

<u>NHCS</u> Medi-Cal Rx: Medi-Cal Contract Drug List

This document is intended to provide a high-level overview of how the Department of Health Care Services (DHCS) manages its Medi-Cal Contract Drug List (CDL), including but not limited to the process by which it makes informed and documented decisions to add and/or delete drugs from the Medi-Cal CDL.

Background:

Medi-Cal covers all drugs approved by the federal Food and Drug Administration (FDA), subject to medical necessity¹. DHCS maintains the Medi-Cal CDL, which generally includes drugs for which there is a current state supplemental drug rebate agreement in place. As a condition of Medi-Cal coverage, some drugs require an approved Treatment Authorization Request (TAR)/Prior Authorization (PA) establishing medical necessity, while others do not.

Generally, under the existing Medi-Cal FFS pharmacy benefit, if a drug is listed on the Medi-Cal CDL, then it would not require an approved TAR/PA for coverage. Alternatively, if a drug is not listed on the Medi-Cal CDL, then it would require an approved TAR/PA for coverage. Please note that even if a drug is listed on the Medi-Cal CDL, it may still require an approved TAR/PA for coverage; however, if a certain drug on the Medi-Cal CDL requires an approved TAR/PA, then DHCS policy would clearly articulate that requirement.

How FDA-Approved Drugs are added to the Medi-Cal CDL:

DHCS can add drugs to the Medi-Cal CDL based upon receipt of either (1) an external Individual Drug Petition (IDP) request from a manufacturer, physician, and/or pharmacist, or (2) a DHCS-initiated IDP review, if applicable. Once an IDP is received, DHCS conducts an extensive review of the request based upon the following drug review criteria, which are outlined in Welfare and Institutions (W&I) Code Section 14105.39(c)(1) and (2):

- The safety of the drug
- The effectiveness of the drug
- The essential need of the drug
- The potential for misuse of the drug
- The cost of the drug to the program

In addition to conducting its own internal review, DHCS also consults with the Medi-Cal Drug Advisory Committee (MCDAC), as required by W&I Code Section 14105.4. The MCDAC is comprised of members who are appointed by the DHCS' Director – including community physicians and pharmacists, faculty members from academic pharmacy institutions, and Medi-Cal beneficiaries – and assist DHCS by providing written recommendations to inform decision-making regarding adding and/or deleting, drug(s) from the Medi-Cal CDL. The MCDAC's final response with detailed, drug-by-drug recommendations is due within 30 calendar days of DHCS requesting consultation, and takes into consideration the W&I Code Section 14105.39(c)(1) and (2) criteria, as well as additional information such as generic name, brand name, FDA indications, manufacturer, fiscal/cost impact, clinical criteria, etc. DHCS then makes an informed and documented decision whether or not to add the drug to the Medi-Cal CDL based upon the MCDAC's recommendations, W&I Code requirements, and other relevant factors.

¹ Except for those FDA-approved drugs where coverage is otherwise prohibited by federal Medicaid statutes, regulations, and/or policies.