



## Commercial/Healthcare Exchange PA Criteria

*Effective: May 4, 2016*

**Prior Authorization:** Lonsurf

**Products Affected:** Lonsurf (trifluridine/tipiracil) oral tablet

**Medication Description:**

Lonsurf is a combination of trifluridine, a nucleoside metabolic inhibitor and tipiracil, a thymidine phosphorylase inhibitor. Inclusion of tipiracil increases trifluridine exposure by inhibiting its metabolism by thymidine phosphorylase. Following uptake into cancer cells, trifluridine is incorporated into DNA, interferes with DNA synthesis and inhibits cell proliferation. Trifluridine/tipiracil demonstrated anti-tumor activity against KRAS wild-type and mutant human colorectal cancer xenografts in mice.

**Covered Uses:**

1. Metastatic Colorectal Cancer
2. Metastatic Gastric Cancer

**Exclusion Criteria:** N/A

**Required Medical Information:**

1. Confirmed RAS mutation status
2. Prior therapies tried
3. Dose and frequency

**Age Restrictions:** 18 years or older

**Prescriber Restrictions:** Prescribed by or in consultation with a hematologist/oncologist

**Coverage Duration:** 12 months

**Other Criteria:**

**1. Metastatic colorectal cancer**

A) The patient has progressed on or after fluoropyrimidine-, oxaliplatin-, and irinotecan-based regimens, and an anti-vascular endothelial growth factor (VEGF) therapy, and an anti-epidermal growth factor receptor (EGFR) therapy if RAS wild-type.

**2. Metastatic gastric or gastroesophageal junction adenocarcinoma**

A) The patient has been 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/neutargeted therapy

Last Res.11.13.2019



Confidential Information

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**References:**

1. Lonsurf tablets [prescribing information]. Princeton, NJ: Taiho Conology, Inc; Revised February 2019. Accessed October 2019.
2. NCCN Clinical Practice Guidelines in Oncology, Colon Cancer v.2.2016. Accessed on December 11, 2015.
3. NCCN Clinical Practice Guidelines in Oncology, Rectal Cancer v.1.2016. Accessed on December 11, 2015.
4. SEER Stat Fact Sheets: Colon and Rectum Cancer, <http://seer.cancer.gov/statfacts/html/colorect.html> Accessed October 8, 2015.
5. Clark JW, et al. Systemic chemotherapy for nonoperable metastatic colorectal cancer: Treatment recommendations In: UpToDate, Goldberg RM (Ed), UpToDate, Waltham, MA. Accessed on Oct 8, 2015.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	03/01/2016

2	Policy Update	<p>CCI Adopted EH Policy-removed from CCI Oncology Policy</p> <p>Shortened Medication Description,</p> <p>Removed Exclusion Criteria to match FDA Label,</p> <p>Added Prescriber Restriction</p> <p>Added Other Criteria for Metastatic gastric or gastroesophageal junction adenocarcinoma</p>	<p>Medication Description</p> <p>Exclusion Criteria</p> <p>Prescriber Restriction</p> <p>Other Criteria</p>	10/15/2019
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