IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 1/6/2020

PACKET: 1965

DRUG: Gemcitabine hydrochloride

USE: Malignant tumor of nasopharynx; Recurrent or metastatic, first-line therapy in combination with cisplatin

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, L, 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
Ma, SX, Zhou, T, Huang, Y, et al: The efficacy of first-line chemotherapy in recurrent or metastatic nasopharyngeal carcinoma: a systematic review and meta-analysis. Ann Transl Med Jun 2018; Vol 6, Issue 11; p. 201.	This was a meta-analysis which compared four regimens for first-line chemotherapy in resurrent or metastatic nasopharyngeal carcinoma. The Downs & Black checklist was used to assess the quality of the included trials, and only studies considered high quality (D&B score equal or greater than 16) were included in the meta-analysis; Two randomized trials and 14 single-arm trials were included. In this systematic review, the authors conducted a comprehensive literature search and provided information on eligibility criteria, study characteristics, and heterogeneity. The appropriate statistical tests were used.	S
Zhang,L., Huang,Y., Hong,S., et al: Gemcitabine plus cisplatin versus fluorouracil plus cisplatin in recurrent or metastatic nasopharyngeal carcinoma: a multicentre, randomised, open-label, phase 3 trial. Lancet Aug 23, 2016; Vol Epub, p. Epub.	This was a multicentre open-label, randomized Phase 3 trial that assessed gemcitabine versus fluorouracil, both in combination with cisplatin, in patients with recurrent or metastatic nasopharyngeal cancer. The risk of potential bias associated with randomization, detection, attrition, and reporting were deemed low. The risk of potential bias associated with allocation concealment and performance were deemed high due to the open-label nature of the trial. No other sources of bias were found.	S
Li, JJ, Gu, MF, Pan, K, et al: Autologous cytokine-induced killer cell transfusion in combination with gemcitabine plus cisplatin regimen chemotherapy for metastatic nasopharyngeal carcinoma. J Immunother Feb 2012; Vol 35, Issue 2; pp. 189-195.		2
Pastor,M., Lopez,Pousa A., Del,Barco E., et al: SEOM clinical guideline in nasopharynx cancer (2017). Clin Transl Oncol Jan 2018; Vol 20, Issue 1; pp. 84-88.		S

Simo, R, Robinson, M, Lei, M, et al: Nasopharyngeal carcinoma: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol May 2016; Vol 130, Issue S2; pp. S97-S103.		S
Lee, HM, Okuda, KS, Gonzalez, FE, et al: Current perspectives on nasopharyngeal carcinoma. Adv Exp Med Biol 2019; Vol 1164, pp. 11-34.		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
Megan Smith	None		
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
IBM MICROMEDEX	Effective	Class IIa: Recommended, in Most Cases		B
John Roberts	Effective	Class IIb: Recommended, in Some Cases	In a single randomized phase 3 trial involving only very good performance status patients, gemcitabine in combination with cisplatin was more effective and less toxic than fluorouracil and cisplatin in the first line treatment of recurrent or metastatic nasopharyngeal carcinoma. Response rates were high, and at three years overall survival favored the gemcitabine combination over the fluorouracil combination (~ 40% v ~ 20%).	
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The addition of Gemcitabine in combination with cisplatin to treat nasopharynx malignancies demonstrated a good degree of progression free survival when compared to other cisplatin regimens. The adverse effect profile might restrict its use however and should be taking into consideration.	
Richard LoCicero	Effective	Class I: Recommended	Phase III trials have established the efficacy of gemcitabine in combination with cisplatin for the treatment of recurrent or metastatic nasopharyngeal cancer. Hematologic toxicity was higher with the combination over comparator arms; with less mucositis.	