# 11. PHARMACY

## A. Formulary Management

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY***:

A. IEHP ensures that the IEHP DualChoice Formulary is reviewed and updated no less than annually, is adequate, and includes a range of drugs in a broad distribution of therapeutic categories and classes that does not substantially discourage enrollment by any group of beneficiaries.[1]

***PROCEDURES:***

**Formulary Management**

A. Formulary management decisions are based on scientific evidence and may also be based on pharmacoeconomic considerations that achieve appropriate, safe, and cost-effective drug therapy.[2] Factors related to optimal pharmacotherapy and considered in formulary deliberations include:

1. Pharmacologic considerations (e.g., drug class, similarity to existing drugs, side effect profile, mechanism of action, therapeutic indication, drug-drug interaction potential, and 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).

[1] Medicare Prescription Drug Benefit Manual, "Chapter 6 - Part D Drugs and Formulary Requirements," Section 30.1.5
[2] Ibid.

B. Formulary includes all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. "Substantially all" in this context means that all drugs and unique dosage forms in these categories are expected to be included in the formulary, with the following exceptions:[3]

1. Multi-source brands of the identical molecular structure;
2. Extended-release products when the immediate-release product is included;
3. Products that have the same active ingredient or moiety; and
4. Dosage forms that do not provide a unique route of administration (e.g., tablets and capsules versus tablets and transdermals).

C. In cases where generic (multi-source) drugs become available and the cost is comparable to similar Formulary drugs within the same class (plus or minus 10%), IEHP Clinical Pharmaceutical Services staff may approve the drug to be added to the IEHP Formulary. The following process will be followed:

1. A generic drug that is cost neutral when comparing to another Formulary agent in the same class;
2. The drug was not voted off the Formulary previously because of drug safety concerns; and
3. The added generic drug will be reported back to the next Pharmacy and Therapeutics (P&T) Subcommittee meeting.

D. In case of a Formulary change, IEHP submits the Formulary file to CMS for approval. IEHP also provides direct written notice to affected Members at least thirty (30) days prior to the effective date of the change; or may provide the Members with a month's supply of the drugs under the same term as previously allowed and provide written notice of the Formulary change. The written notice shall contain the following information:[4]

1. The name of the affected covered Part D Drug;
2. Describe the change of the Formulary status;
3. The reason for the change;
4. Alternative drugs in the same therapeutic category or class; and
5. The means by which Members may obtain a Coverage Determination or exception.

E. CMS may permit to account for new therapeutic uses and newly approved Part D drugs. IEHP shall not change the therapeutic categories and classes in a formulary other than at the

[3] Medicare Prescription Drug Benefit Manual, "Chapter 6 - Part D Drugs and Formulary Requirements," Section 30.1.5
[4] Title 42, CFR §423.120(b)(5)

beginning of each plan year.[5,6]

F. Except when the FDA deems a Part D drug unsafe or manufacturer removes a Part D drug from the market, IEHP shall not make any changes in the preferred or tiered cost-sharing status, nor remove a drug from the Formulary between the beginning of the annual coordinated election period and the end of the contract year.[7]

G. IEHP notifies its Providers in writing about the Formulary additions, deletions, and modifications to policies and procedures.[8] Monthly Formulary updates are posted online on the IEHP Provider website at www.iehp.org.

H. Requests for Formulary additions should be submitted in writing to the IEHP Pharmaceutical Services Staff for placement on the agenda for the next P&T Subcommittee meeting (see Attachment, "Request for Addition or Deletion of a Drug to the Formulary" found on the IEHP website[9]).

I. To ensure accuracy of claims adjudication and benefit logics (i.e. transition logics) at Point-Of-Sales (POS), IEHP conducts daily claims rejection review. The rejection review identifies any discrepancies or outliers by comparing CMS-approved formulary submission, patients' enrollment status, claims submission condition and submitted claims information. All discrepancies shall be addressed immediately to minimize impact on Members.

**Pharmacy and Therapeutics (P&T) Subcommittee**

A. On at least an annual basis, the IEHP P&T Subcommittee reviews for clinical appropriateness the practices and policies of formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization activities that affect access.[10] For more information on the role and function of the P&T Subcommittee, please see Policy 2E, "Pharmacy and Therapeutics Subcommittee."

B. The P&T Subcommittee meets quarterly or more frequently to update the Formulary by reviewing:

1. Medical literature including clinical trials;
2. Relevant findings of government agencies, medical and pharmaceutical associations, National Institutes of Health, and regulatory body publications;
3. Relevant patient utilization and experience;
4. Current therapeutic guidelines and the need for revised or new guidelines;

[5] Title 42, CFR §423.120(b)(4)
[6] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.3.1
[7] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.3.2
[8] Title 42, CFR, §423.120(b)(7)
[9] https://www.iehp.org/en/providers/provider-resources?target=forms#Pharmacy
[10] Title 42, CFR, §423.120(b)(1)

5. IEHP Provider and Practitioner recommendations for addition or deletion of drugs to the Formulary; and
6. The top ten (10) therapeutic classes and top ten (10) 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.

C. The P&T Subcommittee makes reasonable efforts to review a new drug product or indication approved by the United States Food and Drug Administration (FDA) within ninety (90) days of its release onto the market and decides within one hundred eighty (180) days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.[11]

**Formulary Distribution**

A. The IEHP Formulary and Treatment Guide, which includes Formulary status and benefit limitations, is available on the IEHP website. A printed version is available to Members and Providers upon request. The IEHP Formulary and Treatment Guide is published in a booklet format annually and mailed to Providers.

B. IEHP provides an online Formulary search tool on the IEHP website at www.iehp.org. A printed version is available upon request.

C. All new IEHP Providers and pharmacists are informed, as part of their orientation materials, that Formulary information is posted online on the IEHP Provider website.[12] Current Providers are notified annually through written communication of online Formulary information and are notified of updates quarterly via fax following each P&T Subcommittee meeting. Providers can access all Provider communications online at the IEHP website at www.iehp.org.

D. On an annual basis, IEHP notifies the Members regarding the Formulary update schedule through the Member Newsletter. Members also annually receive the Member Handbook providing them instructions to access the IEHP Website to view IEHP's latest Formulary benefits.[13]

| INLAND EMPIRE HEALTH PLAN | | |
|---|---|---|
| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☒ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2007 | |

[11] Medicare Prescription Drug Benefit Manual, "Chapter 6 - Part D Drugs and Formulary Requirements," Section 30.2.5
[12] Ibid.
[13] Medicare Prescription Drug Benefit Manual, "Chapter 6 - Part D Drugs and Formulary Requirements," Section 30.2.5

# 11. PHARMACY

## A. Formulary Management

| | |
|---|---|
| **Revision Effective Date:** | January 1, 2024 |

# 11. PHARMACY

## B. Coverage Determination

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY***:

A. IEHP maintains procedures for making timely Coverage Determinations (CD), including requests for exceptions to the formulary, and addressing grievances and appeals that involve coverage determinations.[1]

***DEFINITIONS:***

A. Coverage Determination (CD) - Any decision made by or on behalf of IEHP with regards the following:[2]

1. A decision not to provide or pay for a Part D drug that is:
    a. Not on the IEHP DualChoice formulary;
    b. Determined not to be medically necessary;
    c. Furnished by an out-of-network pharmacy; or
    d. Otherwise excluded under Section 1862 (a) of the Social Security Act, if applied to Medicare Part D.[3]
2. A decision to provide a CD in an expedited manner, when a delay would adversely affect the health of the Member;
3. Whether a Member has or has not satisfied a prior authorization or other utilization management; or
4. A decision about a formulary exception request.

B. Exception request – A request to obtain a Part D drug that is not included in the IEHP DualChoice formulary, or to request to have a utilization management requirement waived (e.g., step therapy, prior authorization, quantity limit) for a formulary drug.[4]

***PROCEDURES:***

**Coverage Determination Requests**

A. The following individuals may request a standard or expedited CD:[5]

1. A Member;

[1] Title 42 Code of Federal Regulations (CFR) § 423.562
[2] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.2
[3] Social Security Act Section § 1862
[4] https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions
[5] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.6

2. A Member's appointed representative on behalf of the Member (See Attachment, "Appointment of Representative – CMS Form 1696" found on the IEHP website[6]); or
3. A prescribing Physician or other prescriber on behalf of the Member.
4. Staff of said Physician's/prescriber's office acting on said Physician's/prescriber's behalf (e.g., request is on said Physician's/prescriber's letterhead, comes from the Physician/prescriber office fax machine, or otherwise indicates staff is working under the direction of the Physician/prescriber).

B. IEHP supplies all Providers with the CD Forms in threshold languages (See Attachment, "Coverage Determination - Provider & Member" found on the IEHP website[7]) and instructions for their use. CD and Exception requests may be submitted verbally or in writing, using the Coverage Determination or another form:[8]

1. A Member or their appointed representative may contact IEHP Member Services Department at (877) 273-IEHP (4347)/TTY (800) 718-4347 during normal business hours (8:00 a.m. to 8:00 p.m. Monday through Friday). The Member or their representative may leave a secure voice message after-hours.
2. A prescribing Physician or other prescriber may submit a CD or Exception request by phone at (909) 890-2049 or (888) 860-1297, by mail to IEHP at P.O. Box 1800, Rancho Cucamonga, CA 91729, through the secure IEHP Provider portal, or by fax to IEHP Pharmaceutical Services at (909) 890-2058. The prescribing Physician or other prescriber may leave a secure voice message after-hours. The Provider will be instructed by the voicemail message to provide all necessary information (e.g., Provider identification, Member identification, type of request and whether it is expedited or standard).

C. When a medication with prior authorization (PA) requirements is requested through the point-of-sale system, a message is transmitted to the Pharmacy indicating that the drug is not covered. The pharmacy should notify the Member, the Member's appointed representative, the prescribing Physician or other prescriber to request a CD.[9]

D. Requests for cash reimbursements are considered CD requests. The request may be made up to one (1) year from the date of service. See Policy 11P, "Member Request for Pharmacy Reimbursement" for more information.

E. All CD requests must provide information that support the medical necessity or meet the criteria for prior authorization, as well as previous successful or failed therapies, any allergies, or any other clinical condition when applicable.

[6] https://www.iehp.org/en/providers/provider-resources?target=forms
[7] Ibid.
[8] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.7
[9] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.2

F. For information on review of drugs for inclusion and changes to the formulary, please see Policy 11A, "Formulary Management."

**Exception Requests**

A. A prescribing Physician or other prescriber must provide a supporting statement that the requested prescription drug is medically necessary to treat the Member's disease or medical condition for the reasons listed below. If the supporting statement is provided orally, IEHP may require the prescribing Physician or other prescriber to subsequently provide a written supporting statement.[10]

1. All the covered Part D drugs on IEHP's formulary for treatment for the same condition would not be as effective for the Member as the non-formulary drug, or could have adverse effects for the Member, or both;
2. The number of doses available under a dose restriction for the requested drug has been ineffective in the treatment of the Member's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the Member, and known characteristics of the regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or
3. The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements has been ineffective in the treatment of the Member's disease or medical condition or, based on both sound clinical evidence and medical scientific evidence, the known relevant physical or mental characteristics of the Member and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

B. IEHP may apply quantity limits on non-formulary drugs approved through the Exception request process that are based on safety concerns. The Centers for Medicare and Medicaid Services (CMS) permits the following safety-based quantity limits:[11]

1. Quantity limits based on maximum dosing limits, frequency and/or duration of therapy supported by the United States Food and Drug Administration;
2. Quantity limits on topical products in consideration of indication, directions for use, and size of the area being treated; and
3. Quantity limits that support dose optimization that are intended to promote adherence and ensure safe and appropriate utilization.

**Coverage Determination Timeframes**

[10] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.5.3

[11] Health Plan Management System (HPMS) Memo, "Use of Safety-Based Quantity Limits on Approved Non-Formulary Drugs," March 12, 2019

A. Standard CD Requests:[12]

1. Requests for drug benefits:

   a. IEHP notifies the Member, the Member's appointed representative and the prescribing Physician or other prescriber as expeditiously as the Member's health condition requires, but no later than seventy-two (72) hours (including weekends and holidays) after receipt of the request.

   b. For Exception requests, IEHP notifies the Member, the Member's representative and the prescribing Physician or other prescriber within seventy-two (72) hours (including weekends and holidays) after receipt of the Physician's supporting statement or fourteen (14) calendar days after receipt of the request, whichever occurs first.[13]

2. Requests for Member reimbursement: Please see Policy 11M, "Member Request for Pharmacy Reimbursement" for more information, including processing timeframes.

B. Expedited CD Requests:[14]

1. IEHP will expedite a CD, as requested by the Member or the Member's appointed representative, if the health plan determines that applying the standard timeframe may seriously jeopardize the Member's life, health, or ability to regain maximum function.

2. IEHP will expedite a CD if the request is made or supported by a Physician, prescribing Physician, or other prescriber who indicates applying the standard timeframe may seriously jeopardize the Member's life, health, or ability to regain maximum function.

3. Requests for reimbursement for covered Part D drugs that were already furnished to the Member may not be expedited.

4. IEHP will make a determination and notify the Member within twenty-four (24) hours of receipt of request (or for an Exception request, within twenty-four (24) hours of receipt of the physician's supporting statement) if IEHP determines that the Member's life or health will be seriously jeopardized by waiting for a standard decision.[15]

5. If IEHP denies a Member's or a Member's appointed representative's request for an expedited CD, the request is processed using standard processing timeframes. IEHP:[16]

[12] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/ Coverage Determinations and Appeals Guidance", Section 40.5.3
[13] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/ Coverage Determinations and Appeals Guidance", Section 40.5.4
[14] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/ Coverage Determinations and Appeals Guidance", Section 40.8
[15] Ibid.
[16] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.8

a. Provides prompt oral notice to the Member, the Member's appointed representative and the prescribing Physician or other prescriber that the request will be processed under the standard CD;

b. Informs the Member or their appointed representative of his or her right to have the prescribing Physician resubmit a request for an expedited CD;

c. Informs the Member or their appointed representative of his or her right to file an expedited grievance if he or she disagrees with IEHP's decision not to expedite the CD;

d. Provides instructions on IEHP's grievance process and timeframes; and

e. Mails a written confirmation to the Member within three (3) calendar days after the oral notification.

C. Failure to make a decision on a CD request and provide notice of the decision within the timeframe required by CMS constitutes an adverse CD. In this case, IEHP forwards the request to the Independent Review Entity (IRE) within twenty-four (24) hours of the expiration of the adjudication timeframe.[17]

**Coverage Determination Review Process**

A. All clinical criteria for prior authorization of medications are reviewed and updated at least annually or more often, as needed.

B. A CD will be made when a covered Part D drug is dispensed at a non-participating pharmacy if:[18]

1. IEHP cannot reasonably expect the Member to obtain such drugs at a participating Pharmacy in a timely manner; and

2. The Member does not access covered Part D drugs at non-participating pharmacies on a routine basis.

C. Clinical Pharmacists are responsible for reviewing the initial CD. IEHP Clinical Pharmacists have current and unrestricted pharmacist licenses to practice in California.[19]

D. Clinical Pharmaceutical Services staff who provides utilization review services does not contain incentives, direct or indirect, for these individuals to deny, limit, or discontinue medically necessary services to any Member.

E. Pharmaceutical Services staff reviews individual requests by thoroughly surveying the Member's existing medication regimen, previous successful or failed therapies, any allergies, and any other clinical condition when applicable.

[17] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.11
[18] 42 CFR § 423.124
[19] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.9

F. If IEHP approves an Exception request, IEHP may not require the Member to request approval for a refill, or a new prescription to continue using the Part D prescription drug approved under the exception process for the remainder of the plan year, as long as:[20]

1. The Member remains enrolled in IEHP;
2. The prescribing Physician or other prescriber continues to prescribe the drug; and
3. The drug continues to be considered safe for treating the disease or medical condition.

G. If IEHP approves a CD, IEHP notifies the Member, the Member's appointed representative and prescribing Provider or other prescriber within regulatory timeframes. The approval letter shall include conditions of the approval including, but not limited to:[21]

1. Duration of the approval;
2. Limitations associated with an approval; and/or
3. Any coverage rules applicable to subsequent refills.

H. The Clinical Pharmaceutical Services staff discusses the requests that are found to be medically unjustifiable with the Clinical Pharmacist prior to denying them. The Clinical Pharmacist reviews and signs all denied CDs.[22]

I. As part of the determination process, Clinical Pharmacist consults with appropriate Specialists for requests involving unusual or clinically complicated conditions.

J. Prior to denying a request, the Clinical Pharmaceutical Services staff consults with the prescribing Physician to offer an alternative pharmacotherapeutic regimen and to discuss the specific reason for the denial.

K. If IEHP denies a drug benefit, in whole or in part, a denial letter is issued to both Member or their appointed representative and the prescribing Physician or other prescriber.[23] The denial letter shall include the following information:[24]

1. Denial notice language in a readable and understandable form;
2. The specific reason for the denial that takes into account the Member's presenting medical condition, disabilities, and special language requirements, if any;
3. Criteria used in the review process;

[20] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.5.5
[21] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.12.2
[22] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.9
[23] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.8
[24] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.12.3

4. Procedures for obtaining additional information about criteria used in the review process;
5. Information on the Member's right to appoint a representative to file an appeal on the Member's behalf;
6. Information on the Member's right to a redetermination:
    a. If IEHP denies drug coverage, a description of both the standard and expedited redetermination processes, including the conditions for obtaining an expedited redetermination and the appeals process;
    b. If IEHP denies payment, the notice shall describe the standard redetermination process and the appeals process; and
7. Other notice requirements as specified by CMS.

L. The final authority for obtaining medications not included in the IEHP Formulary rests with IEHP Chief Medical Officer. All documents and written materials are forwarded to the Chief Medical Officer or Medical Director designee for review if an appeal is filed by the prescribing Physician or other prescriber, IPA, Pharmacist, Member, or Member's appointed representative.

M. The Member, Member's appointed representative, the prescribing Physician or other prescriber may request a redetermination if the Member has received an adverse CD. See Section 16, "Grievance and Appeal Resolution System" for more information.

N. A CD request that is submitted to the Pharmaceutical Services Department using a Coverage Determination form with the word "appeal" or a Part D denial case for the same requested medication with or without additional information in the past sixty (60) days will be deemed as redetermination and forwarded to the IEHP Grievance & Appeals Department for review.

| **INLAND EMPIRE HEALTH PLAN** | | |
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| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☐ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2012 | |
| **Revision Effective Date:** | January 1, 2024 | |

# 11. PHARMACY

## C. IEHP DualChoice Vaccine Coverage

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY***:

A. Effective January 1st, 2008, the administration of a Part D covered vaccine is included in the definition of "covered Part D drug" under the Part D statute.[1] IEHP thus ensures that IEHP DualChoice Members have adequate access to Part D vaccines and that vaccines are billed appropriately under the Part D, or Part B (where applicable), benefit.[2]

***PROCEDURES:***

A. Members may receive Part D vaccine coverage through one (1) of the following options:
   1. In-Network Vaccine Distribution – Retail Pharmacy[3]
      a. Members can obtain a prescription from their Primary Care Provider (PCP) and bring it to a contracted IEHP Pharmacy Provider for filling.
      b. IEHP Pharmacy Providers who register with the Pharmacy Benefit Manager (PBM) as vaccine Providers may provide service and submit claims online as a single claim (both the vaccine serum and the administration cost).
      c. Pharmacy Providers should collect any applicable cost-sharing for the vaccine and its administration. No Member Reimbursement form is required. The Member's deductible, coinsurance and co-pay should be taken into account, if applicable.
   2. Out-of-Network - IEHP reimburses the Members directly
      a. Member receives and pays for a Part D covered vaccine through a doctor or other health care Provider (other than the Vaccine Network Pharmacy).
      b. Member needs to submit a pharmacy reimbursement request. Please see Policy 11M, "Member Request for Pharmacy Reimbursement" for more information.
   3. Out-of-Network - Receive vaccination through the physician Provider.
      a. The Provider may submit claims on behalf of the Member when they provide Part D covered vaccines. The Member may also obtain the vaccine from the Pharmacy and transport the vaccine to the Physician's office for administration. No Member

[1] Tax Relief and Health Care Act (TRHCA) § 202(b)
[2] Medicare Prescription Drug Manual, "Benefits and Beneficiary Protections," Section 60.2
[3] Ibid.

Reimbursement form is required. The deductible, coinsurance and co-pay will apply.

B. When applicable, one (1) cost-sharing amount should be applied to both the vaccine ingredient cost and the administration cost, resulting in one (1) co-pay for the Member, if the vaccines are distributed.

C. The Part D vaccine program generally covers those vaccines not available under Part B. The following vaccines are covered under the Part B Program:

1. Pneumococcal pneumonia vaccine;
2. Influenza virus vaccine;
3. Hepatitis B vaccine for individuals at high or intermediate risk; and
4. Other vaccines (i.e., tetanus toxoid) when directly related to the treatment of an injury or direct exposure to a disease or condition.

D. IEHP's contracted PBM accepts Part D vaccine administration claims from participating pharmacies when submitted in the National Council for Prescription Drug Programs (NCPDP) approved format.[4] IEHP reimburses any Pharmacy that has agreed to provide vaccine administration services.

E. IEHP and the contracted PBM will monitor the Part D vaccine claims. When administration is billed separately from the dispensing of the vaccine, IEHP and the contracted PBM will review existing claims for the presence of a vaccine charge. Should no vaccine charge be present in the claim's history, IEHP will work with the Member to ensure the Member submits a paper receipt for the vaccine and that appropriate reimbursement has been paid.

F. Medicare payment for the COVID-19 vaccine (if Providers do not receive it for free) and its administration will be made through the original fee-for-service Medicare program.

G. All Part D covered vaccines are listed in the IEHP DualChoice Formulary. No prior authorization is required for covered Part D vaccines. All covered Part D vaccines are restricted to be used according to the latest Centers for Disease Control and Prevention (CDC) recommended Adult Immunization Schedule found online at http://www.cdc.gov/vaccines/schedules/hcp/adult.html.

| **INLAND EMPIRE HEALTH PLAN** | | |
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| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☒ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2009 | |
| **Revision Effective Date:** | January 1, 2024 | |

[4] Medicare Prescription Drug Manual, "Benefits and Beneficiary Protections," Section 60.2.2

# 11. PHARMACY

## D. Claims for Drugs Prescribed or Dispensed by Sanctioned, Excluded and Precluded Providers

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. IEHP's contracted Pharmacy Benefit Manager (PBM) will utilize the reference files from the Office of Inspector General (OIG), U.S General Services Administration (GSA) System for Award Management (SAM), and the Department of Healthcare Services (DHCS) Medi-Cal Suspended & Ineligible (S&I) List monthly updates to ensure the PBM claim system remains updated and denies claims submitted by sanctioned, excluded, and precluded Providers.[1,2]

***PROCEDURES:***

A. IEHP's contracted PBM is responsible for referencing sanctioned, excluded and precluded data and updating their system(s) based on the Centers for Medicare & Medicaid (CMS) requirement, described above. Once updated, all claims related to the sanctioned, excluded and precluded Providers will be denied.[3] IEHP will generate letters to impacted Members.

B. IEHP will monitor the State's Provider licensing department updates.[4] Providers whose licenses are terminated, revoked, or suspended by the State of California are not eligible to write prescriptions for IEHP Members. IEHP will block the National Provider Identifiers (NPIs) listed on the sanctioned Provider list.

| **INLAND EMPIRE HEALTH PLAN** | | |
|---|---|---|
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| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2016 | |
| **Revision Effective Date:** | January 1, 2023 | |

[1] Title 42 Code of Federal Regulations (CFR) § 422.224(a)
[2] Medicare Managed Care Manual, "Compliance Program Guidelines", Section 50.6.8
[3] Center for Medicare & Medicaid Services, "Preclusion List Requirements", December 14, 2018
[4] Medicare Managed Care Manual, "Compliance Program Guidelines", Section 50.6.8

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## E. Pharmacy Access During a Federal Disaster or Other Public Health Emergency Declaration

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. IEHP monitors the Federal Emergency Management Agency (FEMA) for issuance of Presidential major disaster declarations and the Department of Health and Human Services (DHHS) website for public health emergency declarations.

B. IEHP will guarantee immediate refills of medications to any Members located in an "emergency area," as defined by FEMA announcements.

***PROCEDURES:***

A. IEHP works in conjunction with the contracted Pharmacy Benefits Manager (PBM) to remove formulary restrictions and implement Formulary edits to allow full emergency access to medications for Members whose primary residence is located in the geographic area identified in the declarations, regardless of the location at which they are attempting to obtain a refill.[1]

B. At the end of the emergency declaration, IEHP will revert the edits and continue to work closely with Members who were displaced or otherwise impacted by the disaster. An emergency declaration ceases to exist when DHHS announces that the public health emergency no longer exists or upon the expiration of the ninety (90) day period beginning from the initial declaration; or when FEMA announces the closure of Presidential disaster declarations.[2]

| **INLAND EMPIRE HEALTH PLAN** | | |
|---|---|---|
| **Regulatory/ Accreditation Agencies:** | ☒ DHCS | ☒ CMS |
| | ☒ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2016 | |
| **Revision Effective Date:** | January 1, 2023 | |

[1] Medicare Managed Care Manual, "Benefits and Beneficiary Protections," Section 50.12
[2] Ibid.

# 11. PHARMACY

## F. Coverage Determination - Part B vs. D Determination

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY***:

A. IEHP ensures that drugs for which coverage may be available under Part B or Part D, as it is being prescribed or administered to the Member, are provided under the correct benefit coverage.

***PROCEDURES:***

A. IEHP's Medicare Pharmacy staff, and/or assigned delegate will manage all prior authorizations for Part B vs. Part D Coverage Determinations (CDs) as follows:

1. IEHP's Medicare Clinical Pharmacists will rely upon information submitted by the Pharmacy or Prescriber on the CD Form and medical information included with the prescription, if available, such as diagnosis information or the location where the medication is going to be administered (see Attachment, "Coverage Determination – Provider and Member" found on the IEHP website[1]).
2. IEHP's Medicare Clinical Pharmacists, and/or assigned delegate may require the Pharmacy to share the information provided on the prescription to assist in the determination of Part B vs. Part D coverage. IEHP will make a Part B vs. Part D CD based on guidance set forth by the Centers for Medicare and Medicaid Services (CMS).

B. CDs and notifications to the Member or Member's representative and prescribing Physician or other prescriber are made within regulatory timeframes, regardless of benefit determination. For more information on the CD process and requirements, please see Policy 11B, "Coverage Determination."

C. Medications to be considered, and any additional parameters that must be taken into consideration to make a B vs. D Coverage Determination, are as follows:[2]

1. **Durable Medical Equipment Supply Drugs – Infusion Drugs**
   a. Any agent administered in the home via intravenous (IV) drip or push injection would be covered under Medicare Part D.
   b. If the drug is administered using a CMS-approved infusion pump or meets durable medical equipment-maximum allowable cost (DME-MAC) Local Coverage Determination (LCD) criteria, it will be covered by Part B.
   c. The exception to this rule is if the Member resides in a long-term care (LTC) facility and the drug is administered via an infusion pump, then the medication is covered

[1] https://www.iehp.org/en/providers?target=forms
[2] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Appendix C

under Part D.

2. **Durable Medical Equipment Supply Drugs – Respiratory Drugs**
   a. Any agent administered in the home via a hand-held inhaler would be covered under Medicare Part D.
   b. If the drug's approved administration is through a nebulizer in the home, it will be covered by Part B.
   c. The exception to this rule is if the Member resides in a LTC facility, and the drug is administered via a nebulizer, then the medication is covered under Part D.
3. **Intravenous Immune Globulin (IVIG) provided in the home**
   a. For individuals whose diagnosis is primary immune deficiency disease, IVIG are covered by Part B.
   b. Other indications as approved by IEHP's Medicare Administrative Contractor (MAC) Part B carrier in its LCD will also be covered under Part B.
   c. All other medically accepted indications are covered by the Part D.
4. **Parenteral Nutrition**
   a. Part B coverage for parenteral nutrition is limited to individuals with a non-functioning digestive tract.
   b. For all other medically accepted indications, coverage would be under Part D.
5. **Anti-neoplastic Drugs – ORAL**
   a. Oral anti-neoplastics that have an IV formulation for the same indications are covered under Part B.
   b. All other oral anti-neoplastic agents are covered under Part D.
6. **Anti-emetic Drugs – ORAL**
   a. If a request for a Part B vs. D Coverage Determination is received, the Pharmacist will verify if the use is:
      1) Related to cancer treatment;
      2) A full replacement for intravenous administration; and
      3) Being administered within forty-eight (48) hours of cancer treatment.

      In such instances, the medication will be covered by Part B.
   b. Aprepitant (Emend®) will be covered under Part B when it is given prior to, during or right after chemotherapy. Otherwise, the medication will be covered under Part D. Oral anti-emetic drugs dispensed for use after the forty-eight (48) hours period, or any oral anti-emetic prescribed for conditions other than treatment of the effects of cancer treatment, will be covered under Part D.

7. **Immunosuppressant Drugs**

   a. If a request for prior authorization is received, the IEHP Pharmaceutical Services staff will verify with the Clinical Pharmacist whether the Member's transplant was covered by Medicare. If the Member had a Medicare-covered transplant, the medication will be covered under Part B; otherwise, the medication will be covered under Part D.[3]

8. **Injectables**

   a. Coverage for B vs. D cannot generally be determined based solely on the drug itself. The IEHP Pharmaceutical Services staff will consider how the drug was "prescribed and dispensed or administered" with respect to the individual. The same drug may be covered under different circumstances either by IEHP's Part D or Part B.

   b. IEHP will cover Part D eligible injectable drugs not covered by Medicare Part B. Most of these are generally self-administered (e.g., Imitrex).

   c. The fact that an injectable is covered under Part B if provided by and administered in a Physician's office or Hospital outpatient setting does not mean IEHP can deny a claim from a Pharmacy solely based on availability of Part B coverage for drugs given in the Physician's office. If, however, a Member submits an out-of-network claim for an injectable drug administered in-office from a Physician's supply, and this drug is covered in that setting by the Part B contractor for that area, such a claim will be denied under Part D by IEHP based on Part B coverage requirements.

   d. If the medication (including injectable) is being obtained at a retail pharmacy, it may be covered under Part D in accordance with the corresponding National Coverage Determination (NCD) or Local Coverage Determination (LCD). If a Physician is administering the medication, he/she agrees to accept brown bagging of the medication and understands that the Member will obtain the medication from a Pharmacy and have it in their possession until the Member delivers the medication to the Physician office for administration.

9. **Hemophilia Clotting Factors**

   a. Hemophilia clotting factors for hemophilia patients, and items related to the administration of such factors, are always covered under Part B and never under Part D.

10. **Pneumococcal Vaccine**

    a. All vaccines must be dispensed and administered in compliance with California state law.

    b. The vaccine and its administration to a Member are covered under Part B.

11. **Hepatitis B Vaccine**

[3] Medicare Prescription Drug Benefit Manual, "Chapter 14 - Coordination of Benefits," Section 50.15

a. All vaccines must be dispensed and administered in compliance with California state law.

b. The vaccine and its administration to a Member who is at high or intermediate risk of contracting Hepatitis B are covered under Part B.

c. The vaccine prescribed to be administered prophylactically will be covered under Part D.

12. **Influenza Vaccine**

a. All vaccines must be dispensed and administered in compliance with California state law.

b. The vaccine and its administration to a Member are covered under Part B.

13. **Antigens**

a. These formulations are usually prepared by a Physician (e.g., an allergist) for a specific patient. The Physician or Physician's nurse generally administers these drugs in the Physician's office. This would be covered under Part B.

14. **Erythropoietin (EPO)**

a. For an end-stage renal disease (ESRD) patient undergoing dialysis in a facility the EPO claim must be submitted as part of their bundled payment, covered by Part B.

b. For ESRD patients not receiving dialysis, the EPO prescription can be filled in the retail setting and covered under Part D.

D. **Long Term Care (LTC) Accessibility**[4]

1. IEHP's Medicare Clinical Pharmacists, and/or assigned delegate will approve coverage for medically necessary prescription drug treatments for Part D Members who reside in LTC facilities, including dosage forms of drugs that are utilized in the LTC setting, such as unit dose products and liquid, chewable, and parenteral preparations.

2. IEHP will also cover these dosage forms for Part D Members under circumstances in which Part B coverage is not available.

E. **Denials**

1. If the decision is made by the Clinical Pharmacists that the medication will be covered under Medicare Part B, then the Part D Coverage Determination Request is denied as a "Non-Covered Benefit" in the medical management system. A notification will be sent to the Member or Member's representative and prescribing Physician or other prescriber that the medication is denied under Part D but it is covered under Medicare Part B benefit.

F. IEHP applies beneficiary-level prior authorization requirements on four (4) categories of

[4] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.2.3

drugs that are always used for ESRD treatment (access management, anemia management, bone and mineral metabolism, cellular management).[5] These four (4) drug categories are determined by CMS and do not include other drug categories, unless otherwise stated by CMS. If it is determined through routine utilization review or otherwise that a renal dialysis service drug has been inappropriately billed to Part D, IEHP and the ESRD facility will negotiate repayment.

| INLAND EMPIRE HEALTH PLAN | | |
|---|---|---|
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[5] Health Plan Management System (HPMS) Memo, "Two Updates Pertaining to End-Stage Renal Disease (ESRD)-Related Drugs," May 12, 2015

# 11. PHARMACY

## G. Coordination of Benefits

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. IEHP's Coordination of Benefits (COB) program prevents duplication of payments for the same health care services and prevents Medicare from paying as the primary when it is the secondary payer.[1]

B. IEHP and the contracted Pharmacy Benefit Manager (PBM) must comply with all administrative processes and requirements established by Centers for Medicare and Medicaid Services (CMS) to ensure effective exchange of information and coordination between IEHP and Other Health Coverage for:[2]

   1. Payment of premiums and coverage; and
   2. Payment for supplemental prescription drug benefits for Members enrolled in IEHP and an entity that provides other prescription drug coverage.

***DEFINITIONS:***

A. True Out-of-Pocket (TrOOP) - Incurred allowable costs that are paid by the beneficiary or by specified third parties on their behalf within the limits of the standard benefit, up to a legislatively specified out-of-pocket threshold.[3]

B. Nx Transactions – Information reporting transaction containing information on a paid supplemental claim and sent by the Part D Transaction Facilitator to the enrollee's Part D plan.[4] The National Council for Prescription Drug Programs (NCPDP) developed this set of transactions that provides a record of a payment, by a plan supplemental to Part D, to a Part D Plan.

***PROCEDURES:***

**COB Program**

A. COB serves as a mechanism to:[5]

   1. Collect information from a Member regarding Other Health Coverage; and
   2. Support the tracking and calculating of beneficiaries' "true out-of-pocket" (TrOOP) expenditures.

[1] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 20
[2] Ibid.
[3] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Appendix F
[4] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 30.4.6
[5] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 20

B. The COB program includes:[6]

1. Enrollment file sharing;
2. Claims processing and payment;
3. Claims reconciliation reports;
4. Third-party reimbursement of out-of-pocket costs;
5. Application of protection against high out-of-pocket expenditures; and
6. Other processes that CMS determines.

**Member Responsibilities**

A. Members are legally obligated to report information about Other Health Coverage or reimbursement for prescription drugs costs that they have or expect to receive under the Medicare Modernization Act (MMA).[7]

B. Members or other payers have up to thirty-six (36) months from the date on which the prescription for a covered Part D drug was filled to seek reimbursement from IEHP.[8]

**IEHP Responsibilities**

A. IEHP provides coordination of benefits with the PBM, CMS-contracted COB Contractor, and the TrOOP Facilitators.

B. IEHP coordinates benefits with State pharmaceutical assistance programs, other payers, Members and others paying on the Members' behalf for up to thirty-six (36) months from the date on which the prescription for a covered Part D drug was filled.[9]

C. When IEHP receives a Nx transaction but has no supplement payer information on file to identify the payer; IEHP shall attempt to make contact with the Member to identify the payer.[10] IEHP sends the payer information to the COB Contractor via Electronic Correspondence Referral System (ECRS) verification. IEHP must report changes to the COB information and COB Contractor within thirty (30) days of receipt.[11] IEHP shall maintain connectivity with CMS systems to allow direct access to Other Health Coverage status information.[12]

D. IEHP may impose user fees to Other Health Coverage for costs related to coordination of benefits between IEHP and Other Health Coverage under the provision of MMA. The user fees must be reasonable and related to the IEHP's actual costs of COB with the Other Health Coverage.[13]

[6] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 20
[7] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 40.1
[8] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 50.14.4
[9] Ibid.
[10] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 50.4.1
[11] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 50.3.2
[12] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 50.3.1
[13] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 20

E. IEHP shall retroactively adjust claims and TrOOP balances based on prescription drug events and claims records.[14]

F. IEHP's PBM will process claims and track TrOOP in real time.[15]

G. IEHP will assist Members with billing issues from the IEHP-contracted PBM, the DHCS Medi-Cal Rx-contracted PBM, Magellan, and the CMS-contracted COB Contractor when Members issues arise.

1. IEHP will contact the pharmacy, prescriber, the IEHP-contracted PBM and/or the DHCS Medi-Cal Rx contracted PBM, Magellan, to help resolve billing issues.[16]
2. IEHP will notify the Member about the outcome and resolution.

H. IEHP will not turn Members away or require them to contact the IEHP-contracted PBM, the DHCS Medi-Cal Rx-contracted PBM, Magellan, or the CMS-contracted COB Contractor to resolve issues with obtaining prescriptions.

I. When necessary, IEHP will contact the prescriber for new prescriptions to be in compliance with CMS requirements for prescriptions processing at pharmacy.

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|---|---|---|
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[14] Medicare Prescription Drug Benefit Manual, "Chapter 14 – Coordination of Benefits," Section 50.4
[15] Ibid.
[16] Department of Health Care Services (DHCS)-IEHP State Medicaid Agency Contract, Exhibit A, Attachment 1, Provision 1.D., Coordination of Care

# 11. PHARMACY

## H. Best Available Evidence

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY***:

A. IEHP provides access to Part D drugs at the correct Low-Income Subsidy (LIS) cost-sharing level when presented with evidence of LIS eligibility, even if IEHP's system and Centers for Medicare and Medicaid Services' (CMS) systems do not yet reflect that eligibility.[1]

***DEFINITIONS:***

A. Best Available Evidence (BAE) – Documentation used by IEHP to support a favorable change to a low-income subsidy (LIS) eligible Member's LIS status.[2]

B. Institutionalized Individual - A Medicare Advantage (MA)-eligible individual who resides or is expected to reside continuously for ninety (90) days or longer in a:

1. Skilled Nursing Facility (SNF)
2. Nursing Facility (NF)
3. Intermediate Care Facility for individuals with intellectual and developmental disabilities
4. Psychiatric Hospital
5. Rehabilitation Hospital
6. Long Term Care Hospital
7. Swing-Bed Hospital

These individuals are considered long-term institutional residents for purposes of determining who can enroll in a special needs plan.[3]

***PROCEDURES:***

A. This process only applies to Members who are "deemed" eligible for LIS and may not be used for LIS applicants.

B. Payment for institutionalized individuals or SNF residents is made under Medicaid throughout a full calendar month. These Members remain deemed for zero co-pay throughout the remainder of the calendar year. IEHP accepts and uses BAE to substantiate the Member's

[1] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Best_Available_Evidence_Policy
[2] Medicare Prescription Drug Benefit Manual, "Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 20
[3] Centers for Medicare & Medicaid Services, "Medicare Advantage (MA) Special Needs Plans Guidance," January 19, 2006

correct LIS cost-sharing level. The institutionalized Members have an indicator of "3" under the LIS level to return copay of zero.

C. IEHP accepts BAE at point-of-sale (POS) and updates the eligibility system within forty-eight to seventy-two (48-72) hours of the receipt of the documentation.

D. If the case is urgent, IEHP shall allow a minimum of seventy-two (72) hours' worth of medications until the case is resolved.

1. IEHP accepts any of the following documents to validate the correct LIS cost-sharing level and effective date for Members who should be deemed eligible for LIS 2 (full dual eligible). The document must show that the Member was eligible for Medicaid (IEHP Medi-Cal) during a month after June of the previous calendar year.[4]

   a. A copy of the Member's Medicaid card which includes the Member's name and eligibility date;

   b. A copy of a state document that confirms active Medicaid status;

   c. A printout from the State electronic enrollment file showing Medicaid status;

   d. A screen print from the State's Medicaid systems showing Medicaid status;

   e. Other documentation provided by the State showing Medicaid status;

   f. A report of contact, including the date a verification call was made to the State Medicaid Agency and the name, title and telephone number of the State staff person who verified the Medicaid status;

   g. A remittance from a long-term care facility showing Medicaid payment for a full calendar month for that individual;[5]

   h. A copy of a state document that confirms Medicaid payment to a long-term care facility for a full calendar month on behalf of the individual;[6]

   i. A screen print from the State's Medicaid systems showing that individual's institutional status based on at least a full calendar month's stay for Medicaid payment purposes;[7]

   j. Supplemental Security Income (SSI) Notice of Award with an effective date;

   k. An Important Information letter from the Social Security Administration (SSA) confirming that the beneficiary is automatically eligible for extra help; [8]

[4] Medicare Prescription Drug Benefit Manual, "Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 70.5.2
[5] Health Plan Management System (HPMS) Memo, "Best Available Evidence Policy – Update," August 4, 2008
[6] Ibid.
[7] Ibid.
[8] Medicare Prescription Drug Benefit Manual, "Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 70.6

l. An application filed by Deemed Eligible confirming that the beneficiary is "…automatically eligible for extra help…" (SSA publication HI 03094.605); or

m. A copy of the Deeming notice pub. No. 11166 (Purple Notice).[9]

2. IEHP accepts any one of the following documents to validate the correct LIS cost-sharing level and effective date for Members who should be deemed eligible for LIS 3. The document must show that the Member was eligible for Medicaid (IEHP Medi-Cal) during a month after June of the previous calendar year.[10]

   a. A remittance from the facility showing Medicaid payment for that individual;

   b. A copy of a state Medicaid document showing the individual's institutional status;

   c. A screen-print from the State's Medicaid systems showing the individual's institutional status;

   d. A copy of the Deeming notice – pub. No. 11166 (purple notice);[11]

   e. A copy of a State-issued Notice of Action, Notice of Determination, or Notice of Enrollment that includes the beneficiary's name and Home and Community-Based Services (HCBS) eligibility date;

   f. A copy of a State–approved HCBS Service Plan that includes the beneficiary's name and effective date;

   g. A copy of a State-issued prior authorization approval letter for HCBS that includes the beneficiary's name and effective date;

   h. Other documentation provided by the State showing HCBS eligibility status; or

   i. A State-issued document, such as a remittance advice, confirming payment for HCBS, including the beneficiary's name and the dates of HCBS.

E. IEHP updates the systems to reflect the LIS status indicated by the BAE and submits a request to CMS for manual update within sixty (60) days if routine reporting does not correct for deemed Members.[12]

[9] Medicare Prescription Drug Benefit Manual, "Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 70.6
[10] Medicare Prescription Drug Benefit Manual, "Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 70.5.2
[11] Medicare Prescription Drug Benefit Manual, "Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 70.5.6
[12] Medicare Prescription Drug Benefit Manual, "Chapter 13 – Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 70.5.4

# 11. PHARMACY

## H. Best Available Evidence

| INLAND EMPIRE HEALTH PLAN | | |
|---|---|---|
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# 11. PHARMACY

## I. Transition Process

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY***:

A. IEHP provides a transition process for Members whose current drug therapies may not be included in their new Part D plan's formulary, and will effectuate a meaningful transition for the following:[1]

1. New Members into IEHP DualChoice on January 1st of the new year following the previous year's annual coordinated election period;
2. The transition of newly eligible Medicare beneficiaries from other coverage in the new year;
3. The transition of individuals who switch from one plan to another after January 1st of the new year;
4. Enrollees residing in Long-Term Care (LTC) facilities; and
5. Members affected by negative Formulary changes from one (1) contract year to the next.

***PURPOSE:***

A. To promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of an Exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated.[2]

***PROCEDURES:***

A. The transition process and requirements apply to:[3]

1. Part D drugs that are not on the IEHP DualChoice Formulary;
2. Part D drugs that were approved for coverage under an exception once the exception expires; and
3. Part D drugs that are on the IEHP DualChoice Formulary but require prior authorization, step therapy, or have an approved quantity limit lower than the beneficiary's current dose, under IEHP utilization management rules.

[1] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.4.1
[2] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.4
[3] Ibid.

B. IEHP assures that all transition processes are applied to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.[4]

C. IEHP provides a transition supply when the Member requests a non-formulary drug within ninety (90) days of their enrollment with IEHP DualChoice. If the Member disenrolls from IEHP and re-enrolls during this ninety (90) day transition period, the transition period begins again with the new enrollment date.[5]

D. IEHP assures that in the outpatient (retail) setting, the transition fill of non-formulary Part D drug is for at least a month's fill, unless the prescription is written for a shorter period. In which case, IEHP will allow multiple fills to equal at least a month's supply.[6]

E. IEHP assures that in the Long-Term Care (LTC) setting, such as nursing facility or sub-acute care facility, the transition supply of non-formulary Part D drug is for a one month fill (unless the Member presents with a prescription written for less than a month), with multiple refills as necessary (up to a month's supply).[7]

F. IEHP assures that in the Long-Term Care setting, after the transition period has expired, the transition policy provides for a month-long emergency supply of non-formulary Part D drugs (unless the Member presents with a prescription written for less than a month) while an exception or prior authorization is being processed.[8]

G. Under circumstances where the transition policy does not apply, all non-formulary Part D drugs are subject to the coverage determination process. See Policy 11B, "Coverage Determination."

H. Claims will automatically process if the Member and the drug are both eligible for transition. Eligible claims will process and approve upon initial submission and messages will indicate when claims have paid under transition fill rules. The messages will be returned with paid transition fill claims so pharmacies can remind Members of actions that should be taken to ensure access to prescription drugs in accordance with Part D formularies and benefits.

I. If a transition claim fails to process and the Pharmacy believes the IEHP Member and the drug should be eligible under this policy, the Pharmacy should call the IEHP Pharmaceutical Services Department at (888) 860-1297 to request a temporary supply override.

[4] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.4.3
[5] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.4.4
[6] Title 42, Code of Federal Regulations (CFR) §423.120(b)(3)(iii)
[7] 83 Federal Register 73 (April 16, 2018) (to be codified at 42 Code of Federal Regulations § 423.120)
[8] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.4.6

# 11. PHARMACY

## I. Transition Process

J. IEHP assures that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts.[9]

K. IEHP's Pharmacy Benefit Manager (PBM) sends a written notice via U.S. mail to the Member within three (3) business days of adjudicating their first transition fill. IEHP ensures all reasonable efforts are made to notify Prescribers of a transition fill. This CMS Model Transition Notice includes:[10]

1. An explanation of the temporary nature of the transition supply the Member has received;
2. Instructions for working with IEHP and the Member's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary;
3. An explanation of the Member's right to request a formulary exception;
4. A description of the procedures for requesting a Formulary exception; and
5. An explanation of the Member's right to request an appeal if IEHP issues an unfavorable decision on a formulary exception.

