COMPENDIA TRANSPARENCY TRACKING FORM

DATE: March 26, 2026

OFF-LABEL ID #: MDXOLS-439

DRUG NAME: Fam-Trastuzumab Deruxtecan-nxki

OFF-LABEL USE: Early breast cancer, HER2-positive, adjuvant monotherapy in patients with residual disease after neoadjuvant taxane and trastuzumab-based treatment

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

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
Loibl S, Park YH, Shao Z, et al. Trastuzumab Deruxtecan in Residual HER2-Positive Early Breast Cancer. *N Engl J Med*. 2026;394(9):845-857. PMID: 41370739.	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		
Elizabeth Hall, PharmD	None		

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Effective	Class I: Recommended		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Fam-Trastuzumab Deruxtecan (T-Dxd) to treat HER-2 positive breast cancer patients demonstrated a higher disease-free survival when compared to another Trastuzumab formulation. A rare lung adverse effect should be monitored for in the T-Dxd group however	
Todd Gersten	Effective	Class I: Recommended	High level clinical trial evidence exists for use of Fam-Trastuzumab Deruxtecan-nxki in patients with residual disease after surgery for HER2 positive BRC after prior NACT. Data supports a reduction in relapse/metastatic disease and secondarily in death.	

Warren Brenner	Effective	Class I: Recommended	This very large phase III randomized trial establishes this agent as a practice changing therapy based on important and meaningful end points including significantly less invasive disease events and death cutting the risk of these important primary end points in half. It was compared to the current standard of care in these HEr2 positive high-risk patients who have residual disease post neoadjuvant therapy and surgery. The HR of 0.47 makes this a highly effective regimen resulting in my effective rating. I gave it a class I recommendation as it was a large phase III trial compared to the current standard of care and the HR of 0.47 for its important primary end points as well as other important endpoints including distant recurrences and CNS recurrences. The adverse events do require close monitoring particularly interstitial lung disease and GI toxicities, but the overall impressive efficacy data still warrants a class I recommendation	