PARTNERSHIP HEALTHPLAN OF CALIFORNIA

POLICY/ PROCEDURE

<table>
<tr><td colspan="4">Policy/Procedure Number: MCRP4068</td><td colspan="2">Lead Department: Health Services</td></tr>
<tr><td colspan="4">Policy/Procedure Title: Medical Benefit Medication TAR Policy</td><td colspan="2">☒External Policy
☐ Internal Policy</td></tr>
<tr><td colspan="3">Original Date: 11/11/2020</td><td colspan="3">Next Review Date: 08/14/2025
Last Review Date: 08/14/2024</td></tr>
<tr><td>Applies to:</td><td colspan="3">☐ Medi-Cal</td><td colspan="2">☐ Employees</td></tr>
<tr><td rowspan="2">Reviewing Entities:</td><td colspan="2">☒ IQI</td><td colspan="2">☒ P & T</td><td>☐ QUAC</td></tr>
<tr><td colspan="2">☐ OPERATIONS</td><td colspan="2">☐ EXECUTIVE</td><td>☐ COMPLIANCE</td><td>☐ DEPARTMENT</td></tr>
<tr><td rowspan="2">Approving Entities:</td><td colspan="2">☐ BOARD</td><td colspan="2">☐ COMPLIANCE</td><td>☐ FINANCE</td><td>☒ PAC</td></tr>
<tr><td>☐ CEO</td><td>☐ COO</td><td colspan="2">☐ CREDENTIALING</td><td colspan="2">☐ DEPT. DIRECTOR/OFFICER</td></tr>
<tr><td colspan="4">Approval Signature: Robert L. Moore, MD, MPH,</td><td colspan="2">Approval Date: 08/14/2024</td></tr>
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I. RELATED POLICIES:

A. MCRP4064 – Continuation of Prescription Drugs
B. MPRP4001 – Pharmacy and Therapeutics (P&T) Committee
C. MCUP3037 – Appeals of Utilization Management/Pharmacy Decisions
D. MPRP4062 – PHC Drug Wastage Payments
E. MCUP3042 – Technology Assessment
F. MCUP3138 – External Independent Medical Review

II. IMPACTED DEPTS:

A. Health Services
B. Member Services
C. Grievance and Appeals

III. DEFINITIONS:

A. Administrative Denial: Any denial of service that does not qualify as an Adverse Benefit Determination (ABD). An Administrative Denial is not subject to the appeal process and notification is only communicated to the provider.
B. Adverse Benefit Determination (ABD): The definition of an Adverse Benefit Determination encompasses all previously existing elements of an "Action" as defined under federal regulations with the addition of language that clarifies the inclusion of determinations involving medical necessity, appropriateness, setting, covered benefits, and financial liability. An ABD is defined to mean any of the following actions taken by a Managed Care Plan (MCP) (i.e., Partnership HealthPlan of California):
    1. The denial or limited authorization of a requested service, including determinations based on the type or level of service, medical necessity, appropriateness, setting, or effectiveness of a covered benefit.
    2. The reduction, suspension, or termination of a previously authorized service.
    3. The denial, in whole or in part, of payment for a service.
    4. The failure to provide services in a timely manner.
    5. The failure to act within the required timeframes for standard resolution of Grievances and Appeals.
    6. The denial of the member's request to obtain services outside the network.
    7. The denial of a member's request to dispute financial liability.
C. Approved authorization (Approved TAR): A request approved for the requested service and/or drug (strength/dose and quantity).

D. Covered Outpatient Drugs, Limiting Definition: The term "covered outpatient drug" **does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following** (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):
   1. Inpatient hospital services
   2. Hospice services
   3. Dental services, except that drugs for which the state plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs
   4. Physicians' services
   5. Outpatient hospital services
   6. Nursing facility services and services provided by an intermediate care facility for the developmentally disabled.
   7. Other laboratory and x-ray services
   8. Renal dialysis

   Covered Outpatient Drugs thus can be summarized from SSA 1927(k)(2), as those drugs that are FDA approved as being dispensed by a pharmacy only upon a prescription issued by a prescriber and are not provided or administered as part of a medical service. Covered Outpatient Drugs are fully in scope of Medi-Cal Rx (see below) and Partnership will not be responsible for the management and administration of drug benefits that meets the SSA 1927(k)(2) definition of Covered Outpatient Drugs. Partnership will be responsible for the administration of the drug benefits for drugs administered in the clinic setting and excluded from the definition of Covered Outpatient Drugs according to the Covered Outpatient Drugs, Limiting Definitions.

