Medi-Cal Rx Monthly Bulletin

February 1, 2023

The monthly bulletin consists of alerts and notices posted to the Bulletins & News page on the Medi-Cal Rx Web Portal. Sign up for the Medi-Cal Rx Subscription Service to be notified when new information is posted.

1. Changes to the Contract Drugs List (CDL)

The below changes have been made to the Contract Drugs List posted to the Medi-Cal Rx Web Portal, effective February 1, 2023.

Drug Name	Description	Effective Date
Aminocaproic Acid	Added to CDL.	February 1, 2023
Baclofen	Additional formulation (oral suspension) added with restriction.	February 1, 2023
Busulfan	Updated Code I restriction.	February 1, 2023
Caffeine Citrate	Added to CDL with restriction.	February 1, 2023
Carmustine	Additional strengths (50 mg/vial, 300 mg/vial) added.	February 1, 2023
Chlorambucil	Updated Code I restriction.	February 1, 2023
Cyclophosphamide	Additional strength (200 mg/vial) added.	February 1, 2023
Mycophenolate Mofetil	Additional formulation (tablet) added.	February 1, 2023
Olutasidenib	Added to CDL with restriction.	February 1, 2023
Pexidartinib	Additional strength (125 mg) added with restriction.	February 1, 2023
Rivaroxaban	Additional formulation (suspension) added with restriction.	February 1, 2023
Sotalol HCL	Additional formulations (oral solution) added with restriction.	February 1, 2023
Thioguanine	Updated Code I restriction.	February 1, 2023
Valganciclovir	Additional formulations (oral solution) added and Code I restriction removed.	February 1, 2023
Warfarin Sodium	Additional strength (6 mg) added.	February 1, 2023
DATA 2000 Waiver	Policy updated to remove requirement from medications used to treat opioid use disorder.	February 1, 2023

2. Updates to the Provider Manual

The updates/additions below have been made to the *Medi-Cal Rx Provider Manual* version 4.0.

Updates

Section	Update Description	Effective Date
Section 12.5 – Billing Requirements and Limitations	• Removed the sentence, "Rounding quantities on claims for eternal nutrition products is not permitted." • Created a formula. • Added language about current policy.	February 1, 2023
Section 17.0 – COVID-19 Vaccines, OTC Antigen Test Kits, and Therapeutics: Coverage and Reimbursements	• Updated NDCs.	February 1, 2023
Appendix D – NCPDP Reject Codes	• Added Reject Code 816.	February 1, 2023
Appendix G – OHC Carrier Information	• Updated contact and payer information for Other Health Coverage carriers pertaining to drug-related coverage.	January 27, 2023
Appendix H – List of Physician Administered Drugs (PADs) with Reject Code 816	• Added to the list.	January 13, 2023

3. 90-Day Countdown – Phase III: Retirement of the Transition Policy for Beneficiaries 22 Years of Age and Older

What is Happening?

Starting March 24, 2023, as part of Phase III of reinstatement, Medi-Cal Rx will initiate a series of transition policy lifts for beneficiaries 22 years of age and older. A transition lift is the retirement or phasing out of the Transition Policy for identified Standard Therapeutic Classes (STCs). The specific STCs impacted during each lift will be communicated 30 days prior to retirement.

- **Beneficiaries 21 years of age and younger are exempt from the Phase III Transition Policy retirement.**
- **Enteral nutrition products for beneficiaries of all ages are also exempt from Phase III Transition Policy retirement.**

What Pharmacy Providers and Prescribers Need to Know

Starting March 24, 2023, prior authorization (PA) requirements will apply to select drugs impacted by the first transition lift. For beneficiaries 22 years of age and older who were receiving a medication through the Transition Policy (due to historical paid claims data or grandfathered PAs that are expiring), the prescription will now be subject to Medi-Cal Rx PA requirements if the medication is identified for transition lift.

What Pharmacy Providers and Prescribers Need to Do

- For more information, visit the Medi-Cal Rx Education & Outreach page on the Medi-Cal Rx Web Portal and select **Medi-Cal Rx Reinstatement**.
- Review the *Medi-Cal Rx Reinstatement of Prior Authorizations and Retirement of the Transition Policy: Phases II, III, and IV* slide deck.

