Formulary Design – Keeping Cancer Drugs Affordable for Patients

Most health insurance plans that cover prescription drugs use formularies for categorizing the drugs the plan will cover and determining the amount of cost-sharing that will be applied. Formularies are generally organized into "tiers" – starting with the least expensive generic drugs on the lowest tiers and the most expensive drugs on the top or specialty tier. The placement of a drug on a particular tier has a direct bearing on the copay or coinsurance a patient will pay.

Note that some drugs cancer patients take, like some forms of chemotherapy, are administered intravenously in a doctor's office. These types of drugs are generally covered under a plan's medical benefit (instead of the pharmacy benefit). While ACS CAN strongly encourages plans to list these medical benefit drugs on formularies – or in other ways provide transparency to which drugs they cover and cost-sharing – many plans do not do so, and therefore the proposals related to formulary tiering discussed below are more relevant to pharmacy drugs.

In an effort to help control spending on prescription drugs, policymakers at both the state and federal levels have introduced legislative proposals to change formulary structures, regulate tiers and tiering decisions, and impose cost-sharing limits. As formulary tiers are directly related to a patient's out-of-pocket costs for cancer and survivorship care, ACS CAN believes such proposals should be seriously considered, while also balancing the need for plans to have flexibility in designing their benefits.

Benefit Design

Most insurance plans determine how many tiers to include in their formularies and which drugs are placed on each tier. This flexibility in formulary design can result in a disconnect between the actual price of a drug and its placement on a formulary tier. For instance, sometimes a lower cost drug may actually be placed on a higher tier. This is compounded by the current trend towards formularies with multiple tiers as well as the use of **specialty tiers**.[1]

Specialty Tier: generally the highest tier on a formulary. While there is no standard definition of a specialty drug, specialty drugs generally are more expensive, more complex, and/or only available at specialty pharmacies.

Insurers and pharmacy benefit managers claim that flexibility in formulary design allows them to negotiate more effectively with drug manufacturers – i.e., an insurer can offer better placement on a formulary for a bigger discount on the drug price. However, this flexibility also allows plans to design their formularies in ways that potentially disadvantage patients. If all of a patient's drugs are on the highest formulary tier – which has the highest cost-sharing – that patient may have serious problems affording the drugs that they need. Additionally, if a plan places all drugs used to treat a certain disease in the highest tier, they may be actively trying to discourage patients who have that disease from enrolling in their plan – a practice called discriminatory benefit design, or "adverse tiering." Multiple ACS CAN analyses have found that plans offered in the individual market often place all oral chemotherapy drugs on the highest formulary tier.[2]

One way to potentially prevent discrimination and adverse tiering is to establish rules for which drugs plans may place on specialty or higher tiers. Federal law establishes such rules for Medicare Part D plans which are only allowed to have one specialty tier, and the negotiated price of drugs placed on the

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specialty tier must exceed a threshold amount. That threshold amount, established annually in regulation, is $670 (per month at an in-network pharmacy) in 2017.[3] This type of policy could also be instituted federally for plans in the individual and small group market, and/or at the state level for plans regulated by the state. Another way to prevent or curtail discriminatory benefit design is for regulators to clearly define what practices they consider to be discriminatory, actively monitor plans for this behavior, and take action as needed.

