2025 in Oncology Therapeutics:
Targeted Agents, ADCs, and the Cost-of-Care Implications

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In 2025, oncology again led FDA therapeutic-area activity, underscoring why oncology remains a primary driver of health plan specialty spend and operational complexity. There were 54 oncology-related FDA actions across the year, spanning not only new approvals but also supplemental indications, conversions, and formulation/biosimilar events—each of which can influence utilization patterns and downstream total cost of care.
From a "new drug" perspective, FDA/CDER reported 46 new drugs approved in 2025, and 16 (35%) were oncology agents that were novel-to-market therapeutic products and select novel formulations.

While small molecules predominated—particularly biomarker-defined targeted agents—the modality mix also included two antibody–drug conjugates (ADCs), one BCMA×CD3 bispecific T-cell engager for multiple myeloma. There were 14 new indications for immune checkpoint inhibitor (ICI) drugs, three of which were for pembrolizumab (Keytruda) specifically. And there was also approval in September 2025 (earlier than expected) of the subcutaneous-enabling pembrolizumab formulation (pembrolizumab and berahyaluronidase alfa-pmph; Keytruda QLEX)

There is continued acceleration of biomarker-defined solid tumor care, where therapy selection is tightly coupled to testing strategy, specimen adequacy, and line-of-therapy decisions. Non–small cell lung cancer (NSCLC) is the most concentrated example, with multiple new targeted entrants keyed to ROS1, EGFR exon 20, HER2 activating mutations, and high c-Met protein overexpression. Breast cancer also features prominently, including an ESR1-mutated ER+ / HER2− targeted therapy and an ADC for HR+ / HER2− disease. This is not merely a drug-management issue; it is a molecular diagnostics management issue. Effective utilization management (UM) is essential in medical oncology treatment and genetic testing and requires increasing sophistication to embed biomarker gating and line-of-therapy criteria directly into prior authorization to reduce off-label drift and also ensure that testing (tissue and/or ctDNA) is appropriately aligned with treatment intent.

Finally, drug spend will continue to skew toward infused/clinic-administered specialty therapies (ADCs, bispecifics, immune checkpoint inhibitors and other biologics). The fact that there are now seven systemic anti-cancer therapy biologics with subcutaneous delivery options may shift some aspects of care delivery and workflow mechanics for providers, but this should not be assumed to automatically reduce gross drug spend.