

Medi-Cal Rx Monthly Bulletin

October 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.

- 1. Changes to the Contract Drugs List
- 2. <u>Changes to the Contract Drugs List Authorized Drug Manufacturer Labeler Codes</u>
- 3. <u>Changes to the Pharmacy Reimbursable Physician Administered Drugs</u>
- 4. Updates to the Medi-Cal Rx Provider Manual
- 5. <u>30-Day Countdown: Phase IV, Lift III: Reinstatement of Reject Code 76: Plan Limitations</u> <u>Exceeded</u>
- 6. <u>30-Day Countdown: Reinstatement of Cost Ceiling and Prior Authorization for Enteral</u> <u>Nutrition and Specific Standard Therapeutic Classes</u>
- 7. <u>Enteral Nutrition for Members 22 Years of Age and Older: New Start Prior Authorization</u> <u>Reminders</u>
- 8. How to Resolve Claim Reject Code 78: Cost Exceeds Maximum
- 9. Update: Reimbursement for New Commercial COVID-19 Vaccines
- 10. <u>State of Emergency Override Activation: Submission Clarification Code 13</u>
- 11. Lift of Labeler Code Restriction for Truvada
- 12. <u>Diabetic Supplies Update: Changes to Continuous Glucose Monitoring Systems Policy,</u> <u>Effective October 1, 2023</u>
- 13. <u>Medical Supplies Update: Updates to Contracted Diabetic Test Strips and Lancets List,</u> <u>Effective October 1, 2023</u>
- 14. <u>Recommencement of Pharmacy Retroactive Claim Adjustments: Publication of Updated</u> <u>Frequently Asked Questions (FAQs)</u>
- 15. Maximum Allowable Ingredient Cost 30-Day Pharmacy Provider Notice

1. Changes to the 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 October 1, 2023.

Drug Name	Description	Effective Date	
Abrysvo (Respiratory Syncytial Virus Vaccine)	Added to CDL with restriction.	October 1, 2023	
Alogliptin	Effective November 1, 2023: Labeler restriction removed.	October 1, 2023	
Arexvy (Respiratory Syncytial Virus Vaccine, Adjuvanted)	Added to CDL with restriction.	October 1, 2023	
Arsenic Trioxide	Effective November 1, 2023: Labeler restriction removed.	October 1, 2023	
Bortezomib	Effective November 1, 2023: Labeler restriction removed.	October 1, 2023	
Fulvestrant	Effective November 1, 2023: Labeler restriction removed.	October 1, 2023	
Leuprolide Acetate	Additional strength (6-Month Syringe Kit 45 mg) added to CDL with diagnosis and labeler restriction.	October 1, 2023	
Quizartinib	Added to CDL with labeler restriction.	October 1, 2023	
Tobramycin	Additional formulation (inhalation powder) added to CDL with diagnosis and labeler restriction.	October 1, 2023	

2. Changes to the Contract Drugs List – Authorized Drug Manufacturer Labeler Codes

The below changes have been made to the <u>Medi-Cal Rx Contract Drugs List – Authorized Drug</u> <u>Manufacturer Labeler Codes</u> with their respective effective dates and posted to the Medi-Cal Rx Web Portal.

Labeler Code Additions:

NDC Labeler Code	Contracting Company's Name	Effective Date
72542	ACER THERAPEUTICS	October 1, 2023
83257	BIOCON BIOLOGICS, INC	October 1, 2023
58284	BRAEBURN, INC.	October 1, 2023
82194	KRYSTAL BIOTECH, INC.	October 1, 2023
72336	LIFSA DRUGS LLC	October 1, 2023
82685	OLIVIA THERAPEUTICS, LLC	October 1, 2023
73179	REATA PHARMACEUTICALS, INC.	October 1, 2023
63824	RECKITT BENCKISER, INC.	October 1, 2023
70095	SUN PHARMACEUTICAL INDUSTRIES LIMITED	October 1, 2023
81942	TARSUS PHARMACEUTICALS, INC.	October 1, 2023
83592	TRUE MARKER PHARMACEUTICALS, INC.	October 1, 2023
71349	VERRICA PHARMACEUTICALS, INC.	October 1, 2023

Labeler Code Terminations:

