

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Oxaliplatin

INDICATION: Metastatic pancreatic adenocarcinoma, first-line treatment, in combination with 5-fluorouracil, leucovorin, and irinotecan

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, 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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Conroy,T., et al: FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer. N Engl J Med May 12, 2011; Vol 364, Issue 19; pp. 1817-1825.	<u>Study methodology comments:</u> This was a randomized, multicenter, comparative trial conducted with a three stage design. Many potential confounding factors were controlled through the study design, statistical analyses, and eligibility criteria. A major strength of the study was that CT scans were independently reviewed. Additional strengths included 1) confirmed diagnosis; 2) presented both inclusion and exclusion criteria; 3) defined primary and secondary outcomes; 4) defined responses; 5) responses were confirmed at 4 weeks; 6) analyzed the intent-to-treat population; and 7) compared baseline characteristics of groups. Weaknesses included 1) possible selection bias since patients were not recruited in a random or consecutive manner; and 2) partial explanation of method of randomization.	S
Conroy,T., et al: Irinotecan plus oxaliplatin and leucovorin-modulated fluorouracil in advanced pancreatic cancer--a Groupe Tumeurs Digestives of the Federation Nationale des Centres de Lutte Contre le Cancer study. Journal of Clinical Oncology Feb 20, 2005; Vol 23, Issue 6; pp. 1228-1236.		2
Lowery,M.A. and O'Reilly,E.M.: New approaches to the treatment of pancreatic cancer: from tumor-directed therapy to immunotherapy. BioDrugs Aug 01, 2011; Vol 25, Issue 4; pp. 207-216.		4
Oberstein,P.E. and Saif,M.W.: First-line treatment for advanced pancreatic cancer. Journal of the Pancreas Mar 2011; Vol 12, Issue 2; pp. 96-100.		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
Margi Schiefelbein, PA	None	Edward P. Balaban, D.O	None
Stacy LaClaire, PharmD	None	Thomas McNeil Beck, M.D.	None
Felicia Gelsey, MS	None	James E. Liebmann, M.D.	None
		Keith A. Thompson, M.D.	None
		John M. Valgus, Pharm.D.	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, D.O	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Oxaliplatin as posed in first 1 week tx appears efficacious, but with a considerable 'physiologic' cost. May be only appropriate for the most 'hearty' (good performance status) only.	N/A
Thomas McNeil Beck, M.D.	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Evidence supports benefit with increased toxicity – consider only in good performance patients	N/A
James E. Liebmann, M.D.	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	This was a well done trial with a believable control group. The major limitation is fairly restrictive entry criteria (ECOG 0,1; no one over 76) However, for eligible patients, FOLFIRINOX is a reasonable option.	N/A
Keith A. Thompson, M.D.	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	None	N/A

John M. Valgus, Pharm.D.	Effective	Class IIa - Recommended, In Most Cases	Multicenter Phase II – III trial clearly demonstrates benefits of Oxaliplatin based treatment in OS and PFS. Can only be applied to patients with good PS.	N/A
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