L. IEHP ensures continued compliance with these requirements by routinely testing the efficacy of the PBM's transition logic.

| **INLAND EMPIRE HEALTH PLAN** | | |
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[9] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.4.9

[10] Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements," Section 30.4.10

# 11. PHARMACY

## J. Pharmacy Access Standards

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. IEHP ensures the Retail Pharmacy Access Standards are in accordance with requirements set by Centers for Medicare & Medicaid Services (CMS) which include:[1]

1. In urban areas, at least 90% of enrollees in a plan must, on average, live within two (2) miles of a retail Pharmacy participating in the network;
2. In suburban areas, 90% of enrollees within five (5) miles of a retail Pharmacy participating in the network; and
3. In rural areas, 70% of enrollees within fifteen (15) miles of a retail Pharmacy participating in the network.

B. IEHP ensures Long-Term Care (LTC) Pharmacy Access Standards are in accordance with requirements set by CMS. [2,3]

C. IEHP delegates all pharmacy network contracting responsibilities to the Pharmacy Benefit Management (PBM) Company. When applicable, IEHP contracts with pharmacies, including home infusion and specialty, for health care services such as equipment, nursing, and per diems.

***PROCEDURES:***

A. IEHP ensures that the hours of operation of all Pharmacy Network Providers are convenient to the population served and do not discriminate against Members. Services are available twenty-four (24) hours a day, seven (7) days a week.

B. IEHP Members may call IEHP's Member Services Department at (877) 273-IEHP (4347) or access the IEHP Member Portal to find the nearest Pharmacy Provider in our network.

C. IEHP Members may receive ninety (90) day supply of the maintenance medications through retail Pharmacies or mail order Pharmacies.[4]

D. IEHP ensures Members have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when the Members:[5]

1. Cannot reasonably be expected to obtain such drugs at a network pharmacy; and
2. Do not access covered Part D drugs at an out-of-network pharmacy on a routine basis.

[1] Title 42, Code of Federal Regulations §423.120(a)
[2] Medicare Prescription Drug Manual, "Chapter 5: Benefits and Beneficiary Protections," Section 50.5
[3] 42 CFR § 423.120
[4] Ibid.
[5] Medicare Prescription Drug Manual, "Chapter 5: Benefits and Beneficiary Protections," Section 60.1

E. IEHP does not limit access of Part D drugs to a limited distribution through a subset of network pharmacies, except when necessary, to meet Food and Drug Administration's (FDA) limited distribution requirements or to ensure the appropriate dispensing of Part D drugs that require extraordinary requirements that cannot be met by a network Pharmacy.[6]

F. IEHP may specify, on a drug-by-drug basis, reasonable requirements for network Pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention.

G. Any Willing Pharmacy Requirement - IEHP allows and accepts any willing pharmacy that will accept IEHP's standard contracting terms and conditions.[7] IEHP's PBM contracts on behalf of IEHP using standard contracting terms and conditions which include requirements, responsibilities, and reimbursement rates.

H. IEHP contracts with a Mail Order Pharmacy to process mail order requests. Drugs that are on the Maintenance Lists are available through the Mail Order Pharmacy. All mail order requests must be for a ninety (90) day supply of the drug. The Mail Order Pharmacy is not meant for emergency refills. If an emergency refill is needed, the Member will need to refer to their local Pharmacy for the necessary medication.

I. IEHP may arrange delivery of medications from Specialty Pharmacies if a referral is made by a Physician and approved by IEHP. Member will be notified upon delivery by the Specialty Pharmacy.

J. IEHP Members may receive home infusion pharmacy services for infusion drugs if a referral is made by a Physician and approved by IEHP.

**Oversight**

A. On an annual basis, IEHP assesses the Pharmacy Access Standards with our contracted PBM. If IEHP fails to meet the Pharmacy Access Standards, an investigation will be conducted to identify root cause. IEHP will work with the contracted PBM to remediate any deficiency identified.

B. IEHP assesses and analyzes the Consumer Assessments of Healthcare Providers and Systems (CAHPS) score for Member satisfaction related to access; identifies trends, barriers, and improvement opportunities; develops interventions to address opportunities and evaluates outcome of actions tables.

C. IEHP shall notify CMS and the Department of Health Care Services (DHCS) in writing when material change is expected within IEHP Pharmacy network before the change is in effect.

[6] Medicare Prescription Drug Manual, "Chapter 5: Benefits and Beneficiary Protections," Section 50.3
[7] Medicare Prescription Drug Manual, "Chapter 5: Benefits and Beneficiary Protections," Section 50.8.1

# 11. PHARMACY

## J. Pharmacy Access Standards

| INLAND EMPIRE HEALTH PLAN | | |
|---|---|---|
| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☐ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2007 | |
| **Revision Effective Date:** | January 1, 2024 | |

# 11. PHARMACY

## K. Medication Therapy Management Program

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. IEHP's Medication Therapy Management (MTM) Program is designed to ensure that covered Part D drugs prescribed to targeted Members are appropriately used to optimize therapeutic outcomes through improved medication use. It is also designed to reduce the risk of adverse events, including adverse drug interactions, and to increase Member adherence with prescription medications.[1]

***PROCEDURES:***

**Program Eligibility**

A. IEHP's MTM Program is available for Members who meet the following criteria set forth by the Centers for Medicare and Medicaid Services (CMS):[2]

1. Member is likely to incur costs (total drug costs) for Covered Part D drugs that exceed a predetermined level as specified by CMS;
2. Member has multiple chronic diseases, with three (3) chronic diseases being the maximum needed for enrollment; and
3. Member is taking multiple Part D drugs, with two (2) being the minimum and eight (8) being the maximum needed for enrollment.

B. Under the IEHP Drug Management Program (DMP), at-risk beneficiaries (ARBs) are auto-enrolled in the MTM program.

C. On a quarterly basis, IEHP identifies and notifies qualified Members by mail or phone as potential candidates for the MTM Program within 60 days of enrollment.[3,4]

**Member Participation**

A. All identified Members, including Members in Long-Term Care (LTC), who are qualified are enrolled into the MTM Program. Members may call IEHP's Member Services Department to disenroll/opt-out from the program.[5]

B. The MTM Program is voluntary. IEHP does not deny a Member access to prescription drugs based on the Member's failure to participate in the MTM Program.

[1] Title 42, Code of Federal Regulations (CFR) § 423.153(d)(2)
[2] Ibid.
[3] Health Plan Management System (HPMS) Memo, "CY 2022 Medication Therapy Management Program Guidance and Submission Instructions," April 30, 2021
[4] 42 CFR § 423.153(d)(1)(vi)
[5] 42 CFR § 423.153(d)

C. Members will be screened for eligibility for the MTM Program every year. IEHP will honor a Member's desire to permanently opt-out of the MTM Program and not re-enroll the Member in future years; however, the Member may seek enrollment into the MTM Program at a later time.

D. In the event the Member no longer meets one (1) or more of the three (3) eligibility criteria for the program, the Member will remain enrolled in the program for the remainder of the calendar year. They will be reconsidered for eligibility at the beginning of the following calendar year.

**IEHP's MTM Program**

A. The MTM Program was developed in cooperation with licensed and practicing pharmacists and physicians. Program services are furnished by pharmacists or other qualified Providers that have completed an appropriate training program as determined by IEHP.[6]

B. The MTM Program distinguishes between services in ambulatory and institutional settings.[7]

C. The MTM Program includes the following components:[8,9]

1. Annual Comprehensive Medication Review (CMR):
    a. Medication review, at a minimum, on an annual basis;
    b. Interactive, person-to-person or telehealth consultation; and
    c. Individualized, written summary of consultation or recommended medication action plan.

    If the Member is offered annual CMR and is unable to accept the offer to participate, the pharmacist or other qualified Provider may perform the CMR with the Member's prescriber, caregiver, or other authorized individual.
2. Quarterly Targeted Medication Review (TMR):[10]
    a. Individualized, written "take-away" materials such as personal medication record, reconciled medication list, action plan, recommendations for monitoring, education, or self-management; and
    b. Follow-up interventions as necessary after initial TMR.
3. Medication Therapy Review:
    a. Assesses the appropriateness of the current medication therapy;

[6] 42 CFR § 423.153(d)
[7] Ibid.
[8] 42 CFR § 423.153(d)(1)(vii)(B)(2)
[9] Medicare Prescription Drug Benefit Manual Chapter 7 "Medication Therapy Management and Quality Improvement Program," Section 30.3
[10] 42 CFR § 423.153(d)(1)(vii)(C)

b. Interviews (i.e. phone, interactive, etc.) with Members to ensure the adherence and appropriateness of the dose and dosing regimen of each medication;

c. Checks for therapeutic duplications;

d. Interprets, monitors and assesses patient laboratory results;

e. Checks for drug to disease interactions and drug-drug interactions;

f. Checks for contraindications and adverse effects; and

g. Checks for over-utilization and under-utilization.

4. The pharmacist or other qualified Provider reviews the Member's medications, history and any information collected from the Member's questionnaire and conducts interactive person-to-person or telehealth comprehensive medication review.

5. A medication action plan:

   a. Develops a modification/recommendation plan based on the Member interviews, medication record evaluation and patient assessment.[11]

6. Intervention and referral:

   a. Provides education and training on the appropriate use of medications and monitoring devices;

   b. Provides information regarding safe disposal of prescription drugs that are controlled substances, including opioids;

   c. Emphasizes the importance of medication adherence and understanding of the treatment goals; and

   d. Communicates with the physician or other health care Providers on the findings when appropriate.

