Real-world utilization patterns of PD-1 and PD-L1 therapies in oncology

A disease-state–driven analysis of U.S. health system practice (2023–2025)

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Executive summary

Immune checkpoint inhibitors targeting the programmed death-1 (PD-1) and programmed death-ligand 1 (PD-L1) pathways have become foundational therapies across a wide range of solid tumor malignancies. Over the past decade, rapid expansion of regulatory approvals has increased both clinical adoption and financial impact, prompting assumptions of therapeutic interchangeability within the PD-1 and PD-L1 class. In practice, however, oncology decision-making is shaped by disease-specific evidence, clinical pathways, and population characteristics that constrain the extent to which PD-1 and PD-L1 agents can be considered interchangeable.

This report examines real-world utilization patterns of PD-1 and PD-L1 therapies across U.S. health systems using data from the Vizient Clinical Data Base (CDB) from Q1 2023 through Q2 2025. Utilization was attributed to primary disease state using International Classification of Diseases, Tenth Revision (ICD-10) diagnosis codes and analyzed as the percentage distribution of use within each product. This approach was designed to characterize how individual PD-1 and PD-L1 agents are used across malignancies in routine clinical practice, rather than to assess comparative clinical efficacy or appropriateness.

PD-1 and PD-L1 therapies demonstrated consistent disease-state–driven utilization. While certain agents functioned as broad oncology backbones with use distributed across multiple tumor types, others were overwhelmingly concentrated within a single disease state despite shared mechanisms of action or overlapping approved indications. Apparent competition at the class level frequently does not translate into meaningful cross-indication use in real-world practice.

These findings have important implications for oncology stakeholders navigating an increasingly complex therapeutic landscape. For health systems and clinical pharmacy leaders, real-world utilization data can support alignment between clinical pathways and operational strategy. For contracting and strategic stakeholders, the results suggest that disease-specific approaches may be more realistic and sustainable than class-wide assumptions of interchangeability. Ultimately, strategies grounded in observed practice patterns will better support clinically aligned and economically sustainable decision-making as oncology care continues to evolve.

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Introduction

Immune checkpoint inhibitors targeting the programmed death-1 (PD-1) and programmed death-ligand 1 (PD-L1) pathways were first approved for use in solid tumors in 2014 and have since gained numerous indications across a wide range of malignancies, including lung cancer, melanoma, renal cell carcinoma, head and neck cancers, breast cancer, gastrointestinal malignancies, gynecologic cancers, and others. This rapid expansion has driven widespread clinical adoption and increased financial impact, while also contributing to assumptions of therapeutic interchangeability in settings where indications overlap. In routine oncology practice, however, treatment selection is shaped by disease state-specific evidence, clinical pathways, and population characteristics that may limit true substitutability across indications.

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Although PD-1 and PD-L1 therapies have been extensively evaluated with respect to clinical efficacy, safety, and approved indications, limited published literature describes their real-world utilization across multiple disease states. Existing evidence has largely focused on treatment patterns within individual malignancies rather than characterizing how these therapies are distributed across tumor types in broader oncology practice. For example, a retrospective claims-based analysis by Veluswamy and colleagues examined longitudinal first-line treatment patterns among patients with non-small-cell lung cancer in the United States and demonstrated increasing adoption of PD-1 and PD-L1 inhibitors over time; however, it remained limited to a single disease state.[1]

To address this gap, this analysis looks to examine disease-state utilization of PD-1 and PD-L1 therapies, providing a cross-malignancy perspective that remains largely absent from the current oncology literature.

Current PD-1 and PD-L1 landscape

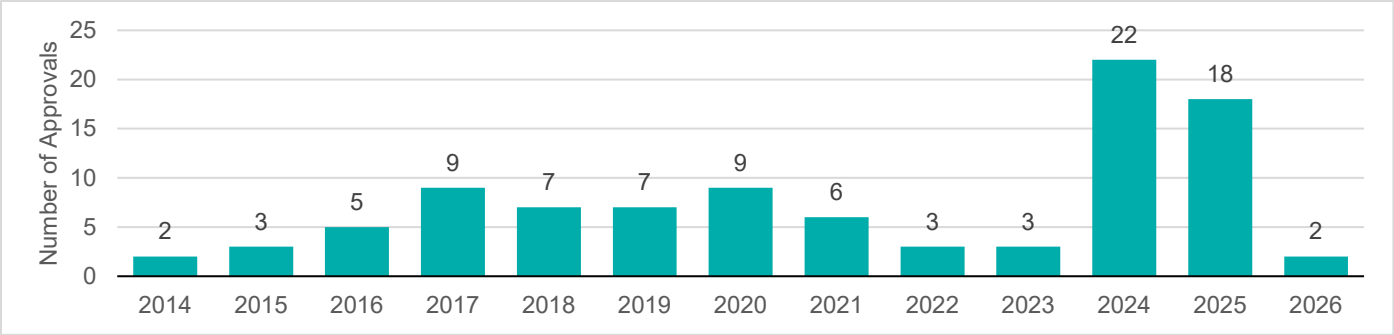
There are currently 15 PD-1 and PD-L1–targeting therapies approved by the U.S. Food and Drug Administration (FDA). Since their initial approvals in the mid-2010s, these agents have expanded across a broad range of oncological disease states, creating a rapidly evolving indication landscape with substantial overlap in several high-prevalence cancers. Table 1 summarizes the disease-state approvals by year for FDA approved PD-1 and PD-L1 therapies.

