Policy Brief

COST-EFFECTIVENESS ANALYSIS OF T-DM1 / TRASTUZUMAB EMTANSINE BIOSIMILAR DRUG FOR THE HER2- POSITIVE BREAST CANCER PATIENTS IN INDIA

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Recommendations:

- The present study does not recommend the inclusion of T-DM1 at current price of ₹24,000 per 100 mg vial of T-DM1, in oncology related health benefit packages under the world's largest health insurance scheme i.e. AB-PMJAY.
- The cost of T-DM1 needs to be reduced by 33% to make it a cost-effective treatment strategy for HER2 positive early breast cancer patients with residual invasive disease in India.
- The study insights can be used for clinical decision-making, guideline development, reimbursement decisions, and price negotiations.

Key Findings:

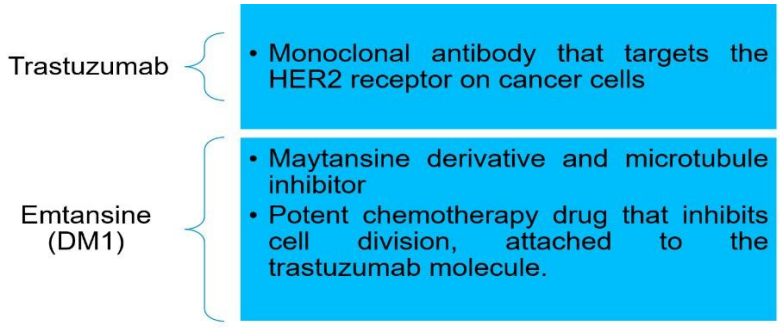
- T-DM1 provides 1.19 more QALYs with additional costs of ₹4,59,957 than trastuzumab using an abridged societal perspective.
- The incremental cost per LY gained and QALY gained with use of T-DM1 as compared to trastuzumab was estimated as ₹ 3,51,112 and ₹ 3,86,518 respectively.
- The incremental cost-effectiveness ratio (ICER) is substantially higher than the currently accepted willingness-to-pay (WTP) threshold (1.6 times), defined as one-time India's per capita GDP.
- Probabilistic sensitivity analysis suggested that at the current WTP threshold of one-time per capita GDP (₹ 2,30,892) of India, T-DM1 has 17.2% probability to be cost-effective.
- Accordingly, T-DM1 is not cost-effective at the WTP threshold of ₹ 2,30,892 (US$2,710) as of 2024-25.

Background

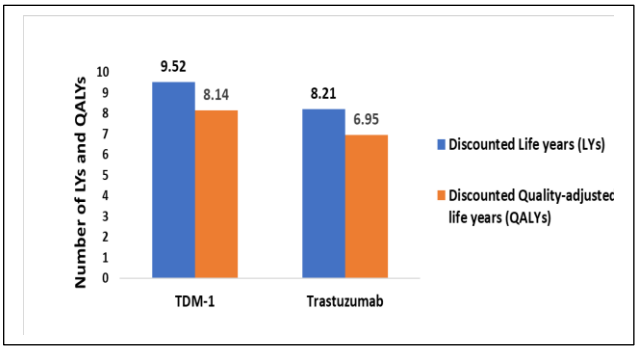
- Breast cancer is the most common cancer among women in India, and accounts for 27% of all cancers in the country (1).
- In approximately 20% of breast cancers, tumour cells overexpress the protein human epidermal growth receptor 2 (HER2), leading to more rapid cancer growth, worsened prognosis, and high risk of recurrence (2-6).
- Trastuzumab is a monoclonal antibody that targets HER2 receptors, substantially improving survival for this type of breast cancer (7-9).
- However, patients who have residual invasive cancer after neoadjuvant chemotherapy in combination with HER2 directed therapy have worse outcomes than patients showing pathological complete response (pCR) (10).
- The new standard of care for such early breast cancer patients with residual disease after neoadjuvant HER 2 directed therapy consists of shifting these patients to Trastuzumab emtansine (T-DM1) in the adjuvant setting (11).

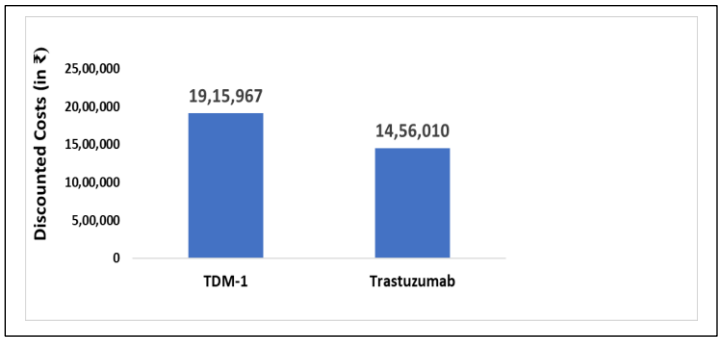
PICO	Description of components of PICO
Population	Surgically resected HER2-positive early breast cancer patients with residual invasive disease
Intervention	T-DM1 at a dose of 3.6 mg per kg of body weight intravenously every 3 weeks for 14 cycles
Control	Trastuzumab infusion at 6 mg/kg of body weight every 3 weeks for 14 cycles
Outcome	Cost and health benefits in terms of life-years and quality-adjusted life years

Mechanism of action of Trastuzumab and T-DM1



T-DM1 retains trastuzumab activity while providing intracellular delivery of DM1 to HER2-overexpressing cells

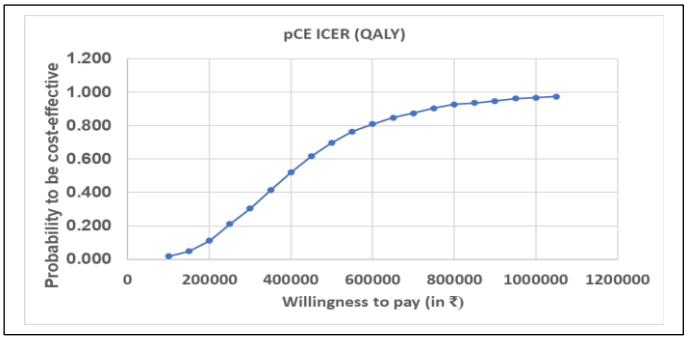




Discounted health outcomes and costs associated with use of Trastuzumab and T-DM1 for treatment of HER2-positive early breast cancer with residual invasive disease in India

Price threshold Analysis:

- At the current WTP threshold of one-time per capita GDP (₹ 2,30,892) of India, T-DM1 has 17.2% probability to be cost-effective.
- A price reduction of 33% reduction is required in current market price (₹24,000 per 100 mg vial) of T-DM1 to make it a cost-effective treatment strategy for HER2 positive early breast cancer patients with residual invasive disease in India.
- Thus, the value-based price of T-DM1 was estimated as ₹16, 080 for 100 mg vial in India.



Probability of cost- effectiveness of Trastuzumab and T-DM1 for treatment of HER2-positive early breast cancer with residual invasive disease in India

Conclusion:

- The use of T-DM1 is not a cost-effective treatment option for HER2- positive early breast cancer patients with residual invasive disease in India.
- Therefore, the present study does not recommend the inclusion of T-DM1 (at current price ₹24,000 per 100 mg vial of T-DM1) in oncology related health benefit packages under the world's largest health insurance scheme i.e. AB-PMJAY (46).
- The cost of T-DM1 needs to be reduced by 33% to make it a cost-effective treatment strategy for HER2 positive early breast cancer patients with residual invasive disease in India.

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