Utilization Management in Breast Cancer and Hepatocellular Carcinoma

Executive Summary

Utilization management (UM) refers to a variety of practices that health plans and pharmacy benefit managers employ to confirm the use of specific drugs or services aligns with the payer's policy. Plans can use UM to shift utilization between therapeutically equivalent products to ensure that a prescribed drug is medically necessary, or to limit utilization of high-priced, specialty medications. UM use in oncology may have unintended consequences to patient care, such as delaying patient access to medication or increased administrative burden for the patient and provider.

Prior to 2019, Medicare Advantage Prescription Drug (MA-PD) plans were only allowed to use step therapy (ST) for provider-administered drugs (i.e., drugs available via the medical benefit) if the local Medicare Administrative Contractor had a local coverage determination requiring ST. Starting in 2019, MA-PD plans were allowed to apply ST to provider-administered drugs for patients initiating treatment, which may require patients to step through another provider-administered (i.e., medical benefit) drug, or step through a self-administered drug available via the pharmacy benefit.

Avalere conducted an analysis to understand the extent to which ST restrictions exist in MA for a subset of oncology drugs for breast cancer and hepatocellular carcinoma (HCC), a form of liver cancer. For breast cancer, Avalere reviewed the extent to which MA-PD plans require ST among provider-administered innovator and biosimilar products. For HCC, Avalere reviewed the extent to which MA-PD plans require ST through one brand drug, whether provider- or self-administered, to receive another brand drug.

Apart from biosimilars Kanjinti and Trazimera, most analyzed breast cancer drugs require ST in MA (70-95% of the time); most plans increased their use of step therapy from 2023 to 2024, particularly for innovator products Herceptin and Herceptin Hylecta. Fewer than 20% of plans required step therapy for Kanjinti or Trazimera in both 2023 and 2024.

Five of the HCC products analyzed are innovator biologic products (provider-administered) and two are oral products (self-administered). Under the medical benefit, plans did not require ST for Imfinzi or Tecentriq in 2023 or 2024. Keytruda, Opdivo, and Yervoy have ST approximately 30% of the time in 2024. Among the drugs analyzed, ST is most often required for Avastin, at 71% of the time in 2024. Avastin is the only product, of the drugs analyzed, that has a double ST requirement, which is present about 9% of the time.

Introduction

Background

Utilization management (UM) refers to a variety of practices that health plans and pharmacy benefit managers employ to confirm the use of specific drugs or services aligns with the payer's policy. Plans can use UM to shift utilization between therapeutically equivalent products to ensure that a prescribed drug is medically necessary, or to limit utilization of high-priced, specialty medications.

UM can be divided into two categories: step therapy (ST), and prior authorization (PA). ST requires a patient to try a lower cost prescription drug that treats a given condition before "stepping up" to a similar acting, but higher cost drug. Other names for step therapy are "step protocol" and "fail first" requirements. PA is a process that requires the prescriber to receive pre-approval for prescribing a particular drug in order for that medication to qualify for coverage under the terms of the benefit plan.[1] Drug coverage parameters are determined by the setting where drugs are used. Drugs administered by a provider, including in an office setting or hospital outpatient department, are generally covered under the medical benefit, while drugs that are self-administered are generally covered under the pharmacy benefit. For beneficiaries enrolled in traditional Medicare, most provider-administered drugs are covered through Part B and most self-administered drugs are covered through Part D.

Medicare beneficiaries have the option of receiving benefits from private plans through Medicare Advantage (MA) rather than from the traditional Medicare program (i.e., Medicare Part A and Part B). Medicare Advantage Prescription Drug plans (MA-PDs) include Part D drug coverage within the MA plan, instead of the beneficiary enrolling in a standalone Part D Prescription Drug Plan (PDP). Prior to 2019, MA-PDs were only allowed to use ST for provider-administered drugs (i.e., drugs available via the medical benefit) if the local Medicare Administrative Contractor had a local coverage determination requiring ST. Starting in 2019, MA-PD plans were allowed to apply ST to provider-administered drugs for patients initiating treatment, which may require patients to step through another provider-administered drug, or step through a self-administered drug available via the pharmacy benefit.