Table 1. PD-1 and PD-L1 therapies FDA approvals by disease state

	PD-1										PD-L1				
Disease state	Cemiplimab (Libtayo)	Dostarlimab (Jemperli)	Nivolumab (Opdivo)	Nivolumab and hyaluronidase (Opdivo Qvantig)	Nivolumab and Relatimab (Opdualag)	Pembrolizumab (Keytruda)	Pembrolizumab and berahyaluronidase alfa (Keytruda Qlex)	Retifanlimab (Zynyz)	Tislelizumab (Tevimbra)	Toripalimab (Loqtorzi)	Atezolizumab (Tecentriq)	Atezolizumab/ Hyaluronidase (Tecentriq Hybreza)	Avelumab (Bavencio)	Cosibelimab (Unloxcyt)	Durvalumab (Imfinzi)
Melanoma			2014	2024	2022	2014	2025				2020	2024			
Non-small cell lung cancer (NSCLC)	2021		2015	2024		2015	2025				2016	2024			2018
Head and neck squamous cell cancer (HNSCC)			2016	2024		2016	2025								
Any solid tumor with genetic feature		2021				2017	2025								
Urothelial carcinoma			2017	2024		2017	2025				2016	2024	2017		
Classical Hodgkin lymphoma (cHL)			2016			2017									
Primary mediastinal LBCL (PMBCL)						2018									
Cervical cancer						2018	2025								
Hepatocellular carcinoma			2017	2024		2018	2025				2020	2024			
Merkel cell carcinoma						2018	2025	2023					2017		
Endometrial		2021				2019	2025								2024
Small cell lung cancer (SCLC)			2018			2019					2019	2024			2020
Renal cell carcinoma			2015	2024		2019	2025						2019		
Esophageal squamous cell			2020	2024		2019	2025		2024						
Colorectal cancer (MSI-H/dMMR)			2017	2024		2020									
Advanced squamous cell carcinoma (CSCC)	2018					2020	2025							2024	
Breast TNBC						2020	2025				2019	2024			
Bladder cancer						2020					2017	2024			2025
Gastric/GEJ			2021	2024		2021	2025		2024						
Advanced basal cell carcinoma	2021														
Sarcoma											2022	2024			
Biliary tract						2023	2025								2022
Nasopharyngeal carcinoma										2023					
Mesothelioma			2020			2024	2025								
Squamous cell carcinoma of the anal canal								2025							
Ovarian cancer						2026	2026								
Total FDA-approved disease states	3	2	12	9	1	22	16	2	2	1	8	8	3	1	5

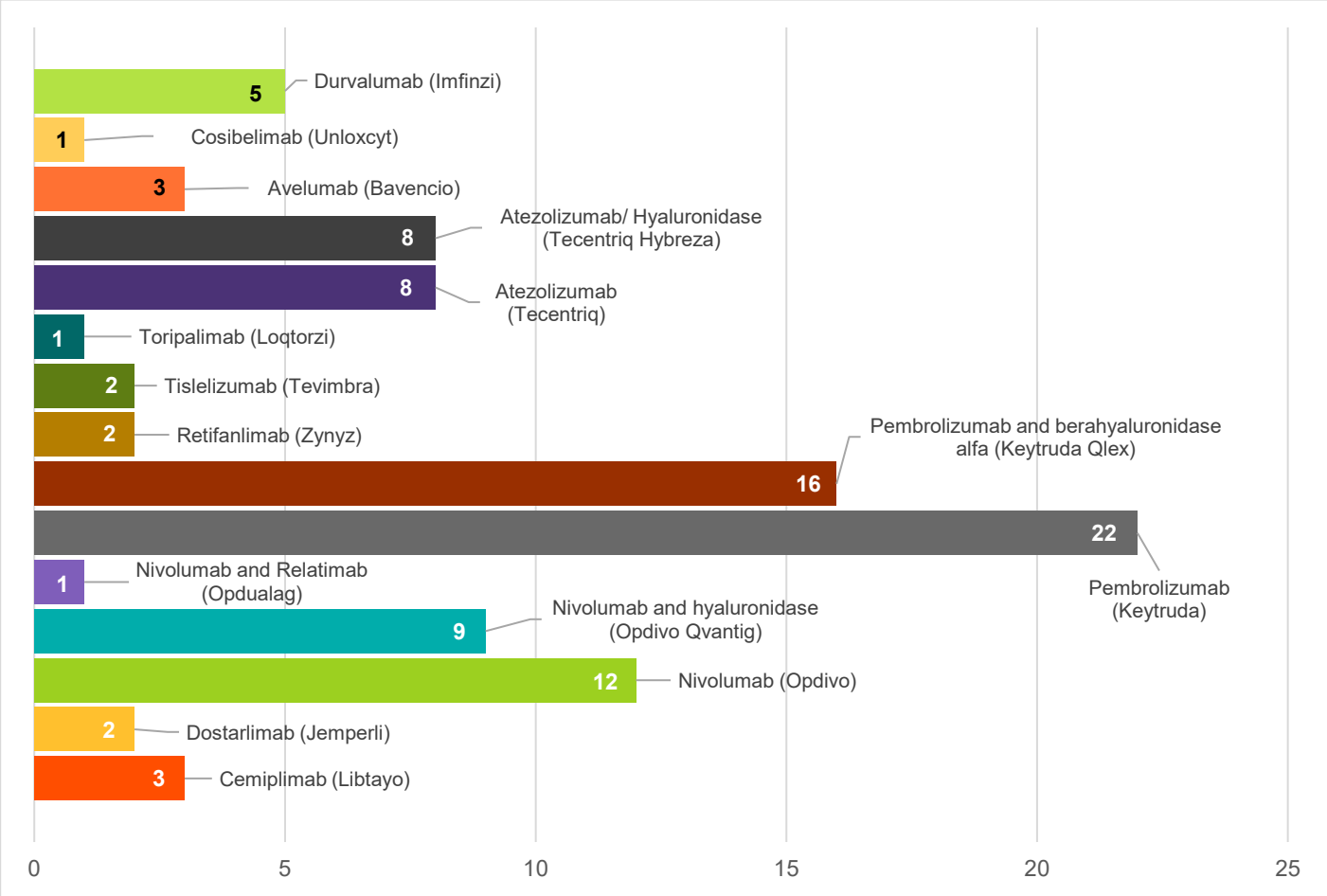
Over time, the pace of new indication approvals has increased with the highest number occurring in the most recent years. While annual approvals were modest from 2014 to 2023, new indication approvals increased sharply in 2024 (22 approvals) and remained elevated in 2025 (18 approvals), reflecting a continued broadening of the PD-1 and PD-L1 class across oncological disease states (Figure 1).

Figure 1. New FDA indication approvals for PD-1 and PD-L1 therapies by year



FDA approvals have created a broad and increasingly complex PD-1 and PD-L1 label landscape, but the breadth of labeled use is not evenly distributed across therapies (Figure 2). A small number of agents account for a disproportionate share of the overall FDA indication footprint, led by pembrolizumab (Keytruda) with the greatest number of disease-state approvals at 22, followed by pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex) (16) and nivolumab (Opdivo) (12). In contrast, most other PD-1 and PD-L1 therapies remain approved in a more limited set of malignancies. This imbalance suggests that label overlap alone may overstate practical interchangeability and underscores the importance of examining real-world utilization patterns.

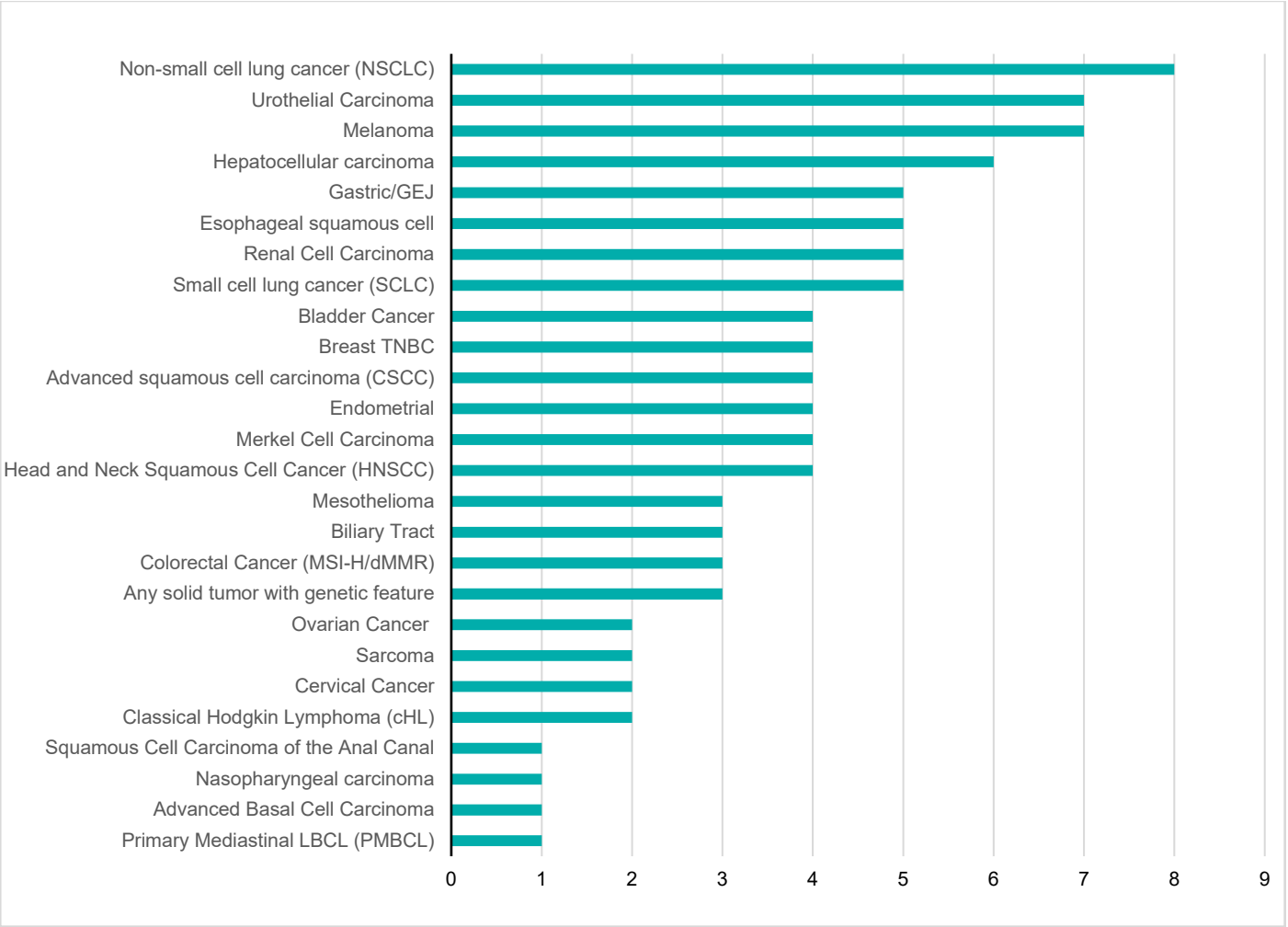
Figure 2. Total FDA-approved indications by molecule



