dinutuximab (Unituxin®)

Medical Benefit Drug Policy

Place of Service
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: ANTINEOPLASTICS
Mechanism of Action: GD2-binding monoclonal antibody
HCPCS:
C9399:Unclassified drugs or biologicals
J3490:Unclassified drugs
J3590:Unclassified biologics
J9999:Not otherwise classified, antineoplastic drugs
How Supplied:
17.5 mg (single-use vial)

Condition(s) listed in policy *(see coverage criteria for details)*

- Neuroblastoma, high-risk

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

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.

The following condition(s) require Prior Authorization/Preservice:

Neuroblastoma, high-risk

1. Patient has received prior first-line therapy, AND
2. Used in combination with Leukine (sargramostim), Proleukin (aldesleukin), and isotretinoin

Covered Doses:
17.5 mg/m^2/day IV infusion (over 10 to 20 hours) for 4 consecutive days for up to 5 cycles.
Cycles 1, 3, and 5 are 24 days in duration
Cycles 2 and 4 are 32 days in duration

Coverage Period:

Up to 5 cycles (20 doses total) over one year

References

1. AHFS®. Available by subscription at http://www.lexi.com
2. DrugDex®. Available by subscription at http://www.micromedexsolutions.com
3. Unituxin® (Dinutuximab) [Prescribing information]. Research Triangle Park, NC: United Therapeutics Corp.; 9/2020.

Review History

Date of Last Annual Review: 1Q2024

Date of last revision: 04/03/2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

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