As a result of this policy change, there may be more hurdles for patients to access the drug originally prescribed. While beneficiaries are rarely required to get PA under traditional Medicare Part B, almost all MA plans (99%) required PA for some services in 2023, including the use of medical benefit, provider-administered, drugs.[2] As a result, product access considerations in MA are now more like those in the commercial market. In recent rulemaking, the Centers for Medicare and Medicaid Services (CMS) addressed questions around UM requirements of MA organizations as well as concerns around the use of artificial intelligence (AI) in making coverage determinations. In a February 2024 memo, CMS noted that MA organizations may only use an algorithm or software tool in a way that is consistent with publicly available

[1] Academy of Managed Care Pharmacy. "Prior Authorization" (2019); Available here.
[2] KFF. Medicare Advantage in 2023: Premiums, OOP Limits, Cost Sharing, Supplemental Benefits, Prior Authorization and Star Ratings (2023); Available here.

coverage criteria, and that AI cannot be used to shift coverage criteria over time.[3] In addition, CMS required that starting January 1, 2024, MA plans must establish a Utilization Management Committee to annually review the MA organization's UM policies and ensure consistency with traditional Medicare's national and local coverage decisions and guidelines.[4]

Impact of UM on Beneficiary Access

However, UM use in MA plans may make it challenging for beneficiaries to access needed medications.[5] It is essential that beneficiaries with a serious condition such as cancer can access the right medication as soon as possible to avoid preventable progression of disease. Patient out-of-pocket (OOP) costs incurred due to UM are also a concern. Patients may incur additional OOP costs when required to step through a cross-benefit product (i.e., stepping through a pharmacy benefit product to access a medical benefit product, or vice versa). The use of UM in MA has come under increased scrutiny in recent years, with some stakeholders asserting that MA-PD plans' use of UM can inappropriately restrict beneficiary access to care.[6]

Protected Classes in Medicare Pharmacy Benefit

All Medicare pharmacy benefit (i.e., Part D) formularies must include drug classes covering most disease states, with a minimum of two chemically distinct drugs in each class. To ensure beneficiaries with certain health issues receive necessary treatment, federal law requires that all PDPs and MA-PDs cover "all or substantially all" drugs in each of six protected classes (i.e., anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants) on their formularies.[7] The purpose of this policy is to ensure beneficiaries with certain conditions receive the treatment they require without fear of their plan having no coverage for their condition.

As a result of this policy, self-administered oncology drugs are typically covered under Part D but may require PA or ST. MA-PDs may still require patients to step through another oncology product before receiving their intended treatment. Depending on the indication, there may be alternate treatment options that are provider- or self-administered.

Project Overview

ACS CAN sought to assess UM practices among MA-PD plans for certain oncology drugs. To that end, Avalere reviewed UM policies for Plan Years 2023 and 2024 for select drugs with one of two cancer indications: breast cancer and hepatocellular carcinoma (HCC). For breast cancer, Avalere reviewed the extent to which MA-PD plans require ST among one innovator provider-administered biologic (Herceptin) and its biosimilar products. For HCC, Avalere

[3] CMS. "Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)" February 6, 2024. Available here.
[4] CMS. Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly/ 2023. Available here.
[5] Office of Inspector General. "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care". 2022. Available here.
[6] United States Senate Committee on Homeland Security and Government Affairs. Examining Health Care Denials and Delays in Medicare Advantage. May 17, 2023. Available here.
[7] Social Security Act §1860D-4. Available here.

reviewed the extent to which MA-PD plans require ST through one brand drug, whether provider- or self-administered, to receive another brand drug. Avalere partnered with Clarivate™ to obtain formulary and restrictions data and pharmacy lives covered across MA-PD plans.[8]

Methodology

Avalere evaluated 2023 and 2024 medical and pharmacy UM policies for two cancer indications which included the following drugs:

Breast Cancer	Hepatocellular Carcinoma	
Medical Benefit	**Medical Benefit**	**Pharmacy Benefit**
Herceptin (Innovator Biologic)	Avastin (Reference Biologic)	Lenvima (Branded Oral Drug)
Herceptin Hylecta (Innovator Biologic)	Imfinzi (Reference Biologic)	Nexavar (Branded Oral Drug)
Herzuma (Biosimilar of Herceptin)	Keytruda (Reference Biologic)	Sorafenib (Nexavar Generic)
Kanjinti (Biosimilar of Herceptin)	Opdivo (Reference Biologic)	
Ogivri (Biosimilar of Herceptin)	Tecentriq (Reference Biologic)	
Ontruzant (Biosimilar of Herceptin)	Yervoy (Reference Biologic)	
Trazimera (Biosimilar of Herceptin)		