Indication overlap between molecules is substantial and concentrated in select cancer types (Figure 3). Non-small cell lung cancer (NSCLC) demonstrates the greatest overlap, with eight PD-1 and PD-L1 therapies approved, followed by urothelial carcinoma and melanoma (seven each) and hepatocellular carcinoma (six). Several additional disease states, including gastric/GEJ, esophageal squamous cell carcinoma, renal cell carcinoma, and small cell lung cancer, overlap with five therapies – underscoring a crowded landscape in which multiple agents share approvals in same disease-state and utilization remains highly variable across drugs.

Understanding how PD-1 and PD-L1 therapies are utilized across cancer types in routine clinical practice is essential.

Figure 3. Number of PD-1 and PD-L1 FDA approvals per cancer type



Against this landscape of expanding approvals and overlapping indications, understanding how PD-1 and PD-L1 therapies are utilized across cancer types in routine clinical practice is essential.

Data sources and methods

This retrospective descriptive analysis utilized data from the Vizient Clinical Data Base (CDB), a national repository representing academic medical centers and large integrated health systems across the United States. The CDB captures inpatient and hospital-based outpatient encounters and includes detailed information on medication utilization and associated diagnoses, enabling evaluation of real-world oncology practice patterns across diverse care settings. Analyses were conducted for the period spanning Q1 2023 through Q2 2025.

The study population included adult patients receiving PD-1 or PD-L1 inhibitor therapy at Vizient client provider institutions with active data submission to the CDB during the study period. Analyses were limited to therapies

mapped in the CDB during the analysis period. Therapies evaluated included atezolizumab (Tecentriq), avelumab (Bavencio), cemiplimab (Libtayo), dostarlimab (Jemperli), durvalumab (Imfinzi), nivolumab (Opdivo), nivolumab-relatlimab (Opdualag), pembrolizumab (Keytruda), and toripalimab (Loqtorzi).

Drug utilization was attributed to disease state by using the primary International Classification of Diseases, Tenth Revision (ICD-10) diagnosis codes associated with each infusion encounter. An encounter was defined as a single infusion or drug administration. Disease-state categories were defined to support consistent reporting across oncology indications. Secondary malignancy diagnoses were summarized descriptively and excluded from focused disease-state comparisons. The analysis was not restricted by line of therapy (e.g., second or third-line treatment) or treatment setting (e.g., inpatient or ambulatory infusion), reflecting routine clinical practice.

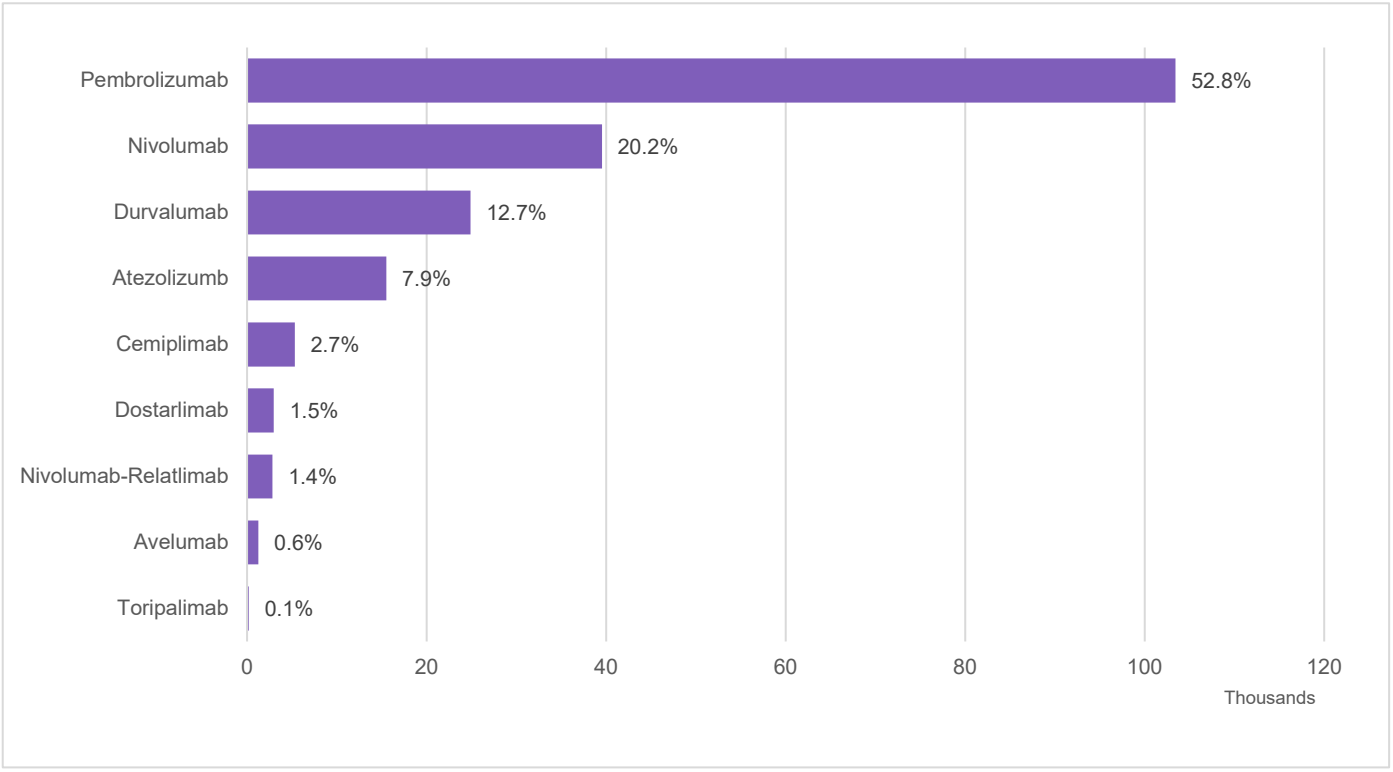
Utilization was summarized using two complementary perspectives. First, results were examined by therapy to describe the distribution of each PD-1 and PD-L1 agent across disease states. Second, results were examined by disease state to characterize how PD-1 and PD-L1 utilization varied across primary oncology diagnoses. In both perspectives, encounter counts were used to calculate percentage distributions to describe relative utilization by agent and by disease state.

