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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

FILED
04/01/2022 1:36 PM
ARCHIVES DIVISION
SECRETARY OF STATE

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

FILING CAPTION: Amending PDL and PA Criteria April 1, 2022 DUR/P&T Action

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/21/2022 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 Division needs to amend OAR 410-121-0030 and & 410-121-0040 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the February 3, 2022, meeting. 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.

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 accepts 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 open to the public, and comments are considered, representation from community members, small business and stakeholders in the Oregon is encouraged. Attendance has grown since the meetings began being held virtually since April of 2020.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
410-121-0030, 410-121-0040

AMEND: 410-121-0030

RULE SUMMARY: The Pharmaceutical Services Program administrative rules (Division 121) govern Division payments for services provided to certain clients. The Division needs to amend rules as follows:
410-121-0030:
Changes based on February P&T recs
Page 6 – addition of RAAS inhibitors – candesartan, quinapril, fosinopril
Page 12 – addition of glucocorticoid class

Non-P&T changes
Page 4 – modification of brand only language
Page 5 – addition of carbotegravir - new formulation
Page 5 – removal of indinavir sulfate – all termed/obsolete
Page 11 – modification of brand only language
Page 11 – addition of Baqsimi brand name

Page 12 – addition of Nutropin brand name
Page 20 – removal of PNV no.175/iron fum/folic acid – change in rebate status
Page 25 - modification of brand only language
Page 26 – addition invega hafyera brand name

Clerical - Various clerical changes were made to system class, drug and form names.

410-121-0040:
The Pharmaceutical Services program administrative rules (division 121) govern Division payments for services provided to certain clients. The Authority needs to amend this rule to update the Oregon Medicaid Fee for Service Prior Authorization Criteria Guide found at http://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx based on the P&T (Pharmacy and Therapeutic) Committee recommendations February 3rd, 2022.
Substantive:
Alglucosidase alfa *retired
Anifrolumab *new criteria
Antifungals
Belimumab
Palivizumab
Pompe Disease *new criteria, replaces alglucosidase alfa
Voclosporin *new criteria

Clerical:
Oncology
Risperdal Consta

CHANGES TO RULE:

410-121-0030
Practitioner-Managed Prescription Drug Plan ¶

(1) The Practitioner-Managed Prescription Drug Plan (PMPDP) is a plan that ensures that OHP fee-for-service clients have access to the most effective prescription drugs appropriate for their clinical conditions at the best possible price:¶
(a) Licensed health care practitioners, who are informed by the latest peer reviewed research, make decisions concerning the clinical effectiveness of the prescription drugs;¶
(b) Licensed health care practitioners also consider the client's health condition, personal characteristics, and the client's gender, race, or ethnicity.¶
(c) The PDL includes over-the-counter (OTC) products determined to be cost-effective and clinically appropriate by the Oregon Pharmacy and Therapeutics (P&T) Committee. Select OTC product classes are included as a covered pharmacy benefit for Oregon FFS members.¶
(2) PMPDP Preferred Drug List (PDL):¶
(a) The PDL is the primary tool the Division uses to inform licensed health care practitioners about the results of the latest peer-reviewed research and cost effectiveness of prescription drugs;¶
(b) The PDL contains a list of prescription drugs that the Division, in consultation with the Drug Use Review (DUR)/Pharmacy & Therapeutics Committee (P&T), has determined represent the most effective drugs available at the best possible price;¶
(c) The PDL shall include drugs that are Medicaid reimbursable and the Food and Drug Administration (FDA) has determined to be safe and effective.¶
(3) PMPDP PDL Selection Process:¶
(a) The Division shall utilize the recommendations made by the P&T that result from an evidence-based evaluation process as the basis for selecting the most effective drugs;¶
(b) The Division shall ensure the drugs selected in section (3)(a) of this rule are the most effective drugs available for the best possible price and shall consider any input from the P&T about other FDA-approved drugs in the same