7. Documentation and follow up:

   a. The pharmacist or other qualified Provider documents all interventions on the CMS MTM Standard form.

D. The MTM Programs are coordinated with the Member's Individual Care Plan.[12]

**Monitoring and Oversight**

A. The MTM Program and all mid-year changes to the program must be approved by CMS.

B. IEHP evaluates and measures the effectiveness of the MTM Program through:[13]

[11] 42 CFR § 423.153(d)(1)(vii)(D)
[12] 42 CFR § 423.153(d)(4)
[13] HPMS Memo, "CY 2022 Medication Therapy Management Program Guidance and Submission Instructions," April 30, 2021

1. Statistics on individual Members according to the Member medication profiles- the adoption of recommended treatment regimen, the number of chronic medications, and projected annual pharmacy expenditures per Member;
2. Statistics on the overall MTM Program- Number of changes in medication regimens, average number of chronic medications per Member, average projected annual pharmacy expenditures per Member;
3. Financial impact – pharmacy cost changes;
4. Member satisfaction surveys; and
5. CMR completion rate.

| **INLAND EMPIRE HEALTH PLAN** | | |
|---|---|---|
| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☐ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2007 | |
| **Revision Effective Date:** | January 1, 2023 | |

# 11. PHARMACY

## L. Insulin Administration Devices and Diabetes Testing Supplies

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. Diabetes testing supplies are covered under both the IEHP pharmacy and medical benefit. This includes, but is not limited to, blood glucose meters, test strips, lancets, and ketone test strips.

***PROCEDURES:***

A. IEHP ensures coverage for the following as pharmacy benefit:
   1. Insulin and Glucagon Emergency Kits;
   2. Syringes and needles utilized as insulin administration devices.[1,2]

B. Diabetes testing supplies may be obtained through retail Pharmacies.

C. Requests for insulin pen devices for Members with special medical needs are subject to the Coverage Determination process. See Policy 11B, "Coverage Determination" for more information.

D. IEHP covers diabetic testing supplies using the criteria approved by the IEHP Pharmacy and Therapeutics Subcommittee.

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| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☒ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2009 | |
| **Revision Effective Date:** | January 1, 2023 | |

[1] Title 42 Code of Federal Regulations (CFR) § 423.100
[2] Health Plan Management System (HPMS) Memo, "Medical Supplies Associated with the Injection of Insulin," January 5, 2018

# 11. PHARMACY

## M. Member Request for Pharmacy Reimbursement

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. IEHP Members or their appointed representative, which may be the prescribing physician or other prescriber, may submit Direct Member Reimbursement (DMR) requests to IEHP for drugs that the Member believes he or she was incorrectly charged.[1]

***PROCEDURES:***

A. All DMR requests are considered Coverage Determination (CD) requests and are subject to the same evaluation standards. All requests will be evaluated based on the medical necessity. See Policy 11B, "Coverage Determination" for more information.

B. Members must submit a written request for reimbursement and must include proof of payment.

C. The prescribing Physician may only submit the request if acting on behalf of the Member.

D. The DMR request must be submitted within one (1) year from the date of service.

E. IEHP and/or assigned delegate will notify the Member, or the Member's representative, and the prescribing Physician, or other Prescriber (when applicable), of the Plan's decision no later than fourteen (14) calendar days from the date of receipt of the written request.[2]

   1. If the DMR request is denied by IEHP, the Member, or Member's representative, and the prescribing Physician, or other Prescriber (when applicable), will receive a denial notification.

   2. If the DMR request is approved, the Member, or Member's representative, and the prescribing Physician, or other Prescriber (when applicable), will receive an approval notification and the reimbursement check will be mailed directly to the Member by IEHP or its Pharmacy Benefit Manager within the fourteen (14) calendar day timeframe.

F. IEHP will make reasonable and diligent efforts to obtain any missing supporting information within the fourteen (14) calendar day timeframe, including outreaching to the Pharmacy and/or prescribing Physician, as applicable.

G. IEHP and/or assigned delegate may also approve a payment request by approving drugs retrospectively or due to a decision by the Independent Review Entity (IRE), which must be authorized within seventy-two (72) hours.[3] The Pharmacy processes the approved medication

[1] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 40.6
[2] Title 42 of Code of Federal Regulations (CFR) § 423.568(c)
[3] Medicare Managed Care Manual, "Part C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance", Section 90

and provides a refund to the Member. IEHP and/or assigned delegate may approve payment directly to the Member if the Member is unable to return to the dispensing Pharmacy.

| INLAND EMPIRE HEALTH PLAN | | |
|---|---|---|
| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☐ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | January 1, 2011 | |
| **Revision Effective Date:** | January 1, 2023 | |

# 11. PHARMACY

## N. Pharmacy Credentialing and Re-Credentialing

***APPLIES TO:***

A. This policy applies to all Pharmacies in the IEHP Pharmacy network.

***POLICY:***

A. IEHP delegates all pharmacy credentialing and re-credentialing activities to its contracted Pharmacy Benefit Manager (PBM). The contracted PBM must have credentialing and recredentialing policies and procedures that meet IEHP standards.

***PROCEDURES:***

A. The contracted PBM must credential all pharmacies prior to inclusion in the IEHP Pharmacy network. The contracted PBM is responsible for ensuring that all network Pharmacies are qualified, properly licensed, and maintain appropriate levels of malpractice insurance.

B. The contracted PBM must recredential all IEHP network Pharmacy Providers every two (2) years. The PBM must notify IEHP when a pharmacy is terminated from the network (voluntarily or involuntarily) within sixty (60) days after termination.

C. The contracted PBM is also responsible for monitoring the performance of all IEHP network Pharmacy Providers. The PBM must promptly notify IEHP when the PBM becomes aware of any breach of the contracted Pharmacy's obligations. The Medicare Advantage (MA) Organizations employing or contracting with health providers have a responsibility to check the sanction list with each new issuance of the list, as they are prohibited from hiring, continuing to employ, or contracting with individuals named on that list.[1,2] The MA organizations should check the Office of the Inspector General (OIG) Web site at https://oig.hhs.gov/exclusions/index.asp for the listing of excluded providers and entities. This includes, but is not limited to, the following:

    1. License surrender, revocation, or suspension;
    2. Drug Enforcement Agency (DEA) license surrender, revocation or suspension; and
    3. Loss of malpractice insurance.

D. Network Pharmacy Providers must update the credentialing information via IEHP's online portal on a bi-annual basis.

[1] The Social Security Act §1862(e)(1)(B)
[2] Prescription Drug Benefit Manual, "Chapter 9 – Compliance Program Guidelines," Section 50.6.8

# 11. PHARMACY

## N. Pharmacy Credentialing and Re-Credentialing

| INLAND EMPIRE HEALTH PLAN | | |
|---|---|---|
| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☒ CMS |
| | ☐ DMHC | ☐ NCQA |
| **Original Effective Date:** | July 1, 2013 | |
| **Revision Effective Date:** | January 1, 2023 | |

# 11. PHARMACY

## O. Drug Management Program

***APPLIES TO:***

A. This policy applies to all IEHP DualChoice (HMO D-SNP) Members.

***POLICY:***

A. All Part D sponsors must exercise a Drug Management Program (DMP), consistent with section 2004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act).[1]

***PURPOSE:***

A. To carry out an effective DMP that addresses overutilization of frequently abused drugs (FADs) while maintaining access to such drugs, as medically necessary.

***DEFINITIONS:***

A. Frequently Abused Drugs (FADs) – A controlled substance that the Secretary determines, based on several factors, is frequently abused, or diverted.[2] For the purposes of this policy, opioids (except buprenorphine for medication-assisted treatment [MAT] and injectables) and benzodiazepines are FADs.

B. Potential At-Risk Beneficiary (PARB) – A Part D beneficiary who Centers for Medicare and Medicaid Services (CMS) believes is potentially at the highest risk of opioid-related adverse events or overdose. PARBs are not exempted from DMPs, meet the clinical guidelines described at 42 CFR § 423.153(f)(16), or who were identified as a PARB by the sponsor of the beneficiary's immediately prior Part D plan under its DMP and such identification was not terminated before disenrollment.[3]

C. At-Risk Beneficiary (ARB) – A beneficiary who meets the clinical guidelines described at 42 CFR § 423.153(f)(16), is not exempted from DMPs, and is identified to be at-risk by their Part D plan sponsor under its DMP, or who was identified as an ARB by the sponsor of the beneficiary's immediately prior Part D plan under its DMP and such identification had not been terminated before disenrollment.[4]

D. Overutilization Monitoring System (OMS) Criteria – Standards used by CMS to identify PARBs and ARBs. These standards are based on a beneficiary's level of opioid use or history of an opioid-related overdose.[5]

[1] Health Plan Management System (HPMS) Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 1
[2] Title 42 of the Code of Federal Regulations (CFR) § 423.100
[3] 42 CFR §423.100
[4] Ibid.
[5] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 4.1

***PROCEDURES:***

**Member Identification**

A. IEHP identifies PARBs and ARBs via:[6]

1. MARx's Daily Transaction Reply Report (DTRR) – Identifies newly enrolled beneficiaries who were declared PARBs and/or ARBs by their previous Part D plan;
2. OMS' quarterly PARB report – identifies Part D Members who meet OMS' PARB criteria;
3. Internal claims data;
4. Internal review of Members against OMS' PARB and ARB criteria; and
5. Care coordination with the Member's previous Part D plan.

