

COMPENDIA TRANSPARENCY TRACKING FORM FOR ONCOLOGY OFF-LABEL USES DERIVED FROM GUIDELINES

DATE: May 27, 2025

DRUG NAME: Aspirin

OFF-LABEL USE: Colorectal 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 *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
Lecomte, T, Tougeron, D, Chautard, R, et al: Non-metastatic colon cancer: French Intergroup Clinical Practice Guidelines for diagnosis, treatments, and follow-up (TNCD, SNFGE, FFCD, GERCOR, UNICANCER, SFCD, SFED, SFRO, ACHBT, SFP, AFEF, and SFR). Dig Liver Dis May 2024; Vol 56, Issue 5; pp. 756-769. Pubmed ID: 38383162.	S
Figueiredo JC, Jacobs EJ, Newton CC, Guinter MA, Cance WG, Campbell PT. Associations of Aspirin and Non-Aspirin Non-Steroidal Anti-Inflammatory Drugs With Colorectal Cancer Mortality After Diagnosis. J Natl Cancer Inst. 2021 Jul 1;113(7):833-840. doi: 10.1093/jnci/djab008. PMID: 33528005; PMCID: PMC8246799.	S
Baron JA, Cole BF, Sandler RS, Haile RW, Ahnen D, Bresalier R, McKeown-Eyssen G, Summers RW, Rothstein R, Burke CA, Snover DC, Church TR, Allen JI, Beach M, Beck GJ, Bond JH, Byers T, Greenberg ER, Mandel JS, Marcon N, Mott LA, Pearson L, Saibil F, van Stolk RU. A randomized trial of aspirin to prevent colorectal adenomas. N Engl J Med. 2003 Mar 6;348(10):891-9. doi: 10.1056/NEJMoa021735. PMID: 12621133.	S
Chan AT, Ogino S, Fuchs CS. Aspirin use and survival after diagnosis of colorectal cancer. JAMA. 2009 Aug 12;302(6):649-58. doi: 10.1001/jama.2009.1112. PMID: 19671906; PMCID: PMC2848289.	S
Palaire, L, Puntoni, M, Clavarezza, M, et al: PIK3CA Mutation, Aspirin Use after Diagnosis and Survival of Colorectal Cancer. A Systematic Review and Meta-analysis of Epidemiological Studies. Clin Oncol (R Coll Radiol) May 2016; Vol 28, Issue 5; pp. 317-326. Pubmed ID: 26712086	S
Liao, X, Lochhead, O, Nishihara, R, et al: Aspirin use, tumor PIK3CA mutation, and colorectal-cancer survival. N Engl J Med Oct 25, 2012; Vol 367, Issue 17; pp. 1596-1606. Pubmed ID: 23094721.	S
Chia, JWK, Segelov, E, Deng, Y, et al: Aspirin after completion of standard adjuvant therapy for colorectal cancer (ASCOLT): an international, multicentre, phase 3, randomised, double-blind, placebo-controlled trial. Lancet Gastroenterol Hepatol Jan 14, 2025; Vol Epub, p. Epub. Pubmed ID: 39824200.	1
Lin, JL, Lin, JX, Zheng, CH, et al: Relationship between aspirin use of esophageal, gastric and colorectal cancer patient survival: a meta-analysis. BMC Cancer Jul 09, 2020; Vol 20, Issue 1; p. 638. Pubmed ID: 32646396.	1
Michel, P, Boige, V, Andre, T, et al: Aspirin versus placebo in stage III or high-risk stage II colon cancer with PIK3CA mutation: A French randomised double-blind phase III trial (PRODIGE 50-ASPIK). Dig Liver Dis Mar 2018; Vol 50, Issue 3; pp. 305-307. Pubmed ID: 29402752.	4
Kothari, N, Kim, R, Jorissen, RN, et al: Impact of regular aspirin use on overall and cancer-specific survival in patients with colorectal cancer harboring a PIK3CA mutation. Acta Oncol Apr 2015; Vol 54, Issue 4; pp. 487-492. Pubmed ID: 25549537.	2
Domingo, E, Church, DN, Sieber, O, et al: Evaluation of PIK3CA mutation as a predictor of benefit from nonsteroidal anti-inflammatory drug therapy in colorectal cancer. J Clin Oncol Dec 01, 2013; Vol 31, Issue 34; pp. 4297-4305. Pubmed ID: 24062397.	2

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
Stacy LaClaire, PharmD	
Catherine Sabatos, PharmD	

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Evidence favors efficacy	Class IIb	B