



MEDI-CAL Rx DRUG REVIEW POLICY AND PROCEDURES

This document represents the drug evaluation policies and procedures in effect for the Department of Health Care Services and Medi-Cal Pharmacy Benefits Division

POLICY

This document applies to the review of drugs dispensed by pharmacy providers to Medi-Cal beneficiaries. It incorporates criteria and timeframes mandated by statute. In addition, it shall be used by the Medi-Cal Contract Drug Advisory Committee (MCDAC) and Department of Health Care Services (DHCS) staff to make recommendations and decisions regarding the addition or retention of drugs on the Medi-Cal List of Contract Drugs (CDL).

Drugs Eligible for Review

A drug is eligible for petition and review only when the following conditions are met:

1. The drug has received FDA approval through an NDA, ANDA, or BLA.
2. The manufacturer has signed a rebate agreement with the Centers for Medicare & Medicaid Services (CMS)
3. The drug is available in outpatient pharmacies.
4. The drug is not FDA approved for the treatment of cancer or HIV/AIDS. For these drugs, state law provides that FDA approved drug for the treatment of cancer or HIV/AIDS do not undergo the petition process but are instead added to the CDL in accordance with Welfare & Institutions Code (WIC) 14105.436 & 14105.33.

Drug Evaluation Criteria

WIC 14105.39 establishes the drug evaluation criteria, which are further defined in Section 51313.6 of Title 22, California Code of Regulations, as follows:

- a. The safety of the drug.
- b. The effectiveness of the drug.
- c. The essential need for the drug.
- d. The potential for misuse of the drug.

Note: DHCS considers off-label use a "misuse potential" only when the use of the product is inappropriate according to the medical community. Medical literature, staff, academic, and provider experience are used to confirm which off-label uses are inappropriate.

- e. The cost of the drug (Note: also refer to additional provisions below for the definition of best price in California).
 - i) It is the policy of DHCS that evaluation of the cost criterion shall include:
 - (1) Off-label use of drugs
 - (2) Comparisons related to the following, for example:
 - (a) Two or more treatment alternatives having identical outcomes (Cost Minimization Analysis)
 - (b) Treatment alternatives which have different cost and treatment outcomes associated with them (Cost-Benefit Analysis)
 - (c) Total health care system costs of treatment alternatives having similar treatment outcomes (Cost-Effective Analysis)
 - (d) Cost data that reflects the Medi-Cal program's reimbursement methods
 - (e) Realistic offsets for drug displacement (including single-source and multisource drugs), which should be included along with data quantifying therapeutic category growth.
- 2. The deficiency of a drug when measured by one of these criteria may be sufficient to support a decision that the drug should not be added or retained. However, the superiority of a drug under one criterion may be sufficient to warrant the addition or retention of the drug, notwithstanding a deficiency in another criterion.

DRUG REVIEW PROCEDURES

Individual Drug Petition

A manufacturer, physician, or pharmacist may request an Individual Drug Petition (IDP) review of a drug; alternatively, DHCS may initiate an IDP review.

Petitions

To be considered complete, the petition package must contain at least the following information regarding the drug product:

1. A letter (e-mail or postal mail) specifically requesting that the drug be reviewed for addition to the CDL;
2. The FDA classification (e.g., 1P, 3S, etc.) of the drug product at the time of approval;
3. A copy of or link to the FDA approval letter; and
4. A copy of or link to the FDA-approved labeling (e.g., product package insert, product monograph).

At the start of each calendar quarter, The Chief of Drug Contracting will assign pharmacists to coordinate the review of each newly received petition. Manufacturer-initiated petitions for P-rated (Priority Review) drugs are given an expedited review if the petition is requested within 6 months of FDA approval. (See “Fast-Track Review,” below.)

