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PERMANENT ADMINISTRATIVE ORDER

FILED
12/22/2023 10:36 AM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

DMAP 96-2023

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

FILING CAPTION: Amending Pharmacy Rules; PDL, Exclusions & Limitations, Dispensing Limitations, Criteria to Reference EPSDT & P&T Recommendations.

EFFECTIVE DATE: 01/01/2024

AGENCY APPROVED DATE: 12/21/2023

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RULES:
410-121-0030, 410-121-0032, 410-121-0040, 410-121-0146, 410-121-0147

AMEND: 410-121-0030

NOTICE FILED DATE: 10/25/2023

RULE SUMMARY: Practitioner-Managed Prescription Drug Plan Oregon Preferred Drug List.

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~~January 1, 202~~3~~4 is adopted and incorporated by reference and is found at: www.orpdl.org.¶
(8) Table 121-0030-2, PMPDP OTC dated ~~October~~January 1, 202~~3~~4 is adopted and incorporated by reference and is found at: www.orpdl.org.
Statutory/Other Authority: ORS 413.032, 413.042, 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, 414.334, 414.361, 414.369, 414.371, 414.353, 414.354

AMEND: 410-121-0032

NOTICE FILED DATE: 11/13/2023

RULE SUMMARY: Amend Supplemental rebate rules to include Value Based agreements.

CHANGES TO RULE:

410-121-0032
Supplemental Rebate Agreements ¶

(1) The Division of Medical Assistance Programs (Division) has ~~a~~both a, Centers for Medicare and Medicaid Services (CMS) approved Supplemental Rebate Agreement and a (CMS) approved Value based Agreement. Th~~is~~ese templates and instructions are available on the Oregon Health Authority's (Authority) web site at~~; http://~~: www.oregon.gov/~~oha~~OHA/healthplan/~~tools/Model%20(Supplemental%20Rebate%20Agreement.pdf.~~pages/pharmacy-policy.aspx ¶
(2) The Division negotiates Supplemental Rebate Agreements for specific drug products through the Sovereign States Drug Consortium (SSDC) multi-state pool and pharmaceutical manufacturers. Negotiations are confidential, and shall not be disclosed, except in connection with an agreement/contract or as may be required by law. Confidentiality is required of any third party involved in administration of the agreement/contract. ¶
(3) Manufacturers may submit supplemental rebate offers or value base offers for consideration to include their drug(s) on the Practitioner's-Managed Prescription Drug Plan (PMPDP) Preferred Drug List (PDL), OAR 410-121-0030 after gaining access to the SSDC secure web-based offer entry system. ¶
(4) Manufacturers must abide by requirements of the SSDC. ¶
(5) The Practitioner-Managed Prescription Drug List (PMPDP) also called the Preferred Drug List (PDL) consist of drugs after the Food and Drug Administration (FDA) has determined to be safe and effective and reimbursable as determined by the Centers for Medicaid and Medicare Services (CMS), and evaluated using an evidence-based review process by the Pharmacy & Therapeutics Committee (P&T). If pharmaceutical manufacturers enter into supplemental rebate agreements with the SSDC, the Authority may include that drug on the PDL. ¶
(6)-Acceptance of the offer: ¶
(a) The Division may accept an offer through the SSDC; ¶
(b) The SSDC ~~wi~~shall notify manufacturers of the status of their offer(s). ¶
(c) Supplemental Agreements ~~wi~~shall be executed after signed by all parties, approved by CMS if required, and added to the PMPDP Preferred Drug List by the Administrative rule process. ¶
(d) The Division may contract for the functions of tracking utilization, invoicing, and dispute resolution for supplemental rebate products.
Statutory/Other Authority: ORS 41~~3.042, 414.065~~4.065, ORS 413.042, ORS 409.025, 409.040, 409.110
Statutes/Other Implemented: ORS 414.065

AMEND: 410-121-0040

NOTICE FILED DATE: 10/25/2023

RULE SUMMARY: This rule clarifies that for EPSDT members exceptions to the HERC Prioritized List of Health Services are made through prior authorization and case by case review. Also amends for changes to Prior authorization criteria based on recommendations from the Pharmaceutical and Therapeutics committee following the December 7th, meeting.

