

## Lonsurf (trifluridine and tipiracil) (Oral)

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

### 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)

† 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**
- Tumor response with 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
Colorectal cancer	35 mg/m <sup>2</sup> 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)

#### 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 May 2018.
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 May 2018.

#### Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm duodenum
C17.1	Malignant neoplasm jejunum

ICD-10	ICD-10 Description
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
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
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 Government Benefit Administrators, 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