

Lonsurf (trifluridine and tipiracil) (Oral)

Document Number: IC-0255

Last Review Date: 03/04/2019

Date of Origin: 09/29/2015

Dates Reviewed: 07/2016, 09/2015, 07/2016, 08/2017, 07/2018, 03/2019

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Lonsurf 15 mg/6.14 mg tablet: 60 tablets per 28 days
- Lonsurf 20 mg/8.19 mg tablets: 80 tablets per 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

- 160 mg daily for 10 days per 28-day cycle

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Must be used as a single agent; **AND**

Colorectal cancer †

- Patient has unresectable advanced or metastatic disease; **AND**
- Patient has been previously treated with **ALL** of the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy regimens (e.g., FOLFOX, FOLFIRI, FOLFIRINOX, etc.); **AND**
- Patient has been previously treated with an anti-EGFR therapy (if RAS wild-type) (e.g. panitumumab, cetuximab, etc.); **AND**
- Patient has been previously treated with an anti-VEGF biological therapy (e.g. bevacizumab)

Gastric and Gastro-esophageal Junction Adenocarcinoma †

- Patient has metastatic disease; **AND**

- Patient has received at least two prior lines of chemotherapy that included: fluoropyrimidine-, a platinum, and either a taxane or irinotecan; **AND**
- Patient has been previously treated with HER2/neu-targeted therapy (if HER2 positive disease) (e.g. trastuzumab)

† FDA-labeled indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in Section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe myelosuppression, etc.

V. Dosage/Administration

Indication	Dose
All indications	35 mg/m ² up to a maximum of 80 mg per dose (based on the trifluridine component) orally twice daily on Days 1 through 5 and Days 8 through 12 of each 28-day cycle (round dose to the nearest 5 mg increment) until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- J8999 - Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals

NDC:

- Lonsurf 15 mg/6.14 mg tablet: 64842-1025-xx
- Lonsurf 20 mg/8.19 mg tablet: 64842-1020-xx

VII. References

1. Lonsurf [package insert]. Princeton, NJ; Taiho Oncology Inc; March 2017. Accessed February 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) trifluridine/tipiracil. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm duodenum
C17.1	Malignant neoplasm jejunum
C17.2	Malignant neoplasm ileum
C17.8	Malignant neoplasm of overlapping sites of small intestines
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of large intestines
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C78.00	Secondary malignant neoplasm of unspecified lung

LONSURF (trifluridine and tipiracil) Prior Auth Criteria

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ICD-10	ICD-10 Description
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC