Lonsurf

Description

Lonsurf (trifluridine/tipiracil)

Background

Lonsurf is a medication used to treat patients with metastatic colorectal cancer and metastatic gastric or gastroesophageal junction adenocarcinoma who are no longer responding to other therapies such as chemotherapy and biological therapy. Lonsurf is a combination of two drugs, trifluridine and tipiracil. Trifluridine works by imitating a component of DNA (genetic material in every cell) called thymidine, and permanently inhibiting an essential enzyme for DNA to work called thymidylate synthetase. By inhibiting this important enzyme, as well as incorporating itself into the DNA, trifluridine stops the DNA from working properly and the cell dies. Tipiracil, the second drug, works by stopping an enzyme called thymidine phosphorylase from breaking down the first drug, trifluridine, so that it can work better (1).

Regulatory Status

FDA-approved indications: Lonsurf is a combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor, indicated for the treatment of adult patients with: (1)

1. 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.
2. 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.

Lonsurf can cause severe and life-threatening myelosuppression. High rates of anemia, neutropenia, thrombocytopenia, and febrile neutropenia were observed. Due to this risk, complete blood counts need to be obtained prior to and on Day 15 of each cycle of Lonsurf. They may be done more frequently if clinically indicated. In the case of febrile neutropenia, Grade 4 neutropenia, or platelets less than 50,000/mm³, withhold Lonsurf. When the patient recovers, Lonsurf may be resumed at a lower dose (1).

The safety and effectiveness of Lonsurf in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lonsurf may be considered medically necessary for patients 18 years of age or older for the treatment of metastatic colorectal cancer and metastatic gastric or gastroesophageal junction adenocarcinoma and if the conditions indicated below are met.

Lonsurf is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age

18 years of age or older

Diagnosis

Patient must have ONE of the following:

1. Metastatic colorectal cancer
   a. Previously treated with fluoropyrimidine-based, oxaliplatin-based, and irinotecan-based chemotherapy
   b. Previously treated with an anti-VEGF biological therapy
c. If RAS wild-type, previously treated with an anti-EGFR therapy

2. Metastatic gastric or gastroesophageal junction adenocarcinoma
   a. Previously treated with ALL of the following:
      i. A fluoropyrimidine
      ii. A platinum
      iii. A taxane or irinotecan
   b. If patient has a HER2-positive tumor, the patient has received prior anti-HER2 therapy

   AND the following:
   1. Complete blood counts monitored prior to each cycle and on Day 15 of each cycle

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have ONE the following:

1. Metastatic colorectal cancer
2. Metastatic gastric or gastroesophageal junction adenocarcinoma

AND ALL of the following:
1. Complete blood counts monitored prior to each cycle and on Day 15 of each cycle
2. NO disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months
Prior – Approval Renewal Limits
Duration 12 months

Rationale

Summary
Lonsurf is a combination medication used to treat patients with metastatic colorectal cancer and metastatic gastric or gastroesophageal junction adenocarcinoma that are no longer responding to other chemotherapy and biological therapy. Lonsurf works by interfering with DNA synthesis through various mechanisms. There are no adequate and well-controlled studies to document the safety and efficacy of Lonsurf in pediatric patients (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Lonsurf while maintaining optimal therapeutic outcomes.

References

Policy History

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<tr>
<td>October 2015</td>
<td>Addition to PA</td>
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<tr>
<td>December 2015</td>
<td>Annual review</td>
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<tr>
<td>June 2016</td>
<td>Annual editorial review</td>
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<tr>
<td>June 2017</td>
<td>Policy code changed from 5.04.64 to 5.21.64</td>
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<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2019</td>
<td>Addition of indication of metastatic gastric or gastroesophageal junction adenocarcinoma</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.