11. PHARMACY

A. Pharmacy Benefits and Services

APPLIES TO:

A. This policy applies to all IEHP Medi-Cal Members.

POLICY:

A. Department of Health Care Services' (DHCS) contracted Pharmacy Benefit Manager (PBM) provides administrative services and supports relative to the Medi-Cal pharmacy benefit (Medi-Cal Rx). Administrative services include claims management, prior authorization and utilization management, pharmacy drug rebate administration, Provider and Member support services, and other ancillary and reporting services to support the administration of Medi-Cal Rx.[1]

PURPOSE:

A. To support DHCS' effort to ensure the standardization of the Medi-Cal Rx benefit statewide, under one delivery system and improving access to pharmacy services.

PROCEDURES:

Pharmacy Benefit

A. Medi-Cal Rx does not change the following:[2]

1. The scope of existing Medi-Cal pharmacy coverage for prescribed drugs, products, and services;
2. The ~~Provision~~ provision of pharmacy services that are billed on medical or institutional claims and/or as part of a bundled/all-inclusive billing structure in an inpatient ~~, including~~ or long-term care (LTC) setting, including Skilled Nursing Facilities (SNFs) ~~and other Intermediate Care Facilities (ICFs)~~ , regardless of delivery system;
3. Covered pharmacy services that have historically been ~~Existing Medi-Cal managed care pharmacy~~ carved -out~~s~~ of managed care, including ~~(e.g.,~~ blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat substance use disorder); ~~and~~
4. Any pharmacy services that are billed as a medical and/or institutional claim instead of a pharmacy claim~~.~~;
5. DHCS' process for adding drugs to the Medi-Cal Contract Drug List (CDL) for which Medi-Cal Rx is responsible for when billed by a pharmacy on a pharmacy claim, including drugs that may not be physician administered; and

[1] Department of Health Care Services (DHCS) All Plan Letter (APL) 22-012 Supersedes 20-020, "Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx"
[2] Ibid.

~~4.~~6. Reporting of fraud, waste, and abuse to DHCS.

B. Medi-Cal Rx is responsible for the following benefits, when billed by a pharmacy on a pharmacy claim:[3]

1. Covered outpatient drugs, including physician administered drugs (PADs);
2. Medical supplies;
3. Enteral nutritional products; and
4. Prescription drugs related to major organ transplant, unless a Member has other primary health insurance or Medicare.[4]

IEHP and IPA Responsibilities

A. IEHP and IPAs remain responsible for the processing and payment of all pharmacy services billed on medical and institutional claims.[5] This includes the cost of facility-administrated drugs, depending on the case history, for major organ transplants, as well as Physician Administered Drugs (PADs).[6] Financial and prior authorization responsibilities between IEHP and IPAs for ~~Physician Administered Drugs (~~PADs~~)~~ are outlined in the Division of Financial Responsibility (DOFR). Please refer to the DOFR for details.

B. IEHP ensures the identification of the appropriate health plan and IPA staff as Designated Users, which include but are not limited to pharmacy staff, care management and behavioral health staff. Designated Users will have access to the Medi-Cal Rx secure Pharmacy portal and IEHP's Medi-Cal Rx Clinical Liaison.[7]

C. IEHP ensures Providers are informed of how to obtain access to the Medi-Cal Rx User Administration Console (UAC). The UAC allows access to prior authorization request system, chat and messaging features, beneficiary drug look-up tool, and claim submissions.

D. IEHP and its IPAs remain responsible for activities including but not limited to the following:

1. Overseeing and maintaining all activities necessary for Medi-Cal Member care coordination, continuity of care, and related activities; and
2. Providing oversight and management of all the clinical aspects of pharmacy adherence, including providing medication therapy management, medication reconciliation, and comprehensive medication management activities.

Please see Section 12, "Coordination of Care" and Policy 25C1, "Care Management – Delegation and Monitoring" for more information.