The above minimum information is sufficient for DHCS to *initiate* the review and evaluation of a single drug petition. However, DHCS will require additional information such as the following:

1. Detailed therapeutic information (e.g., clinical studies); and
2. Cost information (i.e., the current National Average Drug Acquisition Cost (NADAC) for all package sizes as reported by CMS [alternatively, WAC may be provided only if no NADAC is available], the Average Manufacturer Price per the federal Medicaid rebate agreement.)

To facilitate the drug evaluation, manufacturers are encouraged to provide such information to DHCS as early as possible in the review process.

Initial Notification

For manufacturer initiated IDP, DHCS will notify manufacturers by email when the review has been started. The notification will include at least the following:

1. Identification of the regulatory/statutory five criteria (safety, efficacy, essential need, misuse potential, and cost) used to evaluate the drug.
2. Specification of manufacturer contract negotiation timeframes and DHCS expectations regarding the manufacturer’s business proposal.
3. Information on how to handle manufacturer contacts with the MCDAC and associated timeframes, unless MCDAC review is not required. (While petitions for the addition of new drug strengths, dosage forms, and product formulations of already-listed drugs do not generally go to the MCDAC for review, occasionally, DHCS may seek their recommendation.)
4. Name and contact information for the DHCS pharmacist assigned to coordinate the review.

Medi-Cal Contract Drug Advisory Committee (MCDAC)

The MCDAC is a committee established by, and defined in California state law (Welfare & Institutions Code, Section 14105.4) to provide written recommendations to the DHCS Director as to the addition of any drug or deletion of any drug from the Contract Drugs List (CDL). The Committee consists of pharmacists, physicians, pharmacologists or representatives from schools of pharmacy, and Medi-Cal beneficiaries. MCDAC members serve at the discretion of the Department of Health Care Services’ (DHCS) Director. These recommendations are to be in accordance with the five evaluation criteria, and the evaluation of cost will be done without access to manufacturer rebate/cost information, due to its confidential nature. For additional details about the MCDAC please refer to the [MCDAC FAQs](#).

Analytical Process

In most cases, DHCS will send correspondence to the MCDAC within 90 calendar days of the date of the petition requesting their review of the petitioned drug(s). The letter to the MCDAC includes, at least, the following for each drug:

1. Generic name, brand name, manufacturer, and the FDA approved indications under review.
2. A statement specifying that the review must be based on the regulatory/statutory five criteria of safety, efficacy, essential need, misuse potential, and cost.
3. The response timeframe.
4. An enclosed form to indicate, on a drug-by-drug basis, recommendations and comments.

DHCS will allow the opportunity for an online clinical presentation with the manufacturer's representatives. DHCS's representatives will generally include the Drug Contracting Branch senior manager(s) from PBD including the staff pharmacist assigned to coordinate the review; other PBD staff may also attend. The purpose of this clinical presentation is to discuss information related to the five criteria. A business proposal for a supplemental rebate is mandatory as part of the manufacturer's petition and must be provided at the time of the clinical presentation.

An electronic copy of the presentation materials must be provided no later than 24 hours prior to the start of the presentation. Failure to provide clinical presentation materials will result in cancellation and rescheduling at the discretion of DHCS.

Please note that copies provided will be kept for reference and must be identical to the actual presentation materials. This requirement is mandatory. If any information presented during the presentation has not been provided for DHCS's retention, the information will not be considered for evaluation of the product. There are no exceptions.

Records Retention

The Medi-Cal Pharmacy Benefits Division (PBD) will retain all records associated with recommendations and decisions regarding addition or retention of drugs on the CDL for a period of three years or for the duration of the contract that added or retained the reviewed drug, whichever is greater.

Evaluation

DHCS staff next will conduct an internal meeting to review and evaluate the drug product(s). The pharmacist assigned to the review will initiate discussion of each drug product. The format for documenting consideration of each drug product shall include the following information at a minimum:

1. Generic name, brand name, FDA rating, and manufacturer of the drugs.
2. Recommendations of MCDAC responses.

3. Recommendations of other entities if appropriate (e.g., healthcare providers, provider organizations, schools of pharmacy.)
4. Brief documentation of each of the five regulatory/statutory criteria of safety, efficacy, essential need, misuse potential, and cost.
5. Manufacturer's input.
6. Pertinent medical literature or other information.
7. Department staff analyses.

Negotiation and Decision

Following DHCS' evaluation of the five evaluation criteria, the reviewing pharmacist may present a counter proposal, which may include utilization controls and a state supplemental rebate counteroffer. The manufacturer will have *30 business days* to accept, reject, or present an alternative to DHCS' counteroffer. Such responses should be communicated to the pharmacist assigned to the drug petition. If the manufacturer fails to respond within the 30 business days, DHCS may conclude that the manufacturer is rejecting the counteroffer or cannot provide the requested information. The assigned pharmacist will update the group and a decision will be made whether or not to add the petitioned drug to the list.

Decision Notification

DHCS will notify the manufacturer of a decision with an explanation of the five regulatory/statutory criteria on which the decision was made. If DHCS has decided to add the manufacturer's drug, DHCS will send a contract to the manufacturer via DocuSign® or by U.S. mail if requested. Only upon receipt of the contract signed by the manufacturer's representative, will DHCS' pharmacist staff begin the procedure for provider notification of the addition of a drug to the CDL and the pharmacy claims processing system.

The effective date to add a drug will not be official until the Medi-Cal Rx provider bulletin is published. Therefore, manufacturers must not announce or market an effective date prior to Medi-Cal Rx bulletin publication. DHCS reserves the right to take administrative action and delay the addition of a drug when a manufacturer prematurely announces or markets the drug as being on the CDL.

Appeals

WIC 14105.39 provides that a manufacturer denied a contract because of an IDP review, may appeal that decision with the Director within 30 calendar days of the date of the written notice of DHCS' decision. Within 30 calendar days of the manufacturer's appeal, the law requires the Director to request a recommendation regarding the appeal from the MCDAC. The committee must provide this recommendation in writing to the Director within 30 calendar days of the Director's request. DHCS may schedule a meeting with the manufacturer and the Department's designee, to review any additional information supplied with the appeal. DHCS will not consider new financial business proposals during the appeal process. However, the appeal process can include further discussion and clarification of the manufacturer's most

recent financial business proposal or any proposed fiscal effect to the Medi-Cal Rx program that the addition of the drug would have. The Director must issue a decision within 30 calendar days of the MCDAC recommendation.

Fast-Track Drug Petition Review Procedures

New drugs approved by the FDA that are designated P-Priority Review, will be evaluated by DHCS within 120 days of the start of the review process (unless the manufacturer requests an extension of the evaluation period) subject to the following conditions:

1. The petition request is complete (see above under “Petitions”).
2. The manufacturer responds to requests for information (including counteroffers) within reasonable timeframes specified by DHCS (at all steps in the review and negotiation process).

This 120-day period for P-designated drugs will include the above Individual Drug Petition Review Procedures. This includes submitting the drug to the MCDAC, evaluating the petition request according to the statutorily required criteria, and initiating negotiations with manufacturers, if applicable.

Additional Provisions

WIC 14105.332 provides authority for DHCS to recoup rebates as a result of a manufacturer revising lower an AMP or CMS RPU during a quarter in which rebate was due. This provision shall apply only to AMP-based contracts as noted in section 3.2 of the AMP-based Supplemental Rebate Agreement. Please refer to the calculation examples located on the Contracting Branch main page for additional details.

WIC 14105.31 defines best price in California to include the manufacturer’s lowest negotiated price available to any foreign or domestic class of trade organization or entity, including, but not limited to, wholesalers, retailers, hospitals, repackagers, providers, or governmental entities, that contracts with a manufacturer for a specified price for drugs, inclusive of cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits, shall be based upon the manufacturer’s commonly used retail package sizes for the drug sold by wholesalers to retail pharmacies.