RESOLUTION NO. 508 (New Jersey B)

Pharmacy Formularies

Introduced by New Jersey Chapter

Referred to the Reference Committee on Advocacy

WHEREAS, Physicians carefully choose medications for their patients, and

WHEREAS, patients are often on the same medication for many years which are working well for that patient, and

WHEREAS, insurance companies change their formularies at least yearly and arbitrarily drop generic medications from their formularies in lieu of others, and

WHEREAS, changing a patient's medication yearly poses a health hazard and adds to cost of medical care, and

WHEREAS, software solutions available to health insurance companies such as CoverMyMeds have the ability to efficiently automate the prior authorization process, now, therefore, be it

RESOLVED, That the American Academy of Family Physicians petition the Centers for Medicare and Medicaid Services, as well as all national health insurance companies and pharmacy benefits managers to include all generic medication in a class within a health plan's formulary, and be it further

RESOLVED, That the American Academy of Family Physicians petition the Centers for Medicare and Medicaid Services, as well as all national health insurance companies and pharmacy benefits managers, to implement a system that informs the prescribing provider of all formulary alternatives to a medication when denying the same medication immediately upon denial, while also providing a mechanism to rapidly appeal the denial.

(Received 06/03/19)

Fiscal Impact: None

Background

Drug formularies list which drugs are available to insurance plan beneficiaries. They provide guidance on which prescription medications are covered.[i] They also incentivize and are structured to encourage cost containment by using tiering system or through the benefit design. Plans often provide a tier of "preferred" lower cost medication requiring patients to pay less out-of-pocket costs. They also manage drug costs by using containment measures such as prior authorizations and regulating which drugs are covered within a plan. Most legislative activity has occurred at the state level.

Marketplace Plans

Prescription drug coverage is one of 10 essential health benefits required by the *Patient Protection and Affordable Care Act (ACA*). All marketplace health plans must include prescription drug coverage within the qualified health plans (QHP), but each state establishes

the list of covered medicines within its formulary. The Centers for Medicare and Medicaid Services (CMS) provides some general guidance about state market place plans but does not provide strict mandates about what is covered except that they be governed by pharmacy and therapeutics (P&T) committees. These multidisciplinary committees provide drug coverage and design determinations. These guidelines were outlined in CMS 2016 Call letter and 2017 final rule.

According to a 2017 *Health Affairs* article, formularies have grown in importance as both drug-selection and cost-control tools over the past three decades. The emergence of formularies in the late 1980s was driven by a structural change in the drug industry—the development of several multi-brand categories in which up to a half-dozen related, but not interchangeable, brands existed, with each commanding a similar price. Formularies gained prominence as a tool for purchasers to use in selecting among these treatment options, with purchasers often obtaining rebates from drug manufacturers in exchange for preferred formulary placement. The cost benefits for patients from choosing a preferred product create incentives for them to ask for specific brands and for plans to attempt to influence doctors to prescribe them.

Traditionally, P&T committees limited the impact of their decisions to the populations associated with their hospital or health plan; however, as hospitals have begun to transform into larger health systems and even integrated payer organizations, P&T committees must consider both inpatient and outpatient needs of patients in multiple hospitals and ambulatory care settings.[ii] The function of the P&T committee has not necessarily changed, but its scope has expanded.[iii] Considerations of quality, cost (reimbursement), and access (accreditation) affecting P&T committees over the past decade will become even more important as new drugs and biotech therapies enter the market and the shortage of primary care physicians intensifies.[iv] These committees generally comprise clinicians (primary care and specialists), pharmacists, nurses, legal experts, and administrators.

Medicare Part D

The Centers for Medicare & Medicaid Services (CMS) developed rules in 2006 to control how private plans under Part D create and manage formularies. CMS also required annual review of Part D plan formularies to assure adequate coverage: Each formulary must include at least two products in each of fifty-seven designated major therapeutic categories.

CMS also established six protected classes of drugs (anticonvulsants, antidepressants, anti-neoplastics, antipsychotics, antiretrovirals, and immunosuppressants) for which plans must cover all, or substantially all, medications. This was an effort to ensure that Part D plans would provide patients with broad access to different drugs in these categories. However, it also limited PBM formulary management tools in those classes. To permit more formulary management to lower prices, CMS in 2014 suggested removing protections for three of the six categories. That effort was blocked by Congress, which objected to a number of Part D changes by CMS that year.

Medicaid

According to a Kaiser Family Foundation report, due to the structure of Medicaid's rebate program, states are generally obligated to provide a drug to their beneficiaries when it comes on the market and currently cannot exclude high cost drugs from their programs. In the early 2000s, prescription management programs, which included preferred drug lists, supplemental rebates, and script limits, were implemented and expanded by states in an effort to control costs.

States have used a variety of strategies to contain pharmacy costs and have done so for many years. Common strategies include implementing prescription limits, negotiating supplemental rebates, requiring prior authorizations, and using state Maximum Allowable Cost (MAC) programs. States also have joined multi-state purchasing pools when negotiating supplemental Medicaid rebates to increase their negotiating power, and states have switched ingredient cost methodologies. Most state Medicaid programs also maintain a preferred drug list (PDL) of outpatient prescription drugs, which is a list of drugs states encourage providers to prescribe over other drugs. A state may require a prior authorization for a drug not on a preferred drug list. PDLs create incentives for a provider to prescribe a drug on the PDL if possible. Often, drugs on PDLs are cheaper or include drugs for which a manufacturer has provided supplemental rebates. While states may require prior authorization, restrict access to drugs only being used for medically accepted indications, or not cover certain specific drugs that are listed in the statute, outside of these allowances, they are required to provide nearly all prescribed drugs made by manufacturers that have entered into a rebate agreement. This requirement holds regardless of whether the beneficiary receives prescriptions in a managed care or fee-for-service setting.