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[3] ~~Ibid.~~DHCS APL 22-012
[4] DHCS APL 21-015, "Benefit Standardization and Mandatory Managed Care Enrollment Provisions of the CalAIM Initiative," Attachment 2, "Major Organ Transplants (MOT) Requirements"
[5] DHCS APL ~~20-020~~22-012
[6] DHCS APL 21-015
[7] DHCS APL ~~20-020~~22-012

11. PHARMACY

A. Pharmacy Benefits and Services

Provider Responsibilities and Resources

A. Primary Care Providers (PCPs) are responsible for supervising, coordinating, and providing initial and primary care to patients; for initiating referrals; and for maintaining continuity of care.[8] Please see Policy 12A1, "Care Management Requirements – PCP Role" for more information.

B. Providers may claim reimbursement for Physician Administered Drugs (PADs) or drugs administered by clinical staff in a physician's office, outpatient facility, or hospital outpatient facility as follows:[9]

1. If billing on medical or institutional claim form such as CMS-1500, submit to IEHP per Policy 20A, "Claims Processing;" or

2. If billing on pharmacy claim form, submit to:

Medi-Cal Rx Customer Service Center
ATTN: Provider Paper Claims
P.O. Box 610
Rancho Cordova, CA 95741-0610

All ancillary codes including, but not limited to, Per Diem S-Codes or nursing codes associated with administration of the drug, are billed on a CMS-1500 form, and are therefore, IEHP's responsibility unless otherwise specified in the contract between IEHP and the Provider.

C. DHCS' Medi-Cal Rx processes and resolves Provider prior authorization and claim payment appeals. Providers that need to file a prior authorization or claim appeal will complete the Medi-Cal Rx Provider Appeal form and submit the completed form to:[10]

Medi-Cal CSC, Provider Claims Appeals Unit
P.O. Box 610
Rancho Cordova, CA 95741-0610

For more information about the Medi-Cal Rx Provider appeal process, including to access the Medi-Cal Rx Provider Appeal form, please visit the Medi-Cal Rx website: https://medi-calrx.dhcs.ca.gov/home/

D. Please see Section 16, "Grievance and Appeals Resolution System" for information on the Member grievance and appeal process.

[8] DHCS APL 22-012~~Ibid.~~
[9] ~~DHCS APL 20-020~~Ibid.
[10] Ibid.

11. PHARMACY

A. Pharmacy Benefits and Services

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11. PHARMACY

~~C~~B. Medical Drug Prior Authorization List

APPLIES TO:

A. This policy applies to all IEHP Medi-Cal Members.

POLICY:

A. IEHP is responsible for the Medi-Cal pharmacy benefits that are billed on medical and institutional claims, including Physician Administered Drugs (PADs).[1,2] As of May 1, 2022, to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes, IEHP manages and maintains a Medical Drug Prior Authorization List to be used by medical providers when directly administering pharmacologic treatment to Members.

B. IEHP does not impose quantitative treatment limitations (QTL) or non-quantitative treatment limits (NTQL), such as prior authorization, tiers, or network standards, more stringently on mental health and substance use disorder drugs as compared to medical/surgical drug prescriptions.[3]

DEFINITIONS:

A. Medical Drug Prior Authorization List – A continually updated list of preferred drugs made available to Members and Providers.

B. Physician Administered Drugs – An outpatient drug provided or administered to a recipient and billed by a provider and not self-administered by a patient or caregiver. Such providers include, but are not limited to, physician offices, clinics, and hospitals. Physician-administered drugs include both injectable and non-injectable drugs.

PROCEDURES:

A. The IEHP Pharmacy and Therapeutics (P&T) Subcommittee objectively appraises, evaluates, and selects pharmaceutical products for Medical Drug Prior Authorization List inclusion and exclusion. This is an ongoing process to ensure the optimal use of therapeutic agents. Products are evaluated based on efficacy, safety, ease of use, and cost.

B. On at least an annual basis, the ~~IEHP Pharmacy and Therapeutics (~~P&T~~)~~ Subcommittee reviews for clinical appropriateness the practices and policies for Medical Drug Prior Authorization List management activities regarding Physician Administered Drugs, such as

[1] Governor of California Executive Order N-01-19 (EO N-01-19), January 7, 2019.
[2] Department of Health Care Services (DHCS) All Plan Letter (APL) APL ~~20~~22-~~020~~012, "Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx (Supersedes APL 20-020)."
[3] Title 42, Code of Federal Regulations (CFR~~RF~~) § 438.900

prior authorizations, step therapies, quantity limitations, biosimilar and generic substitutions, and other drug utilization activities that affect access.[4]

C. Medical Drug Prior Authorization List management decisions for Physician Administered Drugs are based on scientific evidence and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost-effective drug therapy.[5] IEHP does not accept any incentives to use a specific drug on a preferred status; therefore, the IEHP Medical Drug Prior Authorization List does not contain any drugs with preferred status. Factors related to optimal pharmacotherapy and considered in Medical Drug Prior Authorization List deliberations include:[6]

1. Pharmacologic considerations (e.g., drug class, similarity to existing drugs, side effect profile, mechanism of action, therapeutic indication, drug-drug interaction potential, clinical advantages over other products in the specific drug class);
2. Unlabeled uses and their appropriateness;
3. Bioavailability data;
4. Pharmacokinetic data;
5. Dosage ranges by route and age;
6. Risks versus benefits regarding clinical efficacy and safety of a particular drug relative to other drugs with the same indication;
7. Patient risk factors relative to contraindications, warnings, and precautions;
8. Special monitoring or drug administration requirements;
9. Cost comparisons against other drugs available to treat the same medical condition(s);
10. Pharmacoeconomic data; and
11. Strength of scientific evidence and standards of practice (assessing peer-reviewed medical literature, pharmacoeconomic studies, outcome research data, and other such information as it determines appropriate).

D. The P&T Subcommittee meets at least quarterly or more frequently to update the Medical Drug Prior Authorization List for Physician Administered Drugs by reviewing: [7],[8]

1. [9]Medical literature including clinical trials;
2. Relevant findings of government agencies, medical and pharmaceutical associations, National Institutes of Health, and regulatory body publications;

[4] National Committee for Quality Assurance (NCQA), 2023 Health Plan (HP) Standards and Guidelines, UM 11, Element D, Factor 2
[5] NCQA, 2023 HP Standards and Guidelines, UM 11, Element A, Factor 2
[6] NCQA, 2023 HP Standards and Guidelines, UM 11, Element B, Factor 1
[7] Ibid.
[8] NCQA, 2023 HP Standards and Guidelines, UM 11, Element D, Factor 4
[9] ~~NCQA, 2023 HP Standards and Guidelines, UM 11, Element D, Factor 4~~

3. Relevant patient utilization and experience;
4. Current therapeutic guidelines and the need for revised or new guidelines;
5. IEHP Provider recommendations for addition or deletion of drugs to the Medical Drug Prior Authorization List; and
6. The top therapeutic classes and medications that were submitted for prior authorization. IEHP P&T Subcommittee determines if any of the medications or criteria need modifications to improve access, quality and safety of pharmaceutical care.

E. In cases where drugs become available and the cost is comparable to similar drugs on the Medical Drug Prior Authorization List within the same class, IEHP Pharmaceutical Services may approve the drug to be added on to the Medical Drug Prior Authorization List immediately. In cases where there are drug safety concerns, IEHP Pharmaceutical Services may remove drugs from the Formulary immediately. All additions and deletions will be reported back to the next P&T Subcommittee meeting.[10]

F. Selected drugs have generic equivalents or biosimilar products available and approved by the Food and Drug Administration (FDA). IEHP encourages generic dispensation for all quality generic products. Quality generic products are drugs that have received an "A" rating by the FDA. Biosimilar products approved by the FDA are also covered by the IEHP Formulary.

G. Drug(s) used in the treatment of "severe mental illness" diagnosis that are not otherwise specifically carved out to Medi-Cal Rx, will be represented on the Formulary.

Medical Drug Prior Authorization List Distribution

A. The Medical Drug Prior Authorization List, which includes Medical Drug Prior Authorization List status and benefit limitations is available on the IEHP website. A printed version is available upon request to Members and Providers.[11]

B. When necessary, between annual publications, IEHP notifies its Providers by fax about changes to the Medical Drug Prior Authorization List, e.g. additions, deletions, benefit limitations.[12] Providers and Members can access the updated Medical Drug Prior Authorization list on the IEHP website at www.iehp.org. Information can be mailed upon request.[13]

C. Requests for Medical Drug Prior Authorization List additions should be submitted to the P&T Subcommittee in writing prior to the next P&T Subcommittee meeting.

D. On an annual basis, IEHP notifies Members regarding the Medical Drug Prior Authorization List update schedule through the Member Newsletter. Members also annually receive the Member

[10] NCQA, 2023 HP Standards and Guidelines, UM 11, Element B, Factor 5
[11] NCQA, 2023 HP Standards and Guidelines, UM 11, Element B, Factor 1, 3, 5
[12] NCQA, 2023 HP Standards and Guidelines, UM 11, Element A, Factor 4
[13] NCQA, 2023 HP Standards and Guidelines, UM 11, Element B, Factor 2

Handbook providing them instructions to access the IEHP website to view IEHP's latest Formulary benefits.

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~~C~~B. Medical Drug Prior Authorization List

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11. PHARMACY

~~D~~C. Prior Authorization or Exception Requests for Physician Administered Drugs

APPLIES TO:

A. This policy applies to all IEHP Medi-Cal Members.

POLICY:

A. Physician Administered Drug (PAD) requests for exceptions to prior authorization criteria or coverage of drugs not on the Medical Drug Prior Authorization List may be submitted by Prescribers or Members to review of coverage when medically necessary.[1]

PROCEDURES:

A. Referral requests must include the following information:[2]

1. Designation of the referral request as either Standard or Expedited to define the priority of the response. Referrals that are not prioritized are handled as Standard;
    a. Requests that are designated as Eexpedited must include supporting documentation that the Member's condition is such that the Member faces ai~~n~~ imminent and serious threat to their health or that the non-urgent timeframe for making a determination would be detrimental to the Member's life or could jeopardize the Member's ability to regain maximum function.[3,4,5]
2. The diagnosis (ICD-10), drug (HCPC), and procedure codes (CPT) being requested; and
3. Any pertinent clinical information to support the request,~~.~~ i~~I~~ncluding but not limited to medication history, chart notes, lab values.

B. IEHP supplies all Providers with the referral form and instructions for its use on the IEHP website. Physicians may submit RxUM referral request forms via fax at (909) 890-5751, secure online Provider portal or by calling the IEHP Provider Relations Team at (909) 890-2054.[6]

C. Members may submit referral requests by calling IEHP Member Services at (800) 440-4347/(800) 718-4347 (TTY).

D. IEHP RxUM staff reviews individual referral requests for PADs. The staff thoroughly surveys the Member's existing medication regimen, duration of treatment, previous successful or failed therapies, any allergies, and other clinical conditions (including, but not limited to age,

