Medical Policy:

Unituxin (dinutuximab) Intravenous

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

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/m^2 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

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

Limitations and Exclusions

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