

## Medi-Cal Rx Monthly Bulletin

#### September 1, 2023

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

- Changes to the Medi-Cal Rx Contract Drugs List
- 2. Updates to the Medi-Cal Rx Provider Manual
- 3. <u>90-Day Countdown: Reinstatement of Prior Authorization Requirements for Enteral Nutrition Claims for Members 22 Years of Age and Older</u>
- 4. Reminder: Medi-Cal Rx Billing Policy for Physician Administered Drugs
- 5. Recommencement of Pharmacy Retroactive Claim Adjustments in August 2023
- 6. Remittance Advice (RA): Amount Billed/Total Claim Charge Amount Content Update
- 7. <u>Prior Authorization Submission Using the Electronic Health Record to Initiate an Electronic</u>
  Prior Authorization Request via CoverMyMeds®

### 1. Changes to the Medi-Cal Rx Contract Drugs List

The below changes have been made to the <u>Medi-Cal Rx Contract Drugs List</u> posted to the Medi-Cal Rx Web Portal, effective September 1, 2023.

| Drug Name              | Description                                  | Effective Date    |
|------------------------|--|-------------------|
| Ciprofloxacin HCL and  | Labeler restriction (00065) removed from     | September 1, 2023 |
| Dexamethasone          | otic suspension.                             |                   |
| Cyclophosphamide       | Additional formulation (vials) added to CDL. | September 1, 2023 |
| Emtricitabine and      | Labeler restriction removed.                 | September 1, 2023 |
| Tenofovir Disoproxil   |  | ·                 |
| Fumarate               |  |                   |
| Glofitamab-gxbm        | Added to CDL with labeler restriction.       | September 1, 2023 |
| Glucagon               | Labeler restriction removed from nasal       | September 1, 2023 |
|                        | spray.                                       |                   |
| Niraparib              | Additional formulation (tablets) added to    | September 1, 2023 |
|                        | CDL with labeler code restriction.           |                   |
| Ozanimod Hydrochloride | Additional strength (0.23 mg x 4,            | September 1, 2023 |
|                        | 0.46 mg x 3, 0.92 mg x 21 starter kit)       |                   |
|                        | added to CDL with age, diagnosis, and        |                   |
|                        | labeler restriction.                         |                   |
| Talazoparib            | Additional strengths (0.1 mg and             | September 1, 2023 |
|                        | 0.35 mg) added to CDL with labeler           |                   |
|                        | restriction.                                 |                   |

### 2. Updates to the Medi-Cal Rx Provider Manual

The updates/additions below have been made to the <u>Medi-Cal Rx Provider Manual</u> version 10.0.

### **Updates**

| Section   | Update Description   | Effective Date    |
|---|--|-------------------|
| Section 3.3.3.1 – Paper<br>Remittance Advice<br>Example | <ul> <li>Updated table description verbiage for "Amount Billed."</li> <li>Added Figure 3.3.3.1-3 to depict the Amount Billed field populated with the Gross Amount.</li> </ul>           | September 1, 2023 |
| Section 12.0 – Enteral<br>Nutrition Products            | <ul> <li>Updated language pertaining to<br/>eligibility and prior authorization<br/>requirements.</li> <li>Overall section revised and rearranged.</li> </ul>                            | September 1, 2023 |
| Section 12.1 – Noncovered<br>Nutrition Products         | Removed language to refer to the CDL regarding dietary supplements.  | September 1, 2023 |
| Section 12.2 – Covered<br>Products                      | <ul><li>Updated section title.</li><li>Updated language to reflect categories of covered products.</li></ul>   | September 1, 2023 |
| Section 12.3 – Prescription<br>Requirements             | <ul><li>Updated section number and title.</li><li>Language refined to one section.</li></ul>   | September 1, 2023 |
| Section 12.4 –<br>Documentation<br>Requirements         | Language refined.  | September 1, 2023 |
| Section 12.5 –<br>Authorization                         | <ul> <li>Updated section title.</li> <li>Refined language regarding requirements for coverage.</li> <li>Removed language regarding initial prior authorization documentation.</li> </ul> | September 1, 2023 |

| Section  | Update Description   | Effective Date    |
|--|--|-------------------|
| Section 12.5.1 – Standard<br>Products                                  | <ul><li>Updated section title.</li><li>Removed language regarding product specific criteria.</li></ul>   | September 1, 2023 |
| Section 12.5.2 – Specialized<br>Products                               | <ul> <li>Removed language regarding<br/>documentation requirements for<br/>diabetic, renal, and hepatic products.</li> <li>Refined language for modular products.</li> </ul>   | September 1, 2023 |
| Section 12.5.3 – Elemental<br>and Semi-Elemental<br>Products Criteria  | Refined language regarding documentation requirements.   | September 1, 2023 |
| Section 12.5.4 – Metabolic<br>Products Criteria                        | <ul> <li>Updated language regarding member criteria diagnoses.</li> <li>Added sentence, "A contracted product has been tried and considered and contracted alternatives are otherwise considered to be clinically inappropriate/inadequate to meet the medical needs of the member."</li> <li>Updated ICD-10-CM Code E71.1.</li> <li>Removed language regarding authorizations for members 22 years of age and older for ICD-10-CM diagnosis codes listed in the table.</li> </ul> | September 1, 2023 |
| Section 12.5.5 – Specialty<br>Infant Products                          | <ul><li>Updated section title.</li><li>Removed specifications for product types.</li></ul>   | September 1, 2023 |
| Section 12.6 – Enteral<br>Nutrition Dispensing<br>Quantity Limitations | <ul><li>Updated section title.</li><li>Added language regarding restrictions<br/>based on quantity limitations.</li></ul>  | September 1, 2023 |

| Section   | Update Description   | Effective Date    |
|---|--|-------------------|
| Section 12.7 – Billing<br>Requirements  | <ul> <li>Updated section number.</li> <li>Updated language regarding coverage of products with an approved prior authorization.</li> </ul>   | September 1, 2023 |
| Section 12.8 – Product Interchangeability ( <b>NEW!</b> )   | Added information about the enteral<br>nutrition coverage policy, substitution,<br>and prescription requirements.  | September 1, 2023 |
| Section 15.7.1 – Emergency<br>Dispensing of 14-Day<br>Supply  | Added language specifying the exemption of prior authorizations for Pharmacy Emergency Dispensing.   | September 1, 2023 |
| Section 15.7.3 – Protocol<br>for Overriding Utilization<br>Management (UM) During<br>State of Emergency | Updated section title.   | September 1, 2023 |
| Section 17.0 – COVID-19 Vaccines, OTC Antigen Test Kits, and Therapeutics: Coverage and Reimbursements  | <ul> <li>Removed language regarding specific vaccines and booster doses for multiple NDCs (Pfizer, Comirnaty, Moderna, Janssen, Pfizer-BioNTech).</li> <li>Removed tables.</li> <li>Added additional guidelines for Novavax.</li> <li>Removed language regarding the use of Janssen per Emergency Use Authorization.</li> <li>Removed language pertaining to pediatric vaccine coverage.</li> <li>Overall section revised and renumbered.</li> </ul> | September 1, 2023 |