Formulary coverage and restrictions analyses were based on coverage of over 200 MA-PD plans (representing approximately 78% of MA lives) and include both the medical and pharmacy benefits. Formulary data were analyzed at static points in September 2023 and January 2024.[9]

Medical and pharmacy coverage and utilization management results are weighted based on total covered lives. Preferred drug percentages may add up to more than 100% of covered lives as plans may list more than one drug as preferred. Avalere also conducted subgroup analyses by plan sponsor size (large vs. small). Large plan sponsors had more than 100,000 enrollees across their plans; small plan sponsors had 100,000 or fewer enrollees. In this report, only overall results and results by plan sponsor size are presented.

Results

MA-PD Plan Breast Cancer Drug Coverage and ST Restrictions Results: Examining Coverage of Medical Benefit Innovator Products Versus Biosimilar Products

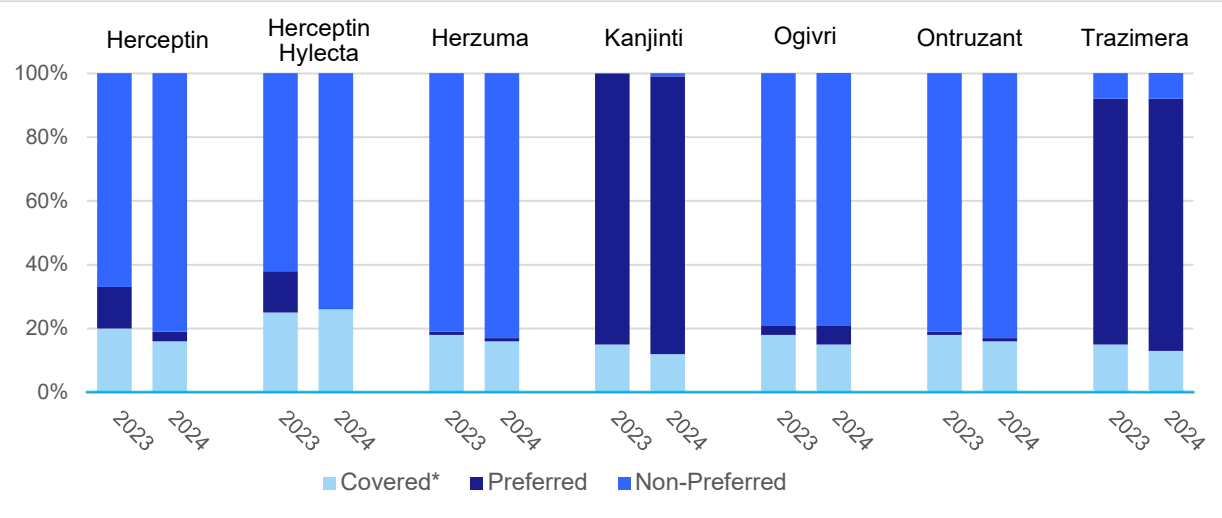
The breast cancer drugs analyzed were innovator biologic Herceptin and five biosimilars of Herceptin (Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera), and Herceptin Hylecta, a version of Herceptin that is administered on a different schedule. The seven breast cancer drugs analyzed were covered 100% of the time by MA-PD plans in the medical benefit. Plan coverage and

[8] Certain data included herein are derived from the Fingertip Analytics© of Clarivate. All rights reserved.
[9] Plans can and do change their formularies over the course of the plan year. New plan data in 2023 may not be reflected in the data due to slow implementation of UM.

tiering for breast cancer drugs were classified as covered, preferred (covered), or non-preferred (covered).

Biosimilars Kanjinti and Trazimera were most often listed as preferred drugs in 2023 and 2024 (Figure 1). Innovator products Herceptin and Herceptin Hylecta each had preferred status in 13% of plans in 2023, which decreased to 3% and 0% preferred status, respectively, in 2024. Innovators Herceptin and Herceptin Hylecta, and biosimilars Herzuma, Ogivri, and Ontruzant were listed as non-preferred covered drugs for the majority of plan lives in 2023 and 2024.