Descriptive analyses were performed using encounter counts and percentage distributions. No statistical comparisons or clinical outcome assessments were conducted, as the intent of the analysis was to characterize real-world utilization patterns rather than assess comparative effectiveness or infer causal relationships.

Results

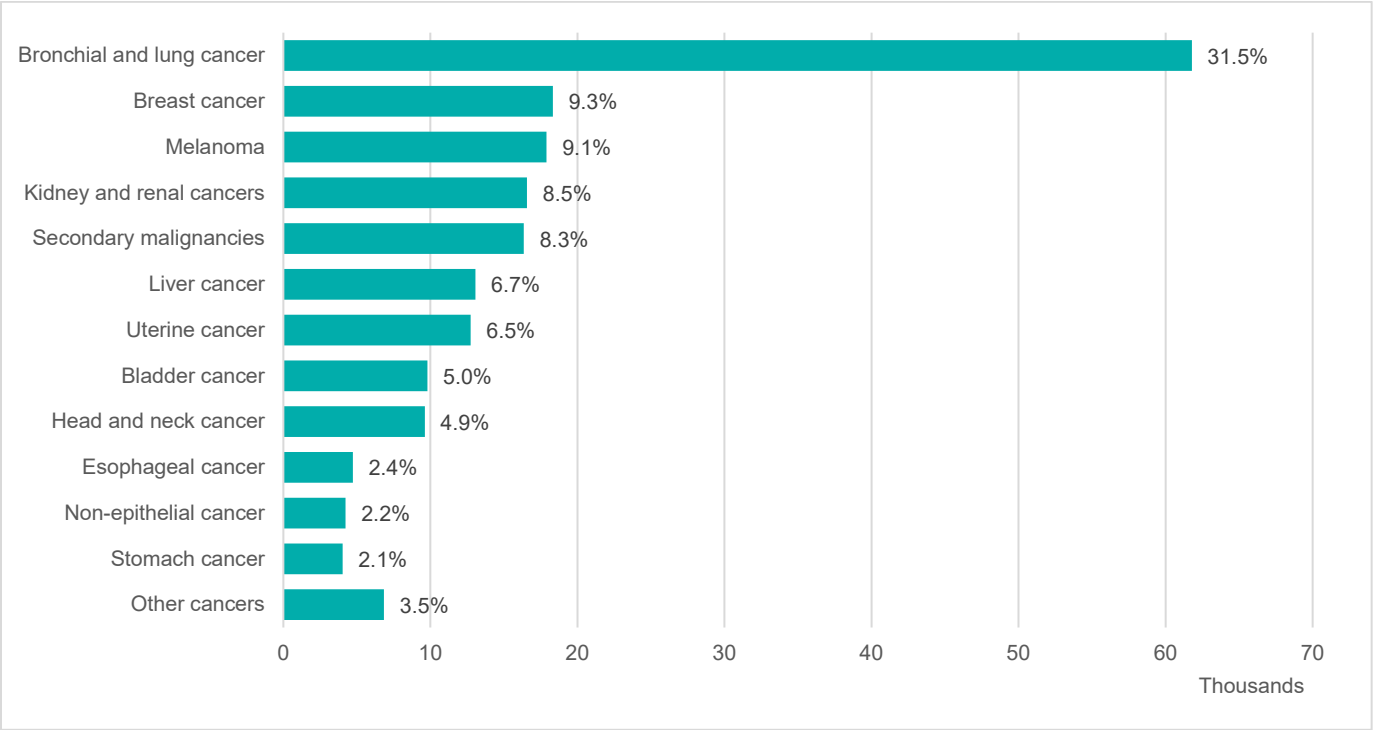
During the study period (Q1 2023 through Q2 2025), PD-1 and PD-L1 inhibitor utilization was substantial, totaling 195,970 infusion encounters across participating institutions. Utilization was dominated by pembrolizumab accounting for 52.8% of all infusion encounters, followed by nivolumab (20.2%), durvalumab (12.7%), and atezolizumab (7.9%) (Figure 4). All remaining therapies accounted for relatively small proportions of encounter volume, including cemiplimab (2.7%), dostarlimab (1.5%), nivolumab–relatlimab (1.4%), avelumab (0.6%), and toripalimab (0.1%), reflecting a utilization profile heavily weighted toward a single PD-1 agent.

