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Physician perspectives on treatment decision making process in high-risk early-stage triple negative breast cancer (esTNBC) in a community oncology setting

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Background

- Pembrolizumab was approved by the Food and Drug Administration (FDA) in July 2021 for the treatment of high-risk esTNBC, based on results of the KEYNOTE-522 trial which demonstrated significantly improved event-free survival (EFS) in the neoadjuvant setting when combined with chemotherapy, compared to chemotherapy alone.[1] In 2024, final analyses for the trial showed that pembrolizumab also significantly improved overall survival (OS).[2] As a result, it has become the standard of care for high-risk esTNBC patients in both neoadjuvant and adjuvant settings.[3]
- Despite clinical evidence supporting its efficacy, the integration of pembrolizumab into clinical practice remains inconsistent, with some high-risk esTNBC patients not receiving the drug in the neoadjuvant setting.[4] Understanding the factors contributing to this gap between clinical trial outcomes and real-world integration is critical for optimizing treatment strategies and improving patient outcomes.
- Physicians are central to the therapeutic decision-making process, weighing clinical guidelines, emerging evidence, and individual patient factors when determining the appropriateness of pembrolizumab.[5] Their perspectives are critical for understanding decision-making for treating high-risk esTNBC patients and identifying barriers to optimal care.
- This study investigated physician perspectives on the use of pembrolizumab in the neoadjuvant and adjuvant settings, focusing on the decision-making processes for treating patients with high-risk esTNBC. By identifying the factors that influence treatment choices, we aim to identify opportunities to better align high-risk esTNBC patients with the most effective therapies.

Methods

- Focus group participants were recruited from physicians within The United States (US) Community Oncology Network who had treated patients with high-risk esTNBC that were part of a real-world data-based study of pembrolizumab therapy for TNBC. The selection ensured geographical distribution across the US and included physicians managing patients receiving pembrolizumab neoadjuvant therapy and those not receiving neoadjuvant treatment.[3]
- A brief online survey was developed to capture participant insights on treatment patterns and potential barriers to pembrolizumab use and administered before the focus group. A two-hour virtual focus group, facilitated by a trained moderator using a semi-structured discussion guide was held in January 2025. Discussions were recorded and transcribed verbatim using Microsoft's automated transcription technology.
- Quantitative survey data were analyzed descriptively, and themes emerging from the focus group discussion transcript were identified qualitatively to provide insights into esTNBC management practices.

Results

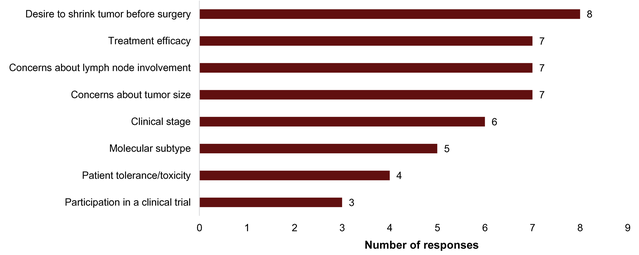
- Six medical oncologists and two breast surgeons completed the survey and focus group discussion. Each physician reported managing at least six esTNBC patients in the past year, with practice sizes ranging from over 20 to more than 500 providers. All practices were based in urban areas across the US.
- Survey responses are summarized in **Figures 1** and **2**.

- Four major themes emerged regarding pembrolizumab use and potential barriers to neoadjuvant use for high-risk esTNBC: (a) adoption as standard of care (SOC); (b) rare exceptions for non-use; (c) treatment of ER-low/HER2-breast cancer; and (d) adjuvant use considerations.

Adoption as SOC

- Physicians unanimously reported widespread adoption of pembrolizumab as SOC for esTNBC, citing its demonstrated survival benefit and manageable safety profile.
- Physicians estimated they use neoadjuvant pembrolizumab plus chemotherapy in 90%-100% of their esTNBC patients. KEYNOTE-522 trial's overall survival (OS) findings further reinforced its use, particularly in facilitating patient discussions regarding treatment decisions.
- Physicians reported that tumor boards are central to treatment planning, with most high-risk esTNBC cases discussed there. Adverse events (AEs) were considered manageable.
- All physicians reported no financial or access-related barriers to neoadjuvant pembrolizumab, attributing this to adequate reimbursement.

