COMPENDIA TRANSPARENCY TRACKING FORM

DATE: November 8, 2023

OFF-LABEL ID #: 2590

DRUG NAME: Sotorasib

OFF-LABEL USE: Pancreatic cancer, Locally advanced or metastatic, KRAS G12C-mutated, in patients who have received at least 1 prior systemic therapy

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, 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	LITERATURE CODE
Strickler, JH, Satake, H, George, TJ, et al: Sotorasib in KRAS p.G12C-mutated advanced pancreatic cancer. N Engl J Med Jan 05, 2023; Vol 388, Issue 1; pp. 33-43. Pubmed ID: 36546651.	S
He, Q, Liu, Z, and Wang, J: Targeting KRAS in PDAC: a new way to cure it. Cancers (Basel) Oct 11, 2022; Vol 14, Issue 20; p. 4982. Pubmed ID: 36291766.	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
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
MERATIVE MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Sotorasib in previously treated metastatic pancreatic cancer patients demonstrated enhanced progression free survival and overall survival. These patients had the biomarker KRAS G12-C mutation. The medication has well tolerated in this small study.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	In a phase I/II trial, sotorasib treatment resulted in a 21% response rate in patients with locally advanced or metastatic, KRAS G12C-mutated, who had received at least 1 prior systemic therapy. Median overall survival was 6.9 months. No unexpected toxicity was observed.	

Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	Limited therapeutic options remain for pancreatic cancer patients who have progressed on 1or more lines of treatment. In tumors with a KRASG12C mutation, sotorasib induced responses/stabilized disease, led to months of disease control, and may lead to a prolongation in survivorship.	