



An Advocate's Guide to Medi-Cal Services

January 2020

**Chapter II:
Prescription Drugs**

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Prescription Drug Services Covered in this Chapter*

- Prescription Drugs Covered by Medi-Cal
 - Coverage of every Food and Drug Administration approved drug
 - Excluded drugs
- Medi-Cal Contract Drug List (CDL)
 - No prior authorization required, although some exceptions
 - Removal of a drug from CDL
 - State fair hearing rights
 - Continuing care status
- Prior Authorization
 - Department of Health Care Services (DHCS) establishes prior authorization criteria
 - Cannot be so restrictive that denies access to drug for “medically accepted indication”
 - Beneficiary’s prescriber/pharmacist submits Treatment Authorization Request
 - DHCS or health plan must respond within 24 hours of request, and
 - Dispense a 72-hour supply of covered outpatient drug in an emergency situation pending TAR response
- Other Utilization Controls
 - No more than 100 calendar day supply
 - Six prescriptions per month limit
 - Generic drugs
- Prescription Drug Coverage Under Managed Care
 - Same right to access to covered Medi-Cal drugs
 - Some drug coverage carved out of managed care
 - Per Executive Order N-01-19, DHCS will transition Medi-Cal pharmacy services for Medi-Cal managed care to fee-for-service

Prescription Drug Services Covered in this Chapter* (continued)

- Prescription Drugs for Dual Eligibles
 - Must receive most prescription drugs through Medicare Part D plan
 - Drug categories excluded from Part D may be covered by Medi-Cal

*This is a non-exhaustive list of services. It may not include all available services.

Medi-Cal benefits include coverage of prescription drugs, which are an optional service under the federal Medicaid Act.¹ Subject to certain narrow limitations, Medi-Cal must cover nearly every drug approved by the Food and Drug Administration (FDA). Nevertheless, Medi-Cal beneficiaries may face barriers to obtain a drug even if they have a prescription for it. For example, a beneficiary may need prior authorization for the drug. Also, additional limitations apply to any drug that is not on the state’s “Contract Drugs List.”

A. Prescription Drugs Covered by Medi-Cal²

Under federal law, Medi-Cal typically must cover every FDA approved drug sold by a manufacturer that has entered into a drug rebate agreement with the federal government.³ Since nearly all manufacturers have entered into such rebate agreements, the effect of this statute is that Medi-Cal has an “open formulary”, i.e., Medi-Cal beneficiaries can receive coverage of almost any FDA approved drug.

However, federal law allows states to exclude coverage of certain categories of drugs, and Medi-Cal has adopted some coverage restrictions. For example, Medi-Cal does not cover over-the-counter cough and cold products, unless provided to a beneficiary under 21 years of age through the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit.⁴

Medi-Cal does cover some classes of drugs even though federal law allows for their exclusion. For example, federal law allows states to exclude coverage of smoking cessation products provided to adults who are not pregnant women.⁵ Medi-Cal, however, covers both prescription and over-the-counter tobacco cessation products for all beneficiaries.⁶

B. Medi-Cal Contract Drug List

Not every covered Medi-Cal drug appears on Medi-Cal’s “Contract Drugs List.”⁷ The Contract Drugs List (CDL) is a type of preferred drug list. Drugs on the list are preferred because they are generally available to a beneficiary without prior authorization, meaning that a beneficiary only needs a prescription – and not

pre-approval from the Department of Health Care Services (DHCS) – in order to obtain a drug.⁸ Manufacturers sometimes get their drugs placed on the list by signing a contract with Medi-Cal in which they agree to provide additional rebates to Medi-Cal in addition to the rebates required under federal law. Ultimately, DHCS, as advised by the Medi-Cal Contract Drug Advisory Committee, determines which drugs get placed on the CDL based on a drug’s safety, efficacy, cost, and potential misuse, as well as whether there is an “essential need” for the drug.⁹

Although a beneficiary typically can obtain a drug on the CDL without having to obtain prior authorization, there are circumstances in which this is not the case:

