Pharmacy Policy

Colorectal Cancer Agents – Unified Formulary

Policy Number: 9.710
Version Number: 1
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth- MCO
	☒ MassHealth- ACO
	☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Clinical Background Information and References

Reference Table:

Drugs that require PA	No PA
Stivarga® (regorafenib)	Gleevec® # (imatinib)

Procedure:

Approval Diagnosis:	• Metastatic colorectal cancer (Stivarga®) • Gastrointestinal stromal tumor (GIST) (Stivarga®) • Hepatocellular carcinoma (HCC) (Stivarga®)
Approval Criteria: **Stivarga®** (regorafenib)	*For Metastatic Colorectal Cancer* Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of metastatic colorectal cancer 2. Prescriber is an oncologist 3. Appropriate dose 4. Inadequate response or adverse reaction to **ONE** of the following

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	regimens or a contraindication to **ALL** of the following regimens*: (*Claims are NOT sufficient*) a. CAPEOX b. FOLFIRI c. FOLFOX d. FOLFOXIRI e. irinotecan-based therapy f. oxaliplatin-based therapy 5. If KRAS/NRAS/BRAF wild-type cancer is present, inadequate response or adverse reaction to **ONE** or a contraindication to **BOTH** of the following†: (*Claims are NOT sufficient*) a. Erbitux® (cetuximab) b. Vectibix® (panitumumab) *For Gastrointestinal Stromal Tumor* Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of gastrointestinal stromal tumor 2. Prescriber is an oncologist 3. Appropriate dose 4. Inadequate response, adverse reaction, or a contraindication to **BOTH** of the following: (*Claims are NOT sufficient*) 1. Gleevec® (imatinib) 2. Sutent® (sunitinib) *For Hepatocellular Carcinoma* Prescriber provides documentation of **ALL** of the following: 1. Diagnosis of hepatocellular carcinoma 2. Prescriber is an oncologist 3. Appropriate dose 4. Member has Child-Pugh Class A 5. Inadequate response, adverse reaction or a contraindication to Nexavar® (sorafenib) (*Claims are NOT sufficient*) *Notes:* • **Please see appendix for guidance regarding components of commonly used regimens for the treatment of colorectal cancer.* • *Please see appendix for guidance on requests for renal cell carcinoma.* • *Due to the severity of the disease treated with this agent, if a request is denied the prescriber should be contacted and informed of the additional clinical documentation that is required upon resubmission.* • †*The RAS oncogene exists as three cellular variants, HRAS, KRAS, and NRAS; the latter two may be predictive of tumor response to treatment. Non-mutated or wild-type (WT) RAS genes do not have mutations while mutated or mutant type (MT) RAS genes contain a mutation that affects its function and is associated with absence of response to agents that target EGFR. Therefore, only patients with WT mutations should have trials to EGFR inhibitors. If it is unclear whether the member has WT or mutated NRAS/KRAS, please contact the office for clarification.*
Denial Criteria:	Cases that do not meet the approval criteria will be denied.

	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	Prior authorization may be issued for up to **6 months**
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy and request can be recertified for **up to 6 months**

Appendix:

Stability

Stability alone on the agents in this guideline is not a reason to bypass approval criteria. However, requests for members who have already started treatment on these agents should be reviewed with clinical review and approval is strongly considered for any member with any FDA-approved indication.

Grandfathering

Not applicable.

Additional Information

Components of Commonly Used Regimens for Treatment of Colorectal Cancer

Regimen Abbreviation	Drug Components
5-FU	fluorouracil
CAPEOX	capecitabine/oxaliplatin
FOLFIRI	leucovorin calcium (folinic acid)/fluorouracil/irinotecan
FOLFOX	leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin
FOLFOXIRI	leucovorin calcium (folinic acid)/5-fluorouracil/oxaliplatin/irinotecan

Requests for Renal Cancer

Stivarga® (regorafenib) has been used off-label in the treatment of renal cancer. A phase II trial demonstrated efficacy in patients with unresectable renal cancer (N=49). Nineteen patients (39.6%; 90% confidence interval, 27.7 to 52.5) had an objective response, all of which were partial responses. Current NCCN guidelines do not address the role in therapy of this agent.

If a request documents that the member has unresectable cancer; please review request with clinical review. The decision should be based upon current NCCN guidelines recommendations and the availability of other less costly treatment alternatives.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	New policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee

Next Review Date

2021

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.