[1] National Committee for Quality Assurance (NCQA), 2023 Health Plan (HP) Standards and Guidelines, UM 11, Element E, Factor 1
[2] NCQA, 2023 HP Standards and Guidelines, UM 11, Element E, Factor 2
[3] California Health & Safety (Health & Saf.) Code § 1367.01
[4] DHCS-IEHP Two-Plan Contract, 1/10/20 (Final Rule A27), Exhibit A, Attachment 5, Provisions 3, Timeframes for Medical Authorization
[5] NCQA, 2023 HP Standards and Guidelines, UM 11, Element E, Factor 4
[6] NCQA, 2023 HP Standards and Guidelines, UM 11, Element B, Factor 2

comorbidities, complications, progress of treatment, psychosocial situation, service area availability, and home environment). When applicable, the staff then references approved prior authorization criteria and/or clinical guidelines to appropriately make a decision on the request.[7,8,9]

E. IEHP RxUM staff conducts outreach to the submitting provider to obtain missing information or clarification of the request prior to making a decision on the request. Outreach attempts are documented in the medical management system.[10,11]

F. The IEHP Clinical Pharmacist may consult with the requesting Provider or the IEHP Medical Director(s) as part of the decision process for requests involving unusual or clinically complicated conditions. The IEHP Clinical Pharmacist may consult with the IEHP Medical Director(s) or the requesting Provider to discuss the specific reason for the denial and seek suggestions for an alternative pharmacotherapeutic regimen. Outreach attempts are documented in the medical management system.[12,13]

G. IEHP Clinical Pharmacist and/or IEHP Medical Director performs the final clinical review of a RxUM referral and are the only personnel authorized to issue adverse pharmacy decisions. The IEHP Clinical Pharmacist or IEHP Medical Director electronically signs all denied RxUM notifications.[14,15]

H. The Notice of Action is faxed or mailed (if fax fails) to the requesting Provider within seventy-two (72) hours of receiving the request for urgent concurrent and urgent preservice referrals, and five (5) days for nonurgent preservice referrals.[16,17]

I. In retrospective referral cases, the Notice of Action (NOA) is sent to the Member within thirty (30) calendar days of the receipt of the information that is reasonably necessary to make a decision.[18]

J. The NOA letter includes the name and phone number of the IEHP Pharmaceutical Services Pharmacist who reviewed and finalized the denial of the RxUM request. The Member or prescribing Provider can contact the IEHP Pharmaceutical Services Pharmacist to discuss the

[7] NCQA, 2023 HP Standards and Guidelines, UM 2, Element A, Factor 1, 2, 3
[8] NCQA, 2023 HP Standards and Guidelines, UM 11, Element B, Factor 4
[9] NCQA, 2023 HP Standards and Guidelines, UM 4, Element A, Factor 2
[10] NCQA, 2023 HP Standards and Guidelines, UM 11, Element E, Factor 2
[11] NCQA, 2023 HP Standards and Guidelines, UM 6, Element C
[12] NCQA, 2023 HP Standards and Guidelines, UM 11, Element E, Factor 2
[13] NCQA, 2023 HP Standards and Guidelines, UM 6, Element C
[14] NCQA, 2023 HP Standards and Guidelines, UM 11, Element E, Factor 3
[15] NCQA, 2023 HP Standards and Guidelines, UM 4, Element E
[16] NCQA, 2023 HP Standards and Guidelines, UM 5, Element C, Factor 2, 4, 7
[17] NCQA, 2023 HP Standards and Guidelines, UM 11, Element E, Factor 4
[18] NCQA, 2023 HP Standards and Guidelines, UM 5, Element C, Factor 8

denial decision.[19,20] The communication for reason of denial based on medical necessity includes the guidelines used to make the decision.

K. Provider may appeal any adverse determination by IEHP. Provider appeals of denied RxUM referrals are to be submitted to the IEHP Grievance and Appeals Department.[21] See Policy 16B, "Member Appeal Resolution Process" for more information.

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[19] NCQA, 2023 HP Standards and Guidelines, UM 7, Element G
[20] CA Health & Saf. Code § 1367.01(h)(4)
[21] NCQA, 2023 HP Standards and Guidelines, UM 11, Element E, Factor 5

~~D~~C. Prior Authorization or Exception Requests for Physician Administered Drugs

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