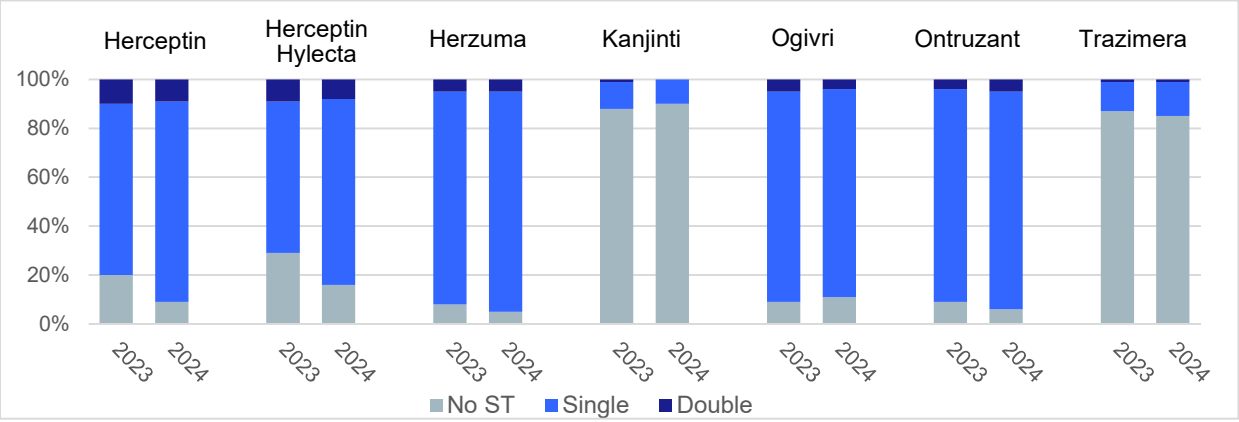
Figure 1. Breast Cancer Medical Benefit Coverage by Drug Across all MA-PD Plans, 2023 to 2024



* The "covered" category represents plan lives that do not indicate a preferred or non-preferred status in medical coverage data.

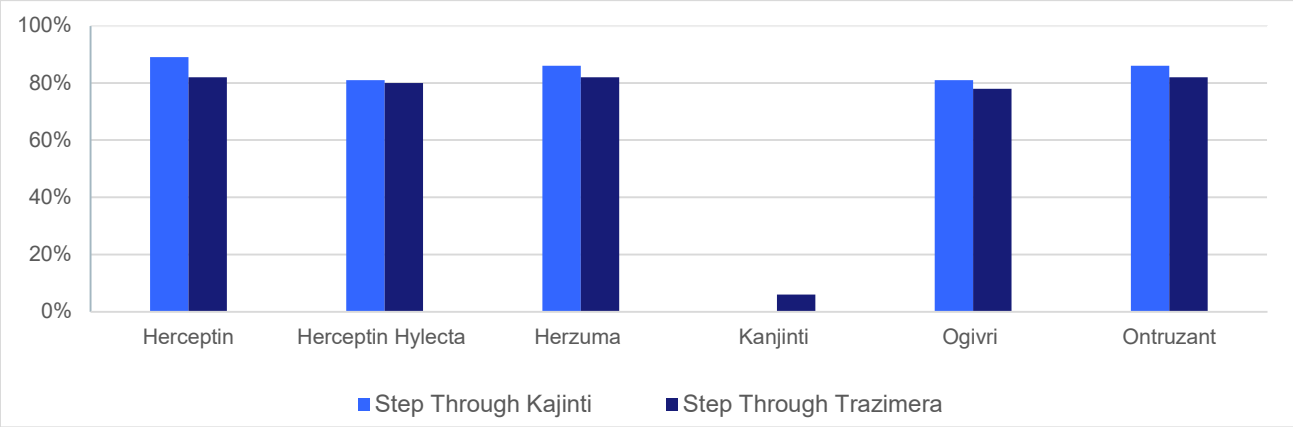
Except for biosimilars Kanjinti and Trazimera, most innovator and biosimilar products analyzed require ST in MA-PDs (approximately 70-95% of the time); most plans increased their use of ST from 2023 to 2024, particularly for innovator products Herceptin and Herceptin Hylecta (Figure 2). When ST is present, the vast majority of plans require beneficiaries to step through one or two drugs. Triple or quadruple step requirements were present, on average, less than 1% of the time for any analyzed drug across all MA-PD plans and are excluded from Figure 2.

