P&T Committees Get New Leeway to Control Part C and Part D Drug Costs

Door Opens to More Step Therapy And Indication-Based Formularies

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Pharmacy and therapeutics (P&T) committees are attempting to take advantage of greater leeway in Medicare Advantage (Part C) and stand-alone outpatient (Part D) pharmacy plans to control costs while providing reasonable formulary access. For the first time, the Centers for Medicare and Medicaid Services (CMS) is allowing Medicare Advantage (MA) plans to use step therapy in formularies for Part B drugs beginning in November, and has given prescription-drug plans (Part D) the authority to use indication-based formularies starting in 2020. But P&T committees will face pressure from insurance companies and their pharmacy benefit managers (PBMs) to use those new tools to their fullest capacity, while dealing with counterpressure from drug manufacturers, physicians, and patient advocacy groups to go slow.

Both Part C and Part D plans already allow step therapy for outpatient drugs to be used. But the CMS’ decision, effective January, to ditch its 2012 guidance prohibiting Part C managed-care plans from using step therapy for expensive Part B drugs led to an outcry. Those drugs typically include the expensive oncology and diabetes drugs that are infused or injected in a physician’s office or an outpatient setting.

Nicole Longo, spokeswoman for the Pharmaceutical Research and Manufacturers Association (PhRMA), voiced serious reservations about the move. “Step therapy will delay many patients’ access to medicines they need, interfere with the patient–physician relationship, and increase burdens on physicians to comply with new, more complicated requirements. The bottom line is this guidance prioritizes the interests of middlemen while increasing out-of-pocket costs for some patients,” she stated. Physician groups also raised concerns about loss of access.

In an August 7, 2018 memorandum to MA Organizations, Seema Verma, the CMS administrator, announced the elimination of the 2012 prohibition as long as MA plans used step therapy as part of a patient-centered care coordination program. “The allowance of step-therapy practices for Part B drugs will help achieve the goal of lower drug prices while maintaining access to covered services and drugs for beneficiaries,” Verma wrote in her memo.

The Pharmaceutical Care Management Association (PCMA), which represents the PBM industry, hailed Verma’s decision. “Some of the highest priced drugs are found in Medicare Part B, where PBMs currently don’t play any meaningful role,” the group said in a statement.

Verma established some guardrails for the use of step therapy in MA plans. The CMS “strongly recommended” that MA plans use their P&T committees to determine when it is medically appropriate to use step therapy for selected drugs in Part B. To that end, step therapy cannot be deployed to control the use of services in a manner that creates undue access barriers for beneficiaries. It can only be applied to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication, and must be used as part of a larger drug-management care-coordination plan. The CMS expects that plan to include such items as:

- Interactive medication reviews and associated consultations for enrollees to discuss all current medications and perform medication-reconciliation and follow-up when necessary;
- The provision of educational materials and information to enrollees about drugs within the drug-management care-coordination program; and
- The implementation of medication adherence strategies to help enrollees with their medication regimens.

The CMS anticipates that MA plans will opt to apply step therapy, encouraging enrollees by offering rewards in exchange for participating in drug-management care-coordination programs.

Clearance for P&T committees to use indication-based formularies for Part D drugs in 2020 has also raised concerns. Current CMS policy is that each on-formulary drug is covered for all indications approved by the U.S. Food & Drug Administration (FDA), except for those uses that are statutorily excluded from Part D coverage. The CMS explained its decision to allow indication-based formularies: “The ability to exclude drugs from their formulary for specific indications will provide additional negotiating leverage with manufacturers, which can ultimately reduce beneficiary and program costs.”

The CMS based its decision in part on the fact that private sector formularies already use indication-based formularies. For example, Jennifer Luddy, spokeswoman for ExpressScripts, says, “Some of the programs within our SafeGuardRx suite of products leverage an indication-based pricing model for the plans who enroll in those programs. For example, we leverage this model in our Inflammatory Conditions Care Value program and our Oncology Care Value program.”

The PhRMA wants to make sure that indication-based coverage supports patient access to the medicines that best

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meet patient needs, as well as supporting innovation, according to Nicole Longo. Physician groups are wary of indication-based formularies for the same reason. The American College of Rheumatology said in a statement on August 30, 2018: “We have serious concerns about a new CMS guidance to allow Medicare Part D plan sponsors to implement indication-based formulary designs that allow plans to select drugs for their formularies based only on the disease indications they want to use.”

P&T committees serving Part C and Part D plans will have to carefully and sensitively navigate these new cost control initiatives to avoid lurking shoals.