POLICY: Unituxin Utilization Management Medical Policy

- Unituxin® (dinutuximab injection for intravenous use – United Therapeutics Corp)

EFFECTIVE DATE: 3/15/2021
LAST REVISION DATE: 01/07/2026

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Unituxin, a glycolipid disialoganglioside (GD2)-binding monoclonal antibody, is indicated for the treatment of pediatric patients with high-risk **neuroblastoma** who achieve at least a partial response to prior first-line multi-agent, multimodality therapy, in combination with granulocyte-macrophage colony-stimulating factor, interleukin-2, and 13-cis-retinoic acid.[1]

Dosing Information

The recommended dose of Unituxin is 17.5 mg/m^2/day administered by intravenous infusion over 10 to 20 hours for 4 consecutive days for a maximum of 5 cycles.[1]

Guidelines

The National Comprehensive Cancer Network neuroblastoma (version 1.2025 – April 16, 2025) treatment guidelines recommend Unituxin following induction, consolidation, or post-consolidation therapy for high-risk disease.[2,3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Unituxin. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Unituxin as well as the monitoring required for adverse events and long-term efficacy, approval requires Unituxin to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Unituxin is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Neuroblastoma.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≤ 18 years of age; AND
   B) The medication is used as subsequent therapy; AND
   C) The medication is prescribed by or in consultation with an oncologist.
   Dosing. Approve up to 17.5 mg/m^2/day administered by intravenous infusion for 4 days in each treatment cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Unituxin is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Unituxin intravenous infusion [prescribing information]. Silver Spring, MD: United Therapeutics; October 2025.
2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 5, 2026. Search term: dinutuximab.
3. The NCCN Neuroblastoma Clinical Practice Guidelines in Oncology (version 1.2025 – April 16, 2025). © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 5, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/14/2022
Annual revision	No criteria changes.	12/20/2023
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	01/22/2025
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/15/2025
Annual Revision	No criteria changes.	01/07/2026