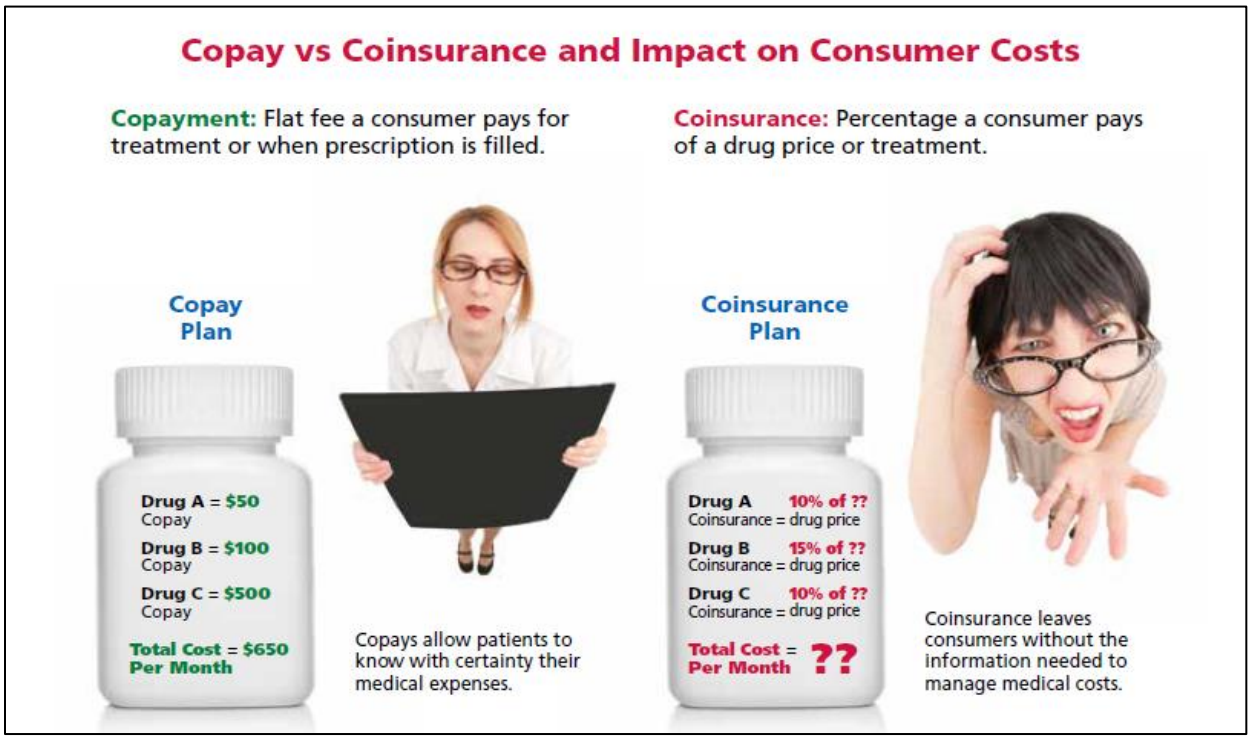
ACS CAN Position

- ACS CAN supports establishing a reasonable and evidence-based definition for specialty drugs at the federal or state level in non-Medicare Part D plans and rules for which drugs may be placed on specialty tiers.
- ACS CAN has encouraged the U.S. Department of Health and Human Services to clearly define what they consider to be discriminatory benefit design and actively enforce such rules.
- ACS CAN encourages state insurance commissioners to also monitor plan design for discriminatory practices and take action against it when necessary.

Limits on the Use of Co-Insurance

Multiple ACS CAN analyses of individual marketplace plans have shown that most oral cancer drugs are found in the highest tier of the formulary. This also holds true for intravenous cancer drugs, to the extent to which those drugs are listed on the formulary. Additionally, the vast majority of these formularies require co-insurance for these upper formulary tiers. Requiring co-insurance – or a percentage of the cost of the drug – instead of flat-fee co-payments can make it challenging for patients to understand how much they will have to pay for their drugs, and also present challenges in affording drugs.

> It's often difficult to determine the price of a drug or treatment that establishes the actual amount of the patient's coinsurance.



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A few states have experimented with policies that ensure that patients in the individual market have the option of buying an insurance plan that does not charge co-insurance for drugs. Proposed legislation is modeled after regulatory guidance from Montana and Colorado and usually requires that each carrier operating in a state or federal exchange offer at least one plan in the silver, gold, and platinum metal levels that applies only flat dollar co-payments to each tier in the plan's drug benefit.[4] Some versions of the legislation require a health carrier to offer at least 25 percent of plans in each metal level that have only flat co-payments applied to each tier in the plan's drug benefit. Other versions of legislation also prohibit plans from applying a deductible to drugs.

