TRIFLURIDINE/TIPIRACIL

Generic	Brand	HICL	GCN	Exception/Other
TRIFLURIDINE/TIPIRACIL	LONSURF	42544		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer and meets the following criterion?
   - Previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy [e.g., Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)]

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient also have RAS mutation negative (i.e., RAS wild-type)?

   If yes, continue to #3.
   If no, **approve for 12 months by GPID for the requested strength with the following quantity limits (PAC NOTE: Enter prior authorizations for all strengths):**
   - **Trifluridine/tipiracil 15/6.14mg tablet (GPID 39596): #100 tablets per 28 days.**
   - **Trifluridine/tipiracil 20/8.19mg tablet (GPID 39597): #80 tablets per 28 days.**

3. Has the patient had previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]?

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits (PAC Note: Enter prior authorizations for all strengths):**
   - **Trifluridine/tipiracil 15/6.14mg tablet (GPID 39596): #100 tablets per 28 days.**
   - **Trifluridine/tipiracil 20/8.19mg tablet (GPID 39597): #80 tablets per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet the following criterion?
   - Previous treatment 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

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits (PAC NOTE: Enter prior authorizations for all strengths):**
   - **Trifluridine/tipiracil 15/6.14mg tablet (GPID 39596): #100 tablets per 28 days.**
   - **Trifluridine/tipiracil 20/8.19mg tablet (GPID 39597): # 80 tablets per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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TRIFLURIDINE/TIPIRACIL

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires a diagnosis of metastatic colorectal cancer, metastatic gastric or gastroesophageal junction adenocarcinoma. The following criteria must also be met:

For patients with a diagnosis of metastatic colorectal cancer, approval requires:

- The patient must have had previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, and an anti-VEGF biological therapy [e.g., Avastin (bevacizumab), Zaltrap (ziv-aflibercept), or Cyramza (ramucirumab)]
- For patients who are negative for the RAS mutation (e.g., patient is RAS wild-type), approval requires that the patient had a previous treatment with an anti-EGFR agent [e.g., Erbitux (cetuximab), Vectibix (panitumumab)]

For patients with a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma, approval requires:

- Previous treatment 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

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lonsurf.

REFERENCES

- Lonsurf [Prescribing Information]; Princeton, NJ: Taiho Oncology, Inc; February 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/08/19

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