Figure 2. Herceptin and Biosimilar ST Requirements, MA-PD Medical Benefit, 2023 to 2024



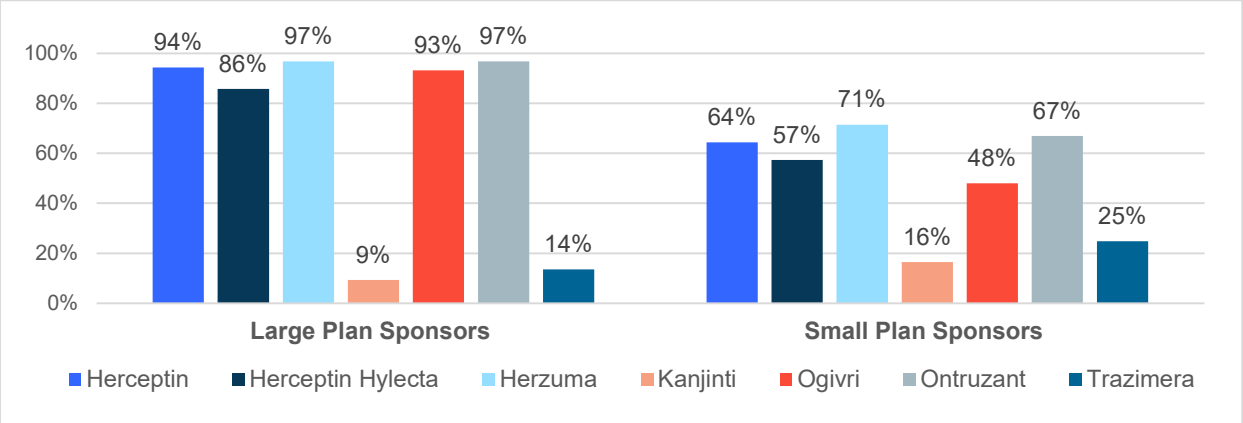
MA-PD plans that cover Ontruzant require enrollees to step through Trazimera 82% of the time and Kanjinti 86% of the time in 2024. Biosimilars Kanjinti and Trazimera are often listed as preferred drugs in the medical benefit and are the most common drugs that patients were required to step through for innovator products Herceptin and Herceptin Hylecta, and biosimilars Herzuma, Ogivri, and Ontruzant (Figure 3).

Figure 3. Herceptin and Biosimilar ST Requirements MA-PD Medical Benefit, 2024



Among covered lives, enrollees in health plans from larger plan sponsors face step therapy requirements more often to access the analyzed breast cancer therapies, except for biosimilars Kanjinti and Trazimera. Between 86% to 97% of enrollees covered by large plans sponsors were required to step through at least one of the analyzed drugs before accessing innovators Herceptin or Herceptin Hylecta, or biosimilars Herzuma, Ogivri, or Ontruzant in 2024 (Figure 4). This range among large plan sponsors is higher compared to a range of 48% to 71% of enrollees in MA-PD plans with small plan sponsors requiring step therapy to access those drugs.

Figure 4. Percent of Covered Lives with Herceptin and Biosimilar Step Therapy Requirements, Medical Benefit, by Plan Sponsor Size, 2024



MA-PD Plan HCC Drug Coverage and ST Restrictions Results: Examining Coverage of ST Involving Innovator Products Across the Medical and Pharmacy Benefits

