



An Advocate's Guide to Medi-Cal Services

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Chapter II: Prescription Drugs

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Outline of Medi-Cal Prescription Drug Services*

- Prescription Drugs Covered by Medi-Cal
 - Coverage of every Food and Drug Administration approved drug
 - Excluded drugs
- Other Items Covered by Medi-Cal Rx
 - Over-the-counter medications
 - Vaccines
 - Certain medical supplies
 - Certain enteral nutrition products
- 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 prior authorization request
 - Medi-Cal Rx must respond within 24 hours of request, and
 - Dispense a 72-hour supply of covered outpatient drug in an emergency situation pending prior authorization response
- Other Utilization Controls
 - No more than 100 calendar day supply
 - Generic drugs
- 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 prescription 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” or “CDL.”

Starting in 2022, most prescription drugs for almost all Medi-Cal beneficiaries are delivered through the Medi-Cal Rx program, which is currently administered by Magellan Medicaid Administration, Inc.² The implementation of Medi-Cal Rx came about after Governor Newsom in 2019 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.³ Through Medi-Cal Rx, DHCS has “carved out” the prescription drug benefit for Medi-Cal so that prescription drugs for Medi-Cal beneficiaries are paid on a fee-for-service basis, even for people who are enrolled in a managed care plan for their other Medi-Cal benefits.⁴ Beneficiaries will still obtain their prescription from their managed care provider as long as those providers are also enrolled in Medi-Cal Rx, but those prescriptions will be reviewed by Medi-Cal Rx and not their plan, and if approved, will be filled at a Medi-Cal participating pharmacy.⁵

Medi-Cal Rx uses a uniform approval process as well as uniform authorization and scope-of-coverage rules for Medi-Cal prescription drugs.⁶ For beneficiaries who had prescriptions in place before the transition to Medi-Cal Rx, the state has implemented continuity of care protections to ensure that beneficiaries do not experience gaps in their prescription drug coverage and access.⁷

A. Prescription Drugs Covered by Medi-Cal⁸

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.⁹ 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 extended-release over-the-counter cough and cold products.¹⁰

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.¹¹ Medi-Cal, however, covers both prescription and over-the-counter tobacco cessation products for all beneficiaries.¹²

B. Other Items Covered by Medi-Cal Rx

In addition to covering most prescription medications, the Medi-Cal Rx program is responsible for providing beneficiaries with other related Medi-Cal benefits, for example, select over-the-counter medications.¹³ Consistent with federal Medicaid law, Medi-Cal only covers over-the-counter medications dispensed when they are prescribed by an authorized prescriber.¹⁴ Medi-Cal covers a limited selection of over-the-counter medications, including certain cold and cough medications, pain killers, allergy medications, contraceptives, smoking cessation preparations, and topical dermatological treatments.¹⁵ Medi-Cal Rx also covers vaccines when they are billed on a pharmacy claim, including vaccines against COVID-19.¹⁶

Medi-Cal Rx also covers certain medical supplies, including insulin syringes, pen needles, lancets, and diabetic test strips.¹⁷ Other medical supplies, including condoms, diaphragms / cervical caps, heparin / saline flush, continuous glucose monitoring systems, blood pressure monitoring devices and cuffs, and Covid antigen tests, are covered by Medi-Cal Rx when they are billed on a pharmacy claim, but covered by Medi-Cal managed care when they are billed on a medical claim.¹⁸ Still other medical supplies, such as incontinence supplies, thermometers, alcohol wipes, and waterproof sheets, are always covered by Medi-Cal managed care plans, not Medi-Cal Rx.¹⁹

Medi-Cal Rx also covers enteral nutrition products when they are billed on a pharmacy claim, but these products are covered by Medi-Cal managed care when they are billed on a medical claim.²⁰ In addition, related supplies, including intubation tubing and pumps, are always covered by Medi-Cal managed care plans, not Medi-Cal Rx.²¹