- Refer to the Medi-Cal Rx Bulletins & News and Medi-Cal Rx Forms & Information pages of the Medi-Cal Rx Web Portal for guidance to successfully submit PAs.

4. How to Prepare for Retirement of the Transition Policy

What Pharmacy Providers and Prescribers Need to Know

On December 20, 2022, Medi-Cal Rx announced the *90-Day Countdown – Phase III: Retirement of the Transition Policy for Beneficiaries 22 Years of Age and Older*. In anticipation of the retirement of the Transition Policy, pharmacy providers and prescribers are encouraged to plan ahead!

Consider transitioning beneficiaries 22 years of age and older to covered alternatives that may not require a prior authorization (PA); if a covered alternative is not appropriate, submit a PA to Medi-Cal Rx beginning February 24, 2023.

- **Early submission of PA requests for beneficiaries 21 years of age and younger will not be accepted at this time.**
- **Early submission of PAs for enteral nutrition products will not be accepted at this time.**

What Pharmacy Providers and Prescribers Need to Do

1. Consider covered therapies that may not require a PA, if clinically appropriate.
   a. Review the following:
      - Medi-Cal Rx Contract Drugs Lists & Covered Products Lists
      - Medi-Cal Rx Approved National Drug Code (NDC) List
      - Prescribers: Refer to your ePrescribing application.
2. If a change in therapy is not appropriate, plan ahead! Submit PA requests beginning February 24, 2023.
   a. Early PA requests can be submitted via the Medi-Cal Rx PA Submission Methods:
      - CoverMyMeds®
      - Medi-Cal Rx Secured Provider Portal
      - NCPDP P4 Transaction

- Fax
- U.S. Mail

b. Review PA resources by selecting the **Prior Authorization (PA)** tab on the Forms & Information page.

3. Review the *Medi-Cal Rx Provider Manual*.

Resources

For more information about Medi-Cal Rx Reinstatement, visit the Medi-Cal Rx Education & Outreach page on the Medi-Cal Rx Web Portal and select **Medi-Cal Rx Reinstatement**.

For more information regarding the Pharmacy Transition Policy, visit the Medi-Cal Rx Education & Outreach page on the Medi-Cal Rx Web Portal and select **Medi-Cal Rx Pharmacy Transition Policy**.

5. 30-Day Countdown – Reinstatement of Prior Authorization Requirements for 39 Drug Classes

What is Happening?

On January 20, 2023, prior authorization (PA) requirements will be reinstated for 39 additional drug classes for new start medications for beneficiaries 22 years of age and older. "New starts" are defined as new therapies or medications not previously prescribed to the beneficiary during the 15-month lookback period. Historical claims data and PAs will be used to review for grandfathering.

- New start prescriptions for beneficiaries 21 years of age and younger within these 39 drug classes will not be subject to PA reinstatement.

Note: For prescriptions requiring a PA that either do not have an approved PA or a historical claim on file, PA requirements will remain in place.

Do not submit PA requests prior to January 20, 2023, for a medication in one of the following 39 Standard Therapeutic Classes (STCs) that will require a PA. PA requests submitted prior to January 20, 2023, will be returned with a message that no PA is required.

Phase II, Wave I Drug Classes		
All Other Dermatologicals	Corticotropins	Other Antibiotics
Anabolics	Emollients Protectives	Other Hormones
Androgens	Erythromycins	Penicillins
Anesthetic Local, Topical	Estrogens	Progesterone
Antiarthritics	Fat Soluble Vitamins	Streptomycins
Antifungals	Folic Acid Preparations	Sulfonamides
Antimalarials	General Antibacterials and Antiseptics	Systemic Contraceptives
Antiparasitics	Glucocorticoids	TB Preparations
Antiparkinson	Iodine Therapy	Tetracyclines
Anti-Ulcer Preps/Gastrointestinal Preps	Multivitamins	Thyroid Preps
Antivirals	Muscle Relaxants	Topical Nasal and Otic Preparations
Biologicals	Non-Opioid Analgesics	Urinary Antibacterials
Cephalosporins	Ophthalmic Preparations	Vitamin K

Note: For drug classes either not listed above or not reinstated during Phase I, Wave III, the PA requirements will remain temporarily suspended. Medi-Cal Rx will continue to utilize PA and claims data to allow for grandfathering of previously approved PAs after July 2, 2022.

PAs that are submitted prior to the transition policy being phased out for beneficiaries currently on a drug therapy and covered under the transition policy **will not** be accepted at this time.

- **When prescribing a drug in one of these drug classes for a patient who has not been on the drug over the last 15 months, check the Covered Products List.**
- **For beneficiaries already on a drug therapy for qualified or "grandfathered" drugs, the transition policy will continue to allow access to care.**

Next Steps

- For more information, visit the Medi-Cal Rx Education & Outreach page on the Medi-Cal Rx Web Portal and select **Reinstatement** from the left-hand menu.
- Review the *Medi-Cal Rx Reinstatement of Prior Authorizations and Retirement of the Transition Policy: Phases II, III, and IV* presentation.
- Refer to the Medi-Cal Rx Bulletins & News and Medi-Cal Rx Forms & Information pages of the Medi-Cal Rx Web Portal for guidance to successfully submit PAs.
- Assess business processes and workflows to account for the reinstatement of PA edits for the drug classes.

6. Mpox Vaccine as a Family PACT Pharmacy Benefit

Effective for dates of service on or after August 17, 2022, the Department of Health Care Services (DHCS) will reimburse the administration of Mpox Vaccine as a pharmacy benefit under the Family Planning, Access, Care and Treatment (Family PACT) Program through the end of the federal Mpox public health emergency (PHE) when administered in accordance with the U.S. Food and Drug Administration (FDA) approval or authorization as well as recommendations from the Centers for Disease Control and Prevention (CDC).

Mpox vaccine administration is a Family PACT benefit only when furnished in connection to a family planning visit, as a family planning-related service. Mpox vaccine administration is not a stand-alone benefit.

On May 18, 2022, the United States confirmed its first case of Mpox, and the U.S. Federal Government declared Mpox a national PHE on August 4, 2022. The CDC recommends vaccination for people who have been exposed to Mpox and people who may be more likely to get Mpox.

JYNNEOS™ (also known as Imvamune® or Imvanex®) is a vaccine that may be used for the prevention of the Mpox virus infection, although no data is available yet on its effectiveness in treating the current outbreak. JYNNEOS is licensed (or approved) by the FDA for subcutaneous injection for the prevention of the Mpox virus infection. In the context of the current national PHE, the standard regimen was authorized for people up to 18 years of age under an Emergency Use Authorization (EUA). An alternative regimen involving intradermal (ID) administration was also authorized for people 18 years of age and older to increase available JYNNEOS doses by up to five-fold. JYNNEOS is the primary vaccine being used during this Mpox outbreak.

Due to a limited supply, the California Department of Public Health (CDPH) is currently prioritizing the JYNNEOS Vaccine for individuals who are at high risk for the Mpox infection. For the most recent dose prioritization information or availability of additional doses and expansion of vaccination to a larger group, see the guidance from the CDPH on its Mpox web page. Additional guidance on Mpox can be found on both the CDPH and CDC websites.

Important Billing Instructions

- Mpox Vaccine is a Family PACT benefit when administered in accordance with FDA approval/authorization and CDC recommendations, and when furnished in connection to a family planning visit, as a family planning-related service.
- Since the vaccine is supplied by the U.S. Federal Government free to pharmacy providers, pharmacy providers will not be reimbursed the ingredient cost or professional dispensing fee.
- A prior authorization (PA) is not required.
- DHCS will only reimburse the professional services associated with an immunization when a pharmacy provider submits a claim for reimbursement of the vaccine administration.

- DHCS will reimburse for the Mpox Vaccine administration at 100 percent of the corresponding Medicare rate for the same or similar service, effective August 17, 2022, through the end of the declared PHE.
  - To receive the professional services immunization administration fee, the pharmacy provider must identify on the claim that the pharmacy is administering the vaccine.
  - By populating the incentive fee, Incentive Amount Submitted (438-E3), field with a dollar amount and populating the following fields as outlined below:
    - Reason for Service Code (NCPDP field 439-E4): PH = Preventive Health Care
    - Professional Service Code (NCPDP field 440-E5): MA = Medication Administration
    - Result of Service Code (NCPDP field 441-E6): 3N = Medication Administration
- JYNNEOS is administered as 2 doses 28 days apart (a minimum of 24 days apart per CDC guidance). Claims must be submitted for each dose administered as described below:
  - NCPDP compliant claims:
    - First dose: Submission Clarification Code (SCC) = "2"
    - Second dose: Submission Clarification Code (SCC) = "6"
  - Non-NCPDP compliant paper forms:
    - First Dose: Fill Number value of "0"
    - Second Dose: Fill Number value of "1"
- DHCS will reimburse all eligible retroactive claims for dates of service on or after August 17, 2022.

Pharmacy providers must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their medical record system within 24 hours and to the California Immunization Registry (CAIR2) within 72 hours.

Pharmacy providers may bill for the dispensing of JYNNEOS Vaccine NDC using NCPDP D.0 claims, web, batch, and paper claims according to the table below:

NDC	Label Name	Generic Name	PA Required (Y or N)	Claim Quantity	Max Quantity
50632000101	JYNNEOS 0.5 ml vial	Smallpox and Mpox vaccine	N	0.5 ml (subcutaneous) **OR** 0.1 ml (intradermal)	0.5 ml

Product Availability

- JYNNEOS is currently available in the United States via the Strategic National Stockpile (SNS).
- JYNNEOS is currently not available to pharmacy providers but is provided to states through CDC and SNS.
- At this time, the U.S. Federal Government has allocated a limited number of JYNNEOS Vaccine doses to Californians. CDPH is working with local health departments to make these doses available to protect against Mpox.
- Pharmacy providers may consult with their local health services/offices to identify available locations in the area that may have vaccines to administer.

For population of claim form fields other than those identified in this guidance, review the *Medi-Cal Rx Provider Manual*.

Any concerns regarding delay in reimbursement should not cause pharmacy providers to decline administering the vaccine to patients.

7. Bebtelovimab No Longer Authorized to Treat COVID-19

Effective for dates of service on or after November 30, 2022, the Department of Health Care Services (DHCS) will no longer reimburse Bebtelovimab as a pharmacy benefit. Bebtelovimab is a monoclonal antibody for the treatment of coronavirus disease 2019 (COVID-19). On November 30, 2022, the U.S. Food and Drug Administration (FDA) announced that Bebtelovimab is not currently authorized for emergency use in the United States (U.S.)

because it is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1, according to data included in the Health Care Provider Fact Sheet.

Nowcast data from the Centers for Disease Control and Prevention (CDC) published in December 2022 estimates that the combined proportion of COVID-19 cases caused by the Omicron BQ.1 and BQ.1.1 subvariants to be above 57 percent nationally, and already above 50 percent in all individual regions but one, and data shows a sustained trend of increasing prevalence across all regions. Given that a COVID-19 infection is likely to be caused by a non-susceptible SARS-CoV-2 variant, and consistent with the terms and conditions of the Letter of Authorization, **Bebtelovimab is not currently authorized for emergency use in any U.S. region at this time**.

Consequently, providers must not submit claims for Bebtelovimab for dates of service on or after November 30, 2022, as they will be denied.

- Refer to Variant Proportions in the U.S. on the CDC website for general information.
- Refer to Tracking Variants on the California Department of Public Health (CDPH) website for California-specific information.

Providers should note that there are several other therapies that are still authorized or approved to treat patients with mild-to-moderate COVID-19 who are at high risk for progression to severe disease, including hospitalization or death. Medi-Cal covers these therapies which are listed below:

- Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use)
- Veklury (Remdesivir)
- Lagevrio (molnupiravir)
- Evusheld (tixagevimab co-packaged with cilgavimab)

For more information on services covered by Medi-Cal Rx, providers should refer to the Medi-Cal Rx Web Portal.

8. Medical Supplies: Updates to the *List of Covered Disposable Insulin Delivery Devices*

The *List of Covered Disposable Insulin Delivery Devices (DIDD)* has been updated on the Medi-Cal Rx Web Portal. The effective date of the changes is February 1, 2023.

This update lowers the Maximum Acquisition Cost (MAC) per each pod for Mannkind Corporation's V-Go® products on and after February 1, 2023.

Product Label Name	Medi-Cal 11-digit billing number (NDC)	MAC/MAPC Price per each	Effective Date of Change
V-Go 20 Disposable Insulin Delivery (20 insulin units), package size of 30 pods	08560940003	$17.2300	February 1, 2023
V-Go 30 Disposable Insulin Delivery (30 insulin units), package size of 30 pods	08560940002	$17.2300	February 1, 2023
V-Go 40 Disposable Insulin Delivery (40 insulin units), package size of 30 pods	08560940001	$17.2300	February 1, 2023

Refer to the *List* for specific NDCs to bill for refills and additional coverage criteria and restrictions. Providers should bill for a minimum of 30 pods, the amount per package, with a maximum of a 90 days supply. **The MAC/Maximum Allowable Product Cost (MAPC) is per pod** and packages cannot be broken.

Kits should be billed as "1 Each" regardless of the quantity of pods contained within the kit. The **MAC/MAPC is per kit** and kits cannot be broken.

Product addition or inclusion on the *List* does not guarantee supply nor individual specific coverage.

Products deleted from the *List* will no longer be reimbursable, even with an approved prior authorization (PA), on or after the effective date of deletion. The MAC for these products is no longer guaranteed.

9. Reminder: Drugs Supplied to Nursing Facilities

Summary

This alert concerns submitting claims to Medi-Cal Rx for drugs dispensed to beneficiaries who reside in nursing facilities (NFs). NFs include Skilled Nursing Facilities, inpatient Intermediate Care Facilities (ICFs), and Long-Term Care (LTC) facilities. Medi-Cal-enrolled pharmacy providers submitting pharmacy claims for legend drugs or over-the-counter (OTC) insulin for beneficiaries residing in NFs should use pharmacy claim processing information to submit those claims to Medi-Cal Rx. Non-legend OTC drugs (excluding insulin) are included in the NF daily rates and should not be billed separately to Medi-Cal Rx. Claims submitted for non-legend OTC drugs, except insulin, will not be reimbursed.

What Pharmacy Providers Need to Know

- OTC products (except insulin and products listed in *Section 8.2.1* of the *Medi-Cal Rx Provider Manual*) are an excluded pharmacy benefit of Medi-Cal for beneficiaries residing in NFs. As a result, these claims will not be reimbursed if billed to Medi-Cal Rx.
- If an enrolled Medi-Cal pharmacy provider receives prescriptions for a legend drug or insulin for beneficiaries residing in NFs, the pharmacy claim should be submitted to Medi-Cal Rx.
- All claims for Medi-Cal beneficiaries should be billed to Medi-Cal Rx using pharmacy claims processing information.
- Claims submitted to Medi-Cal Rx are subject to coverage restrictions of Medi-Cal. As a result, prior authorizations (PAs) and Prospective Drug Use Review (ProDUR) requirements will apply. Pharmacy providers should refer to the *Medi-Cal Rx Provider Manual* and Contract Drugs Lists for additional information.
- For claim submission, a Patient Residence value must be entered to identify a beneficiary as LTC. Pharmacy providers must use one of the following Patient Residence values (NCPDP Field ID: 384-4X):
  - 3 – Nursing Facility
  - 9 – Intermediate Care Facility/Individuals with Intellectual Disabilities.

  Note: Patient Location (NCPDP Field ID: 307-C7) is no longer utilized to identify LTC.

Resources

For further information regarding claim submission to Medi-Cal Rx, refer to the *Medi-Cal Rx Provider Manual* and additional resources below:

- *Medi-Cal Rx Payer Specification Sheet*
- *Medi-Cal Rx Billing Tips*

10. Now Active – Cal MediConnect Transition to Medicare Medi-Cal Plans

What is Happening?

Effective January 1, 2023, beneficiaries enrolled in Cal MediConnect have been transitioned to Medicare Medi-Cal Plans (MMPs or Medi-Medi Plans). Medi-Medi Plans are offered in the following seven counties: Los Angeles, Orange, Riverside, San Bernardino, San Diego, San Mateo, and Santa Clara.

Medi-Medi Plans provide Medicare Part A, B, and D services, specialized care coordination, and wrap-around Medi-Cal services. Medi-Medi Plans coordinate benefits and services across both Medicare and Medi-Cal including Part D drug coverage. **Medi-Cal Rx** will resume the role as the Medi-Cal pharmacy benefits administrator for non-Medicare prescription drug coverage.

What Providers Need to Know

For impacted beneficiaries, drug coverage will continue to be processed through coordination of benefits with Medicare Part B and Part D prior to coverage through Medi-Cal. Pharmacy benefits for Medi-Cal are processed through Medi-Cal Rx as the payor of last resort for drugs/products that are **specifically** excluded from Medicare Part D.

What Providers Need to Do

- Refer to the Medi-Cal Rx Covered Products Lists.
- Review coordination of benefits billing information and claim processing information for other healthcare coverage in the *Medi-Cal Rx Provider Manual*.

- View the *Medi-Cal Rx 101: Cal MediConnect Transition* webinar.
- Review the *Medi-Cal Rx Billing Tips* for claim submission information.
- For more information regarding the transition and Medi-Medi Plans, refer to the Department of Health Care Services (DHCS) Integrated Care for Dual Eligible Beneficiaries page on the DHCS website.

11. Medi-Cal Rx IVR Enhancement to Enable Additional Self-Service Option!

Medi-Cal Rx is pleased to announce that an enhancement has been made to its Customer Service Interactive Voice Response (IVR) system (phone number is 1-800-977-2273) by providing self-service for prior authorization (PA) status.

For both pharmacy calls (option 2) and prescriber calls (option 3), the IVR now has an option to select if you are calling about "PA Status." Select "PA Status" from the menu if you are calling to find out the status of a PA that you have already submitted through one of the proper channels described in *Five Ways to Submit a Prior Authorization (PA)*.

Note: PAs have a 24-hour turn-around time and the status of all PAs is also available utilizing a pharmacy provider's National Provider Identifier (NPI) in the Medi-Cal Rx Provider Portal once logged in.

When you call the Medi-Cal Rx Customer Service Center (CSC) and select the option for PA Status, the system prompts you to enter the beneficiary's date of birth and first eight digits of the cardholder identification number. If the beneficiary is found, the system does a 7-day look back for open or decisioned PAs for the given beneficiary. The system provides status on up to three PAs found that have one of the following statuses:

- Approved
- Denied
- In Process/Under Review

If no PAs, or more than three PAs are found, the system automatically routes to a Customer Service Representative (CSR).

If up to three PAs are found that meet the above specifications, the system reads the status of each PA found.

Once your first inquiry is completed, the system will prompt you to complete one of the following actions:

- Hang up.
- Press 1 to repeat the information.
- Press 2 to return to the IVR menu.
- Press 3 to route to a CSR for additional inquiries.

12. Drug Use Review (DUR) Alert System Issue: Additive Toxicity (AT)

Medi-Cal Rx has identified a system issue with **NCPDP Reject Code 88 – DUR (Drug Use Review) for Reason for Service Code Additive Toxicity (AT)**. The result is that the system is not stopping the claims adjudication process for the pharmacist to evaluate the risk against medical necessity and may result in a paid claim without notifying the dispensing pharmacist of the potential AT. Currently, Medi-Cal Rx does not have an estimated timeline for resolution of this system issue. Once the issue is resolved, an alert will be posted to inform pharmacy providers.

What Pharmacy Providers Need to Do

- Medi-Cal Rx is asking pharmacy providers to be mindful of potential AT concerns prior to dispensing medications to beneficiaries.
- AT alerts are triggered when a target drug exceeds the threshold of four or more active prescriptions within the following therapeutic categories: opioid pain or cough medications, benzodiazepines, skeletal muscle relaxants, other sleep drugs and tranquilizers (non-benzodiazepine), antipsychotic medications, and other selected psychotropic medications with central nervous system (CNS) depressant properties. Review the *Drug Use Review (DUR) Alert: Additive Toxicity* for more information.

Be alert! Check beneficiary dispensing history at point of sale (POS) to identify potential DUR for AT, and then address any concerns prior to dispensing medications to the beneficiary.

Contact Information

You can call the Medi-Cal Rx Customer Service Center (CSC) at 1-800-977-2273, which is available 24 hours a day, 7 days a week, 365 days per year.

For other questions, email Medi-Cal Rx Education & Outreach at MediCalRxEducationOutreach@magellanhealth.com.