California HealthCare Foundation

Disease Matters:
Comparing Prescription Drug Benefits in Covered California Plans

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About the Foundation

The California HealthCare Foundation works as a catalyst to fulfill the promise of better health care for all Californians. We support ideas and innovations that improve quality, increase efficiency, and lower the costs of care. For more information, visit www.chcf.org.

Introduction

The Affordable Care Act of 2010 (ACA) transformed the individual health insurance market. Among myriad reforms, health insurance companies can no longer deny coverage to consumers with pre-existing conditions, they must cover prescription drugs and other "essential health benefits" (EHBs), and limits are placed on consumers' out-of-pocket costs. Millions of Californians without access to job-based coverage can now purchase individual insurance through Covered California, the state's health insurance marketplace set up under the ACA. Those who qualify can receive subsidies to make Covered California's insurance plans more affordable. Taken together, these changes have greatly reduced barriers to coverage, including coverage for prescription medications, for large numbers of consumers.

Even with these changes, however, there appears to have been considerable variation in coverage for prescription drugs among health plans offered through Covered California in 2014, as well as differences in coverage between these plans and California's most common employer-sponsored health plans. Researchers compared these new individual market plans to employer-sponsored insurance in this study because most Californians get their insurance through their jobs. Although coverage in the individual market is typically less generous than employer-sponsored insurance, comparing individual and employer-sponsored products on formulary placement and utilization management requirements for specific drug classes provides insight into which consumers are most affected by the differences between the benefits offered in the two markets.

This report examines these differences and considers how easy it is for consumers to compare their options. The report also offers insights on how barriers to necessary prescription drugs might further be reduced and how consumer access to drug cost and coverage information could be improved across the individual market.

While this report focuses on 2014 Covered California plans, many of the characteristics and issues identified here are reflective of the broader individual market as well as larger trends in formulary design. Issuers that offer plans on and off California's health insurance exchange report that they use the same formulary for all segments of the individual market. And while broader market dynamics and state and federal regulatory requirements shape drug coverage in California's individual market as a whole, Covered California has a unique opportunity to influence coverage in this larger market through standardized benefit design decisions.

Background

Prior to implementation of the ACA, consumer participation in California's individual market for health coverage was fairly low compared to employer-based group coverage. The market also experienced substantial turnover as nationally, fewer than half of people with nongroup policies retained their coverage for more than 12 months.[1] In 2013, about 1.5 million in California purchased individual coverage compared to 12.4 million in the group market.[2] Wide variation in plan design and benefits made comparison shopping in the individual market difficult. Consumers with pre-existing conditions could be denied coverage or face much higher premiums based on their health status. Insurers and health plans were not required to provide coverage for prescription drugs or could offer a severely limited formulary that consisted of a small number of generic drugs. Nationally, nearly one out of five health insurance plans in the individual market lacked prescription drug coverage.[3]

The ACA insurance reforms and coverage mandates and associated California laws seek to make the individual market more stable and more affordable, establishing it as a viable option for the uninsured. Created in compliance with the ACA, state health insurance exchanges, including California's, serve as a portal where individuals can access information about available health plans, compare coverage options, and enroll in the plan that best matches their needs.[4] To make insurance more affordable, premium tax credits and cost-sharing subsidies are available to enrollees who qualify based on income and immigration status. The exchanges have transformed the individual market for health insurance and have expanded access to coverage to many consumers who were previously uninsured due to cost or their health status.

By the end of 2014 open enrollment, nearly 1.4 million California residents selected a plan through the exchange. As of April 2014, about 88% of Covered California enrollees were receiving subsidies to help reduce overall costs.[5]

Prescription Drug Coverage Requirements

The ACA requires that all health plans offered in the individual market, including those in Covered California, cover a standard set of EHBs, which include hospitalizations, doctor visits, emergency services, and prescription drugs, among other benefits.[6] This sets a minimum standard for coverage. The Affordable Care Act also requires EHBs to be equal in scope to benefits offered by a "typical employer plan" as defined by a state-selected EHB benchmark plan. For prescription drugs, health plans subject to the EHB requirement must cover the greater of one drug in every category and class, or the same number of drugs in each category and class,[7] as the state-selected EHB benchmark plan.[8,9]

ACA regulations require that health plans providing EHBs have procedures in place to allow enrollees to request and gain access to clinically appropriate drugs not listed on the plan's formulary.[10] In cases where an enrollee's life, health, or ability to regain maximum function may be seriously jeopardized, or where the enrollee is undergoing a current course of treatment using a nonformulary drug, the health plan must expedite the process and notify the enrollee of its coverage determination no later than 24 hours after it receives the request.[11]

Federal rules also limit the amount of annual out-of-pocket costs patients pay for care. Prescription drug costs for on-formulary medications are counted toward the out-of-pocket cap. Federal law does not require that costs for medications not listed on plan formularies be counted toward the cap; however, California state regulations require consumer costs to be "reasonable so as to allow access to medically necessary outpatient prescription drugs."[12,13]

California applies additional requirements to health plans with the aim of ensuring consumer access to necessary medications. All health plans and insurance offered in individual and small group markets, including those in Covered California, must provide coverage for any medically necessary prescription drugs.[14] If a plan has denied the claim for a particular drug, the route to coverage is a formal process of requesting an exception to the denial. Similarly, California plans must offer an expeditious process to authorize exceptions to step therapy requirements.[15] Step therapy, sometimes called "fail first," refers to the requirement that before accessing a prescribed drug, patients must "fail" first on at least one alternative drug. It is usually applied to more expensive drugs to ensure less expensive alternatives are first tried.

To ensure drug continuity when appropriate, plans are prohibited from limiting coverage for a drug previously prescribed and approved by the plan — provided that the physician continues to prescribe the drug, the drugs is prescribed for an approved US Food and Drug Administration (FDA) use, and it is considered safe and effective for treating the enrollee's medical condition.[16] By contract, Covered California requires health plans to give enrollees advance notice prior to removing a drug from their formularies.

The California law that created Covered California also imposed specific requirements on both exchange and nonexchange plans related to the products they must offer.[17] To make comparison shopping easier, the ACA groups plans into four "metal levels" — platinum, gold, silver, and bronze and a catastrophic plan — based on how much of the costs, on average, the plan covers. California law requires all issuers participating in Covered California to offer at least one product at each of the five levels. In addition, for all its offerings, Covered California developed standardized benefit designs, which established fixed deductibles and cost-sharing amounts for each type of service, including prescription drugs.

California law also requires issuers to offer the standardized benefit designs for products outside Covered California. Issuers not participating in the exchange must offer at least one of the standard benefit design products in each of the four metal tiers.[18] (They may also offer nonstandardized benefit products.) The vast majority of individuals in plans regulated by the Department of Managed Health Care (DMHC) are in plans with standardized benefits. In the first quarter of 2014, 1.4 million of the 1.9 million lives in the segment of the individual market regulated by DMHC were in standardized benefit designs, including 1 million enrolled in Covered California as of March 31, 2014, and 400,000 in the outside market.[19,20]

All of these requirements mean that prescription drug coverage in California's post-ACA individual market is more comprehensive overall than it was prior to implementation of health reform. The standardization of benefits on and off Covered California, the participation of the state's

largest commercial insurers in the exchange, and the fact that the exchange comprises a large and growing portion of the individual market all make the examination of Covered California plans an important exercise in understanding the larger individual market.

Methodology

The researchers examined formularies from the 11 carriers participating in Covered California in 2014 and assessed variations in coverage, tier placement, and utilization management.[21] All but one carrier in Covered California maintained the same formulary for all their plan offerings in the exchange.[22] The report presents the findings based on combinations of formulary and benefit design; it does not provide enrollment-weighted averages.

To approximate the prescription drug needs for exchange enrollees, researchers analyzed coverage for the 100 most commonly prescribed drugs in the US commercial market based on 2014 data from Symphony Health Solutions, a health care data analytics company that focuses on physician prescribing and pharmacy fulfillment, among other issues.

Researchers also focused on 11 drug classes used to treat five common chronic conditions that rely heavily on medication management: HIV/AIDS, mental health, diabetes, autoimmune disorders, and asthma/chronic obstructive pulmonary disease (COPD).[23] (See Figure 1.) The selected drug classes represent therapies for a mix of primary care conditions and more specialized disorders commonly treated with long-term medications. Medications analyzed represent those on the market as of mid-2014; new products have launched in these areas since the time of analysis.

Researchers reviewed formulary inclusion, tiering, and utilization management for each product in the class, combining brands and their generic equivalents when available.[24] Combination drugs and distinct formulations like extended-release and intramuscular (IM) formulations were counted separately. Drugs administered by a physician are typically covered under plans' medical benefits and not usually included in formularies. As such, these products were excluded from the analysis.

Comparing Individual Market and Employer-Sponsored Plans

Researchers also compared exchange formularies to those of selected employer-sponsored health insurance plans.[25] The comparator group includes the formularies for fully insured plans from the top four fully insured carriers in the California group market. Each of these insurers reported using a single formulary for both large and small

Figure 1. Categories and Classes of Drugs Analyzed, 2014

	USP CATEGORY	USP CLASS
HIV/AIDS	Antivirals	Anti-HIV agents: ▶ Non-nucleoside reverse transcriptase inhibitors (NNRTIs) ▶ Nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs) ▶ Protease inhibitors (PIs) ▶ Other (HIV-other)
Mental Health	Antidepressants	Serotonin/norepinephrine reuptake inhibitors (SNRIs)
	Antipsychotics	Second generation/atypicals (atypicals)
Diabetes	Blood glucose regulators	▶ Antidiabetic agents (antidiabetics) ▶ Insulins
Immunology	Immunological agents	Immune suppressants
COPD/Asthma	Respiratory tract agents	▶ Bronchodilators, sympathomimetic (B_2 agonists) ▶ Anti-inflammatories, inhaled corticosteroids (ICS)

group products. In addition, researchers examined the formulary used by CalPERS, the health and retirement benefits administrator for state employees.

The purpose of this comparison is to offer a common point of reference from an established market. Employer-based insurance, which covers 53% of nonelderly California residents, is used as this point of comparison for examining benefits because it is the single largest source of insurance for Californians,[26] and because it is frequently considered to be the standard when stakeholders assess the merits and limitations of other types of coverage.

There are, however, important differences between the individual and employer-sponsored insurance markets. Employer-sponsored coverage has historically included richer benefits packages than insurance offered in the individual market, including more generous prescription drug benefits. Employer plan formularies are less likely to use four tiers than individual market plans. In 2014, on average, 91% of exchange formularies nationwide had four or more tiers, compared to 20% in the employer market.[27] Further, benefits at large firms tend to be, on average, more generous than those offered by smaller firms.[28]

Therefore, it is not surprising that formularies in the individual market, whether on or off the exchange, might generally be more restrictive than employer-sponsored plans. Comparing individual and employer-sponsored products on formulary placement and utilization management requirements for specific drug classes allows more insight into these differences and which consumers are most affected.

Limitations of the Data

Researchers relied on publicly available formulary documents, which vary in format, comprehensiveness, and accuracy across carriers. Due to the ever-evolving nature of coverage policies and the lag time in updating public documents, the formularies reviewed in this study may not reflect the most up-to-date prescription drug benefits for the plans analyzed.

Many formularies include language that specifically stresses that the document is not a comprehensive list of medications available and that it is possible that additional products may be covered without requiring a patient to navigate an appeals and exceptions process. For example, some plans might choose to include the most commonly used medications and then only add additional drugs as they are requested by enrollees and as claims are processed.

In addition, some carriers may routinely cover nonlisted drugs without a prior authorization and subject these medications to the nonpreferred branded drug cost-sharing amount. Moreover, it is also possible that some plans cover over-the-counter medications, which may not typically appear on formularies, under the pharmacy benefit. In such cases, due to the limitations of publicly available information, these products would be classified as "not listed" for the purposes of this report. The limitations and challenges in using publicly available formularies apply to all segments of the health insurance market and are not a product of or specific to Covered California.

The analysis focused on pharmacy-benefit drugs and excluded over-the-counter medications. The researchers used the most updated formularies and summaries of benefits and coverage information as of May 2014, but plans can change formulary documents at any time and may not include all covered medications in formulary lists.

Findings

Commonly Used Medications

For consumers with relatively limited drug needs, Covered California plans provided comprehensive, affordable access to the most commonly used medications, which were predominantly generic drugs. Ninety of the top 100 most commonly prescribed drugs in 2014 were generics, which were widely included on Covered California formularies and almost always placed on a generic tier with low cost sharing.

For instance, the top 100 list included generic medications used to treat high blood pressure, high cholesterol, and acid reflux, as well as prescription painkillers. Copayments for generic drugs ranged from $5 to $19 and were as low as $3 for the lowest-income enrollees receiving cost-sharing reductions in enhanced silver plans.[29] On average, 94% of the generics most commonly used and 82% of the top brand medications reviewed were included in Covered California formularies.

Chronic Disease Drug Access

While commonly used medications were broadly included on plan formularies with low cost sharing, some consumers with chronic diseases or those who rely on specialty drugs may have faced access and affordability challenges in 2014.

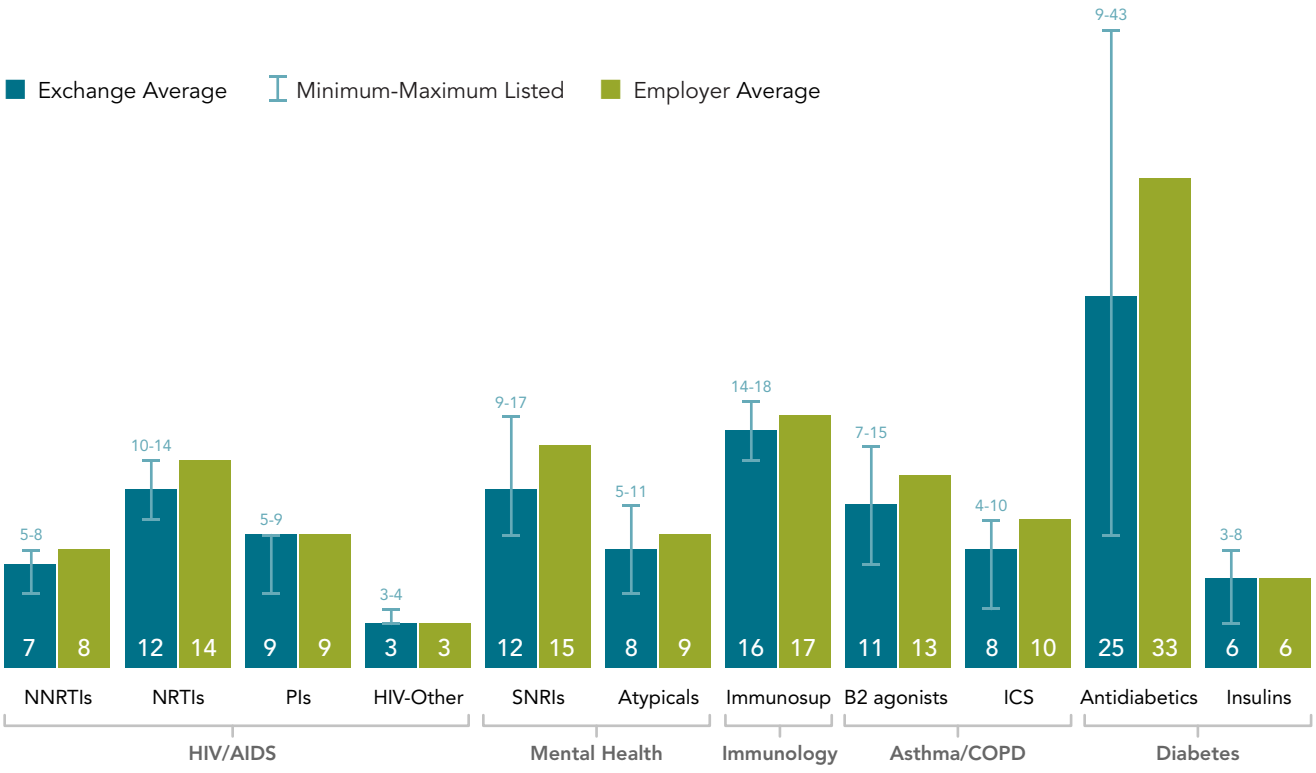
Formulary Breadth

Compared to typical products in the employer market, Covered California plans, on average, included slightly fewer listed drugs for the chronic diseases studied. In an analysis of 11 classes of drugs for medication-dependent chronic diseases, exchange plans listed an average of 80% of analyzed drugs in their formularies, while selected employer plans listed an average of 88%. Exchange formulary breadth varied substantially by class from a low of 58% for antidiabetic agents to a high of 97% of protease inhibitors, a class of antiviral drugs that can be used in a drug regimen for patients with HIV/AIDS.

The analysis uncovered wide variation in breadth of formularies among different plans offered on Covered California. For example, the number of listed atypical antipsychotics used to treat severe mental illness ranged from a low of 5 listed drugs to a high of 11 products. Variation was even more pronounced for antidiabetics, where out of the 44 unique drugs in the class, plans ranged from listing a low of 9 products to a high of 44 products. On average, exchange plan formularies included 58% of antidiabetic agents, which was significantly less than the 75% of products listed in employer plans. (See Figure 2.)

On average, Covered California formulary inclusion for HIV/AIDS drugs was broad, but formulary breadth varied across plans: On average, Covered California plans listed 88% of HIV/AIDS drugs; formularies ranged from listing 75% to 100% of HIV/AIDS products across plans. However, combination therapies used to treat HIV/AIDS

Figure 2. Number of Chemical Entities Listed in Exchange Plan Formularies, 2014



Notes: Anti-HIV agents: **NNRTIs** – nonnucleoside reverse transcriptase inhibitors; **NRTIs** – nucleoside and nucleotide reverse transcriptase inhibitors; **PIs** – protease inhibitors. **SNRIs** – serotonin/norepinephrine reuptake inhibitors; **Atypicals** - second generation/atypical. **B_2 Agonists** – bronchodilators, sympathomimetic; **ICS** – anti-inflammatories, inhaled corticosteroids. **Antidiabetics** – antidiabetic agents.

Source: Author analysis of Covered California exchange plan formularies using Avalere's PlanScape, a proprietary tool to analyze exchange plan features.

Is a Broader Formulary Better?

A broader formulary is not necessarily a better formulary. For example, in the case of antidiabetics, the more limited qualified health plan (QHP) formulary breadth means that consumers who have successfully controlled their diabetes symptoms with a particular medication under nonexchange coverage may want to verify whether their drug is included on an exchange plan's formulary before they enroll in a new plan. But because antidiabetics are a particularly large class with many therapeutic alternatives, patients may be able to work with their physicians to switch to another listed drug that is equally or more effective and perhaps less costly.[30]

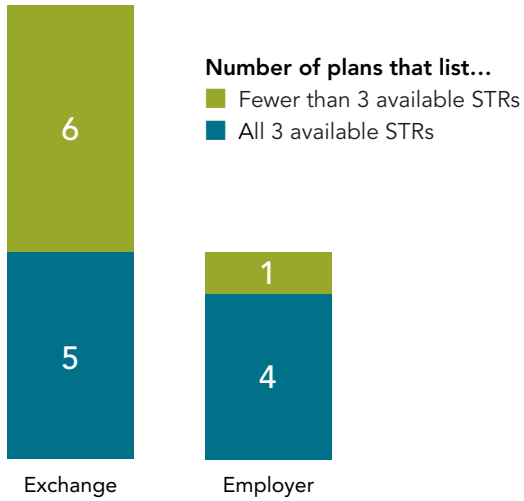
were less likely to be listed on Covered California formularies relative to employer plans.

HIV/AIDS treatment is complicated and usually requires a combination of antiretroviral therapies from at least two different classes to keep the virus from developing. A single-tablet regimen (STR) contains several different drugs in one tablet, which reduces pill burden for patients and has been shown to improve drug adherence. Appropriate adherence slows disease progression, improves individual health outcomes, and can dramatically reduce the risk of transmitting HIV disease to partners. As a result, STRs are now widely recommended and used as first-line treatment since they have been found to improve medication adherence and result in improved viral suppression.[31] Individual differences in tolerance, blood HIV levels, side-effects, and interactions with diet and with other medications make it important for plans to cover the suite of available single-tablet regimens.

Despite these advantages, however, 6 of 11 Covered California plans (55%) did not list all available STRs on their formularies, compared to only 1 of 5 analyzed plans in the employer market (20%). (See Figure 3.)[32]

STRs are a newer and more expensive therapy, and do not have generic equivalents at this time. As a result, patients may not be able to readily access other equivalent therapies on plan formularies.

Figure 3. Formulary Inclusion of Single-Tablet Regimens, Exchange and Employer Plans, 2014



Source: Author analysis of Covered California exchange plan formularies using Avalere's PlanScape, a proprietary tool to analyze plan features.

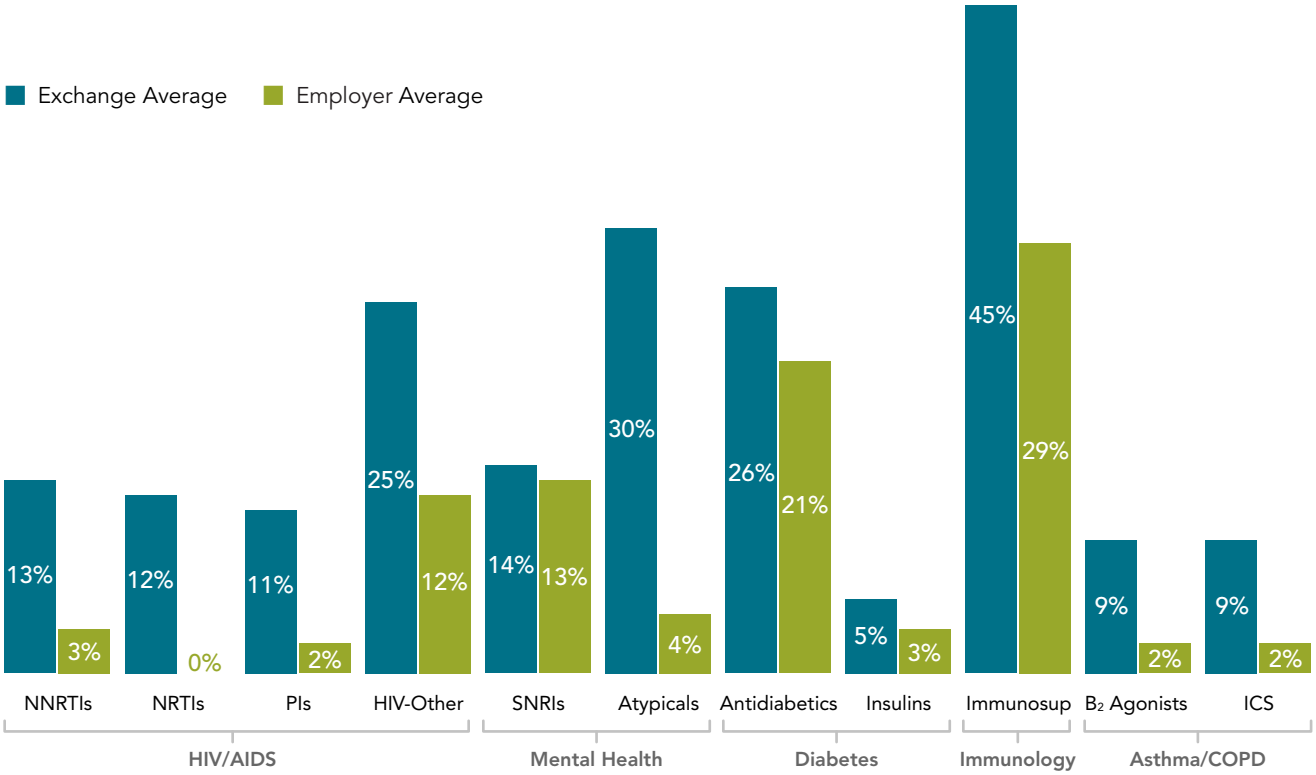
Utilization Controls

Covered California plans were more aggressive than selected employer plans in managing drug use through administrative controls, such as prior authorization and step therapy. Although the average formulary breadth of exchange plans was only slightly less than employer coverage, Covered California plans imposed utilization management much more frequently than employer-based plans. On average among classes reviewed, the percentage of listed medicines subject to utilization management was twice as high in the exchange plans compared to employer plans. The difference was particularly pronounced for immune suppressants, HIV/AIDS drugs, and antipsychotics. (See Figure 4 on page 9.)

Exchange plans placed restrictions on immune suppressants 45% of the time, whereas the selected employer plans imposed utilization management 29% of the time. Antipsychotic medications were more than seven times as likely to be subject to utilization management in exchange plans compared to the selected employer plans (30% in exchanges versus 4% in employer plans).

Finally, across the four HIV classes examined, exchange plans exercised much stricter control, while the selected employer plans generally provided open access to these drugs. On average, Covered California QHPs required

Figure 4. Listed Medicines Subject to Utilization Management, Exchange and Selected Employer Plans, 2014



Notes: Anti-HIV agents: **NNRTIs** – nonnucleoside reverse transcriptase inhibitors; **NRTIs** – nucleoside and nucleotide reverse transcriptase inhibitors; **PIs** – protease inhibitors. **SNRIs** – serotonin/norepinephrine reuptake inhibitors; **Atypicals** - second generation/atypical. **Antidiabetics** – antidiabetic agents. **B_2 Agonists** – bronchodilators, sympathomimetic; **ICS** – anti-inflammatories, inhaled corticosteroids.

Source: Author analysis of Covered California exchange plan formularies using Avalere's PlanScape, a proprietary tool to analyze exchange plan features.

utilization management for HIV/AIDS drugs 15% of the time compared to only 4% in select employer plans.

Medicare prohibits utilization management for HIV/AIDS drugs, citing that prior authorization and step therapy controls are not considered best practice in formulary design.[33] Similarly, low-income individuals in California who are enrolled in Medi-Cal do not face utilization controls for HIV/AIDS medications. Under Medi-Cal, all FDA-approved drugs for treating AIDS and AIDS-related conditions are included on the drug list and carved out of managed care,[34] thus offering Medicaid beneficiaries more unrestricted access to their therapies than exchange enrollees.[35]

Because the purpose of utilization management is to help ensure that drugs are being used appropriately (e.g., targeting indicated patients and ensuring no contraindications), high rates of utilization management for certain medications that have contraindications are not necessarily inappropriate. However, the disparity in utilization management among plans both in and outside Covered California could be cause for concern, because for some prescribers, strict administrative controls can be a barrier that translates to restricted access for consumers. In particular, providers who work in small office practices with limited administrative staff support, or specialists who have not previously had to process frequent utilization management controls (e.g., infectious disease doctors specializing in HIV/AIDS), may find these procedures burdensome. For consumers, this could ultimately lead to rejected claims or administrative delays.

Tier Placement

Products used to treat complex chronic conditions, especially those for autoimmune conditions like rheumatoid arthritis, were disproportionately placed on the specialty tier in Covered California plans compared to the selected employer plans. Specialty tiers are typically reserved for high-cost medications and

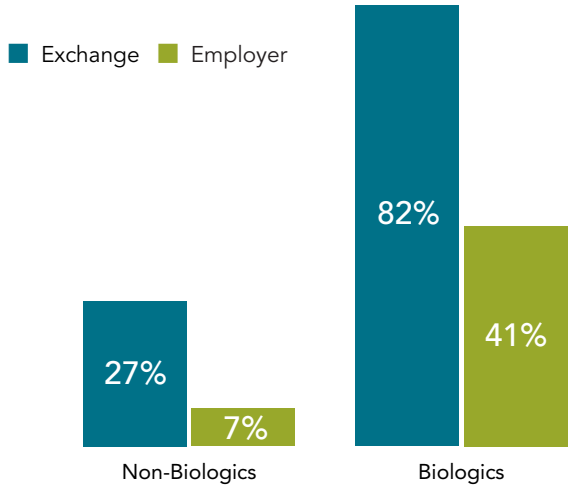
require higher copayments or coinsurance for enrollees. By putting particular drugs on higher tiers, plans are discouraging consumers from using these drugs because of their high out-of-pocket cost.

California law does not provide a uniform definition of a specialty product. Covered California standardized benefit designs allow participating plans to establish specialty tiers and to define the drugs to be included in the tiers.[36] Among Covered California plans, 82% of formularies included a specialty tier, while only 40% of the employer plans selected for this analysis had a structure with more than three formulary tiers; consequently, more drugs in exchange plans are placed on a high tier with high cost sharing. Unlike lower formulary tiers, for which insurers charge consumers a set copay amount, specialty tiers usually impose a coinsurance as a percentage of the drugs' cost. The Covered California standard benefit designs allow for specialty tier coinsurance ranges from 10% of the drug cost in platinum plans and up to 40% in a bronze plan. Since specialty drugs can cost several hundred to several thousand dollars per month, consumers who take these medications may experience high out-of-pocket costs until they reach the annual out-of-pocket cap, which was $6,350 in 2014.[37]

Products in the immune suppressant class, which treat rheumatoid arthritis (RA), Crohn's disease, psoriasis, and organ transplant patients, were placed on a specialty tier 42% of the time in Covered California plans compared to 15% of the time in the selected employer plans. The disparity was particularly pronounced for biologic medications, which were three times as likely to appear on the specialty tier compared to oral pills among Covered California plans.

While most RA patients begin therapy on a traditional oral pill medication, those with severe conditions may progress to biologic medications, which are more effective at slowing disease progression. At the extreme, Covered California plans placed as many as 82% of listed biologic immune suppressants on specialty tiers. Which tier a plan chooses for these drugs has a big impact on consumer out-of-pocket costs. (See Figure 5.) For example, for the 2014 and 2015 plan years, someone taking a biologic RA drug on the specialty tier of a silver plan can expect to pay approximately $550 each time they fill their medication after the deductible.[38] By comparison, if a plan places the same drug on a nonpreferred brand tier, the cost per fill would be $70.

Figure 5. Listed Medicines on Specialty Tier (Tier 4), Biologic and Non-biologic Immune Suppressants, Exchange and Employer Plans, 2014



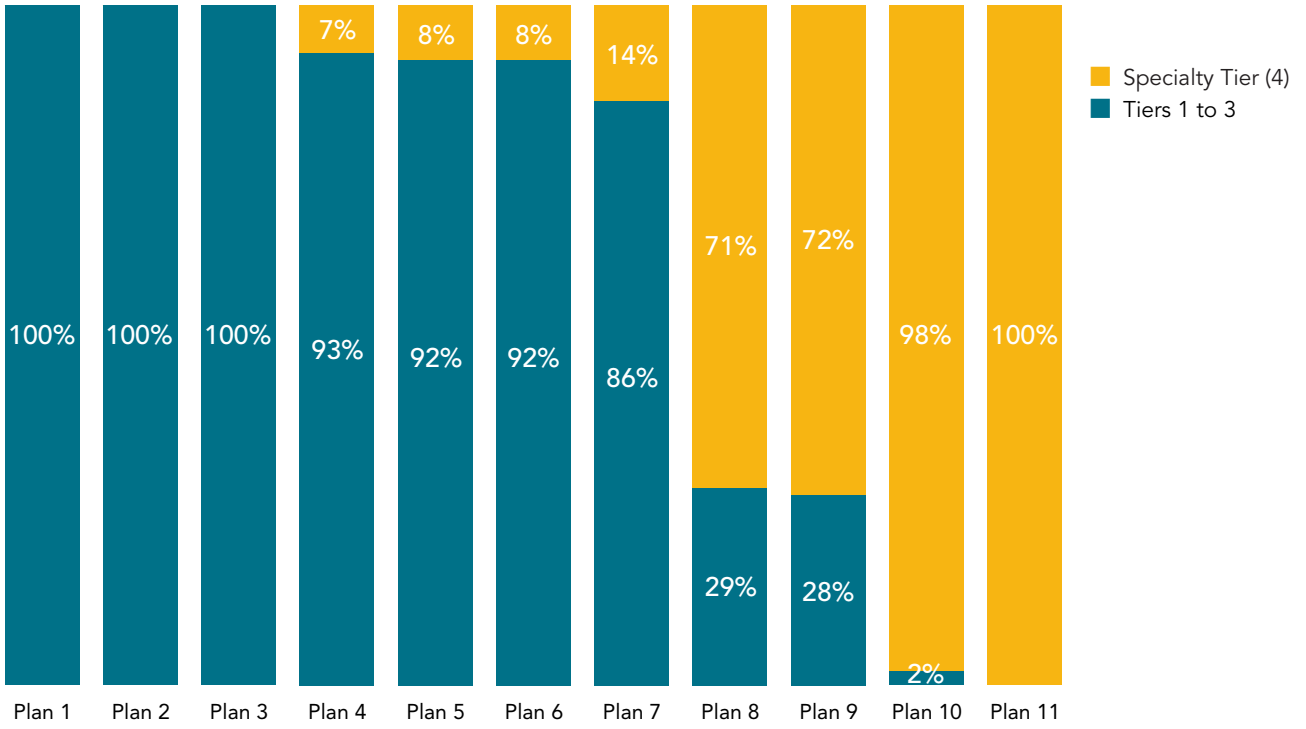
Source: Author analysis of Covered California exchange plan formularies using Avalere's PlanScape, a proprietary tool to analyze plan features.

Tier placement for HIV/AIDS drugs varied dramatically across Covered California plans, with a few plans placing most or all of the listed drugs on the specialty tier. When combination therapies were listed, they were more likely to be placed on high tiers in Covered California plans than in selected employer plans.

Some Covered California insurers placed HIV/AIDS drugs, which are typically oral medications, on the specialty tier. On average, Covered California plans used specialty tiers for listed HIV medicines 27% of the time compared to only 1% in the selected employer plans, but there was wide variation among exchange plans. (See Figure 6 on page 11.)

One plan placed all listed HIV/AIDS drugs on the specialty tier for its Covered California products, including brands and generics. Another plan placed 98% of listed drugs in the HIV/AIDS class on the specialty tier. Two other carriers placed more than 70% of listed HIV/AIDS drugs on the specialty tier for Covered California products. Among the other seven plans in the market, three did not use specialty tiers and an additional four placed more than two-thirds of HIV/AIDS drugs on non-specialty tiers. Notably, some of the plans that placed many HIV/AIDS drugs on specialty tier are small carriers. The four plans that placed more than 70% of listed HIV/

Figure 6. Frequency of Placement of HIV/AIDS Medicines on Specialty Tier Among Listed Products, 2014



Source: Author analysis of Covered California exchange plan formularies using Avalere's PlanScape, a proprietary tool to analyze exchange plan features.

AIDS drugs on the specialty tier represented 5% of 2014 Covered California enrollment.[39]

Availability of Information

Comprehensive information on drug coverage and out-of-pocket costs was difficult to find. This lack of access could be a barrier to consumers who wish to make informed purchasing decisions. Across all segments of California's health care market, it was difficult for researchers to find comprehensive, easily understandable information on drug cost and coverage information by health plan. In addition, during the 2014 enrollment period, formularies for Covered California plans were not available on the exchange website, and instead needed to be retrieved from individual carriers' web pages, where ease of navigation varied widely. While Covered California launched a web page with carrier formulary information after this study's data analyses were completed, formulary links were not readily available on the same web page where consumers shop for and compare plans at the time of the writing of this report.

This lack of consolidated information makes it difficult for consumers in California to consider drug coverage and tier placement when selecting a plan. Researchers found inconsistent formulary formats and structures, which may make it hard for individuals to understand whether their products are listed and whether utilization management controls apply. Furthermore, public formulary information was often found to be incomplete, and it was unclear whether the public documents represented 100% of covered pharmacy-benefit drugs. Cost information was not always easily identifiable or understandable. Researchers experienced these challenges firsthand as they gathered and interpreted data for this report.

Incomplete and nonstandardized public formulary information also makes comparison of plan coverage to the state-selected EHB benchmark difficult, creating challenges for enforcement. For example, in rare instances, based on publicly posted data, plans appeared to cover fewer drugs per class than the number required by the state-selected EHB benchmark. While these differences were small in some cases, in others, plans listed only half of the required number of drugs per class.

Generally, plans reported that these discrepancies reflected incomplete public formulary lists, rather than noncompliance, and that they cover more drugs than were listed on publicly available formularies. In other cases, plans covered additional drugs under the medical benefit, instead of the pharmacy benefit. For example, unlike traditional oral drugs, injectables can be covered under a medical benefit, a pharmacy benefit, or both. Plans typically list coverage for medical benefit drugs in a series of documents called medical coverage policies on their websites or in physician manuals or fee schedules, which can make it difficult for consumers to assess which products are covered.

While the federal government has created a drug counting tool for the purpose of ensuring that formularies meet EHB standards, they do not publish a crosswalk of how drugs are mapped and counted in the tool compared to publicly available formularies. Without public lists of all covered drugs, it is difficult to verify whether plans are meeting the regulatory standards.

Policy Considerations

Relative to the pre-ACA individual market, California's implementation of the ACA and creation of Covered California has greatly improved access to medicines, especially for many previously uninsured individuals. However, some chronically ill patients are likely to face access and affordability challenges in the individual market. Policymakers, regulators, and Covered California staff might consider the following policy changes that would improve transparency and enhance access to prescription drugs for Californians purchasing coverage in the individual market.

Monitor Health Plans for Discrimination

Based on the publicly available formularies, the research found that one Covered California plan placed all HIV/AIDS drugs on the highest-cost specialty tier; another placed 98% of these medications on the specialty tier. Also, Covered California plans excluded STR from formularies at a higher rate than selected employer-sponsored plans. These benefit design choices could amount to a form of discrimination against patients with HIV/AIDS. High rates of specialty tier placement for medicines used to treat other complex chronic conditions are also cause for concern.

While the ACA prohibits discrimination by health plans, federal rules provide limited guidance on the definition of discrimination for drug benefits. States are given primary responsibility for enforcing nondiscrimination rules. In the preamble to proposed federal guidance released November 2014, the US Department of Health and Human Services (HHS) explicitly stated that they believe plan designs that place all or most of the drugs that treat a specific condition on the highest-cost tiers "effectively discriminate against, or discourage enrollment by, individuals who have those chronic conditions."[40]

HHS also noted that "if an issuer refuses to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, we believe that, absent an appropriate reason for such refusal, such a plan design effectively discriminates against, or discourages enrollment by, individuals who would benefit from such innovative therapeutic options."[41]

California regulators should actively monitor all health plans to ensure that formulary exclusions and tier placement of particular classes of drugs do not constitute discrimination.

Strengthen Oversight and Rules for Formulary Coverage

Covered California's standard benefit design allows issuers to develop formularies that include a fourth tier — the specialty tier — primarily used for expensive specialized drugs, but state law does not impose a definition of specialty drugs, nor specify what drugs are appropriate to include on that tier. Researchers found significant variation in formulary tier placement for certain classes of drugs. Products used to treat complex chronic conditions, such as autoimmune conditions like rheumatoid arthritis, were more likely to be placed on the specialty tier in Covered California plans than the employer-sponsored plans that were examined.

California law does not impose a definition of specialty drugs for any market segment. In comparison, in the Medicare Part D market, CMS allows plans to place drugs on specialty tiers only if their negotiated prices exceed the dollar-per-month threshold established annually.[42]

Proposed federal guidance released in the November 2014 design points to clinical guidelines and reasonable medical management, rather than cost thresholds, as critical for formularies regulated under the Affordable Care Act. If California implemented a standardized definition of specialty medications, depending on this definition, plans might be precluded from placing all drugs in a class, including generics, on the highest tier. A definition of specialty drugs should take into account the development of new medications and potential new classes of medication as well as variations in approaches by health plans to managing prescription drug costs.

California could also consider additional regulatory scrutiny of formulary designs to identify outlier plans that, compared to other plans, list on formulary significantly fewer drugs in a class, require more utilization management, or fail to list whole sets of drugs (e.g., combination therapies) that are commonly considered clinical best practice. Alternatively, California could pursue a more extreme approach that would specify a standard drug list that must be used by all Covered California plans. Such an approach has been used by some state Medicaid programs, though it has not been attempted in the exchange market at date of publication.

Increase Transparency of Plans' Prescription Drug Coverage for Consumers[43]

Implement new market-wide reforms. Accessing accurate, comprehensive, and consistent information about which drugs are covered by California health plans and what utilization controls or formulary tiers are applied to those products is difficult. These challenges exist across California's health insurance markets; more restrictive drug coverage in the individual market makes transparency in this setting even more important.

In an effort to improve the transparency of drug coverage policies, in September 2014 California enacted SB 1052.[44] This law requires the Department of Insurance and the Department of Managed Health Care to jointly develop a standard formulary template for reporting and displaying formulary information, including coverage, tiering, and utilization management information, as well as details about the plan's medical benefit drug coverage. All plans offering prescription drug coverage will be required to post searchable formularies following this format on their websites and keep them updated monthly. In addition, the law requires Covered California to create a direct link from its website to each QHP's formulary — a requirement that has been implemented.

This legislation represents an important step toward presenting information to consumers clearly. The law applies to formularies in the group as well as the individual markets and to plans inside and outside of Covered California. This level of comprehensiveness is appropriate, as the challenges exist across market segments. State regulators can enhance the effectiveness of the new law by:

- Working together to swiftly develop the template and put it in place
- Using information on consumer needs and preferences to inform development of the template
- Monitoring health plans' compliance with posting and updating complete and searchable formularies

State policymakers should consider future enhancements to the requirements, such as including standardized, easy-to-understand cost information in the template.[45]

Meanwhile, federal policymakers are also considering sweeping changes to improve transparency with a target implementation date of 2016. Plans would be required to make public an up-to-date, accurate, and complete list of all covered drugs, with all corresponding tiering and utilization management clearly outlined. HHS is also considering nationwide implementation of a standardized formulary display template.

Improve consumers' ability to comparison shop Covered California plans based on medication needs. Covered California staff might consider building an online formulary search tool that allows consumers to compare plans based specifically on drug coverage and restrictions. Medicare Part D uses such a tool, known as the Plan Finder,[46] which enables beneficiaries to search for plans by entering their specific medication list and preferred pharmacy. The tool's results include premiums, out-of-pocket costs for the beneficiary's specific medications, and any related utilization controls. Nevada was the only exchange website in 2014 that offered a drug lookup tool to help consumers chose plans based on coverage of medications, but unlike Medicare's Plan

Finder, it did not provide users with the ability to estimate out-of-pockets costs. Such search tools allow consumers to more easily compare plans side-by-side as opposed to searching individual plan formulary documents.

Strengthen the transparency of the EHB regulatory standards regarding prescription drugs. In 2014, federal EHB regulations set requirements for minimum formulary coverage by class in QHPs. However, public information about how particular drugs map to these classes and how state and federal regulators oversee and enforce these rules is extremely limited, even for participating plans.

In recognition of the shortcomings of the current standards for drug coverage in the exchanges, HHS recently proposed changes to EHB drug coverage requirements and solicited comments from stakeholders on the best model to ensure adequate access for consumers. The agency also reiterated the statutory prohibition on benefit design that discriminates based on a person's age, gender, or health status. In addition to the federal guidance, given that states have the primary responsibility for enforcing EHB requirements, California policymakers should consider more specifically identifying criteria for measuring compliance with the ACA nondiscrimination requirement.

Better inform California consumers about the exceptions process and other relevant consumer protections. The lack of clear information about drug coverage for consumers makes consumer awareness of existing protections and alternative routes to coverage particularly important. Health plans, state regulators, and Covered California should ensure that easy-to-understand information on how to access needed drugs is widely available. As part of its partnership with Health Consumer Alliance (HCA), Covered California may want to consider an aggressive consumer education effort on the topic. Regulators may consider ways to increase awareness across markets.

Specify Utilization Management and Exceptions/Appeals Processes

Until recently, the prior authorization (PA) process could vary significantly among health plans. To ease the burden on patients and providers, the California legislature passed a law in 2011 requiring a uniform PA form for all health plans in the state. The new requirement, fully implemented on October 1, 2014, also reduces turnaround time, giving plans two business days to respond to a PA request. While existing California regulations[47] outline requirements for appeals and utilization management, policymakers could consider additions to such rules. For example, policymakers could consider specifying the level of cost sharing that would apply when an appeal is granted, which would help consumers understand what to expect in out-of-pocket costs.

Glossary

Actuarial Value. The average percentage of total health care costs that a plan will pay for covered benefits based on a standard population. For example, a silver plan in Covered California has an actuarial value of 70%, meaning that on average, the plan covers 70% of enrollees' annual health costs.

Biologic Drugs. Medicines generated by genetically engineering a living system, like plant or animal cells. Many biologics must be stored under refrigeration and administered via injection.

Cost-Sharing Subsidy. Additional financial assistance to reduce out-of-pocket costs in Covered California plans for individuals earning between 100% and 250% of the federal poverty level ($11,670 to $29,175 for an individual and $23,850 to $59,625 for a family of four in 2014). Qualified consumers must purchase specific cost-sharing reduction plans at the silver level to take advantage of this subsidy.

Essential Health Benefits (EHBs). Ten categories of services, including hospitalization and prescription drugs, that must be covered by Covered California plans and plans sold on the individual and small group markets outside of the exchange.

EHB Benchmark Plan. The health plan that sets the minimum standards for coverage of EHBs in Covered California. In 2014 and 2015, California's benchmark plan is the Kaiser Foundation Health Plan Small Group HMO 30 ID 40513CA035. For prescription drugs, Covered California plans must cover, at a minimum, the same number of distinct chemical entities in each category and class of medicines covered by the benchmark plan.

Exceptions and Appeals Process. Procedure for consumers to request coverage of certain medicines and services from their health insurance plan. Through a formulary exception process, patients may work with their prescriber to request access to a drug that is not covered by the patient's plan.

Formulary. A list of pharmacy-benefit drugs that are covered by a given health plan. Formularies typically include information about required utilization management. Most formularies use multiple tiers that tie to increasing patient cost sharing to encourage use of preferred medications.

Maximum Out-of-Pocket. The maximum amount that an individual can pay in deductibles, copayments, and coinsurance toward covered, in-network benefits in a benefit year.

Metal Level. Description of the actuarial value of a health plan. In Covered California, plans are offered at four metal levels: bronze (60% actuarial value), silver (70%), gold (80%), and platinum (90%). Catastrophic coverage with a lower actuarial value is available only to people under age 30 or who obtain a hardship exemption from the exchange.

Out-of-Pocket Costs. Consumer spending on deductibles, copayments, and coinsurance related to the use of health services; does not include premiums.

Pre-Existing Condition. A disease or condition for which an individual had received a diagnosis and/or sought treatment prior to enrolling in a new insurance policy.

Premium Tax Credit. Known officially as an Advanced Premium Tax Credit, financial assistance offered through Covered California that reduces premiums for people earning between 100% and 400% of the federal poverty level ($11,670 to $46,680 for an individual and $23,850 to $95,400 for a family of four in 2014). (Note that those earning up to 138% FPL may qualify for Medi-Cal.)

Qualified Health Plan. Health plan offered through Covered California that meets standards for actuarial value, covers the EHBs, and meets requirements for deductibles and cost-sharing structure.

Single-Tablet Regimens. HIV/AIDS medications that combine several chemical compounds into a single pill.

Standardized Benefit Design. Covered California created standard plan designs, including deductibles, copayment, and coinsurance amounts for services and prescription drugs, and maximums on out-of-pocket spending.

Tier Placement. Covered California plans group covered drugs into four tiers. Typically, drugs placed on higher tiers are subject to higher cost sharing.

- **Generic Tier.** The lowest formulary tier (Tier 1), usually reserved for generic drugs and with the lowest cost sharing and fewest limits on access.
- **Preferred Brand Tier.** The second formulary tier (Tier 2), for a plan's recommended branded drugs. Preferred drugs are selected based on a combination of price and quality.
- **Nonpreferred Brand Tier.** The third formulary tier (Tier 3) for branded drugs whose use is discouraged by the plan due to cost or clinical considerations.
- **Specialty Tier.** The highest formulary tier (4 or higher), on which drugs are subject to the highest cost sharing.

Utilization Management. Procedures required by health plans or pharmacy benefit managers that govern patient access to drugs.

- **Prior Authorization.** Requirement that a health plan reviews requests for certain medicines, on an individual patient basis, before granting coverage.
- **Step Therapy.** Requirement that, before accessing a prescribed drug, patients try and "fail" on at least one alternative drug.

Appendix A: Unique Products Analyzed by Issuer, by Metal Level, 2014

CARRIER	REGIONS	BRONZE	SILVER	GOLD	PLATINUM	TOTAL
Anthem Blue Cross	19	4	3	3	3	**13**
Blue Shield of California	19	4	2	2	2	**10**
Chinese Community Health Plan	2	1	1	1	1	**4**
Contra Costa Health Plan*	1	1	1	1	1	**4**
Health Net	13	1	2	2	2	**7**
Kaiser Permanente	18	2	1	1	1	**5**
L.A. Care	2	1	1	1	1	**4**
Molina Healthcare	4	1	1	1	1	**4**
Sharp Health Plan	1	2	2	2	2	**8**
Valley Health	1	1	1	1	1	**4**
Western Health Advantage	2	2	1	1	1	**5**
Total	—	**20**	**16**	**16**	**16**	**68**

*Not participating in Covered California in 2015.

Appendix B: Employer Formularies Analyzed, by Issuer, 2014

INSURANCE CARRIER	FORMULARY ANALYZED
Anthem*	Group
Blue Shield of California*	Group
CalPERS	Preferred Drug List
Health Net*	Group
Kaiser Permanente*	Group

*Report using the same formulary in the small and large group markets.

Endnotes

1. B. D. Sommers, "Insurance Cancellations in Context: Stability of Coverage in the Nongroup Market Prior to Health Reform," Health Affairs (Millwood) 33, no. 5 (May 2014): 887-94.
2. CHCF-supported independent analysis of Department of Managed Health Care (DMHC), Enrollment Summary Report – 2013, www.dmhc.ca.gov; California Department of Insurance (CDI), Covered Lives Report, www.insurance.ca.gov. Publication forthcoming.
3. Kev Coleman, "Almost No Existing Health Plans Meet New ACA Essential Health Benefit Standards," HealthPocket.com, September 28, 2014, www.healthpocket.com.
4. Although the ACA also creates exchange options for small businesses, this report focuses solely on the individual market.
5. Covered California Enrollment Statistics, April 17, 2014, 3.bp.blogspot.com.
6. The federal EHB requirement applies to all fully insured nongrandfathered health plans in the individual and small group market. It does not apply to self-funded plans, large group plans, or grandfathered plans. The full list of EHBs is as follows: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.
7. Drug counts reflect unique chemical entities, meaning that they combine brands and their generic equivalents as well as drugs with multiple formulations.
8. For 2014 and 2015, California's selected benchmark plan is Kaiser Foundation Health Plan Small Group HMO 30 ID 40513CA035, www.cms.gov.
9. The drug classes are defined by the US Pharmacopeial Convention (USP), a scientific nonprofit required by federal law to maintain a classification system whereby drugs are categorized based on their therapeutic uses.
10. 45 CFR 156.122.
11. Ibid.
12. 28 CCR 1300.67.24.
13. Building off the 24-hour exceptions process for exigent circumstances, in the November 2014 proposed 2016 Notice of Benefit and Payment Parameters, HHS proposed to create a standard 72-hour process for nonurgent drug exception requests. Furthermore, the proposed rule stipulates that if the exception is granted, any cost sharing would count toward the consumer's out-of-pocket maximum.
14. 28 CCR 1367.215.
15. 28 CCR 1300.67.24 and CIC §10112.27; see also 10 CCR 2594.4. Requirement applies to all nongrandfathered plans in the individual and small group markets and all managed care plans (regardless of market).
16. HSC §1367.22.
17. AB 1602, Chapter 655, Statutes of 2010.
18. Issuers are prohibited from offering catastrophic plans outside the exchange.
19. The California Department of Managed Health Care (DMHC) regulates health care service plans, which offer benefit coverage to their enrollees through health plan contracts. The California Department of Insurance (CDI) regulates health insurers, which offer benefit coverage to their enrollees through health insurance policies.
20. Individual Market Enrollment Data, Q1 2014 changes, August 20, 2014 meeting of Financial Solvency Board, Department of Managed Health Care. Market-wide figures for CDI-regulated plans are not available at this time.
21. One carrier is captured in the analysis that is not participating in Covered California in 2015.
22. One carrier uses separate Northern and Southern California formularies; for ease of analysis, the Northern formulary is used in this analysis as this formulary captures a larger share of enrollment. Differences between the Northern and Southern California formularies are nominal and would not materially impact the findings of this analysis.
23. Drug classes are based on the US Pharmacopeia Medicare Model Guidelines 5.0, which are the basis for the EHB drug count requirements.
24. Many Covered California plans operate across multiple regions in the state, including three plans that operate nearly statewide. As a result, researchers found very limited variation in results across regions.
25. Select employer plans include Anthem's large group formulary, Blue Shield of CA's large group formulary, CalPERS's preferred drug list, Health Net's large group formulary, and Kaiser Permanente's large group formulary, which is the same formulary as the small group formulary — the state-selected EHB benchmark.
26. Avalere analysis of Census Bureau Current Population Survey for 2013 Insurance Coverage.
27. Exchange data: Avalere PlanScape plan information from both federally facilitated and state-based exchanges in a sample of over 600 plans, updated November 2013. Employer data: Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2014 Annual Survey.
28. Jon Gabel et al., "Health Insurance Reforms: How Will They Affect Employment-Based Coverage in California?," UC Berkeley Center for Labor and Education, April 2012, laborcenter.berkeley.edu. "Large" is defined as 1,000+ employees; "small" is defined as 3 to 49 employees.

29. This excludes the 40% HDHP bronze standard plan. Cost-sharing subsidies that lower consumers' out-of-pocket costs are also available to individuals with incomes up to 250% of the federal poverty line who purchase a silver plan. This is referred to as the "enhanced silver" plan. See www.coveredca.com.
30. Also, as noted, consumers have access to an exceptions process to seek access to off-formulary medications.
31. P. E. Sax et al., "Adherence to Antiretroviral Treatment and Correlation with Risk of Hospitalization Among Commercially Insured HIV Patients in the United States," PLoS ONE 7 no. 2 (2012): e31591, doi:10.1371/journal.pone.0031591.
32. Note that at the time of analysis only three STRs were available on the market.
33. The Medicare "Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures" notes that CMS's formulary review focuses on best practices in existing drug benefits to ensure appropriate access for Medicare beneficiaries.
34. California Code §14105.43.
35. *Medicare Prescription Drug Benefit Manual,* Chapter 6: 24, www.cms.gov.
36. For Medicare Part D, CMS uses a specialty tier threshold of $600 per month based on the negotiated price; 2015 Call Letter, February 21, 2014, www.cms.gov.
37. The out-of-pocket limit for Covered California plans for the 2015 plan year will be $6,250.
38. Healthcare Blue Book "fair price" for Humira and Enbrel in Los Angeles, assuming 20% coinsurance.
39. This statistic represents individuals who finished their applications and selected plans through April 15, 2014. Covered California blog, April 17, 2014, news.coveredca.com.
40. 45 CFR 144, 146, 147, et seq. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016; Proposed Rule.
41. Ibid.
42. For 2014, the Medicare Part D specialty threshold is $600 for a 30-day supply of the medication.
43. While not the subject of this report, information about coverage for physician-administered drugs is especially challenging to find. Many plans do not list these drugs on formularies, which are typically limited to pharmacy-benefit products. As a result, consumers must navigate separate medical-benefit coverage policies, for which public availability is variable.
44. Senate Bill 1052 (Torres, 2014) approved by the governor on September 25, 2014.
45. At publication time, CMS has solicited comments on whether to mandate inclusion of cost information in published exchange formularies. CMS does not specify a planned implementation date for such a requirement.
46. Medicare Plan Finder tool: www.medicare.gov.
47. California HSC Code §1367.24.