

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lonsurf Prior Authorization Policy

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

REVIEW DATE: 02/07/2024

OVERVIEW

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

- **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, as a single agent or in combination with bevacizumab.
- **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 1.2024 – January 29, 2024) and **rectal cancer** (version 1.2024 – January 29, 2024) 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 with or without bevacizumab, Fruzaqla (fruquintinib capsules), or Stivarga® (regorafenib tablets).^{2,3,6}
- **Gastric cancer** (version 3.2023 – January 26, 2024), and **esophageal and esophagogastric junction cancers** (version 4.2023 – January 26, 2024) 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 ≤ 2 (category 1).⁴⁻⁶

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

02/07/2024

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1. **Colon, Rectal, or Appendiceal Cancer.** Approve for 1 year if the patient meets the following (A, B, C, and D):
 - A) Patient has been previously treated with a fluoropyrimidine; AND
Note: Examples of fluoropyrimidines include capecitabine and 5-fluorouracil (5-FU).
 - 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.
Note: Example chemotherapy 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; August 2023.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – January 29, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: January 30, 2024.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 1.2024 – January 29, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: January 30, 2024.
4. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – January 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: January 30, 2024.
5. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 4.2023 – January 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on: January 30, 2024.
6. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on January 29, 2024. Search term: trifluridine/tipiracil.