Generic Name: Tovorafenib

Therapeutic Class or Brand Name: Ojemda

Applicable Drugs: Kinase Inhibitor

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/18/2024

Date Last Reviewed / Revised: 11/18/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of the following diagnosis AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Relapsed or refractory pediatric low-grade glioma

i. Documentation of BRAF fusion/rearrangement, or BRAF V600 mutation.

ii. Ojemda will be used as monotherapy.

iii. Documentation that systemic therapy is required.

iv. Documentation of disease progression on at least one line of prior systemic therapy.

v. Minimum age requirement: 6 months old.

II. Treatment must be prescribed by or in consultation with an oncologist, pediatric oncologist, or neuro-oncologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Tumors harboring additional activating molecular alterations (e.g. IDH1/2 or FGFR mutations, etc.).
- Known or suspected diagnosis of NF1 (neurofibromatosis type 1).

OTHER CRITERIA

- Liver function tests prior to administration and during treatment.
- Routine monitoring of growth in pediatric patients.

- Requests for oral suspension formulations must be accompanied by documentation confirming patient's inability to swallow tablets.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Maximum weekly dose of 600 mg
  - 100 mg tablets: 24 tablets per 28 days
  - 25 mg/mL oral suspension: 96 mL per 28 days

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease

APPENDIX

Recommended Ojemda Tablets Dosage Based on BSA	
Body Surface Area (m^2)	**Recommended Dosage**
0.30-0.89	Administer OJEMDA oral suspension once weekly
0.90-1.12	400 mg once weekly
1.13-1.39	500 mg once weekly
≥ 1.40	600 mg once weekly

Recommended Ojemda Oral Suspension Dosage Based on BSA		
Body Surface Area (m^2)	**Dose Volume (mL)**	**Dosage**
0.30-0.35	5	125 mg once weekly
0.36-0.42	6	150 mg once weekly
0.43-0.48	7	175 mg once weekly
0.49-0.54	8	200 mg once weekly
0.55-0.63	9	225 mg once weekly
0.64-0.77	11	275 mg once weekly
0.78-0.83	12	300 mg once weekly
0.84-0.89	14	350 mg once weekly
0.90-1.05	15	375 mg once weekly
1.06-1.25	18	450 mg once weekly
1.26-1.39	21	525 mg once weekly
≥1.40	24	600 mg once weekly

REFERENCES

1. Ojemda. Prescribing information. Day One Biopharmaceuticals, Inc.; 2024. Accessed October 10, 2024.

   https://www.dayonebio.com/wp-content/uploads/DAY101-USPI.pdf

2. NCCN Clinical Practice Guidelines in Oncology. Pediatric central nervous system cancers. V.1.2024. Updated February 26, 2024. Accessed October 9, 2024.

   https://www.nccn.org/professionals/physician_gls/pdf/ped_cns.pdf

3. NCCN Clinical Practice Guidelines in Oncology. Central nervous system cancers. V.3.2024. Updated September 30, 2024. Accessed October 9, 2024.

   https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.