LAROTRECTINIB

Generic	Brand	HICL	GCN	Exception/Other
LAROTRECTINIB	VITRAKVI	45494		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of a solid tumor and meet **ALL** of the following criteria?
   - The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
   - The tumor is metastatic or surgical resection is likely to result in severe morbidity
   - There are no satisfactory alternative treatments, or the patient has progressed following treatment

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Vitrakvi oral capsules?

   If yes, **approve for 12 months by GPID for all strengths as follows:**
   - **Vitrakvi 25mg (GPID 45793): #6 capsules per day.**
   - **Vitrakvi 100mg (GPID 45794): #2 capsules per day.**

   If no, continue to #3.

3. Is the request for Vitrakvi oral solution and the patient meets **ONE** of the following criteria?
   - The request is for a pediatric patient
   - Physician attestation that the patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
   - Physician attestation that the patient has other medical need for the oral solution

   If yes, **approve for 12 months by GPID as follows:**
   - **Vitrakvi 20mg/mL oral solution (GPID 45789): #10mL per day.**

   If no, do not approve Vitrakvi oral suspension. **Please enter a proactive PA for Vitrakvi capsules and approve for 12 months by GPID for all strengths as follows:**
   - **Vitrakvi 25mg (GPID 45793): #6 capsules per day.**
   - **Vitrakvi 100mg (GPID 45794): #2 capsules per day.**

CONTINUED ON NEXT PAGE

LAROTRECTINIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **LAROTRECTINIB (Vitrakvi)** requires a diagnosis of a solid tumor. In addition, the following criteria must be met:

- The tumor has a neurotrophic receptor tyrosine kinase (*NTRK*) gene fusion without a known acquired resistance mutation
- The tumor is metastatic or surgical resection is likely to result in severe morbidity
- There are no satisfactory alternative treatments, or the patient has progressed following treatment
- **Requests for Vitrakvi oral solution also requires that ONE of the following is met:**
  - The request is for a pediatric patient
  - Physician attestation that the patient is unable to take Vitrakvi capsules due to difficulty swallowing or dysphagia
  - Physician attestation that the patient has other medical need for the oral solution

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vitrakvi.

REFERENCES

- Vitrakvi [Prescribing Information]. Stamford, CT: Loxo Oncology, Inc: November 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/19
Created: 03/19
Client Approval: 03/19
P&T Approval: 01/19