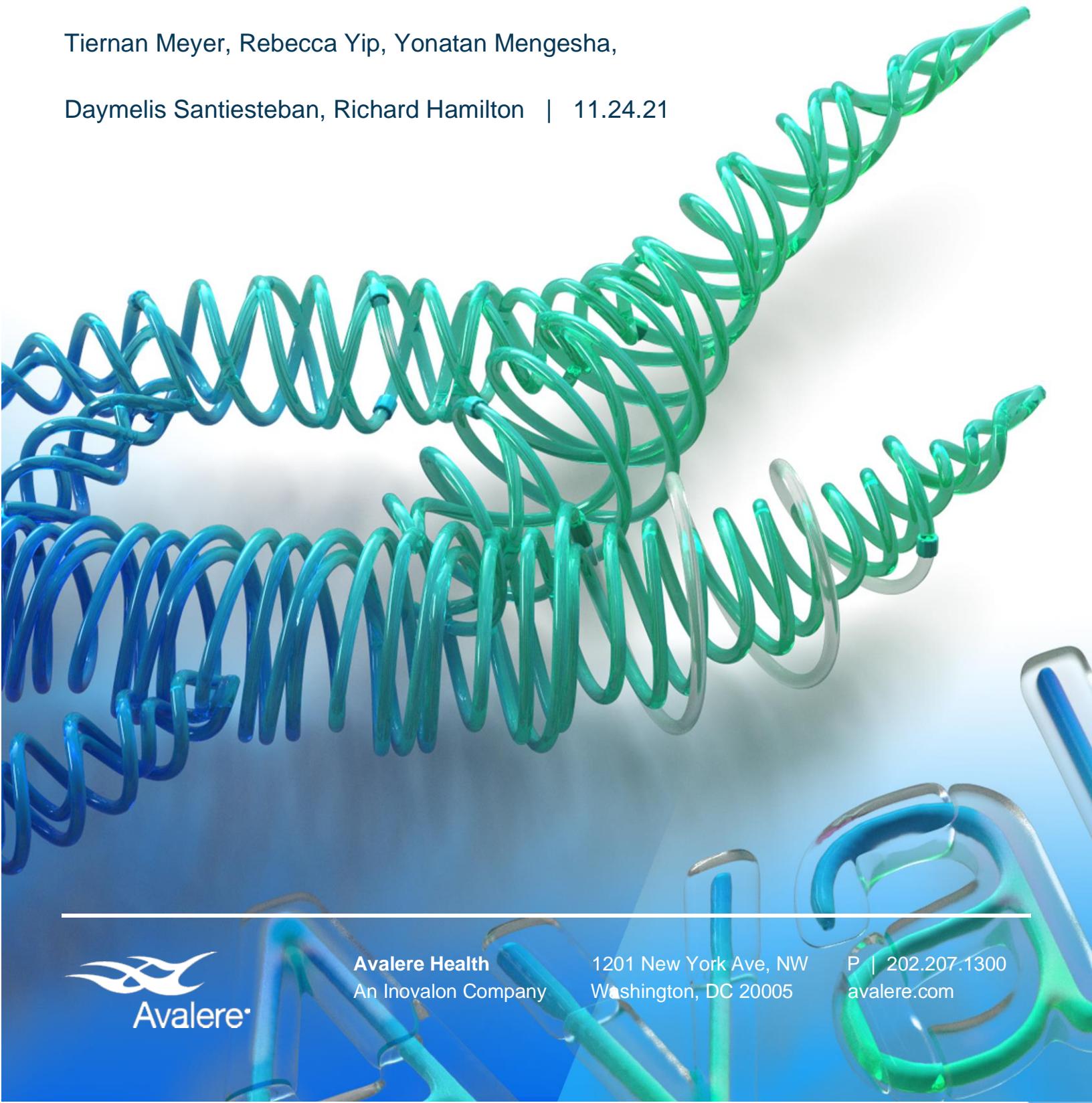


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# Utilization Management Trends in the Commercial Market, 2014–2020

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# Executive Summary

Health insurance plans use utilization management (UM) to manage spending on prescription drugs, address safety concerns, and promote quality care. Many factors influence drug coverage and the use of UM, including drugs' clinical profiles, therapeutic competition, costs, and rebate dynamics. As healthcare costs continue to increase across the spectrum of covered services, insurers may increasingly manage access to new drugs as a strategy to reduce spending.

PhRMA commissioned Avalere to examine the prevalence of UM over time in the commercial market, which includes employer-sponsored health plans and the health insurance exchanges. For the purposes of this study, drugs subject to UM are those covered on a plan's formulary with prior authorization (PA) or step therapy (ST) requirements.

This paper focuses on coverage policies of single-source brand drugs for 12 therapeutic areas (TAs) from 2014 to 2020. This sample represents Food and Drug Administration (FDA)-approved brand medicines produced by only 1 manufacturer (single source) on the market during the study period. More information on our method is included in the *Detailed Methodology* section.

Avalere's findings provide a view into the evolution of how insurers approach coverage for single-source brand drugs. Because of this focus, the list of drugs included each year changed as new drugs entered the market and some brands lost their single-source status when generic equivalents became available. Therefore, findings should not be construed as an analysis of coverage policies for a specific static list of drugs over time.

Therapeutic Areas Studied		
Cancer <ul style="list-style-type: none"><li>● Chronic Myeloid Leukemia (CML)</li><li>● Multiple Myeloma (MM)</li></ul>	Autoimmune Disorders <ul style="list-style-type: none"><li>● Multiple Sclerosis (MS)</li><li>● Psoriasis</li><li>● Rheumatoid Arthritis (RA)</li></ul>	Other Chronic Conditions <ul style="list-style-type: none"><li>● Asthma/Allergy</li><li>● Corticosteroids (AAC)</li><li>● Cardiovascular (CV) Agents<sup>1</sup></li><li>● Diabetes Glucagon-like Peptide-1 (GLP1) Agonist</li><li>● Diabetes Sodium-glucose Cotransporter-2 (SGLT2) Inhibitor</li><li>● HIV</li></ul>
Mental Health <ul style="list-style-type: none"><li>● Atypical Antipsychotics (AA)</li><li>● Depression</li></ul>		

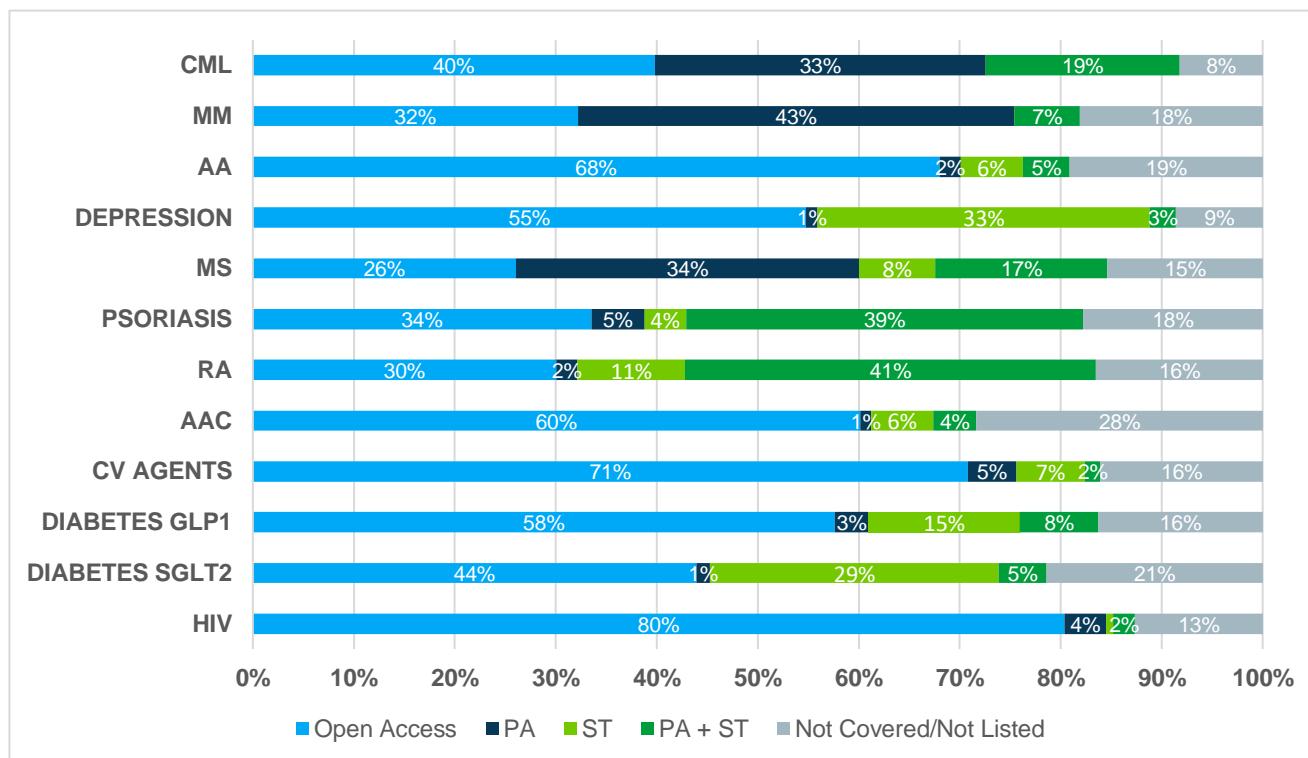
<sup>1</sup> Sample does not include data for cardiovascular (CV) agents in 2014 and 2015; all outputs showing change over the study period reflect change from 2016-2020 for this TA.

## Highlights Include:

- From 2014 to 2020, use of UM in the commercial market increased for all studied TAs.
- The share of medicines covered without UM (i.e., open access) decreased for all included TAs, except depression and psoriasis, over the study period.
- In 2020, PA was used more often for MM, CML, and autoimmune disorders than for the other TAs studied.
- ST was used most frequently for medicines to treat RA and psoriasis.
- Within the commercial market, exchange plans impose UM more often than employer plans.

Many factors influence drug coverage and the use of UM by commercial plans. As healthcare costs continue to increase and more innovative and specialized therapies enter the market, insurers and employer plan sponsors may be pursuing more aggressive management of access to new drugs as a strategy to manage spending. As a result, providers treating patients with serious chronic conditions may experience increased administrative burdens associated with UM processes, and patients may experience delays in accessing prescribed medicines.

**Figure 1. Coverage and UM Status for Single-Source Brand Drugs, by TA,<sup>2</sup> 2020**



<sup>2</sup> CML: Chronic Myeloid Leukemia, MM: Multiple Myeloma, AA: Atypical Antipsychotics, MS: Multiple Sclerosis, RA: Rheumatoid Arthritis, AAC: Asthma/Allergy Corticosteroids, CV: Cardiovascular, GLP1: Glucagon-like peptide-1, SGLT2: Sodium-glucose Cotransporter-2

# Overview of Utilization Management

Health plans use a variety of UM techniques to guide patients to lower-cost drugs or to prevent safety issues. Insurers have Pharmacy and Therapeutics committees that review medical evidence and make recommendations about which drugs should be covered, tier placement for covered drugs, and whether covered drugs should be subject to UM. UM policies typically account for both clinical and cost considerations.

The most common types of UM are PA and ST.

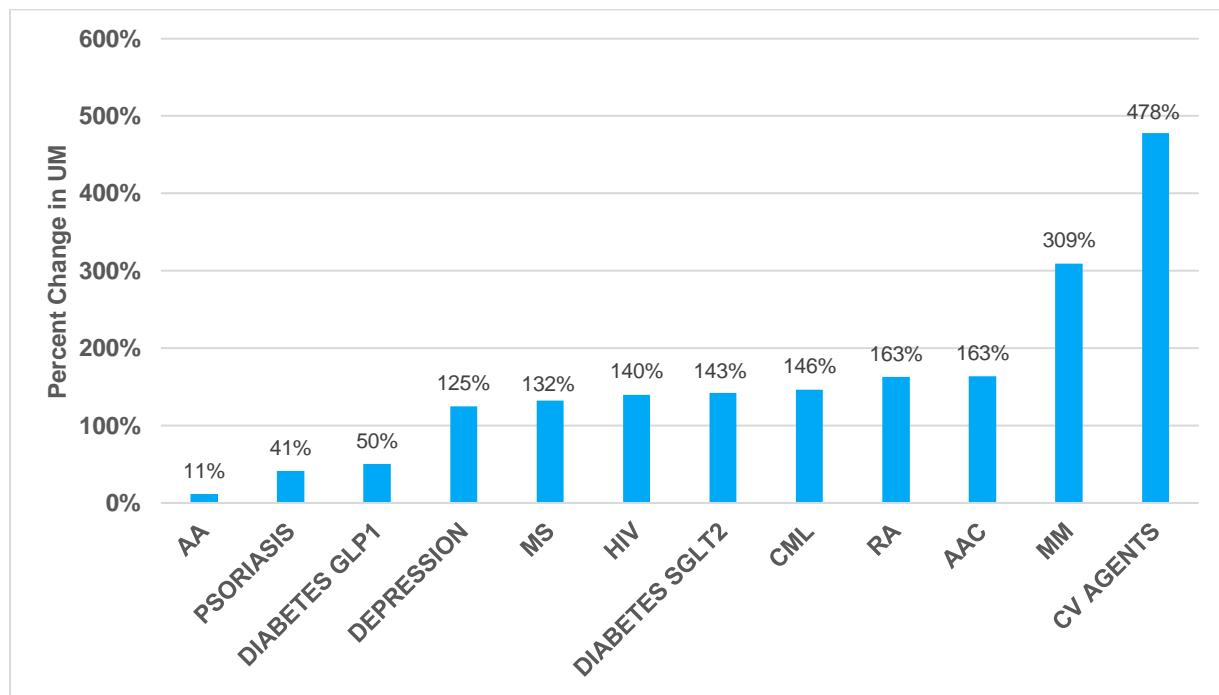
- PA requires patients to obtain approval from the health plan before a medication is covered. Typically, the prescribing provider must submit a PA request on behalf of their patient to the patient's insurance company. The insurer usually requires the patient's clinician to provide specified information in the PA request, such as proof of diagnosis, information on diagnostics performed, or information on other treatments that have already been tried. The PA process can be lengthy, with several stages of back-and-forth between the insurer and provider before the insurer approves or rejects the PA request.
- ST requires patients to try 1 or more alternative medications to treat their condition before the plan covers the drug originally prescribed by the provider. The alternative medications are typically lower-cost drugs or drugs deemed more clinically appropriate by the plan. A drug with ST may be covered only if a preferred drug is not effective (i.e., the patient experiences no clinically meaningful improvements) or if it causes adverse effects.

Throughout this paper, all references to UM include only PA and ST. In some cases, plans apply both PA and ST to the same drug. Some plans use other UM techniques, such as limits on the quantity of a drug that will be covered for a specified period. However, other techniques were not evaluated in this study. Drugs that are not subject to PA or ST but are covered on the plan formulary are referred to as "open access." Findings apply only to single-source brand drugs within the 12 TAs included in the study.

# Study Findings

**(1) In 2020, commercially insured patients who relied on single-source brand drugs were more likely to face UM restrictions than they would have in 2014 across all TAs studied.** Between 2014 and 2020, use of UM increased for single-source brand drugs across all 12 TAs included in the study. As a result, doctors and other healthcare providers are increasingly likely to face administrative burdens to ensure their patients can access these prescribed treatments.

**Figure 2. Change in Use of UM for Single-Source Brand Drugs in the Commercial Market by TA,<sup>3</sup> 2014-2020**



In 2020, UM was most prevalent for classes considered to comprise primarily “specialty medicines”—the oncology and autoimmune disorders products—and least prevalent for drugs treating mental health conditions and other chronic conditions. Of the chronic conditions, single-source HIV products had the least management, with UM applied 7% of the time. State and federal policies, such as exchange non-discrimination standards, dictate stronger regulatory oversight for HIV medications than for many other drugs, which may contribute to HIV’s lower rates of UM.

<sup>3</sup> AA: Atypical Antipsychotics, GLP1: Glucagon-like peptide-1, MS: Multiple Sclerosis, SGLT2: Sodium-glucose Cotransporter-2, CML: Chronic Myeloid Leukemia, RA: Rheumatoid Arthritis, AAC: Asthma/Allergy Corticosteroids, MM: Multiple Myeloma, CV: Cardiovascular

**Table 1. Prevalence of UM for Single-Source Brand Drugs in the Commercial Market by TA,<sup>4</sup> 2020**

TA	Use of UM	Use of PA <sup>5</sup>	Use of ST <sup>6</sup>	Open Access	Not Covered/Not Listed
MS	58.6%	51.0%	24.6%	26.1%	15.4%
RA	53.5%	42.9%	53.5%	30.0%	16.5%
CML	52.0%	52.0%	19.2%	39.8%	8.2%
MM	49.7%	49.7%	6.5%	32.2%	18.1%
Psoriasis	48.7%	44.6%	48.7%	33.5%	17.8%
Depression	36.6%	3.7%	35.5%	54.8%	8.6%
Diabetes SGLT2	34.7%	6.1%	33.3%	43.9%	21.4%
Diabetes GLP1	26.1%	11.0%	22.8%	57.6%	16.3%
CV Agents	13.1%	6.3%	13.1%	70.8%	16.1%
AA	12.9%	6.7%	10.8%	68.0%	19.1%
AAC	11.5%	5.4%	10.4%	60.1%	28.4%
HIV	7.0%	6.3%	2.8%	80.4%	12.7%

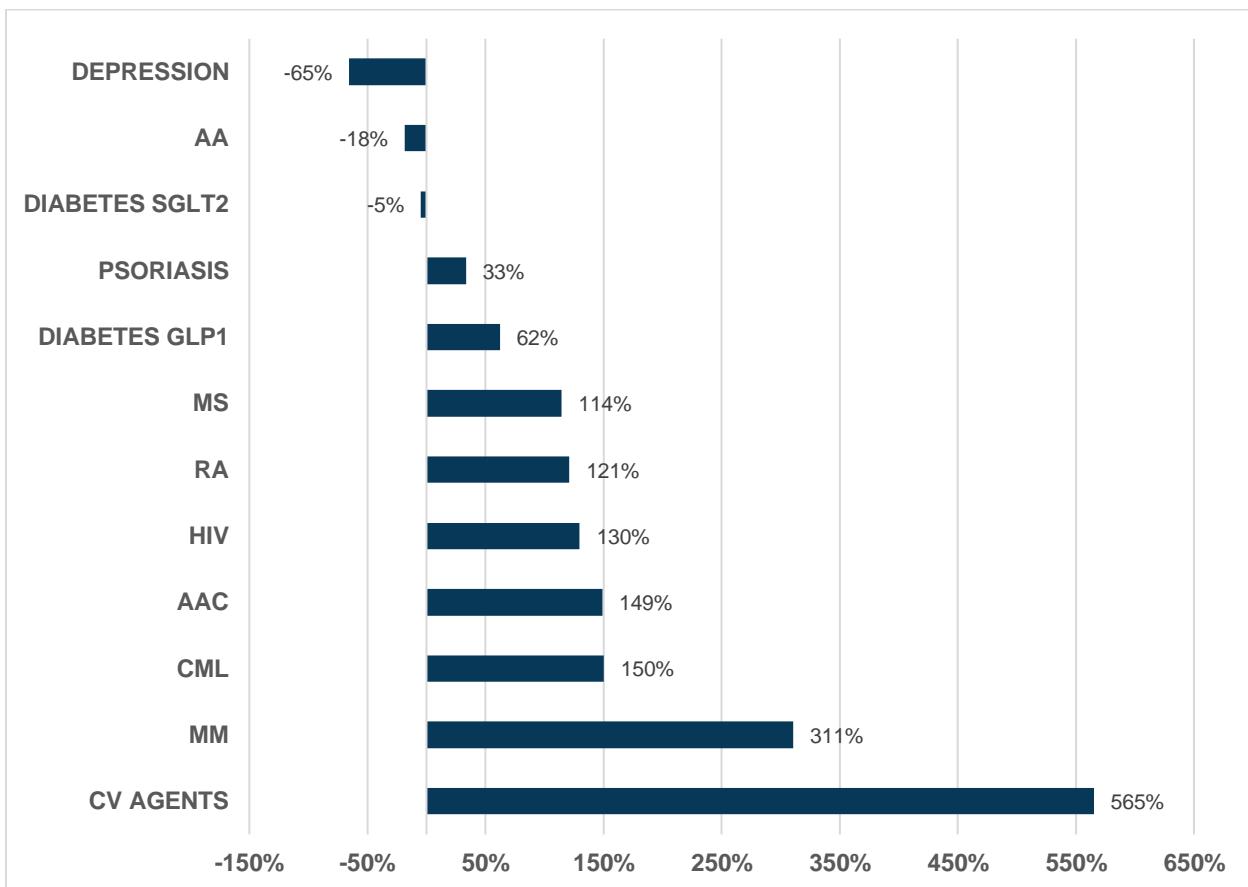
**(2) From 2014 to 2020, use of PA on commercial plan formularies for single-source drugs increased in 9 of the 12 studied TAs.** In 2020, the use of PA by disease area aligned with the overall UM trend—with the greatest use of PA for oncology and autoimmune classes and lowest use of PA for medications treating other chronic conditions. Though use of PA declined for studied antipsychotics, depression, and diabetes SGLT2 drugs, the use of ST for those TAs increased substantially during the same period.

4 MS: Multiple Sclerosis, RA: Rheumatoid Arthritis, CML: Chronic Myeloid Leukemia, MM: Multiple Myeloma, SGLT2: Sodium-glucose Cotransporter-2, GLP1: Glucagon-like peptide-1, CV: Cardiovascular, AA: Atypical Antipsychotics, AAC: Asthma/Allergy Corticosteroids

5 The PA and ST columns include any use of PA or ST (i.e., the PA column captures use of PA alone and instances where a drug requires PA and ST). Therefore, the sum of the PA and ST columns will not equal the UM column.

6 See footnote 5.

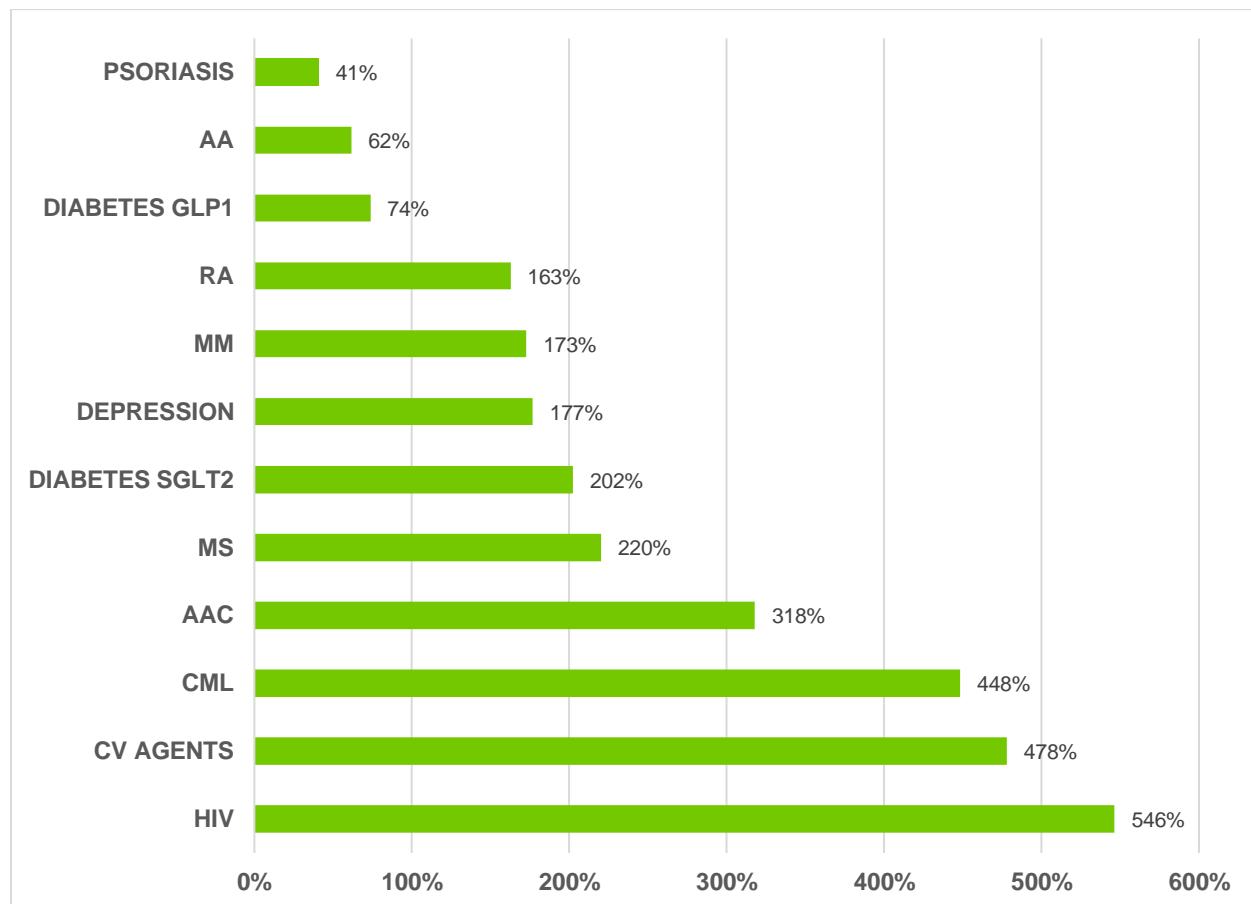
**Figure 3. Change in PA for Single-Source Brand Drugs in the Commercial Market by TA,<sup>7</sup> 2014–2020**



<sup>7</sup> AA: Atypical Antipsychotics, SGLT2: Sodium-glucose Cotransporter-2, GLP1: Glucagon-like peptide-1, MS: Multiple Sclerosis, RA: Rheumatoid Arthritis, AAC: Asthma/Allergy Corticosteroids, CML: Chronic Myeloid Leukemia, MM: Multiple Myeloma, CV: Cardiovascular

**(3) Patients faced greater use of ST in 2020 than in 2014 for single-source drugs across all studied TAs—and the margin of increase was more dramatic than for PA.** However, the large increases in use of ST (with increases of over 200% for half of TAs studied) do not necessarily reflect a high use of ST within those TAs, but rather plans' increasing use of this strategy for TAs that have historically been less managed. For example, HIV saw the greatest increase in use of ST (546.3%) but also had the lowest use of ST in 2020, with ST applied just 2.8% of the time. Conversely, the TAs with the highest use of ST (e.g., RA, psoriasis) saw less change in use of ST over time, showing these TAs have historically been more highly managed.

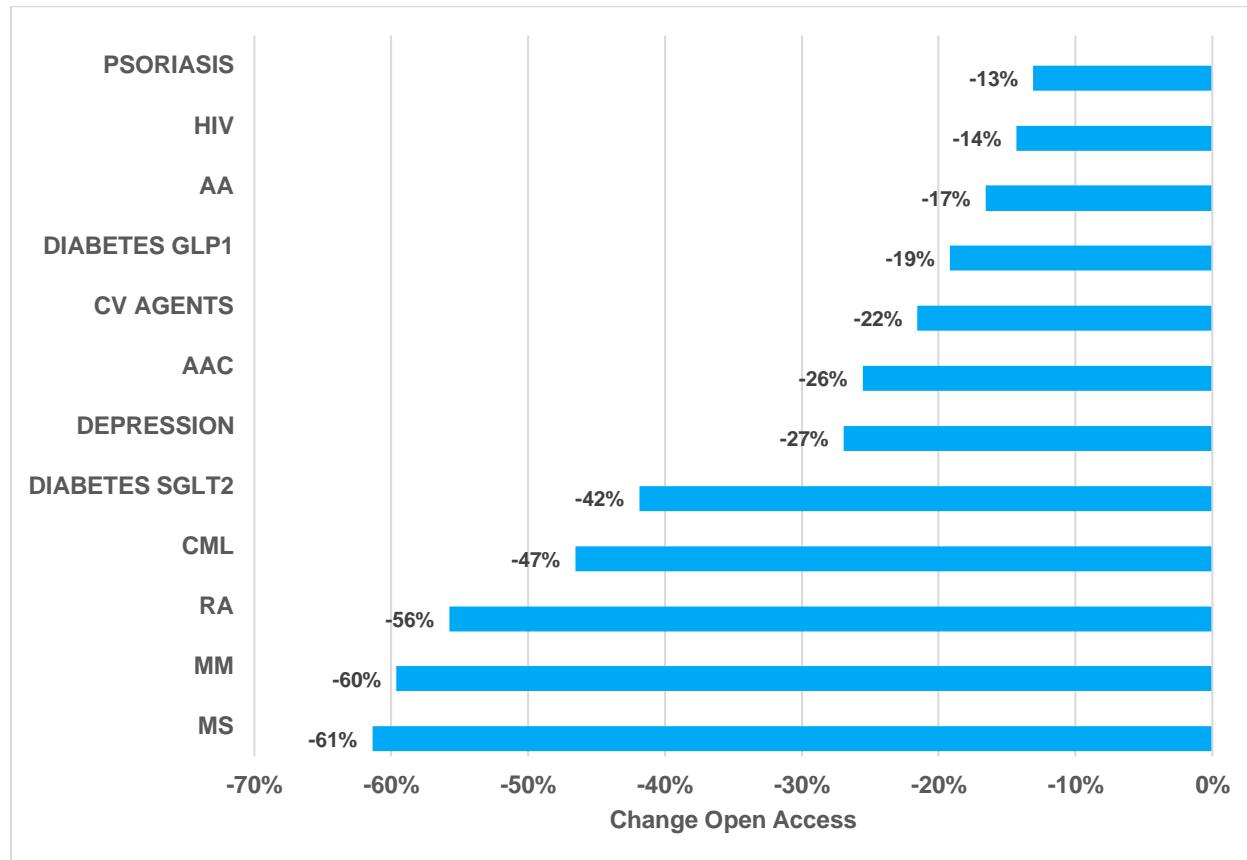
**Figure 4. Change in ST for Single-Source Brand Drugs in the Commercial Market by TA,<sup>8</sup> 2014–2020**



<sup>8</sup> AA: Atypical Antipsychotics, GLP1: Glucagon-like peptide-1, RA: Rheumatoid Arthritis, MM: Multiple Myeloma, SGLT2: Sodium-glucose Cotransporter-2, MS: Multiple Sclerosis, AAC: Asthma/Allergy Corticosteroids, CML: Chronic Myeloid Leukemia, CV: Cardiovascular

**(4) Commercially insured patients generally faced more restrictions in accessing these single-source brand drugs in 2020 than in 2014.** Coverage without UM decreased for single-source brand drugs across all TAs over the study period. Changes in the share of open access for single-source brand medicines from 2014 to 2020 ranged from a 13% reduction in coverage for psoriasis to 61% reduction in coverage for multiple sclerosis.

**Figure 5. Change in Share of Single-Source Brand Medicines Covered with Open Access in the Commercial Market, by TA,<sup>9</sup> 2014–2020**

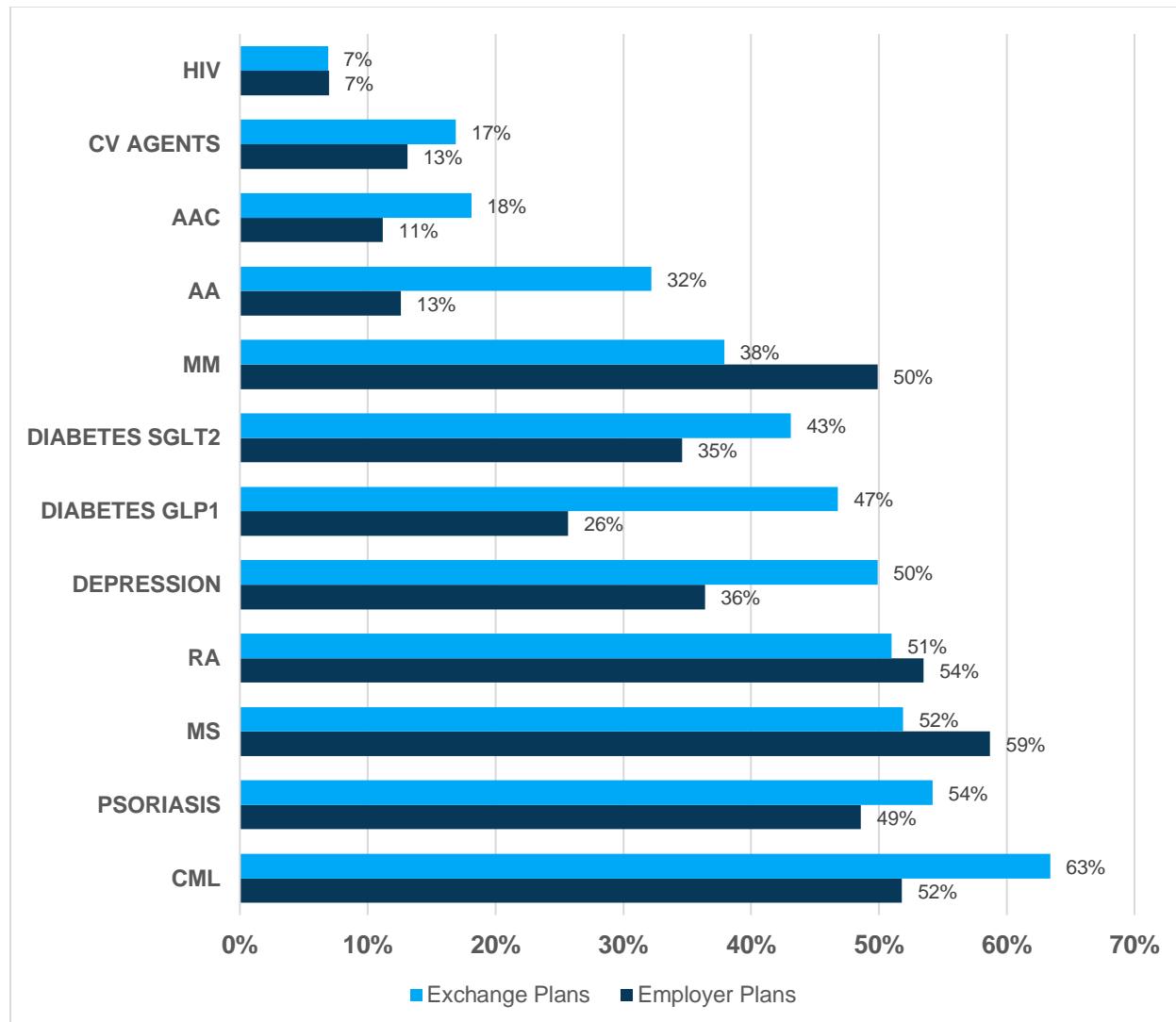


**(5) In 2020, patients insured on exchange plans were more likely to face UM restrictions than patients with employer-sponsored insurance across all studied TAs.** Exchange plans more frequently require UM for single-source brand drugs compared to employer plans. This could mean that a person who switches from an employer plan to an exchange plan may face new barriers to accessing their single-source brand medicines.

<sup>9</sup> AA: Atypical Antipsychotics, GLP1: Glucagon-like peptide-1, CV: Cardiovascular, AAC: Asthma/Allergy Corticosteroids, SGLT2: Sodium-glucose Cotransporter-2, CML: Chronic Myeloid Leukemia, RA: Rheumatoid Arthritis, MM: Multiple Myeloma, MS: Multiple Sclerosis

Over 150 million people are covered on employer plans, while approximately 12 million are covered on exchanges.<sup>10</sup> Accordingly, far fewer patients are subject to exchange formulary requirements than to employer plan formularies. While the number of people enrolled on exchanges is smaller, many exchange enrollees have limited income and do not have access to resources larger employers often provide to help enrollees navigate UM.

**Figure 6. Employer and Exchange Plans' Use of UM for Single-Source Brand Drugs, by TA,<sup>11</sup> 2020**



<sup>10</sup> [Health Insurance Coverage of the Total Population](#), Kaiser Family Foundation (KFF), 2019, and [Marketplace Enrollment 2014-2021](#), Kaiser Family Foundation.

<sup>11</sup> CV: Cardiovascular, AAC: Asthma/Allergy Corticosteroids, AA: Atypical Antipsychotics, MM: Multiple Myeloma, SGLT2: Sodium-glucose Cotransporter-2, GLP1: Glucagon-like peptide-1, RA: Rheumatoid Arthritis, MS: Multiple Sclerosis, CML: Chronic Myeloid Leukemia

## Detailed Methodology

In this study, Avalere analyzed formularies using comprehensive formulary and medical policy data across a range of payer channels provided by Managed Markets Insight & Technology, LLC (MMIT). Looking across insurance markets, MMIT's data include formularies used for 98% of enrolled lives. For this work, Avalere analyzed MMIT's data from the commercial insurance channel, which includes fully and self-funded employer-sponsored insurance and exchange plans. Results are enrollment weighted.

Avalere assessed single-source brand drugs in 12 TAs. Single-source drugs are drugs that are only available from 1 manufacturer. The products included in each TA were selected using the US Pharmacopeia Medicare Model Guidelines version 8.0, augmented by Avalere's clinical staff to account for drugs added or removed over time.

TAs in the analysis include oncology (CML and MM classes), mental health (second-generation/AA and depression (selective serotonin reuptake inhibitors and serotonin and norepinephrine reuptake inhibitors classes), autoimmune diseases (psoriasis, RA, and MS classes), AAC (anti-inflammatories and inhaled corticosteroids classes), diabetes (GLP1 and SGLT2 classes), human immunodeficiency virus (HIV), and CV agents. CV agents only had data available from 2016 to 2020; percent change datapoints for those drugs focused on just this period.

Avalere utilized historical Medi-Span drug reference files to determine whether each product in a class was a single-source brand, a multi-source brand, or a generic drug. Due to new drug entrants and the appearance of generics, the drug lists for each TA vary by year (2014–2020). To account for this, new brand drugs were added to the sample across TAs as they became available. Some products were removed from the single-source brand sample as they lost single-source status. Given that this analysis focuses on trends for single-source brand drugs, trends over time do not represent a shift in coverage for a set group of drugs but for a changing group of single-source brand products available to treat a specific condition.

Outputs examine how frequently drugs in a set of TAs are covered, not covered, or subject to UM when looking across the studied formularies. Given that each datum element in these graphics reflects multiple drugs and multiple formularies—as well as the enrollment in plans that use each formulary—the resulting figures capture the frequency of these measures of formulary coverage. This approach considers which formularies have higher enrollment and indicates the share of people insured on commercial plans who would be subject to a specific formulary feature like UM if they sought coverage for the specific drug(s).

# About Us

Avalere is a vibrant community of innovative thinkers dedicated to solving the challenges of the healthcare system. We deliver a comprehensive perspective, compelling substance, and creative solutions to help you make better business decisions. As an Inovalon company, we prize insights and strategies driven by robust data to achieve meaningful results. For more information, please contact [info@avalere.com](mailto:info@avalere.com). You can also visit us at [avalere.com](http://avalere.com).

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