

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Lonsurf Prior Authorization Policy

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

**REVIEW DATE:** 02/15/2023

---

### OVERVIEW

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

- **Colorectal cancer**, metastatic, in adults who have been previously treated with oxaliplatin-, fluoropyrimidine-, 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.
- **Gastric or gastroesophageal junction adenocarcinoma**, metastatic, in adults 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

Lonsurf is addressed in National Comprehensive Cancer Network guidelines:

- **Colon cancer** (version 3.2022 – January 25, 2023) and **rectal cancer** (version 4.2022 – January 25, 2023) 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. This recommendation is for patients who have progressed through all available regimens, besides Lonsurf or Stivarga® (regorafenib tablets) with or without bevacizumab.<sup>2,3,6</sup>
- **Gastric cancer** (version 2.2022 – January 11, 2022), and **esophageal and esophagogastric cancer** (version 5.2022 – December 5, 2022) guidelines recommend Lonsurf as a single agent for third line or subsequent therapy for locoregional disease in patients who are not surgical candidates or have 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  $\leq 2$  (category 1).<sup>4-6</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Lonsurf. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

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

#### FDA-Approved Indications

1. **Colon, Rectal, or Appendiceal Cancer.** Approve for 1 year 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 *NRAS* wild-type) [that is, the tumors or metastases are *KRAS* and *NRAS* mutation negative], Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion) has been tried.
2. **Gastric or Gastroesophageal Junction Adenocarcinoma.** Approve for 1 year 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; December 2019.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – January 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: February 7, 2023.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – January 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: February 7, 2023.
4. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – January 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: February 7, 2023.
5. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 5.2022 – December 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: February 7, 2023.
6. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 7, 2023. Search term: trifluridine/tipiracil.

### HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<b>Colon and Rectal Cancer:</b> Removed “or” from “ <i>KRAS</i> wild-type and/or <i>NRAS</i> wild-type”.	02/23/2022
Selected Revision	<b>Colon and Rectal Cancer:</b> Changed approval duration from 3 years to 1 year. <b>Gastric or Gastroesophageal Junction Adenocarcinoma:</b> Changed approval duration from 3 years to 1 year.	06/22/2022
Annual Revision	<b>Colon, Rectal, or Appendiceal Cancer:</b> Added appendiceal to the condition of approval.	02/15/2023