NDC Labeler Code	Contracting Company's Name	Effective Date
24689	APNAR PHARMA LP	October 1, 2023
71518	BAUDAX BIO, INC.	October 1, 2023
64543	CAPELLON PHARMACEUTICALS, LTD.	October 1, 2023
42847	CURRAX PHARMACEUTICALS, LLC	October 1, 2023
44183	CURRAX PHARMACEUTICALS, LLC	October 1, 2023
60258	CURRAX PHARMACEUTICALS, LLC	October 1, 2023
71428	GLASSHOUSE PHARMACEUTICALS LLC	October 1, 2023
71777	LOXO ONCOLOGY, INC.	October 1, 2023
72000	NABRIVA THERAPEUTICS US, INC.	October 1, 2023
51267	NALPROPION PHARMACEUTICALS	October 1, 2023
65224	PERSION PHARMACEUTICALS, LLC	October 1, 2023
00813	PHARMICS, INC.	October 1, 2023

3. Changes to the Pharmacy Reimbursable Physician Administered Drugs

The below changes have been made to the <u>Medi-Cal Rx Pharmacy Reimbursable Physician</u> <u>Administered Drugs</u> posted to the Medi-Cal Rx Web Portal, effective October 1, 2023.

Drug Name	Description	Effective Date
Buprenorphine Extended- Release Prefilled Safety Syringe	Added to Pharmacy Reimbursable Physician Administered Drugs.	October 1, 2023
Risperidone Extended- Release Injectable Suspension	Added to Pharmacy Reimbursable Physician Administered Drugs with restriction.	October 1, 2023

4. 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 11.0.

Updates

Section	Update Description	Effective Date
Section 12.4 – Documentation Requirements	 Removed the sentence, "If an attachment is provided, the attachment must be signed and dated by the physician and the physician's name, address, and telephone number must also be clearly supplied." Linked the <u>Medi-Cal Rx Enteral</u> <u>Nutrition Prior Authorization Form</u>. 	October 1, 2023
Section 12.5.3 – Elemental and Semi-Elemental Products Criteria	 Revised language that a member must meet both requirements to be considered for authorization of elemental or semi-elemental products. Removed language "disease-specific." 	October 1, 2023
Section 12.5.4 – Metabolic Products Criteria	 Revised language that the required documentation confirms that a member meets one of the diagnoses for metabolic ketogenic formulas. 	October 1, 2023
Section 16.3 – Automatic Refill Programs for Members (NEW!)	 Added language regarding automatic refill programs for members. 	October 1, 2023

30-Day Countdown: Phase IV, Lift III: Reinstatement of Reject Code 76: Plan Limitations Exceeded

Background

The purpose of this alert is to notify pharmacy providers and prescribers that on October 13, 2023, Phase IV, Lift III (P4/L3) will be implemented.

What Pharmacy Providers and Prescribers Need to Know

Reject Code 76 – Plan Limitations Exceeded applies to new start claims for all ages and will apply to refill claims for members 22 years of age and older beginning October 13, 2023. Claims that reject with Reject Code 76 can also reject for the following reasons:

- Minimum Billed Quantity
- Maximum Billed Quantity
- Days' Supply Limit Exceeded

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Notes

- Quantity Limit Exceeded
- Maximum Quantity Per Day Limit Exceeded
- Number of Fills Per Specific Time Limit Exceeded



• New start claims for all ages including enteral nutrition products, continue to be subject to Reject Code 76.

What Pharmacy Providers and Prescribers Need to Do

Pharmacy providers and prescribers should:

 Review Quantity Limit (QL) requirements included in the <u>Contract Drugs Lists & Covered</u> <u>Products Lists</u> on the <u>Medi-Cal Rx Web Portal</u>.

- 2. Submit a prior authorization (PA) request, if resubmission of the claim that meets the established quantity limitations is not appropriate, via one of the approved Medi-Cal Rx PA submission methods:
 - <u>CoverMyMeds®</u>
 - Medi-Cal Rx Secured Provider Portal
 - NCPDP P4 Transaction
 - Fax
 - U.S. Mail

Note: If a claim rejects due to quantity limitations exceeding 100 days' supply for drugs/products, a PA is not reviewable for coverage consideration as it must meet this limitation of up to and including a 100-day supply (except U.S. Food and Drug Administration [FDA]-approved self-administered hormonal contraceptives **[this includes transdermal patches and vaginal rings in addition to oral dosage forms]** and sodium fluoride products/drops/solutions).

Resources

- Review Medi-Cal Rx billing guidelines in the <u>Medi-Cal Rx Billing Tips</u>.
- Review Appendix D and other parts of the <u>Medi-Cal Rx Provider Manual</u>.
- Review the <u>NCPDP Payer Specification Sheet</u>.
- Review the *Prior Authorization Submission Reminders* alert.
- Review PA resources by selecting **Prior Authorization (PA)** on the <u>Forms & Information</u> page.
- Continue to review the <u>Medi-Cal Rx Web Portal</u> for additional information.

30-Day Countdown: Reinstatement of Cost Ceiling and Prior Authorization for Enteral Nutrition and Specific Standard Therapeutic Classes

Background

The purpose of this alert is to notify pharmacy providers and prescribers that on September 22, 2023, Phase IV, Lift 2 (P4/L2) was implemented for members 22 years of age and older. P4/L2:

- Reinstated utilization management (UM) claim edits for Reject Code 78 Cost Exceeds
 Maximum.
- Reinstated prior authorization (PA) requirements for new start therapies for standard therapeutic classes (STCs) 68, 86, and 87, including enteral nutrition products.
- Enabled PA submissions in advance of the retirement of the Transition Policy for renewing/refilling prescriptions for products in STCs 68, 86, and 87, which include enteral nutrition products.

Note: Claims for members 21 years of age and younger are not impacted.

Reinstatement of Cost Ceiling Claim Edits for Reject Code 78

What Pharmacy Providers and Prescribers Need to Know

Effective September 22, 2023, Medi-Cal Rx reinstated cost ceiling claim edits for members 22 years of age and older. Reject Code 78 has been reinstated for all STCs with some exclusions (see list below). To improve pharmacy claim submission and processing quality and to mitigate potential fraud, waste, and abuse (FWA) in Medi-Cal Rx, the previous \$10,000 cost ceiling policy has been revised to cost ceiling categories by drug type as outlined in the following table:

Cost Ceiling Limits		
Drug/Product Cost Ceiling		
Over-the-counter (OTC)	\$50/claim	
Generic \$1,000/claim		
Single and Multi-Source Brand \$4,000/claim		
High-Cost Generics and Brands * \$14,000/claim		
Claims over the Cost Ceiling Maximum for each category will trigger Reject Code 78 and will		
require a PA or a real-time override by the Medi-Cal Rx Customer Service Center (CSC).		

* Drugs/products in this category include generic and brand drugs not in the *Generic* or *Single and Multi-Source Brand* categories, where the claim threshold amount is equal to or greater than \$14,000.

The updated policy will apply when a point of service (POS) pharmacy claim exceeds the dollar claim amount threshold as specified in the table and claims will reject for Reject Code 78 with the following supplemental message, "[\$XX.00] Maximum Cost Exceeded. For override, call CSC (1-800-977-2273) or submit a Prior Authorization."

Note: Drug classes that are exempt from the cost ceiling requirements include (but are not limited to) the following:

- Blood clotting factors and related treatments for hemophilia
- Treatments for cancer (including antineoplastic and immunologic agents as well as myelo-supportive therapies)
- Immunosuppressive and immunologic agents (including immune globulins)
- HIV and hepatitis C virus (HCV) medications
- Gene therapies and other select targeted biologic therapies
- Specific disposable medical supplies, diabetic testing supplies, insulins, and compounds

Additional drugs exempt from cost ceiling requirements can be found in the <u>Medi-Cal Rx</u> <u>Provider Manual</u>.

What Pharmacy Providers and Prescribers Need to Do

Reject Code 78 requires approval of an override with clinician review to receive a paid claim. Providers should perform the following steps:

- 1. Consider prescribing a less costly therapy, if clinically appropriate.
- 2. If a change in therapy is not appropriate,
 - a. Contact the Medi-Cal Rx CSC for consideration of a real-time override; or
 - b. Submit a PA request via one of the approved Medi-Cal Rx PA submission methods.

Refer to the *Prior Authorization Submission Reminders* alert and the *Medi-Cal Rx Provider Manual* for more information on submitting a PA.

Reinstatement of PA Requirements for STCs 68, 86, and 87

What Pharmacy Providers and Prescribers Need to Know

PA requirements have been reinstated for new start therapies for STCs 68, 86, and 87. New starts are defined as new therapies or medications not previously prescribed to the member during the 15-month lookback period.

Phase IV, Lift 2 (P4/L2) Drug Classes			
Protein Lysates (STC 68)	Infant Formulas (STC 86)	Electrolytes and Miscellaneous Nutrients	
(STC 87)			

 Enteral nutrition products are included within STCs 68, 86, and 87.
 Members 21 years of age and younger are not impacted.

What Pharmacy Providers and Prescribers Need to Do

- Pharmacy providers should assess business processes and workflows to account for the reinstatement of PA requirements for drugs/products in STCs 68, 86, and 87 for new starts for members 22 years of age and older.
- If a member is 22 years of age and older and currently receiving a drug/product in STCs 68, 86, and 87, pharmacy providers and prescribers should prepare for the November 2023 retirement of the Transition Policy in the following ways:
 - Consider alternate therapies that may not require a PA, if clinically appropriate. Review the <u>Contract Drugs & Covered Products Lists</u> page on the <u>Medi-Cal Rx Web Portal</u>.
 - If a change in therapy is not appropriate, submit a PA request in advance of the retirement of the Transition Policy via one of the approved Medi-Cal Rx PA submission methods. Refer to the *Prior Authorization Submission Reminders* alert and the *Medi-Cal Rx Provider Manual* for more information on submitting a PA.



