TRUVEN HEALTH ANALYTICS™
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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 5/31/2017

PACKET: 1427

DRUG: Gemcitabine

USE: Peripheral t-cell lymphoma

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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Zinzani,P.L., et al: Gemcitabine as single agent in pretreated T-cell lymphoma patients: Evaluation of the long-term outcome. Annals of Oncology Apr 2010; Vol 21, Issue 4; pp. 860-863.	Comments: This was a prospective, single-arm, phase 2 study. There was low risk of bias associated with selection of cohorts and assessment of outcome. All patients were included in the analyses. Patients were followed for up to 120 months. A major caveat of the study was the absence of a control group or active comparator.	S
Mahadevan,D., et al: Phase 2 trial of combined cisplatin, etoposide, gemcitabine, and methylprednisolone (PEGS) in peripheral T-cell non-Hodgkin lymphoma: Southwest Oncology Group Study S0350. Cancer Jan 15, 2013; Vol 119, Issue 2; pp. 371-379.		1
Dong,M., et al: Gemcitabine-based combination regimen in patients with peripheral T-cell lymphoma. Medical Oncology Mar 2013; Vol 30, Issue 1; p. 351.	Comments: This was a retrospective observational single-arm study. Study participants were consecutively presenting patients at two institutions. Data was gathered from medical records. All subjects were included in the analyses. Median follow-up was 25 months (range 7-60 months). A major caveat of the study was the absence of a control group or active comparator.	1
Park,B.-B., et al: Salvage chemotherapy of gemcitabine, dexamethasone, and cisplatin (GDP) for patients with relapsed or refractory peripheral T-cell lymphomas: a consortium for improving survival of lymphoma (CISL) trial. Annals of Hematology Nov 2015; Vol 94, Issue 11; pp. 1845-1851.	Comments: This was a prospective, single-arm, phase 2 study. There was low risk of bias associated with selection of cohorts and assessment of outcome. All patients were included in the analyses. Patients were followed for up to 48 months. A major caveat of the study was the absence of a control group or active comparator.	S

Qi,F., et al: Gemcitabine, dexamethasone, and cisplatin (GDP) as salvage chemotherapy for patients with relapsed or refractory peripheral T cell lymphoma - not otherwise specified. Annals of Hematology Feb 01, 2017; Vol 96, Issue 2; pp. 245-251.	Comments: This was a retrospective observational single-arm study. Study participants were consecutively presenting patients at two institutions. Data was collected from a hospital database. All subjects were included in the analyses. Median follow-up was 9 months (range 2–68 months). A major caveat of the study was the absence of a control group or active comparator.	S
Yao,Y.-Y., et al: Gemcitabine, oxaliplatin and dexamethasone as salvage treatment for elderly patients with refractory and relapsed peripheral T-cell lymphoma. Leukemia and Lymphoma Jun 2013; Vol 54, Issue 6; pp. 1194-1200.	Comments: This was a prospective, single-arm, phase 2 study. There was low risk of bias associated with selection of cohorts and assessment of outcome. All patients were included in the analyses. Patients were followed for up to 48 months. A major caveat of the study was the absence of a control group or active comparator.	S
Pellegrini,C., et al: A phase II study on the role of gemcitabine plus romidepsin (GEMRO regimen) in the treatment of relapsed/refractory peripheral T-cell lymphoma patients. Journal of Hematology and Oncology Apr 12, 2016; Vol 9, p. 38.	Comments: This was a multicenter, prospective, single-arm, phase 2 study conducted at four sites. There was low risk of bias associated with selection of cohorts and assessment of outcome. All patients were included in the analyses. Median follow-up was 18 months. A major caveat of the study was the absence of a control group or active comparator.	2
Qian C, et al: Gemcitabine, navelbine, and doxorubicin as treatment for patients with refractory or relapsed T-cell lymphoma. Biomed Res Int. 2015;2015:606752.	Comments: This was a retrospective study. There was low risk of bias associated with selection of cohorts and assessment of outcome. A major caveat of the study was the absence of a control group or active comparator. Data was gathered from clinical records. All patients underwent a reevaluation with complete physical examination, laboratory tests, and previously positive radiographic examinations. Follow-up data was available for more than 60 months. All patients were included in the analyses. Potential confounding factors were analyzed.	S

Yim KL, Ashley S. Assessment of gemcitabine, cisplatin and methylprednisolone (GEM-P) combination treatment for non-Hodgkin T cell lymphoma. Med Oncol. 2012 Dec;29(5):3535-9.	Comments: This was a 10-year retrospective study. There was low risk of bias associated with selection of cohorts and assessment of outcome. A major caveat of the study was the absence of a control group or active comparator. Data was gathered from hospital records. All patients were included in the analyses.	S
Crump M, et al. A randomized phase III study of gemcitabine, dexamethasone, and cisplatin versus dexamethasone, cytarabine, and cisplatin as salvage chemotherapy followed by posttransplantation rituximab maintenance therapy versus observation for treatment of aggressive B-Cell and T-Cell non-Hodgkin's lymphoma. Clin Lymphoma. 2005 Jun;6(1):56-60.		1
Crump M, et al. Randomized comparison of gemcitabine, dexamethasone, and cisplatin versus dexamethasone, cytarabine, and cisplatin chemotherapy before autologous stem-cell transplantation for relapsed and refractory aggressive lymphomas: NCIC-CTG LY.12. J Clin Oncol. 2014 Nov 1;32(31):3490-6.		1
Arkenau, et al. Gemcitabine, cisplatin and methylprednisolone for the treatment of patients with peripheral T-cell lymphoma: the Royal Marsden Hospital experience. Haematologica February 2007 92: 271-272.		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)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Felicia Gelsey, MS	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		Preeti Sudheendra	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
MICROMEDEX	Effective	Class I: Recommended		B
Preeti Sudheendra	Effective	Class I: Recommended	All the studies supported the effectiveness of gemcitabine based therapy in treating relapsed/refractory PTCL. However, the studies were very small, not randomized, and included a few different gemcitabine containing regimens.	N/A
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	The use of Gemcitabine in combination with various agents and in different regimens proved to be quite effective in treating relasped or refractory T-cell lymphoma. Adding Gemcitabine was a good alternative to other standard agents. However, the studies were quite small and a decent amount of patients exhibited degrees of neutropenia and thrombocytopenia which delayed or halted treatment.	N/A

Richard LoCicero	Effective	Class I: Recommended	Multiple clinical trials have evaluated the role for treatment of relapsed or refractory peripheral T-cell lymphoma with gemcitabine as a single agent of part of a combination regimen. Such treatment has been shown to be effective with acceptable toxicity.	N/A