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BULLETIN 24-13

Date: May 24, 2024

To: Insurers, Nonprofit Health Service Plans, Health Maintenance Organizations, and Private Review Agents

Re: Prescription Drug Utilization Review

The purpose of this Bulletin is to remind insurers, nonprofit health service plans, health maintenance organizations (collectively "carriers"), and private review agents ("PRAs") of the requirements under Maryland law when conducting utilization review of prescription drugs, including step therapy, and to provide guidance on how and when it is permitted to consider **prescription drug costs** as a factor for any utilization review determination related to prescription drugs.

Over the years, the Maryland General Assembly has enacted a substantial number of laws impacting prescription drug utilization review requirements. Maryland's step therapy law, § 15-142 of the Insurance Article,[1] was originally enacted in 2014, and has been amended multiple times since then, including amendments that went into effect on January 1, 2024. Additionally, the General Assembly enacted House Bill 932 and Senate Bill 791 during the 2024 legislative session,[2] effective January 1, 2025, which make significant changes to several different utilization review laws. In light of these recent legislative changes, the Maryland Insurance Administration ("MIA") is issuing this bulletin to clarify and explain the interplay between step therapy, prior authorization, and other utilization review protocols for prescription drugs.

General Requirements for Utilization Review of Pharmacy Services

Under §§ 15-1001 and 15-10B-03 of the Insurance Article, a carrier or PRA is required to obtain a certificate from the Commissioner in order to conduct utilization review in Maryland.

[1] All statutory references herein are to the Insurance Article of the Annotated Code of Maryland.
[2] As of the date of this bulletin, House Bill 932 and Senate Bill 791 are pending approval by the Governor.

Utilization review is defined in § 15-10B-01(m) as "a system for reviewing the appropriate and efficient allocation of health care resources and services given or proposed to be given to a patient or group of patients." A utilization review system typically includes categories of health care services for which utilization review is performed and various forms of utilization review. This bulletin will discuss the utilization review of pharmacy services and two types of utilization review, step therapy and prior authorization.

Step Therapy

Step therapy is a process used in a utilization review system where an insured is required to first try and use less costly drugs before more expensive drugs are covered to treat the same condition. "Step therapy or fail–first protocol" is defined in § 15-142 as "a protocol established by carrier "that requires a prescription drug or sequence of prescription drugs to be used by an insured or an enrollee before a prescription drug ordered by a prescriber for the insured or the enrollee is covered." An amendment to this definition, effective January 1, 2024, clarified that "Step therapy or fail–first protocol" includes a protocol that meets the above definition regardless of the name, label, or terminology used by the carrier to identify the protocol.

Managing prescription drug costs is one of the primary objectives of a step therapy protocol and it is acceptable for a carrier to consider costs as a factor in determining which drugs are subject to step therapy. Step therapy is a permissible form of utilization review and may be imposed *except* in the specific circumstances described in § 15-142(c) and (e):

- the step therapy drug (i.e. the drug or series of drugs that the carrier wants the individual to try before the prescribed drug is given) has not been approved by the U.S. Food and Drug Administration (FDA) for the medical condition being treated;
- the prescribed drug is covered under the individual's contract, and the prescriber provides supporting medical information that the prescribed drug was ordered by a prescriber for the individual in the past 180 days and, based on the professional judgment of the prescriber, was effective in treating the individual's disease or medical condition; or
- the prescribed drug is approved by the FDA and is used to treat the individual's stage four advanced metastatic cancer and use of the prescription drug is supported by peer-reviewed medical literature and is consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

Prior Authorization

Prior authorization is a utilization management technique where prior approval by the carrier or PRA is required before an insured or enrollee is eligible for coverage of a prescription drug.[3] Prior authorization is used to determine whether a prescription drug is medically necessary, appropriate or efficient. Except in cases where prior authorization is expressly prohibited under state law,[4] prior authorization is a permissible form of utilization review for prescription drugs,

[3] Carriers and PRAs also impose prior authorization requirements on other treatments, services, and procedures, but the discussion in this bulletin is limited to utilization review of pharmacy services.
[4] See, for example, §§ 15-826.1, 15-850, 15-851, and 15-858.

and may be imposed if the carrier or PRA complies with all applicable requirements and limitations described in § 15-140, § 15-854, and Title 15, Subtitles 10A and 10B.

A denial of a prior authorization request for a prescription drug is considered an adverse decision. An adverse decision is defined in § 15-10A-01 as "a utilization review determination by a private review agent, a carrier, or a health care provider acting on behalf of a carrier that 1. a proposed or delivered health care service covered under the member's contract is or was not medically necessary, appropriate, or efficient; and 2. may result in non-coverage of the health care service." House Bill 932 and Senate Bill 791 amend this definition to expressly include "a utilization review determination based on a prior authorization or step therapy requirement." When an adverse decision is made, § 15-10A-02(f)(1)(ii) requires a written notice of adverse decision to be sent to the member, member's representative, and health care provided acting on behalf of the member within 5 working days. The statute also specifies that certain information must be included in the notice, including, effective January 1, 2025, "the reasoning used to determine that the health care service is not medically necessary and did not meet the carrier's criteria and standards used in conducting the utilization review," and "the specific reference, language, or requirements from the criteria and standards, including any interpretive guidelines on which the decision was based."

Utilization Review and Drug Cost Considerations

It is widely acknowledged that the high cost of prescription drugs is a significant factor contributing to increasing premium over the last several years. In an effort to mitigate these premium increases, carriers may utilize a variety of techniques to manage prescription drug costs.

