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5.21.058

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 24, 2015
Subject:	Unituxin	**Page:**	1 of 4

Last Review Date: June 13, 2024

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 indication: 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).

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
Danyelza, Iwilfin

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** if the conditions indicated below are met.

Unituxin may be considered **investigational** 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

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.
2. NCCN Drugs & Biologics Compendium® Dinutuximab 2024. National Comprehensive Cancer Network, Inc. Accessed on April 11, 2024.

Policy History

Date	Action
July 2015	New policy addition

September 2015	Annual review
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.
December 2022	Annual review. Changed policy number to 5.21.058
December 2023	Annual review
June 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.