New strategies include state spending caps for Medicaid prescription drugs and a proposal of a closed formulary in Medicaid.

Private Insurance Plans

According to a **September 2014 *New York Times* article**, health insurance companies are no longer allowed to turn away patients because of their pre-existing conditions or charge them more because of those conditions. But some health policy experts say insurers are forcing patients to pay more for their drugs and by increasing deductibles. As a result, patients with multiple chronic health conditions pay more for their drugs.

Insurers have long tried to use cost-containment/non-preferred lists to steer members away from more expensive brand name drugs, labeling them as “non-preferred” and charging higher co-payments. But according to an American Journal of Managed Care editorial, several prominent health plans have taken it a step further by applying that same concept to generic drugs.

Federal Regulatory Action

In 2018, the Administration announced its American Patients First drug pricing plan also known as the “blueprint.” The proposal includes plans aimed at directly influencing drug prices and to address prescription drug administration issues, such as eliminating “gag rule” language within pharmacy contracts under the Medicare program.

As part of the “blueprint,” the administration issued a rule to revisit Medicare’s six protected drug classes, a group of therapies for high-risk patients that plans are required to cover, with some exceptions. As written, the rule would loosen coverage requirements for these classes, opening the door for plans to expand their use of utilization management tools like step therapy and prior authorization. The proposal also would allow plans to exclude a protected-class drug from formularies if it doesn’t represent a significant improvement upon an older version of the same drug, or if the list price has increased dramatically.

Congress enacted bills to address drug pricing in 2018, including to prohibit pharmacy “gag rule” requirements within Medicare, Medicare Advantage and other insurance contracts. Congress has not enacted any legislation to address drug formularies and there are no bills under consideration to manage access to low-cost drugs within current insurance plans. However, there is language within the Medicare Drug Negotiation Act (HR 448/S. 99),

introduced by Rep. Elijah Cummings (D-MD) and Senator Bernie Sanders (I-VT) that directs CMS to include drug formularies as part of its drug negotiation process.

State Legislative Activity

The National Academy of State Health Policy's Center for State Drug Pricing reports that, as of June 27, 47 states have filed 268 bills to control prescription drug costs. A total of 45 bills have been enacted and 117 bills were introduced seeking to regulate pharmacy benefit managers in 2019. The Center for State Policy's Model Legislation Library has model legislation which allows states to define new standards for pharmacy benefit manager business practices. The model legislation also addresses PBMs' fiduciary responsibilities and bans PBM gag clauses that prevent pharmacists from sharing lower cost drug options with consumers. The Center for State Policy responded to several chapter inquiries regarding prescription drug costs and helped the Minnesota AFP with their grassroots advocacy on pharmacy benefit managers. Minnesota AFP set up a state SpeakOut encouraging legislators to support legislation which would require PBMs to operate under a license and prevent mid-year formulary switching once a patient is established with a treatment. The Center for State Policy also has a backgrounder on Drug Pricing and Transparency.

AAFP's Regulatory Actions

The AAFP has commented to CMS about the importance of balancing costs, while maintaining robust drug coverage for patients particularly for its review of the Medicare's protected drug classes. In a 2019 letter, the AAFP opposed any actions that limit a patient' access to medications prescribed by their physician(s). For this reason, the AAFP opposes the proposed changes to the current status of the protected drug classes. The letter also opposed utilization management strategies, like prior authorizations, that would unjustifiably limit access or disrupt patient care.

Current Policy

Patient-Centered Formularies

Prior Congress Action

Resolution No. 609 to the 2014 COD (Referred to the Board of Directors):

RESOLVED, That the American Academy of Family Physicians pursue national legislation to mandate that all insurance companies operating in this country providing drug coverage to their insured be required to:

1. Provide continuously updated drug formularies for each insured's plan, that at the drug and patient record level, will interface with all electronic medical record technology providing knowledge at the time a prescription is written, relative to whether a drug is covered, its status as preferred drug, and if non-preferred, its "tier" of coverage and prior authorization requirements; and
2. Provide continuously updated online drug formularies electronically searchable by simple entry of the brand name, generic name, and/or drug category and abandon non-searchable lists altogether; and
3. Provide the designated website address on the insured's health insurance and/or drug insurance card where formularies can be accessed and searched; and
4. Provide online prior authorization forms that are directly linked to those drugs searched.

Please see Page 64 in the 2014 Transactions for details.
Please see Resolution No. 609 on the AAFP website for follow-up details.

Prior Board Action

None

References

i. Huskamp HA, Keating NL. "The new medicare drug benefit: formularies and their potential effects on access to medications". *J Gen Intern Med*. **20**: 662–5. doi:10.1111/j.1525-1497.2005.0110.x. PMC 1403290. PMID 16050866

ii. Vogenberg FR, Gomes J. The changing roles of p&t committees: a look back at the last decade and a look forward to 2020. *P T*. 2014;39(11):760–772. Accessed online: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4218672/

iii. Vogenbrg, 2014

iv. Ibid