VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Modeyso Prior Authorization Policy
- Modeyso™ (dordaviprone capsules– Jazz)

REVIEW DATE: 08/13/2025; selected revision 09/10/2025

OVERVIEW
Modeyso, a protease activator, is indicated for the treatment of diffuse midline **glioma harboring a histone 3 (H3) K27M mutation** in adult and pediatric patients ≥ 1 year of age with progressive disease following prior therapy.[1]

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on central nervous system (CNS) cancers (version 2.2025 – August 28, 2025) recommend Modeyso for recurrent or progressive high-grade glioma with H3 K27M mutation as "Useful in Certain Circumstances (category 2A).[2] For H3-mutated high-grade unmethylated tumors, NCCN recommends clinical trial, standard radiation therapy (category 2A), standard radiation therapy + concurrent and adjuvant temozolomide (category 2B), or standard radiation therapy + adjuvant temozolomide (category 2B). For recurrent diffuse H3-mutated high-grade glioma, the recommendation is to consider clinical trials, systemic therapy, surgery for symptomatic, large lesions, or palliative/best supportive care if the patient has a poor performance status. NCCN guidelines for pediatric CNS cancers (version 3.2025 – September 2, 2025) recommend Modeyso for recurrent or progressive diffuse high-grade glioma with a H3 K27M mutation (category 2A).[3] There is a footnote that states the FDA approval is based on adult patient data and includes very limited efficacy data in pediatric patients.

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

Automation: None.

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

FDA-Approved Indication

1. **High-Grade Glioma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   Note: Examples of high-grade glioma include World Health Organization (WHO) Grade 3 or 4 gliomas, such as diffuse midline glioma or glioblastoma.
   A) Patient has a histone 3 (H3) K27M mutation; AND
   B) Patient has recurrent or progressive disease; AND
   C) Patient has received at one least prior therapy.
   Note: Examples of prior therapy include radiation, temozolomide, procarbazine, lomustine, or vincristine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Modeyso 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. Modeyso™ capsules [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; August 2025.
2. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 2.2025 – August 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 29, 2025.
3. The NCCN Pediatric Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 3.2025 – September 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 3, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	08/13/2025
Selected Revision	**High-Grade Glioma**: Previously this condition of approval was worded as "Diffuse Midline Glioma." A note was added with examples of high-grade glioma. An option for approval was added for a patient with recurrent disease.	09/10/2025