

# 5.21.58

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2021
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	July 24, 2015
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**Last Review Date:** March 12, 2021

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## Unituxin

### Description

#### Unituxin (dinutuximab)

#### Background

Neuroblastoma is a rare cancer that forms from immature nerve cells that usually begins in the adrenal glands but may also develop in the abdomen, chest or in nerve tissue near the spine. Neuroblastoma typically occurs in children younger than five years of age. Unituxin is an antibody that binds to the surface of neuroblastoma cells. Unituxin is part of a multimodality regimen (the use of multiple methods), including surgery, chemotherapy, and radiation therapy for patients who achieved at least a partial response to prior first-line multi-agent, multimodality therapy such as induction combination chemotherapy, myeloablative consolidation chemotherapy followed by autologous stem cell transplant, and radiation therapy (1).

#### Regulatory Status

FDA-approved indications: 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 multi-agent, multimodality therapy (1).

Unituxin carries a boxed warning alerting patients and health care professionals that Unituxin irritates nerve cells, causing severe pain that requires treatment with intravenous narcotics and can also cause nerve damage and life-threatening infusion reactions, including upper airway swelling, difficulty breathing, and low blood pressure, during or shortly following completion of the infusion. Unituxin may also cause other serious side effects including infections, eye problems, electrolyte abnormalities and bone marrow suppression (1).

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Unituxin may cause fetal harm. Females of reproductive potential should be advised to use effective contraception during treatment and for two months after the last dose of Unituxin (1).

## Related policies

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### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Unituxin may be considered **medically necessary** in patients 15 years of age or less with neuroblastoma and if the conditions indicated below are met.

Unituxin may be considered **investigational** in patients older than 15 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 15 years of age or younger

### Diagnosis

Patient must have the following:

Neuroblastoma

**AND ALL** of the following:

1. Used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA)
2. Achieved partial response to prior first-line multi-agent (combination therapy), multimodality therapy for the treatment of neuroblastoma
3. Prescriber agrees to monitor for infusion reactions, neurotoxicity, electrolyte abnormalities, bone marrow suppression, capillary leak syndrome and hypotension
4. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Unituxin and for 2 months after the final dose

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## Prior – Approval *Renewal* Requirements

None

### Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Duration**      6 months

## Prior – Approval *Renewal* Limits

None

### Rationale

#### Summary

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 multi-agent, multimodality therapy. Unituxin carries a boxed warning regarding drug-induced severe neuropathic pain and life-threatening infusion reactions, including upper airway swelling, difficulty breathing, and low blood pressure, during or shortly following completion of the infusion (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Unituxin while maintaining optimal therapeutic outcomes.

#### References

1. Unituxin [package insert]. Silver Spring, Maryland: United Therapeutics; September 2020.

### Policy History

Date	Action
July 2015	New Policy Addition
September 2015	Annual review

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June 2016	Annual editorial review and reference update Policy code changed from 5.04.58 to 5.21.58
June 2017	Annual editorial review and reference update
June 2018	Annual review
June 2019	Annual review
June 2020	Annual review
March 2021	Annual review and reference update. Added monitoring and pregnancy requirements per FEP.

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.**