

Clinical Policy: Tovorafenib (Ojemda)

Reference Number: CP.PHAR.686

Effective Date: 09.10.24

Last Review Date: 08.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Tovorafenib (Ojemda™) is a kinase inhibitor.

FDA Approved Indication(s)

Ojemda is indicated for the treatment of pediatric 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.*

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Ojemda is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Pediatric Low-Grade Glioma (must meet all):**

1. Diagnosis of relapsed or refractory LGG;
2. Prescribed by or in consultation with an oncologist;
3. Age $\geq$ 6 months;
4. Disease is positive for one of the following (a or b):
 - a. BRAF fusion or rearrangement;
 - b. BRAF V600 mutation;
5. Failure of at least one line of prior systemic therapy (*see Appendix B for examples*);
6. For Ojemda requests, member must use tovorafenib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Documentation of the member's current body surface area (BSA)(m²);
8. Request meets one of the following (a or b):*
 - a. Dose does not exceed both of the following (i and ii):
 - i. 380 mg per m² of BSA;
 - ii. 600 mg once weekly;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. NCCN Recommended Uses (off-label) (must meet all):

1. Diagnosis of one of the following (a or b):
 - a. Adult glioma (e.g., circumscribed glioma);
 - b. Adult Langerhans cell histiocytosis (LCH);
2. Prescribed by or in consultation with an oncologist;
3. Age $\geq$ 18 years;
4. Disease is positive for one of the following (a or b):
 - a. BRAF fusion, rearrangement, or alterations;
 - b. BRAF V600 mutation;
5. For Ojemda requests, member must use tovorafenib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Ojemda for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Ojemda requests, member must use tovorafenib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):*
 - a. Both of the following (i and ii):

- i. Documentation of the member's current body surface area (BSA)(m²);
- ii. Dose does not exceed both of the following (1 and 2):
 - 1) 380 mg per m² of BSA;
 - 2) 600 mg once weekly;
- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

- 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
- 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BRAF: B-Raf proto-oncogene,

serine/threonine kinase

BSA: body surface area

FDA: Food and Drug Administration

LGG: low grade glioma

WHO: World Health Organization

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
vincristine [†] / carboplatin [†]	Ages > 3 months to ≤ 16 years	See dosing regimen

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	<u>Induction Therapy</u> vincristine 1.5 mg/m² IV continuous infusion once weekly; carboplatin 175 mg/m² IV continuous infusion once weekly on weeks 1 - 4 and 7 - 10. <u>Maintenance Therapy</u> vincristine 1.5 mg/m² IV continuous infusion once weekly for 3 weeks; carboplatin 175 mg/m² IV continuous infusion once weekly for 4 weeks; repeat every 6 weeks for 8 cycles.	
vinblastine [†]	vinblastine 6 mg/m ² IV continuous infusion once weekly until disease progression or unacceptable toxicity	See dosing regimen

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

[†]Off-label

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- Information on FDA-approved tests for the detection of *BRAF* fusions, *BRAF* rearrangements, and *BRAF V600* mutations is available at: <https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools>.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pediatric LGG	Recommended dosage of Ojemda based on BSA: 380 mg/m² Tablets: 0.30 to 0.89 m²: Administer Ojemda oral suspension once weekly 0.90 to 1.12 m²: 400mg PO once weekly 1.13 to 1.39 m²: 500mg PO once weekly ≥1.40 m²: 600mg PO once weekly Oral Suspension: 0.30 to 0.35 m²: 125 mg (5 mL) PO once weekly 0.36 to 0.42 m²: 150 mg (6 mL) PO once weekly 0.43 to 0.48 m²: 175 mg (7 mL) PO once weekly 0.49 to 0.54 m²: 200 mg (8 mL) PO once weekly	600 mg/week

Indication	Dosing Regimen	Maximum Dose
	0.55 to 0.63 m²: 225 mg (9 mL) PO once weekly 0.64 to 0.77 m²: 275 mg (11 mL) PO once weekly 0.78 to 0.83 m²: 300 mg (12 mL) PO once weekly 0.84 to 0.89 m²: 350 mg (14 mL) PO once weekly 0.90 to 1.05 m²: 375 mg (15 mL) PO once weekly 1.06 to 1.25 m²: 450 mg (18 mL) PO once weekly 1.26 to 1.39 m²: 525 mg (21 mL) PO once weekly ≥1.40 m²: 600 mg (24 mL) PO once weekly The recommended duration of treatment is until disease progression or unacceptable toxicity.	

VI. Product Availability

- Tablets: 100 mg
- Oral suspension: 300 mg/12 mL

VII. References

- Ojemda Prescribing Information. Brisbane, CA: Day Biopharmaceuticals, Inc.; August 2025. Available at: <https://www.ojemda.com/>. Accessed April 16, 2026.
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- Bouffet E, Jakacki R, Goldman S, et al. Phase II study of weekly vinblastine in recurrent or refractory pediatric low-grade glioma. J Clin Oncol. 2012;30(12):1358-63.
- US Food and Drug Administration. List of cleared or approved companion diagnostic devices (in vitro and imaging tools). FDA. Available at: <https://www.fda.gov/medical-devices/in-vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-in-vitro-and-imaging-tools>. Accessed May 13, 2026.
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- National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: <http://www.nccn.org>. Accessed May 13, 2026.
- National Comprehensive Cancer Network. Central Nervous System Cancers Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed May 13, 2026.
- National Comprehensive Cancer Network. Histiocytic Neoplasms Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf. Accessed May 13, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.20.24	08.24
3Q 2025 annual review: no significant changes; references reviewed and updated.	04.17.25	08.25

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2026 annual review: added off-label criteria for adult glioma and adult Langerhans cell histiocytosis as supported by NCCN; added oral oncology generic redirection for brand Ojemda requests; added ICHRA line of business; references reviewed and updated.	04.16.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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