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DENNIS RICHARDSON
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LESLIE CUMMINGS
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ARCHIVES DIVISION
MARY BETH HERKERT
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

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

FILING CAPTION: CCO Prior Authorization Response Times for Provider-Administered Drugs

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CONTACT: Sandy Cafourek
503-945-6430
sandy.c.cafourek@dhsoha.state.or.us

500 Summer St. NE
Salem,OR 97301

Filed By:
Sandy Cafourek
Rules Coordinator

RULES:
410-141-3070, 410-141-3225

AMEND: 410-141-3070

RULE TITLE: Preferred Drug List Requirements

NOTICE FILED DATE: 10/11/2018

RULE SUMMARY: This rule change is needed to conform to requirements of 42 CFR 438.210(d)(3) and Section 1927(d)(5)(A) of the Social Security Act to include Provider-Administered Drugs (PADs) in the definition of Covered Outpatient Drugs and the requirement for CCOs to provide a response to Prior Authorization requests for PADs within 24 hours.

RULE TEXT:
(1) Prescription drugs are a covered service based on the funded Condition/Treatment Pairs. MCEs shall pay for prescription drugs except:
(a) As otherwise provided, mental health drugs that are in Standard Therapeutic Class 7 (ataractics-tranquilizers) or Standard Therapeutic Class 11 (psychostimulants-antidepressants) (based on the National Drug Code (NDC) as submitted by the manufacturer to First Data Bank);
(b) Depakote, Lamictal, and their generic equivalents and those drugs that the Authority specifically carved out from capitation according to sections (13), (14), and (15) of this rule;
(c) For drugs covered under Medicare Part D when the client is fully dual eligible.
(2) MCEs may use the statewide Practitioner-Managed Prescription Drug Plan under ORS 414.330 to 414.337.
(3) MCEs may use a restrictive drug list if it allows access to other drug products not on the drug list through prior authorization (PA).
(4) MCEs shall publish up-to-date, accurate, and complete lists of all covered drugs on their preferred drug lists, including any tiering structures, that have been adopted and any restrictions on the way certain drugs may be obtained.
(5) As specified in 45 CFR 156.122, the preferred drug list must:
(a) Exist in a manner easily accessible to members and potential members, state and federal government, and the public;
(b) Be accessible on the plan's public website in a machine-readable format through a clearly identifiable web link or tab

without requiring an individual access account or policy number;
(c) Be made available in paper form if requested by a member; and
(d) If the issuer has more than one plan, the member shall be easily able to discern which of the preferred drug lists applies to which plan.
(6) The preferred drug list shall:
(a) Include Federal Drug Administration (FDA) approved drug products for each therapeutic class sufficient to ensure the availability of covered drugs with minimal prior approval intervention by the provider of pharmaceutical services;
(b) Include at least one item in each therapeutic class of over-the-counter medications; and
(c) Be revised periodically to assure compliance with this requirement.
(7) MCEs shall cover at least one form of contraception within each of the eighteen methods identified by the FDA. As set forth in OAR 410-141-3320, the member may refer themselves directly to family planning services without getting a referral from a PCP or other participating provider.
(8) MCEs shall provide their participating providers and their pharmacy subcontractor with:
(a) Their drug list and information about how to make non-drug listed requests;
(b) Updates made to their drug list within 30 days of a change that may include but are not limited to:
(A) Addition of a new drug;
(B) Removal of a previously listed drug; and
(C) Generic substitution.
(9) Prior authorization for prescription drug requests shall be addressed by the MCEs as described in OAR 410-141-3225.
(10) MCEs shall authorize the provision of a drug requested by the Primary Care Provider or referring provider if the prescriber certifies medical necessity for the drug such as:
(a) The equivalent of the drug listed has been ineffective in treatment; or
(b) The drug listed causes or is reasonably expected to cause adverse or harmful reactions to the member.
(11) Prescriptions for Physician Assisted Suicide under the Oregon Death with Dignity Act are excluded. Payment is governed by OAR 410-121-0150.
(12) MCEs may not authorize payment for any Drug Efficacy Study Implementation (DESI) Less Than Effective (LTE) drugs that have reached the FDA Notice of Opportunity for Hearing (NOOH) stage, as specified in OAR 410-121-0420 (DESI)(LTE) Drug List. DESI LTE drugs are identified by the Covered Outpatient Drug (COD) Status equal to 05 or 06 in the list available at:
https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e
(13) An MCE may seek to add drugs to the list contained in section (1) of this rule by submitting a request to the Authority no later than March 1 of any contract year. The request must contain all the following information:
(a) The drug name;
(b) The FDA approved indications that identify the drug may be used to treat a severe mental health condition; and
(c) The reason the Authority should consider this drug for carve out.
(14) If an MCE requests that a drug not be paid within the global budget, the Authority shall exclude the drug from the global budget for the following January contract cycle if the Authority determines that the drug has an approved FDA indication for the treatment of a severe mental health condition such as major depressive, bi-polar, or schizophrenic disorders.
(15) The Authority shall pay for a drug that is not included in the global budget pursuant to the Pharmaceutical Services program rules (chapter 410, division 121). An MCE may not reimburse providers for carved-out drugs.
(16) MCEs shall submit quarterly utilization data within 45 days after the end of the quarter pursuant to 42 CFR 438.3.
(17) MCEs are encouraged to provide payment only for outpatient and physician administered drugs produced by manufacturers that have valid rebate agreements in place with the CMS as part of the Medicaid Drug Rebate Program. MCEs may continue to have some flexibility in maintaining preferred drug lists regardless of whether the manufacturers

