TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Doxorubicin hydrochloride liposome

INDICATION: Mycosis fungoides, advanced or refractory, after failure of previous treatments

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**
*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
Dummer R, Quaglino P, Becker JC, et al. Prospective international multicenter phase II trial of intravenous pegylated liposomal doxorubicin monochemotherapy in patients with stage IIB, IVA, or IVB advanced mycosis fungoides: final results from EORTC 21012. J Clin Oncol 2012;30(33):4091-4097.	Study methodology comments: This was an open-label, single-arm, phase 2 trial. There was low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively for objective outcomes. All subjects were included in the analysis. The results should be interpreted with caution due to lack of a control group.	S
Quereux G, Marques S, Nguyen J-M, et al. Prospective multicenter study of pegylated liposomal doxorubicin treatment in patients with advanced or refractory mycosis fungoides or Sezary syndrome. Arch Dermatol 2008;144(6):727-733.	Study methodology comments: This was an open-label, single-arm trial. There was low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively for objective ouctomes. All subjects were included in the analyses. The results should be interpreted with caution due to lack of a control group.	S
Pulini S, Rupoli S, Goteri G, et al. Pegylated liposomal doxorubicin in the treatment of primary cutaneous T-cell lymphomas. Haematologica 2007;92(5):686-689.	Study methodology comments: This was an open-label, single-arm, phase 2 trial. There was a low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively for objective outcomes. All subjects were included in the analyses. The results should be interpreted with caution due to lack of a control group.	S
Wollina U, Dummer R, Brockmeyer NH, et al. Multicenter study of pegylated liposomal doxorubicin in patients with cutaneous T-cell lymphoma. Cancer 2003;98(5):993-1001.	Study methodology comments: This was an open-label, single-arm, retrospective, phase 2 trial. There was a low risk of bias associated with selection of cohorts and assessment of outcomes. Outcomes were assessed by defined response criteria. All subjects were included in the analyses. The results should be interpreted with caution due to lack of a control group.	S
Di Lorenzo G, Di Trolio R, Delfino M, et al. Pegylated liposomal doxorubicin in stage IVB mycosis fungoides. Br J Dermatol 2005;153:183-185	Study methodology comments:	3

Lybaek D & Iversen L. Pegylated liposomal doxorubicin in the treatment of mycosis fungoides	Study methodology comments: letter	4
Wilcox RA. Cutaneous T-cell lymphoma: 2011 update on diagnosis, risk-stratification, and management. Am J Hematology 2011;86:929-948	Study methodology comments: review article	4
Willemze R & Dreyling M. Primary cutaneous lymphomas: ESMO clinical practice guidelines for diagnosis, treatment and follow-up. Annals Oncol 2010;21(supplement 5):177-180.	Study methodology comments: guideline	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)

TRUVEN HEALTH ANALYTICS

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	Thomas McNeil Beck, MD	None
Felicia Gelsey, MS	None	James E. Liebmann, MD	None
		Jeffrey A. Bubis, DO	Other payments: Dendreon
		John M. Valgus, PharmD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, DO	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	Repeated results look quite favorable particularly in regards to response rate. Experience thus far has focused on those patients that have been heavily pretreated and with aggressive disease. Adverse effects seem acceptable also.	N/A
Thomas McNeil Beck, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Good evidence of efficacy with acceptable toxicity – no control group in any study.	N/A
James E. Liebmann, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	There are no real standard treatments for refractory MF, particularly in the setting of lymph node or visceral organ involvement. The papers reviewed show reasonable response rates to Liposomal-Doxorubicin and acceptable toxicity. Whether this drug should be preferred over other options (eg; Pentostatin, Gemcitabine, others) is not known.	N/A

Jeffrey A. Bubis, DO	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Data is from non-randomized trials and there are agents that have demonstrated a benefit in better-designed prospective trials, but if patients are refractory to other interventions, this is a viable consideration.	N/A
John M. Valgus, PharmD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	Multiple single arm studies demonstrating activity of liposomal doxorubicin in this setting include CRs.	N/A