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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

DMAP 45-2022

CHAPTER 410

OREGON HEALTH AUTHORITY

HEALTH SYSTEMS DIVISION: MEDICAL ASSISTANCE PROGRAMS

FILED

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ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Amending PDL DUR/P&T Actions And PA Approval Criteria Guide Effective April 2022

EFFECTIVE DATE: 04/01/2022 THROUGH 06/25/2022

AGENCY APPROVED DATE: 03/31/2022

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NEED FOR THE RULE(S):

OAR 410-121-0030: The Pharmaceutical Services program administrative rules (chapter 410, division 121) govern Division payments for services provided to certain clients. The Authority needs to implement changes to the Prior Authorization Guide and the Preferred Drug List to ensure the safe and appropriate use of cost-effective prescription drugs for the Oregon Health Plan's fee-for-service recipients. The Authority is amending these rules to update the Oregon Medicaid Fee for Service Prior Authorization Criteria Guide and the Oregon Preferred Drug List found at <http://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx> based on the P&T (Pharmacy and Therapeutic) Committee recommendations made February 3rd, 2022.

OAR 410-121-0040: The Authority finds that failure to act promptly will result in prejudice to the public interest, the Authority, and clients enrolled in Oregon's Medicaid Program by delaying the reassessment and update of prior authorization requirements. These rules need to be adopted promptly so the Authority can ensure the safe and appropriate use of Medicaid covered drugs.

JUSTIFICATION OF TEMPORARY FILING:

OAR 410-121-0030: The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and recipients of Medicaid benefits. These rules need to be adopted promptly so that the Authority may continue the legislatively mandated Pharmacy & Therapeutics Committee to convene and conduct official business with the Oregon Health Authority. It is also necessary for the health and safety of Oregon Health Plan recipients receiving drugs and prior authorizations.

OAR 410-121-0040: The Authority finds that failure to act promptly will result in serious prejudice to the public interest, the Authority, and clients enrolled in Oregon's Medicaid Program by delaying the reassessment and update of preferred drug lists and prior authorization requirements. These rules need to be adopted promptly so the Authority can ensure the safe and appropriate use of Medicaid covered drugs

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

RULES:

410-121-0030, 410-121-0040

AMEND: 410-121-0030

SUSPEND: Temporary 410-121-0030 from DMAP 54-2021

RULE SUMMARY: The Authority needs to implement changes to the Preferred Drug List to ensure the safe and appropriate use of cost-effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

P&T recommendations

Page 6 – addition of RAAS inhibitors – candesartan, quinapril, fosinopril

Page 12 – addition of glucocorticoid class

Clerical 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

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, 2021~~ 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

SUSPEND: Temporary 410-121-0040 from DMAP 54-2021

RULE SUMMARY: 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, 2021~~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