C. Medi-Cal Contract Drug List

DHCS maintains the Medi-Cal Contract Drugs List (CDL), which operates as preferred drug list.²² That is, the CDL generally includes drugs that do not require prior authorization for coverage, 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.²³ In some cases, however, drugs listed on the Medi-Cal CDL may still require prior authorization for coverage (for example, a drug may require prior authorization when prescribed to treat certain conditions), although the prior authorization requirements will be noted in the CDL.²⁴ Medi-Cal covered drugs that do not appear on the CDL require prior authorization from Medi-Cal.²⁵

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.²⁶ 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.²⁷

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.²⁸ 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.²⁹ In addition, beneficiaries who were prescribed a particular medication that is not on the CDL prior to January 1, 2022 are entitled to continue that prescription for a period of time, depending on the drug, consistent with Medi-Cal Rx's Transition of Care Policy.³⁰

D. 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.³¹ 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.³²

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."³³ 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.³⁴ 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 request to Medi-Cal Rx in order to obtain such prior authorization.³⁵ Medi-Cal Rx must: 1) provide a response by telephone or other telecommunication device within 24 hours of the request or receipt of the prior authorization request; 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 request for prior authorization.³⁶ If DHCS or a Medi-Cal MCP denies the prior authorization request, both the beneficiary and the beneficiary's provider should receive a notice explaining why authorization was denied, and the beneficiary may request a fair hearing.³⁷

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.³⁸ A pharmacist may not induce the Medi-Cal beneficiary to 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 prior authorization request were submitted.³⁹

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.⁴⁰

E. 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.⁴¹
- California has adopted policies to promote the use of generic drugs.⁴² Although the Medi-Cal program does not require generic substitution, the program is required to purchase the most cost-effective drug.⁴³

Medi-Cal no longer charges any copayments for prescription drugs.⁴⁴ In addition, co-payments are not permitted for contraceptive drugs and devices.⁴⁵

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.⁴⁶ These beneficiaries are entitled to and should be automatically enrolled in the Low-Income Subsidy (LIS) program.⁴⁷ Dual eligibles may receive Medi-Cal coverage for medications that are categorically excluded under Medicare Part D but are covered by Medi-Cal.⁴⁸ 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.⁴⁹

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 Cal. Dep't Health Care Servs., *Medi-Cal Rx: Transitioning Medi-Cal Pharmacy Services from Managed Care to Fee-for-Service Frequently Asked Questions* 14 (V. 13.0, 2022), https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/faq/Medi-Cal_Rx_Transitioning_Medi-Cal_Pharmacy_Services_from_Managed_Care_to_FFS_FAQs.pdf [hereinafter *Medi-Cal Rx FAQs*]. Note that a few drugs are still covered by Medi-Cal plans, including certain contraceptives and physician administered drugs when they are billed by a facility or institution as part of a medical claim. See Cal. Dep't Health Care Servs., All Plan Letter 20-020 at 4, 6–8 (Nov. 4, 2020), <https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2020/APL20-020.pdf> [hereinafter All Plan Letter 20-020]. In addition, pharmacist services are the responsibility of Medi-Cal plans. *Id.* at 9.
- ³ Cal. Exec. 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>.
- ⁴ Cal. Dep't Health Care Servs., *Medi-Cal Rx Scope* (V. 5.0, 2021), <https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MediCalRxScopeV5-11222021.pdf>.
- ⁵ Cal. Dep't Health Care Servs., *Medi-Cal Rx Provider Manual* § 2.1 (2022), https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/manuals/Medi-Cal_Rx_Provider_Manual.pdf [hereinafter *Medi-Cal Rx Provider Manual*]; see *Medi-Cal Rx FAQs*, *supra* note 2, at 14.
- ⁶ See *Medi-Cal Rx FAQs*, *supra* note 2, at 4.
- ⁷ See *id.* at 22–23; see also Cal. Dep't Health Care Servs., *Medi-Cal Rx Pharmacy Transition Policy* (V. 8.3, 2021), <https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/Pharmacy-Transition-Policy-Ver8.3-4-30-2021.pdf>.
- ⁸ 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>.
- ⁹ 42 U.S.C. § 1396r-8(d)(1)(B), (4).
- ¹⁰ Compare *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 4.6.11 with 42 U.S.C. § 1396r-8(d)(2)(D).

