCS:

J3386:Injection, etuvetidigene autotemcel, per treatment

How Supplied:

Packaged in one to eight infusion bags overall containing a suspension of 2 - 11.4 x 10^6 cells /mL (1.9–11.4 x 10^6 CD34+ cells/mL) in a cryopreservative solution.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

References

1. Waskyra (etuvetidigene autotemcel). Prescribing Information. Fondazione Telethon ETS, Rome Italy: 7/2026.

Review History

Date of Last Annual Review: NA

Changes from previous policy version:

- Placeholder

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee