UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lonsurf

Program	Prior Authorization
Medication	Lonsurf (trifluridine/tipiracil)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2015
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Lonsurf (trifluridine/tipiracil) 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 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.
- 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.

In addition, the National Cancer Comprehensive Network (NCCN) also recommends the use of Lonsurf for the treatment of rectal cancer as a single agent for unresectable advanced or metastatic disease not previously treated with Lonsurf in patients who have progressed through all available regimens besides Stivarga or Lonsurf.

2. Coverage Criteria:

A. <u>Colorectal Cancer</u>

1. Lonsurf will be approved based on **<u>all</u>** of the following criteria:

a. Diagnosis of metastatic colorectal cancer (mCRC)

-AND-

b. History of failure, contraindication, or intolerance to treatment with **<u>all</u>** of the following:

(1) Fluoropyrimidine-based chemotherapy
(2) Oxaliplatin-based chemotherapy

(3) Irinotecan-based chemotherapy
(4) Anti-VEGF biological therapy

-AND-

c. **One** of the following:

(1) Tumor is *RAS* mutant-type

-OR-

(2) **Both** of the following:

(a) Tumor is *RAS* wild-type
(b) History of failure, contraindication, or intolerance to anti-EGFR therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Lonsurf** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lonsurf therapy

Authorization will be issued for 12 months.

B. Gastric/Gastroesophageal Junction Adenocarcinoma

1. Lonsurf will be approved based on **both** of the following criteria:

a. Diagnosis of **one** of the following:

(1) Metastatic gastric cancer
(2) Metastatic gastroesophageal junction adenocarcinoma

-AND-

b. History of failure, contraindication, or intolerance to treatment with at least **two** prior lines of chemotherapy that consisted of the following agents:

(1) Fluoropyrimidine (e.g., fluorouracil)
(2) Platinum (e.g., carboplatin, cisplatin, oxaliplatin)
(3) Taxane (e.g., docetaxel, paclitaxel) or irinotecan
(4) HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Lonsurf** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lonsurf therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Lonsurf** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Lonsurf** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Lonsurf therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Lonsurf [package insert]. Cambridge, MA: ARIAD Pharmaceuticals, Inc.; February 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org. Accessed February 24, 2020.

Program	Prior Authorization- Lonsurf (trifluridine/tipiracil)
Change Control	
Date	Change
9/2015	New program
9/2016	Updated clinical criteria to align with E&I notification policy and updated policy template.
9/2017	Annual Review. Updated References.
9/2018	Annual review. Added NCCN Recommended Regimen criteria. Updated references.
4/2019	Revised coverage criteria for RAS wild type disease to match the intent of the prescribing information and NCCN guidelines. Added coverage for metastatic gastric cancer. Updated background and references.
4/2020	Annual review. Updated references.