- ¹¹ 42 U.S.C § 1396r-8(d)(2). CMS, Dear State Medicaid Director Letter (June 24, 2011) (SMD # 11-007) (New Medicaid Tobacco Cessation Services), <https://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD11-007.pdf>.
- ¹² CAL. WELF. & INST. CODE § 14134.25(b)(2).
- ¹³ All Plan Letter 20-020, *supra* note 2, at 7.
- ¹⁴ *Id.* § 1396r-8(k)(4); CMS, *Defining a “Prescribed Drug” and a “Covered Outpatient Drug”* 4 (Oct. 5, 2016) (No. 178), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-178.pdf>; see also Abbi Coursolle & Liz McCaman Taylor, Nat’l Health Law Prog., *Coverage of Over-the-Counter Drugs in Medicaid* (Rev. Ed. 2022), <https://healthlaw.org/resource/coverage-of-over-the-counter-drugs-in-medicaid>.
- ¹⁵ For the full list of covered over-the-counter medications, see Cal. Dep’t Health Care Servs., *Medi-Cal Rx Contract Drugs List – Over-the-Counter Drugs* (2022), https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/cdl/Medi-Cal_Rx_Contract_Drugs_List_OTC_FINAL.pdf.
- ¹⁶ See Cal. Dep’t Health Care Servs., *Medi-Cal Rx Contract Drugs List – Therapeutic Classifications* 33 (2022), https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/cdl/Medi-Cal_Rx_CD_L_Therapeutic_Classifications_FINAL.pdf; Cal. Dep’t Health Care Servs., *Covered Products List*, <https://medi-calrx.dhcs.ca.gov/provider/forms> (last visited Aug. 8, 2022); All Plan Letter 20-020, *supra* note 2, at 7. Vaccines provided in a facility or institution billed on a medical claim must be covered by the beneficiary’s Medi-Cal plan. *Id.* Medi-Cal will cover the Monkeypox vaccine, and providers should administer the vaccine to people when it is administered consistent with FDA and CDC but as of this writing, DHCS has not determined how providers should bill those claims. Cal. Dep’t Health Care Servs., *Coming Soon: Monkeypox Vaccines as Medi-Cal Benefits* (Aug. 5, 2022), https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_31823_01.aspx.
- ¹⁷ All Plan Letter 20-020, *supra* note 2, at 7–8; Cal. Dep’t Health Care Servs., *Covered Products List*, *supra* note 16.
- ¹⁸ All Plan Letter 20-020, *supra* note 2, at 7–8; Cal. Dep’t Health Care Servs., *Covered Products List*, *supra* note 16.
- ¹⁹ All Plan Letter 20-020, *supra* note 2, at 7–9; Cal. Dep’t Health Care Servs., *Covered Products List*, *supra* note 16.
- ²⁰ All Plan Letter 20-020, *supra* note 2, at 9; Cal. Dep’t Health Care Servs., All Plan Letter 22-012 at 3 (July 11, 2022), <https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2022/APL22-012.pdf> [hereinafter All Plan Letter 22-012]; Cal. Dep’t Health Care Servs., *Covered Products List*, *supra* note 16.

