

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

**DATE:** May 1, 2025

**DRUG NAME:** Budesonide

**OFF-LABEL USE:** Diarrhea, Chemotherapy-induced, refractory to loperamide

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, \*to meet requirement 1(C, A, L)

CODE	EVALUATION/PRIORITIZATION CRITERIA
A	Treatment represents an established standard of care or significant <b>advance</b> over current therapies
C	<b>Cancer</b> or cancer-related condition
E	Quantity and robustness of <b>evidence</b> for use support consideration
L	<b>Limited</b> alternative therapies exist for condition of interest
P	<b>Pediatric</b> condition
R	<b>Rare</b> disease
S	<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
Bossi P, Antonuzzo A, Cherny NI, Rosengarten O, Pernot S, Trippa F, Schuler U, Snegovoy A, Jordan K, Ripamonti CI; ESMO Guidelines Committee. Diarrhoea in adult cancer patients: ESMO Clinical Practice Guidelines. Ann Oncol. 2018 Oct 1;29(Suppl 4):iv126-iv142. doi: 10.1093/annonc/mdy145. PMID: 29931177.	S
Lenfers BH, Loeffler TM, Droege CM, Hausamen TU. Substantial activity of budesonide in patients with irinotecan (CPT-11) and 5-fluorouracil induced diarrhea and failure of loperamide treatment. Ann Oncol. 1999 Oct;10(10):1251-3. doi: 10.1023/a:1008390308416. PMID: 10586346.	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
Stacy LaClaire, PharmD	None
Deanna Rossi	None

#### ASSIGNMENT OF RATINGS:

\*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Evidence Favors Efficacy	Class IIB	B