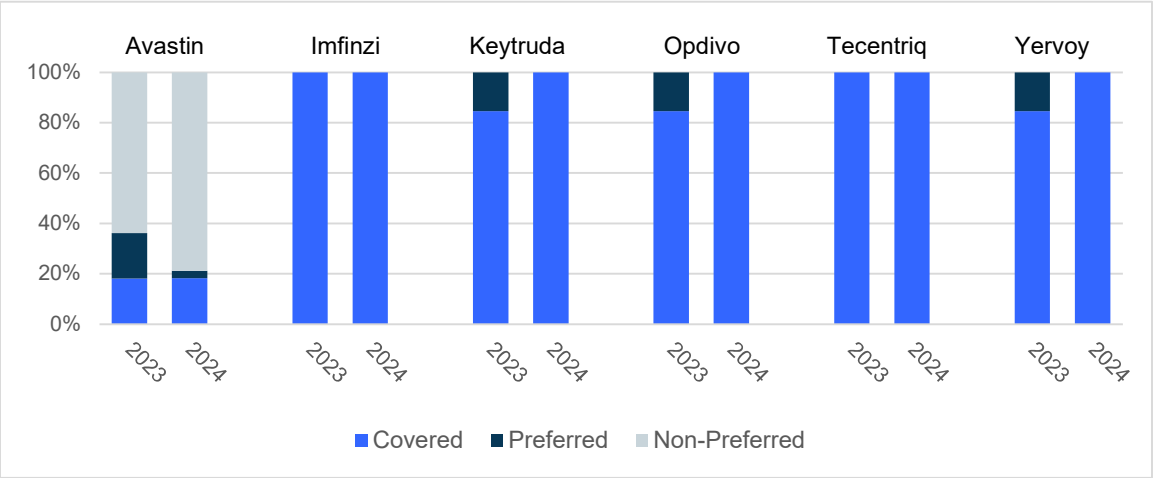
Six of the HCC products analyzed are innovator, provider-administered biologic products (Avastin, Imfinzi, Keytruda, Opdivo, Tecentriq, Yervoy) and the others are self-administered oral products (Lenvima, Nexavar, and sorafenib). The provider-administered biologics are covered under the medical benefit 100% of the time by MA-PD plans. Because antineoplastics are a protected class in the pharmacy benefit, the oral HCC drugs were covered by plans 100% of the time in the pharmacy benefit.

In the medical benefit, plan coverage and tiering for HCC drugs were classified as covered, preferred (covered), or non-preferred (covered). In the pharmacy benefit, plan coverage and tiering for HCC drugs were classified as preferred (covered) or specialty (covered).

In 2023 and 2024, MA-PD plans covered the analyzed provider-administered drugs 100% of the time (Figure 5). Of the products analyzed, Avastin was the only drug listed as non-preferred and grew in proportion of non-preferred status from 2023 to 2024. Tecentriq was listed as covered without a preferred designation by 100% of plans in both years. The remaining four provider-

administered products (Imfinzi, Keytruda, Opdivo, and Yervoy) were listed as preferred 15% of the time in 2023 but are listed as covered without a preferred designation in 2024.

Figure 5. HCC Medical Benefit Coverage by Drug Across all MA-PD Plans, 2023 to 2024

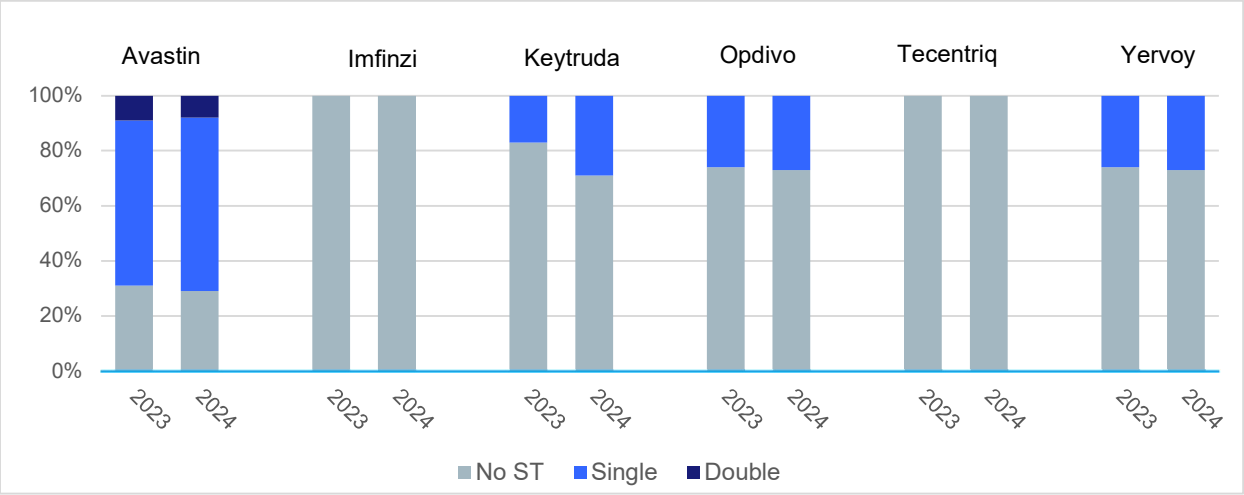


* The "covered" category represents plan lives that do not indicate the coverage status (i.e., preferred, non-preferred) in formulary coverage data.