- Some drugs on the list are subject to prior authorization if they are being prescribed for certain conditions, but are not subject to prior authorization if they are prescribed for other conditions.¹⁰
- Enbrel, which is used to treat a variety of conditions such as rheumatoid arthritis, is subject to prior authorization even though it appears on the CDL.¹¹
- Celebrex, a COX-2 inhibitor, is subject to step therapy even though it appears on the CDL.¹² This means that the Medi-Cal beneficiary must try another COX-2 inhibitor prior to receiving Celebrex.¹³

All drugs not listed on the CDL require prior authorization from Medi-Cal.¹⁴

Sometimes, a Medi-Cal beneficiary may be taking a drug that Medi-Cal seeks to remove from the CDL. In that case, Medi-Cal must provide beneficiaries with notice about the proposed removal, and such notice must inform beneficiaries of the right to a fair hearing to challenge such removal.¹⁵ Even if the drug is removed from the CDL, a Medi-Cal beneficiary may still receive the drug without prior authorization if the beneficiary is granted continuing care status. Continuing care status is for beneficiaries who are taking a drug at the time that DHCS removes the drug from the CDL and continue to seek prescriptions for the drug at least once every 100 days.¹⁶

C. Prior Authorization

DHCS establishes prior authorization criteria for drugs not on the CDL, as well as drugs on the CDL when not used for the indications specified on the CDL. In the case where a beneficiary is seeking access to a drug that is not on the CDL, prior authorization may be granted when the clinical condition of the beneficiary requires the use of an unlisted drug and listed drugs have been adequately considered or tried and do not meet their medical needs, or the use of an unlisted drug results in a less expensive treatment than would otherwise occur.¹⁷

Federal law prohibits state Medicaid programs from making their criteria so restrictive that they deny access to a drug when a beneficiary is seeking the drug for a “medically accepted indication.”¹⁸ A “medically accepted indication” is

any indication set forth on a drug's FDA label, as well as off-label indications that are recognized in three different drug compendia.¹⁹ Thus, Medi-Cal is prohibited from imposing prior authorization criteria for a particular drug that would result in a denial of coverage when a drug is prescribed for a medically accepted indication.

In cases where prior authorization of a drug is required, the beneficiary's prescriber or pharmacist should submit a Treatment Authorization Request (TAR) to DHCS, or, for managed care enrollees, the Medi-Cal managed care plan (MCP), in order to obtain such prior authorization. DHCS or the plan must: 1) provide a response by telephone or other telecommunication device within 24 hours of the request or receipt of the TAR; and 2) provide for the dispensing of at least a 72-hour supply of a covered outpatient drug in an emergency situation pending a response on the TAR.²⁰ If DHCS or a Medi-Cal MCP denies the TAR, both the beneficiary and the beneficiary's provider should receive a notice explaining why the TAR was denied, and the beneficiary may request an expedited fair hearing.²¹

When a provider has verified a Medi-Cal beneficiary's eligibility for services, the provider may not deny services because the service requires the provider to obtain authorization.²² A pharmacist may not make the Medi-Cal beneficiary pay for the medication by claiming that Medi-Cal does not cover it. Such a statement may constitute fraud if Medi-Cal could pay for the drug if a TAR were submitted.²³

ADVOCACY TIP:

- ✓ California state law prohibits providers from imposing medical management techniques, including prior authorization and step therapy, on beneficiaries seeking contraceptive drugs and devices.²⁴

D. Other Utilization Controls

In addition to the imposition of prior authorization for drugs not on the CDL, Medi-Cal imposes additional drug utilization controls:

- Beneficiaries typically can obtain no more than a 100-calendar day supply of a drug, except for sodium fluoride tablets, drops, or when necessary to comply with minimum quantities otherwise specified in the regulation.²⁵
- Prior authorization is needed for prescription drugs that exceed a six prescriptions-a-month limit (family planning drugs and patients receiving care in a nursing facility are not subject to this limit).²⁶
- California has adopted policies to promote the use of generic drugs.²⁷ Although the Medi-Cal program does not require generic substitution, the program is required to purchase the most cost-effective drug.²⁸

Medi-Cal also imposes a copayment of one dollar per each prescription or refill, although in practice, beneficiaries are generally not charged any copayments for their prescriptions.²⁹ Co-payments are not permitted for contraceptive drugs and devices.³⁰