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) ~~A~~Except as provided in section (3) of this rule, 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) ~~dated November 0~~January 1, 202~~3~~4, adopted and incorporated by reference and found at https://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx¶
(4~~5~~) 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~~6) 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~~7) 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 (3~~4~~) or (4~~5~~) of this rule applies, follow that criteria;¶
(B) If section (~~6~~7)(~~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.¶
(~~7~~8) 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~~9) 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, 414.31~~8~~,6, ORS 414.325~~, 414.320~~
Statutes/Other Implemented: ORS 414.065, 414.334, 414.361, 414.371, 414.353, 414.354, ORS 414.325, ORS 414.369

AMEND: 410-121-0146

NOTICE FILED DATE: 11/13/2023

RULE SUMMARY: Amending dispensing limitations to allow 365 days supply for select Family Planning medications.

CHANGES TO RULE:

410-121-0146
Dispensing Limitations ¶

(1) The Division of Medical Assistance Programs (Division) ~~wi~~shall reimburse the pharmacy for dispensed medication the lesser of:¶
(a) The quantity indicated by the prescriber on the prescription;¶
(b) The quantity indicated by the Division dispensing limitations as outlined in this rule; or¶
(c) The quantity needed for Prescription Synchronization.¶
(2) The pharmacy may only dispense less than the prescribed quantity when the prescribed quantity exceeds the Division's dispensing limitations, or when a lesser quantity is needed for Prescription Synchronization.¶
(3) The pharmacy may, at the client's direction, dispense less than the prescribed quantity of a maintenance medication in order to align the refill dates if the client has received the same dose for two months or more. (4) Unless otherwise specified in this rule, the Division ~~wi~~shall not reimburse claims for medications exceeding a 34-day supply.¶
(5) Exceptions to the 34-day supply do not apply to claims for the following Standard Therapeutic Classes of medications. Claims exceeding a 34-day supply for these medications ~~wi~~shall not be reimbursed under any circumstances:¶
(a) Ataractics, Tranquilizers - 07;¶
(b) Muscle Relaxants - 08;¶
(c) CNS Stimulants - 10;¶
(d) Psychostimulants, Antidepressants - 11;¶
(e) Amphetamine Preps - 12;¶
(f) Narcotic Analgesics - 40;¶
(g) Sedative Barbiturate - 46;¶
(h) Sedative Non-Barbiturate - 47.¶
(6) The Division ~~wi~~shall allow reimbursement for more than a 34-day supply if the medication's original package size cannot be divided.¶
(7) Except for medications listed in (5), claims for up to a 100-day supply of the following types of medications may be reimbursed to the Division's mail order pharmacy contractor, Indian Health mail order pharmacy providers, and 340B providers:¶
(a) A preferred PDL generic; and¶
(b) A generic drug not on the PDL, costing $10 per month or less.¶
(8) Any pharmacy provider ~~wi~~shall be reimbursed for up to a ~~100~~365-day supply of family planning drugs.¶
(9) Maintenance Medications - Any pharmacy provider ~~wi~~shall be reimbursed for up to a 100-day supply of select classes of medications if the client has received the same dose for two months or more. Maintenance medications shall be determined by the Division based on the following criteria:¶
(a) Have low probability for dosage or therapy changes due to side effects; and¶
(b) Are used most commonly to treat a chronic disease state and not considered curative or promoting recovery; and¶
(c) Are administered continuously rather than intermittently.¶
(10) Selected medications identified by the Division ~~wi~~shall be limited to a 15-day supply for initial fills. These medications have been identified as having high side effect profiles, high discontinuation rates, or needing frequent dose adjustments.¶
(11) After stabilization of a diabetic, the pharmacy should provide a minimum of a one-month supply of insulin per dispensing.¶
(12) For vaccines available in multiple dose packaging, the Division ~~wi~~shall allow a dispensing fee for each multiple dose. When vaccines are administered at the pharmacy, refer to Oregon Administrative Rule (OAR) 410-121-0185.¶
(13) Splitting prescriptions:¶
(a) For compounded prescriptions, bill components of the prescription separately. Third party payments for compounded prescriptions must be split and applied equally to each component;¶
(b) The Division ~~wi~~shall consider any other form of prescription splitting as a billing offense and take appropriate

