VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

TAC APPROVAL DATE: 03/06/2019

OVERVIEW

Lonsurf is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine-, oxaliplatin-, 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.[1] Fluoropyrimidines include 5-fluorouracil (5-FU) intravenous (IV) injection and capecitabine tablets. Anti-VEGF therapies for mCRC include Avastin® (bevacizumab solution for IV injection) and Cyramza® (ramucirumab injection for IV use). Anti-EGFR therapies for mCRC include Erbitux® (cetuximab injection for IV infusion) and Vectibix® (panitumumab injection for IV infusion).

Lonsurf is indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma 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.[1]

Guidelines

Colon and/or Rectal Cancer

The National Comprehensive Cancer Network (NCCN) colon cancer (version 4.2018 – October, 19, 2018) and rectal cancer (version 3.2018 – August 7, 2018) guidelines recommend Lonsurf as subsequent therapy as a single agent for unresectable advanced or metastatic disease not previously treated with Lonsurf for the following uses:[2-3] for first progression (*KRAS/NRAS* mutant only) or second progression for disease previously treated with FOLFOXIRI (5-FU/leucovorin, irinotecan, oxaliplatin) with or without Avastin, for second progression for disease previously treated with irinotecan- and oxaliplatin-based regimens, or for progression for disease that progressed through all available regimens, including Stivarga® (regorafenib tablets). Lonsurf may be given before or after Stivarga.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Lonsurf. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Colorectal Cancer, Metastatic (mCRC).** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):[1]
   - **A)** The patient has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-fluorouracil [5-FU]); AND
   - **B)** The patient has been previously treated with oxaliplatin; AND
   - **C)** The patient has been previously treated with irinotecan; AND
   - **D)** If the patient's tumor or metastases are wild-type *RAS* (*KRAS* wild-type and/or *NRAS* wild-type) [that is, the tumors or metastases are *KRAS* and/or *NRAS* mutation negative], Erbitux (cetuximab injection for intravenous infusion) or Vectibix (panitumumab injection for intravenous infusion) has been tried.

2. **Gastric or Gastroesophageal Junction Adenocarcinoma, Metastatic.** Approve for 3 years if the patient meets the following criteria:
   - **A)** 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

Lonsurf has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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 Inc.; February 2019.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (Version 4.2018 – October 19, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on: October 3, 2018.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (Version 3.2018 – August 7, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on: October 3, 2018.

OTHER REFERENCES UTILIZED

- Mayer RJ, Van Cutsem E, Falcone A, et al; RECOURSE Study Group. Randomized trial of TAS-102 for refractory metastatic colorectal cancer. *N Engl J Med*. 2015;372:1909-1919.
- Yoshino T, Mizunuma N, Yamazaki K, et al. TAS-102 monotherapy for pretreated metastatic colorectal cancer: a double-blind, randomised, placebo-controlled phase 2 trial. *Lancet Oncol*. 2012;13:993-1001.
- Yoshino T, Uetake H, Fujita N, et al. TAS-102 safety in metastatic colorectal cancer: Results from the first postmarketing surveillance study. *Clin Colorectal Cancer*. 2016;15(4):e205-e211.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date

New Policy	--	10/14/2015
Annual	No criteria changes.	10/05/2016
Annual	Colorectal Cancer criteria revised to add wild-type *RAS*. Previously criteria stated *KRAS* and/or *NRAS* that are the components of *RAS*. Wild-type refers to both *KRAS* and *NRAS*.	10/25/2017
Annual	Removed criteria for patient already started on Lonsurf	10/17/2018
Early annual revision	Added gastric and gastroesophageal junction adenocarcinoma, metastatic as a new condition of approval.	03/06/2019

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.