

Unituxin™ (dinutuximab)

(Intravenous)

Document Number: IC-0247

Last Review Date: 1/3/2018

Date of Origin: 04/28/2015

Dates Reviewed: 4/2015, 01/2016, 01/2017, 01/2018

I. Length of Authorization

Coverage is provided for six months and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- 12 vials (17.5mg/5ml per vial) every 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 52.5 mg (billable units) per day

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Patient with Neuroblastoma †

- Patient age is less than 18 years; AND
- Used in combination with GM-CSF; AND
- Used in combination with interleukin-2; AND
- Used in combination with 13-cis-retinoic acid; AND
- Patient had at least partial response to first-line multiagent, multimodality therapy

†FDA-labeled indication(s)

IV. Renewal Criteria

N/A

V. Dosage/Administration

Indication	Dose
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All Indications	17.5 mg/m ² daily for 4 consecutive days for a maximum of 5 cycles. <i>Cycles 1, 3 and 5 are 24 days long</i> <i>Cycles 2 & 4 are 32 days long</i>
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VI. Billing Code/Availability Information

JCode:

- 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 – 66302-014-xx

VII. References

1. Unituxin [package insert]. Silver Spring, MD; United Therapeutics Corp; March 2017. Accessed November 2017.

Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	Diagnosis
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) 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/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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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	Cahaba Government Benefit Administrators, 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