Trifluridine-tipiracil (LONSURF)
Criteria for Use
Updated May 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive Trifluridine-tipiracil.

- ☐ Inability to swallow / tolerate oral medications or known malabsorption condition
- ☐ Known pregnancy
- ☐ Lactating

Inclusion Criteria

All of the following criteria must be met.

- ☐ Care provided by a VA / VA Community Care Hematology or Oncology provider
- ☐ Goals of care and role of palliative care consult has been discussed and documented
- ☐ Eastern Cooperative Oncology Group Performance Status 0 or 1
- ☐ Adequate bone marrow function (hemoglobin ≥ 9 g/dL, Absolute Neutrophil Count ≥ 1500/mm^3, platelet count ≥ 75,000/mm^3)
- ☐ Adequate liver function (total bilirubin ≤ 1.5 X Upper Limit of Normal, ALT/AST ≤ 3 X ULN or ≤ 5 x ULN if liver metastases)
- ☐ Adequate renal function (CrCl > 30 mL/min)

Additional Inclusion Criteria

ONE of the following criteria must be met.

- ☐ Metastatic colon cancer previously treated with all of the following, unless contraindicated: fluoropyrimidine-oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy and if RAS wild-type, an anti-EGFR therapy
- ☐ Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with ≥ two prior regimens including a fluoropyrimidine, a platinum, either a taxane or irinotecan and a HER2/neu-targeted agent (if HER2+), unless contraindicated

Additional Inclusion Criteria *if applicable*

- ☐ For females who can become pregnant: Pregnancy must excluded prior to receiving trifluridine-tipiracil
- ☐ For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and use of effective contraception during therapy and for at least 3 months after stopping treatment

Other justification

- ☐ _____

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