I. Medication Description

Lonsurf consists of a nucleoside metabolic inhibitor, trifluridine, and the thymidine phosphorylase inhibitor, tipiracil. 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.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Lonsurf is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for the following quantities per 28-day cycle:

- 15mg/6.14 mg: up to 100 tablets
- 20mg/8.19 mg: up to 80 tablets

V. Coverage Duration

Coverage is granted for 6 months, and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Lonsurf is available as 15mg/6.14mg and 20mg/8.19mg tablets containing trifluridine/tipiracil.

VIII. Summary of Policy Changes

• 3/15/16: new policy  
• 9/15/16: quantity limits corrected  
• 10/11/17: coverage criteria updated to allow use as supported by current NCCN guidelines; quantity limits updated  
• 11/1/18: tablet quantities adjusted  
• 11/15/19: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.