TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Capecitabine

INDICATION: Rectal cancer, locally advanced, adjuvant or neoadjuvant therapy, in combination with radiotherapy

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: **A, C, S**
*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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Hofheinz,R.D., Wenz,F., Post,S., et al: Chemoradiotherapy with capecitabine versus fluorouracil for locally advanced rectal cancer: a randomised, multicentre, non-inferiority, phase 3 trial. Lancet Oncol Jun 2012; Vol 13, Issue 6; pp. 579-588.	Study methodology comments: This was an open-label, randomized, phase III non-inferiority trial. Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, and no additional biases were identified.	S
Hofheinz,R., Wenz,F.K., Post,S., et al: Capecitabine (Cape) versus 5-fluorouracil (5-FU)-based (neo)adjuvant chemoradiotherapy (CRT) for locally advanced rectal cancer (LARC): Long-term results of a randomized, phase III trial. Journal of Clinical Oncology 2011; Vol 29, Issue 15 SUPPL.	Study methodology comments: Abstract	3

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)

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CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Stacy LaClaire, PharmD	None	Edward P. Balaban, DO	None
Felicia Gelsey, MS	None	James E. Liebmann, MD	None
Margi Schiefelbein, PA	None	Jeffrey A. Bubis, DO	Other payments: Dendreon
		Gerald J. Robbins, MD	None
		Keith A. Thompson, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, DO	Effective	Class IIa - Recommended, In Most Cases	I believe it could be a substitute for 5-FU where infusional therapy may be an issue. However, this experience is too early to comment on. Which Oxaliplatin therapy is being considered.	N/A
James E. Liebmann, MD	Effective	Class I - Recommended	The Hofheinz trial clearly and convincingly shows that capecitabine/radiation is not inferior to standard 5-FU/radiation as pre-operative therapy of rectal cancer. At this point, capecitabine is routinely used in practice in this setting. Note that the NCCN guidelines also support the use of capecitabine as part of adjuvant and neoadjuvant therapy of rectal cancer.	N/A
Jeffrey A. Bubis, DO	Effective	Class I - Recommended	Data equivalent to infusional 5-FU	N/A
Gerald J. Robbins, MD	Effective	Class I - Recommended	Recommended as equivalent to infusional 5-FU based upon this trial and literature review.	N/A

Keith A. Thompson, MD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	None	N/A