

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 4/19/2018

PACKET: 1668

DRUG: Lenalidomide

USE: POEMS syndrome

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 *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
Zagouri,F., et al: Lenalidomide in patients with POEMS syndrome: a systematic review and pooled analysis. Leuk Lymphoma. Sep 2014; Vol 55, Issue 9; pp. 2018-2023.		3
Yang ,H., et al: Improvement of sexual function in POEMS syndrome after combination therapy of lenalidomide and dexamethasone. Orphanet.J Rare Dis Jun 18, 2016; Vol 11, Issue 1; p. 80.		1
Royer B, et al. ,Efficacy of lenalidomide in POEMS syndrome: A retrospective study of 20 patients. Am. J. Hematol. 88:207–212, 2013.	Comments: This was a retrospective study that included 20 POEMS syndrome patients. There was low risk of bias associated with selection of cohorts and assessment of outcome. Data was gathered from medical records. An ONLS score (Overall Neuropathy Limitation Scale), was made retrospectively and independently by three operators to assess the neurological response. All patients were included in the analyses. The median interval from lenalidomide initiation to last follow-up was 22 months (range 6–58). A major caveat of the study was the absence of a control group or active comparator.	S
Nozza,A., et al: Lenalidomide and dexamethasone in patients with POEMS syndrome: results of a prospective, open-label trial. Br J Haematol. Dec 2017; Vol 179, Issue 5; pp. 748-755.	Comments: This was a prospective, open-label, pilot study that included 18 POEMS syndrome patients. There was low risk of bias associated with selection of cohorts and assessment of outcome. Data was gathered prospectively. All patients were included in the analyses. Median follow-up was 39 months. A major caveat of the study was the absence of a control group or active comparator.	S

<p>Cai,Q.Q., et al: Efficacy and safety of low-dose lenalidomide plus dexamethasone in patients with relapsed or refractory POEMS syndrome. Eur J Haematol. Oct 2015; Vol 95, Issue 4; pp. 325-330.</p>	<p>Comments: This was a retrospective study that included 12 POEMS syndrome patients. There was low risk of bias associated with selection of cohorts and assessment of outcome. Data was gathered from medical records. All patients were included in the analyses. Median follow-up was 20 months (range, 6–31 months). A major caveat of the study was the absence of a control group or active comparator.</p>	<p>S</p>
<p>Jaccard,A.: POEMS syndrome: therapeutic options. Hematol Oncol Clin North Am Feb 2018; Vol 32, Issue 1; pp. 141-151.</p>		<p>4</p>
<p>Dispenzieri,A.: POEMS syndrome: 2017 Update on diagnosis, risk stratification, and management. American Journal of Hematology 2017; Vol 92, Issue 8; pp. 814-829.</p>		<p>4</p>
<p>Lestang,E., et al: Lenalidomide as frontline therapy in polyneuropathy, organomegaly, endocrinopathy, monoclonal protein and skin changes syndrome: a retrospective case series of eight patients. Leuk Lymphoma. J3un 2015; Vol 56, Issue 6; pp. 1895-1896.</p>		<p>3</p>

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		
		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
MICROMEDEX	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases		B
John D Roberts	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	In three small single arm studies, including one prospective study, lenalidomide in combination with dexamethasone showed clinically significant benefits in most patients and was well tolerated. There are many treatment options for POEMS and selection of treatment should take into account extent of disease, co-morbidities, and prior treatment, if any.	N/A
Jeffrey Klein	Effective	Class I: Recommended	The use of lenalidomide with a steroid was quite effective in treating POEMS syndrome. Symptom improvement as well as a true neurological response that lasted for upwards of 2 years was demonstrated. The studies were quite small as well as one of them showing a higher incidence of adverse effects. The other two studies interesting enough did not report any adverse reactions.	N/A

Richard LoCicero	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	Two retrospective studies and one prospective study evaluated the efficacy and safety of lenalidomide for the treatment of POEMS syndrome. High response rates and durable responses were observed with acceptable toxicity.	N/A
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