

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 Indication

Lonsurf is indicated for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.

B. Compendial Uses

Unresectable advanced or metastatic colorectal cancer that was not previously treated with Lonsurf

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Colorectal cancer (CRC)

Authorization of 12 months may be granted for treatment of unresectable advanced or metastatic colorectal cancer when the following criterion is met:

Member has progressed on treatment with either (A.) or (B.) listed below:

- A. FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, and irinotecan) regimen
- B. Irinotecan- AND oxaliplatin-based regimens

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Lonsurf [package insert]. Princeton, NJ: Taiho Oncology, Inc.; March 2017.
2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed July 20, 2017.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Colon Cancer. Version 2.2017. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed July 31, 2017.

National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: Rectal Cancer. Version 3.2017. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed July 31, 2017.