of those drugs participate in the Medicaid Drug Rebate Program.
(18) MCEs shall utilize a pharmacy and therapeutics (P&T) committee and a Drug Use Review (DUR) program. The committees may work in tandem or independent of the other, if all committee requirements for both committee types are met. A P&T committee must maintain written documentation of the rationale for all decisions regarding the drug list development and revisions. The committee shall follow the membership and meeting standards specified in 45 CFR 156.122(3)(i) and (ii). Meetings shall be held at least quarterly. MCEs shall provide a detailed description of its P&T committee including its DUR functions on an annual basis. The report shall be in the form and manner required by the OHP. The data requested by the Authority shall be calculated to meet federal reporting obligations.
(19) The committee in its DUR capacity shall assure prescriptions are appropriate, medically appropriate, and not likely to result in adverse medical results. The committee must be designed to educate prescribers and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. The committee shall include prospective DUR, retrospective DUR, and educational programs as each is defined by 42 CFR 456, subpart K.

STATUTORY/OTHER AUTHORITY: 413.042, 414.615, 414.625, 414.635, 414.651

STATUTES/OTHER IMPLEMENTED: 414.610–414.685

AMEND: 410-141-3225

RULE TITLE: MCE Service Authorization

NOTICE FILED DATE: 10/11/2018

RULE SUMMARY: This rule change is needed to conform to requirements of 42 CFR 438.210(d)(3) and Section 1927(d)(5)(A) of the Social Security Act to include Provider-Administered Drugs (PADs) in the definition of Covered Outpatient Drugs and the requirement for CCOs to provide a response to Prior Authorization requests for PADs within 24 hours.

RULE TEXT:

(1) Coverage of services is outlined by MCE contract and OHP benefits coverage outlined in OAR 410-120-1210 and 410-120-1160.

(2) A member may access urgent and emergency services 24 hours a day, seven days a week without prior authorization.

(3) The MCE may not require a member to obtain the approval of a primary care physician to gain access to mental health or substance use disorders assessment and evaluation services. A member may self-refer to mental health and substance use disorders services available from the provider network.

(4) Contractors must permit out-of-network IHCPs to refer an MCE-enrolled Indian to a network provider for covered services as required by 42 CFR 438.14(b)(6).

(5) The MCE shall ensure the services are furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid and as described in ORS chapter 414 and applicable administrative rules, based on the Prioritized List of Health Services and OAR 410-120-1160, 410-120-1210, and 410-141-0520.

(6) MCEs may not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary.

(7) MCEs shall observe required timelines for standard authorizations, expedited authorizations, and specific OHP rule requirements for authorizations for services, including but not limited to residential treatment or substance use disorder treatment services and requirements for advance notice set forth in OAR 410-141-3240 (Notice of Action/Adverse Benefit Determination Notice Requirements).

(8) MCEs may place appropriate limits on a service authorization based on medical necessity and medical appropriateness as defined in OAR 410-120-0000 or for utilization control provided that the MCE:

(a) Ensures the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished;

(b) Authorizes the services supporting individuals with ongoing or chronic conditions or require long-term services and supports in a manner that reflects the member's ongoing need for the services and supports;

(c) Provides family planning services in a manner that protects and enables the member's freedom to choose the method of family planning to be used consistent with 42 CFR §441.20; and

(d) Ensures compensation to individuals or entities that conduct utilization management activities is not structured to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any member.

(9) For authorization of services:

(a) Each MCE shall follow the following timeframes for authorization requests other than for drug services:

(A) For standard authorization requests for services not previously authorized, provide notice as expeditiously as the member's condition requires and no later than 14 days following receipt of the request for service with a possible extension of up to 14 additional days if the following applies:

(i) The member, the member’s representative, or provider requests an extension; or

(ii) The MCE justifies to the Authority upon request a need for additional information and how the extension is in the member's interest.