E. Prescription Drug Coverage Under Managed Care

Medi-Cal enrollees in managed care have the same right to access covered Medi-Cal drugs as beneficiaries in the fee-for-service (FFS) system. Medi-Cal MCP enrollees have the right to coverage of nearly all FDA approved drugs, just as those enrolled in FFS do. Similarly, MCPs must provide a response to a prior authorization request within 24 hours and must provide a 72-hour supply of a drug when an enrollee is seeking a drug in case of an emergency.³¹ Medi-Cal managed care plans must also allow new enrollees to continue to receive brand name (single-source) drugs, which they were taking prior to the date of enrollment in the plan.³² This applies whether or not the drug is covered by the plan, until the plan's doctor decides it is no longer necessary.³³ Also, Medi-Cal MCP enrollees seeking contraceptives may see any qualified family planning provider of their choice, even if the provider is out of network, without a referral, prior authorization and with no cost sharing.³⁴

However, there can be differences in how MCP enrollees access drugs. Several types of drugs – such as HIV drugs, certain psychiatric drugs, drugs to treat alcohol and other substance use disorders, and blood coagulation factors – are carved out of managed care and not covered by MCPs under Medi-Cal.³⁵ Enrollees in these plans are still entitled to coverage of such drugs, but it is the Medi-Cal program itself, not the managed care plan, that covers and pays for such drugs, even though the drugs may be prescribed by a MCP provider.³⁶

Medi-Cal MCPs can also develop their own formularies, and those formularies are not required to include every drug that appears on the Contract Drug List.³⁷ However, underlying federal drug coverage protections continue to apply. If an enrollee needs access to a drug that is not on the formulary, then the managed care plan must cover such drug through prior authorization, and the prior authorization criteria cannot be so strict that they deny coverage for medically accepted indications.³⁸ In addition, managed care plans develop their own pharmacy networks, so in some cases managed care enrollees may be required to receive their drugs from different pharmacies than FFS beneficiaries.

In January 2019, Governor Newsom issued Executive Order N-01-19, calling for an end of Medi-Cal managed care coverage of prescription drugs and requiring DHCS to transition Medi-Cal pharmacy services to FFS with the aim of obtaining greater discounts from manufacturers.³⁹ The Executive Order calls for the transition to occur by January 2021. In August 2019, DHCS solicited proposals from firms that are able to provide administrative services for managing the FFS

pharmacy benefit. DHCS announced it planned to make a single contract award for Medi-Cal prescription drug services to the firm earning the highest evaluation score.⁴⁰ On November 7, 2019, DHCS announced it intends to award a contract to Magellan Medicaid Administration, Inc.⁴¹

F. Prescription Drugs for Dual Eligibles

Medi-Cal beneficiaries who are also eligible for Medicare, known as “dual eligibles”, must receive most of their prescription drugs from a Medicare Part D plan rather than through Medi-Cal.⁴² These beneficiaries are entitled to and should be automatically enrolled in the Low-Income Subsidy (LIS) program.⁴³ Dual eligibles may receive Medi-Cal coverage for medications that are categorically excluded under Medicare Part D but are covered by Medi-Cal.⁴⁴ If a drug is a coverable drug under Medicare Part D, but the beneficiary’s Part D plan does not cover the medication, the beneficiary cannot turn to Medi-Cal for coverage of that drug.⁴⁵

Endnotes

¹ CAL. WELF. & INST. CODE § 14132(d); CAL. CODE REGS. tit. 22, § 51313. See also 42 U.S.C. §§ 1396d(a)(12) (prescription drugs), 1396a(a)(54) (outpatient drugs), 1396r-8 (outpatient drugs); 1396b(i)(5) and (10) (federal payments); 42 C.F.R. § 440.120(a) (defining prescribed drugs).

² California elected to align benefits offered to both the traditional and expansion Medi-Cal populations, and thus provides the same scope of services to all Medi-Cal beneficiaries. CMS, Approval Letter for Cal. State Plan Amendment # 13-035, <https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CA/CA-13-035.pdf>.

³ 42 U.S.C. § 1396r-8(d)(1)(B), (4).

