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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
08/28/2024 9:32 AM
ARCHIVES DIVISION
SECRETARY OF STATE

CHAPTER 410
OREGON HEALTH AUTHORITY
HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILING CAPTION: Amending PA Criteria Implementing Recommendations From DUR/P&T Action.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/21/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S)

The Pharmaceutical Services program administrative rules (division 121) govern Division payments for services provided to certain clients. The Authority needs to implement changes to the Prior Authorization Criteria to ensure the safe and appropriate use of cost-effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Documents Relied Upon, and where they are available: 414.353, 414.354, and Or Law 2011, chapter 720 (HB 2100).

Material and agenda items for the Pharmaceutical & Therapeutics committee meeting are posted by the Oregon State College of Pharmacy.
https://pharmacy.oregonstate.edu/drug-policy/oregon-p-t-committee/meetings-agenda

Meeting minutes are available on the Oregon Pharmacy Services Website.
https://www.oregon.gov/oha/HSD/OHP/Pages/PT-Committee.aspx

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Minority populations in Oregon are impacted by health inequities and often face challenges accessing medical and prescription services. These rule changes are based on recommendations made by the Oregon Pharmaceutical and Therapeutics Committee (P&T) to ensure that pharmacy programs benefits are delivered by community-based organizations for Medicaid recipients. The P&T Committee's continued work represents a positive step toward increasing access to services. Recommendations provided aim to remove barriers, give guidance to providers, and ensure proper utilization of covered pharmacy products. The Pharmacy and Therapeutics (P&T) Committee includes representation from minority members including two members from Tribal communities. P&T allows for public

comment for consideration of recommendations made by the committee. In effort be inclusive OHA posts the meeting agenda 30 days prior and will accept applications for public comment up to 24 hours before the meeting.

FISCAL AND ECONOMIC IMPACT:

No fiscal impact to any entity in Oregon, the Department/Authority does not anticipate there will be a fiscal impact from these rule changes.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) This permanent filing is needed in order for the legislatively mandated Pharmacy & Therapeutics Committee to convene and conduct official business under the auspices of the Oregon Health Authority. It is also necessary for the health and safety of Oregon Health Plan recipients receiving drugs and prior authorizations.

(2)

(a) Small businesses will not be affected by this rule.

(b) There is no anticipated increase.

(c) There is no anticipated increase.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Meetings are held virtually and hosted by OSU College of Pharmacy and OHA representatives. The meeting's are open to the public, and all comments are considered. Representation from community members, small business and stakeholders in the Oregon is encouraged.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

AMEND: 410-121-0040

RULE SUMMARY: The Authority needs to implement changes to the Preferred Drug List and Prior Authorization Criteria to ensure the safe and appropriate use of cost-effective prescription drugs for the Oregon Health Plan's fee-for-service recipients, based on the P&T (Pharmacy and Therapeutic) Committee recommendations.

CHANGES TO RULE:

410-121-0040
Prior Authorization Required for Drugs and Products ¶

(1) Prescribing practitioners shall obtain prior authorization (PA) for the drugs and categories of drugs requiring PA in this rule, using the procedures set forth in OAR 410-121-0060.¶
(2) ~~Except as provided in section (3) of this rule, a~~All drugs and categories of drugs including, but not limited to, those drugs and categories of drugs that require PA shall meet the following requirements for coverage:¶
(a) Each drug shall be prescribed for conditions funded by the Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services (OAR 410-141-3820 through 410-141-3825). If the medication is for a non-covered diagnosis, the medication may not be covered

unless there is a co-morbid condition for which coverage would be allowed. The use of the medication shall meet corresponding treatment guidelines and be included within the client's benefit package of covered services and not otherwise excluded or limited;¶
(b) Each drug shall also meet other criteria applicable to the drug or category of drug in these pharmacy provider rules, including PA requirements imposed in this rule.¶
(3) ~~The Division shall grant exceptions to section (2) of this rule when coverage is required through Early and Periodic Screening, Diagnostic and Treatment (EPSDT) as set forth in Chapter 410 Division 151.¶~~
~~(4)~~ The Authority may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (see OAR 410-141-3820). The drugs and categories of drugs that the Authority requires PA for this purpose are found in the Oregon Medicaid Fee-for-Service Prior Authorization Approval Criteria (PA Criteria guide) ~~July 1, 2024~~at next Pharmaceutical & Therapeutics Committee meeting, adopted and incorporated by reference and found at https://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx¶
(~~5~~4) The Authority may require PA for individual drugs and categories of drugs to ensure medically appropriate use or to address potential client safety risk associated with the particular drug or category of drug, as recommended by the Pharmacy & Therapeutics Committee (P&T) and adopted by the Authority in this rule. The drugs and categories of drugs for which the Authority requires PA for this purpose are found in the Pharmacy PA Criteria Guide.¶
(~~6~~5) New drugs shall be evaluated when added to the weekly upload of the First Databank drug file:¶
(a) If the new drug is in a class where current PA criteria apply, all associated PA criteria shall be required at the time of the drug file load;¶
(b) If the new drug is indicated for a condition below the funding line on the Prioritized List of Health Services, PA shall be required to ensure that the drug is prescribed for a condition funded by OHP;¶
(c) PA criteria for all new drugs shall be reviewed by the DUR/P&T Committee.¶
(~~7~~6) PA shall be obtained for brand name drugs that have two or more generically equivalent products available and that are not determined Narrow Therapeutic Index drugs by the DUR/P&T Committee:¶
(a) Immunosuppressant drugs used in connection with an organ transplant shall be evaluated for narrow therapeutic index within 180 days after United States patent expiration;¶
(b) Manufacturers of immunosuppressant drugs used in connection with an organ transplant shall notify the Authority of patent expiration within thirty (30) days of patent expiration for section (5)(a) of this rule to apply;¶
(c) Criteria for approval are:¶
(A) If criteria established in section (~~4~~3) or (~~5~~4) of this rule applies, follow that criteria;¶
(B) If section (~~7~~6)(~~a~~A) of this rule does not apply, the prescribing practitioner shall document that the use of the generically equivalent drug is medically contraindicated and provide evidence that either the drug has been used and has failed or that its use is contraindicated based on evidence-based peer reviewed literature that is appropriate to the client's medical condition.¶
(~~8~~7) PA shall be obtained for non-preferred Preferred Drug List (PDL) products in a class evaluated for the PDL except in the following cases:¶
(a) The drug is a mental health drug as defined in OAR 410-121-0000;¶
(b) The original prescription is written prior to 1/1/10;¶
(c) The prescription is a refill for the treatment of seizures, cancer, HIV, or AIDS; or¶
(d) The prescription is a refill of an immunosuppressant.¶
(~~9~~8) PA may not be required:¶
(a) When the prescription ingredient cost plus the dispensing fee is less than the PA processing fees as determined by the Authority;¶
(b) For over-the-counter (OTC) covered drugs when prescribed for conditions covered under OHP; or¶
(c) If a drug is in a class not evaluated from the Practitioner-Managed Prescription Drug Plan under ORS 414.334.
Statutory/Other Authority: ORS 413.032, 413.042, 414.065, 414.330 - 414.414, 414.312, 414.316, ORS 414.325, 414.318, 414.320
Statutes/Other Implemented: 414.065, 414.334, 414.361, 414.371, 414.353, 414.354, ORS 414.325, ORS 414.369