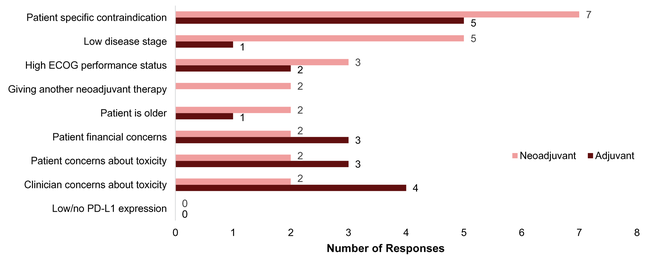
Figure 1. What Clinical Factors Positively Influence Your Decision to Recommend Neoadjuvant Treatment for esTNBC?



Rare exceptions for non-use

- Physicians reported rare exceptions to pembrolizumab as SOC, such as patients with immunotherapy contraindications, like severe autoimmune diseases or kidney transplants.
- Patients occasionally decline neoadjuvant or adjuvant therapy due to side effect concerns or fear of progression and prefer immediate surgery.
- Occasionally patients are referred by general surgeons post-surgery without having received neoadjuvant therapy. Patients with low disease burden, inoperable tumors, or urgent surgical needs also may not receive neoadjuvant pembrolizumab.

Figure 2. Under What Conditions Are You LESS LIKELY to Recommend Pembrolizumab Treatment for esTNBC?



Adjuvant pembrolizumab use

- Seven physicians reported administering adjuvant pembrolizumab to over 75% of high-risk esTNBC patients achieving pCR. Patient-specific contraindications and toxicity concerns remain barriers for pembrolizumab in the adjuvant setting, cited by five and four surveyed physicians, respectively.
- One area of interest expressed by several physicians was the need for further guidance regarding optimal adjuvant treatment among patients who do not achieve pCR with neoadjuvant pembrolizumab plus chemotherapy.

Treatment of ER-Low Breast Cancer

- All physicians reported managing patients with ER-low (1–9% ER expression) BC similarly to those with TNBC, treating patients with pembrolizumab and chemotherapy in the neoadjuvant setting.
- Insurance coverage was not a barrier; physicians noted no issues obtaining approval for TNBC-directed therapies in ER-low cases. One medical oncologist highlighted the routine use of molecular subtyping to confirm basal-like characteristics, which supports clinical decision-making and insurance authorization for immunotherapy.

Discussion

- This study provides qualitative insights into physician perspectives on pembrolizumab use in high-risk esTNBC patients within the US community oncology setting. To our knowledge, this is the first qualitative study assessing physician perspectives on the utilization of pembrolizumab in this study population.

- This study demonstrates that participating physicians routinely administer pembrolizumab plus chemotherapy to nearly all patients with high-risk esTNBC in the neoadjuvant setting and continue treatment into the adjuvant setting, irrespective of pathologic complete response (pCR) status. The findings align with both clinical trial data[3] and emerging real-world evidence[7], reinforcing pembrolizumab's role as SOC in this population.

Implications of Findings and Opportunities for Interventions

- The study highlights key strategies for advancing high-risk esTNBC management, including: improving physician-patient communication, enhancing multidisciplinary care coordination, and ensuring all surgeons performing breast surgeries are aware of updated SOC (including neoadjuvant treatment guidelines) to ensure consistency and efficacy in treatment approaches.
- Focus group discussions demonstrated the need for additional guidance on optimal adjuvant treatments for patients not achieving pCR with neoadjuvant therapy, addressable through targeted research. Addressing these areas can significantly enhance the quality of care and outcomes for patients with high-risk esTNBC.

Strengths and Limitations

- This study's strengths include direct engagement with physicians experienced in the treatment of TNBC from one of the largest U.S. oncology networks, offering crucial insights into real-world practices. The US Oncology Network widely implements decision-support tools, such as Clear Value Plus, which integrates clinical guidelines, patient-specific data, and cost considerations to support evidence-based treatment decisions at the point of care. This likely contributed to the high adoption of pembrolizumab observed in this study.
- However, the treatment practices expressed by physicians in the focus group may not reflect those of the broader physician population in The US Oncology Network

Conclusions

- This qualitative study of breast cancer physicians reveals broad adoption of pembrolizumab as SOC for high-risk esTNBC in The US Oncology Network, due to survival benefits and tolerable side effects. Usage is limited by comorbidities, patient preferences, and post-surgery referrals.
- Future efforts are essential to guide improvements in patient communication, enhance surgeon awareness on current neoadjuvant guidelines, shared decision-making, and multidisciplinary care coordination, ultimately optimizing patient outcomes.

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Disclosures

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