



Real World Data with Off-Label Insurance Approval of Trastuzumab Deruxtecan in Metastatic Breast Cancer

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BACKGROUND

Trastuzumab deruxtecan (T-DXd) improves outcomes in HER2+ and HER2-low (IHC 1+ or IHC 2+/ISH-) previously treated metastatic breast cancer (MBC) patients.^{1,2}

OncoHealth is a digital health care company that leverages managed care-trained, board-certified oncologists and oncology pharmacists to review the appropriateness of prior authorization (PA) requests for cancer treatment regimens.

OncoHealth takes into consideration multiple factors when approving PAs, including but not limited to: payer-specific criteria, FDA approvals, NCCN compendium support, scientific literature eligible for off-label coverage per the Medicare Benefit Policy Manual Chapter 15, Section 50.4.5, as well as clinical judgement guided by compelling, later phase, multi-institutional clinical trial results demonstrating significant benefit, all in efforts to expand access to the latest groundbreaking therapies.

OBJECTIVE

Examine the rate of off-label PA approvals for T-DXd in MBC.

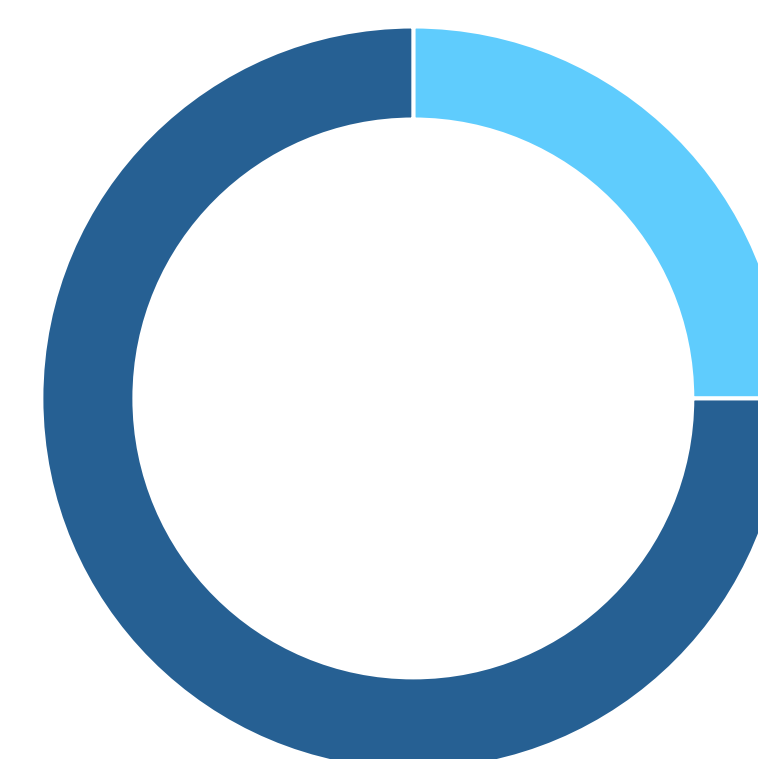
METHODS

- Retrospective review of T-DXd PA approvals by OncoHealth for MBC patients between 1/17/20 – 6/21/22
- Evaluated medical records and utilization management data for PA approval rationale:
 - On-label
 - Off-label NCCN compendium
 - Off-label acceptable scientific literature-only (LIT)
 - Clinical justification (if off-label and without NCCN or LIT support)

RESULTS

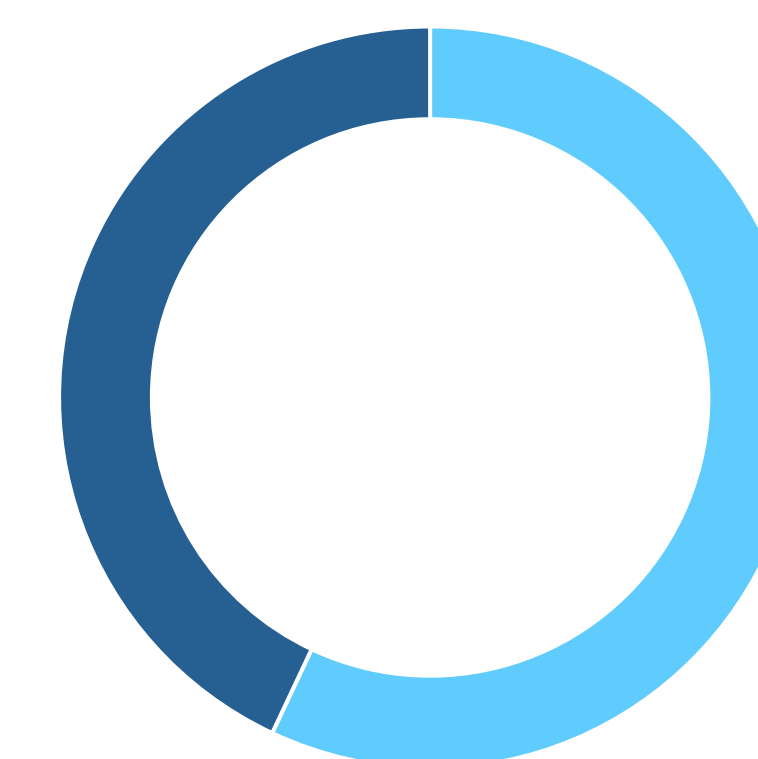
Characteristic	T-DXd (N=156)
Patient age, years – No. (%)	
< 50	38 (24)
50-59	29 (19)
60-69	50 (32)
70+	39 (25)
HER2 status – No. (%)	
HER2-Low	10 (6)
HER2-Positive	146 (94)
Hormone receptor status – No. (%)	
Positive	112 (72)
Negative	44 (28)
Visceral disease – No. (%)	
Yes	133 (85)
No	23 (15)
Brain metastases – No. (%)	
Yes	42 (27)
No	114 (73)
Median prior MBC regimens – No. (range)	
HER2-Low	5 (0-14)
HER2-Positive	2 (0-9)

We identified 156 patients with MBC with a PA approval for T-DXd.