Figure 4. Overall infusions by therapy



Across cancer types, infusion encounters were similarly concentrated in a limited number of disease states. Bronchial and lung cancer represented the largest share at 31.5% followed by breast cancer (9.3%), melanoma (9.1%), kidney and renal cancers (8.5%) and secondary malignancies (8.3%) (Figure 5). These top five cancer types accounted for approximately two-thirds of the overall utilization.

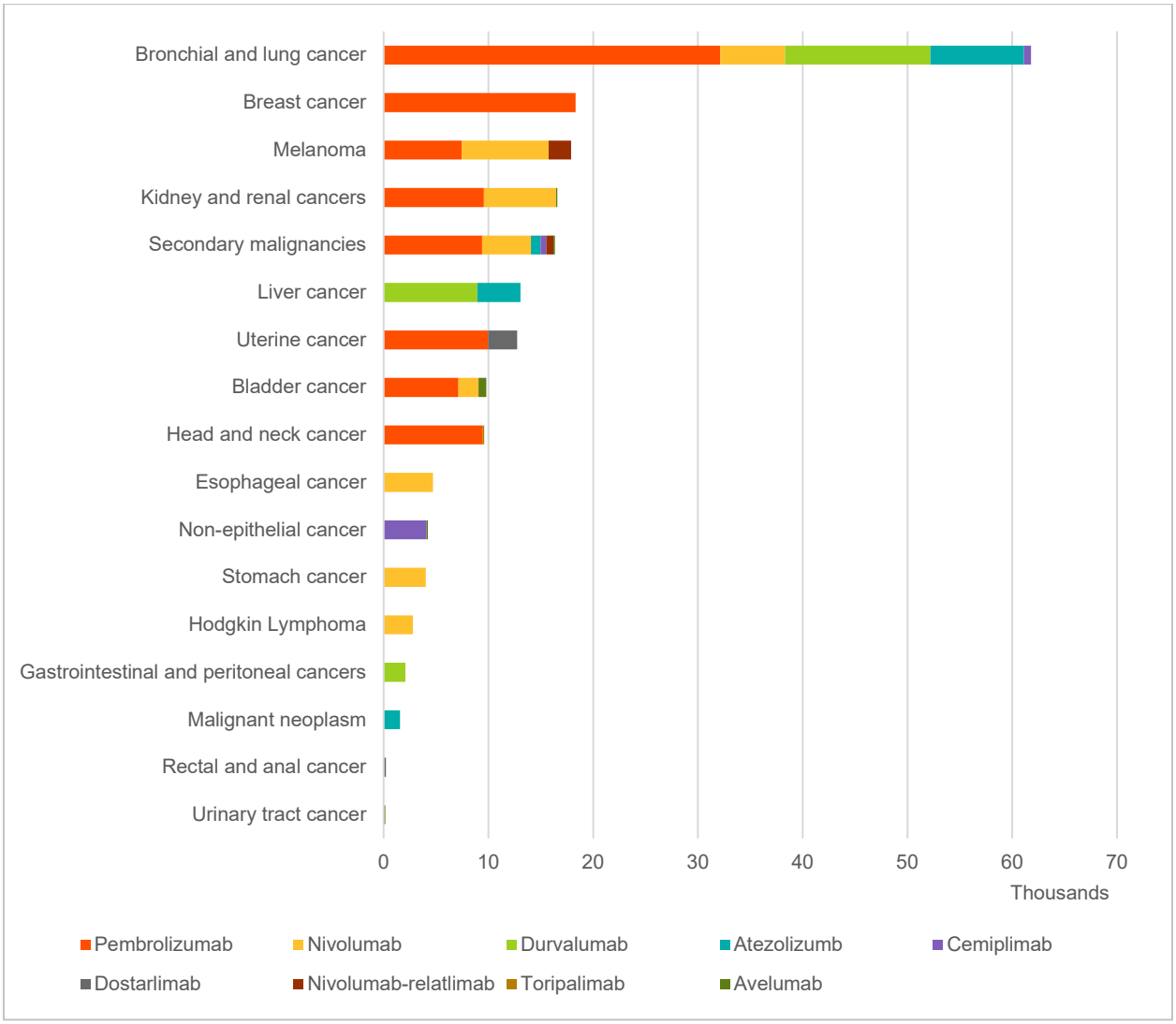
Figure 5. Overall infusions by cancer type



Given the concentration of utilization across both therapies and cancer types, subsequent analyses examine encounter-based patterns by therapy and by disease state to identify where use is most concentrated and how treatment distribution differs across malignancies.

