

**COMPENDIA TRANSPARENCY TRACKING FORM**

**DATE:** January 9, 2024

**OFF-LABEL ID #:** 2588

**DRUG NAME:** Pembrolizumab

**OFF-LABEL USE:** Biliary Tract Cancer

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, 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
Kelly, RK, Ueno, M, Yoo, C, et al: Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (KEYNOTE-966): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Jun 03, 2023; Vol 401, Issue 10391; pp. 1853-1865. Pubmed ID: 37075781	S
Lin, J, Yang, X, Long, J, et al: Pembrolizumab combined with lenvatinib as non-first-line therapy in patients with refractory biliary tract carcinoma. Hepatobiliary Surg Nutr Aug 2020; Vol 9, Issue 4; pp. 414-424. Pubmed ID: 32832493	1
Marabelle,A., Le,D.T., Ascierto,P.A., et al: Efficacy of pembrolizumab in patients with noncolorectal high microsatellite instability/mismatch repair-deficient cancer: Results from the phase II KEYNOTE-158 study. J Clin Oncol Jan 01, 2020; Vol 38, Issue 1; pp. 1-10. Pubmed ID: 31682550	1
aio, M, Ascierto, PA, Manzyuk, L., et al: Pembrolizumab in microsatellite instability high or mismatch repair deficient cancers: updated analysis from the phase II KEYNOTE-158 study. Ann Oncol Sep 2022; Vol 33, Issue 9; pp. 929-938. Pubmed ID: 35680043	1
Lo, JH, Agarwal, R, Goff, LW, et al: Immunotherapy in biliary tract cancers: current standard-of-care and emerging strategies. Cancers (Basel) Jun 23, 2023; Vol 15, Issue 13; p. 3312. Pubmed ID: 37444422	4
Ramjeesingh, R, Chaudhury, P, Tam, VC, et al: A practical guide for the systemic treatment of biliary tract cancer in Canada. Curr Oncol Jul 25, 2023; Vol 30, Issue 8; pp. 7132-7150. Pubmed ID: 37622998	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
Megan Smith	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
IBM MICROMEDEX				B