

Modeyso™ (dordaviprone) (Oral)

Document Number: IC-0805

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I. Length of Authorization ¹

- Initial: Prior authorization validity will be provided initially for 6 months (180-days).
- Renewal: Prior authorization validity may be renewed every 6 months (180-days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 625 mg weekly

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 1 year of age; **AND**

Universal Criteria ¹

- Member will be monitored for electrocardiograms (ECG) and electrolytes at baseline and periodically during treatment as clinically indicated; **AND**
- Member will avoid coadministration with all of the following:
 - Coadministration with strong or moderate CYP3A4 inhibitors (e.g., fluconazole, itraconazole, grapefruit juice, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
 - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, efavirenz, etc.); **AND**
 - Coadministration with drugs that prolong QTc interval (e.g., amiodarone, sotalol, levofloxacin, venlafaxine, quetiapine, sumatriptan, etc.), or if therapy is unavoidable, the administration of Modeyso and the QT-prolonging product will be separated; **AND**
- Members on corticosteroid therapy are stable or are receiving decreasing doses; **AND**

Glioma † Φ ¹⁻⁴

- Member has a diagnosis of diffuse midline glioma; **AND**
- Member's disease harbors an H3 K27M mutation as determined by a Food & Drug Administration (FDA)-approved or Clinical Laboratory Improvement Amendment (CLIA)-compliant test❖; **AND**

- Used as subsequent therapy after progression on previous systemic therapy; **AND**
- Member does not have diffuse intrinsic pontine glioma (DIPG), primary spinal tumors, atypical histologies, or cerebrospinal fluid dissemination

❖ *If confirmed using an immunotherapy assay-<http://www.fda.gov/CompanionDiagnostics>*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria ¹

Prior authorization validity can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: significant hypersensitivity or anaphylaxis, QT-prolongation and/or life-threatening arrhythmias, etc.

V. Dosage/Administration ¹

Indication	Dose
Diffuse midline glioma	Adults The recommended dosage of Modeyso is 625 mg orally once weekly until disease progression or unacceptable toxicity.
	Pediatrics The recommended dosage of Modeyso in pediatric patients aged 1 to <17 years who weigh at least 10 kg is based on body weight and dosed once weekly until disease progression or unacceptable toxicity. <ul style="list-style-type: none"> — 10 kg to <12.5 kg: 125 mg — 12.5 kg to <27.5 kg: 250 mg — 27.5 kg to <42.5 kg: 375 mg — 42.5 kg to <52.5 kg: 500 mg — ≥52.5 kg: 625 mg Take Modeyso on an empty stomach (at least 1 hour before or 3 hours after food intake).

VI. Billing Code/Availability Information

HCPCS Code(s):

- C9399 – Unclassified drugs or biologicals (*For hospital outpatient use only*)
- J8999 – Prescription drug oral, chemotherapeutic, Not Otherwise Specified

NDC(s):

- Modeyso 125 mg capsules: 68727-0250-xx

VII. References

1. Modeyso [package insert]. Palo Alto, CA; Jazz Pharmaceuticals, Inc.; August 2025. Accessed August 2025.
1. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) dordaviprone. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Central Nervous System Cancers. Version 2.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Pediatric Central Nervous System Cancers. Version 2.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2025.
4. Sumrall AL, Allen JE, Bagley SJ, et al. Efficacy and safety of dordaviprone (ONC201) in prospective clinical trials of adult and pediatric recurrent H3 K27M-mutant diffuse glioma patients.. JCO 43, 10017-10017(2025). DOI:10.1200/JCO.2025.43.16_suppl.10017.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior

authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC