



PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/03/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Ojemda® (tovorafenib tablets and oral suspension – Day One Biopharmaceuticals)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Ojemda® (tovorafenib tablets and oral suspension – Day One Biopharmaceuticals)**

is(are) considered experimental, investigational or unproven for ANY other use(s) (criteria will be updated as new published data are available).

- 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	New Policy	05/03/2024

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