Title of Rule: **Error! Reference source not found.**
Rule Number: MSB 21-10-28-A
Division / Contact / Phone: Pharmacy Office / Kristina Gould / 303-866-6715

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   This proposed rule change will clarify that when a new drug becomes available and falls into a Drug Class that is already on the PDL, that the Department will determine whether it's Preferred or Non-preferred within a specified timeframe.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☒ for the preservation of public health, safety and welfare.

   Explain:

   Ensure that members will receive medications that are new to the market in a timely manner.

3. Federal authority for the Rule, if any:

   N/A

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2021);
   Section 25.5-1-108, C.R.S. (2021)

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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   Members will benefit from the proposed rule by ensuring that they receive drugs that are new to the market in a timely manner. There are no costs of the proposed rule.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   Quantitatively, drugs that are new to the market will be designated as Preferred or Non-preferred within a specified timeframe, which in some cases may increase the speed at which new drugs are available to members. Qualitatively, the Department will ensure that members receive drugs that are new to market in a timely manner.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   There are no probable costs of the proposed rule.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   There are no probable costs of the proposed rule and there are no benefits of inaction. The benefit of action is that the Department will ensure that members receive drugs that are new to the market in a timely manner.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   Not applicable.

6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   Not applicable.

8.800 PHARMACEUTICALS

8.800.16 PREFERRED DRUG LIST

8.800.16.A. ESTABLISHING THE PREFERRED DRUG LIST

1. To develop and maintain the PDL, the Department shall take the following steps:

   a. Determine which drugs and Drug Classes shall be reviewed for inclusion on the PDL.

   b. Refer selected drugs and Drug Classes to the P&T Committee for clinical reviews performed without consideration of drug cost-effectiveness. The P&T Committee shall make recommendations pursuant to 10 C.C.R. 2505-10, Section 8.800.17.C.

   c. Make recommendations to the Medical Director based on evaluations of relevant criteria, including but not limited to:

      i) Drug safety;

      ii) Drug efficacy;

      iii) The recommendations of the P&T Committee;

      iv) Public comments received by the Department before a drug or Drug Class is reviewed at the relevant P&T Committee meeting;

      v) Cost-effectiveness; and

      vi) Scientific evidence, standards of practice and other relevant drug information for such evaluation.

2. After the P&T Committee meets, the Medical Director shall review the recommendations of the P&T Committee and the Department and determine whether a reviewed drug is designated a Preferred Drug or a Non-preferred Drug.

3. After the Medical Director has designated a reviewed drug as Preferred or Non-preferred, the Department shall refer that drug to the DUR Board for recommendations on prior authorization criteria.

4. After the DUR Board meets, the Medical Director shall review the recommendations of the P&T Committee, the DUR Board and the Department and determine the efficacy, safety and appropriate prior authorization criteria for Preferred and Non-preferred Drugs to ensure the health and safety of members.

5. The Department shall provide public notice of PDL updates at least ten days before such changes take effect.

6. Drug Classes included on the PDL shall be reviewed at least annually.

8.800.16.B. NEW DRUGS

1. Notwithstanding any other provision of this section, a new drug entity, including new generic drugs and new drug product dosage forms of existing drug entities, in a Drug Class already included on the PDL:

a. Shall be subject to a preliminary evaluation by the Department within 30 days from when the drug is available on the market; and~~automatically designated a Non-preferred Drug; unless~~

b. The Department shall designate the new drug as Preferred or Non-preferred upon completion of the preliminary evaluation. ~~A preliminary evaluation by the Department finds that a new drug must be designated a Preferred Drug because it is medically necessary.~~

2. The Preferred or Non-preferred designation for a new drug shall continue until the relevant Drug Class is reviewed and the designation is changed pursuant to Section 8.800.16.A.

3. New drug prior authorization information is addressed in Section 8.800.7.D.

8.800.16.C. EXCLUSION OF DRUGS, DRUG CLASSES OR INDIVIDUALS FROM THE PDL

1. The following exclusions are intended to promote good health outcomes and clinically appropriate drug utilization and to protect the most vulnerable Medical Assistance Program members.

2. After reviewing the recommendations of the P&T Committee and the Department, the Medical Director may, notwithstanding any other provision of this section and to the extent allowed by federal and state law:

a. Exclude drugs or Drug Classes from consideration for inclusion on the PDL.

b. Determine continuity of care protocols that exempt Medical Assistance Program members stabilized on specified Non-preferred Drugs from prior authorization requirements.

c. Exclude specific Medical Assistance Program populations from prior authorization requirements for all Non-preferred Drugs.

3. Individual Medical Assistance Program members shall be exempted, on an annual basis, from prior authorization requirements for all Non-preferred Drugs if:

a. A member meets clinical criteria recommended by the Department and P&T Committee and approved by the Medical Director; and

b. A member's physician submits a request for exemption and meets the criteria for approval.

8.800.16.D. AUTHORITY OF THE EXECUTIVE DIRECTOR

1. The decisions of the Medical Director, made under the authority of this section, shall be implemented by the Department at the sole discretion of the Executive Director.

2. If the Medical Director position is unfilled, the duties and obligations of that position, as described in this section, shall be performed by the Executive Director.

8.800.16.E. SUPPLEMENTAL REBATES

1. The Department may enter into supplemental rebate agreements with drug manufacturers for Preferred Drugs. The Department may contract with a vendor and/or join a purchasing pool to obtain and manage the supplemental rebates.