⁴ CAL. WELF. & INST. CODE § 14132(d)(4); Cal. Dep’t Health Care Servs., *Drugs: Contract Drug List Introduction 2* (May 2016), https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/drugscdlintr_p00.doc; 42 U.S.C. § 1396r-8(42 U.S.C. § 1396r-8(a)(1).

⁵ 42 U.S.C § 1396r-8(d)(2). CMS, Dear State Medicaid Director (June 24, 2011) (SMD # 11-007) (New Medicaid Tobacco Cessation Services), <https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD11-007.pdf>.

⁶ CAL. WELF. & INST. CODE § 14134.25(b)(2).

- ⁷ See Cal. Dep't Health Care Servs., *Contract Drugs List*, <http://files.medi-cal.ca.gov>. Medications are listed by their generic name.
- ⁸ Cal. Dep't Health Care Servs., *Pharmacy Benefits Frequently Asked Questions*, <https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/PharmFAQ.aspx> (last viewed Dec. 19, 2019).
- ⁹ CAL. WELF. & INST. CODE § 14105.39(c)(1); CAL. CODE REGS. tit. 22, § 51313.6(a).
- ¹⁰ CAL. CODE REGS. tit. 22, § 51313.3(b).
- ¹¹ Cal. Dep't Health Care Servs., *Drugs: Contract Drug List Part 7 – Preferred Prior Authorization Drug List 1*, <http://files.medi-cal.ca.gov>.
- ¹² Cal. Dep't Health Care Servs., *Drugs: Contract Drug List Part 8 – Step Therapy 2*, <http://files.medi-cal.ca.gov>.
- ¹³ In addition, state law allows HIV and cancer drugs to be placed on the Contract Drug List even if their manufacturer has not signed a contract with Medi-Cal. CAL. WELF. & INST. CODE §§ 14105.43, 14133.2. If a manufacturer for such drugs refuses to provide a supplemental rebate to Medi-Cal for such drugs, then those drugs become subject prior authorization even though they appear on the Contract Drug List. CAL. WELF. & INST. CODE § 14105.436(i).
- ¹⁴ CAL. CODE REGS. tit. 22, § 51313(c).
- ¹⁵ CAL. WELF. & INST. CODE § 14105.33(i).
- ¹⁶ CAL. WELF. & INST. CODE § 14105.33(r), (s).
- ¹⁷ CAL. CODE REGS. tit. 22, § 51313(c)(1).
- ¹⁸ 42 U.S.C. § 1396r-8(d)(1)(B)(i), (5).
- ¹⁹ 42 U.S.C. § 1396r-8(k)(6). 42 U.S.C. § 1396r-8(k)(g)(1)(B)(i). See also CAL. CODE REGS. tit. 22, § 51313(c)(4) (allowing .authorization for unlabeled use of drugs if the use represents “reasonable and current prescribing practices” based on: a) reference to current medical literature, and b) consultation with provider organizations, academic and professional specialists).
- ²⁰ CAL. WELF. & INST. CODE § 14133.37(a) & (b), 42 U.S.C. § 1396r-8(d)(5)(A) & (B); 42 C.F.R. §§ 438.3(s)(6), 438.210(d)(3) (managed care).
- ²¹ See Cal. Dep't Health Care Servs., TAR Overview, <https://www.dhcs.ca.gov/provgovpart/Pages/TAROverview.aspx> (last visited Dec. 19, 2019) See Cal. Dep't Health Care Servs., Medi-Cal Fair Hearing, <https://www.dhcs.ca.gov/services/medi-cal/Pages/Medi-CalFairHearing.aspx>; see also Cal. Dep't Health Care Servs., All Plan Letter 17-006 (May 9, 2017) (describing notice requirements for Medi-Cal managed care plans), <https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2017/APL17-006.pdf>.
- ²² See Cal. Dep't Health Care Servs., *Medi-Cal Provider Guidelines 7-8*, https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/provguide_z01.doc.
- ²³ Medi-Cal fraud by providers or beneficiaries may be reported by calling the statewide Medi-Cal Fraud Hotline at 1-800-822-6222.

