11. PHARMACY

A. Formulary Management

APPLIES TO:

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

POLICY:

A. The IEHP Pharmacy and Therapeutics (P&T) Subcommittee makes decisions regarding which medications are included on the Formulary. The IEHP P&T Subcommittee evaluates the clinical use of drugs, develops policies for managing drug use and drug administration, and manages the Formulary system. The Quality Management (QM) Committee has final approval of P&T Subcommittee decisions. For more information on the role and function of the P&T Subcommittee, please see Policy 2E, “Pharmacy and Therapeutics (P&T) Subcommittee”.

B. The P&T Subcommittee objectively appraises, evaluates, and selects pharmaceutical products for Formulary inclusion and exclusion. This is an ongoing process to ensure the optimal use of therapeutic agents. Products are evaluated based on efficacy, safety, ease of use, and cost.

C. IEHP ensures that the IEHP Formulary is comparable to the Fee-for-Service (FFS) Contract Drug List (CDL) with at least one (1) Formulary drug (a drug that does not require prior authorization) available within each mechanism of action of each of the therapeutic categories represented on the FFS CDL.\(^1\)\(^2\)\(^3\) This is done by performing a comparison review annually. IEHP does not accept any incentives to use a specific drug on a preferred status; therefore, the IEHP Formulary does not contain any drugs with preferred status.

D. Due to the multiplicity of drugs on the market and the continuous introduction of new drugs into the market, the IEHP P&T Subcommittee meets quarterly to update the IEHP Formulary.

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

F. IEHP does not impose quantitative treatment limitations (QTL) or non-quantitative treatment limits (NQTL), such as prior authorization, tiers, or network standards, more stringently on mental health and substance use disorder drugs as compared to medical/surgical drug prescriptions.\(^4\)

G. IEHP provides an online Formulary search tool on the IEHP website at [www.iehp.org](http://www.iehp.org). A printed version is available upon request.

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\(^1\) DHCS Final Rule Contract Amendment January 2018, Exhibit A, Attachment 10, Provision 8, Services for All Members.

\(^2\) Department of Health Care Services (DHCS) All Plan Letter (APL), “Medi-Cal Managed Care Health Plan Pharmaceutical Formulary Comparability Requirement”.

\(^3\) NCQA, 2020 HP Standards and Guidelines, Utilization Management (UM) 11, Element D, Factor 2.

\(^4\) Title 42, Code of Federal Regulations (CFR) § 438.900 et.seq.
11. PHARMACY

A. Formulary Management

H. On an annual basis, IEHP notifies 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.

I. Medication(s) used in the treatment of “severe mental illness” diagnosis, that are not otherwise specifically carved out to Medi-Cal Fee-For-Service, will be represented on IEHP’s Formulary as a “non-capitated drug”.

J. Providers are notified annually through written communication of online Formulary information and are notified quarterly by fax following each P&T Subcommittee meeting. Providers can access all Provider communications online at the IEHP website at www.iehp.org.

DEFINITIONS:

A. IEHP Formulary - A continually updated list of medications immediately available to Providers and Members. It contains information on co-payment requirements and the procedures for obtaining Code 1 and non-formulary medications.

B. Code 1 Medications – Medications restricted to specified medical conditions, age group, and/or other specific circumstances, and where the Pharmacist can override the rejecting claim at the point-of-sale, if the defined condition(s) are met. Please see Policy 11D, “Code 1 Medications” for more information.

PROCEDURES:

A. 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);

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5 California Health and Safety Code § 1374.72.
11. PHARMACY

A. Formulary Management

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).

B. The P&T Subcommittee meets quarterly with additional meetings as necessary to update the Formulary by reviewing:

1. Medical literature databases 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 new guidelines;
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. IEHP is a generic mandatory plan. Brand name products, when generics exist, may be requested by submitting the Prescription Drug Prior Authorization or Step Therapy Exception Request Form along with justification of use and proven failure of the generic version (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11). Please refer to Policy 11B, “Prior Authorization for Non-Formulary Medications” for more information.

D. Select medications have available generic equivalents or biosimilar products approved by the Food and Drug Administration (FDA). IEHP mandates generic dispensation for all quality generic products. Quality generic medications are those medications that have received an “A” or “B” rating by the FDA. IEHP only allows payment for “A” or “B” rated generic medications in the orange book or has a rating of NA, NR, or Z in similar nationally recognized pricing references, Medi-Span and First Databank Biosimilar products approved by the FDA are also covered by the IEHP Formulary. Lower quality generics are not covered by the IEHP Formulary. This mandate is enforced by the use of a National Drug Code (NDC) block at the point of sale.

E. Select medications have step-therapy protocols. Step-therapy protocols are built under clinical evidence-based review and are approved by the IEHP P&T Subcommittee. Such medications are formulary, and if the prerequisite criteria are met, the claims are allowed without prior authorization.

F. 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
11. PHARMACY

A. Formulary Management

Pharmaceutical Services staff may approve the drug to be added to the IEHP Formulary immediately. The following policy and procedure will be followed:

1. A generic drug that is cost neutral when comparing to another Formulary agent in the same class (plus or minus 10%);
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 P&T Subcommittee meeting.

G. Annually, IEHP ensures formulary comparability by comparing the IEHP Formulary against Fee-For-Service (FFS) Contract Drug List (CDL). On a quarterly basis, all new FFS CDL revisions are reviewed to ensure our Formulary is compliant to the comparability requirement. The IEHP Formulary and Treatment Guide, which includes Formulary status and benefit limitations, is available on the IEHP website. A printed version is available upon request.

H. When necessary, between annual publications, IEHP notifies its Practitioners and Providers in writing about the IEHP Formulary additions, deletions, Code 1 restriction changes, and modifications to policies and procedures.

I. 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 Delegation of a Drug to the Formulary” in Section 11”.

J. All new IEHP Practitioners and pharmacists are informed, as part of their orientation materials, that Formulary information is posted online on the IEHP Provider website.

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11. PHARMACY

B. Prior Authorization For Non-Formulary Medications

APPLIES TO:

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

POLICY:

A. All non-formulary medications require prior authorization utilizing the Prescription Drug Prior Authorization (RxPA) or Step Therapy Exception Request Form (Form No. 61-211) \(^1\) (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11).

B. For some Physician-administered medications a prior authorization request is not required. The list of these medications on the IEHP “Floor Stock” list can be accessed online at www.iehp.org.

C. IEHP allows Members to continue use of any (single-source) drugs that are part of a prescribed therapy (by a contracted or non-contracted provider) in effect for the Member immediately prior to the date of enrollment, regardless of the drug coverage status by IEHP. The therapy can continue until it is no longer prescribed or medically necessary. Providing samples does not constitute continuation or step therapy.\(^2\)

D. The Pharmacy can fill a seventy-two (72) hour emergency supply while the RxPA request for the full prescription quantity is pending.\(^3\) This is particularly important to consider when the prescriptions are prescribed after business hours, on weekends and holidays, when the Pharmacy is unable to reach the Provider to submit a RxPA request, or for any other reason in which a RxPA approval may be delayed.

E. Updated information regarding formulary status, utilization restrictions, and clinical criteria/guidelines are posted on the IEHP website (www.iehp.org) and are available to Providers and Members through their respective access portals.

F. RxPA requests are reviewed and completed within twenty-four (24) hours. Pharmacists and other Providers are encouraged to exercise appropriate professional and clinical judgment when determining whether to dispense medications pending RxPA approval. IEHP reimburses Pharmacies that dispense a sufficient 72-hour emergency supply of medication to cover the Member’s needs while the RxPA request is in the review process.\(^4\)

G. Requests for additional coverage due to loss of medications are considered RxPA requests. These requests will be reviewed based on the justification and medication history.

H. Member requests for cash reimbursements are considered as RxPA requests. The request form, a copy of the Pharmacy label and the cash register receipt must be submitted. The

\(^1\) Title 28, California Code of Regulations (CCR) § 1300.67.241.
\(^2\) Department of Health Care Services (DHCS) All Plan Letter (APL) Supersedes APL 15-019, “Continuity of Care for Medi-Cal Members Who Transition into Medi-Cal Managed Care”.
\(^3\) DHCS Final Rule Contract Amendment January 2018, Exhibit A, Attachment 10, Provision 8, Services for All Members.
\(^4\) Ibid.
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B. Prior Authorization For Non-Formulary Medications

A reimbursement RxPA request may be considered up to one (1) year from the date of service. Please see Policy 11I, “Member Request for Pharmacy Reimbursement” for more information.

I. All approvals will indicate the authorization expiration date. Providers may access prior authorization status and dates on the secure online IEHP Provider portal.

J. A Provider can appeal any adverse determination by IEHP. Provider appeals of denied RxPA Request should be submitted to the IEHP Grievance and Appeals Department.

PROCEDURES:

A. IEHP supplies all Providers with the RxPA Request Form and instructions for its use on the IEHP website (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11).

B. Members may initiate a request for a Pharmacy Exception based on medical necessity through the Member Portal for non-formulary medications. IEHP staff coordinates outreach attempt to the Provider for RxPA submission request.5

C. The RxPA Request Form must be used for all requests for prior authorization and step therapy exception. All information necessary to make a medical necessity determination must be submitted by the Providers. This includes, but is not limited to, prescribed dosages, duration of treatment, diagnosis, previous successful or failed therapies, any allergies, pertinent laboratory test results, or any other clinical information, when applicable. In the event the information required for RxPA review is incomplete or missing the “Minimum Amount of Material Information” on the RxPA Request Form, the request will be denied.

D. RxPA Request Forms are used for the following:

1. Drugs or dosage forms not included in the IEHP formulary;

2. Code 1 drugs used for treatment of conditions or criteria other than those specified by their Code 1 restrictions (non-Code 1 usage) (please see Policy 11D, “Code 1 Medications” for more information);

3. Dispensing of brand name drugs when generic or biosimilar formulations are available; exceptions are:
   a. Carbamazepine (Tegretol)
   b. Digoxin (Lanoxin)
   c. Levothyroxine (Levothroid, Synthroid)
   d. Phenytoin (Dilantin)
   e. Theophylline (Theo-24)
   f. Valproic Acid/Divalproex Sodium (Depakene/Depakote)

5 NCQA, 2020 HP Standards and Guidelines, UM 11, Element E, Factor 1
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B. Prior Authorization For Non-Formulary Medications

g. Warfarin (Coumadin)

4. Prescriptions for formulary drugs that do not comply with Dose/Duration/or Quantity guidelines (as outlined in the IEHP Formulary); and

5. Non-formulary medications not otherwise carved out to Medi-Cal Fee-for-Service (for a listing of non-capitated drugs, see www.dhcs.ca.gov, www.medi-cal.ca.gov, or the IEHP website).

E. Physicians may submit RxPA Request Forms via the secure IEHP Provider portal, fax at (909) 890-2058 or by calling IEHP Pharmaceutical Services Department at (909) 890-2049 or (888) 860-1297.

F. Members on medications that are deleted from the IEHP Formulary by the Pharmacy and Therapeutics Subcommittee may request to continue receiving these medications. Continual coverage consideration will require a RxPA request and medical justification on why the Member is not a candidate for formulary drugs.

G. IEHP Pharmaceutical Services staff reviews individual RxPA requests by thoroughly surveying the Member’s existing medication regimen, duration of treatment, previous successful or failed therapies, any allergies, and other clinical conditions, when applicable. IEHP staff references the prior authorization criteria and clinical guidelines to render a decision on the request, which is then either approved, dismissed, or denied.

1. Approved: An authorization is entered into the claims processing system to allow the claim to adjudicate online for the span of the approved RxPA. If RxPA Request is submitted for a formulary drug which does not require prior authorization, IEHP will inform Provider that medication can be dispensed at the Pharmacy without an RxPA. An approval notice is sent to the prescribing Provider.

2. Dismissed: RxPA request is submitted to IEHP by mistake; request is retracted or cancelled by the prescribing Provider; request is lacking minimum required information to make a clinical decision; request is for a carve-out medication or medical supply that is covered by the Delegated IPA; Member has California Children’s Services (CCS) coverage; Member is not eligible with IEHP; a duplicate of a previously submitted case; submitted by a sanctioned Provider; or Member has other primary insurance.

3. Denied: Medical justification provided did not satisfy the approval guidelines for medical necessity, medication is not a covered benefit, or experimental treatments. The RxPA request may also be denied for administrative reasons other than lack of medical necessity (e.g. non-contracted physician or servicing pharmacy provider).

H. Prior to denying a request, the IEHP Pharmaceutical Services staff consult with the prescribing Provider or the IEHP Medical Director(s) as part of the decision process for requests involving unusual or clinically complicated conditions. The IEHP Operations Pharmacist may consult with the IEHP Medical Director(s) or the prescribing Provider to discuss the specific reason for the denial and seek suggestions for an alternative pharmacotherapeutic regimen. If IEHP
is unable to reach the Provider, IEHP Pharmaceutical Services staff will document the attempt(s) made in the medical management system.

I. The IEHP Pharmaceutical Services Staff reviews with the Clinical Pharmacist the requests that are found to be medically unjustifiable prior to denying them.

J. Prior to denying a request, IEHP Pharmaceutical Services staff will call the prescribing Provider by phone to advise of the reason(s) for denial, and ask for additional clinical information or comments pertinent to the prior authorization request. Staff will document the contact attempt made in the medical management system.

K. IEHP Pharmaceutical Services Pharmacist or IEHP Medical Director performs the final clinical review of an RxPA and are the only personnel authorized to issue adverse pharmacy decisions. IEHP Pharmaceutical Services Pharmacist or IEHP Medical Director electronically signs all denied RxPA notifications.

L. A copy of the response (for approved or denied RxPA Request Forms) is faxed or mailed (if fax fails) to the requesting Provider within twenty-four (24) hours of receiving the request. A Notice of Action (NOA) for a denial of service/treatment is sent to the Member no later than two (2) business days after the decision by the plan.

M. The NOA letter includes the name and phone number of the IEHP Pharmaceutical Services Pharmacist who reviewed and finalized the denial of the RxPA request. The prescribing Provider can contact the IEHP Pharmaceutical Services Pharmacist to discuss the denial decision.

N. In retrospective review cases, the NOA is sent to the Member within thirty (30) calendar days of the receipt of the information that is reasonably necessary to make a decision.

O. IEHP compensation plan for the IEHP Pharmaceutical Services staff and Medical Directors who provide utilization review services does not contain incentives, direct or indirect, for these individuals to make inappropriate RxPA review decisions.

P. If timely completion of the written RxPA Request Form by the prescribing Physician is not possible, IEHP Pharmaceutical Services staff authorizes the request over the telephone and documents the information for logging into the medical management system.

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6 NCQA, 2020 HP Standards and Guidelines, UM 6, Element C.
8 California Health and Safety Code (HSC) § 1367.01(e).
9 NCQA, 2020 HP Standards and Guidelines, UM 4, Element E.
10 CA HSC § 1367.01(h)(3).
12 CA HSC § 1367.01(h)(4).
13 NCQA, 2020 HP Standards and Guidelines, UM 7, Element G.
11. PHARMACY

B. Prior Authorization For Non-Formulary Medications

Q. After business hours, on weekends and holidays, pharmacy Providers should dispense a sufficient supply of Formulary and non-Formulary medication to IEHP Members in emergent circumstances. Please see Policy 11G “Emergency Department and Hospital Inpatient Discharge Medication Requirement”.

R. The dispensing Pharmacy is guaranteed reimbursement for all emergency fills by completing the RxPA Request Form (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11). Emergency claims require documentation of the nature of the emergency situation. This requirement can be in the form of an Emergency Certification Statement. The Emergency Certification Statement must be attached to the claim and include:

1. The nature of the emergency, including relevant clinical information about the patient’s condition;
2. Why the emergency services rendered were considered to be immediately necessary; and
3. The signature of the physician, podiatrist, dentist, or pharmacist who had direct knowledge of the emergency.

The statement must be comprehensive enough to support a finding that an emergency situation existed. Justification may consist of statements such as: medication is necessary to prevent a break in ongoing treatment, patient has been stabilized and is being discharged from an acute care facility, medication is necessary to prevent patient from being a danger to self or others, etc.

S. Pharmacies can submit an emergency seventy-two (72) hour supply claim without a prompt by the Prescriber. However, it is helpful if the prescriber requests the seventy-two (72) hours medication in addition to submitting the RxPA Request Form— as a reminder to the pharmacy. Pharmacies can contact the IEHP Pharmacy Benefit Manager (PBM) to process an emergency override.

T. The final authority for obtaining medications not included in the IEHP formulary rests with IEHP’s Chief Medical Officer or designee.

U. The Member, Member’s representative, Delegated IPA, Pharmacist, or Provider/Practitioner appealing a denial on behalf of a Member, forwards all documents and written materials to IEHP’s Grievance and Appeals Department for processing of the appeal. Refer to Section 16, “Grievance Resolution System” for more information.

V. Urgent appeal requests that meet criteria will be reviewed and decided upon. A notification as to the outcome will be given in a timely fashion, which is not to exceed two (2) business days after receipt of the request. Please see Section 16, “Grievance and Appeal Resolution System” for more information.
11. PHARMACY

B. Prior Authorization For Non-Formulary Medications
C. Medication Handling Requirements at PCP Sites

APPLIES TO:

A. This policy applies to all Primary Care Physicians (PCPs) who treat IEHP Medi-Cal Members.

POLICY:

A. IEHP requires that the staff at any PCP site dispensing medication follow all applicable policies and procedures. The PCP is responsible for monitoring and tracking all dispensing of medications.

PURPOSE:

A. To ensure proper handling and storage of medications at PCP offices.
B. To ensure that all applicable statutory or regulatory standards regarding medication handling and storage are followed and maintained at the PCP offices.

PROCEDURES:

A. All stock and sample drugs must be checked monthly for their expiration dates.

B. A Physician who dispenses drugs must store all drugs to be dispensed in an area that is secure (Bus. & Prof. Code § 4172).
   1. A secure area must be a locked storage area within the Physician’s office.
   2. The area must be secure at all times.
   3. The keys to the locked storage area must be available only to staff authorized by the Physician.

C. All records for dispensing of medications must be open to inspection at all times during business hours by authorized officers and must be preserved for at least three (3) years.

D. Storage areas must meet the following requirements:
   1. Drug storage areas must be neat and clean.
   2. All medications must be properly labeled with an expiration date and lot number (Bus. & Prof § 4076).
   3. Oral and injectable medications must be stored separately from medications intended for external use.
   4. All medications must be stored in a locked cabinet with access only by authorized persons.

E. Physicians dispensing medications to Members in their offices must meet the following requirements (Bus. & Prof. Code §§ 4170, 4172 and Cal. Code Regs, Title 16, CCR §...
C. Medication Handling Requirements at PCP Sites

1356.3):

1. The medication is dispensed to the Physician’s own patient and the drugs are not furnished by a nurse or attendant, unless registered nurse is functioning pursuant to Section 2725.1.

2. The medications are necessary in the treatment of the condition for which the Physician is attending the patient.

3. Physicians must record the disposition of medications and keep these records for at least three (3) years.

F. Any medication stored in a refrigerator must be completely separate from food or other items in the refrigerator. This can be accomplished by having a separate refrigerator for medications, or by storing medications in a separate container within the refrigerator.

G. The temperature of a refrigerator must be maintained at 35° F to 46° F.

H. The temperature of a freezer must be maintained at -58° F to -57° F.

I. Physicians must follow the storage and handling guidance as described by the Centers for Disease Control and Prevention (CDC).

J. Daily temperature logs for freezers and refrigerators must be maintained.

K. Needles and syringes must be kept in locked secure cabinets.

L. All medications are considered good through the manufacturer’s expiration date; however, physician offices must consider the integrity of the vial and its effects on the potency and/or sterility of the medication before each use.

M. Compliance with IEHP medication handling requirements is monitored during Department of Health Care Services (DHCS) required facility reviews, as described in Policy 6A, “Facility Site Review and Medical Records Review Survey Requirements and Monitoring”.

REFERENCES:

A. Business and Professions Code §§ 2725.1, 4076, 4170 and 4172.

B. Title 16, California Code of Regulations § 1356.3.
11. PHARMACY

D. Code 1 Medications

APPLIES TO:

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

POLICY:

A. Code 1 medications are restricted to specified medical conditions, age groups, and/or other specific circumstances and will adjudicate at point of sale without a prior authorization.

B. All Code 1 drugs and the specific requirements for their use are printed in the IEHP Formulary and available on the IEHP website at www.iehp.org.

C. Physicians who write prescriptions for Code 1 medications must document, on the prescription, the Member’s diagnostic or clinical condition that fulfills the Code 1 restriction.

D. The dispensing Pharmacist is responsible for verifying that the applicable Code 1 requirements have been met.

E. Authorization for dispensing Code 1 medications used for treatment of conditions or criteria other than those specified by their Code 1 restriction may be obtained by submitting a Prescription Drug Prior Authorization or Step Therapy Exception (RxPA) Request form (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11). Refer to Policy 11B, “Prior Authorization for Non-Formulary Medications”.

DEFINITION:

A. Code 1 Medications – Medications restricted to specified medical conditions, age group, and/or other specific circumstances, and where the Pharmacist can override the rejecting claim at the point-of-sale, if the defined condition(s) are met.

PROCEDURES:

A. The dispensing Pharmacist must confirm through drug history or contact with the Prescriber that all applicable Code 1 requirements have been met. The Pharmacist must document this information and make available all such records for desktop or in-store audits.

B. Once verification of the applicable Code 1 requirement(s) has been performed, the Pharmacist is to enter the appropriate override code indicating that the Code 1 requirement(s) have been met. This will allow for claim processing and dispensing.

C. All Code 1 documentation is subject to desktop and in-store audits. An override code shall not be used when there is no appropriate documentation of meeting Code 1 requirements. Payment for these overridden prescriptions may be recouped from the dispensing pharmacy.

D. IEHP Pharmaceutical Services staff produces monthly utilization reports for Code 1 medications. The Senior Director of Pharmaceutical Services, Pharmacy and Therapeutics Subcommittee, and other committees, review these reports and make appropriate determination of Code 1 status, as necessary.
11. PHARMACY

D. Code 1 Medications

REFERENCE:

11. PHARMACY

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

APPLIES TO:

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

B. At the end of the emergency declaration, IEHP will re-implement the edits and continue to work closely with Members who are 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.
APPLIES TO:

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

POLICY:

A. IEHP selects Specialty Pharmacy Providers to provide a Disease Therapy Management Program (DTM) and pharmacy services to IEHP Members who need specialty medications for the following conditions:

1. Crohn’s disease;
2. Diabetes (Blood Glucose Management Program);
3. Growth Hormone Deficiency;
4. Hepatitis B;
5. Hepatitis C;
6. Hereditary Angioedema (HAE);
7. Hyperlipidemia (requiring PCSK9 inhibitors);
8. IVIG Therapy;
9. Multiple Sclerosis;
10. Cancer (Oral Chemotherapy);
11. Psoriasis;
12. Pulmonary Arterial Hypertension;
13. Respiratory Syncytial Virus;
14. Rheumatoid Arthritis;
15. Ulcerative Colitis; and

B. The purpose of the DTM program is to assist with the prior authorization process, promote appropriate use of drugs according to IEHP Clinical Practice Guidelines, optimize treatment, minimize side effects, increase Member quality of life, decrease overall medical cost, promote drug adherence, and report results.

C. Through monthly clinical surveys, pharmacies collect clinical information and alert IEHP of any potential clinical issues. The contracted DTM Specialty Pharmacy provides clinical reports on a quarterly basis detailing the DTM specific metrics.

D. The DTM Specialty Pharmacy shall be responsible for all drugs (pharmacy services) under the assigned disease state. Requests from retail pharmacies shall be redirected to the DTM Program for that disease state during the prior authorization process, as regulations allow.
11. PHARMACY

F. Pharmacy Disease Therapy Management Program

**PURPOSE:**

A. To establish a Pharmacy Disease Therapy Management (DTM) Program for high cost or relevant disease states that provides specialized services including drug and disease management.

**PROcedures:**

A. IEHP identifies a Specialty Pharmacy for conditions requiring Specialty Pharmacy Services. A list of DTM Specialty Pharmacies and assigned drugs can be accessed online at www.iehp.org.

B. The DTM Specialty Pharmacies must meet or exceed IEHP’s DTM expectations and standards based on each disease management protocol and design.

C. The DTM Specialty Pharmacies must communicate findings to IEHP based on the disease management protocol.

D. IEHP Pharmaceutical Services communicates with internal departments based on these findings to proactively manage the Members’ conditions.

E. IEHP presents DTM Program reports to the IEHP Pharmacy & Therapeutics Subcommittee on an annual basis.

F. The Member will receive a notification within thirty (30) days of approval or dispensing of the first fill of a DTM drug, explaining the DTM program and their right to opt out, including the toll-free number and the opt out process, when applicable.

G. Members may call IEHP Member Services Department to opt out of the Diabetes (Blood Glucose Management) DTM program. Additionally, Member may opt out of the other DTM programs only if a quality of care issue(s) has been identified, as allowed by regulations. The opt out period will expire when the Member is disenrolled from IEHP.
11. PHARMACY

G. Emergency Department and Hospital Inpatient Discharge Medication Requirement

APPLIES TO:

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

POLICY:

A. IEHP ensures that Members who were admitted into the hospital have timely access to pharmacy services upon discharge from the Emergency Department (ED) or inpatient unit.

B. IEHP allows Pharmacists to provide a short-term supply of formulary medications until the next business day without financial risk.

C. The Pharmacy can bill a seventy-two (72) hour emergency supply while the Prior Authorization (RxPA) request for the full amount is pending. This is particularly important to consider when the prescription comes in on weekends, where the Pharmacy is unable to reach a Provider in order to obtain information necessary to submit the RxPA request, or for any other reason for which a RxPA approval might be delayed. The pharmacy can call IEHP’s Pharmacy Benefit Manager’s (PBM) twenty-four (24) hour helpline to request a seventy-two (72) hour claim override.

D. Members needing urgent pharmacy services may contact IEHP’s twenty-four (24) hour Nurse Advice Line to find twenty-four (24) hour pharmacy locations.

PROCEDURES:

A. When the course of treatment provided to an IEHP Member in the ED requires the use of medications, a sufficient quantity of such medications may be provided to the Member to cover their medical needs until the Member can reasonably be expected to have a prescription filled at an IEHP Network Pharmacy. In the event such pharmacy service is not available in the hospital or ED, the Member may obtain the medication through one of the network’s twenty-four (24) hour Pharmacies.

B. On a quarterly basis, IEHP will report to the Quality Management Committee grievances related to medication access upon discharge in order to monitor compliance.

C. On a bi-annual basis, IEHP monitors the Geo Access report to ensure adequate twenty-four (24) hour pharmacy coverage around the contracted Hospitals and EDs.

1. The Geo-Access Report and a list of twenty-four (24) hour Pharmacies will be presented to the IEHP Pharmacy and Therapeutics Subcommittee for annual review.

D. Discharge medications (starter-pack) may be provided by the Hospital or ED. Alternatively, medications can be provided at one of the 24-hour Pharmacies within the IEHP Pharmacy Network.

E. The starter-pack medication label must include the following information:

1. Patient name;
11.  PHARMACY

G.  Emergency Department and Hospital Inpatient Discharge Medication Requirement

2.  Medication name, dosage, and quantity;
3.  Direction for use;
4.  Date;
5.  Name of the prescribing physician;
6.  Physician’s signature; and
7.  Medication expiration date.

F.  Members receiving starter-pack or other medications must receive medication counseling prior to discharge.

G.  The Pharmacy receives guaranteed reimbursement for all emergency fills by completing the Prior Authorization or Step Therapy Exception (RxPA) Request Form (Form No. 61-211) (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11).  Emergency claims require documentation of the nature of the emergency which can be in the form of an Emergency Certification Statement.  The Emergency Certification Statement must be attached to the claim and include:

1.  The nature of the emergency, including relevant clinical information about the patient’s condition;
2.  Why the emergency services rendered were considered to be immediately necessary; and
3.  The signature of the physician, podiatrist, dentist or Pharmacist who had direct knowledge of the emergency.

The statement must be comprehensive enough to support a finding that an emergency situation existed.  Justification may consist of statements such as:

1.  Medication is necessary to prevent a break in ongoing treatment;
2.  Patient has been stabilized and is being discharged from an acute care facility; or
3.  Medication is necessary to prevent patient from being a danger to self or others, etc.

H.  Pharmacies can submit an emergency seventy-two (72) hour supply claim without a prompt by the doctor.

I.  After business hours, pharmacies can call the IEHP PBM twenty-four (24) hour helpline to request a seventy-two (72) hour emergency override.
11. PHARMACY

G. Emergency Department and Hospital Inpatient Discharge Medication Requirement

REFERENCE:

11. PHARMACY

H. Insulin Administration Devices and Diabetes Testing Supplies

APPLIES TO:

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

POLICY:

A. Insulin and Glucagon Emergency Kits are covered by the IEHP pharmacy benefit. Members are automatically “opted-in” as part of the Pharmacy Disease Therapy Management (DTM) program. However, Members do have the option to “opt-out”. These requests will be reviewed to ensure they are held to current IEHP Formulary guidelines based on medical necessity on a case by case basis.

B. Syringes and needles utilized as insulin administration devices are covered under the IEHP pharmacy benefit. In the event that the devices are not covered by the IEHP pharmacy benefit, submission of the Prescription Drug Prior Authorization or Step Therapy Exception (RxPA) Request Form would be required (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11).

C. Insulin pumps are covered by the IEHP pharmacy benefit.

D. 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, urine test tape and tablets, ketone test strips and acetone tablets.

PROCEDURES:

A. For Members with special medical needs, an RxPA Request Form must be submitted for all insulin pen devices (See Attachment, “Prescription Drug Prior Authorization or Step Therapy Exception Request Form” in Section 11). See Policy 11B, “Prior Authorization for Non-Formulary Medications” for more information.

B. Diabetes testing supplies, including glucometer, test strips and lancets, may be obtained through the IEHP Diabetes Blood Glucose Management Program or through retail pharmacies.

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

D. IEHP Members may participate in the IEHP Diabetes Blood Glucose Management Program which provides test strips and lancets through mail order vendor. IEHP Providers may refer Members to Preveon Pharmacy (Phone: (877) 301-0636 or Fax: (909) 494-5582). The selected vendor provides comprehensive diabetes care program including education, medication, and disease management to the Members.
11. PHARMACY

H. Insulin Administration Devices and Diabetes Testing Supplies
11. PHARMACY

I. Member Request for Pharmacy Reimbursement

APPLIES TO:

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

POLICY:

A. IEHP Members may submit Pharmacy Reimbursement Requests for consideration of reimbursement for drugs or services covered by IEHP. All Member Reimbursement Requests are subject to IEHP Pharmacy Prior Authorization Request process. See Policy 11B, “Prior Authorization for Non-Formulary Medications”.

PROCEDURES:

A. Members must provide the following two (2) items:
   1. Proof of purchase: a copy of the cash register receipt or a credit card or bank statement; and
   2. Copy of the pharmacy receipt printout. A screenshot of the complete prescription label is acceptable.

B. The Pharmacy printout must contain the pharmacy name, address, phone, medication name, strength and form, the national drug code (NDC), date of service, prescriber’s full name, quantity, and the total amount paid.

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

D. All requests will be evaluated based on the medical necessity and the justification of the request. IEHP will notify Members of the decision and make payment, when appropriate, no later than thirty (30) calendar days after receiving all the requested documentation for reimbursement.

E. If the Member Reimbursement Request and all documentation were received timely and the request is eventually denied, the Member will receive the denial notification by mail. If the request is denied for lack of documentation or exceeds one (1) year from date of service, the Member will receive the denial notification by phone.

F. If a Member has shown a pattern of bypassing IEHP’s Pharmacy Prior Authorization Request process, IEHP may notify the Member of the denial of all future reimbursement requests.

G. Out of the country or cruise ship prescriptions (even if docked in a US port) are not a covered benefit and requests for reimbursement will be denied.

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<thead>
<tr>
<th>INLAND EMPIRE HEALTH PLAN</th>
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<tbody>
<tr>
<td><strong>Chief Approval:</strong> Signature on file</td>
</tr>
<tr>
<td><strong>Chief Title:</strong> Chief Medical Officer</td>
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</tbody>
</table>

IEHP Provider Policy and Procedure Manual 01/20

Medi-Cal Page 1 of 1
11. PHARMACY

J. 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 to a contracted Pharmacy Benefit Management (PBM) company.
B. The contracted PBM must have credentialing and re-credentialing policies and procedures that meet IEHP standards.
C. The contracted PBM must credential all Pharmacies prior to inclusion in the IEHP Pharmacy network.
D. The contracted PBM must re-credential all Pharmacies every two (2) years. The contracted PBM must meet Medi-Cal’s screening and enrollment requirements for network Providers.

PROCEDURES:

A. 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 is also responsible for monitoring the performance of all IEHP network Pharmacy Providers. The PBM is also responsible for promptly notifying IEHP once the PBM becomes aware of any breach of the contracted Pharmacy’s obligations. This includes but 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.
C. The contracted PBM must re-credential 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.
D. The contracted PBM updates network Pharmacies’ enrollment information weekly to verify Medi-Cal Pharmacy Providers’ enrollment in the Medi-Cal program.
E. Network Pharmacy Providers must update the credentialing information via IEHP online portal on a bi-annual basis.
11. PHARMACY

K. Claims for Drugs Prescribed or Dispensed by Excluded and Sanctioned Providers

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

POLICY:
A. IEHP’s contracted Pharmacy Benefit Manager (PBM) will utilize the reference file from the Office of Inspector General (OIG) monthly updates to ensure the PBM claim system is updated to block claims submitted by sanctioned or excluded providers.

B. IEHP’s contracted PBM will reference the State Board licensing department to confirm the provider’s licensure and to receive notices of any actions related to termination, revocation or restriction of a Provider’s license to practice.

PROCEDURES:
A. IEHP’s contracted PBM updates the system based on the Centers for Medicare & Medicaid Services (CMS) requirement described above. Once updated, all claims related to the sanctioned or excluded providers will be denied.

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

REFERENCE:
A. Title 42 Code of Federal Regulations §422.224.
11. PHARMACY

L. Hepatitis B & C — Center of Excellence Program

APPLIES TO:

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

POLICY:

A. IEHP utilizes the Hepatitis Center of Excellence (COE) program to promote the quality of care in Hepatitis treatment. IEHP develops criteria through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and California Department of Health Care Services’ (DHCS) Hepatitis C guidelines.

B. The final Hepatitis Treatment guideline is reviewed and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

C. The COE is directed by an experienced transplant hepatologist or infectious disease specialist with at least two (2) years of experience with the new oral therapies.

D. All Hepatitis B & C referrals or treatment requests shall be directed to the COE. All prescriptions / treatment must be evaluated by the transplant hepatologist at the COE.

E. Prescriptions shall be provided in conjunction with the Hepatitis B & C Program. A pharmacy designated by the COE shall provide all Hepatitis B & C treatment according to the prescription order.

PURPOSE:

A. To establish a Center of Excellence (COE) for the treatment of Hepatitis B & C.

PROCEDURES:

A. All referrals and Prescription Drug Prior Authorization (RxPA) Requests for Hepatitis B & C must be redirected to the COE.

B. IEHP’s Utilization Management (UM) department will make arrangements for Members to see the transplant hepatologist at the COE. Members will be monitored at the COE if treatment is initiated.

C. All prescriptions must be initiated by the hepatologists at the COE and fulfilled by the designated pharmacy at the COE for monitoring purposes.
11. PHARMACY

M. Notification of Prior Authorization Denial

**APPLIES TO:**

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

**POLICY:**

A. IEHP notifies Members, in writing, of any denial of Prescription Drug Prior Authorization or Step Therapy Exception (RxPA) Request.\(^1\)

B. IEHP ensures that a denial of a RxPA Request in no way jeopardizes a Member’s health or welfare and every effort is made to continue optimal coverage of the Member’s pharmaceutical needs at the appropriate level of care.

**PROCEDURES:**

A. RxPA Requests for pharmaceuticals are initiated by prescribing Physicians or Pharmacists by submitting the RxPA Request Form (Form No. 61-211) via the secure IEHP Provider portal, by fax, or by phone (see Attachment, “Prescription Drug Prior Authorization Request or Step Therapy Exception Request Form” in Section 11).\(^2\) The IEHP Pharmaceutical Services staff will evaluate requests for medical necessity and will approve, deny, or dismiss the request within twenty-four (24) hours. All written notification of completed requests will be sent to the submitter within twenty-four (24) hours of receiving the request.

B. IEHP Pharmaceutical Services staff provide formulary alternatives based on the approved Clinical Practice Guidelines and Criteria. IEHP may deny the RxPA Request if no justification is submitted.

C. The IEHP Pharmaceutical Services staff reviews the requests that are found to be medically unjustifiable with the IEHP Pharmaceutical Services Pharmacist prior to denying them. The IEHP Pharmaceutical Services Pharmacist signs all denied RxPA Requests prior to completion.\(^3\)

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

1. If coverage is denied to a Member with a terminal illness, which for the purposes of this section refers to an incurable or irreversible condition that has a high probability of causing death within one year or less, for treatment, services or supplies deemed experimental, the Member and/or their authorized representative are offered the opportunity to request a conference, which shall be held within thirty (30) calendar days

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\(^1\) Title 22, California Code of Regulations (CCR) § 53261.
\(^2\) Title 28, CCR § 1300.67.241.
\(^3\) NCQA, 2020 HP Standards and Guidelines, UM 4, Element E.
11. PHARMACY

M. Notification of Prior Authorization Denial

or as early as five (5) business days (if requested by the prescribing physician) of the denial.

E. IEHP notifies Members of denied RxPA Requests within two (2) working days of receipt of request in writing by the Pharmaceutical Services staff (See Attachments, “Denial Letter – Medi-Cal – English” and “Denial Letter – Medi-Cal - Spanish” in Section 11).

F. If denied, IEHP will fax or mail an RxPA Denial notification (Notice of Action) to the prescribing Provider and if applicable the Pharmacy Provider within twenty-four (24) hours of receipt of request. The denial notification letter will contain an accurate and clear explanation of the specific reason(s) for the decision or an explanation of any specific material information that would be necessary to otherwise approve the request. The notification will also include all pertinent information for the appeals process along with how to file an expedited review.

G. Members have the right to appeal any denial through the IEHP Grievance and Appeals Department or they may exercise their right to request a Fair Hearing. The Member’s rights are delineated in the denial letter. Please see the Grievance Manual for further information.
11. PHARMACY

N. Medi-Cal Vaccine Coverage

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

POLICY:
A. Medi-Cal managed care health plans (MCPs) are contractually required to cover a wide range of preventive services and screenings in accordance with United States Preventive Services Task Force (USPSTF) grade “A” or “B” recommendations, as well as American Academy of Pediatrics/Bright Futures for members under the age of 21.

B. USPSTF views immunizations as preventive services and recommends that all immunizations be provided as recommended by the Advisory Committee on Immunization Practices (ACIP).

C. The MCP contract states that prior authorization requirements are not to be applied to certain services, including preventive services, which aligns with the Medi-Cal Fee for Service (FFS) requirements.

D. IEHP includes the ACIP recommended immunizations in the FFS contract drug list as an IEHP Pharmacy Benefit.

E. Pharmacy Providers who are contracted with IEHP as part of the IEHP Vaccine Network may provide adult immunizations for IEHP Medi-Cal members who are 18 years of age or older.

F. Medi-Cal Members under the age of 18 shall receive immunization from their Primary Care Physician (PCP) through the Vaccine for Children (VFC) program. See Policy 10C2, “Pediatric Preventive Services – Immunization Services” for more information.

G. In order to register with the IEHP Vaccine Network, pharmacies must meet the California State Board of Pharmacy requirements including but not limited to:
   1. Complete an immunization training program endorsed by the Centers for Disease Control and Prevention (CDC);
   2. Certified in Basic Life Support;
   3. Comply with all state and federal recordkeeping requirements;
   4. Provide vaccination documentation to the patient’s Primary Care Physicians and report to the California Immunization Registry (CAIR);
   5. Provide adult vaccines in accordance to the ACIP’s recommended Immunization Schedule; and
   6. Accept Pharmacy Benefit Manager (PBM) payment rate for vaccines as established by the Vaccine Network.

H. Pharmacists must ensure that duplicate immunizations will not be given by checking the Members history via the IEHP Provider Portal and/or CAIR prior to administration.
PROCEDURES:

A. Adult Members may receive vaccines through three (3) options, without prior authorization:
   1. Vaccination from a licensed medical Provider;
   2. Vaccination from a pharmacy in the Vaccine Network; and
   3. Vaccination from a Local Health Department.

B. Pharmacies are required to report administration of vaccine within fourteen (14) days of administration to the immunization registry, California Immunization Registry (CAIR).

C. Members under 18 years of age can receive their vaccines through their Primary Care Physician (PCP) as part of the VFC program. See Policy 10C2, “Pediatric Preventive Services – Immunization Services” for more information.

D. IEHP’s contracted PBM accepts vaccine administration claims from participating pharmacies in the National Council for Prescription Drug Programs (NCPDP)-approved format.

E. IEHP provides all Members with a vaccine-specific notice that the Members could bring to their Physicians. This notice would provide information necessary for a Physician to contact IEHP to receive authorization of coverage for a particular vaccine, reimbursement rates, Member cost-sharing to be collected by the Physician, and instructions on how to submit the out-of-network claim on the Member’s behalf.

F. IEHP and the contracted PBM will monitor 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. If a vaccine charge is not 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 is paid.

REFERENCES:


B. Department of Health Care Services (DHCS) All Plan Letter (APL) 16-009, “Adult Immunizations as a Pharmacy Benefit”.

C. Business and Professions Code §§4005, 4052 and 4052.8.
11. PHARMACY

Attachments

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>POLICY CROSS REFERENCE</th>
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<tbody>
<tr>
<td>Denial Letter – Medi-Cal - English</td>
<td>11M</td>
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<tr>
<td>Denial Letter – Medi-Cal - Spanish</td>
<td>11M</td>
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<tr>
<td>Request for Addition or Deletion of a Drug to the Formulary</td>
<td>11A</td>
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</table>
# Prescription Drug Prior Authorization or Step Therapy Exception Request Form

**Plan/Medical Group Name:** Inland Empire Health Plan  
**Plan/Medical Group Phone#:** (888) 860-1297  
**Plan/Medical Group Fax#:** (909) 890-2058

**Non-Urgent**  
**Exigent Circumstances**

---

**Instructions:** Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization or step-therapy exception request. Information contained in this form is Protected Health Information under HIPAA.

## Patient Information

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<th>First Name:</th>
<th>Last Name:</th>
<th>MI:</th>
<th>Phone Number:</th>
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<th>Female</th>
<th>Circle unit of measure</th>
<th>Height (in/cm):</th>
<th>Weight (lb/kg):</th>
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<tr>
<th>Allergies:</th>
<th>Patient’s Authorized Representative (if applicable):</th>
<th>Authorized Representative Phone Number:</th>
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## Insurance Information

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## Prescriber Information

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<th>Last Name:</th>
<th>Specialty:</th>
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<tr>
<th>Requestor (if different than prescriber):</th>
<th>Office Contact Person:</th>
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<tr>
<th>NPI Number (individual):</th>
<th>Phone Number:</th>
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<tr>
<th>DEA Number (if required):</th>
<th>Fax Number (in HIPAA compliant area):</th>
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| Email Address: | |
|----------------| |
|                | |

## Medication / Medical and Dispensing Information

- **Medication Name:**

- **New Therapy**  
- **Renewal**  
- **Step Therapy Exception Request**

**If Renewal:**  
**Date Therapy Initiated:**  
**Duration of Therapy (specific dates):**

**How did the patient receive the medication?**

- **Paid under Insurance Name:**
  **Prior Auth Number (if known):**

- **Other (explain):**

**Dose/Strength:**  
**Frequency:**  
**Length of Therapy/#Refills:**  
**Quantity:**

**Administration:**

- **Oral/SL**  
- **Topical**  
- **Injection**  
- **IV**  
- **Other:**

**Administration Location:**

- **Patient’s Home**  
- **Long Term Care**

- **Physician’s Office**  
- **Home Care Agency**  
- **Other (explain):**

- **Ambulatory Infusion Center**  
- **Outpatient Hospital Care**

---
## PRESCRIPTION DRUG PRIOR AUTHORIZATION OR STEP THERAPY EXCEPTION REQUEST FORM

### Instructions:
Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g., chart notes or lab data, to support the prior authorization or step therapy exception request.

### 1. Has the patient tried any other medications for this condition? YES (if yes, complete below) NO

<table>
<thead>
<tr>
<th>Medication/Therapy</th>
<th>Duration of Therapy</th>
<th>Response/Reason for Failure/Allergy</th>
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</thead>
<tbody>
<tr>
<td>(Specify Drug Name and Dosage)</td>
<td>(Specify Dates)</td>
<td></td>
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### 2. List Diagnoses:

ICD-10: ______________________

### 3. Required clinical information - Please provide all relevant clinical information to support a prior authorization or step therapy exception request review.

Please provide symptoms, lab results with dates and/or justification for initial or ongoing therapy or increased dose and if patient has any contraindications for the health plan/insurer preferred drug. Lab results with dates must be provided if needed to establish diagnosis, or evaluate response. Please provide any additional clinical information or comments pertinent to this request for coverage, including information related to exigent circumstances, or required under state and federal laws.

- [ ] Attachments

### Attestation:
I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

**Prescriber Signature or Electronic I.D. Verification:** _______________________________ **Date:** _______________________________

### Confidentiality Notice:
The documents accompanying this transmission contain confidential health information that is legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately (via return FAX) and arrange for the return or destruction of these documents.

### Plan/Insurer Use Only:
**Date/Time Request Received by Plan/Insurer:** ________________ **Date/Time of Decision** ________________

Fax Number ( ) ____________________________

- [ ] Approved  - [ ] Denied  **Comments/Information Requested:** ____________________________

---

**Attachment 11 - Prescription Drug Prior Authorization or Step Therapy Exception Request Form**
REQUEST FOR ADDITION OR DELETION
OF A DRUG TO THE FORMULARY

GENERIC NAME: __________________________ BRAND NAME: __________________________

MANUFACTURER(S): ________________________________________________________________

DOSAGE FORM: ________________________________________________________________

Pharmacological Classification: ________________________________________________

Indications: ________________________________________________________________

What similar drugs are currently available? ________________________________________________

What therapeutic advantage(s) does this drug have over the standard drug therapy? ________________

In how many patients do you expect this drug to be used during the next six months? ________________

What drug(s) currently used for this/these indications(s) may be deleted if this product is added to the formulary?

__________________________________________

__________________________________________

Should use of this drug be restricted to certain physicians or institutions because of the potential for misuse, high
cost, or toxicity? __________________________________________

REQUESTER’S NAME: __________________________

ADDRESS & TELEPHONE: __________________________

SIGNATURE OF REQUESTER: __________________________ DATE: ________________
NOTICE OF ACTION
About Your Treatment Request

[Date]

[Member’s Name]      [Treating Provider’s Name]
[Address]      [Address]
[City, State Zip]     [City, State Zip]

[Case Number]

RE:      [Drug name, Form, Strength]

[Name of requesting provider] has asked Inland Empire Health Plan (IEHP) to approve [Drug name, Form, Strength]. The service or item requested was reviewed by our doctor. This requested item has been denied because:

[Blurb]

Please refer to your “Member Handbook”/Evidence of Coverage (EOC) for additional benefit coverage information.

If you need the above explanation translated, please contact:

Inland Empire Health Plan
P.O. Box 1800
Rancho Cucamonga, CA 91729-1800
(800) 440-4347 / (800) 718-4347 TTY

You may ask for free copies of all information used to make this decision. This includes a copy of the actual benefit provision, guideline, protocol, or criteria that we based our decision on. To ask for this, please call or write to:

IEHP Direct
Attn: Medical Director
P.O. Box 1800
Rancho Cucamonga, CA 91729-1800
1-800-440-4347
You may appeal this decision. The enclosed “Your Rights” information notice tells you how. It also tells you where you can get free help. This also means free legal help. You are encouraged to send in any information that could help your case. The “Your Rights” notice tells you the cut off dates to ask for an appeal.

The State Medi-Cal Managed Care “Ombudsman Office” can help you with any questions. You may call them at 1-888-452-8609. You may also get help from your doctor, or call us at 1-800-440-4347.

This notice does not affect any of your other Medi-Cal services.

[Pharmacist’s Signature]

[Pharmacist’s Name], Clinical Pharmacist

Enclosed: “Your Rights under Medi-Cal Managed Care”
“Nondiscrimination Notice”
“Language Assistance”

cc: [Provider’s Name]
[PCP’s Name]
YOUR RIGHTS
UNDER MEDI-CAL MANAGED CARE

IF YOU DO NOT AGREE WITH THE DECISION MADE FOR YOUR MEDICAL TREATMENT, YOU CAN FILE AN APPEAL. THIS APPEAL IS FILED WITH YOUR HEALTH PLAN.

HOW TO FILE AN APPEAL

You have 60 days from the date of this “Notice of Action” letter to file an appeal. But, if you are currently getting treatment and you want to continue getting treatment, you must ask for an appeal within 10 days from the date this letter was postmarked or delivered to you, OR before the date your health plan says services will stop. You must say that you want to keep getting treatment when you file the appeal.

You can file an appeal by phone, in writing, or electronically:

- **By phone:** Contact IEHP between 8:00 AM and 5:00 PM by calling 1-800-440-IEHP (4347). Or, if you cannot hear or speak well, please call 1-800-718-4347.

- **In writing:** Fill out an appeal form or write a letter and send it to:
  
  Inland Empire Health Plan
  P.O. Box 1800
  Rancho Cucamonga, CA 91729-1800

  Your doctor's office will have appeal forms available. Your health plan can also send a form to you.

- **Electronically:** Visit your health plan's website. Go to www.iehp.org.

You may file an appeal yourself. Or, you can have a relative, friend, advocate, doctor, or attorney file the appeal for you. You can send in any type of information you want your health plan to review. A doctor who is different from the doctor who made the first decision will look at your appeal.

Your health plan has 30 days to give you an answer. At that time, you will get a “Notice of Appeal Resolution” letter. This letter will tell you what the health plan has decided. **If you do not get a letter within 30 days, you can:**
• Ask for an “Independent Medical Review” (IMR) and an outside reviewer that is not related to the health plan will review your case.

• Ask for a “State Hearing” and a judge will review your case

Please read the section below for instructions on how to ask for an IMR or State Hearing.

EXPEDITED APPEALS

If you think waiting 30 days will hurt your health, you might be able to get an answer within 72 hours. When filing your appeal, say why waiting will hurt your health. Make sure you ask for an “expedited appeal.”

IF YOU DO NOT AGREE WITH THE APPEAL DECISION

If you filed an appeal and received a “Notice of Appeal Resolution” letter telling you that your health plan will still not provide the services, or you never received a letter telling you of the decision and it has been past 30 days, you can:

• Ask for an “Independent Medical Review” (IMR) and an outside reviewer that is not related to the health plan will review your case

• Ask for a “State Hearing” and a judge will review your case

You can ask for both an IMR and State Hearing at the same time. You can also ask for one before the other to see if it will resolve your problem first. For example, if you ask for an IMR first, but do not agree with the decision, you can still ask for a State Hearing later. However, if you ask for a State Hearing first, but the hearing has already taken place, you cannot ask for an IMR. In this case, the State Hearing has the final say.

You will not have to pay for an IMR or State Hearing.

INDEPENDENT MEDICAL REVIEW (IMR)

If you want an IMR, you must first file an appeal with your health plan. If you do not hear from your health plan within 30 days, or if you are unhappy with your health plan’s decision, then you may then request an IMR. You must ask for an IMR within 180 days from the date of the “Notice of Appeal Resolution” letter.
You may be able to get an IMR right away without filing an appeal first. This is in cases where your health is in immediate danger or the request was denied because treatment is considered experimental or investigational.

The paragraph below will provide you with information on how to request an IMR. Note that the term “grievance” is talking about both “complaints” and “appeals.”

The California Department of Managed Health Care is responsible for regulating health care service plans. If you have a grievance against your health plan, you should first telephone your health plan at 1-800-440-IEHP (4347) and use your health plan’s grievance process before contacting the Department. Utilizing this grievance procedure does not prohibit any potential legal rights or remedies that may be available to you. If you need help with a grievance involving an emergency, a grievance that has not been satisfactorily resolved by your health plan, or a grievance that has remained unresolved for more than 30 days, you may call the Department for assistance. You may also be eligible for an Independent Medical Review (IMR). If you are eligible for an IMR, the IMR process will provide an impartial review of medical decisions made by a health plan related to the medical necessity of a proposed service or treatment, coverage decisions for treatments that are experimental or investigational in nature and payment disputes for emergency or urgent medical services. The Department also has a toll-free telephone number (1-888-HMO-2219) and a TDD line (1-877-688-9891) for the hearing and speech impaired. The Department’s Internet Website (http://www.hmohelp.ca.gov) has complaint forms, IMR application forms, and instructions online.

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**STATE HEARING**

If you want a State Hearing, you must ask for one within 120 days from the date of the “Notice of Appeal Resolution” letter. You can ask for a State Hearing by phone or in writing:

- **By phone:** Call 1-800-952-5253. This number can be very busy. You may get a message to call back later. If you cannot speak or hear well, please call TTY/TDD 1-800-952-8349.

- **In writing:** Fill out a State Hearing form or send a letter to:

  **California Department of Social Services**  
  **State Hearings Division**  
  **P.O. Box 944243, Mail Station 9-17-37**  
  **Sacramento, CA 94244-2430**

Be sure to include your name, address, telephone number, Social Security Number, and the reason you want a State Hearing. If someone is helping you
ask for a State Hearing, add their name, address, and telephone number to the form or letter. If you need an interpreter, tell us what language you speak. You will not have to pay for an interpreter. We will get you one.

After you ask for a State Hearing, it could take up to 90 days to decide your case and send you an answer. If you think waiting that long will hurt your health, you might be able to get an answer within 3 working days. Ask your doctor or health plan to write a letter for you. The letter must explain in detail how waiting for up to 90 days for your case to be decided will seriously harm your life, your health, or your ability to attain, maintain, or regain maximum function. Then, make sure you ask for an “expedited hearing” and provide the letter with your request for a hearing.

You may speak at the State Hearing yourself. Or, you can have a relative, friend, advocate, doctor, or attorney speak for you. If you want another person to speak for you, then you must tell the State Hearing office that the person is allowed to speak on your behalf. This person is called an “authorized representative.”

LEGAL HELP

You may be able to get free legal help. Call the State Department of Consumer Affairs at 1-800-952-5210. You may also call the local Legal Aid Society in your county at 1-888-804-3536.
AVISO DE ACCIÓN
Acerca de Su Solicitud de Tratamiento

[Date]

[Member’s Name]      [Treating Provider’s Name]
[Address]      [Address]
[City, State Zip]     [City, State Zip]

[Case Number]

RE: [Drug name, Form, Strenght]

[Name of requesting provider] solicitó a Inland Empire Health Plan (IEHP) la aprobación de [Drug name, Form, Strenght]. El servicio requerido fue revisado por nuestro doctor. Este servicio ha sido denegado porque:

[Blub]

Consulte su “Manual para Miembros”/Evidencia de Cobertura (Evidence of Coverage, EOC) para obtener más información sobre la cobertura de beneficios.

Si necesita la traducción de la explicación anterior, por favor, comuníquese con:

Inland Empire Health Plan
P.O. Box 1800
Rancho Cucamonga, CA 91729-1800
(800) 440-4347 / (800) 718-4347 TTY

Usted puede solicitar copias gratuitas de toda la información que se utilizó para tomar esta decisión, esto incluye, una copia de la disposición sobre beneficios, las pautas, el protocolo o los criterios en los que basamos nuestra decisión. Para solicitar copias, llame o escriba a:

IEHP Direct
Attn: Medical Director
P.O. Box 1800
Rancho Cucamonga, CA 91729-1800
1-800-440-4347
Usted puede apelar esta decisión. El aviso adjunto con información sobre “Sus Derechos” le indica cómo hacerlo. Además le informa a dónde debe ir para solicitar ayuda gratuita, incluida la ayuda legal gratuita. Le recomendamos que envíe toda la información que podría ayudar en su caso. El aviso “Sus Derechos” contiene las fechas límite para solicitar una apelación.

La “Oficina del Defensor” (Ombudsman Office) de la Atención Médica Coordinada de Medi-Cal del Estado puede responder a sus preguntas. Usted puede llamar a la oficina al 1-888-452-8609. Además, puede recibir ayuda de su doctor, o llamarnos al 1-800-440-4347.

Este aviso no afecta a ninguno de los demás servicios de Medi-Cal que usted recibe.

[Pharmacist’s Signature]

[Pharmacist’s Name], Clinical Pharmacist

Documentos adjuntos: “Sus Derechos conforme a la Atención Médica Coordinada de Medi-Cal”
“Aviso de No Discriminación”
“Asistencia en Idiomas”
SUS DERECHOS
CONFORME A LA ATENCIÓN MÉDICA COORDINADA DE MEDI-CAL

SI NO ESTÁ DE ACUERDO CON LA DECISIÓN QUE SE TOMÓ PARA SU TRATAMIENTO MÉDICO, PUEDE PRESENTAR UNA APELACIÓN. ESTA APELACIÓN SE PRESENTA ANTE SU PLAN DE SALUD.

CÓMO PRESENTAR UNA APELACIÓN

Usted tiene **60 días** a partir de la fecha de esta carta de “Aviso de Acción” para presentar una apelación. Pero, **si actualmente está recibiendo tratamiento y desea continuar recibiendo tratamiento, debe solicitar una apelación dentro de un plazo de 10 días** a partir de la fecha en que esta carta fue sellada o entregada a usted, O BIÉN, antes de la fecha de la interrupción de los servicios que su plan de salud indica. Debe señalar que desea continuar recibiendo tratamiento cuando solicite la apelación.

Puede presentar una apelación por teléfono, por escrito o por vía electrónica:

- **Por teléfono**: Comuníquese con **IEHP** de 8:00 AM a 5:00 PM llamando al **1-800-440-IEHP (4347)**. O, si tiene dificultades para oír o hablar, por favor, llame al **1-800-718-4347**.

- **Por escrito**: Llene un formulario de apelación o escriba una carta y envíela a:

  *Inland Empire Health Plan*
  *P.O. Box 1800*
  *Rancho Cucamonga, CA 91729-1800*

  El consultorio de su doctor tiene que tener formularios de apelación disponibles. Su plan de salud también puede enviarle un formulario.

- **Por vía electrónica**: Visite el sitio web de su plan de salud. Vaya a **www.iehp.org**

Puede presentar una apelación por su cuenta. O bien, puede pedirle a un pariente, amigo, defensor, doctor o abogado que presente la apelación en nombre de usted. Puede enviar cualquier tipo de información que desee que su plan de salud revise. Un doctor, diferente del doctor que tomó la primera decisión, analizará su apelación.

Su plan de salud tiene 30 días para darle una respuesta. En ese plazo, usted recibirá una carta de “Aviso de Resolución de Apelación”. La carta le comunicará la decisión del plan de salud. **Si no recibe una carta dentro de los 30 días, usted puede:**
- Solicitar una “Revisión Médica Independiente” (Independent Medical Review, IMR) y un revisor externo que no está relacionado con el plan de salud revisará su caso.

- Solicitar una “Audiencia Estatal” y un juez revisará su caso

Lea las siguientes instrucciones para pedir una IMR o Audiencia Estatal.

APELACIONES ACCELERADAS

Si considera que esperar 30 días dañará su salud, usted podría obtener una respuesta en un lapso de 72 horas. Cuando presente su apelación, explique por qué esperar dañaría su salud. Asegúrese de pedir una “apelación acelerada”.

SI NO ESTÁ DE ACUERDO CON LA DECISIÓN SOBRE LA APELACIÓN

Si usted presentó una apelación y recibió una carta de “Aviso de Resolución de Apelación” para decirle que su plan de salud aún no le prestará los servicios, o si nunca recibió una carta para comunicarle la decisión y ya pasaron 30 días, usted puede:

- Solicitar una “Revisión Médica Independiente” (Independent Medical Review, IMR) y un revisor externo que no está relacionado con el plan de salud revisará su caso

- Solicitar una “Audiencia Estatal” y un juez revisará su caso

Puede solicitar una IMR y una Audiencia Estatal a la vez. También puede solicitar una antes que la otra para ver si se resuelve su problema. Por ejemplo, si solicita primero una IMR, pero no está de acuerdo con la decisión, todavía puede solicitar una Audiencia Estatal. Sin embargo, si solicita primero una Audiencia Estatal, pero la audiencia ya ha tenido lugar, no puede solicitar una IMR. En este caso, la Audiencia Estatal tiene la última palabra.

No tendrá que pagar por una IMR ni por una Audiencia Estatal.
REVISIÓN MÉDICA INDEPENDIENTE (IMR)

Si usted desea una IMR, primero debe presentar una apelación ante su plan de salud. Si no tiene noticias de su plan de salud dentro de 30 días, o si no está conforme con la decisión de su plan de salud, entonces puede solicitar una IMR. Debe solicitar una IMR dentro de un plazo de 180 días a partir de la fecha de la carta de “Aviso de Resolución de Apelación”.

Usted podría tener derecho a una IMR inmediatamente sin presentar primero una apelación. Esto es para los casos en los que su salud está en peligro inmediato o la solicitud se ha denegado porque el tratamiento se considera experimental o de investigación.

El siguiente párrafo le brindará información sobre cómo solicitar una IMR. Observe que el término “queja formal” hace referencia tanto a “quejas” como a “apelaciones”.

El Departamento de Administración de Servicios Médicos de California es responsable de reglamentar los planes de servicios médicos. Si usted tiene una queja formal en contra de su plan de salud, debe llamar primero a su plan de salud al 1-800-440-IEHP (4347) y usar el proceso de quejas formales de su plan de salud antes de comunicarse con el Departamento. El uso de este proceso de quejas formales no prohíbe el ejercicio de algún derecho o recurso legal potencial que pueda estar a su disposición. Si necesita ayuda con una queja formal relacionada con una emergencia, una queja formal que su plan de salud no haya resuelto satisfactoriamente o una queja formal que haya quedado sin resolver durante más de 30 días, puede llamar al Departamento para solicitar asistencia. También podría ser elegible para una Revisión Médica Independiente (IMR). Si es elegible para una IMR, el proceso de IMR proporcionará una revisión imparcial de las decisiones médicas tomadas por un plan de salud en relación con la necesidad médica de un servicio o tratamiento propuesto, las decisiones de cobertura para los tratamientos que son de naturaleza experimental o de investigación y las disputas por pagos de servicios médicos de emergencia o de urgencia. El Departamento también tiene un número de teléfono gratuito (1-888-HMO-2219) y una línea TDD (1-877-688-9891) para las personas con dificultades auditivas y del habla. El sitio web del Departamento (http://www.hmohelp.ca.gov) tiene formularios de quejas, formularios de solicitud de IMR e instrucciones en línea.
AUDIENCIA ESTATAL

Si desea una Audiencia Estatal, debe solicitarla dentro de un plazo de **120 días** a partir de la fecha de la carta de “Aviso de Resolución de Apelación”. Puede solicitar una Audiencia Estatal por teléfono o por escrito:

- **Por teléfono:** llame al **1-800-952-5253**. Este número puede estar muy ocupado. Es posible que escuche un mensaje que le pide que vuelva a llamar más tarde. Si tiene dificultades para oír o hablar, llame al **TTY/TDD 1-800-952-8349**.

- **Por escrito:** llene un formulario de Audiencia Estatal o envíe una carta a:

  **California Department of Social Services**
  **State Hearings Division**
  **P.O. Box 944243, Mail Station 9-17-37**
  **Sacramento, CA 94244-2430**

  Asegúrese de incluir su nombre, dirección, número de teléfono, Número de Seguro Social y el motivo por el cual desea una Audiencia Estatal. Si alguien le está ayudando a solicitar una Audiencia Estatal, incluya el nombre, la dirección y el número de teléfono de esa persona en el formulario o la carta. Si necesita un intérprete, indíquenos qué idioma habla. No tendrá que pagar por un intérprete. Nosotros le conseguiremos uno.

Después de solicitar una Audiencia Estatal, podrían pasar hasta 90 días antes de que su caso se decida y se le envíe una respuesta. Si considera que esperar ese tiempo dañará su salud, podría obtener una respuesta dentro de 3 días laborables. Solicite a su doctor o plan de salud que escriba una carta en nombre de usted. En dicha carta se debe explicar en detalle de qué manera una espera de hasta 90 días para que se decida su caso dañaría gravemente su vida, su salud o su capacidad de lograr, mantener o recuperar una función al máximo. En ese caso, asegúrese de solicitar una “audiencia acelerada” y presente la carta junto con su solicitud de audiencia.

Puede hablar en la Audiencia Estatal usted mismo. O bien, puede pedirle a un pariente, amigo, defensor, doctor o abogado que hable en nombre de usted. Si desea que otra persona hable en su representación, debe informarle a la oficina de la Audiencia Estatal que la persona está autorizada a hablar por usted. Esta persona se denomina “representante autorizado”.

**AYUDA LEGAL**

Usted podría obtener ayuda legal gratuita. Llame al Departamento del Estado de Protección del Consumidor **1-800-952-5210**. También puede llamar a la Sociedad de Asistencia Legal local de su condado al 1-888-804-3536.