Within the pharmacy benefit, Nexavar was covered by 22% of plans in 2023, and 15% of plans in 2024. Low coverage of Nexavar is likely due to the availability and coverage of its generic equivalent, sorafenib, which was covered by 100% of plans in 2023 and 2024. Lenvima was covered by 100% of plans in 2023 and 2024.

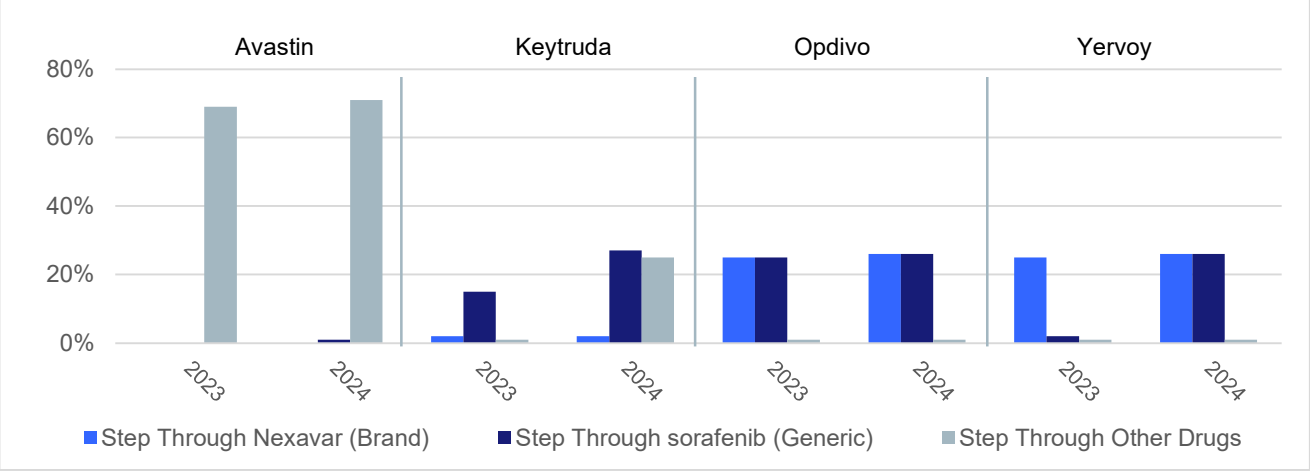
Under the medical benefit, plans did not require ST for Imfinzi or Tecentriq in 2023 or 2024. Keytruda, Opdivo, and Yervoy had a single step approximately 30% of the time in 2024, meaning beneficiaries would need to use one other drug before Keytruda, Opdivo, or Yervoy. Among the drugs analyzed, Avastin has ST requirements most often, at 71% of the time in 2024 (Figure 6). Avastin was the only product analyzed that had double step requirements, which are required by 8% of plans in 2024.

Figure 6. HCC ST Requirements, Medical Benefit, All MA-PD Plans, 2023 to 2024



For Avastin, a reference provider-administered biologic, step edits were primarily through Avastin biosimilars (grouped into "other drugs" in Figure 7). Keytruda, Opdivo, and Yervoy require a step through pharmacy-benefit drug Nexavar or its generic, sorafenib, between 26-27% of the time in 2024. The frequency of step requirements through sorafenib increased significantly for Keytruda and Yervoy from 2023 to 2024. For Keytruda, a step through another drug (specifically, "one prior therapy OR sorafenib") was required 29% of the time in 2024, up from 17% of the time in 2023.

