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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 17, 2024
Subject:	Ojemda	**Page:**	1 of 4

Last Review Date: December 13, 2024

Ojemda

Description

Ojemda (tovorafenib)

Background
Ojemda (tovorafenib) is a Type II RAF kinase inhibitor of mutant BRAF V600E, wild-type BRAF, and wild-type CRAF kinases. Ojemda exhibited antitumor activity in cultured cells and xenograft tumor models harboring BRAF V600 and V600D mutations, and in a xenograft model harboring a BRAF fusion (1).

Regulatory Status
FDA-approved indications: Ojemda is a kinase inhibitor indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation (1).

Prior to initiation of therapy, the presence of BRAF fusion or rearrangement, or BRAF V600 mutation must be confirmed (1).

Hemorrhages, skin toxicity including photosensitivity, hepatotoxicity, and reductions in growth velocity may occur with Ojemda use. Monitor for signs and symptoms of hemorrhage, new or worsening skin reactions, liver function tests, and patient growth during treatment with Ojemda. Depending on severity, treatment should be withheld and resumed at the same or reduced dose upon improvement, or permanently discontinued (1).

Ojemda may promote tumor growth in patients with NF1 tumors. Confirm evidence of a BRAF alteration prior to initiation of treatment with Ojemda (1).

Ojemda may cause fetal harm when administered to a pregnant woman. Advise female patients of reproductive potential to use effective non-hormonal contraception during treatment with Ojemda and for 28 days after the last dose. Advise male patients with female partners of reproductive potential to use effective nonhormonal contraception during treatment with Ojemda and for 2 weeks after the last dose (1).

The safety and effectiveness of Ojemda for pediatric patients less than 6 months of age have not been established (1).

Related Policies
Tafinlar

Policy

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

Ojemda may be considered **medically necessary** if the conditions indicated below are met.

Ojemda may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 6 months of age or older

Diagnosis

Patient must have the following:

1. Relapsed or refractory pediatric low-grade glioma (LGG)
    a. Patient has **ONE** of the following:
        i. BRAF fusion or rearrangement
        ii. BRAF V600 mutation

AND ALL of the following:

1. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ojemda and for 28 days after the last dose

2. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ojemda and for 2 weeks after the last dose

Prior – Approval *Renewal* Requirements

Age 6 months of age or older

Diagnosis

Patient must have the following:

1. Relapsed or refractory pediatric low-grade glioma (LGG)
   a. **NO** disease progression or unacceptable toxicity

AND ALL of the following:

1. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ojemda and for 28 days after the last dose
2. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Ojemda and for 2 weeks after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength/Dosage Form	Quantity
100 mg tablet	72 tablets per 84 days **OR**
25 mg/mL oral suspension	24 bottles per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Ojemda (tovorafenib) is indicated for the treatment of relapsed or refractory pediatric low-grade glioma (LGG). Ojemda has warnings for hemorrhage, skin toxicity, hepatotoxicity, reductions in growth velocity, embryo-fetal toxicity, and NF1 associated tumors. The safety and effectiveness of Ojemda for pediatric patients less than 6 months of age have not been established (1).

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

References

1. Ojemda [package insert]. Brisbane, CA: Day One Biopharmaceuticals, Inc.; June 2024.
2. NCCN Drugs & Biologics Compendium® Tovorafenib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 24, 2024.

Policy History

Date	Action
May 2024	Addition to PA
June 2024	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.