merative

Micromedex

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: October 6, 2023

OFF-LABEL ID #: 2592

DRUG NAME: Trifluridine/Tipiracil

OFF-LABEL USE: Malignant neoplasm of colon and/or rectum Metastatic, first-line treatment in combination with bevacizumab; in patients not eligible for intensive chemotherapy

COMPENDIA TRANSPARENCY REQUIREMENTS	
1	Provide criteria used to evaluate/prioritize the request (therapy)
2	Disclose evidentiary materials reviewed or considered
3	Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest
4	Provide meeting minutes and records of votes for disposition of the request (therapy)

EVALUATION/PRIORITIZATION CRITERIA: C, E *to meet requirement 1

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant **advance** over current therapies
C	**Cancer** or cancer-related condition
E	Quantity and robustness of **evidence** for use support consideration
L	**Limited** alternative therapies exist for condition of interest
P	**Pediatric** condition
R	**Rare** disease
S	**Serious**, life-threatening condition

Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
André T, Falcone A, Shparyk Y, Moiseenko F, Polo-Marques E, Csöszi T, Campos-Bragagnoli A, Liposits G, Chmielowska E, Aubel P, Martín L, Fougeray R, Amellal N, Saunders MP. Trifluridine-tipiracil plus bevacizumab versus capecitabine plus bevacizumab as first-line treatment for patients with metastatic colorectal cancer ineligible for intensive therapy (SOLSTICE): a randomised, open-label phase 3 study. Lancet Gastroenterol Hepatol. 2023 Feb;8(2):133-144. doi: 10.1016/S2468-1253(22)00334-X. Epub 2022 Dec 2. PMID: 36470291.	S
Andre, T, Saunders, M, Kanehisa, A, et al: First-line trifluridine/tipiracil plus bevacizumab for unresectable metastatic colorectal cancer: SOLSTICE study design. Future Oncol Feb 2020; Vol 16, Issue 4; pp. 21-29. Pubmed ID: 31914811	2
Van Cutsem, E, Danielewicz, I, Saunders, MP, et al: Trifluridine/tipiracil plus bevacizumab in patients with untreated metastatic colorectal cancer ineligible for intensive therapy: the randomized TASCO1 study. Ann Oncol Sep 2020; Vol 31, Issue 9; pp. 1160-1168. Pubmed ID: 32497736	2
Van Cutsem, E, Danielewicz, I, Saunders, MP, et al: Fir st-line trifluridine/tipiracil + bevacizumab in patients with unresectable metastatic colorectal cancer: final survival analysis in the TASCO1 study. Br J Cancer Jun 2022; Vol 126, Issue 11; pp. 1548-1554. Pubmed ID: 35440667	2
Oki, E, Makiyama, A, Miyamoto, Y, et al: Trifluridine/tipiracil plus bevacizumab as a first-line treatment for elderly patients with metastatic colorectal cancer (KSCC1602): A multicenter phase II trial. Cancer Med Jan 2021; Vol 10, Issue 2; pp. 454-461. Pubmed ID: 33249761	2
Cervantes, A, Adam, R, Rosello, S, et al: Metastatic colorectal cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol Jan 2023; Vol 34, Issue 1; pp. 10-32. Pubmed ID: 36307056	4

Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		John D Roberts	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Evidence Favors Efficacy	Class III: Not Recommended		B
Jeffrey Klein	Evidence Favors Efficacy	Class III: Not Recommended	The use of Trifluridine/Tipiracil in combination with bevacizumab as a first line metastatic colorectal cancer treatment did not have any advantage over a different regimen in this study. Though efficacy was demonstrated, the high degree of serious adverse effects (most notably neutropenia) was documented with the Trifluridine/Tipiracil group.	
Richard LoCicero	Evidence is Inconclusive	Class III: Not Recommended	Trifluridine/Tipiracil in combination with bevacizumab was evaluated in a phase III randomized trial in comparison with capecitabine/bevacizumab. The trifluridine/tipiracil combination was not superior, failing to meet the primary endpoint.	

Todd Gersten	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The combination of Trifluridine/Tipiracil is active in metastatic CRC. However it's utility is limited, alongside the option of capecitabine and bevacizumab, to the very rare patient who is not deemed eligible for standard chemotherapy.	