| Section   | Update Description   | Effective Date    |
|---|--|-------------------|
| Section 17.1 – COVID-19<br>Vaccine Administration<br>Reimbursement                                  | <ul> <li>Updated section number.</li> <li>Removed language regarding<br/>reimbursement for dates of service prior<br/>to March 15, 2021.</li> </ul>                      | September 1, 2023 |
| Section 17.2 – COVID-19 Supplemental Incentive Fee Reimbursement for In-Home Vaccine Administration | <ul> <li>Updated section number.</li> <li>Removed language regarding<br/>reimbursement for dates of service<br/>between June 8, 2021 and<br/>August 24, 2021.</li> </ul> | September 1, 2023 |
| Section 17.3 – Over-the-<br>Counter (OTC) COVID-19<br>Antigen Test Kits                             | Updated section number.  | September 1, 2023 |
| Section 17.3.1 – OTC<br>COVID-19 Antigen Test<br>Kits Reimbursement                                 | Updated section number.  | September 1, 2023 |
| Section 17.4 – COVID-19<br>Oral Antiviral Product<br>Coverage                                       | Updated section number.  | September 1, 2023 |
| Section 17.4.1 – Paxlovid   | <ul> <li>Updated section number.</li> <li>Removed sentence, "Billable NDCs and maximum quantities are outlined in Table 17.5.2-1 below."</li> </ul>                      | September 1, 2023 |
| Section 17.4.2 – Remdesivir<br>(Veklury)  | <ul> <li>Updated section number.</li> <li>Removed tables and language<br/>regarding age limitations for antiviral<br/>products.</li> </ul>                               | September 1, 2023 |
| Section 17.4.3 – COVID-19<br>Oral Antiviral Products<br>Reimbursement                               | Updated section number.  | September 1, 2023 |

| Section                         | Update Description  | Effective Date    |
|---------------------------------|---|-------------------|
| Appendix D – NCPDP Reject Codes | <ul> <li>Removed previous comment for Reject Code 79, "75 percent or more days supply of previous claim has not been utilized for non-controlled products   90 percent or more days supply of previous has not been utilized for controlled products" and replaced with, "See DUR-88 for Refill Too Soon."</li> <li>Added comment for Reject Code 88, "Note: DUR ER – Overuse Precaution will be triggered if at least 75 percent of the days supply has not been used   For opioid claims, the trigger occurs if at least 90 percent of days supply has not been used."</li> </ul> | September 1, 2023 |

# 90-Day Countdown: Reinstatement of Prior Authorization Requirements for Enteral Nutrition Claims for Members 22 Years of Age and Older

#### **Background**

The purpose of this alert is to notify pharmacy providers and prescribers that beginning November 9, 2023, prior authorization (PA) requirements will be reinstated for all enteral nutrition orders due to retirement of the Transition Policy for members 22 years of age and older. Submission of a new PA will be required effective November 9, 2023.

**Note:** As a reminder, on September 22, 2023, PA requirements for members 22 years of age and older will be reinstated for **new start** enteral nutrition orders.

#### What Pharmacy Providers and Prescribers Need to Know

Beginning November 9, 2023, the Transition Policy will be retired for all enteral nutrition products for members 22 years of age and older. The retirement of the Transition Policy will reinstate PA requirements for all enteral nutrition products for members 22 years of age and older. As a result, claims that previously paid under the Transition Policy will now require a PA.

Requests for **new start** enteral nutrition products will be subject to PA requirements for members 22 years of age and older beginning September 22, 2023. Refer to the <u>90-Day</u> Countdown: Reinstatement of Prior Authorization Requirements for Enteral Nutrition Products for <u>Members 22 Years of Age and Older</u> alert for more information. Additionally, providers can begin PA submissions for enteral nutrition products on and after September 22, 2023.



Reinstatement of PA requirements for enteral nutrition products for members 21 years of age and younger will not occur prior to 2024.

#### What Pharmacy Providers and Prescribers Need to Do

Pharmacy providers and prescribers are encouraged to plan ahead. PAs can be submitted in advance of the retirement of the Transition Policy for enteral nutrition products for members 22 years of age and older, beginning September 22, 2023.

#### Resources

- For more information about Medi-Cal Rx Reinstatement, visit the <u>Medi-Cal Rx Education & Outreach</u> page on the <u>Medi-Cal Rx Web Portal</u> and select **Medi-Cal Rx Reinstatement**.
- Review the <u>90-Day Countdown: Reinstatement of Prior Authorization Requirements for Enteral Nutrition Products for Members 22 Years of Age and Older</u> alert.
- Review the <u>Updates to the List of Contracted Enteral Nutrition Products</u>, <u>Effective July 1, 2023</u>
   <u>and October 1, 2023</u> alert for a list of contracted enteral nutrition products.
- Review the <u>Medi-Cal Rx Phased Reinstatement Frequently Asked Questions (FAQs)</u>.
- Refer to the *Enteral Nutrition Products* section in the <u>Medi-Cal Rx Provider Manual</u> for additional information and criteria guidelines.
- Refer to the <u>Medi-Cal Rx Bulletins & News</u> and <u>Medi-Cal Rx Forms & Information</u> pages of the <u>Medi-Cal Rx Web Portal</u> for guidance to successfully submit PAs.

# 4. Reminder: Medi-Cal Rx Billing Policy for Physician Administered Drugs

#### **Background**

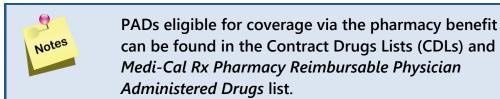
The Department of Health Care Services (DHCS) continues to receive reports of health care providers billing physician administered drugs (PADs) as pharmacy benefits instead of medical benefits, leading to denied access to PAD therapy for Medi-Cal beneficiaries. The purpose of this alert is to remind providers that PADs should be billed as medical benefits.

#### What Pharmacy Providers and Prescribers Need to Know

PADs are defined as drugs that are administered or dispensed by a health care professional outside of a pharmacy setting, such as in physicians' offices, clinics, or hospital outpatient facilities and are non-self-administered by a patient or caregiver. As such, PADs dispensed or administered outside of a pharmacy setting are considered a medical benefit.

Providers should be aware that PADs which were previously covered by a managed care plan's (MCP) pharmacy network provider prior to January 1, 2022, are not automatically covered by Medi-Cal Rx. It is the responsibility of providers to verify the current coverage policy and to determine the appropriate entity to which the claim must be billed.

MCPs or their contracted agents should not reassign member claims across the board, either in full or in part, to be processed through Medi-Cal Rx. Allowable exceptions to this rule are described below in the section titled *PAD Pharmacy Claim Submission*.



#### **PAD Medical Claim Submission**

- For a fee-for-service beneficiary, health care providers should submit the medical claim to the fee-for-service fiscal intermediary.
- For managed care members, health care providers should submit the medical claim to the applicable MCPs.

#### **PAD Pharmacy Claim Submission**

PADs eligible for coverage by Medi-Cal Rx via a pharmacy claim are listed on either the <u>CDLs</u> or the <u>Medi-Cal Rx Pharmacy Reimbursable Physician Administered Drugs</u> list. PADs not identified on the CDLs or <u>Medi-Cal Rx Pharmacy Reimbursable Physician Administered Drugs</u> list are considered a medical benefit and should be billed as a medical claim.

An exception for pharmacy benefit approval may be considered via a prior authorization (PA) request submission. Providers must note that the first step of the PA assessment is to determine whether it is justifiable for a PAD to be billed as a pharmacy claim. Only after that is established will the PAD PA be assessed for medical necessity. If a PA for PADs is submitted to Medi-Cal Rx, the following criteria must be met:

- Providers must include rationale for why the PAD must be billed as a pharmacy claim to Medi-Cal Rx and cannot be billed as a medical claim to the medical benefit for coverage;
   AND
- Providers must include clinical rationale to determine medical necessity for PAD therapy.

If the above criteria are met and a PA is approved by Medi-Cal Rx, a pharmacy provider may order, fill, and submit the claim for a PAD and have it sent to an administering provider to administer the drug appropriately.

