DEPARTMENT OF HEALTH & HUMAN SERVICES
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The Office of the Administrator

DATE: August 29, 2018

TO: All Part D Sponsors

FROM: Seema Verma, Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Indication-Based Formulary Design Beginning in Contract Year (CY) 2020

The Department of Health and Human Services (HHS) has identified four challenges in the American drug market, including seniors and government programs overpaying for drugs due to lack of the latest negotiation tools (https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf). For example, HHS notes that better negotiation may be supported by evaluating options to allow high-cost drugs to be covered differently based on their indication under Part D. The Centers for Medicare & Medicaid Services (CMS) recognizes that providing Part D sponsors with these additional flexibilities to incorporate innovative indication-based utilization management (UM) in their formulary design is a valuable approach to addressing this challenge. On July 25, 2018, CMS issued guidance that made clear to Part D plan sponsors that they could employ indication-based UM strategies in Part D[1]. We also provided instructions on how to update CY 2019 formulary submissions to reflect such strategies. The following guidance builds upon the July 25 memorandum and describes how Part D sponsors can further expand upon these indication-based strategies to include indication-based formulary design beginning in CY 2020.

In the blueprint to reduce drug prices, the Trump Administration identified 4 strategies for reforming the American drug market, one of which centered on better negotiation. The following guidance provides Part D plans with new tools that have been successful in the private sector in reducing drug costs and is an important step in putting patients' needs first and delivering on this important objective.

Background

Part D sponsors are currently permitted through prior authorization (PA) requirements to vary approval criteria for specific indications if their CMS-approved PA clearly define such requirements. The Medicare Plan Finder (MPF) on medicare.gov indicates whether a formulary drug is subject to PA but does not specify the detailed clinical criteria, such as diagnoses, laboratory data / diagnostic tests, and prescriber restrictions that a Part D plan may require prior to authorizing coverage. Part D sponsors are, however, required to post their approved PA (and step therapy) criteria on their websites in order to make these requirements transparent to beneficiaries, prescribers, and other stakeholders.

Current CMS policy is that each on-formulary drug is covered for all indications that are approved by

[1] https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-July-25th.html

the U.S. Food & Drug Administration (FDA), except for those uses that are statutorily excluded from Part D coverage. As outlined in the July 25, 2018, Health Plan Management System (HPMS) memorandum, Part D sponsors may utilize step therapy-like requirements within their PA to promote cost-effective drug therapy by requiring the use of one formulary drug for a certain indication prior to authorizing coverage of a second drug for that indication.

Indication-Based Formulary Design Beginning in CY 2020

While Part D sponsors currently may promote the utilization of preferred agents via UM strategies, we are aware that health plans in the private sector have implemented indication-based formulary designs that tailor on-formulary coverage of drugs predicated on specific indications. Under this type of formulary design, plans negotiate formulary coverage based on specific indications, and only certain indications are considered to be on-formulary for a given drug. As discussed in the blueprint, providing Part D plans with the flexibility to employ the latest formulary tools would enable them to better negotiate for prescription drugs, especially high-cost drugs. 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. Thus, beginning with the 2020 plan year, CMS will permit Part D sponsors to institute this type of formulary design in Part D. We are announcing this policy change at this time in order to provide ample notice to plans prior to their negotiations with manufacturers on CY 2020 formulary inclusion.

If a Part D sponsor will be limiting on-formulary coverage of drugs to certain indications, it must ensure that there is another therapeutically similar drug on formulary for the non-formulary indication. For example, if a tumor necrosis factor (TNF) blocker is FDA-approved for both Crohn's disease and plaque psoriasis, but the Part D plan will include it on the formulary only for plaque psoriasis, the plan must ensure that there is another TNF blocker on formulary that will be covered for Crohn's disease. Otherwise, CMS may determine that the plan design is not meeting the anti-discrimination requirements set forth in section 1860D-11(e)(2)(D)(i) of the Social Security Act. All current formulary requirements outlined in 42 CFR §423.120(b)(2), and detailed in Chapter 6 of the Medicare Prescription Drug Benefit Manual, will still apply (e.g., if a drug is excluded from the formulary for a non-protected class indication, it would still need to be on-formulary for the protected class indication). If a Part D sponsor excludes specific indications for a Part D drug from its formulary, requests for coverage for those excluded indications should be treated as an exception request for an off-formulary drug.

Submission Process

In order for Medicare beneficiaries to be able to make informed enrollment decisions based on information available within the MPF, it is critical for CMS to make the necessary system updates to ensure transparency of these indication-based formulary designs. This will be accomplished through updates to HPMS file layouts and the accompanying data feeds to MPF. If a Part D sponsor intends to limit formulary inclusion of a Part D drug to only certain FDA-approved indications, the indication information must be submitted to HPMS. The file layouts will be shared in advance with stakeholders for review (OMB control number 0938-0763) and comment through the existing Paperwork Reduction Act process. CMS will collect covered indication information based on a standardized terminology system, such as Medication Reference Terminology (MED-RT). This information will be transferred to MPF for display within the restrictions under the drug coverage information section. CMS will provide Part D sponsors with detailed submission instructions in subsequent guidance.

Part D sponsors must update their applicable CY 2020 beneficiary materials to ensure that the indication limitations are displayed to prospective enrollees. If a Part D sponsor opts to implement indication-based formulary design for CY 2020, the plan must disclose that some drugs may be subject to these

requirements in the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents. In the ANOC, this information must be included under the section, "Changes to Part D Prescription Drug Coverage." In the EOC, this information must be included in the chapter, "Using the Plan's Coverage for you Part D Coverage." The 2020 model documents will reflect this change when released in summer 2019. In addition, Medicare & You will be updated to help educate beneficiaries that formulary coverage may also depend on the disease state for which the drug is being prescribed.

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