Proponents of such proposals say this type of policy ensures that patients are offered plans that will best meet their needs. Many cancer patients and survivors take multiple expensive medications, and would benefit from enrolling in a plan that does not use co-insurance on their formulary. Opponents say these policies limit plan flexibility too much.

ACS CAN Position

- ACS CAN supports requiring insurers to use co-pays instead of co-insurance under a plan's drug benefit.
- To the extent that co-insurance is utilized, issuers should be required to provide the consumer with information regarding the expected cost-sharing associated with the prescription drug. Such information can be provided in the form of a range of expected out-of-pocket cost.

Utilization Management Tools – Step Therapy

In an effort to control utilization, health plans may impose step therapy (also called "fail first") policies to encourage enrollees to try a lower-cost prescription drug before moving to a higher-cost drug. Such policies can be helpful in controlling health plan's costs. However, in some instances the enrollee may have a medical justification which would necessitate an exemption from the step therapy protocol.

ACS CAN Position

ACS CAN supports legislation that would require a plan to allow an individual to be exempt from step therapy protocol provided the following conditions are met:

- when, based on the individual characteristics of the patient, the drug is likely to be ineffective or adversely affect the health of the individual;
- the patient has already gone through the process and failed on the initial steps; and
- the patient is already stable on a medication that is subject to step therapy.

Some step therapy proposals also include a required broad exemption for when the provider simply attests that the required drug is not "medically appropriate." ACS CAN only supports such an exemption if the legislation also includes a definition for "medically appropriate".

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Non-Medical Switching

When an individual enrolls in a health plan, absent a qualifying event, the individual is prohibited from changing health plans until the end of the plan year. In some cases, a health plan may change the formulary during the plan year.

In some cases, formulary changes can be beneficial to consumers in cases when new drugs – particularly lower-cost generic drugs – are newly approved by the Food and Drug Administration. However, absent specific requirements, unfettered formulary changes could be misused by a health plan insofar as the plan could market a robust formulary to consumers and then change to a severely restrictive formulary when the enrollee is unable to change to a different health plan. The enrollee may have selected a plan based on its coverage of certain drugs.

ACS CAN Position

ACS CAN supports legislative and regulatory policies that would prohibit negative mid-year formulary changes (e.g., changes that would cause the enrollee to pay more out of pocket and/or lose coverage of a drug) around coverage and cost, for an individual enrolled in a health plan, for a single plan year. This policy helps to ensure that the formulary that was disclosed to consumers at the time they enrolled in the policy remains in effect throughout the plan year.

However, ACS CAN supports formulary changes to ensure coverage of newly-approved drugs. ACS CAN also supports changes to the plan's formulary in instances where the prescription drug is subject to safety issues. Legislation or regulation that prohibits mid-year formulary changes must contain exemptions for these situations.

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[1] Kaiser Family Foundation. Medicare Part D at Ten Years: The 2015 Marketplace and Key Trends, 2006-2015; Section 3: Part D Benefit Design and Cost Sharing. October 5, 2015. Available at http://www.kff.org/report-section/medicare-part-d-at-ten-years-section-3-part-d-benefit-design-and-cost-sharing/.

[2] American Cancer Society Cancer Action Network. ACS CAN Examination of Cancer Drug Coverage and Transparency in the Health Insurance Marketplaces. February 22, 2017. Available at: acscan.org/sites/default/files/QHP%20Formularies%20Analysis%20-%202017%20FINAL.pdf.

[3] Centers for Medicare and Medicaid Services. NOTE TO: Medicare Advantage Organizations, Prescription Drug Plan Sponsors, and Other Interested Parties. April 4, 2016. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.

[4] Milliman. Impact of Prescription Drug Copay Regulatory Action on ACA Exchange Plans in Colorado and Montana. July 2017. http://us.milliman.com/uploadedFiles/insight/2017/Impact-Prescription-Drug-Copay-Guidance-CO-MT.pdf.