Certain situations that may warrant an exception, requiring a claim and PA submission for the PAD to Medi-Cal Rx, may include the following:

- The medical provider is unable to access a specific PAD, and they may obtain it from a local or mail-order pharmacy.
- The PAD will be dispensed by the pharmacy provider and be administered via home infusion.
- The manufacturer has limited the distribution of the PAD to certain specialty pharmacies and/or distributors of specialty drugs.
- The beneficiary requires immediate access to the PAD and the administering provider is unable to provide and bill it as a medical claim.

While these exceptions do exist, it is important to remember that exceptions will be made on a case-by-case basis via an approved Medi-Cal Rx PA and only when absolutely necessary.



PAD claims can only be billed through Medi-Cal Rx with an approved PA that provides justification for billing the health care provider administered drug as a pharmacy claim.

#### What Pharmacy Providers and Prescribers Need to Do

- PADs that are listed on either the <u>CDLs</u> or the <u>Medi-Cal Rx Pharmacy Reimbursable</u>
   <u>Physician Administered Drugs</u> list may be billed to Medi-Cal Rx.
  - All other PADs that are not on these lists are considered a medical benefit.
  - Providers should submit claims via the medical benefit; under certain exceptions, the claim may be submitted to Medi-Cal Rx for a PA review and determination.
- Providers should refer to the <u>Covered Products Lists</u> on the <u>Medi-Cal Rx Web Portal</u>, for more information about products and services covered by Medi-Cal Rx.

#### What Managed Care Plan Providers Need to Know

Medi-Cal beneficiaries should not be directed to obtain PADs from a pharmacy unless there is a warranted exception, as previously described. PA approvals of PADs billed by pharmacy providers are not intended to replace PAD coverage as a medical benefit. PADs will always remain a medical benefit even when made available as a pharmacy benefit on a case-by-case basis.

If a medical provider bills for a pharmacy drug as part of a medical visit or incidental to a medical visit, it should be treated as a medical claim, even if the drug is typically considered a pharmacy drug. MCPs should not deny such claims on the basis of their classification as a pharmacy claim. It is important to recognize that such claims are, in fact, medical claims and should be treated as such.

# 5. Recommencement of Pharmacy Retroactive Claim Adjustments in August 2023

Pursuant to the February 2016 Centers for Medicare & Medicaid Services (CMS) rule on covered outpatient drugs, the Department of Health Care Services (DHCS) is required to use a pricing methodology based on Actual Acquisition Cost (AAC). Adoption of this policy necessitated retroactive adjustments for impacted claims with dates of service from April 1, 2017, through February 23, 2019.

While DHCS had initiated adjustments in May 2019, this effort was paused. The purpose of this alert is to notify pharmacies of the planned resumption of retroactive adjustments at the end of August 2023, with recoupments set to begin in October 2023. As some changes have occurred since the first iteration of adjustments were processed in May 2019, an overview of the process is provided below.

Medi-Cal Rx has published an updated support document, <u>Pharmacy Retroactive Claim</u>
<u>Adjustments Frequently Asked Questions (FAQs)</u>, with additional information about the process and available resources.

#### Background

In February 2016, CMS published its final rule on covered outpatient drugs (CODs) requiring state Medicaid agencies to adopt a methodology based on AAC for CODs. California's State Plan Amendment 17-002 was approved by CMS and became effective April 1, 2017. The associated system changes went into effect on February 23, 2019.

CMS required retroactive adjustments for impacted claims with dates of service from the policy effective date of April 1, 2017, through the implementation date of February 23, 2019. DHCS processed the first iteration of these adjustments (claims with dates of service in April 2017) in May 2019 and paused further adjustments. Claims with dates of service from April 2017 through February 2019 will be reprocessed with this recommencement.

#### **Resumption of Claim Adjustment Phase**

Retroactive claim adjustments are scheduled to begin at the end of August 2023. These adjustments appear on the Medi-Cal Remittance Advice Details (RAD) forms available through the Medi-Cal Provider Portal.

**Note:** This is **not** the Medi-Cal Rx Provider Portal.

The RAD will display the detail of the claims adjusted and the total adjustment. No recoupments will occur during the claim adjustment phase. All adjustments will appear on RAD forms with **Code 0812: Covered Outpatient Drug Retroactive Payment Adjustment**.

