

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lonsurf Prior Authorization Policy

- Lonsurf® (trifluridine and tipiracil tablets – Taiho Oncology)

REVIEW DATE: 03/03/2021

OVERVIEW

Lonsurf, a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, is indicated for the following uses:¹

- **Metastatic colorectal cancer (mCRC)**, in adult patients 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.¹ Fluoropyrimidines include 5-fluorouracil (5-FU) intravenous (IV) injection and capecitabine tablets. Anti-VEGF therapies for mCRC include Avastin® (bevacizumab solution for IV injection) and Cyramza® (ramucirumab injection for IV use). Anti-EGFR therapies for mCRC include Erbitux® (cetuximab injection for IV infusion) and Vectibix® (panitumumab injection for IV infusion).
- **Metastatic gastric or gastroesophageal junction adenocarcinoma**, in adult patients previously treated with at least two lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) **colon cancer** (version 2.2021 – January, 21, 2021) and **rectal cancer** (version 1.2021 – January 22, 2021) guidelines recommend Lonsurf as subsequent therapy as a single agent or in combination with bevacizumab for advanced or metastatic disease not previously treated with Lonsurf in patients who have progressed through all available regimens, besides Lonsurf or Stivarga® (regorafenib tablets) with or without bevacizumab.^{2,3,6}

The NCCN **gastric cancer** (version 1.2021 – February 9, 2021), and the **esophageal and esophagogastric cancer** (version 1.2021 – February 9, 2021) guidelines recommend Lonsurf as a single agent for the third line or subsequent therapy for unresectable locally advanced, recurrent, or metastatic gastric and esophagogastric junction adenocarcinoma and Karnofsky performance score $\geq 60\%$ or Eastern Cooperative Oncology Group performance status of ≤ 2 .^{4,6}

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Lonsurf. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Colon and Rectal Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):
 - A) Patient has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-fluorouracil [5-FU]); AND
 - B) Patient has been previously treated with oxaliplatin; AND
 - C) Patient has been previously treated with irinotecan; AND
 - D) If the patient’s tumor or metastases are wild-type *RAS* (*KRAS* wild-type and/or *NRAS* wild-type) [that is, the tumors or metastases are *KRAS* and/or *NRAS* mutation negative], Erbitux (cetuximab injection for intravenous infusion) or Vectibix (panitumumab injection for intravenous infusion) has been tried.

2. **Gastric or Gastroesophageal Junction Adenocarcinoma.** Approve for 3 years if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma (e.g., regimens containing one or more of the following agents: capecitabine, 5-fluorouracil [5-FU], oxaliplatin, paclitaxel, docetaxel, and irinotecan).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Lonsurf is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lonsurf® tablets [prescribing information]. Princeton, NJ: Taiho Oncology Inc.; February 2019.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (Version 2.2021 – January 21, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on: February 24, 2021.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (Version 1.2021 – January 22, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on: February 24, 2021.
4. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (Version 1.2021 – February 9, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on: February 24, 2021.
5. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (Version 1.2021 – February 9, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on: February 24, 2021.
6. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 24, 2021. Search term: trifluridine/tipiracil.