At the plan or product level, carriers may design and modify their prescription drug formularies in an effort to control drug costs. As lower cost drug alternatives become available, carriers may move drugs to different cost-sharing tiers on the formulary, or remove high-cost drugs from the formulary entirely. Formulary changes based on cost are permissible, provided the formulary exception process and notice requirements in § 15-831 and, if applicable, 45 CFR § 156.122(c) are met. Also, a decision not to provide coverage of a prescription drug in accordance with the required formulary exception process constitutes an adverse decision if the decision is based on a finding that the proposed drug is not medically necessary, appropriate, or efficient.[5] In this case, the notification requirements under § 15-10A-02(f)(1)(ii) would be applicable.

There are several additional ways carriers seek to address the prescription drug cost issue at the individual member level. One lawful member-level method carriers and pharmacy benefits managers ("PBMs") use to reduce prescription drug costs is by therapeutic interchange. A therapeutic interchange occurs when a PBM contacts the prescriber of a medication and requests a change from one prescription drug to another, either for medical reasons that benefit the patient, or because the change will result in financial savings and benefits to the carrier or patient. The definition of "therapeutic interchange" in § 15-1601, however, expressly states that therapeutic interchange does not include a change initiated pursuant to a drug utilization review. Under §§ 15-1634 and 15-1635, before making a therapeutic interchange, a PBM must obtain

[5] See § 15-831(e).

authorization from the prescriber and the interchange must be disclosed to the insured. The disclosure must indicate that the insured may decline the therapeutic interchange if the originally prescribed drug remains on the formulary, and the insured is willing to pay any difference in the copayment or coinsurance.

Within the utilization review framework, carriers may attempt to address prescription drug costs by leveraging step therapy protocols and prior authorization requirements. Managing prescription drug costs is one of the primary objectives of a step therapy protocol, and it is acceptable for a carrier to consider costs as a factor in determining which drugs are subject to step therapy. However, as explained above, there are specific limits and restrictions on when a carrier may impose step therapy. In particular, step therapy may not be required if a prescriber provides supporting medical information that the prescriber ordered an otherwise covered drug for the member within the past 180 days that, based on the professional judgment of the prescriber, was effective in treating the member's condition. The carrier must defer to the prescriber's judgment and is not, in this case, permitted to make its own independent determination of whether the drug was effective[6].

This requirement significantly limits the circumstances when a carrier is permitted to use step therapy as a form of concurrent review to evaluate whether there are lower-cost alternative drugs available for a member who is currently receiving coverage for a specific drug. **Regardless of whether the carrier uses the terminology "step therapy" to describe its process, if the prescriber has ordered the specific drug for the member within the past 180 days and provides the required documentation that the drug has been effective, the carrier is prohibited from requiring the member to use or try a less expensive alternative drug before agreeing to cover or authorize the requested drug.** This includes any new drugs that may have first come to market after the member was originally authorized to use the current drug.

Prior authorization is another way a carrier may attempt to address prescription drug costs at the member level. As stated previously, when a prior authorization request is denied because the prescription drug is determined by the PRA not to be medically necessary, appropriate or efficient, this is considered an adverse decision[7]. The definition of adverse decision includes a determination that a health care service is not "efficient," where cost may be a factor; however, an adverse decision must be based on the specific utilization review criteria and standards used by the PRA in conducting utilization review[8]. Those criteria and standards must be filed with the MIA as part of the application for a PRA certificate under § 15-10B-05. Furthermore, § 15-10B-05(a)(11) establishes specific parameters and requirements for the criteria and standards that a PRA is permitted to use to conduct utilization review. Effective January 1, 2025 under House Bill 932 and Senate Bill 791, these parameters will include additional requirements, including that the criteria must be:

- "generally recognized by health care providers practicing in the relevant clinical specialties;"
- "reflected in published peer-reviewed scientific studies and medical literature;" and

[6] § 15-142(c)(2).
[7] By the express language of House Bill 932 and Senate Bill 791.
[8] See House Bill 932 and Senate Bill 791, page 14, lines 18-25.

- "developed by a nonprofit health care provider professional medical or clinical specialty society, including through the use of patient placement criteria and clinical practice guidelines; or"
- "for criteria not within the scope of a nonprofit health care provider professional medical or clinical specialty society, developed by an organization that works directly with health care providers in the same specialty for the designated criteria who are employed or engaged within the organization or outside the organization to develop the clinical criteria," provided certain conditions are met.[9]

A denial of a prior authorization request for a prescription drug based on the existence of lower cost alternative will, by the express provisions of House Bill 932 and Senate Bill 791, be considered an adverse decision under Maryland law; therefore such denial is required to be supported by specific criteria and standards from the utilization review plan that was submitted to the Commissioner under § 15-10B-05, and must be stated in the denial notice under § 15-10A-02(f)(1)(ii)2. Furthermore, if a prior authorization request is denied on the grounds that less costly drugs were not used before the prescribed drug, this is a step therapy denial, which is subject to the restrictions described above.

In addition, House Bill 932 and Senate Bill 791 add another limitation to the prior authorization process for certain prescription drugs. Under new subsection (g) of § 15-854, an adverse decision is prohibited on a reauthorization for the same prescription drug if:

- the prescription drug is an immune globulin (human) as defined in 21 C.F.R. § 640.100, or is used for the treatment of a mental disorder listed in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders; and
- a prior authorization request for the prescription drug was previously approved for the insured, the insured has been treated with the prescription drug since the initial approval, and the prescriber attests that the prescription drug continues to be necessary to effectively treat the insured's condition.

For these previously approved prescription drugs, adverse decisions based on cost considerations or step therapy are prohibited, even if more than 180 days have passed since the drug was last ordered by the prescriber.

Questions about this Bulletin may be directed to the Life & Health Division of the Maryland Insurance Administration at 410-468-2170.

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Commissioner

By: **Signature on Original**

David Cooney
Associate Commissioner
Life and Health

[9] House Bill 932 and Senate Bill 791, pp. 23-24.