Providers are encouraged to submit a PA in advance of the retirement of the Transition Policy for STCs 68, 86, and 87 (including enteral nutrition products) beginning September 22, 2023 for members 22 years of age and older.

Resources

To prepare for the reinstatement of the claim edit and PA requirements, pharmacy providers and prescribers are encouraged to:

- Refer to the *Reinstatement Spotlight* published weekly on the <u>Bulletins & News</u> page.
- Review the <u>90-Day Countdown: Reinstatement of Prior Authorization Requirements for</u> <u>Enteral Nutrition Products for Members 22 Years of Age and Older</u> alert.
- Review Medi-Cal Rx billing guidelines in the <u>Medi-Cal Rx Billing Tips</u>.
- Review Appendix D in the <u>Medi-Cal Rx Provider Manual</u>.
- Review the <u>NCPDP Payer Specifications Sheet</u>.
- Review the *Prior Authorization Submission Reminders* alert.
- Continue to review the <u>Medi-Cal Rx Web Portal</u> for additional information.

7. Enteral Nutrition for Members 22 Years of Age and Older: New Start Prior Authorization Reminders

Background

On September 22, 2023, prior authorization (PA) requirements were reinstated for new start enteral nutrition products for members 22 years of age and older. "New starts" are defined as new enteral nutrition therapy not previously prescribed to the member during the 15-month lookback period. The purpose of this alert is to inform pharmacy providers and prescribers of the requirements for enteral nutrition product PA submission, as well as introduce the new *Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form*. This is the preferred form to submit enteral nutrition product PA requests.

What Pharmacy Providers and Prescribers Need to Know

- Effective September 22, 2023, all new start enteral nutrition products for members 22 years of age and older require a PA.
 - Claims will deny for Reject Code 75 as all enteral nutrition product claims require a PA.
 - For non-new starts, claims will continue to adjudicate under the Transition Policy.

Enteral nutrition product claims submitted for a date of service (DOS) prior to September 22, 2023 did not deny with **Reject Code 75 – Prior Authorization Required** due to the temporary suspension of Medi-Cal Rx's PA requirements. However, as of September 22, 2023, new start claims for members 22 years of age and older are subject to the following PA reject codes:

- Reject Code 75 Prior Authorization Required
- Reject Code 76 Plan Limitations Exceeded

Claims for enteral nutrition products will deny for Reject Code 75 as all enteral nutrition product claims require a PA. Claims will also deny for **Reject Code 76 – Plan Limitations Exceeded** if the quantity requested for the product exceeds a maximum daily calorie limit of 2,000 kcal/day.

What Pharmacy Providers and Prescribers Need to Do

In preparation of reinstatement of PA requirements for enteral nutrition products, pharmacy providers and prescribers should review the following checklist before submitting a PA to Medi-Cal Rx for coverage considerations:

- Review the <u>List of Contracted Enteral Nutrition Products</u>. Only products on this established Medi-Cal Rx list are covered.
 - If a member is currently receiving a product not found on the *List*, prescribers need to select a therapeutic equivalent from the *List*.

Note: The <u>Drug Lookup Tool</u> on the <u>Medi-Cal Rx Provider Portal</u> does not include enteral nutrition products at this time. Alternatively, refer to the <u>List of Contracted Enteral</u> <u>Nutrition Products</u>.

- Verify prescription requirements are met.
 - A written or electronic prescription signed by a physician is required for authorization of all enteral nutrition products.
 - Enteral nutrition products are covered only when supplied by a pharmacy provider.
 - The physician's full name, address, and telephone number must be clearly supplied if not preprinted on the prescription form.
- Verify billing requirements and limitations are met.
 - Claims should be submitted for a quantity that meets the member's daily caloric requirement and does not exceed a 31-day supply.

Note: Quantity should be rounded up to the smallest available package size. Rounding up **does not** include rounding up to six packs or full cases of the product.

- Verify that providers are including the following required information to meet the PA documentation requirements when submitting a PA request:
 - Medical diagnosis code related to the product requested.
 - Height (length), weight, and daily caloric requirements.
 - This information (along with other medical measurements and labs) must be dated within 365 days (12 months) of the request with the exception of specialty infant products which must be dated within 120 days (4 months) of the request.
 - Route of administration (orally fed or tube fed).
 - 11-digit product NDC.
 - Supporting documentation as attachments must be signed by the physician.

Note: PA requests are considered invalid if the information mentioned above is not provided at the time of PA submission. Providers are asked to submit a new PA request.

Enteral Nutrition PA Submission Reminders

Pharmacy providers and prescribers may submit enteral nutrition product PA requests via the five submission methods (see the *Prior Authorization Submission Reminders* alert). For providers using fax or U.S. Mail for their PA submission needs, Medi-Cal Rx has created the *Medi-Cal Rx*

DHCS – Medi-Cal Rx Monthly Bulletin *Enteral Nutrition Prior Authorization Request Form.* This is the preferred form when submitting an enteral nutrition PA request via fax or U.S. Mail as it provides designated sections to gather product information, route of administration, and clinical justification.

Additional Considerations

- Transition Policy
 - Phase IV, Lift 2 does not affect PA requirements for enteral nutrition products for members 22 years of age and older who are currently receiving the product under the Transition Policy.
 - Override code "55555" remains available for use by pharmacy providers attesting that the member was previously maintained on the product per their pharmacy records (see the <u>Prior Authorization Required: Reject Code 75 Reminder</u> alert).
- Multiple Flavors
 - Claims submitted for the same date of service (DOS) for additional flavors of the enteral nutrition product will deny for **Reject Code 83 – Duplicate Paid/Captured** Claim.
 - For assistance, refer to the <u>NCPDP Reject Code 83 Duplicate Paid/Captured Claim</u> alert.
- Medicare Part B Dual Eligible
 - For dual eligible members receiving the product via a device (tube fed), **do not** submit the claim to Medi-Cal Rx. These claims should be billed to Medicare Part B.
 - For dual eligible members receiving the product orally, claims submitted to Medi-Cal Rx will deny with **Reject Code A6 – Product/Service May Be Covered Under Medicare Part B**. In this situation, pharmacy providers should call the Medi-Cal Rx Customer Service Center (CSC) at 1-800-977-2273 for assistance.
- Enteral Nutrition Product Shortages
 - Claims submitted for a different flavor of the same product will not deny for Reject
 Code 75. A new PA submission will not be required.
 - Claims submitted for an alternate product due to a product shortage will deny for Reject Code 75. A PA submission will be required.

Resources

- Medi-Cal Rx Enteral Nutrition Office Hour
 - Beginning Wednesday, August 16, 2023, Medi-Cal Rx will be hosting an enteral nutrition <u>office hour</u> via Zoom every Wednesday from 12 p.m. to 1 p.m. PT (except holidays).
 - Pharmacy providers and prescribers are encouraged to attend and ask any questions regarding the upcoming reinstatement of enteral nutrition products.
- Enteral Nutrition
 - Review the *Enteral Nutrition Products* section and other parts of the <u>Medi-Cal Rx</u> <u>Provider Manual</u> for additional information.
 - Review the <u>90-Day Countdown: Reinstatement of Prior Authorization Requirements for</u> <u>Enteral Nutrition Products for Members 22 Years of Age and Older</u> alert.
 - Review the *List of Contracted Enteral Nutrition Products*.
 - Continue to review the <u>Medi-Cal Rx Web Portal</u> for additional information.
- Prior Authorizations
 - Review the *Prior Authorization Submission Reminders* alert.
 - Review PA resources by selecting **Prior Authorization (PA)** on the <u>Forms &</u> <u>Information</u> page.
 - Review the <u>Medi-Cal Rx Reinstatement Phases II-IV Webinar</u> recording on YouTube.
- Billing
 - Review Medi-Cal Rx billing guidelines in the <u>Medi-Cal Rx Billing Tips</u>.
 - Review the <u>NCPDP Payer Specification Sheet</u>.
- Assistance
 - <u>Medi-Cal Rx Reinstatement Webinar</u> Attend a live webinar regarding Medi-Cal Rx Reinstatement via Zoom every Friday at 12 p.m. PT.
 - <u>Medi-Cal Rx Office Hour</u> Assistance is available Monday through Friday, from 12 p.m. to 1 p.m. PT (except holidays).

8. How to Resolve Claim Reject Code 78: Cost Exceeds Maximum

Purpose

The purpose of these scenarios is to help pharmacy providers and prescribers understand how the updated cost ceiling limits impact claim response and provide direction on what actions may be taken to resolve **Reject Code 78 – Cost Exceeds Maximum**.

What Is Changing?

- Claims submitted with a date of service (DOS) on or after September 22, 2023, are subject to new cost ceiling limits and will receive a Reject Code 78.
- A previously approved prior authorization (PA) may not satisfy the cost ceiling limits. An override request or PA request submission to address the cost ceiling limits may be required.

Cost Ceiling Limits		
Drug/Product Cost Ceiling		
Over-the-counter (OTC)	\$50/claim	
Generic	\$1,000/claim	
Single and Multi-Source Brand \$4,000/claim		
High-Cost Generics and Brands * \$14,000/claim		
Claims over the Cost Ceiling Maximum for each category will trigger Reject Code 78 and will require a PA or an administrative override by the Medi-Cal Rx Customer Service Center (CSC).		

* Drugs/products in this category include generic and brand drugs not in the *Generic* or *Single and Multi-Source Brand* categories, where the claim threshold amount is equal to or greater than \$14,000.

Reminders

- If a Reject Code 78 is received, pharmacy providers should confirm that the claim is submitted accurately and validate that quantity, billing units, and days' supply are correct.
- Prescribers and pharmacies should consider less costly alternatives, if clinically appropriate.
- Prescribers and pharmacies should consider contracted drugs/products that do not require a PA, if clinically appropriate. For alternatives, providers can consult <u>Contract Drugs and</u> <u>Covered Products Lists</u>.
- Medi-Cal Rx allows providers to dispense a 14-day emergency supply of medications to enable members to have immediate access to medically necessary drugs in emergency situations. See the *Emergency Fills* section in the <u>Medi-Cal Rx Provider Manual</u> for additional details.

Cost Ceiling Limit Scenarios

Claim Exceeds Cost Ceiling Limits (Reject Code 78)	Drug Requires PA (Reject Code 75)	Outcome	Actions
No No	No Yes	Claim will pay. Claim will not deny for Reject Code 78.	 No action required. If an active PA approval for drug coverage (Reject Code 75) exists, no action is required. If an active PA approval for drug coverage (Reject Code 75) does not exist, submit a PA request via one of the approved Medi-Cal Rx PA submission methods.
Yes	No	Claim will deny for Reject Code 78 with the following supplemental message, "\$XXX.00 Maximum Cost Exceeded. For override, call CSC (1-800-977-2273) or submit a Prior Authorization."	 If a clinical PA is not needed: Contact the CSC for consideration of a realtime override. Submit a PA request via one of the approved Medi-Cal Rx PA submission methods.
Yes	Yes	Claim will deny for Reject Code 78 and Reject Code 75.	 If a change in therapy is not appropriate, submit a PA request via one of the approved Medi-Cal Rx PA submission methods.



Claims may reject for other reject codes. Refer to <u>Appendix D</u> of the <u>Medi-Cal Rx Provider Manual</u>. Pharmacy providers should determine next steps to address the reject code, which may include submission of a Medi-Cal Rx PA.

Resources

Additional resources regarding cost ceiling can be found below:

- <u>30-Day Countdown: Reinstatement of Cost Ceiling and Prior Authorization for Enteral</u> <u>Nutrition and Specific Standard Therapeutic Classes</u>
- Medi-Cal Rx Provider Manual
- <u>Contract Drugs & Covered Products Lists</u>
- Medi-Cal Rx Billing Tips

9. Update: Reimbursement for New Commercial COVID-19 Vaccines

Background

On September 11, 2023 and September 21, 2023, alerts were published to update pharmacy providers and prescribers about forthcoming information regarding reimbursement of new commercial COVID-19 vaccines. Refer to the <u>Coming Soon: Commercialization of COVID-19</u> <u>Vaccines</u> and <u>Reimbursement for New Commercial COVID-19 Vaccines</u> alerts.

The purpose of this alert is to provide updated guidance regarding Medi-Cal Rx's reimbursement policy specific to these new commercial COVID-19 vaccines.

What Pharmacy Providers and Prescribers Need to Know

The new COVID-19 vaccines will now appropriately reimburse the cost for the commercial vaccines (in addition to the \$40 incentive fee). Note that the submission clarification code (SCC) of 2 is not required for these commercial COVID-19 vaccines.

What Pharmacy Providers and Prescribers Need to Do

Pharmacy providers are highly encouraged to reverse and resubmit prior claims with an incorrect reimbursement rate to obtain the updated reimbursement policy.

Note: Medi-Cal Rx will perform a claim adjustment on any claims that are not resubmitted and reprocessed to ensure accurate reimbursement. Providers will be notified as soon as additional information is available.

