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TEMPORARY ADMINISTRATIVE RULES

Oregon Health Authority, Division of Medical Assistance
Programs

410

Agency and Division

Administrative Rules Chapter Number

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Upon filing.

Adopted on

08/13/2014 thru ~~02/09/2015~~

1/11/15 SC 8/15/14

Effective dates

RULE CAPTION

Amending Prior Authorization Guide - March 27, May 29, July 31, 2014 DUR/P&T
Action

Not more than 15 words

RULEMAKING ACTION

ADOPT:

AMEND: 410-121-0040

SUSPEND:

Stat. Auth.: ORS 413.032, 413.042, 414.065, 414.325, 414.330 to 414.414, 414.312, 414.316

Other Auth.:

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369, 414.371, 414.353, 414.354

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:

410-121-0040:

Central Nervous (CNS) Sedatives - Non Benzodiazepines - updated criteria

Central Nervous (CNS) Sedatives - Therapy duplication - updated criteria
Hepatitis B Antivirals - updated criteria
Ivacaftor (Kalydeco®) - updated criteria
Multi-Vitamins and Antioxidant Multivitamin Combinations - new criteria
Hormones Testosterone - updated criteria
Oral Direct Factor Xa inhibitor - updated criteria
Oral Direct Thrombin inhibitor - updated criteria
Platelet inhibitor - updated criteria
Sofosbuvir (Sovaldi®)- updated criteria

STATEMENT OF NEED AND JUSTIFICATION

The amending of OAR 410-121-0040

In the Matter of

414.353, 414.354, and Or Law 2011, chapter 720 (HB 2100), :
<http://www.leg.state.or.us/11reg/measpdf/hb2100.dir/hb2100.en.pdf>

Documents Relied Upon, and where they are available

The Pharmaceutical Services Program administrative rules (division 121) govern Division payments for services provided to certain clients. The Division temporarily amended 410-121-0040 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the March 27, July 31, 2014 meeting.

The Authority needs to implement changes to the Prior Authorization Guide to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

410-121-0040:

Central Nervous (CNS) Sedatives - Non Benzodiazepines - updated criteria
Central Nervous (CNS) Sedatives - Quantity Limit - updated criteria
Central Nervous (CNS) Sedatives - Therapy duplication - updated criteria
Hepatitis B Antivirals - updated criteria
Ivacaftor (Kalydeco®) - updated criteria
Multi-Vitamins and Antioxidant Multivitamin Combinations - new criteria
Hormones Testosterone - updated criteria
Oral Direct Factor Xa inhibitor - updated criteria
Oral Direct Thrombin inhibitor - updated criteria
Platelet inhibitor - updated criteria
Sofosbuvir (Sovaldi®) - updated criteria

Need for the Temporary Rule(s)

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.

Justification of Temporary Rules

Rhonda Busel

Authorized Signer

Rhonda Busel

Printed Name

8-12-14

Date

Authorization Page replaces the ink signature on paper filings. Have your authorized signer sign and date, then scan and attach it to your filing. You must complete this step before submitting your Permanent and Temporary filings.

STATEMENT OF NEED AND JUSTIFICATION

A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Oregon Health Authority, Division of Medical Assistance Programs

410

Agency and Division

Administrative Rules Chapter Number

In the Matter of: The amending of OAR 410-121-0040(T)

Rule Caption: Amending PA Guide – March 27, July 31, 2014 DUR/P&T Action

Statutory Authority: ORS 413.032, 413.042, 414.065, 414.325, and 414.330 to 414.414

Other Authority: None

Stats. Implemented: ORS 414.065; 414.325, 414.334, 414.361, 414.369 and 414.371

Need for the Temporary Rule(s): The Pharmaceutical Services Program administrative rules (division 121) govern Division payments for services provided to certain clients. The Division temporarily amended 410-121-0040 per the Drug Use Review (DUR) Pharmacy & Therapeutics (P&T) Committee's recommendations made during the March 27, July 31, 2014 meeting.

The Authority needs to implement changes to the Prior Authorization Guide to ensure the safe and appropriate use of cost effective prescription drugs for the Oregon Health Plan's fee-for-service recipients.

410-121-0040:

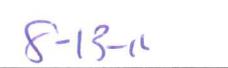
- Central Nervous (CNS) Sedatives – Non Benzodiazepines – updated criteria
- Central Nervous (CNS) Sedatives – Quantity Limit – updated criteria
- Central Nervous (CNS) Sedatives – Therapy duplication – updated criteria
- Hepatitis B Antivirals – updated criteria
- Ivacaftor (Kalydeco®) – updated criteria
- Multi-Vitamins and Antioxidant Multivitamin Combinations – new criteria
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Documents Relied Upon, and where they are available: 414.353, 414.354, and Or Law 2011, chapter 720 (HB 2100),: <http://www.leg.state.or.us/11reg/measpdf/hb2100.dir/hb2100.en.pdf>

Justification of Temporary Rule(s): 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.


Authorized Signer


Rhonda Busek


Date

410-121-0040

Prior Authorization Required for Drugs and Products

- (1) Prescribing practitioners are responsible for obtaining prior authorization (PA) for the drugs and categories of drugs requiring PA in this rule, using the procedures required 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 as described in this rule, are subject to the following requirements for coverage:
 - (a) Each drug must be prescribed for conditions funded by Oregon Health Plan (OHP) in a manner consistent with the Health Evidence Review Commission (HERC) Prioritized List of Health Services (OAR 410-141-0480 through 410-141-0520). If the medication is for a non-covered diagnosis, the medication shall not be covered unless there is a co-morbid condition for which coverage would be extended. The use of the medication must meet corresponding treatment guidelines, be included within the client's benefit package of covered services, and not otherwise excluded or limited;
 - (b) Each drug must 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 Oregon Health Authority (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 410-141-0480). 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 8~~August 13, 2014, incorporated in rule by reference and found on our ~~Web page~~website at:
<http://www.dhs.state.or.us/policy/healthplan/guides/pharmacy/clinical.html>
- (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 (see OAR 410-121-0100 for a description of the DUR program). 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 is required for brand name drugs that have two or more generically equivalent products available and that are NOT determined Narrow Therapeutic Index drugs by the Oregon DUR/P&T Committee:

(a) Immunosuppressant drugs used in connection with an organ transplant must 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 must notify the department of patent expiration within 30 days of patent expiration for (5)(a) to apply;

(c) Criteria for approval are:

(A) If criteria established in subsection (3) or (4) of this rule applies, follow that criteria;

(B) If (6)(A) does not apply, the prescribing practitioner must 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 is required 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.

Stat. Auth.: ORS Chap. 409.110, 413.042, 414.065, 414.325, and 414.334

Stats. Implemented: 414.065