Clinical Policy Title:	regorafenib
Policy Number:	RxA.485
Drug(s) Applied:	Stivarga®
Original Policy Date:	03/06/2020
Last Review Date:	6/14/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Colorectal Cancer (must meet all)**:**

1. Diagnosis of metastatic colorectal cancer (CRC);
2. Previously treated with systemic chemotherapy;
3. Prescribed as a single agent therapy;

Approval duration

All lines of business (except Medicare): 12 months, Split-fill

B. Gastrointestinal Stromal Tumor (must meet all)**:**

1. Diagnosis of gastrointestinal stromal tumor (GIST);
2. Previously treated with imatinib (Gleevec®)* or Sutent®* unless contraindicated or clinically significant adverse effects are experienced;
   *Prior authorization is (or may be) required.

Approval duration

All lines of business (except Medicare): 12 months, Split-fill

C. Hepatocellular Carcinoma (must meet all)**:**

1. Diagnosis of hepatocellular carcinoma (HCC);
   *Prior authorization is (or may be) required.
2. Prescribed as a single agent therapy;
3. Prescribed as a second or subsequent-line therapy;

Approval duration

All lines of business (except Medicare): 12 months, Split-fill

D. Soft Tissue Sarcoma (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, or d):
   a. Non-adipocytic sarcoma (advanced/metastatic, recurrent, unresectable or stage IV disease);
   b. Angiosarcoma;
   c. Pleomorphic rhabdomyosarcoma (advanced/metastatic);
2. Prescribed as a single agent therapy;
3. Prescribed as a second or subsequent-line therapy;

Approval duration

All lines of business (except Medicare): 12 months, Split-fill

E. Osteosarcoma (off-label) (must meet all)**:**
1. Diagnosis of relapsed, refractory or metastatic osteosarcoma;
2. Prescribed as a second-line single agent therapy;

Approval duration: 12 months, Split-fill
All lines of business (except Medicare)**Approval duration**
All lines of business (except Medicare): 12 months, Split-fill

F. Glioblastoma (off-label) (must meet all)**:**
1. Diagnosis of recurrent glioblastoma;
2. Request will be used as a single agent;

Approval duration
All lines of business (except Medicare): 12 months, Split-fill

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration
All lines of business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Colon cancer. Version 3.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed June 14, 2024.
2. National Comprehensive Cancer Network Guidelines. Rectal cancer. Version 2.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed June 14, 2024.
3. National Comprehensive Cancer Network Guidelines. Soft tissue sarcoma. Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed June 14, 2024.
4. National Comprehensive Cancer Network Guidelines. Hepatocellular Carcinoma. Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed June 14, 2024.
5. National Comprehensive Cancer Network Guidelines. Bone cancers. Version 2.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed June 14, 2024.
6. National Comprehensive Cancer Network Guidelines. CNS cancers. Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed June 14, 2024.
7. National Comprehensive Cancer Network Guidelines. Gastrointestinal Stromal Tumors. Version 1.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed June 14, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of business policy applies was updated to All lines of business. 3. Drug(s) Applied was updated. 4. Continued therapy criteria II.A.1 was	09/01/2020	12/07/2020

rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. Initial Approval criteria: Commercial, HIM and Medicaid approval duration were updated from length of benefit to 6 months. 6. Continued Approval criteria: Commercial, HIM and Medicaid approval duration were updated from length of benefit to 12 months. 7. Initial approval criteria is updated for Soft Tissue Sarcoma to include angiosarcoma in criteria. 8. Updated Initial Approval Criteria for Osteosarcoma and Glioblastoma. 9. References were updated.		
Policy was reviewed: 1. Initial and Continued Therapy Approval Criteria was updated to remove HIM approval duration. 2. Continued Therapy Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 3. References were reviewed and updated.	09/15/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated to include new criteria pertaining to indication Colorectal Cancer, Prescribed as a single agent therapy. 2. Initial Approval Criteria, I.A.6.a: Updated dosing criteria from Dose does not exceed 160 mg/day to Dose does not exceed 160 mg/day on days 1 to 21 of each 28-day cycle. 3. Initial Approval Criteria, I.B.5.a: Updated dosing criteria from Dose does not exceed 160 mg/day to Dose does not exceed 160 mg/day on days 1 to 21 of each 28-day cycle. 4. Initial Approval Criteria, I.C.4: Updated to include new criteria pertaining to indication Hepatocellular Carcinoma, Prescribed as a single agent therapy. 5. Initial Approval Criteria, I.C.5: Updated to include new criteria pertaining to	04/05/2022	07/18/2022

indication Hepatocellular Carcinoma, Prescribed as a second or subsequent-line therapy. 6. Initial Approval Criteria, I.D.4: Updated to include new criteria pertaining to indication Soft Tissue Sarcoma, Prescribed as a single agent therapy. 7. Initial Approval Criteria, I.D.5.a: Updated dosing criteria from Dose does not exceed 160 mg/day to Dose does not exceed 160 mg/day on days 1 to 21 of each 28-day cycle. 8. Initial Approval Criteria, I.E.5: Updated to include new criteria pertaining to indication Osteosarcoma (off -label), Prescribed as a single agent therapy. 9. Initial Approval Criteria, I.E.6.a: Updated dosing criteria from Dose does not exceed to Dose does not exceed 160 mg/day on days 1 to 21 of each 28-day cycle. 10. Initial Approval Criteria, I.F.4: Updated to include new criteria pertaining to indication Glioblastoma, Request will be used as a single agent. 11. Initial Approval Criteria, I.F.5.a: Updated dosing criteria from Dose does not exceed 160 mg/day to Dose does not exceed 160 mg/day on days 1 to 21 of each 28-day cycle. 12. Continued Therapy Approval Criteria, II.A.3.a: Updated dosing criteria from Dose does not exceed 160 mg/day to Dose does not exceed 160 mg/day on days 1 to 21 of each 28-day cycle. 13. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.E.5: Updated prescribed criteria from Prescribed as single agent therapy to Prescribed as a second-line single agent therapy; 2. Initial Approval Criteria I.C.2: Removed criteria “Previously treated with sorafenib (Nexavar®)* or lenvatinib (Lenvima®)…” since covered in other criteria.	06/30/2023	07/13/2023

3. Initial Approval Criteria, I.D.1.d: Updated to remove prior criteria pertaining to indication Soft Tissue Sarcoma Solitary Fibrous Tumor. 4. Initial Approval Criteria I.D.5: Added "Prescribed as a second or subsequent-line therapy" to align with treatment guidelines. 5. Initial Approval Criteria I.E.2: Removed "Previously treated with cisplatin* and doxorubicin*…" to align with treatment guidelines. 6. Initial approval duration for all indications: Updated from 6 months to 12 months for all lines of business. 7. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Age Criteria Removed. 2. Dose criteria Removed. 3. Approval Duration Updated. 4. Continuation Criteria Updated. 5. References were reviewed and updated.	6/14/2024	6/14/2024