Reminder

- For members 6 months through 18 years of age, coverage of the vaccine will be available only through the Vaccines For Children (VFC) program. Products remain federally funded. To locate an eligible provider, visit <u>https://eziz.org/</u> or call 1-877-243-8832. Claims submitted to Medi-Cal Rx for members 6 months to 18 years of age will reject with **Reject Code 60 Product/Service Not Covered For Patient Age**.
- Uninsured and underinsured adults may obtain free COVID-19 vaccines through the <u>Centers for Disease Control and Prevention's (CDC) Bridge Access Program</u>. The vaccines can be accessed through local pharmacies and health care providers, including Federally Qualified Health Centers (FQHCs). For additional details, see the guidance from California Department of Public Health (CDPH)'s <u>California Bridge Access Program</u>.

COVID-19 Vaccines	NDCs
Comirnaty (COVID-19 Vaccine, mRNA)	00069-2362-01,
(2023-2024 Formula)	00069-2362-10,
	00069-2392-10
Moderna (COVID-19 Vaccine)	80777-0287-07,
(2023-2024 Formula)	80777-0287-92
Pfizer-BioNTech (COVID-19 Vaccine)	59267-4315-01,
(2023-2024 Formula)	59267-4315-02,
	59267-4331-02
Spikevax COVID-19 Vaccine, mRNA)	80777-0102-95,
(2023-2024 Formula)	80777-0102-96,
	80777-0102-93

• New commercial COVID-19 Vaccines (2023-2024 formulas) are listed in the following table:

COVID-19 Vaccines

NDCs

Note: Claims submitted for the following four NDCs will deny for **Reject Code 85** – **Claim Not Processed** with the following supplemental messaging, "*No price exists for the NDC submitted*." Medi-Cal Rx is awaiting the pricing information from the manufacturer to be updated with First DataBank.

- 00069-2392-01 (**Comirnaty**)
- 59267-4331-01 (**Pfizer-BioNTech**)
- 80777-0102-01 (**Spikevax**)
- 80777-0102-04 (**Spikevax**)

Resources

- <u>COVID-19 Vaccine Commercialization FAQs</u>
- Fact Sheet: HHS Announces 'HHS Bridge Access Program For COVID-19 Vaccines and Treatments' to Maintain Access to COVID-19 Care for the Uninsured
- <u>CDC's Bridge Access Program</u>

10. State of Emergency Override Activation: Submission Clarification Code 13

Background

The purpose of this alert is to notify pharmacy providers and prescribers that, pursuant to the Governor's recent Proclamation of State of Emergency, due to ongoing fires, Medi-Cal Rx is permitting emergency overrides on pharmacy claims for members residing in impacted Del Norte and Siskiyou counties. These overrides were accepted for 31 days, effective for dates of service (DOS) August 29, 2023 – September 29, 2023.

What Pharmacy Providers and Prescribers Need to Know

This emergency override allowed applicable claim submissions to bypass certain edits by utilizing the Submission Clarification Code (SCC) of 13. An SCC of 13 indicates a Payer Recognized – Emergency/Disaster Assistance Request.

Impacted Counties Eligible for Emergency Override (Utilizing SCC 13 *)

Del Norte Siskiyou

* SCC 13 overrides may be applied to pharmacy claims as needed for members residing within impacted counties and will be administered based upon members' county of residence.

What Pharmacy Providers and Prescribers Need to Do

Pharmacy providers serving members residing within impacted counties who are requesting an emergency override due to the State of Emergency should enter SCC 13 when submitting claims under the following circumstances:

- Resolution for displaced persons or medications:
 - Reject Code 88 Early refill, ingredient duplication, therapeutic duplication, etc.
 - Reject Code 83 Duplicate fill
 - Reject Code 76 Quantity over time and frequency of dispensing limits
- Resolution for potential issues with newly prescribed medications in addition to the edits listed above:
 - Reject Code 60 Age limit
 - Reject Code 61 Gender limit
 - Reject Code 75 Prior authorization (PA) required
 - SCC 13: By submitting SCC 13 on the claim, the pharmacy provider is attesting that the prescription and refill supply is dispensed in response to the natural disaster situation related to the recent Proclamations of State of Emergency due to ongoing fires.
 - Drug Use Review (DUR) Reject Code 88: Pharmacy providers maintain their ability to override early refill (Reject Code 88 – DUR Reject Error) at point of sale (POS) if medically necessary. See the following resources for additional information.