- ²¹ All Plan Letter 20-020, *supra* note 2, at 9; All Plan Letter 22-012, *supra* note 20, at 30; Cal. Dep’t Health Care Servs., *Covered Products List*, *supra* note 16.
- ²² The Contract Drugs List may be found at <https://medi-calrx.dhcs.ca.gov/home/cdl>. Medications are listed by their generic name.
- ²³ Cal. Dep’t Health Care Servs., *Medi-Cal Rx: Medi-Cal Contract Drugs List* (2022), <https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-CDL.pdf> [hereinafter *Medi-Cal Contract Drugs List*].
- ²⁴ CAL. CODE REGS. tit. 22, § 51313.3(b); *see generally* *Medi-Cal Contract Drugs List*, *supra* note 23; *see also* *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 11.
- ²⁵ CAL. CODE REGS. tit. 22, § 51313(c); *see also* *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 14.
- ²⁶ *See* *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 11.0.
- ²⁷ CAL. WELF. & INST. CODE § 14105.39(c)(1); CAL. CODE REGS. tit. 22, § 51313.6(a).
- ²⁸ CAL. WELF. & INST. CODE § 14105.33(i).
- ²⁹ CAL. WELF. & INST. CODE § 14105.33(r), (s).
- ³⁰ *See* Cal. Dep’t Health Care Servs., *Medi-Cal Rx Pharmacy Transition Policy* (2021), <https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/Pharmacy-Transition-Policy-Ver8.3-4-30-2021.pdf>.
- ³¹ *See* *Medi-Cal Rx Provider Manual*, *supra* note 5, at §§ 11, 14.
- ³² CAL. CODE REGS. tit. 22, § 51313(c)(1).
- ³³ 42 U.S.C. § 1396r-8(d)(1)(B)(i), (5).
- ³⁴ 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). *Cf.* Abbi Coursolle, Nat’l Health Law Prog., *More Transparency Needed to Ensure Medicaid Beneficiaries Have Access to Necessary Off Label Prescription Drugs* (2022), <https://healthlaw.org/wp-content/uploads/2022/04/2022-04-07-Off-Label-Paper-Final.pdf>.
- ³⁵ *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 14.1.
- ³⁶ CAL. WELF. & INST. CODE § 14133.37(a) & (b), 42 U.S.C. § 1396r-8(d)(5)(A) & (B); *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 14.1.
- ³⁷ CAL. WELF. & INST. CODE § 14133.37(a); *see also* *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 14.1 (provider notice); *Medi-Cal Rx FAQs*, *supra* note 2, at 39 (beneficiary notice and hearing rights); Cal. Dep’t Health Care Servs., *Medi-Cal Fair Hearing*, <https://www.dhcs.ca.gov/services/medi-cal/Pages/Medi-CalFairHearing.aspx> (last visited Aug. 3, 2022).
- ³⁸ *See* *Medi-Cal Rx Provider Manual*, *supra* note 5, at § 2.1.3.4.

- ³⁹ Medi-Cal fraud by providers or beneficiaries may be reported by calling the statewide Medi-Cal Fraud Hotline at 1-800-822-6222.
- ⁴⁰ S.B. 1053, Contraceptive Coverage Equity Act (2014).
- ⁴¹ CAL. CODE REGS. tit. 22, § 51313(b).
- ⁴² CAL. BUS. & PROF. CODE § 4073; CAL. HEALTH & SAFETY CODE § 1367.22(a).
- ⁴³ 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.
- ⁴⁴ CAL. WELF. & INST. CODE § 14134(a)(3).
- ⁴⁵ 42 U.S.C. §§ 1396o(a)(2), (b)(2); 42 C.F.R. § 447.56(a)(2)(ii).
- ⁴⁶ CAL. WELF. & INST. CODE § 14133.23(a).
- ⁴⁷ 42 C.F.R. §§ 423.772, 423.773(c)(1)(i), 423.780, 423.782.
- ⁴⁸ CAL. WELF. & INST. CODE § 14133.23(b) & (c).
- ⁴⁹ *See* Randolph T. Boyle, Nat'l Health Law Prog., *Medicare Part D and Dual Eligibles: A Guide for California Advocates* (2008), https://healthlaw.org/wp-content/uploads/2018/09/medicare_ptD_dualsadvocates_guide.pdf.