Therapy utilization varied substantially by cancer type, reflecting disease-state differences as well as local clinical practice patterns, including institutional pathways and prescribing preferences. Lung cancer, the largest contributor to overall infusion activity, showed contributions from multiple PD-1 and PD-L1 therapies, consistent with indication overlap in the FDA landscape; however, utilization remained concentrated among the approved therapies (Figure 6). Within lung cancer encounters, pembrolizumab accounted for 52.0% of all infusions, followed by durvalumab (22.4%) and atezolizumab (14.5%), with nivolumab contributing an additional 10.0% and cemiplimab representing a minimal share. Overall, despite multiple approved options, lung cancer utilization was dominated by a single agent with a smaller secondary tier of therapies.

Figure 6: PD1 and PD-L1 utilization by cancer type



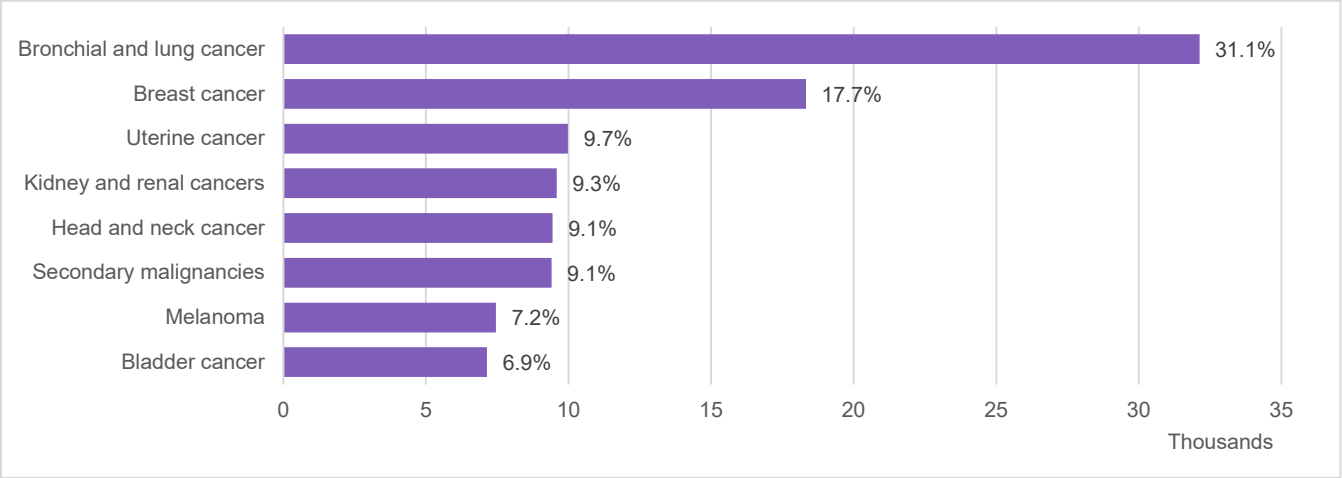
Melanoma and kidney/renal cancers demonstrated a more distributed mix across PD-1 agents, consistent with greater therapeutic competition and flexibility in treatment selection, whereas breast and head and neck cancer are largely driven by pembrolizumab. Uterine cancer also exhibited a concentrated pattern with a notable contribution from dostarlimab, consistent with its more disease-anchored role. Distinct anchoring patterns were similarly evident for PD-L1 therapies, with liver/hepatobiliary utilization driven primarily by durvalumab and atezolizumab.

Collectively, these findings indicate the breadth of use varies meaningfully by therapy and disease state, with broader integration observed among earlier-approved PD-1 therapies and more concentrated utilization among newer agents. These observations motivated deeper evaluation by therapy and by cancer type in the sections that follow.

Results by therapy

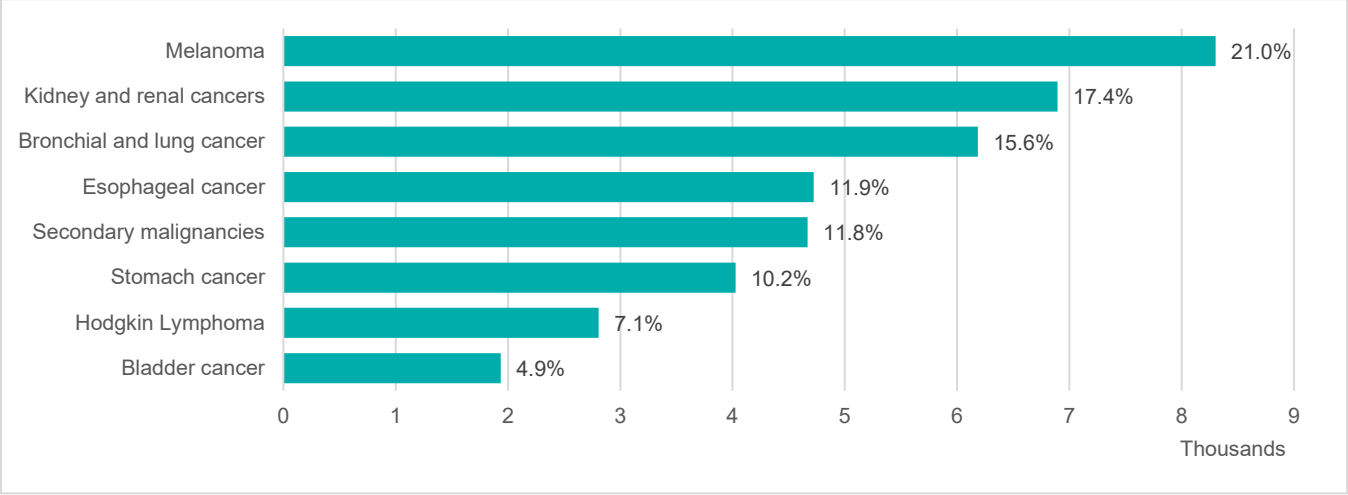
Pembrolizumab utilization was distributed across several high-volume cancer types, with bronchial and lung cancer accounting for 31.1% of pembrolizumab infusion encounters and breast cancer accounting for 17.7% (Figure 7). Remaining utilization was spread across uterine cancer (9.7%), kidney and renal cancers (9.3%), head and neck cancer (9.1%), secondary malignancies (9.1%), melanoma (7.2%), and bladder cancer (6.9%). This distribution reflects broad integration across multiple malignancies rather than reliance on a single disease state, consistent with pembrolizumab's expansive FDA footprint and sustained role as the dominant PD-1 therapy in real-world practice.

