



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TRIFLURIDINE/TIPIRACIL

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TRIFLURIDINE/ TIPIRACIL HCL	LONSURF	42544		GPI-10 (2199000275)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of metastatic colorectal cancer and meet **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has received previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy in combination with an anti-VEGF biological therapy [e.g., Zaltrap (ziv-aflibercept), Cyramza (ramucirumab)]
 - Lonsurf will be used as a single agent OR in combination with bevacizumab

If yes, continue to #2.
If no, continue to #4.
2. Is the patient's metastatic colorectal cancer RAS wild-type?
 - If yes, continue to #3.
 - If no, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
 - **15/6.14mg: #100 per 28 days.**
 - **20/8.19mg: #80 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 or GPI-14 for all strengths with the following quantity limits:**
 - **15/6.14mg: #100 per 28 days.**
 - **20/8.19mg: #80 per 28 days.**
 - If no, do not approve.
 - DENIAL TEXT:** See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of metastatic gastric or gastroesophageal junction adenocarcinoma and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
 - The patient has received 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 or GPI-14 for all strengths with the following quantity limits:**

- **15/6.14mg: #100 per 28 days.**
- **20/8.19mg: #80 per 28 days.**

If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TRIFLURIDINE/TIPIRACIL (Lonsurf)** requires the following rule(s) be met for approval:

- A. You have **ONE** of the following diagnoses:
1. Metastatic colorectal cancer (a type of digestive system cancer that has spread to other parts of the body)
 2. Metastatic gastric or gastroesophageal junction adenocarcinoma (a type of digestive system cancer that has spread to other parts of the body)
- B. **If you have metastatic colorectal cancer, approval also requires:**
1. You are 18 years of age or older
 2. Lonsurf will be used as a single agent OR in combination with bevacizumab
 3. You had previous treatment with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (drugs used to treat cancer) in combination with an anti-VEGF biological therapy such as Zaltrap (ziv-aflibercept) or Cyramza (ramucirumab)
 4. If your metastatic colorectal cancer is RAS wild-type (a type of gene), you also had a previous treatment with an anti-EGFR agent such as Erbitux (cetuximab), Vectibix (panitumumab)
- C. **If you have metastatic gastric or gastroesophageal junction adenocarcinoma, approval also requires:**
1. You are 18 years of age or older
 2. You had previous treatment with at least two prior lines of chemotherapy (drugs used to treat cancer) that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2 (type of gene)/neu-targeted therapy

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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; August 2023.

Library	Commercial	NSA
Yes	Yes	No

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