

Specialty Guideline Management

Lonsurf

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lonsurf	trifluridine and tipiracil

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- Lonsurf is indicated as a single agent or in combination with bevacizumab for the treatment of adult patients with metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.
- Lonsurf is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma 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.

Compendial Uses^{2,3}

- Advanced or metastatic colon cancer
- Advanced or metastatic rectal cancer
- Esophageal and esophagogastric junction cancers

- Gastric cancer

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Colorectal Cancer (CRC)¹⁻⁴

Authorization of 12 months may be granted for treatment of advanced or metastatic colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, as a single agent or in combination with bevacizumab when the member has progressed on previous treatment with all the following regimens unless the member has a contraindication or intolerance:

- Fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (with or without bevacizumab).
- If RAS mutation status is negative (wild-type), an anti-epidermal growth factor receptor (EGFR) therapy, such as Erbitux (cetuximab) or Vectibix (panitumumab), for rectal cancer, appendiceal adenocarcinoma, anal adenocarcinoma, or left-sided colon cancer.

Esophageal, Gastric, or Gastroesophageal Junction Adenocarcinoma^{1,2}

Authorization of 12 months may be granted as a single agent for treatment of esophageal, gastric, or gastroesophageal junction adenocarcinoma when the member has been previously treated with at least two prior lines of chemotherapy and either of the following criteria are met:

- The disease is unresectable locally advanced, recurrent, or metastatic.
- The member is not a candidate for surgery.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Lonsurf [package insert]. Princeton, NJ: Taiho Oncology, Inc.; August 2023.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 14, 2025.

Reference number(s)
1896-A

3. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed July 14, 2025.
4. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed July 14, 2025.