blue of california

regorafenib (STIVARGA)

Diagnoses Considered for Coverage:

- Hepatocellular carcinoma (HCC)
- Metastatic colorectal cancer (m-CRC)
- Advanced gastrointestinal stromal tumors (GIST)
- Osteosarcoma
- Ewing sarcoma
- Recurrent glioblastoma
- Appendiceal cancer
- Soft tissue Sarcoma

Coverage Criteria:

1. **For diagnosis of colon or appendiceal or rectal cancer:**
   - Disease is advanced or metastatic, **and**
   - Being used as a single agent, **and**
   - Being used as subsequent therapy following previous systemic treatment for advanced or metastatic disease, **and**
   - Dose does not exceed 160 mg per day.

2. **For diagnosis of advanced gastrointestinal stromal tumor (GIST):**
   - For single agent use:
     - One of the following:
       - Disease progression with imatinib (Gleevec) AND either sunitinib (Sutent) or Qinlock (ripretinib) if patient is intolerant to sunitinib (Sutent), or
       - Patient is succinate dehydrogenase (SDH)-deficient

     OR
   - For use in combination with everolimus:
     - Being used as subsequent therapy after disease progression with all of the following:
     - imatinib (Gleevec)
     - Sutent (sunitinib)
     - Stivarga (regorafenib)
     - Qinlock (ripretinib)

     and
   - Dose does not exceed 160 mg per day for 21 days per 28-day cycle.

3. **For diagnosis of hepatocellular carcinoma (HCC):**
   - Patient has disease progression despite prior therapy for HCC, **and**
   - Being used as a single agent, **and**

- Dose does not exceed 160 mg per day for 21 days per 28-day cycle.

4. **For diagnosis of Ewing sarcoma or osteosarcoma**:
   - Disease is relapsed, refractory, progressive, or metastatic, **and**
   - Being used as a single agent, **and**
   - Being used for second-line therapy, **and**
   - Dose does not exceed 160 mg per day for 21 days per 28-day cycle.

5. **For diagnosis of glioblastoma:**
   - Patient has recurrent or progressive disease, **and**
   - Being used as a single agent, **and**
   - Dose does not exceed 160 mg per day for 21 days per 28-day cycle.

6. **For diagnosis of soft tissue sarcoma:**
   - Being used as a single agent, **and**
   - One of the following:
     - Being used for non-adipocytic subtype as subsequent treatment for recurrent unresectable or metastatic disease, or
     - Being used for angiosarcoma, or
     - Being used as subsequent treatment for advanced or metastatic pleomorphic rhabdomyosarcoma,

     and
   - Dose does not exceed 160 mg per day for 21 days per 28-day cycle.

Coverage Duration: one year

Effective Date: 02/28/2024