action as described in the General Rules (OAR 410 division 120).
Statutory/Other Authority: ORS 413.042, 414.065
Statutes/Other Implemented: ORS 414.065

AMEND: 410-121-0147

NOTICE FILED DATE: 11/03/2023

RULE SUMMARY: Amending Exclusions and limitations to reference EPDST.

CHANGES TO RULE:

410-121-0147
Exclusions and Limitations ¶

(1) The following items are not covered for payment by the ~~Division of Medical Assistance Programs~~Health Systems Division (Division) Pharmaceutical Services Program:¶
(a) ~~D~~Except as provided in section (2) of this rule, drug products for diagnoses below the funded line on the Health ~~Services~~Evidence Review Commission (HERC) Prioritized List of Health Services or an excluded service under Oregon Health Plan (OHP) coverage;¶
(b) Home pregnancy kits;¶
(c) Fluoride for individuals over 18 years of age ~~or older~~;¶
(d) Expired drug products;¶
(e) ~~D~~Except as provided in section (3) of this rule, drug products from non-rebateable manufacturers~~, with the exception of selected oral nutritionals, vitamins, and vaccines~~;¶
(f) Active Pharmaceutical Ingredients (APIs) and Excipients as described by Centers for Medicare and Medicaid (CMS);¶
(g) Drug products that are not assigned a National Drug Code (NDC) number;¶
(h) Drug products that are not approved by the Food and Drug Administration (FDA);¶
(i) Drug products dispensed for Citizenship Waived Medical (CWM) client benefit type except when prescribed as an emergency medical service as defined by OAR 410-134-0005~~(2~~3(3). The CWM ~~B~~benefit ~~Package~~plan end~~ed~~s on June 30, 2023~~.~~;¶
(j) Drug Efficacy Study Implementation (DESI) drugs (see OAR 410-121-0420); and¶
(k) Medicare Part D covered drugs or classes of drugs for fully dual eligible clients (see OAR 410-121-0149, ~~OAR~~ 410-120-1200 & ~~OAR~~ 410-120-1210).¶
(2) The Division shall cover drug products for diagnoses below the funded line on the HERC Prioritized List of Health Services when such coverage is required through Early and Periodic Screening, Diagnostic and Treatment (EPSDT) as set forth in Chapter 410 Division 151.¶
(3) The Division shall cover drug products from non-rebateable manufacturers under any one or a combination of the following circumstances:¶
(a) Coverage is required through Early and Periodic Screening, Diagnostic and Treatment (EPSDT) as set forth in Chapter 410 Division 151;¶
(b) The drug is a vaccine; or¶
(c) The drug is an oral nutritional or vitamin selected for coverage by the Division.¶
(4) Effective on or after April 1, 2008, Section 1903(i) of the Social Security Act requires that written (nonelectronic) prescriptions for covered outpatient drugs for Medicaid clients be executed on a tamper-resistant pad in order to be eligible for federal matching funds. To meet this requirement, the Division shall only reimburse for covered Medicaid outpatient drugs only when the written (nonelectronic) prescription is executed on a tamper-resistant pad, or the prescription is electronically submitted to the pharmacy.¶
(~~3~~5) Drugs requiring a skilled medical professional for safe administration shall be billed by the medical professional's office; unless otherwise specified by the Division.
Statutory/Other Authority: ORS 413.042, ORS 414.065
Statutes/Other Implemented: ORS 414.065~~, ORS 414.329~~