E. DESI drug: Drugs that fall under the Drug Efficacy Study Implementation program. This program evaluates drugs that entered the market prior to the current FDA approval process (prior to 1962), for the purpose of classifying the pre-1962 drugs as either effective, ineffective, or needing further study. Those assigned to DESI 5 are considered less than effective; DESI 6 drugs are neither safe nor effective and are removed from the market. DHCS does not reimburse DESI 5/6 drugs.

F. Medi-Cal Rx: The program title established by the State of California Department of Health Care Services (DHCS) for the new system of administering Medi-Cal pharmacy benefits through the fee-for-service (FFS) delivery system effective January 1, 2022.

G. Medical necessity: Reasonable and necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury.

H. Physician-Administered Drug (PAD) or Medical Benefit Medications: A physician-administered drug is an outpatient drug other than a vaccine that is typically administered by a health care provider in a physician's office or other outpatient clinical setting. For example, drugs that are infused or injected are typically physician-administered drugs. The provider bills the appropriate state Medicaid program (fee-for-service, managed care plan, or county operated health system) for the drug using the appropriate national drug code (NDC) and Healthcare Common Procedure Coding System code.

I. Prior authorization/treatment authorization request (TAR): A formal process requiring a health care provider to obtain advance approval of Covered Services and to what amount, duration, and scope, except in the case of an emergency. This includes urgent and standard requests.
   1. Non-urgent/Routine (Standard) Request: A request for a medical benefit medication or service for which application of the time periods for making a decision does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.
   2. Urgent Request: A request for a medical benefit medication or service where application of the time periods for making a routine or non-life threatening determinations: 1) could seriously jeopardize the life, health or safety of the member or others, due to the member's psychological state, or 2) in the

opinion of a practitioner with knowledge of the member's medical or behavioral condition, would subject the member to adverse health consequences without the care or treatment that is the subject of the request. Requests for an urgent determination should be submitted by the provider clearly marked "Urgent" or "Expedited" with a reason stated. Urgent TAR status is subject to Partnership review and determination using the criteria stated here.

J. Pre-service Request: A request for coverage of a medical benefit medication that the organization must approve in advance, in whole or in part.

K. Post-service or Retroactive Request: A request for a medical benefit medication that has already been administered to a beneficiary.

L. Self-administered Drug: Drugs that are FDA-approved for self-administration at home rather than necessarily being administered in a healthcare setting by a medical provider.

IV. ATTACHMENTS:

A. Medi-Cal Treatment Authorization Request Form

B. Partnership Treatment Authorization Request Form (Medical Drug Benefit – PAD Form)

V. PURPOSE:

The purpose of this policy is to clarify and delineate roles and responsibilities between DHCS Medi-Cal Rx and Partnership HealthPlan of California (Partnership) Pharmacy Services in administering pharmacy benefits and medical benefits for Physician-Administered Drugs (PAD). This policy also describes the guidelines for reviewing Treatment Authorization Requests (TAR) for medication services billed on medical or institutional claims and applies to standard, urgent, pre-service, and post-service TARs.

