Reference number(s)
1896-A

SPECIALTY GUIDELINE MANAGEMENT

LONSURF (trifluridine and tipiracil)

POLICY

I. 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.

A. FDA-Approved Indications
1. Lonsurf is indicated 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.

2. 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.

B. Compendial Uses
1. Advanced or metastatic colon cancer
2. Advanced or metastatic rectal cancer
3. Esophageal and esophagogastric junction cancers
4. Gastric cancer

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

II. CRITERIA FOR INITIAL APPROVAL

A. Colorectal Cancer (CRC)
Authorization of 12 months may be granted for treatment of advanced or metastatic colorectal cancer when all of the following criteria are met:
1. Member was previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy; AND
2. An anti-VEGF biological therapy; AND
3. If member is RAS wild type, failure of a cetuximab or panitumumab-containing regimen.

B. Gastric or Gastroesophageal Junction Adenocarcinoma
Authorization of 12 months may be granted for treatment of unresectable locally advanced, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma when the member has been previously treated with at least two prior lines of chemotherapy.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Lonsurf [package insert]. Princeton, NJ: Taiho Oncology, Inc.; December 2019.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 7, 2021