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Editorial

Transforming cancer care in India - Steps in the right direction

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Cancer remains a formidable public health challenge, with the financial burden of treatment placing many families under severe economic distress, particularly in low- to middle-income countries like India. Recognizing this, the Indian Union Budget for 2024–2025 introduced customs duty exemptions and GST reduction (from 12% to 5%) on three high-impact cancer drugs: trastuzumab deruxtecan (TDxd), osimertinib, and durvalumab. This policy change marks a critical step toward making life-saving therapies more accessible and affordable, potentially significantly improving patient outcomes.

TRASTUZUMAB DERUXTECAN (TDXD)

TDxd, an antibody–drug conjugate, has revolutionized the treatment of human epidermal growth factor receptor 2 (HER2)-positive breast cancer and made strides in HER2-low breast cancer and HER2-mutated non-small cell lung cancer (NSCLC). Clinical trials, such as DESTINY-Breast03, demonstrated a near doubling of progression-free survival (PFS) compared to trastuzumab emtansine (T-DM1) for patients with metastatic HER2-positive breast cancer. Additionally, the DESTINY-Breast04 trial highlighted its groundbreaking efficacy in HER2-low disease, which is traditionally seen as having fewer targeted treatment options. The standard dose is 5.4 mg/kg, which is administered intravenously once every 3 weeks for breast cancer and 6.4 mg/kg for gastric cancer and is continued until disease progression or unacceptable toxicity. Prior to customs duty exemption, the cost of 300 mg (usual dose for an average patient in India) TDxd was approximately ₹ 5.61 lakhs per cycle. Following the exemption, this has come down to about ₹ 5.01 lakhs, saving nearly 10.6% per cycle. These savings are helpful in the context of the disease and impact the patient, potentially impacting treatment adherence and overall survival outcomes. Further, patient assistance programs (PAPs) can play a pivotal role in ensuring broader access. While PAP for deruxtecan has not yet been made available, it is eagerly anticipated by clinicians and patients alike.

OSIMERTINIB

Osimertinib is a third-generation Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor. It has been approved as a first-line treatment for EGFR-mutant NSCLC, supported by data from the FLAURA trial. It demonstrated a median overall survival (OS) of 38.6 months compared to 31.8 months with older EGFR inhibitors. Furthermore, the ADAURA trial, where it was given up to 3 years after surgery, underscored osimertinib's role in reducing recurrence in early-stage resected disease, showcasing its broad applicability across disease™ stages. A similar impact has

been elicited in the LAURA study post-radiation as adjuvant. For osimertinib, an 80 mg dosage is taken once daily orally as long as the patient is responding to the treatment or does not experience significant toxicity. Previously, osimertinib's annual treatment cost after PAP was ₹ 13.65 lakhs, a figure well beyond the reach of many Indian families. The customs duty exemption and GST reduction have reduced this cost to ₹ 12.79 lakhs per year for the 1st year and subsequent years at ₹ 8.53 lakhs, yielding a saving of 6.3% annually. This reduction can reduce financial toxicity to some extent, help reduce treatment abandonment, and improve survival.