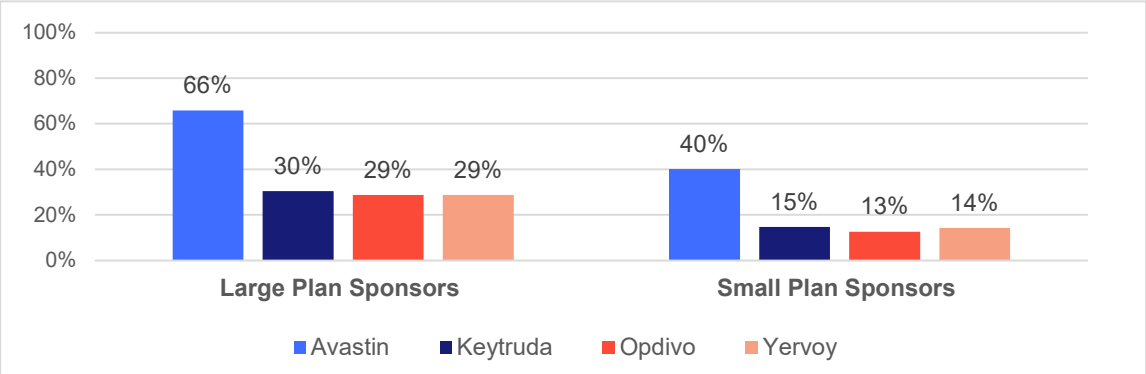
Figure 7. HCC Products Requiring a Single Step Through Sorafenib or Other Drugs, Medical Benefit, All MA-PD Plans, 2023 to 2024



Note: Imfinzi and Tecentriq had no step requirements listed and are excluded from the graph above.

Step therapy for Avastin, Keytruda, Opdivo, and Yervoy is required 29% to 66% of the time for enrollees in 2024 MA-PD plans from large plan sponsors, compared to 13% to 40% of the time for enrollees in MA-PD plans from small plan sponsors (Figure 8). Imfinzi and Tecentriq never require ST, consistent across large and small plan sponsors.

Figure 8. Percent of Covered Lives with Step Therapy Requirements, Medical Benefit, by Plan Sponsor Size, 2024



Note: Imfinzi and Tecentriq had no step requirements listed and are excluded from the graph above.

As shown in the analysis, Herceptin and its biosimilars often required ST in MA-PD plans, with the rate at which plans are applying ST increasing between 2023 and 2024. In HCC, cross-benefit steps were required for three of the drugs analyzed (Keytruda, Opdivo, and Yervoy), stepping through oral Nexavar or its generic sorafenib to access the medical benefit product around 25% of the time in 2024. No plans required a step through an analyzed medical benefit drug to get to a pharmacy benefit drug.

Conclusion

In the broader policy landscape, the Inflation Reduction Act (IRA) will substantially shift liability for all stakeholders, including increased costs in the pharmacy benefit for MA-PD plans due to IRA provisions including the $2,000 beneficiary OOP cap, eliminating the coverage gap phase of the Part D benefit, and an increase in MA-PD plan liability for costs in the catastrophic phase from 15% pre-IRA to 60% in 2025 and beyond.

As more beneficiaries enroll in MA-PDs, plan choices on benefit design and UM will impact a larger share of beneficiaries. There is potential for additional OOP and overall costs if beneficiaries must step through multiple drugs, and a potential impact on treatment outcomes if ST delays access to the drug selected by the provider as the most likely to be effective.

MA-PDs have more tools available to both offset higher liability under the IRA and mitigate the policy changes' effects on bids and premiums. Because MA-PDs are responsible for both medical and pharmacy benefits, MA-PDs can manage spending across benefits and leverage medical spending offsets. In addition, MA-PDs can offer narrower provider networks than traditional Medicare and can employ cross-benefit ST to further manage drug costs.

Cross-benefit ST may have cost-sharing implications for beneficiaries compared to within-pharmacy benefit or within-medical benefit ST. For example, a patient may be required to meet separate deductibles in the pharmacy and medical benefit categories, and thus may be subject to higher cost sharing due to cross-benefit ST.

As new treatments come to market and drug prices continue to increase, plans must balance increasing costs of care with maintaining appropriate and efficient access to medications. This balance is particularly important in oncology, where getting the right treatment at the right time is essential. Stakeholders and policymakers should closely monitor the UM practices implemented by MA-PD plans to ensure they are appropriate. Additional criteria and parameters for MA-PD plan UM may be warranted to ensure appropriate application of policies.

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