VI. POLICY / PROCEDURE:

A. Established by State of California Executive Order N-01-19, the administration and management of all pharmacy benefits for California State Medi-Cal beneficiaries is transitioned from Managed Care Contracted Plan Partners (MCP) to the State's fee-for-service (FFS) delivery system, effective January 1, 2022. As of the implementation, Partnership Pharmacy Services will be responsible for activities including, but not limited to, the following:

1. Overseeing and maintaining all activities necessary for enrolled Medi-Cal beneficiary care coordination and related activities, consistent with contractual obligations
2. Providing oversight and management of all clinical aspects of pharmacy adherence, including providing disease and medication management
3. Processing and payment of all pharmaceutical services billed on medical and institutional claims, including pharmacy services that are billed on medical or institutional claims as part of a bundled/all-inclusive billing structure in an inpatient or long-term (LTC) setting, including Skilled Nursing Facilities (SNFs) regardless of delivery system.
4. Participating in Medi-Cal Global Drug Utilization Review (DUR) Board and other DHCS pharmacy committee meetings

B. As of the implementation date of Medi-Cal Rx, DHCS will be responsible for activities including, but not limited to, the following:

1. Developing, implementing, and maintaining all Medi-Cal pharmacy policy, including, but not limited to:
   a. Pharmacy Drug coverage
   b. Pharmacy medication TARs and utilization management (UM)
   c. Reviewing and issuing final determinations regarding all TAR denials for Medi-Cal Rx benefits

d. Establishing Medi-Cal Rx pharmacy reimbursement methodologies, consistent with applicable state and federal requirements
e. Establishing and maintaining the Medi-Cal pharmacy provider network

C. For medication and pharmacy services billed on medical or institutional claims, Partnership Pharmacy Services will conduct reviews for TARs for medications and services for PADs provided in a clinical setting and outside the scope of responsibility of Medi-Cal Rx. Reviews of these requests will require, but are not limited to, the following:
   1. Providers will be required to furnish information for the TAR and include supplemental documents when needed to establish medical necessity for therapeutic/clinical TAR determinations.
      a. Partnership will attempt to gather clinical information when necessary for determining medical necessity. Insufficient clinical information provided to support medical necessity may result in a denial. Attempts to gather the clinical information, by Chief Medical Officer (CMO) or Physician Designee, Pharmacist, or Pharmacy Technician, will be documented in the TAR notes.
      b. Partnership does not review TARs received for medications and services in scope of Medi-Cal Rx. The pharmacy or provider submitting the TAR will be notified to send the TAR to DHCS contracted pharmacy administrator for review and processing.
   2. When Partnership criteria are not yet established, TARs are reviewed for medical necessity using case-by-case review guidelines that include (but are not limited to): established prior authorization criteria requirements or with criteria available in nationally recognized treatment guidelines, and/or State Medi-Cal published criteria. See section VI.C.6. for details governing Partnership case-by-case review.
   3. A Partnership Clinical Pharmacist or Pharmacy Technician will perform all initial reviews. Reviews by Pharmacy Technicians will adhere to Partnership written criteria and/or internal desktop procedures and guidelines, under the supervision of a Partnership Pharmacist.
      a. Pharmacy Technicians may make approvals and administrative denials using aforementioned criteria, but shall not make denials with any indication of medical necessity, which shall only be determined by Clinical Pharmacist or above.
   4. The Partnership Clinical Pharmacist, Pharmacy Technician, or Pharmacy Director may take the following TAR actions:
      a. Approved: An approved TAR meets criteria for the requested drug, strength/dose and quantity as requested. Note that "quantity" encompasses the number of doses necessary for the requested dates of service and the requested duration of treatment administration.
      b. Approved as Modified (Partnership Clinical Pharmacist and Pharmacy Director only): A TAR Approved as Modified is a TAR that is approved with a different total Rx quantity affecting number of doses or duration of treatment, or a daily dose quantity other than the requested quantity &/or day supply submitted by the provider. A correction made to the number of billing units needed to achieve the requested dose, frequency and duration is operational in nature and thus qualifies as an Approved TAR rather than a modification. The reviewer may approve a TAR as Modified on the basis of their clinical judgment without consultation from the Medical Director.
      c. Administrative Denial (Not subject to the Appeal Process): An administrative denial is a determination based on administrative criteria only (determinations not based on medical necessity criteria).
         1) TAR not required
         2) Duplicate request
   5. The Chief Medical Officer (CMO) or Physician Designee must be available, physically or by telephone, during business hours to assist with the review of TARs, including for that of consultation with the prescribing physician and/or consultants.
      a. Clinical Pharmacist may escalate review of TAR to CMO/Physician Designee for additional

clinical advisement before rendering a final decision.

