TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Capecitabine

INDICATION: Gastric cancer, stage ll to lllB, adjuvant therapy in combination with oxaliplatin

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, R, 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
Bang,Y.J., et al: Adjuvant capecitabine and oxaliplatin for gastric cancer after D2 gastrectomy (CLASSIC): a phase 3 open-label, randomised controlled trial. Lancet Jan 28, 2012; Vol 379, Issue 9813; pp. 315-321.	Study methodology comments: This was an open-label, randomized-controlled trial that had limitations for one or more criteria sufficient to substantially lower ones confidence in the estimate of effect. The results should be interpreted with much caution since the study was terminated early due to the favorable results of a preplanned interim analysis. This analysis was conducted after 257 disease-free survival events. The final analysis was planned for after 385 disease-free events. In order to conclusively establish overall survival in this clinical setting, the authors are continuing with patient follow-up and will conduct an analysis after a median follow-up of 5 years. Additionally, there was potentially high bias from lack of blinding since this was an open-label trial that did not use independent reviewers or assessors. There was low risk of bias from incomplete accounting of patients and outcome events, selective outcome reporting, and allocation concealment.	S
Tham,C.K, et al: Capecitabine with radiation is an effective adjuvant therapy in gastric cancers. World Journal of Gastroenterology 2010; Vol 16, Issue 29; pp. 3709-3715.		3
Hofheinz,R.D., et al: Oxaliplatin and capecitabine-based chemoradiotherapy for gastric cancer--an extended phase I MARGIT and AIO trial. Int J Radiat Oncol Biol Phys Jan 01, 2009; Vol 73, Issue 1; pp. 142-147.		1
Liu,T., et al: Adjuvant chemotherapy for gastric cancer: Less drug, same efficacy. Journal of Clinical Oncology 2011; Vol 29, Issue 4 SUPPL. 1.; p. 1.	This was an abstract.	3
Nishida,T.: Adjuvant therapy for gastric cancer after D2 gastrectomy. The Lancet Jan 2012; Vol 379, Issue 9813; pp. 291-292.		4

Van Cutsem,E., et al: Expert opinion on management of gastric and gastro-oesophageal junction adenocarcinoma on behalf of the European Organisation for Research and Treatment of Cancer (EORTC)-gastrointestinal cancer group. Eur J Cancer Jan 2008; Vol 44, Issue 2; pp. 182-194.		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)

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CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Jeffrey F. Patton, MD	None
Stacy LaClaire, PharmD	None	Jeffrey A. Bubis, DO	Other payments: Dendreon
Felicia Gelsey, MS	None	Gerald J. Robbins, MD	None
		Keith A. Thompson, MD	None
		John M. Valgus, PharmD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Jeffrey F. Patton, MD	Effective	Class IIa - Recommended, In Most Cases	None	N/A
Jeffrey A. Bubis, DO	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	At this time, evidence favors efficacy, but final results are still pending from CLASSIC. Survival benefit should be followed to ensure that it holds up as data matures.	N/A
Gerald J. Robbins, MD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	Although trial stopped early and mature data on OS pending (3 year OS data p<0.05), the improvement over 5FU alone significant and compatible with other data using oxaliplatin in advanced disease. One caveat is that there may be some ethnic differences in prognosis so that additional data would be helpful in other populations.	N/A
Keith A. Thompson, MD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	None	N/A

John M. Valgus, PharmD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	Comparative trial demonstrates OS benefit over surgery alone. No comparative data with alternative treatment.	N/A