

Medical Policy:

Unituxin (dinutuximab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.51	February 7, 2025	December 30, 2020

Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Unituxin is a GD2-binding monoclonal antibody indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

Length of Authorization

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

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 17.5 mg/m² daily for 4 consecutive days for a maximum of 5 cycles
 - Cycles 1, 3, and 5 are 24 days long
 - Cycles 2 and 4 are 32 days long
- **Max Units (per dose and over time) [HCPCS Unit]:**

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

Guideline

Unituxin (dinutuximab) may be considered medically necessary when the coverage is provided in the following conditions:

1. Neuroblastoma

- Patient has a diagnosis of neuroblastoma; **AND**
- Patient age is less than 18 years; **AND**
- Used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13—cis-retinoic acid (RA); **AND**
- Patient had at least partial response to first-line multiagent, multimodality therapy

Limitations and Exclusions

- Coverage is provided for six months and may not be renewed
- Will not be used in combination with other GD2-binding monoclonal antibodies (i.e., naxitamab, etc.)

Applicable Procedure Codes

Code	Description
J9999	Not otherwise classified, antineoplastic drug
C9399	Unclassified drugs or biologicals (Hospital outpatient use only)

Applicable NDCs

Code	Description
66302-0014-01	Unituxin 3.8mg/1mL intravenous

ICD-10 Diagnoses

Code	Description
C74.0	Malignant neoplasm of cortex of adrenal gland
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland
C74.01	Malignant neoplasm of cortex of right adrenal gland
C74.02	Malignant neoplasm of cortex of left adrenal gland
C74.1	Malignant neoplasm of medulla of adrenal gland
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland
C74.11	Malignant neoplasm of medulla of right adrenal gland
C74.12	Malignant neoplasm of medulla of left adrenal gland
C74.9	Malignant neoplasm of unspecified part of adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland

Revision History

Company(ies)	DATE	REVISION
--------------	------	----------

EmblemHealth & ConnectiCare	02/07/2025	Annual Review: added max units, No criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	4/13/2023	Annual Review: Corrected formatting, Added Exclusion Criteria: Will not be used in combination with other GD2-binding monoclonal antibodies (i.e., naxitamab, etc.)
EmblemHealth & ConnectiCare	1/17/2023	Transfer to New Template, added NDC code 66302-0014-01
EmblemHealth & ConnectiCare	12/30/2020	New Policy

References

1. Unituxin [package insert]. Silver Spring, MD; United Therapeutics Corp; March 2017. Accessed September, 2020