(B) For notice of actions/adverse benefit determinations that affect services previously authorized, the MCE shall mail the notice at least ten days before the date the adverse benefit determination takes effect:

(i) The MCE shall make an expedited authorization decision and provide notice as expeditiously as the member's health condition requires and no later than 72 hours after receipt of the request for service;
(ii) The MCE may extend the 72-hour period up to 14 days if the member requests an extension or if the MCE justifies to the Authority upon request a need for additional information and how the extension is in the member's interest.
(b) Prior authorization requests for prescription drugs, including a practitioner administered drug (PAD), shall be addressed by the MCEs as follows:
(A) Respond to prior authorizations for prescription drugs within 24 hours as described in CFR 438.210(d)(3) and section 1927(d)(5)(A) of the Social Security Act. A response may include:
(i) A decision to approve or deny the drug;
(ii) A written, telephonic, or electronic request for additional documentation when the prior authorization request lacks sufficient information or documentation to render a decision; or
(iii) A written, telephonic, or electronic acknowledgment of receipt of the prior authorization request that gives an expected timeframe for a decision. An initial response indicating only acceptance of a request shall not delay a decision to approve or deny the drug within 72 hours.
(B) If the response is a request for additional documentation, the MCE shall identify the required documentation and comply within the following timeframes:
(i) The MCE shall issue a decision within 72 hours or as expeditiously as the member's health requires upon receiving the necessary documentation if additional information or documentation is received; and
(ii) The MCE shall deny a request for prior authorization if the necessary additional documentation is not received within 72 hours of the request for additional documentation.
(C) If an emergency situation justifies the immediate medical need for the drug during this review process, an emergency supply of 72 hours or longer shall be made available until the MCE makes a coverage decision.
(c) For members with special health care needs as determined through an assessment requiring a course of treatment or regular care monitoring, each MCE shall have a mechanism in place to allow members to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the member's condition and identified needs;
(d) Any service authorization decision not reached within the timeframes specified in this rule shall constitute a denial and becomes an adverse benefit determination. A notice of action/adverse benefit determination shall be issued on the date the timeframe expires;
(e) MCEs shall give the member written notice of any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested or when reducing a previously authorized service authorization. The notice shall meet the requirements of CFR §438.404 and OAR 410-141-3240;
(f) The MCE and its subcontractors shall have and follow written policies and procedures to ensure consistent application of review criteria for service authorization requests including the following:
(A) MCEs shall consult with the requesting provider for medical services when necessary:
(i) Requesting all the appropriate information to support plan decision making as early in the review process as possible; and
(ii) Adding documentation in the authorization file on outreach methods and dates when additional information was requested from the requesting provider.
(B) Decisions shall be made by an individual who has clinical expertise in addressing the member's medical, behavioral health, or oral needs or in consultation with a health care professional with clinical expertise in treating the member's condition or disease. This applies to decisions to:
(i) Deny a service authorization request;
(ii) Reduce a previously authorized service request; or
(iii) Authorize a service in an amount, duration, or scope that is less than requested.
(C) MCEs shall have written policies and procedures for processing prior authorization requests received from any provider. The policies and procedures shall specify time frames for the following:

(i) Date stamping prior authorization requests when received;
(ii) Determining within a specific number of days from receipt whether a prior authorization request is valid or non-valid;
(iii) The specific number of days allowed for follow-up on pended prior authorization requests to obtain additional information;
(iv) The specific number of days following receipt of the additional information that an approval or denial shall be issued;

(v) Providing services after office hours and on weekends that require prior authorization.
(D) An MCE shall make a determination on at least 95 percent of valid prior authorization requests within two working days of receipt of a prior authorization or reauthorization request related to:
(i) Drugs;
(ii) Alcohol;
(iii) Drug services; or
(iv) Care required while in a skilled nursing facility.
(g) MCEs shall notify providers of an approval, a denial, or the need for further information for all other prior authorization requests within 14 days of receipt of the request as set forth in OAR 410-141-3240 unless otherwise specified in OHP program rules:
(A) MCEs shall make three reasonable attempts using two methods to obtain the necessary information during the 14-day period;
(B) If the MCE needs to extend the timeframe, the MCE shall give the member written notice of the reason for the extension;
(C) The MCE shall make a determination as the member's health or mental health condition requires, but no later than the expiration of the extension.

STATUTORY/OTHER AUTHORITY: 413.042, 414.065, 414.651, 414.615, 414.625, 414.635

STATUTES/OTHER IMPLEMENTED: 414.065, 414.610-414.685