

Unituxin[®] (dinutuximab) (Intravenous)

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I. Length of Authorization

Coverage is provided for 6 months (total therapy is 5 cycles) and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Unituxin 17.5 mg/5 mL single-dose vial: 12 vials every 24 days for a maximum of 5 cycles

B. Max Units (per dose and over time) [HPCS Unit]:

- 52.5 mg per day for four doses every 24 days for a maximum of 5 cycles

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

- Patient is less than 18 years of age; **AND**

Universal Criteria ¹

- Will not be used in combination with other GD2-binding monoclonal antibodies (i.e., naxitamab, etc.); **AND**

High-Risk Neuroblastoma † Φ ^{1,2}

- Used in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF] (e.g., sargramostim); **AND**
- Used in combination with interleukin-2 [IL-2] (e.g., aldesleukin); **AND**
- Used in combination with 13-cis-retinoic acid (e.g., isotretinoin); **AND**
- Patient had at least partial response to first-line multiagent, multimodality therapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria ¹

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
High-Risk Neuroblastoma	Administer 17.5 mg/m ² /day intravenously over 10 to 20 hours for 4 consecutive days for a maximum of 5 cycles. <ul style="list-style-type: none">– Infuse on Days 4, 5, 6 and 7 of Cycles 1, 3 and 5 (24 days per cycle)– Infuse on Days 8, 9, 10, and 11 of Cycles 2 and 4 (32 days per cycle)

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – not otherwise classified, antineoplastic drugs
- C9399 – unclassified drugs or biologicals (*Hospital Outpatient Use ONLY*)

NDC:

- Unituxin 17.5 mg/5 mL single-dose vial: 66302-0014-xx

VII. References

1. Unituxin [package insert]. Research Triangle Park, NC; United Therapeutics Corp; September 2020. Accessed December 2023.
2. Yu AL, Gilman AL, Ozkaynak MF, et al. Anti-GD2 Antibody with GM-CSF, Interleukin-2, and Isotretinoin for Neuroblastoma. N Engl J Med. 2010 Sep 30; 363(14): 1324–1334. Doi: 10.1056/NEJMoa0911123.

Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	Description
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents:

<https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC