

## COMPENDIA TRANSPARENCY TRACKING FORM

**DATE:** March 6, 2026

**OFF-LABEL ID #:** MDXOLS-444

**DRUG NAME:** Pembrolizumab

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

| 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 <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 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Tolaney SM, de Azambuja E, Kalinsky K, et al. Sacituzumab Govitecan plus Pembrolizumab for Advanced Triple-Negative Breast Cancer. <i>N Engl J Med</i> . 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                    |
| Warren Brenner      | Effective | Class I: Recommended                  | This large phase III trial in a difficult group of patients with metastatic triple negative PDL1 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 |                      |
| Todd Gersten        | Effective | Class IIb: Recommended, in Some Cases | Pembrolizunab + sacituzumab 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 in patients with a PD-L1 score of 10 or greater.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                      |

|               |                          |                                       |                                                                                                                                                                                                                                                                                                                                                                    |  |
|---------------|--------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Jeffrey Klein | Evidence Favors Efficacy | Class IIa: Recommended, in Most Cases | The use of Pembrolizumab with Sacituzumab to treat previously untreated metastatic triple negative breast cancer patients demonstrated a better progression free survival over the use of Pembrolizumab/chemo combination. In addition, the length of response was greater with the non-chemo combination. Adverse effects were higher with the chemo combination. |  |
|---------------|--------------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|