DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid
Services 7500 Security Boulevard
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CENTER FOR MEDICARE

DATE: March 12, 2019

TO: All Part D Sponsors

FROM: Amy Larrick Chavez-Valdez
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SUBJECT: Use of Safety-Based Quantity Limits on Approved Non-Formulary Drugs

The purpose of this memorandum is to provide clarification on the use of safety-based quantity limits (QLs) on non-formulary drugs in the Part D program. While the Centers for Medicare & Medicaid Services (CMS) generally limits Part D sponsors' use of utilization management tools, such as prior authorization and step therapy, to formulary drugs that are subject to CMS review and approval, QLs based on safety concerns can be applied to non-formulary drugs covered by the plan as the result of an approval through the formulary exceptions process. Because sponsors already must consider the dose and quantity when evaluating the medical necessity of an exception request for a non-formulary drug, this guidance primarily is intended to clarify the permissible application of additional QL edits if doses/quantities increase after a non-formulary drug exception request was previously approved.

CMS permits the following safety-based QLs on non-formulary drugs:

- QLs based on clearly stated maximum dosing limits specified in the FDA-approved label[1];
- QLs based on the dose, dosing frequency, and/or duration of therapy limits supported by the FDA-approved label *if no clearly stated maximum dosing limits are specified in the FDA-approved label* (e.g., short- and long-acting opioids). Limits cannot be based solely upon precautions in the label if the label otherwise supports higher doses;
- QLs that limit topical products to a reasonable quantity over time taking into consideration the indication, directions for use, and size of the area being treated; and
- QLs that support dose optimization that is intended to promote adherence and ensure safe and appropriate utilization by reducing pill burden when multiple strengths of the same drug are available (e.g. one 40 mg tablet daily instead of two 20 mg tablets daily when the appropriate dosing frequency is once daily).

CMS regulations at 42 CFR §423.578(c)(4)(i) prohibit Part D plan sponsors from requiring the enrollee to request additional approvals for a refill or a new prescription to continue using the Part

[1] For on-formulary drugs, CMS continues to require sponsors to submit QLs for review, except those based on a clearly stated maximum dosing limit specified in the FDA-approved label.

D drug approved under the formulary exceptions process for the remainder of the plan year, as long as 1) the enrollee remains in the plan, 2) the prescriber continues to prescribe the drug, and 3) the drug continues to be considered safe for treating the enrollee's disease or medical condition. If the prescribed dose or quantity previously approved through the formulary exception process is subsequently increased on a future prescription, the sponsor may require another coverage determination to ensure that the increased dose or quantity is safe and medically necessary.

CMS expects sponsors' Pharmacy and Therapeutics (P&T) committees to be involved in the development of plan policies and procedures related to the application of QLs for approved non-formulary drugs to ensure such policies are based on sound scientific evidence and accepted standards of practice. Additionally, plan sponsors are reminded that 42 CFR §423.562(a)(5) requires plans to employ a medical director who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity.

Coverage Determination Decision Letters

When adjudicating exception requests for non-formulary drugs, Part D sponsors must consider the dose and quantity being prescribed as part of their medical necessity determination. For example, if the request indicates that the enrollee is seeking a quantity above a safety-based QL established under the plan policy, the plan must address the higher dose requested in its decision letter (approval notice if the higher dose is approved; denial notice if the plan denies the requested dose and will only approve a lower dose). Sponsors must require prescribers to provide a supporting statement if the exception request exceeds the applicable safety-based QL in accordance with section 30.2 of Chapter 18 of the Prescription Drug Benefit Manual.

Opioid Point-of-Sale Safety Edits

The 2019 final Call Letter provided sponsors additional guidance on the application of point-of-sale (POS) safety edits specific to opioids (whether formulary or non-formulary), including limits for initial therapies and soft and hard edits for prescriptions exceeding specified Morphine Milligram Equivalent (MME) thresholds. Nothing in this memorandum changes the guidance issued under the heading "Improving Drug Utilization Review Controls" in the 2019 final Call Letter.

Days' Supply of Approved Non-Formulary Exceptions

Part D sponsors may limit the days' supply of approved non-formulary exceptions to a one month supply per fill if the Part D plan limits all or some formulary drugs to one month supplies per fill and the approved non-formulary drug would qualify for such limitation under the benefit design if it was on the formulary. For example, a Part D plan that limits drugs on its specialty tier to a one month supply per fill may limit approved exceptions for non-formulary drugs that satisfy the specialty tier cost-threshold requirement to a one month supply per fill. This limitation is permitted regardless of which tier the sponsor designates for purposes of cost sharing for approved non-formulary exceptions.

Please submit general questions regarding this memorandum to PartDPolicy@cms.hhs.gov.