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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 6/24/16

PACKET: 1319

DRUG: Cisplatin

USE: Malignant tumor of urinary bladder, Muscle invasive, as neoadjuvant combination 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, 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
Yin,M., Joshi,M., Meijer,R.P., et al: Neoadjuvant Chemotherapy for Muscle-Invasive Bladder Cancer: A Systemic Review and Two-Step Meta-Analysis. Oncologist Apr 06, 2016	Comments: This was a two-step meta-analysis. First, a meta-analysis of 15 randomized clinical trials (3,285 patients) was performed to compare neoadjuvant chemotherapy plus local treatment with the same local treatment alone. Secondly, since there is an absence of randomized trials comparing MVAC versus GC in the neoadjuvant setting, a meta-analysis of 13 retrospective studies (1,766 patients) was performed to compare MVAC with GC. This systematic review conducted a comprehensive literature search and provided information on the eligibility criteria, study characteristics, and heterogeneity. The appropriate statistical tests were used. There was one major caveat of the study. The authors did not present information on the quality of the included studies.	S
Zagouri,F., Peroukidis,S., Tzannis,K., et al: Current clinical practice guidelines on chemotherapy and radiotherapy for the treatment of non-metastatic muscle-invasive urothelial cancer: A systematic review and critical evaluation by the Hellenic Genito-Urinary Cancer Group (HGUCG).		4
Milowsky,M.I., Rumble,R.B., Booth,C.M., et al: Guideline on Muscle-Invasive and Metastatic Bladder Cancer (European Association of Urology guideline): American Society of Clinical Oncology Clinical Practice Guideline Endorsement. J Clin Oncol Mar 21, 2016		S

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
Felicia Gelsey, MS	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		Jeffrey Klein	None
		John Roberts	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
MICROMEDEX	Effective	Class I: Recommended		B
Jeffrey Klein	Effective	Class I: Recommended	The use of cisplatin based combination regimens in muscle invasive bladder cancer has long been a mainstay of the treatment plan. Newer studies reconfirm the need for cisplatin in the care of such patients. The question remains as to which combination regimen containing cisplatin is more effective in terms of overall survival. It appears the regimen MVAC is superior to GC in that regard, though potentially more toxic.	N/A
John Roberts	Effective	Class IIa: Recommended, In Most Cases	Cisplatin-based combination therapy is effective as neoadjuvant chemotherapy for muscle invasive carcinoma of the bladder. The benefit is modest. Treatment should be offered only to fit, cisplatin eligible patients. Carboplatin-based combination therapy is not recommended.	N/A

Richard LoCicero	Effective	Class I: Recommended	Cisplatin-based combination chemotherapy is an established neoadjuvant therapy for muscle invasive bladder cancer. Its effectiveness has been established by high quality randomized clinical trials.	N/A