6. The Chief Medical Officer (CMO) or Physician Designee or a Clinical Pharmacist may render TAR decisions case-by-case including those:
   a. Based on medical necessity criteria or make any exceptions to the established medical policy/criteria for pharmaceutical management.
   b. Based on billing/coverage requirements (for example, but not limited to, dose or age limits, diagnosis restrictions, and documentation requirements such as weight or body surface area) when medical necessity for exception to the requirement has been established.
   c. When dose consolidation is available by changing to another marketed strength or concentration that would result in the equivalent dose given as fewer units and less waste and is in accordance with the FDA approved package labeling regarding dosing and administration. See MPRP4062—Drug Wastage Payments.
   d. For products which the HealthPlan and Pharmacy and Therapeutics (P&T) Committee, in accordance with Department of Health Care Services (DHCS) guidelines, has determined a product is not a covered benefit (not reimbursable). See section VI.H-I for more details on non-reimbursable medications.
   e. Based on medical necessity, clinical prior authorization criteria &/or nationally recognized treatment guidelines (for example, but not limited to, National Comprehensive Cancer Network [NCCN], Infectious Diseases Society of America [IDSA], American Dental Association [ADA], American Heart Association [AHA], National Institutes of Health [NIH]).
   f. Based on medical necessity, for drugs that are FDA approved for self-administration and requested by the provider for medical administration at a clinical setting, and includes reasons why the member is unable to administer the drug at home &/or obtain from a pharmacy for at-home administration. Lack of medical necessity for administration in a clinical setting may result in the provider being referred to use the pharmacy benefit (Medi-Cal Rx).
   g. Based on member's individual needs and assessment of access and local delivery system.
   h. Based on DHCS-issued instructions, e.g., All-Plan Letters (APLs), fee-for-service provider directory or other formal written guidance that a product is not a covered benefit.
7. References used to determine authorization decisions shall include, but are not limited to:
   a. Medical references which list U.S. Food and Drug Administration (FDA) labeling information, including:
      1) Current editions of Physician's Desk Reference
      2) Drug Facts & Comparisons
      3) U.S. Pharmacopeia (USP) Drug Information for the Health Professional
      4) Other reference material available via internet search
   b. Partnership prior authorization criteria
   c. Partnership Clinical Practice Guidelines
   d. Society and Government-sponsored Clinical Practice Guidelines
   e. Evidence-based clinical decision support resources, such as UpToDate®
   f. Consultation with Medical Directors and or outside consultants.

D. TAR determination and provider notification by telephone, fax or other telecommunication device of Partnership determinations will be made based on DHCS and National Committee for Quality Assurance (NCQA) established timelines for type of request. Partnership shall follow the more stringent of DHCS and NCQA timeliness for decision and notifications.

1.

Type of Request	Decision Time Frame	Notification Time Frame	Extended Time Frame
Urgent Concurrent Review	72 hours from receipt of request	72 hours of receipt of request[1]	May be extended one time up to 14 calendar days

			from receipt of request
Urgent pre-service	72 hours from receipt of request	72 hours of receipt of request[1]	May be extended one time up to 14 calendar days from receipt of request
Non-urgent pre-service	5 business days of receipt of request	24 hours of determination date[1]	May be extended two (2) times for up to 14 calendar days each period (28 days total from receipt of request) [2]
Post-service	30 calendar days of receipt of request	30 calendar days of receipt of request	N/A

[1]Notification: Give electronic or written notification of decision to practitioner (and member when required pursuant to APL 21-011).
Per DHCS requirement, written notification must be mailed to a member within two (2) business days of the decision.
[2]Per DHCS regulations

