



Unituxin® (dinutuximab) (Intravenous)

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Last Review Date: 01/05/2023

Date of Origin: 04/28/2015

Dates Reviewed: 04/2015, 01/2016, 01/2017, 01/2018, 01/2020, 01/2021, 01/2022, 01/2023

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 per vials: 12 vials every 24 days

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

- 52.5 mg per day for four doses every 24-day cycle

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-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. – 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 2022.
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: <https://www.cms.gov/medicare-coverage-database/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

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PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

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ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013) .

ဟ်သ့ဟ်သး- နမာ်ကတိ၊ ကညီ ကိုက်အယိ၊ နမာ် ကိုက်အတၢ်မၤစၢၤလၢ တလၢ်ဘျၣ်လၢ်စၢၤ နီတမံၤဘၣ်သန့လီၤ. ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

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주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

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Minneapolis, MN 55459-0212
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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