UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1447-1
Program	Prior Authorization/Notification
Medication	Ojemda™ (tovorafenib)
P&T Approval Date	6/2024
Effective Date	9/1/2024

1. Background:

Ojemda is a kinase inhibitor indicated for the treatment of 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.[1]

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).

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Ojemda** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. <u>Low-grade Glioma</u>

1. **<u>Initial Authorization</u>**

   a. **Ojemda** will be approved based on **<u>all</u>** the following criteria:

      (1) Diagnosis of pediatric low-grade glioma

      -AND-

      (2) Disease is relapsed or refractory

-AND-

(3) Presence of **one** of the following genetic mutations:

(a) BRAF fusion or rearrangement
(b) BRAF V600 mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Ojemda** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Ojemda therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.

4. References:

1. Ojemda [package insert]. Brisbane, CA: Day One Biopharmaceuticals, Inc. April 2024.

Program	Prior Authorization/Notification – Ojemda™ (tovorafenib)
Change Control	
6/2024	New program