

## COMPENDIA TRANSPARENCY TRACKING FORM

**DATE:** March 6, 2026

**OFF-LABEL ID #:** MDXOLS-428

**DRUG NAME:** Sacituzumab govitecan-hziy

**OFF-LABEL USE:** Non-small cell lung cancer, Advanced/metastatic disease, previously treated with platinum-based chemotherapy and anti-PD-L1 therapy

| 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, 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 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| Paz-Ares LG, Juan-Vidal O, Mountzios GS, et al. Sacituzumab Govitecan Versus Docetaxel for Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer: The Randomized, Open-Label Phase III EVOKE-01 Study. <i>J Clin Oncol</i> . 2024;42(24):2860-2872. PMID: 38843511.    | S               |
| Ansab M, Rath S, Alam U, Burhan M, Siddiqui HT, Desai A. TROP-2-directed antibody-drug conjugates in advanced NSCLC: A systematic review and meta-analysis of efficacy, safety, and reconstructed survival outcomes. <i>Crit Rev Oncol Hematol</i> . 2026;218:105093. PMID: 41443486. | 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 | 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 | Evidence Favors Efficacy | Class IIb: Recommended, in Some Cases |                                                                                                                                                                                                                                                                                                       | B                    |
| Todd Gersten        | Evidence Favors Efficacy | Class IIb: Recommended, in Some Cases | In the general population of NSCLC post first/second line (after prior chemo and immunotherapy) there was no clinical benefit for sacituzumab over docetaxel. However, an overall survivorship advantage was present by 3.5 months in patients who did not respond to the prior anti-PD-L1 treatment. |                      |
| Jeffrey Klein       | Evidence Favors Efficacy | Class IIb: Recommended, in Some Cases | The use of Sacituzumab in previously treated NSCLC patients, showed a modest advantage over the use of docetaxel with regard to overall survival. In addition, Sacituzumab had less adverse effects than the patients receiving docetaxel.                                                            |                      |

|                |                          |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  |
|----------------|--------------------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Warren Brenner | Evidence is Inconclusive | Class IIb: Recommended, in Some Cases | <p>The Sacituzumab treatment was numerically superior as far as its primary end point, but this was not statistically significant. Although not statistically significant its roughly 6-week improvement in OS shows some benefit but overall data is inconclusive given its non-statistical significance. The retrospective analysis showing an improvement in OS in the subgroup</p> <p>previously nonresponsive to PDL-1 regimen is hypothesis generating and no conclusions regarding efficacy in this subgroup can be drawn again resulting in inconclusive evidence. I recommended in some cases as it could be considered in the subgroup mentioned above and also as it has some safety profiles better than the chemotherapy arms and less patients discontinued treatment therefore could be considered in some patients warranting a class lib recommendation.</p> |  |
|----------------|--------------------------|---------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|