class that are available for a lesser relative price. The Division shall determine relative price using the methodology described in section (4)~~;~~ of this rule;¶
(c) The Division shall evaluate selected drugs for the drug classes periodically:¶
(A) The Division may evaluate more frequently if new safety information, or the release of new drugs in a class, or other information makes an evaluation advisable;¶
(B) New drugs in classes already evaluated for the PDL shall be non-preferred until the new drug has been reviewed by the P&T;¶
(C) The Division shall make all revisions to the PDL using the rulemaking process and shall publish the changes on the Division's Pharmaceutical Services provider rules website.¶
(4) Relative cost and best possible price determination:¶
(a) The Division shall determine the relative cost of all drugs in each selected class that are Medicaid reimbursable and that the FDA has determined to be safe and effective;¶
(b) The Division may also consider dosing issues, patterns of use, and compliance issues. The Division shall weigh these factors with any advice provided by the P&T in reaching a final decision.¶
(5) Pharmacy providers shall dispense prescriptions in the generic form unless:¶
(a) The practitioner requests otherwise pursuant to OAR 410-121-0155;¶
(b) The Division notifies the pharmacy that the cost of the brand name particular drug, after receiving discounted prices and rebates, is equal to or less than the cost of the generic version of the drug.¶
(6) The exception process for obtaining non-preferred physical health drugs that are not on the PDL drugs shall be as follows:¶
(a) If the prescribing practitioner in their professional judgment wishes to prescribe a physical health drug not on the PDL, they may request an exception subject to the requirements of OAR 410-121-0040;¶
(b) The prescribing practitioner must request an exception for physical health drugs not listed in the PDL subject to the requirements of OAR 410-121-0060;¶
(c) Exceptions shall be granted when:¶
(A) The prescriber in their professional judgment determines the non-preferred drug is medically appropriate after consulting with the Division or the Oregon Pharmacy Call Center; or¶
(B) Where the prescriber requests an exception subject to the requirement of section (6)(b) of this rule and fails to receive a report of PA status within 24 hours, subject to OAR 410-121-0060.¶
(7) Table 121-0030-1, PMPDP PDL dated ~~October~~April 1, 2022 is adopted and incorporated by reference and is found at: www.orpdl.org.¶
(8) Table 121-0030-2, PMPDP OTC dated April 1, 202~~1~~2 is adopted and incorporated by reference and is found at: www.orpdl.org.
Statutory/Other Authority: ORS 413.032, 413.042, ~~ORS~~ 414.065, 414.325, 414.330 to 414.414, ORS 413.032, ORS 414.312, ORS 414.316
Statutes/Other Implemented: ORS 414.065, 414.325, ~~ORS~~ 414.334, 414.361, 414.369, 414.371, 414.353, 414.354

AMEND: 410-121-0040

RULE SUMMARY: The Pharmaceutical Services Program administrative rules (Division 121) govern Division payments for services provided to certain clients. The Division needs to amend rules as follows:
410-121-0030:
Changes based on February P&T recs
Page 6 – addition of RAAS inhibitors – candesartan, quinapril, fosinopril
Page 12 – addition of glucocorticoid class

Non-P&T changes
Page 4 – modification of brand only language
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Page 11 – addition of Baqsimi brand name
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Page 20 – removal of PNV no.175/iron fum/folic acid – change in rebate status
Page 25 - modification of brand only language
Page 26 – addition invega hafyera brand name

Clerical - Various clerical changes were made to system class, drug and form names.

410-121-0040:
The Pharmaceutical Services program administrative rules (division 121) govern Division payments for services provided to certain clients. The Authority needs to amend this rule to update the Oregon Medicaid Fee for Service Prior Authorization Criteria Guide found at http://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx based on the P&T (Pharmacy and Therapeutic) Committee recommendations February 3rd, 2022.
Substantive:
Alglucosidase alfa *retired
Anifrolumab *new criteria
Antifungals
Belimumab
Palivizumab
Pompe Disease *new criteria, replaces alglucosidase alfa
Voclosporin *new criteria

Clerical:
Oncology
Risperdal Consta

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) 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 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) dated ~~July~~April 01, 202~~1~~2, adopted and incorporated by reference and found at~~:~~ https://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx¶
(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. ¶
(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.¶
(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 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 (3) or (4) of this rule applies, follow that criteria; ¶
(B) If section (6)(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. ¶
(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. ¶
(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 to 414.414, 414.312, 414.316
Statutes/Other Implemented: ORS 414.065, 414.334, 414.361, 414.371, 414.353, 414.354