MEDICAL MUTUAL®

Drug Policy

Policy:	Lonsurf (trifluridine and tipiracil)	Annual Review Date: 01/21/2021 Last Revised Date: 01/21/2021

OVERVIEW

Lonsurf is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) biological therapy, and if RAS wild-type, an anti-epidermal growth factor receptor (EGFR) therapy.

POLICY STATEMENT

This policy involves the use of Lonsurf. Prior authorization is recommended for pharmacy benefit coverage of Lonsurf. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Lonsurf as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Lonsurf be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lonsurf is recommended in those who meet the following criteria:

1) **Metastatic Colorectal Cancer.** Approve if the patient meets the following criteria (A, B, and C) OR (D)
   - **A)** Previously treated with fluoropyrimidine-, oxaliplatin-and irinotecan-based chemotherapy; AND
   - **B)** Previously treated with anti-VEGF biological therapy; AND
   - **C)** If RAS wild-type, treated with an anti-EGFR therapy
   - **D)** Subsequent therapy as a single agent for unresectable advanced or metastatic disease not previously treated with trifluridine and tipiracil after (a or b or c)
     a. First progression (*KRAS/NRAS* mutant only) or second progression for disease previously treated with FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen with or without bevacizumab.
     b. Second progression for disease previously treated with irinotecan- and oxaliplatin-based therapy.
     c. Progression for disease that progressed through all available regimens.

2) Metastatic gastric or gastroesophageal junction adenocarcinoma, Treatment.

a. Approve if the patient has been previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy;

b. Palliative therapy for patients who are not surgical candidate or have unresectable locally advanced, recurrent, or metastatic cancer and Karnofsky performance score ≥ 60% or ECOG performance score ≤ 2 as preferred third-line or subsequent therapy as a single agent.

3) Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.
Prescriber will provide specific diagnosis for documentation. Approve

4) Patient has been started on Lonsurf (continuation of therapy).
Approve for an indication or condition addressed as an approval in this document.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Lonsurf [prescribing information]. Princeton, NJ: Taiho Oncology Inc.; February 2019.
2. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed 12 January 2021. Search term: trifluridine and tipiracil.
3. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (Version 4.2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. January 16, 2019.
4. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (Version 3.2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org January 16, 2019.