- ²⁴ S.B. 1053, Contraceptive Coverage Equity Act (2014), CAL. HEALTH & SAFETY CODE § 1367.25.
- ²⁵ CAL. CODE REGS. tit. 22, § 51313(b).
- ²⁶ CAL. WELF. & INST. CODE § 14133.22.
- ²⁷ CAL. BUS. & PROF. CODE § 4073; CAL. HEALTH & SAFETY CODE § 1367.22(a).
- ²⁸ CAL. CODE REGS. tit. 22, § 51313(c)(1)(B); *see also* Cal. Dep't Health Care Servs., *California Medi-Cal Drug Use Review (DUR) Program Federal Fiscal Year (FFY) 2016 Annual Report*, Attachment 4-42, http://files.medi-cal.ca.gov/pubsdoco/dur/Articles/packet20170516_25904.pdf.
- ²⁹ CAL. WELF. & INST. CODE § 14134(a)(3); Cal. Health Care Found., *The Medi-Cal Prescription Drug Benefit*, at 3 (2009) (noting that all Medi-Cal managed care plans decline to charge copayments for prescription drugs), <https://www.chcf.org/wp-content/uploads/2017/12/PDF-MediCalPrescriptionDrugBenefitOverview.pdf>.
- ³⁰ 42 U.S.C. §§ 1396o(a)(2), (b)(2); 42 C.F.R. § 447.56(a)(2)(ii).
- ³¹ 42 C.F.R. § 438.3(s)(6).
- ³² CAL. WELF. & INST. CODE § 14185(b).
- ³³ *Id.*
- ³⁴ This federal protection is known as “freedom of choice” in family planning and was codified in state law with the enactment of the “Protection of Choice for Family Planning Act.” *See* Chapter 6 on Reproductive and Sexual Health Services of this Guide for more information about freedom of choice requirements.
- ³⁵ *See* Cal. Dep't Health Care Servs., *Medi-Cal Provider Manual, MCP: County Organized Health System (COHS)* 6-11, http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part1/mcpcohs_z01.doc. For more information on carved-out behavioral health medications, *see* Chapter III on Mental Health Services and Chapter IV on Substance Use Disorder services of this Guide.
- ³⁶ 81 Fed. Reg. 27497, 27544 (May 6, 2016).
- ³⁷ Cal. Dep't Health Care Servs., *County Organized Health Systems Boilerplate Contract*, Exhibit A, Attachment 10, § F(2), <https://www.dhcs.ca.gov/provgovpart/Documents/COHSBoilerplate032014.pdf>.
- ³⁸ “The MCO, PIHP, or PAHP may be permitted to maintain its own formularies for covered outpatient drugs, but when there is a medical need for a covered outpatient drug that is not included in their formulary but that is within the scope of the contract, the MCO, PIHP, or PAHP must cover the covered outpatient drug under a prior authorization process.” 81 Fed. Reg. 27497, 27544 (May 6, 2016).
- ³⁹ Cal. Executive Dep't, Executive Order N-01-19, <https://www.gov.ca.gov/wp-content/uploads/2019/01/EO-N-01-19-Attested-01.07.19.pdf>.

- ⁴⁰ Cal. Dep't Health Care Servs., *Request for Proposal # 19-96125*, https://www.dhcs.ca.gov/provgovpart/rfa_rfp/Pages/CSBmcrxHome.aspx.
- ⁴¹ Cal. Dep't Health Care Servs., *Notice of Intent to Award*, https://www.dhcs.ca.gov/provgovpart/rfa_rfp/Documents/MCRx-NOIA.pdf.
- ⁴² CAL. WELF. & INST. CODE § 14133.23(a).
- ⁴³ 42 C.F.R. §§ 423.772, 423.773(c)(1)(i), 423.780, 423.782.
- ⁴⁴ CAL. WELF. & INST. CODE § 14133.23(b) & (c).
- ⁴⁵ See Randolph T. Boyle, Nat'l Health Law Prog., *Medicare Part D and Dual Eligibles: A Guide for California Advocates* (2008), https://9kqpw4dcaw91s37kozm5jx17-wpengine.netdna-ssl.com/wp-content/uploads/2018/09/medicare_ptD_dualsadvocates_guide.