Generic Name: Regorafenib

Therapeutic Class or Brand Name: N/A

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 10/24/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documentation of one of the following diagnoses A through J AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

I. Metastatic colorectal cancer (CRC) and criteria i through iii are met:

i. Prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy has been ineffective, contraindicated, or not tolerated.

II. Prior treatment with an anti-VEGF therapy (i.e. bevacizumab, ramucirumab, or zivaflibercept) has been ineffective, contraindicated, or not tolerated.

III. Prior treatment with an anti-EGFR therapy (i.e. cetuximab, panitumumab) has been ineffective, contraindicated, or not tolerated if RAS wild-type.

IV. Locally advanced, unresectable, or metastatic gastrointestinal stromal tumor (GIST) and criterion i is met:

V. Prior treatment with imatinib and sunitinib have been ineffective, contraindicated, or not tolerated.

VI. Hepatocellular carcinoma (HCC) and criterion i is met:

VII. Prior treatment with sorafenib has been ineffective, contraindicated, or not tolerated.

Other Uses With Supportive Evidence

VIII. Angiosarcoma and criteria i through iii are met:

IX. Used as single agent.

X. Prior treatment with paclitaxel or docetaxel, vinorelbine, and pazopanib have been ineffective, contraindicated, or not tolerated.

XI. Prior treatment with anthracycline- or gemcitabine-based regimens have been ineffective, contraindicated, or not tolerated.

XII. Appendiceal Adenocarcinoma and criteria i through iv are met:

XIII. Used as single agent.

XIV. Prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy has been ineffective, contraindicated, or not tolerated.

XV. Prior treatment with an anti-VEGF therapy (i.e. bevacizumab, ramucirumab, or zivaflibercept) has been ineffective, contraindicated, or not tolerated.

XVI. Prior treatment with an anti-EGFR therapy (i.e. cetuximab, panitumumab) has been ineffective, contraindicated, or not tolerated if RAS wild-type.

XVII. Brain Cancer - glioblastoma or H3-mutated high-grade glioma and criteria i and ii are met:

XVIII. Recurrent or progressive disease.

XIX. Used as single agent.

XX. Ewing Sarcoma and criteria i through iii are met:

XXI. Used as single agent.

XXII. Used for relapsed/refractory or metastatic disease.

XXIII. Prior treatment with doxorubicin, vincristine, cyclophosphamide, ifosfamide, etoposide, topotecan, irinotecan, gemcitabine, and cabozantinib has been ineffective, contraindicated, or not tolerated.

XXIV. Osteosarcoma and criteria i through iii are met:

XXV. Used as single agent.

XXVI. Used for relapsed/refractory or metastatic disease.

XXVII. Prior treatment with cisplatin + doxorubicin, or MAP (high-dose methotrexate, cisplatin, and doxorubicin), or doxorubicin + cisplatin + ifosfamide + high-dose methotrexate has been ineffective, contraindicated or not tolerated.

XXVIII. Rectal Cancer and criteria i through iv are met:

XXIX. Used as single agent.

XXX. Prior treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy has been ineffective, contraindicated, or not tolerated.

XXXI. Prior treatment with an anti-VEGF therapy (i.e. bevacizumab, ramucirumab, or zivaflibercept) has been ineffective, contraindicated, or not tolerated.

XXXII. Prior treatment with an anti-EGFR therapy (i.e. cetuximab, panitumumab) has been ineffective, contraindicated, or not tolerated if RAS wild-type.

XXXIII. Soft Tissue Sarcoma with ONE of the following diagnosis i through iii:

XXXIV. Non-adipocytic retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive after initial treatment for unresectable localized disease OR subsequent therapy for stage IV disease with disseminated metastasis, OR

XXXV. Non-adipocytic sarcoma of the extremity/body or head/neck that is advanced/metastatic with disseminated metastases, OR

XXXVI. Pleomorphic rhabdomyosarcoma that is advanced/metastatic.

AND meets all of the following criteria iv AND v:

XXXVII. Used as single agent.

XXXVIII. Prior treatment with anthrycline-based regimen (ex: doxorubicin, epirubicin) AND gemcitabine-based regimen, AND dacarbazine, AND ifosfamide, AND pazopanib have been ineffective, contraindicated, or not tolerated.

XXXIX. Minimum age requirement: 18 years old.

XL. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

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

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

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 84 tablets per 28 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Stivarga. Prescribing information. Bayer HealthCare Pharmaceuticals Inc; 2020. Accessed October 24, 2024. https://labeling.bayerhealthcare.com/html/products/pi/Stivarga_PI.pdf
2. National Comprehensive Cancer Network (NCCN). Colon Cancer. Version 1.2024. Updated January 29, 2024. Accessed October 24, 2024. https://www.nccn.org/patients/guidelines/content/PDF/colon-patient.pdf
3. National Comprehensive Cancer Network (NCCN). Gastrointestinal Stromal Tumors. Version 2.2024. Updated July 31, 2024. Accessed October 24, 2024. https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf
4. National Comprehensive Cancer Network (NCCN). Hepatobiliary Cancers. Version 3.2024. Updated September 24, 2024. Accessed October 24, 2024. https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf
5. National Comprehensive Cancer Network (NCCN). Bone Cancer. Version 1.2025, August 20, 2024. Accessed October 24, 2024. www.nccn.org/professionals/physician_gls/pdf.bone.pdf
6. National Comprehensive Cancer Network (NCCN). Central Nervous System Cancers. Version 3.2024, September 30, 2024. Accessed October 24, 2024. www.nccn.org/professionals/physician_gls/pdf/cns.pdf
7. National Comprehensive Cancer Network (NCCN). Rectal Cancer. Version 4.2024, August 22, 2024. Accessed October 24, 2024. www.nccn.org/professionals/physician_gls/pdf/rectal/pdf
8. National Comprehensive Cancer Network (NCCN). Soft Tissue Sarcoma. Version 3.2024, September 27, 2024. www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf