Cancer Drug Coverage in Health Insurance Marketplace Plans

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Summary

This analysis examines two issues of particular interest to the American Cancer Society Cancer Action Network (ACS CAN) and its members: the extent of coverage and cost-sharing for cancer drugs, and whether information on the coverage of cancer drugs can be readily obtained, compared, and understood by patients.

To address these two areas of interest, we examined health plan prescription drug formularies available for the Qualified Health Plans (QHPs) of 62 health insurance issuers in five states and the District of Columbia.[1] For the two classes of cancer drugs we examined that consist solely of oral medications, we found that most Marketplace plans cover all 14 of the medications counted as part of essential health benefits. However, barriers to accessing prescription drugs remain in some plans as not all cancer drugs are covered on all plans, these drugs are frequently found on the plan's highest cost-sharing tier, and plans often require coinsurance and prior authorization.[2] In addition, we note that many new cancer drugs have been approved by the Food and Drug Administration (FDA) since the creation of the United States Pharmacopeia Medicare Model Guidelines (USP MMG) version 5.0, which was used by the Department of Health and Human Services (HHS) to assess plan formularies, and these new drugs are not included in the definition of essential health benefits or counts of covered drugs by class.

Cancer drugs typically administered by a physician, such as intravenous chemotherapy, are often not listed on formularies. This is likely because these drugs are covered under the medical, as opposed to the prescription drug, benefit. We were unable to find publicly-available lists of drugs covered under the medical benefit for plans not listing these drugs on their formulary.

While oral cancer drug coverage in the classes we examined appears to be fairly comprehensive across plans, cost-sharing design features vary widely. Therefore, it is critical for patients to be able to access and easily compare coverage and cost-sharing designs. We found, however, that cancer patients would face a difficult, and in some cases impossible, task in making apples-to-apples comparisons of health plans based on drug coverage. Healthcare.gov provides a link to plan formularies in the window-shopping function,[3] but issuers have not consistently provided

[1] Data are as of January 17, 2014. Hereafter, we use the term "issuers" to refer to health insurance issuers. For the purposes of this paper, a health insurance issuer is a health insurance company licensed in a particular state. For example, Aetna in Florida and Aetna in Texas would be two issuers.

[2] Prior authorization requires a patient or their provider to request permission from the health plan before obtaining a covered prescription drug.

[3] A window-shopping function allows consumers to view available health plans without submitting an application.

direct links to these formularies,[4] and many issuers do not provide an exhaustive list of all covered drugs. California and New York do not have a window-shopping function, and the District of Columbia's window-shopping function does not include web links to formularies, so data for these states had to be gathered directly from issuer websites. Issuers do not use a common organizational structure for formularies, making comparisons difficult. Finally, the lack of information on medical benefit drugs may make it impossible for cancer patients to find out if their intravenous chemotherapy is covered.

Based on these findings, we recommend that HHS, State Departments of Insurance, and State-based Marketplaces improve formulary transparency, develop standardized cost-sharing designs that use copays rather than coinsurance, and conduct robust oversight of prescription drug benefits.

Background

An estimated 1.7 million Americans will be diagnosed with cancer in 2014, and approximately one-half of all American men and one-third of all American women will develop cancer at some point in their lifetime.[5] In 2009, direct medical spending for cancer in the US was $86.6 billion.[6] While private or public insurance provides coverage for many cancer patients, these patients often face high out-of-pocket costs due to their plans' cost-sharing requirements or coverage limitations. In addition, with the increase in availability of oral chemotherapy medications, more cancer patients are relying on their prescription drug benefits to cover their chemotherapy regimens. Therefore, it is critically important for cancer patients to be able to access clear, consistent, and comparable information on prescription drug coverage and cost-sharing, including coverage of physician-administered drugs, in order to choose a health plan. Prior to the implementation of the Affordable Care Act (ACA), such information was not widely available, but various ACA provisions aim to improve the comprehensiveness, comparability, and transparency of health plan benefits for Marketplace and non-Marketplace plans.

The ACA requires that all non-grandfathered health plans in the individual and small group markets cover essential health benefits, which includes prescription drugs.[7] Through regulation, HHS requires that states define essential health benefits by reference to a benchmark plan for the 2014 and 2015 benefit years. The federal implementing rules gave the states several options for benchmark plans, including the largest small group plans in the state and the largest state employee health plans. The benchmark policy requires that, as of January 1, 2014, all

[4] On February 4, 2014, the Centers for Medicare and Medicaid Services published the "Draft 2015 Letter to Issuers in the Federally-facilitated Marketplace." This letter proposes to collect direct formulary links from all issuers in the Federally-facilitated Marketplace for the 2015 plan year. The guidance in this letter does not apply to State-based Marketplaces.

[5] American Cancer Society, *Cancer Facts and Figures 2014*. Available at: http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-041770.pdf.

[6] American Cancer Society, *Cancer Facts and Figures 2014*. Available at: http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-041770.pdf.

[7] Prior to the Affordable Care Act, many plans did not cover prescription drugs or other key benefits. See http://aspe.hhs.gov/health/reports/2011/IndividualMarket/ib.shtml.

health plans in the individual and small group markets in a state cover substantially the same benefits as the state benchmark plan. For prescription drugs, all plans in a state's individual and small group markets must cover a particular number of drugs in each category and class, with the number of drugs set by the state's chosen benchmark.[8] In no case can a plan cover less than one drug in a given class. The federal essential health benefits regulation does not require coverage of any particular drugs, nor does it require coverage of drugs on any particular formulary tier. The coverage of essential health benefits, including prescription drugs, is subject to non-discrimination requirements that prevent benefit designs or issuer practices from discriminating against individuals based on their age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

The Affordable Care Act also seeks to improve transparency and comparability in health benefits through the Health Insurance Marketplace and consumer-friendly tools such as the standardized summary of benefits and coverage. All but one Marketplace, however, rely on links to issuer websites to provide prescription drug formulary information.[9] Also, while the Affordable Care Act standardizes cost-sharing levels through the use of actuarial value targets and a cap on out-of-pocket expenses, issuers have designed plans with a wide variety of cost-sharing requirements for specific drugs and services. Some states, including California and New York,[10] have pursued more standardized cost-sharing to help consumers more easily compare plans.

Methodology

To determine the availability of plan formulary information in the Marketplace, as well as the cost-sharing requirements for cancer drugs, we examined the prescription drug formularies for all Marketplace health insurance issuers in five states and the District of Columbia.[11] These five states include California, Florida, New York, Ohio, and Texas. We chose these states to represent a mix of geographic regions and Federally-facilitated and State-based Marketplaces.

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[8] For further information, see the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation final rule at http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf. HHS provides a drug count service for issuers to determine that the correct number of drugs is covered. Details on the methodology for this tool are available at http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf.

[9] Only the Nevada Marketplace has a drug search tool for consumers. It is unclear if some State-based Marketplaces include formulary links, as plans can only be viewed after completing an application. For a review of the window-shopping functions of all Marketplace websites, see Families USA. Evaluating the Consumer Window-Shopping Experience in Health Insurance Marketplace Websites: A Comparative Analysis. January 2014. Available at: http://www.familiesusa.org/marketplace-window-shopping/?src=partners.

[10] New York allows non-standard plans to be sold in the Marketplace as well. However, the New York State of Health website does not allow window shopping, so we were unable to determine the characteristics of non-standard plans. A separate New York law that applies to all comprehensive health plans limits prescription drug coverage to three tiers.

[11] Data are as of January 17, 2014. Nearly all health insurance issuers are using one formulary for the entire state. The only exception is Humana, which appears to have both a 4-tier and a 5-tier formulary. This analysis focused on the 4-tier Humana formulary. In total, this analysis includes one formulary from each of 62 issuer-state combinations. For issuers excluded due to lack of formulary information, see Appendix A.

In addition, California, New York, Texas, and Florida have the highest expected cancer incidence in the United States for 2014.[12]

To access formularies, we used links provided by the Federally-facilitated Marketplace QHPs to healthcare.gov. For the State-based Marketplaces, we searched issuer websites, as none of the states provided a window-shopping function that included prescription drug formulary links. We used state press releases to determine the complete list of issuers offering coverage on each State-based Marketplace.[13] For our qualitative analysis, we tracked formulary problems such as indirect links, incomplete listings, non-searchable formularies, lack of clarity on plans to which the formulary applies, lack of tier or other cost-sharing information, and disclaimer language indicating that the formulary may be incomplete or could be changed at any time.

Our quantitative analysis focused on four classes of cancer drugs in the antineoplastic category, totaling 21 distinct chemical entities on the USP MMG 5.0: antiangiogenic agents, enzyme inhibitors, molecular target inhibitors, and monoclonal antibodies (See Table 1 for descriptions).[14] To illustrate the variety of plan design options facing patients, we summarized the cost-sharing provisions of silver plans in Florida, Ohio, and Texas and compared them to the standardized benefit packages in California and New York. A complete discussion of our methodology is available in Appendix A.

Table 1: Descriptions of chosen cancer drug classes

	Description of drug action	**Examples of cancers treated**	**Reason selected**
Antiangiogenic agents	Prevent formation of new blood vessels, which can stop or slow cancer growth or spread.	Multiple myeloma, mantle cell lymphoma	3 state benchmarks had no coverage in this class.
Enzyme inhibitors	Bind to enzymes necessary for cell duplication, which prevents cancer cells from proliferating.	Small cell lung cancer, testicular cancer, cervical cancer, ovarian cancer	4 state benchmarks had no coverage in this class.

[12] American Cancer Society, *Cancer Facts and Figures 2014*. Available at: http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-041770.pdf.

[13] For California, a complete list of issuers is available at: https://www.coveredca.com/hbex/insurance-companies/. For DC, see http://hbx.dc.gov/publication/january-2014-rates-plans-dc-health-link. For New York, see http://www.healthbenefitexchange.ny.gov/sites/default/files/Health%20Plan%20Provider%20Networks_3.pdf

[14] The HHS drug count service includes thee monoclonal antibodies. However, the USP MMG 5.0 lists only two. We have supplemented with two additional drugs listed by some issuers as monoclonal antibodies. To the extent possible, we have used the methodology outlined by CMS at http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf.

	Description of drug action	Examples of cancers treated	Reason selected
Molecular target inhibitors	Interfere with specific molecules involved in cancer growth and/or progression.	A wide variety of cancers, including certain breast, kidney, pancreatic, liver, thyroid, skin, and lung cancers, as well as certain leukemias and sarcomas	USP MMG 6.0 nearly doubles the number of drugs in this class.
Monoclonal antibodies	Bind to specific substances on cancer cells.	A wide variety of cancers, including certain breast, colorectal, brain, lung, kidney, and stomach cancers, as well as certain leukemias and lymphomas	21 state benchmarks had no coverage in this class.

Results

Availability and Transparency of Formulary Information

To analyze the placement of cancer drugs on Marketplace plan formularies, we used the formulary links provided in the downloadable health plan data available on healthcare.gov. These links are the same as those that appear in the window-shopping function and in the post-application plan compare function on healthcare.gov.

None of the states in this analysis include formulary information directly on the Marketplace website. Only one state, Nevada, has developed a tool to allow consumers to filter plans on the Marketplace by coverage of their prescription drugs, though this tool does not include cost-sharing information.

Of the 32 issuers examined in Federally-facilitated Marketplace states (Florida, Ohio and Texas), three only provide links to their homepage in the formulary link field, leaving patients to hunt for formularies. One issuer left the formulary link field blank, and a search of that issuers' website yielded only a list of covered drugs with no cost-sharing information. An additional issuer provides a formulary so limited that it listed none of the cancer drugs we examined, and one issuer provides no information on drug tiers.

The three State-based Marketplaces (California, the District of Columbia, and New York) do not provide a window-shopping function, so we searched issuer websites directly for formularies. We were unable to find sufficient formulary information to complete our analysis for one issuer in California and one issuer in New York. In addition, one issuer in California and one issuer in the District of Columbia do not provide information on drug tiers.

Even among the issuers that provide more direct formulary links, most provide links to PDFs that, to varying degrees, are incomplete or not uniformly applicable to all plans according to disclaimers on the documents themselves. [15] In addition, nearly all PDFs state that drug coverage could change at any time. Many formularies refer consumers to the members-only section of the website for more complete formulary information, meaning that complete information would only be available after a plan was purchased. While some issuers indicate specifically that the formulary applies to Marketplace plans, others provide no or limited information on the specific plans to which the formulary applies.

Aetna, Cigna, Coventry, and Humana consistently provide drug search tools with complete formularies including drug cost-sharing tiers, though it is not always possible to tell whether the formularies apply to all Marketplace plans. In addition, the searchable formularies sometimes display confusing or inconsistent information, such as listing intravenous drugs as "not covered" without any indication that these drugs may be covered under the medical plan.

In general, patients would find it difficult or impossible to make apples-to-apples comparisons of prescription drug coverage across Marketplace plans. There is no consistent formulary display format across issuers, and issuers use a variety of category and class systems and drug cost-sharing tier structures. Formularies in our sample have anywhere from three to five drug cost-sharing tiers, and some formularies have special designations for intravenous drugs or oral medications available only through specialty pharmacies. The window-shopping function on the healthcare.gov lists cost-sharing for only four tiers of drugs, however, so it is unclear how patients would match a 5-tier formulary to the cost-sharing information provided.[16] No issuer provides a drug-by-drug list of copays or coinsurance rates for each plan, so patients would have to match up formulary information to cost-sharing data to calculate their potential costs.

Finally, cancer patients will find it nearly impossible to determine which plans cover their intravenous chemotherapy regimens, as these drugs are often covered on the medical benefit and are therefore not listed consistently on the formulary. We were unable to find a list of covered medical-benefit drugs from any issuer.

Placement of Cancer Drugs on Formularies

Despite the difficulties in accessing formularies, we were able to determine the coverage of at least some of the 21 cancer drugs on 62 formularies. Across the five states and the District of

[15] For example, see the formulary for Blue Cross Blue Shield of Florida at http://www.bcbsfl.com/DocumentLibrary/Providers/Content/MedGuide.pdf.

[16] The Summary of benefits and Coverage similarly only lists 4 cost-sharing tiers, though issuers have the flexibility to modify the format if they use additional tiers.

Columbia, most plans cover a significant number of orally-administered cancer drugs in the four classes examined. Coverage of intravenous drugs, which are prevalent in the enzyme inhibitor and monoclonal antibodies classes, is less clear, potentially because those drugs are covered under the medical benefit.

The 14 cancer drugs in the two classes we examined consisting exclusively of oral medications are generally covered. Both of the antiangiogenic agents are covered on 59 of the 62 formularies examined, and all 12 molecular target inhibitors are covered on 48 of the 62 formularies (See Table 2). However, these drugs are very frequently placed on the plan's highest cost-sharing tier (see Table 3), and most plans require prior authorization for nearly all of these cancer medications. Among the 21 drugs we examined, plans covering these drugs require prior authorization 84 percent of the time. For the 14 oral medications discussed above, plans covering these drugs require prior authorization 92 percent of the time. Plans also frequently require that these medications be obtained through a specialty pharmacy.

While coverage is broad in the oral chemotherapy classes we examined, we found some gaps in specific plans. In every state, at least one plan appears to cover fewer drugs than the benchmark in at least one class. In the two classes consisting entirely of oral medications, it is unlikely these drugs are covered under the medical benefit. It is possible, however, that the posted formularies are incomplete.

For molecular target inhibitors, we note that many new drugs have been approved by the FDA in the past two years, but these drugs are not listed in the USP MMG 5.0 and are therefore not counted in the benchmarks or as part of the essential health benefits process. For example, the USP MMG 6.0 includes 22 molecular target inhibitors, as opposed to the 12 counted as part of essential health benefits. [17]

Table 2 below shows the average, minimum, and maximum number of drugs covered in each of the four classes we examined as compared to each state's essential health benefits benchmark plan. Table 3 shows similar information for each specific drug, including placement on cost-sharing tiers.

[17] See http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2013-09-27_usp_mmg_v6_draft3.pdf.

Table 2: Coverage of Four Antineoplastic Classes by State

		Antiangiogenic Agents	***Enzyme Inhibitor***	**Molecular Target Inhibitor**	***Monoclonal Antibodies***
CA - 10 issuers	Benchmark	2	3	12	1
	Average Listed	1.9	1.9	11.6	1.5
	Maximum Listed	2	3	12	4
	Minimum Listed	1	0*	10	0*
DC - 3 issuers	Benchmark	2	1	12	1
	Average Listed	2	1.3	12	0*
	Maximum Listed	2	2	12	0*
	Minimum Listed	2	0*	12	0*
FL - 10 issuers	Benchmark	2	1	12	1
	Average Listed	2	2	11.5	1.4
	Maximum Listed	2	3	12	4
	Minimum Listed	2	0*	10	0*
NY - 17 issuers	Benchmark	2	1	11	1
	Average Listed	1.9	2.7	11.8	1.2
	Maximum Listed	2	4	12	4
	Minimum Listed	1	2	10	0*
OH - 12 issuers	Benchmark	2	3	12	3
	Average Listed	2	2.6	11.2	1.9
	Maximum Listed	2	3	12	4
	Minimum Listed	2	1	8	0*
TX - 10 issuers	Benchmark	2	1	12	1
	Average Listed	2	2.1	11.8	1.3
	Maximum Listed	2	3	12	4
	Minimum Listed	2	1	11	0*

NOTES: In California, DC, and Ohio, Kaiser Permanente provided a list of covered drugs but not an indication of drug tiering structure. Therefore, in these three states, Kaiser Permanente is included in this table but not Table 3 below. In addition, Medical Mutual in Ohio also only provided a list of covered drugs and no indication of tiering structure, so it is similarly included in this table and excluded from Table 3 below. For a complete list of excluded issuers, see Appendix A.

*The enzyme inhibitor and monoclonal antibodies classes contain IV drugs typically administered by a physician. Many of the enzyme inhibitors are also available via oral capsule. Apparent gaps in coverage in these classes may be due to drugs being covered under the medical benefit. This analysis focused exclusively on publicly available formularies, as we were unable to find any publicly available list of prescription drugs covered under the medical benefit.

Table 3: Coverage of four classes of cancer medications in 5 states and the District of Columbia

Drug Name (Brands in all caps)	Class	CA - 9 issuers		DC - 2 issuers		FL - 10 issuers		NY - 17 issuers		OH - 10 issuers		TX - 10 issuers	
		Percent Listed	Percent on Tier 4+	Percent Listed	Percent on Tier 3	Percent Listed	Percent on Tier 4+	Percent Listed	Percent on Tier 3	Percent Listed	Percent on Tier 4+	Percent Listed	Percent on Tier 4+
REVLIMID	Antiangiogenic Agents	100%	100%	100%	50%	100%	80%	100%	71%	100%	100%	100%	90%
THALOMID	Antiangiogenic Agents	89%	100%	100%	50%	100%	80%	88%	73%	100%	100%	100%	90%
ETOPOPHOS	*Enzyme Inhibitors*	33%	100%	0%	n/a	40%	75%	59%	30%	70%	86%	20%	100%
Etoposide	Enzyme Inhibitors	100%	56%	50%	0%	90%	56%	82%	7%	100%	50%	100%	70%
Topotecan	*Enzyme Inhibitors*	78%	86%	50%	0%	70%	71%	100%	41%	90%	67%	90%	89%
AFINITOR	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	82%	90%	100%	100%	90%
GLEEVEC	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	53%	100%	100%	100%	90%
INLYTA	Molecular Target Inhibitors	78%	100%	100%	50%	80%	75%	82%	86%	70%	100%	90%	89%
NEXAVAR	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	82%	100%	100%	100%	90%
SPRYCEL	Molecular Target Inhibitors	100%	100%	100%	50%	90%	78%	100%	76%	90%	100%	90%	89%
SUTENT	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	82%	100%	100%	100%	90%
TARCEVA	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	71%	100%	100%	100%	90%
TASIGNA	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	82%	100%	100%	100%	90%
TYKERB	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	82%	100%	100%	100%	90%
VOTRIENT	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	88%	90%	100%	100%	90%
XALKORI	Molecular Target Inhibitors	100%	100%	100%	50%	100%	80%	100%	88%	90%	89%	100%	90%
ZELBORAF	Molecular Target Inhibitors	100%	100%	100%	50%	80%	75%	94%	88%	80%	100%	100%	90%
ARZERRA	*Monoclonal Antibodies*	11%	100%	0%	n/a	30%	100%	12%	100%	70%	100%	30%	100%
AVASTIN	*Monoclonal Antibodies*	11%	100%	0%	n/a	30%	100%	18%	100%	10%	100%	20%	100%
HERCEPTIN	*Monoclonal Antibodies*	22%	100%	0%	n/a	30%	100%	18%	100%	20%	100%	20%	100%
RITUXAN	*Monoclonal Antibodies*	56%	100%	0%	n/a	50%	100%	76%	100%	90%	100%	60%	100%

NOTES: All plans offered in DC and New York have only 3 drug cost-sharing tiers. Drugs in italics are intravenous, though topotecan is also available in capsule form. Drug names in all caps are brand names. This list represents the distinct chemical entities we believe are counted by the essential health benefits formulary count service, to the extent it could be determined. The drug count service includes only three monoclonal antibodies, but we were unable to determine which three are represented in that count service. For further information, see Appendix A.

Cost-Sharing Requirements for Cancer Drugs

Table 3 shows that most of the cancer drugs we examined are covered on the highest cost-sharing tiers. Therefore, we examined cost-sharing provisions for specialty or tier 4 prescription drugs across individual silver plans in Florida, Ohio, and Texas, as well as the standard benefit designs in California and New York.[18] We supplemented this analysis with the average silver plan cost-sharing provisions for all 36 states using healthcare.gov. We focused on silver plans as they currently account for 62 percent of all Marketplace enrollments.[19] The second lowest cost silver plan is also the benchmark for the premium assistance available to those between 100 and 400% federal poverty level (FPL).

In California, individual silver plans are required to have a $250 drug deductible, a $2,000 medical deductible, and standard 20 percent coinsurance on specialty drugs. New York requires a standard silver plan design that has a $2,000 combined deductible and copays of $70 after the deductible for the highest-tier prescription drugs.[20] New York also requires plans to have no more than three prescription drug tiers.

In Florida, Ohio, and Texas, cost-sharing designs are much more varied. In Florida, over 80 percent of unique silver plans have a separate medical and prescription drug deductible.[21] In Ohio, 53 percent of plans have separate deductibles, and in Texas 64 percent of plans have separate deductibles. Across all three states, drug deductibles vary from $0 to $1,500, and medical deductibles vary from $0 to $6,250 for a silver plan. In all three states, the use of separate medical and drug out-of-pocket maximums is less pronounced.[22] In Florida, 27 percent of plans have a separate medical and drug out-of-pocket maximum, compared to 16 percent in Ohio and none in Texas. Combined out-of-pocket maximums, which are most common, vary from $3,000 to $6,350 (the legal maximum). In addition, cost-sharing for specialty tiers varies from a $150 copay to 50 percent coinsurance, with coinsurance used in 73 percent of plans across all three states.

Cost-sharing reduction plans are available to enrollees with incomes between 100 and 250 percent of the FPL, and these silver-level plans have reduced deductibles, out-of-pocket maximums, and other cost-sharing. The differences across plans noted above persist for cost-

[18] We did not include a sample plan for the District of Columbia because downloadable data was not available and DC has not implemented standard plan designs.

[19] ASPE. *Health Insurance Marketplace: February Enrollment Report.* Available at: http://aspe.hhs.gov/health/reports/2014/MarketPlaceEnrollment/Feb2014/ib_2014feb_enrollment.pdf.

[20] New York allows non-standard plans to be sold in the Marketplace as well. However, the New York State of Health website does not allow window shopping, so we were unable to determine the characteristics of non-standard plans. A separate New York law that applies to all comprehensive health plans limits prescription drugs to three tiers, but that law allows for the application of coinsurance rather than copays.

[21] Unique plans refers to plans with a unique identifier or plan name in the healthcare.gov database, regardless of rating area.

[22] While not specified in regulation, the actuarial value calculator allows for the application of separate medical and drug out-of-pocket maximums in QHPs as long as the total out-of-pocket maximum amount does not exceed $6,350.

sharing reduction plans.[23] These plans use separate deductibles with the same frequency as standard silver plans, though the deductibles range was lower at $0 to $1,750 for medical and $0 to $500 for drugs. These plans also use separate out-of-pocket maximums just as frequently as standard silver plans, with combined out-of-pocket maximums between $1000 and $2250. The cost-sharing variation plans are slightly less likely to use coinsurance for specialty tier drugs, with 68 percent using coinsurance.

More broadly, among the 877 silver plans available for all 36 states on healthcare.gov, 54 percent (471 plans) have a separate drug deductible. For these plans, the average individual drug deductible is $442, the average medical deductible is $3,183, and the average out-of-pocket maximum is $6,010.[24] Seventy-two percent of these plans require coinsurance after the deductible for their highest-tier prescription drugs, with an average coinsurance rate of 35.7 percent.

For those 406 plans with a unified medical and drug deductible, the average individual deductible is $2,232 and the average out-of-pocket maximum is $5,483. Sixty-seven percent of these plans require coinsurance after the deductible for their highest-tier prescription drugs, with an average coinsurance rate of 29.3 percent.

Table 4 shows sample plans from Florida, Ohio, and Texas, as well as the standard plans from California and New York, to illustrate how cost-sharing varies across plans.

Table 4: Variation across Plans, Sample of Cost-Sharing Designs

Plan Design and Sample Out-of-Pocket Costs	Florida Sample Plan	Ohio Sample Plan	Texas Sample Plan	California Standard Plan	New York Standard Plan
Medical Deductible	$5,000	$3,000	$4,600	$2,000	$2,000
Drug Deductible	$0	N/A	$1,500	$250	N/A
Maximum out-of-pocket	$6,250	$6,350	$6,300	$6,350	$5,500
Specialty drug cost-sharing after deductible	$150	25%	50%	20%	$70

The Florida, Ohio, and Texas sample plans were chosen because they were the most common unique plan design.

To illustrate how this cost-sharing variation might affect cancer patients, we determined one-month out-of-pocket costs for a patient taking Gleevec for chronic myelogenous leukemia (CML).[25] We chose this particular scenario for simplicity: Gleevec must be taken for an entire

[23] Our analysis focused on the 87 percent cost-sharing variation, which is available to enrollees in silver plans with incomes between 150 and 200 percent of the FPL.

[24] Nearly 10% of plans with separate medical and drug deductibles also used separate medical and drug out-of-pocket maximums. Among those with a separate out-of-pocket maximum, the drug portion averaged $1,503. In the Marketplaces, plans are allowed to use separate medical and drug out-of-pocket maximums as long as the total of the two does not exceed $6,350.

[25] Prices are from http://www.mskcc.org/sites/www.mskcc.org/files/node/25097/documents/chemo-prices-methods-bach-center-health-policy-and-outcomes-v3.pdf in 2013 dollars. Gleevec is $4,462 per month. Prices are illustrative only and do not reflect changes in price since FDA approval or negotiation between health plans and pharmaceutical companies.

lifetime after CML diagnosis, and it is possible that a patient with CML on Gleevec would have no other costs in a given month. In the Florida plan, a patient taking Gleevec would pay only $150 for their first month, as there is no drug deductible and the prescription drug specialty tier uses copays. However, this patient would still have a $5,000 medical deductible if he or she needed medical services. In the Ohio plan, the same patient would pay $3,366 for the first month's supply of Gleevec, but would satisfy the entire combined deductible in the process. The Texas plan would require an out-of-pocket cost of $2,981 for the first month's supply of Gleevec, and leave the patient with a remaining $4,600 deductible for medical services. The New York Plan would require $2,070 in cost-sharing for the first month of Gleevec, but that cost would satisfy the patient's combined deductible for the remainder of the year.

As this example illustrates, cancer patients attempting to choose the best plan for them face a difficult challenge, even after confirming that their drugs are covered. The wide variety of cost-sharing designs at the silver level, combined with the variety of services used by cancer patients, would make it very difficult for patients to choose the best plan for them.

In general, plans using copays for prescription drugs and commonly used services have more predictable out-of-pocket expenses for patients, because the out-of-pocket cost does not depend on the underlying cost of the drug or service. When choosing plans, patients do not have access to information on the total cost of services or drugs, or the discounts negotiated by issuers, so they are unable to accurately calculate out-of-pocket costs or compare plans that use coinsurance.

While the out-of-pocket maximum lends significant annual protection to cancer patients, it still represents a significant portion of annual income for Marketplace enrollees. For a patient at 350 percent of the FPL, for example, a $6,350 out-of-pocket maximum would represent nearly 16 percent of annual income. Therefore, it is critical that patients have access to tools that allow them to easily compare plans based on total costs, including both premium and out-of-pocket costs. The lack of transparent information from issuers and consumer-friendly tools on healthcare.gov and most other State-based Marketplace websites prevents consumers from effectively weighing their options and choosing the best plan for them. In addition, the number of factors that can vary between plans, including cost-sharing and covered benefits and drugs, make it difficult for patients to synthesize the necessary information even under the best of circumstances. This is particularly a concern for cancer patients, who need to consider benefits and coverage for a wide variety of services, including prescription drugs, hospitalization, and subspecialists.

Conclusions

Overall, the inconsistency and incompleteness of formulary information available from issuers in the Marketplace poses a significant problem for cancer patients. It is simply not possible for patients with significant prescription drug needs to make an apples-to-apples comparison of Marketplace plans in the states we examined. The essential health benefits and actuarial value policies provide some standardization of prescription drug coverage and cost-sharing, but issuers have created a wide variety of Marketplace plan designs. Cost-sharing for specific drugs

and services, in particular, varies widely, complicating choices for cancer patients. Without clear, consistent, complete, and up-to-date formulary and cost-sharing information, patients will be unable to determine the best plan for them.

Our analysis shows that while many oral cancer drugs are covered, issuers frequently place the drugs on the highest cost-sharing tier and require coinsurance, rather than copays. There is significant variation in cost-sharing structures even within silver plans, so patients need access to clear, comprehensive information and cost estimation tools in order to make plan decisions. We also found that cancer drugs often require prior authorization and must be purchased at specialty pharmacies, and we intend to monitor those plan requirements to determine whether they present a significant barrier for cancer patients.

Finally, while most of the oral cancer drugs were covered by most plans, some plans have coverage gaps and appear to be covering fewer than the required number of drugs. In addition, many new drugs have come to market in the past two years that are not included in the USP MMG 5.0. If HHS continues to use the USP MMG 5.0, these new drugs will not be counted in benchmarks or in Marketplace plans, potentially allowing significant gaps in some classes.

We therefore provide three recommendations with regard to prescription drug benefits: transparency, standardized benefits, and robust oversight.

Recommendations

Transparency

We strongly recommend that states and HHS collect and display prescription drug formularies, including drugs covered under the medical benefit,[26] in a comparable, consistent, and searchable manner. Links to issuer websites are insufficient to allow consumers to make apples-to-apples comparisons of plans, and a significant subset of issuers have provided only general links or incomplete formularies. We further recommend that HHS and State-based Marketplaces develop out-of-pocket cost calculators as required by the Affordable Care Act. A major goal of the Affordable Care Act is to increase insurance market competition by enabling consumers to more completely and accurately compare plans, but the lack of comparable formulary information and tools to estimate total costs significantly undermines that goal.

> **Medicare as a Model**: The Medicare Plan Finder, which allows Medicare beneficiaries to enter their drugs and see examples of out-of-pocket costs for each plan option, provides a model for displaying formulary information collected by HHS or the states. The Plan Finder also automatically incorporates reduced cost-sharing for low-income enrollees. Only one state, Nevada, currently provides formulary information on the Marketplace website. Nevada's prescription medication search allows users to see which plans cover

[26] On February 4, 2014, the Centers for Medicare and Medicaid Services published the "Draft 2015 Letter to Issuers in the Federally-facilitated Marketplace." This letter proposes to collect drugs covered under the medical benefit for the drug count service used by CMS to ensure that plans are covering the required number of drugs in each category and class.

their prescription drugs. It does not, however, provide information on the cost-sharing requirements for those drugs, which is a key strength of the Medicare Plan Finder.

Standardized Formularies: We recognize that a tool similar to the Medicare Plan Finder may take time to develop. We therefore recommend that states and HHS immediately pursue formulary display requirements for plans. Plans should, at a minimum, provide a list of all covered drugs, including those covered under the medical benefit; use a standard organizational structure that includes the cost-sharing for each drug; update formularies frequently; and provide a description of the process to request a non-formulary drug.

Cost Calculators: The Affordable Care Act requires Marketplaces to develop a calculator to determine the total cost of coverage.[27] We recommend that HHS and State-based Marketplaces develop a cost calculator tool that allows for a variety of consumer inputs and includes both premiums and out-of-pocket costs. Without such a tool, patients will be unable to navigate the wide variety of cost-sharing structures and choose the best plan for them.

Data Transparency: As part of the QHP certification process, HHS collects a list of all covered drugs to ensure that plans meet the required counts in each category and class. We recommend that HHS release this data, along with any cost-sharing information collected, to allow third parties to develop tools to help consumers compare plans. To the extent that states also collect this information, we recommend release of this data by Departments of Insurance or State-based Marketplaces.

Standardized Benefits

The actuarial value requirements of the ACA provide for some standardization of cost-sharing across plans at the same metal level. However, issuers have created a wide variety of plan designs that differ significantly in cost-sharing for specific services. States like California and New York have created standardized plans at each metal level to allow enrollees to more easily compare plans.[28] We recommend that states and HHS pursue plan standardization through their authority to approve QHPs for sale on the Marketplaces, as standardization reduces the number of factors patients must consider when choosing a plan. In addition, we recommend this standardization emphasize the use of copays rather than coinsurance.

Copays, Not Coinsurance: Copays are more predictable for patients, and are therefore a better tool to help patients understand and compare their coverage options. When shopping for plans, patients do not know the prices for individual drugs or services, or the discounts negotiated by each issuer. Therefore, patients cannot easily estimate the out-of-pocket costs associated with coinsurance, and cannot directly compare two plans

[27] Section 1311(d)(4)(G) of the Affordable Care Act requires Exchanges to: "Establish and make available by electronic means a calculator to determine the actual cost of coverage after the application of any premium tax credit under section 36B of the Internal Revenue Code of 1986 and any cost sharing reduction under section 1402."

[28] We note that New York also allows non-standard plan designs on its Marketplace, New York State of Health.

with similar coinsurance rates. We therefore recommend that standardized benefits for QHPs focus on copays for prescription drugs and commonly-used services.

Robust Oversight

Currently, the approach to prescription drug benefits in the Marketplaces focuses on the number of drugs covered, rather than on the quality of the benefit provided. We recommend that states and HHS begin in-depth reviews of formularies for clinical appropriateness, coverage gaps, and non-discrimination to inform essential health benefits requirements for the 2016 plan year. We further recommend that HHS update to the USP MMG 6.0 for the 2015 plan year.

Update to USP MMG 6.0: We recommend that HHS adopt the USP MMG 6.0 for the 2015 plan year to avoid using an outdated drug list to determine adequacy of drug benefits. The USP MMG 6.0 adds an additional class of antineoplastic drugs, antiandrogens, which includes drugs to treat prostate cancer.[29] In addition, USP MMG 6.0 nearly doubles the number of drugs in the molecular target inhibitors class from 12 in the current HHS drug count service to 22. In most states, the current benchmark for coverage of molecular target inhibitors is 12 drugs. If HHS does not update to the USP MMG 6.0, these new drugs will not be considered part of the essential health benefit requirements.

Even if plans do choose to cover these new medications, it is unclear how regulators will assess the adequacy of formulary designs or determine that plan designs are non-discriminatory when using an outdated benchmark and classification system to make comparisons. Many of the new drugs approved to treat cancer are highly specific to the type and cause of cancer, which means issuers could discriminate against patients with a particular diagnosis by leaving just a handful of new cancer drugs off their formularies.

Non-Discrimination and Formulary Adequacy: While we recognize that HHS conducts and will continue to conduct outlier analysis on QHP cost-sharing and utilization management,[30] this type of analysis is insufficient to detect widespread discrimination against patients with expensive, complex conditions such as cancer. States and HHS must improve the tools they use to detect inadequate or discriminatory plan designs. We recommend that HHS and states undertake a thorough non-discrimination review of formularies and plan designs focused on high-cost conditions such as cancer. This review should not focus exclusively on finding "outlier" plans, but should examine the market to determine whether patients with certain conditions are subject to disproportionately higher cost-sharing or utilization management regardless of issuer. The results of this review should be released publicly and should inform both the QHP approval processes and rulemaking for essential health benefits.

[29] See http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2013-09-27_usp_mmg_v6_draft3.pdf.

[30] Centers for Medicare and Medicaid Services. Draft 2015 Letter to Issuers in the Federally-facilitated Marketplace. February 2014. Available at http://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/draft-issuer-letter-2-4-2014.pdf.

Appendix A: Methodology

We examined formularies in five states and the District of Columbia, chosen to represent a mix of geographies and State-based and Federally-facilitated Marketplaces. In addition, California, New York, Texas, and Florida had the highest projected number of new cancer diagnoses in the United States in 2014. We attempted to find formularies for all issuers in each of these states, but we had to exclude several issuers due to incomplete or inaccessible formulary information. The excluded issuers are: United Healthcare in New York; Sharp Health Plan in California; and Firstcare Health Plan in Texas. We did not encounter any health insurance issuers using separate formularies for different plans or regions, with the exception of Humana. However, Humana used only two formularies, a 4-tier and a 5-tier version, each of which covered most cancer medications on the highest tier. Finally, Kaiser Permanente and Medical Mutual of Ohio did not provide tiering information on their formularies, so these four issuers were included in Table 2 but not Table 3.[31] All data are as of January 17, 2014.

To narrow our formulary search, we focused on four classes of drugs in the antineoplastic category. We used the USP MMG 5.0, as it is the classification system required by the essential health benefits rule. We chose to investigate the following four classes of antineoplastic drugs: antiangiogenic agents, enzyme inhibitors, molecular target inhibitors, and monoclonal antibodies. We chose antiangiogenic agents, enzyme inhibitors, and monoclonal antibodies because several states require that only one drug be covered in these classes under essential health benefits. The fourth category, molecular target inhibitors, was chosen because a large number of new drugs are proposed to be added to the class in the USP MMG 6.0. If HHS does not update its Marketplace benchmarks and drug count services to USP MMG 6.0, there could be significant coverage gaps in this class. Table 5 below shows the cancers treated by each drug in these four classes.

Table 5: Cancers Treated by Four Classes of Antineoplastic Drugs

Drug Name (Brands in all caps)	Class	Cancers Treated
REVLIMID	Antiangiogenic Agents	Mantle cell lymphoma, multiple myeloma, anemia caused by myelodysplastic syndrome
THALOMID	Antiangiogenic Agents	Multiple myeloma
ETOPOPHOS	Enzyme Inhibitors	Small cell lung cancer, testicular cancer
Etoposide	Enzyme Inhibitors	Small cell lung cancer, testicular cancer
Topotecan	Enzyme Inhibitors	Cervical cancer, ovarian cancer, small cell lung cancer
AFINITOR	Molecular Target Inhibitors	Breast cancer, pancreatic cancer, renal cell carcinoma, subependymal giant cell astrocytoma
GLEEVEC	Molecular Target Inhibitors	Acute lymphoblastic leukemia, chronic eosinophilic leukemia, chromic myelogenous leukemia, dermatofibrosarcoma protuberans, gastrointestinal stromal tumor, myelodysplastic/myeloproliferative disorders, systemic mastocytosis.
INLYTA	Molecular Target Inhibitors	Renal cell carcinoma

[31] Kaiser Permanente is available in three states: California, the District of Columbia, and Ohio.

Drug Name (Brands in all caps)	Class	Cancers Treated
NEXAVAR	Molecular Target Inhibitors	Hepatocellular carcinoma, renal cell carcinoma, thyroid cancer
SPRYCEL	Molecular Target Inhibitors	Acute lymphoblastic leukemia, chronic myelogenous leukemia
SUTENT	Molecular Target Inhibitors	Gastrointestinal stromal tumor, pancreatic cancer, renal cell carcinoma
TARCEVA	Molecular Target Inhibitors	Non-small cell lung cancer, pancreatic cancer
TASIGNA	Molecular Target Inhibitors	Chronic myelogenous leukemia
TYKERB	Molecular Target Inhibitors	Breast cancer
VOTRIENT	Molecular Target Inhibitors	Renal cell carcinoma, soft tissue sarcoma
XALKORI	Molecular Target Inhibitors	Non-small cell lung cancer
ZELBORAF	Molecular Target Inhibitors	Melanoma
ARZERRA	Monoclonal Antibodies	Chronic lymphocytic leukemia
AVASTIN	Monoclonal Antibodies	Colorectal cancer, glioblastoma, non-small cell lung cancer, renal cell cancer
HERCEPTIN	Monoclonal Antibodies	Adenocarcinoma of the stomach or gastroesophageal junction, breast cancer
RITUXAN	Monoclonal Antibodies	B-cell non-Hodgkin lymphoma, chronic lymphocytic leukemia

NOTE: Cancers treated from the National Cancer Institute Cancer Drug Information available at: http://www.cancer.gov/cancertopics/druginfo/alphalist.

For several of these four classes, we had difficulty determining the list of chemically distinct drugs that make up the class. We followed the guidelines used in determining benchmark drug counts for essential health benefits.[32] However, the USP MMG 5.0 did not always include the same number of drugs as the maximum number available in the drug count process. For example, the USP MMG 5.0 lists two monoclonal antibodies.[33] However, the essential health benefits benchmarks indicate three drugs exist in this class.[34] From plan formularies, we found four drugs listed as monoclonal antibodies by at least some plans. We were unable to resolve the discrepancy, and so have listed all four drugs in this analysis.

Finally, we examined cost-sharing information for silver plans and one type of cost-sharing reduction plan in California, Florida, New York, Ohio, and Texas. This cost-sharing examination focused on deductibles, out-of-pocket limits, and cost-sharing for specialty-tier prescription drugs. For context, we also examined average cost-sharing provisions for silver plans in all 36 states using healthcare.gov.

[32] CMS. *Essential Health Benefits Rx Crosswalk Methodology.* Available at: http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf.
[33] See http://www.usp.org/sites/default/files/usp_pdf/EN/healthcareProfessionals/2011-03-11frf-uspmgintegratedfile.xls.
[34] CMS. *Guam EHB Benchmark Plan.* Available at: http://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/guam-ehb-benchmark-plan.pdf. Guam uses the Federal Employee Blue Cross and Blue Shield Standard Option plan as a benchmark, which has an open formulary.