

**COMPENDIA TRANSPARENCY TRACKING FORM**

**DATE:** November 8, 2023

**OFF-LABEL ID #:** 2644

**DRUG NAME:** Adagrasib

**OFF-LABEL USE:** Malignant tumor of pancreas Unresectable 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
<b>A</b>	Treatment represents an established standard of care or significant <b>advance</b> over current therapies
<b>C</b>	<b>Cancer</b> or cancer-related condition
<b>E</b>	Quantity and robustness of <b>evidence</b> for use support consideration
<b>L</b>	<b>Limited</b> alternative therapies exist for condition of interest
<b>P</b>	<b>Pediatric</b> condition
<b>R</b>	<b>Rare</b> disease
<b>S</b>	<b>Serious</b> , 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
Bekaii-Saab TS, Yaeger R, Spira AI, Pelster MS, Sabari JK, Hafez N, Barve M, Velastegui K, Yan X, Shetty A, Der-Torossian H, Pant S. Adagrasib in Advanced Solid Tumors Harboring a <i>KRAS</i> <sup>G12C</sup> Mutation. J Clin Oncol. 2023 Sep 1;41(25):4097-4106. doi: 10.1200/JCO.23.00434. Epub 2023 Apr 26. PMID: 37099736.	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
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
<b>MERATIVE MICROMEDEX</b>	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Adagrasib in previously treated metastatic pancreatic cancer patients demonstrated decent duration of response and good progression free survival. These patients had the biomarker KRAS G12-C mutation. The medication was well tolerated in this study.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	In a phase II cohort study, Adagrasib treatment resulted in a response rate of 33.3% in patients with KRAS G12C-mutated, previously treated advanced pancreatic cancer. Unexpected toxicity was not observed.	

Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	Limited therapeutic options remains for pancreatic cancer patients who have progressed on 1-2 lines of treatment. In tumors with a KRASG12C mutation, the use of adagrasib appears to induce responses/stabilize disease, lead to months of disease control, and potentially to longer life.	
--------------	--------------------------	---------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--