DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: July 25, 2018

TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Indication-Based Utilization Management

The purpose of this memorandum is to make clear to Part D sponsors that they can employ indication-based utilization management (UM) in Part D via prior authorization (PA) requirements, and to provide instructions to Part D sponsors on how to update CY 2019 formulary files to reflect such programs.

As discussed in Chapter 6, section 30.1.5 of the Medicare Prescription Drug Benefit Manual, a Part D sponsor's pharmacy and therapeutics (P&T) committee must base formulary management decisions on scientific evidence, and may also base decisions on pharmacoeconomic considerations that achieve appropriate, safe, and cost-effective drug therapy. In evaluating other best practice formularies, such as those offered through the Federal Employees Health Benefits (FEHB) Program, we have identified that a commonly used formulary strategy involves differing utilization management (UM) requirements depending upon a patient's indication for a drug. The Centers for Medicare & Medicaid Services (CMS) recognizes that these indication-based UM strategies could help Part D sponsors achieve more cost-effective drug therapy, while still providing Part D beneficiaries access to the drugs they need to treat their disease states.

Part D sponsors, through the use of PA, may require beneficiaries to utilize a preferred formulary agent prior to authorizing coverage of the non-preferred agent, and these requirements may differ across indications. For example, a Part D sponsor may require a specific tumor necrosis factor (TNF) blocker be used first for plaque psoriasis, but that same agent might not be authorized for rheumatoid arthritis until a trial of a different TNF blocker. If a plan applies this type of UM strategy, the HPMS formulary submission and accompanying PA criteria must clearly define the requirements.

For CY 2019, sponsors will be given the opportunity to modify their formulary submissions during the August 6-8, 2018 limited formulary update window in order to incorporate P&T committee-approved indication-based UM. These updates can include both the addition of PA edits to drugs that will be subject to indication-based UM, as well as criteria changes that may be necessary to clearly define the requirements. CMS will provide further technical instruction regarding how to modify the submissions in a subsequent HPMS August formulary update memorandum.

If you have any questions relating to the submission, review, or implementation of this type of utilization management strategy, please email partdformularies@cms.hhs.gov.