Significant Change Coming in 2018 in Tiering Exceptions Policy for Part D

Stephen Barlas

Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.

The Centers for Medicare and Medicaid Services (CMS) took a controversial step toward making drugs more affordable for Part D subscribers in its 2018 Call Letter.[1] The CMS's new policy requires prescription drug plans (PDPs) to give a member the "lowest available price" when granting a tiering exception, one of a number of affordability changes patient advocacy groups have been pushing for. Push-back from the Academy of Managed Care Pharmacy (AMCP) didn't stop the CMS from making the change, even though the AMCP says the change "would undermine the formulary process and could result in unnecessary costs for plans, beneficiaries, and the government by increasing administrative costs."[2]

Here is the issue. Say a patient receives a prescription from his or her physician for a statin that costs $500 a month. Assume the formulary has four tiers: generics, preferred, nonpreferred, and specialty. There are statins on tiers 1–3. The prescribed statin is a brand-name product on tier 3. In the past, the patient could ask for a tiering exception for a tier 3 drug with a high copayment, arguing he or she couldn't afford it. The Part D plan would then typically give the patient that $500-a-month drug at the tier 2 copayment, which is cheaper for the patient. But the plan member would never be given the $500 drug for the price of a generic statin on tier 1, given that tier 1 typically, in years past, only offered generics.

The tiering world has changed over the past few years, and today it would not be unusual for tiers 1–3 to contain generics, authorized generics, and brand-name products. The new policy requires the PDP to give that same patient that same $500 a month statin at *the lowest available price* for a statin on the plan's formulary, even if it is the tier 1 price.

The AMCP explains its opposition to the change by saying the lowest available price policy undermines the development of evidence-based formularies that enhance the quality of patient care by selecting the most appropriate medications for patients with the goals of reducing treatment failures, adverse drug events, and hospitalizations, and improving patient adherence and health outcomes.

However, the Call Letter could have been worse from the AMCP's perspective. Groups such as the Medicare Rights Center pressed the CMS to allow tiering exceptions for drugs on the specialty tier "both as a matter of fairness and to promote affordable access to high-cost medications." The CMS made no changes to tiering exceptions for specialty drugs. But it acknowledged that tiering exception requests are consistently associated with significantly lower approval rates than all other types of coverage and exception requests. The CMS implies that if it can close "information gaps," it may take additional action to restrict how pharmacy benefit managers (PBMs) and plans can administer tiering exceptions.

Even though the Call Letter guidance is not legally enforceable, the CMS uses it as a yardstick when auditing Part D programs. In its most recent audits of Part C (the Medicare Advantage program) and Part D programs, released in the fall of 2016 and based on 2015 audits, the CMS audited a total of 23 organizations and imposed enforcement actions on 15 of them. Most plans received civil monetary penalties in the program areas of Part D Formulary and Benefit Administration.

Babette Edgar, PharmD, MBA, FAMCP, Principal at BluePeak Advisors and Past President of AMCP, explains that the most common formulary condition cited has to do with the formulary quantity limits. In 2015, 63.6% of the 22 PDPs that participated in a CMS program audit were cited with applying an unapproved quantity limit. In addition, 36.3% of these sponsors were also cited with applying unapproved prior authorization edits. "Overall, plans continue to struggle with validating the accuracy of their formulary and ensuring all utilization management criteria are applied appropriately," Dr. Edgar notes. "This is due to inadequate testing of formularies at the PBM level for formulary setup and inadequate rejected claims monitoring by the plans."

Going forward, audits will look for formulary compliance with version 7.0 of the USP Medicare Model Guidelines, released in February.[3] The 2018 Call Letter substitutes those for version 6.0. This probably isn't a huge change for P&T committees. To accommodate new drugs and therapeutic uses, a total of three new USP classes were developed for this update, including Pulmonary Fibrosis Agents and Treatment Adjuncts (in the Antineoplastics category). The USP class previously named Hepatitis C (HCV) Agents was split into two new classes: Anti-hepatitis C (HCV) Direct-Acting Agents and Anti-hepatitis C (HCV) Agents, Other. No new drug categories were added.

The 2018 final Call Letter does not upgrade requirements for how P&T committees design formularies or the composition and requirements for the committees, as some Call Letters have done in the recent past. However, it does mention P&T committees in the context of another hot-button issue: opioid overutilization. It reiterates its expectation that Part D sponsors implement retrospective drug utilization review criteria to identify patients who are at risk of adverse events due to opioids. P&T committees are expected to establish these criteria, which will enable plans to identify potential, nonborderline opioid overutilizers who may warrant case management and exclude beneficiaries with cancer or in hospice where the benefit may outweigh the risk associated with high opioid doses.

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REFERENCES

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