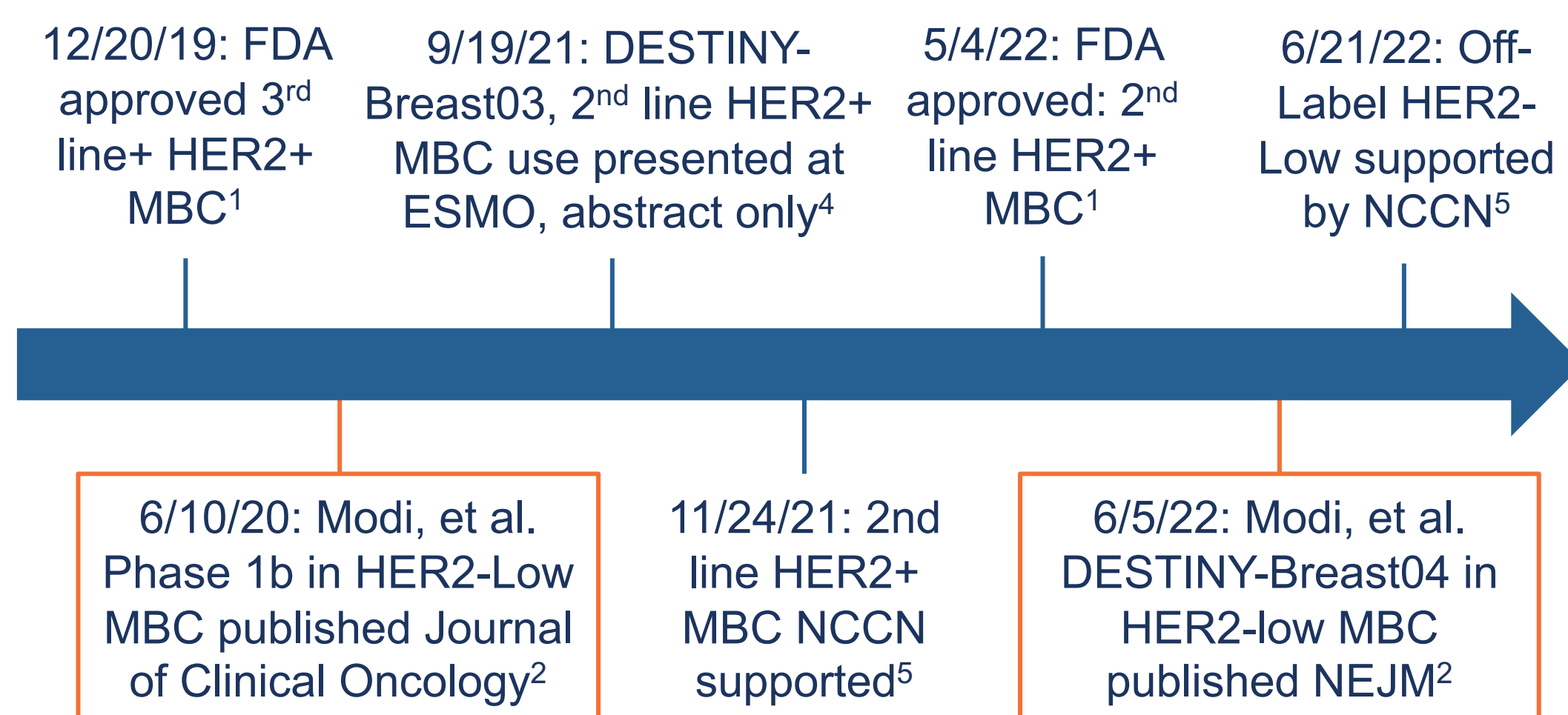
■ Off-Label ■ On-Label

25% (37/146) of T-DXd PA approvals in HER2+ MBC were off-label.



■ NCCN ■ Clinical Justification

57% (21/37) off-label HER2+ PA approvals were supported by NCCN. Remaining **43% (16/37)** were approved by clinical justification, mainly based on ESMO 2021 data from DESTINY-Breast03, > 7 months prior to its FDA approval.



- 100%** HER2-low T-DXd was approved based on LIT, prior to NCCN incorporation.
- Limitation: Data was collected up to 6/21/22, prior to T-DXd's FDA approval in HER2-Low MBC.
- Off-label coverage approval for T-DXd in HER2-low began **6/30/20** supported by the Phase 1b Modi publication, ~ 2 years prior to publication of DESTINY-Breast04.

CONCLUSION

- Access to the latest cancer therapies can be expanded by leveraging managed care, board-certified oncology clinicians to review PAs, using additional eligible coverage sources beyond NCCN.
- 25% of all T-DXd approvals in HER2+ MBC were off-label.
- T-DXd was approved off-label in HER2-low MBC prior to an FDA approval and NCCN support, expanding access.
- We will evaluate outcomes data with longer follow-up and report the impact of expanding coverage access to off-label T-DXd to study whether faster access translates to better outcomes.

REFERENCES

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- NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/

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