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).
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

**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

**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

Policy History

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<td>June 2016</td>
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Keywords

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June 20, 2019 and is effective on July 1, 2019.