DURVALUMAB

Durvalumab, an anti-programmed cell death ligand 1 (anti PD L1) monoclonal antibody, has shown efficacy in unresectable Stage III NSCLC in the PACIFIC trial, demonstrating improved PFS and OS when used as consolidation therapy after chemoradiotherapy. In addition, ongoing trials like HIMALAYA and TOPAZ have expanded their role in treating biliary tract and hepatocellular cancers, further broadening their clinical utility. A dose of 10 mg/kg as an intravenous infusion every 2 weeks for 12 months (or until disease progression or unacceptable toxicity) is generally administered. Durvalumab is also used in combination with etoposide and platinum-based chemotherapy (cisplatin or carboplatin) as a first-line treatment for patients with extensive-stage small-cell lung cancer. After completing the chemotherapy phase, durvalumab can be continued as a single-agent maintenance therapy. A dosage of 1500 mg is given every 3 weeks during the initial combination phase with chemotherapy for up to four cycles, followed by every 4 weeks as maintenance monotherapy. It is also approved in combination with gemcitabine and cisplatin for the treatment of patients with locally advanced or metastatic biliary tract cancer, including cholangiocarcinoma and gallbladder cancer. For this indication, it is administered intravenous (IV) at 1500 mg with chemotherapy every 3 weeks for eight cycles, followed by 1500 mg every 4 weeks as a monotherapy. It is continued until disease progression or unacceptable toxicity. It is currently being tested in various phases of clinical research for bladder cancer, hepatocellular carcinoma, and head-and-neck squamous cell carcinoma. The price of durvalumab has also been reduced by 6.3% after the aforementioned exemptions. As long-term administration is often required, these savings are crucial. For several patients, completing an entire course of durvalumab could mean the difference between disease progression and durable remission. The expansion of PAPs and reduced costs can ensure that durvalumab reaches a few more patients who previously considered it less affordable. This dual approach, policy-driven cost reduction and patient-centered assistance programs can potentially improve access to cancer care in India.

IMPLICATIONS FOR THE INDIAN HEALTHCARE SYSTEM

While customs duty exemptions and GST reductions are a promising start, more is needed. The Indian government has underscored its commitment to addressing non-communicable diseases with an increased health sector allocation of ₹90,958.63 crore for the fiscal year 2024–2025, a notable rise from the previous year's ₹80,517.62 crore. This positive increase still falls short of the 2% of GDP allocation targeted by the health experts. Notably, the budget also includes ₹2,143 crore for production-linked incentives in the pharmaceutical sector, aiming to bolster domestic drug manufacturing. Additionally, equitable drug distribution remains a challenge, particularly in rural areas. Systematic efforts to increase domestic manufacturing and improve healthcare infrastructure are imperative. The health sector continues to advocate for increased GDP spending on health care, prioritization of health care as a national issue, and support for domestic manufacturing of medical devices. The exemptions for TDxd, osimertinib, and durvalumab offer a beacon of hope for Indian patients with cancer. However, to fully realize their impact, we must continue pushing for comprehensive healthcare reforms and investments. Collaboration between the government, pharmaceutical companies, and healthcare providers is essential to break down barriers to treatment and ensure that every patient, regardless of economic status, has a fighting chance. The estimated 6–10% price reduction will help more patients access this highly effective treatment for longer. This program needs to be expanded to include other crucial drugs.

Indigenous research, like biosimilar development and innovations like the Indian chimeric antigen receptor T-cell therapy (CAR-T) evolution, showcases the capabilities of researchers and the pharmaceutical industry in India. Eventually, we will have to expand "Make in India" to every sphere to make treatments more and more affordable for the masses. Our country can not only provide for our population but also can help the world solve the problem of access and affordability.

This editorial serves as both a call to action and a testament to the power of thoughtful policy in transforming lives.

SUMMARY OF APPROXIMATE COST REDUCTIONS[1]

Drugs	Strength	Current PAP	Old MRP	New MRP	% Reduction in MRP
Osimertinib	80 mg	1+2	₹1,51,670	₹1,42,190	6.3
Durvalumab	500 mg	1+2	₹1,89,585	₹1,77,735	6.3
Trastuzumab deruxtecan	100 mg	No PAP	₹1,87,000	₹1,67,069	10.6

PAP: Patient assistance programs, , MRP: Maximum retail price

Note:

1. From 1st October, 2024 GST decreased from 12 % to 5%.
2. Osimertinib: The patient buys one strip and gets assisted for two strips by the company (10 tabs in 1 strip) for 9 months and subsequently 3 months fully assisted. From next year, the patient buys one strip and gets assisted for two strips by the company (10 tabs in 1 strip) for 6 months and subsequently for 6 months fully assisted by the company.
3. Durvalumab: The patient buys one vial and gets assisted with two vials by the company.
4. Trastuzumab deruxtecan: Currently, PAP support not available
5. Disclaimer: All figures and calculations have been taken at approximations to highlight the numeric significance, the actual figure may vary at the time of publication or when inferred with actual data figures.

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