PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ojemda Prior Authorization Policy
- Ojemda® (tovorafenib tablets and oral suspension – Day One Biopharmaceuticals)

REVIEW DATE: 05/03/2024

OVERVIEW
Ojemda, a kinase inhibitor, is indicated for the treatment of **relapsed or refractory pediatric low-grade glioma** in patients 6 months of age and older, harboring a *BRAF* fusion or rearrangement, or *BRAF V600* mutation.[1]

This indication is approved under accelerated approval based on response rate and duration of response.[1] Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Guidelines
Ojemda is not addressed in the National Comprehensive Cancer Network (NCCN) guidelines for Central Nervous System Cancers (version 1.2023 – March 24, 2023) or the Pediatric Central Nervous System Cancers (version 1.2024 – February 26, 2024).[2,3]

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Ojemda. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Ojemda is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Pediatric Low-Grade Glioma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 6 months of age; AND
   - **B)** Patient has relapsed or refractory disease; AND
   - **C)** The tumor is positive for ONE of the following (i, ii, or iii):
     - **i.** *BRAF* fusion; OR
     - **ii.** *BRAF* rearrangement; OR
     - **iii.** *BRAF V600* mutation.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ojemda 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. Ojemda® tablets and oral suspension [prescribing information]. Brisbane, CA: Day One Biopharmaceuticals; April 2024.
2. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2023 – March 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on May 2, 2024.
3. The NCCN Pediatric Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2024 – February 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on May 2, 2024.