Figure 7. Pembrolizumab utilization by cancer type



Nivolumab demonstrated a utilization pattern which is also evenly distributed across several malignancies. Melanoma represented 21.0% of nivolumab infusion encounters, followed by kidney and renal cancers (17.4%), bronchial and lung cancer (15.6%), esophageal cancer (11.9%), secondary malignancies (11.8%), stomach cancer (10.2%), and Hodgkin lymphoma (7.1%), and bladder cancer accounting for 4.9% (Figure 8). Compared with pembrolizumab, nivolumab demonstrates a more balanced presence across melanoma, renal, lung, and several gastrointestinal malignancies, aligning with its established use across multiple mature disease-state markets.

Figure 8. Nivolumab utilization by cancer type



Discussion and implications

These findings suggest that the practical market for PD-1 and PD-L1 therapies is defined less by class membership and more by disease-specific clinical context. Although approvals have created extensive label overlap, real-world use reflects guideline and pathway positioning as well as established prescribing norms that determine which agents function as default choices versus niche options. In this encounter-based analysis, competitive dynamics were highly disease-dependent even in settings with substantial FDA indication overlap. As a result, broad assumptions of interchangeability may overestimate the degree of actionable competition available to health systems.

From an operational and strategic standpoint, utilization patterns imply two distinct management profiles. First, portfolio backbone therapies – those integrated across multiple tumor types – drive systemwide impact and are best addressed through enterprise approaches such as pathway alignment, utilization governance, and site-of-care optimization. Second, disease-anchored therapies function more like indication-specific markets; their performance and budget impact are disproportionately influenced by guideline updates, emerging competitors, and shifts in clinical practice within narrow patient populations. For these agents, targeted disease-state strategies may be more effective than class-wide approaches.

Importantly, regulatory footprint alone is insufficient to anticipate real-world leverage. Some therapies with multiple approved indications remained concentrated in limited use settings, whereas established agents demonstrate broader integration across malignancies. This gap between approval breadth and observed adoption underscores the value of utilization-based evidence when informing contracting assumptions, forecasting, and pathway updates. It also helps differentiate where therapeutic competition is likely to be meaningful versus largely theoretical, supporting disease-by-disease decision-making rather than blanket class strategies.

The practical market for PD-1 and PD-L1 therapies is defined less by class membership and more by disease-specific clinical context.

Overall, these results reinforce that utilization-informed planning can better align clinical pathways with operational and contracting strategy. For clinical pharmacy leaders, this framework can support prioritization of pathway standardization and governance in the disease states driving the greatest volume and variation. For contracting stakeholders, differentiating enterprise backbone therapies from disease-anchored therapies may help set realistic expectations for leverage, risk, and value in an increasingly complex immuno-oncology landscape.

Conclusion

This analysis provides a real-world, disease-state–based view of PD-1 and PD-L1 utilization across U.S. health systems, addressing a gap in the oncology literature. Despite overlapping FDA indications, most agents remained anchored to one or a limited number of disease states, and approval footprint did not reliably predict breadth of adoption. Meaningful multi-agent utilization was confined to a small number of malignancies. Together, these findings support disease-specific, utilization-informed strategies for pathway alignment and contracting rather than class-wide assumptions of interchangeability.

Limitations

This analysis has several limitations. Utilization was assessed using claims-based attribution to primary disease state and did not account for line of therapy, disease stage, or clinical outcomes. Findings reflect practice patterns within academic and integrated health systems represented in the Vizient Clinical Data Base and may not be generalizable to all care settings. Nevertheless, the analysis provides a comprehensive, real-world view of PD-1 and PD-L1 utilization across malignancies that is largely absent from existing literature.

1. Veluswamy R, Hirsch FR, Taioli E, Wisnivesky J, Strauss R, Harrough D, Tang B, Barnes G. Real-world longitudinal practice patterns in the use of PD-1 and PD-L1 inhibitors as first-line therapy in patients with non-small cell lung cancer in the United States. Cancer Med. 2022 Nov;11(22):4265-4272. doi: 10.1002/cam4.4785. Epub 2022 May 2. PMID: 35499294.

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