TRUVEN HEALTH ANALYTICS
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 11/30/16

PACKET: 1378

DRUG: Pasireotide

USE: Carcinoid syndrome inadequately controlled with first generation somatostatin analogs, in patients with metastatic neuroendocrine tumors of the digestive tract

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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Wolin,E.M., Jarzab,B., Eriksson,B., et al: Phase III study of pasireotide long-acting release in patients with metastatic neuroendocrine tumors and carcinoid symptoms refractory to available somatostatin analogues. Drug Des Devel Ther 2015; Vol 9, pp. 5075-5086.	Comments: This was an international, randomized, double-blind, phase lll study that compared pasireotide long-acting release (pasireotide LAR) with octreotide long-acting repeatable (octreotide LAR) in managing carcinoid symptoms refractory to first-generation somatostatin analogues. Key bias criteria evaluated were (1) random sequence generation of randomization, (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria. The study terminated early which may introduce high risk of bias. At the time of a planned interim analysis, the data monitoring committee recommended halting the study because of a low predictive probability of showing superiority of pasireotide over octreotide for symptom control.	S
Pavel,M., O'Toole,D., Costa,F., et al: ENETS consensus guidelines update for the management of distant metastatic disease of intestinal, pancreatic, bronchial neuroendocrine neoplasms (NEN) and NEN of unknown primary site. Neuroendocrinology Apr 01, 2016; Vol 103, Issue 2; pp. 172-185.		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		
		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 IIb: Recommended, In Some Cases		B
John D Roberts	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Options for control of carcinoid syndrome due to metastatic neuroendocrine tumors of the digestive tract include first (somatostatin and lanreotide) and second (pasireotide) generation somatostatin analogs that are variably available in short-acting and long-acting formulations. In patients with inadequately controlled symptoms, changes in analog, formulation, dose, and/or schedule may lead to improved symptom control.	N/A

Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	The use of Pasireotide as a second generation somatostatin analog in patients with digestive tract tumors seems to have a modest improvement in reducing tumor size over the first generation. In addition, pasireotide appears to have a longer progression free survival over the original somatostatin analogs.	N/A
Richard LoCicero	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	Insufficient clinical trial evidence exists to support the use of pasireotide for carcinoid syndrome inadequately controlled with first generation somatostatin analogs.	N/A