COMPENDIA TRANSPARENCY TRACKING FORM

DATE: March 6, 2026

OFF-LABEL ID #: MDXOLS-438

DRUG NAME: Sacituzumab govitecan-hziy

OFF-LABEL USE: Triple-negative breast cancer, Unresectable locally advanced or metastatic disease, PD-L1 positive, previously untreated, in combination with pembrolizumab

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, 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
Tolaney SM, de Azambuja E, Kalinsky K, et al. Sacituzumab Govitecan plus Pembrolizumab for Advanced Triple-Negative Breast Cancer. *N Engl J Med*. 2026;394(4):354-366. PMID: 41564397.	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		

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Effective	Class IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Sacituzimab with Pembrolizumab to treat previously untreated metastatic triple negative breast cancer patients demonstrated a better greater free survival over the use of the Pembroblizumab/chemo combination. In addition, the duration of response was greater with the non-chemo combination. Adverse effects were greater with the chemo group. of Sacituzimab with Pembrolizumab to treat previously untreated metastatic triple negative breast cancer patients, demonstrated a better greater free survival over the use of the Pembroblizumab/chemo combination. In addition, the duration of response was greater with the non-chemo combination. Adverse effects were greater with the chemo group.	

Todd Gersten	Effective	Class IIb: Recommended, in Some Cases	Sacituzumab + pembrolizumab statistically improves disease control versus the current SOC of chemotherapy + pembro by nearly 3.5 months in front-line treatment of advanced TNBC. The main caveat being this is restricted to patients with a PD-L1 score of 10 or greater.	
Warren Brenner	Effective	Class I: Recommended	This large phase III trial in a difficult group of patients with metastatic triple negative POL 1 positive breast cancer clearly established this as an effective regimen in a poor prognostic subgroup of BC patients with a poor prognosis. The combination of Sacituzuma/pembro was clearly superior to the chemo/pembro group with clinically relevant improvements in PFS and DOR. Due to multiple lines of therapy in BC PFS is an established clinically relevant end point. Together with its efficacy and improved safety profile outside of diarrhea, this study clearly in my opinion shows it to be a highly effective regimen favoring an effective rating and given its efficacy and acceptable safety profile I give it a class I recommendation	