#### **Resumption of Recoupments Phase**

The retroactive claim adjustments will be transitioned to Medi-Cal Rx and Account Receivables (AR) will be created. The first recoupment is planned for October 2023. A recoupment schedule and additional information are available in the <u>Pharmacy Retroactive Claim Adjustments</u>
<u>Frequently Asked Questions (FAQs)</u>.

Pharmacies meeting the requirements of Assembly Bill 179, Statutes of 2022, which allowed DHCS to forego the recoupment of overpayments from independent pharmacies, will be notified of their AR cancellations in early 2024.

# 6. Remittance Advice (RA): Amount Billed/Total Claim Charge Amount Content Update

#### What Pharmacy Providers Need to Know

On September 12, 2023, the contents of a field on the Medi-Cal Rx Remittance Advice (RA) will change to include the NCPDP-recommended Gross Amount Due (NCPDP 430-DU) from the submitted claim, rather than the Usual & Customary Charge (NCPDP 426-DQ) amount from the submitted claim. No field names or formats are changing on the RA. The *Medi-Cal Rx Provider Manual* will be updated to reflect this information on September 1, 2023.

RAs delivered before the Medi-Cal Rx September 12, 2023 payment release date contain the Usual & Customary Charge (NCPDP 426-DQ) amount from the submitted claim.

To view the content change in the Paper RA, refer to the **Amount Billed** column. See *Figure 1*.

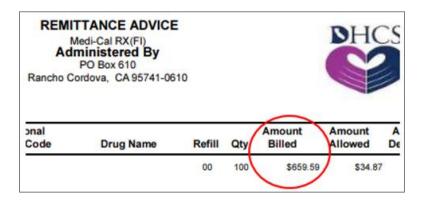


Figure 1: Paper RA – Amount Billed Column

To view the content change in the HIPAA 835 Electronic Data Interchange (EDI) RA, refer to the **CLP03 – Total Claim Charge Amount** segment in the Claim Payment (CLP) Information Loop section. See *Figure 2*.

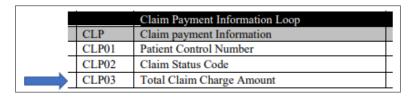


Figure 2: HIPAA 835 EDI RA Companion Guide - CLP03 Total Claim Charge Amount Segment

#### What Pharmacy Providers Need to Do

Pharmacy providers should be aware of the changes to their RAs to ensure proper and accurate reimbursement. Reviewing RA documents carefully can ensure accurate and timely reimbursement. Refer to the following resources for additional information:

- Remittance Advice (RA) Frequently Asked Questions (FAQs)
- Medi-Cal Rx Provider Manual
- Medi-Cal Rx Finance Portal Job Aid

For questions regarding RA documentation, pharmacy providers can contact the Medi-Cal Rx Finance Portal Support Team via the following methods:

- Send an email to <u>MediCalRxFinancePortalSupport@magellanhealth.com</u>.
- Call the Medi-Cal Rx Customer Service Finance Portal Support Team at 1-800-977-2273,
   select Option 2, enter your NPI, and then select Option 2 for Checkwrite.

# 7. Prior Authorization Submission Using the Electronic Health Record to Initiate an Electronic Prior Authorization Request via CoverMyMeds®

#### What Prescribers Need to Know

An issue was identified with the electronic prior authorization (ePA) process when submitted from an electronic health record (EHR) where prescribers would receive a message stating that eligibility could not be found, and that the request would automatically be converted to a manual fax process for review by Medi-Cal Rx. This issue has been resolved.

#### What Prescribers Need to Do

Prescribers do not need to take any action. Requests submitted prior to the issue resolution converted to fax and were reviewed upon submission. This issue will no longer occur on ePAs submitted from an EHR to CoverMyMeds.

#### **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.