

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Unituxin Prior Authorization Policy

- Unituxin® (dinutuximab intravenous infusion – United Therapeutics)

REVIEW DATE: 12/20/2023

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

Guidelines

Unituxin is not addressed in National Comprehensive Cancer Network treatment guidelines.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Unituxin. 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 the following (A, B, and C):
 - A) Patient is ≤ 18 years of age; AND
 - B) Unituxin is used as subsequent therapy; AND
 - C) Unituxin is prescribed by or in consultation with an oncologist.

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, ND: United Therapeutics; September 2020.