B. A beneficiary is automatically exempt from the DMP if the beneficiary:[7]

1. Is being treated for active cancer-related pain;
2. Has elected to receive hospice care or is receiving non-hospice palliative or end-of-life care;
3. Is a resident of a long-term care (LTC) facility, a facility described in section 1905(d) of the Act, or another facility for which FADs are dispensed for residents through a contract with a single pharmacy; or
4. Has sickle cell disease.

**Case Management**

A. IEHP conducts case management of newly identified PARBs and ARBs to verify the prescribers of FADs for PARBs, request the prescribers confirm whether they believe the Member in question to be at risk for abuse or misuse of FADs and if so, to agree on a drug coverage limitation, as appropriate.

1. Newly enrolled Members who were previously identified as a PARB or an ARB by their previous Part D plan will not undergo an initial case management. Instead, IEHP may reach out to their previous plan and request the Member's DMP information.[8]

[6] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 2
[7] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 5
[8] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 7.2.2

B. Case Management is conducted by clinical staff or other appropriate health care professionals with sufficient expertise to conduct medical necessity reviews related to potential opioid overutilization.[9]

C. Written notification is sent to the Member's Prescriber(s) informing them that the Member in question may qualify for IEHP's DMP because they meet OMS' criteria. The Prescriber may provide documentation regarding the Member's treatment demonstrating why they do or do not believe the Member is an ARB.

1. IEHP may "Wait and See" if the Prescriber(s) adjust their care of the PARB and whether this results in the Member no longer meeting the OMS criteria. The "Wait and See" approach is used on a case-by-case basis, as appropriate, prior to initiating the three (3) outreach attempts.[10]

**Drug Coverage Limitations**

A. Prescriber Limitations – IEHP will obtain consensus from a provider prescribing FADs to the Member in question, agreeing to serve as the Member's designated Prescriber(s) of FADs and implement the outlined prescriber limitations. This agreement also serves as the Prescribers' agreement with the proposed coverage limitation.[11] A Member may have more than one designated Prescriber of FADs, but no less than one (1).

B. Pharmacy Limitation – If a Prescriber does not respond to the written notification and request to serve as the Member's designated Prescriber of FADs, the Plan will follow-up with three (3) outreach attempts to the Prescriber(s) within a span of ten (10) business days.[12] If no response is received, the Prescriber(s) will be considered non-responsive. If no response is received from any of the Prescribers, IEHP's clinical staff may implement a beneficiary-specific point of sale (POS) claim edit if the Member is determined to be an ARB.

**Member Notification**

A. Initial Notice – Upon completion of case management, IEHP sends the Member an Initial Notice, in accordance with requirements outlined in 42 CFR § 423.153(f)(5-8).

1. Newly enrolled Members who were a part of their previous Part D Plan's DMP are exempt from receiving an Initial Notice from IEHP as long as their previous plan's coverage limitations of FADs was shared with IEHP and remains up-to-date and in effect. In instances where IEHP intends to change the Member's coverage limitations, an Initial Notice will be mailed.

[9] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 7.1
[10] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 7.2
[11] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 7.4.1
[12] Ibid.

2. Members have thirty (30) days from the date of the Initial Notice to submit any relevant information including, but not limited to, Member's preferred prescriber(s) of FADs, and information that may be material to the Plan's determination of whether the Member is an ARB.[13]
3. If IEHP learns that the Member is exempt after sending the Initial Notice, IEHP will inform the Member that IEHP has become aware that the beneficiary is exempt and that the Initial Notice is rescinded.[14]

B. Second Notice – If IEHP determines a Member is in fact an ARB, the Plan will send the Member a Second Notice informing them of their participation in the Plan's DMP and of their right to a redetermination of their at-risk determination, no later than sixty (60) days following the date of the Initial Notice.[15]

1. IEHP may send the Second Notice to newly enrolled Members who were a part of their previous Part D Plan's DMP immediate as long as their previous plan's coverage limitations of FADs remains up to date with the same prescriber or pharmacy.
2. A Second Notice is also sent to existing ARBs whose coverage limitation of FADs are extended for an additional year.
3. Members have sixty (60) days from the date of the Second Notice to request a redetermination.[16]
4. Redeterminations are conducted by the Grievance & Appeals Department. Please refer to Section 16, "Grievance and Appeals Resolution System" for more information.
5. Cases resulting in an adverse redetermination decision are automatically forwarded to the Independent Review Entity (IRE) for review with 24 hours of the expiration of the applicable adjudication timeframe.[17]

C. Retraction Notice – If IEHP determines the Member to be exempt from the Plan's DMP and less than 30 days has passed since the Initial Notice, the Member will receive a Retraction Notice informing them of such.[18]

D. Alternative Second Notice – If IEHP determines a Member is not an ARB and will not experience coverage limitations of FADs under the Plan's DMP, the Member will receive an Alternative Second Notice informing them of such.[19] Alternative Second Notices are mailed

[13] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 8.1
[14] HPMS Memo, "Correction - Contract Year 2023 Part D Drug Management Program Guidance," April 20, 2023. Section 11.2
[15] 42 CFR § 423.153(f)(6)
[16] 42 CFR § 423.580
[17] 42 CFR § 423.590(i)
[18] HPMS Memo, "Correction - Contract Year 2023 Part D Drug Management Program Guidance," April 20, 2023. Section 11.2
[19] 42 CFR § 423.153(f)(7)

not less than 30 days after the date of the Initial Notice and not more than the earlier of the date the Plan makes the relevant determination or 60 days after the date of the Initial Notice.[20]

E. Copies of the notices are shared with the Member's designated Prescriber(s) of FADs.

**Member's Preferences & Considerations for Reasonable Access**

A. When determining a Member's designated Prescriber(s) of FADs and dispensing pharmacy(ies), IEHP takes into account a several factors, including, but not limited to the following, to avoid any undue negative impact to the Member's access to care:[21]

1. Member's preferences;
2. Member's predominant usage of a prescriber or pharmacy, or both, for FADs;
3. Member's health conditions;
4. Geographic location; and
5. Reasonable travel time.

B. If a Member does not indicate their preference or if the preferred Prescriber does not agree to be the Member's designated Prescriber of FADs, IEHP will assign an alternative provider to be the designated Prescriber of FADs, based on the considerations noted above. A Member may have multiple designated prescribers, as necessary, to ensure adequate access to care.

C. An out-of-network Pharmacy and/or Prescriber may be designated as a Member's Prescriber/Pharmacy of FADs, if the Member does not have reasonable access to contracted providers who can assist with the DMP.[22]

D. Selected Prescribers and pharmacies have the right to refuse participation in a Member's DMP. Only providers who agree to serve as a Member's designated prescriber of FADs will be included in the respective Member's DMP.

**Length of Coverage Limitations**

A. A Member's ARB status and their consequent coverage limitation is effective the date of the Second Notice and typically lasts one (1) year.[23]

B. Participation in a DMP may end sooner if the Member no longer meets OMS criteria or if they demonstrate that they are no longer likely to be at risk for abuse or misuse of FADs without the limitation, through a subsequent determination or a successful appeal.

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[20] HPMS Memo, "Correction - Contract Year 2023 Part D Drug Management Program Guidance," April 20, 2023. Section 11.2

[21] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 9.2

[22] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 9.3

[23] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 10

C. A Member's ARB status may also be extended for an additional year if determined to be clinically necessary by their prescriber(s) or, if non-responsive, by IEHP's clinical staff.[24,25]

1. IEHP mails Members another Second Notice to inform them of their ARB extension. If the Member does not agree with the extension, they may request a redetermination.

**Care Coordination**

A. The Pharmacy Department completes requests from other Part D sponsors for information about PARBs and ARBs who recently disenrolled from IEHP's DualChoice product. All relevant information and communications regarding the beneficiary's PARB or ARB determination are securely transferred as soon as possible, but no later than two (2) weeks from the date of the request.

1. These file transfers are documented in the former Member's profile in the medical management system.

B. IEHP identifies newly enrolled PARBs and ARBs via the DTRR and uses CMS' Part D Overutilization Contact List to request the Members' PARB/ARB information from their previous Part D sponsor.

C. The Pharmacy department uses internal systems to maintain other Member-facing departments informed of confirmed ARB Members and facilitate appropriate coordination of care.

**Reporting**

A. IEHP reports the following information via MARx to assist with care coordination of a Member:[26]

1. The date of the Initial Notice to a PARB (Notification start date);
2. The date of the Second Notice to an ARB (Implementation start date; and
3. The date that IEHP terminates an "active CARA status," or the date of the Model Part D Drug Management Program Retraction Notice of Exempted Beneficiaries.[25] This may include terminating an ARB's coverage limitation(s) sooner than the original termination date.

B. IEHP reports case management status updates for the following PARB & ARB to OMS within 30 days of receiving OMS' PARB report:[27]

1. Each PARB & ARB enrolled with the Plan, who was listed in the OMS PARB report;

[24] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022, Section 10.3
[25] 42 CFR § 423.153(f)(14)(ii)(B)
[26] HPMS Memo, "Contract Year 2023 Part D Drug Management Program Guidance," November 28, 2022Section 11.2
[27] Ibid.

2. Each PARB identified internally by the Plan; and
3. Each PARB & ARB identified by the Member's previous plan, who has a Transaction Reply Code (TRC) 376 (New Enrollee CARA Status Notification) from the DTRR.

| INLAND EMPIRE HEALTH PLAN | | |
|---|---|---|
| **Regulatory/ Accreditation Agencies:** | ☐ DHCS | ☐ CMS |
| | ☐ DMHC | ☐ NCQA |
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