

Unituxin™ (dinutuximab) (Intravenous)

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I. Length of Authorization

Coverage is provided for six 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 per vials: 12 vials every 28 days

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

- 52.5 mg per day

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

- Patient age is less than 18 years; **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-labeled indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration ¹

Indication	Dose
High-Risk Neuroblastoma	Administer 17.5 mg/m ² daily, infused over 10-20 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 use vial – 66302-0014-xx

VII. References

1. Unituxin [package insert]. Silver Spring, MD; United Therapeutics Corp; September 2020. Accessed December 2020.
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)

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 Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered 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