E. Post-Service or Retroactive TARs must be received by Partnership within fifteen (15) business days of requested date of service or within 60 days of the date that a member's retroactive eligibility is established with Partnership. Retroactive TARs received after fifteen (15) business days of requested date of service may be submitted for consideration. Retroactive TARs received after 365 calendar days of requested date of service are out-of-timeframe based on contractual obligations with the health plan and are not subject to review and approval by the plan. Determination and provider notification for retroactive TAR will be made within 30 calendar days from the date and time the retroactive TAR is received or DHCS's established timeframe for retroactive TARs, whichever is sooner. Members do not have financial liability in this instance and may not be billed by the provider for services rendered. Consideration for review of a TAR received after fifteen (15) business days may be done under the following conditions:
   1. When certification of the Medi-Cal beneficiary's eligibility by the county welfare department was delayed.
   2. When other coverage (e.g., Medicare or other health insurance programs) denied payment of a claim for services.

F. For information on the process for a member, member's authorized representative, or a provider on behalf of a member to appeal Partnership Pharmacy decisions, see Partnership Policy MCUP3037 Appeals of Utilization Management/Pharmacy Decisions.

G. All FDA-approved medications are a potential medical drug benefit when medical necessity is established, unless the medication is specifically prohibited from being reimbursed per the State Plan, State Plan Amendments, Title 22, DHCS All Plan Letters, or any State Policies or contracts which specify that Partnership is not to reimburse, or is not responsible for reimbursement.

H. Non-covered services and exclusions from Partnership Medical Drug Benefits:
   1. Exclusions from the Partnership medical drug benefit are as follows:
      a. SSA 1927(k), "Covered Outpatient Drugs": This section of the Social Security Act serves to define what is (and isn't) an outpatient drug benefit for Medicaid beneficiaries. "Covered Outpatient Drugs" do not include any drug, biological product, or insulin, provided as part of, or as incident to, the provision of and billing for medical or institutional services. Outpatient drugs that are *not* incident to a medical or institutional service, such as those provided by a pharmacy, fall under the scope of the pharmacy benefit (Medi-Cal Rx).

b. Non-FDA approved drug products (including DESI 5 and 6)
c. Drugs used for the treatment of sexual dysfunction (erectile dysfunction and infertility)
d. Drugs used for the treatment of conditions which are cosmetic in nature and do not meet the DHCS/Partnership definition of being medically necessary treatment
e. Drugs carved out to State Fee For Service (HIV/AIDS, habit abatement, hemophilia, and certain psychiatric agents)
f. Medications provided to a member to self-administer at home (or to be administered by a caregiver in the home) are not a medical benefit. Unless otherwise allowed per provider contract, medical providers can submit TARs and claims directly to Partnership only for those services *rendered in the medical setting for a specific date of service*. Providing additional medication supply for a member to take on their own outside of the medical office/clinic/hospital falls within the scope of the pharmacy benefit, administered by Medi-Cal Rx/ DHCS contracted pharmacy administrator and is not covered byPartnership.

VII. REFERENCES:

A. California State Department of Health Care Services (DHCS) Medi-Cal Rx Resources and Reference Materials: https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx
B. DHCS APL 22-12, Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal RX (Supersedes APL 20-020)
C. DHCS APL 21-011 *revised*: Grievance And Appeal Requirements, Notice And "Your Rights" Templates (Aug. 31, 2022 supersedes APL 17-006)
D. SSA 1927(k)(2): Definition of Covered Outpatient Drugs
E. CMS/DHCS regulations, Final Rule
F. DHCS State Plan and State Plan Amendment
G. State of California Code of Regulations, Title 22: § 51107. Pharmaceutical Services
H. DHCS State Medi-Cal Provider Manual: Medi-Cal Program and Eligibility: MCP: *County Organized Health System (COHS) (mcp cohs)*

VIII. DISTRIBUTION:

A. Partnership Department Directors
B. Partnership Provider Manual

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE:

Director, Pharmacy Services

X. REVISION DATES: 11/10/21; 05/11/22; 08/10/22, 08/09/23; 08/14/24

PREVIOUSLY APPLIED TO:
N/A

XI. POLICY DISCLAIMER:

A. In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:
   1. Consistent with sound clinical principles and processes;
   2. Evaluated and updated at least annually;
   3. If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request.

B. The materials provided are guidelines used by Partnership to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership.
C. Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.