Resources

- California Proclamations of State of Emergency:
 - <u>Del Norte County</u>
 - <u>Siskiyou County</u>
- NCPDP Payer Specification Sheet
- <u>Medi-Cal Rx Billing Tips</u>
- <u>NCPDP Emergency Preparedness Guidance</u>
- Reject Code 88 information:
 - Now Active Reinstatement of Reject Code 88
 - NCPDP Reject Code 88 DUR Reference Guide
 - Appendix A: Reject Code 88 DUR: Service Codes Scenarios

11. Lift of Labeler Code Restriction for Truvada

What Pharmacy Providers and Prescribers Need to Know

Medi-Cal Rx lifted Code I Labeler Code restriction for all strengths of Truvada (Emtricitabine/Tenofovir) on August 21, 2023. This will be retroactive to August 4, 2023.

- Pharmacy providers who received a denied claim for Reject Code 606 Brand
 Drug/Specific Labeler Code Required, when submitting for Emtricitabine/Tenofovir, should resubmit the claim.
- The generic form of Truvada (Emtricitabine/Tenofovir) will be available without a prior authorization (PA).

Reminders

Medi-Cal Rx allows providers to dispense a 14-day emergency supply of medications to enable members to have immediate access to medically necessary drugs in emergency situations. Supply chain shortages are appropriate for an emergency fill. See the *Emergency Fills* section in the *Medi-Cal Rx Provider Manual* for additional details. Medi-Cal Rx published guidance on how providers can request alternative medications when the prescribed product is not available or only available in a limited, insufficient quantity. See *Medi-Cal Rx Policy for Requesting Alternative Medication in Case of Supply Shortage*.

12. Diabetic Supplies Update: Changes to Continuous Glucose Monitoring Systems Policy, Effective October 1, 2023

Effective October 1, 2023, the coverage requirements for Medi-Cal Rx contracted Continuous Glucose Monitoring (CGM) Systems have been updated. These changes are effective for requests on and after October 1, 2023.

The language will be updated within the *Diabetic Supplies – Continuous Glucose Monitoring (CGM) Systems* section of the <u>Medi-Cal Rx Provider Manual</u> on the <u>Medi-Cal Rx Web Portal</u> at a later date.

The manufacturer has guaranteed Medi-Cal Rx providers may purchase, upon request, for dispensing to eligible Medi-Cal Rx members, covered products at or below the Maximum Acquisition Cost (MAC)/Maximum Allowable Product Cost (MAPC). Providers can locate MAC price suppliers by calling manufacturer phone numbers referenced in the *List* on the <u>Medi-Cal Rx Web Portal</u>.

Also effective October 1, 2023, the *List of Contracted Continuous Glucose Monitoring (CGM) Systems* has been updated on the Medi-Cal Rx Web Portal to add Dexcom G7 products as Medi-Cal Rx covered pharmacy benefits. A prior authorization (PA) is required for coverage and quantity, and frequency limits apply.

Product Label Name	Billing Code (11-digit NDC-like Number)	MAC/MAPC Price per each
Dexcom G7 Receiver	08627007801	\$299.0000
Dexcom G7 Sensor	08627007701	\$118.3300

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

Medi-Cal Rx members denied coverage of a requested Medi-Cal Rx product have the right to a fair hearing. A state hearing may be requested by contacting the California Department of Social Services, State Hearings Division, at the following address:

State Hearings

P.O. Box 944243, MS 21-37 Sacramento, CA 94244-2430 Toll Free: 1-800-743-8525 or 1-855-795-0634 Fax: 1-833-281-0905

Medi-Cal Rx members have the right and are encouraged to consult their primary care provider or prescriber to determine if an appropriate substitute product is available and covered by Medi-Cal Rx.

Medical Supplies Update: Updates to the Contracted Diabetic Test Strips and Lancets List, Effective October 1, 2023

Effective October 1, 2023, the <u>List of Contracted Diabetic Test Strips and Lancets</u> has been updated on the <u>Medi-Cal Rx Web Portal</u> to add LifeScan, Inc. OneTouch[®] UltraSoft[®] 2 Lancets Box of 100, Medi-Cal Rx billing code/NDC-like number 53885027810, as a Medi-Cal Rx covered pharmacy benefit.

The manufacturers have guaranteed that Medi-Cal Rx providers may purchase, upon request, for dispensing to eligible Medi-Cal Rx beneficiaries, covered products at or below the Maximum Acquisition Cost (MAC). Providers can locate MAC price suppliers by calling manufacturer phone numbers referenced in the *List of Contracted Diabetic Test Strips and Lancets* on the Medi-Cal Rx Web Portal.

Effective July 1, 2023, LifeScan, Inc. OneTouch Verio Test Strips, 100-Strip Box, billing code 53885027210, requires a prior authorization (PA), as stated in the alert titled <u>Updates to</u> <u>Diabetic Testing Supplies, Effective July 1, 2023</u>. Effective on and after January 1, 2024, this billing code will no longer be a covered Medi-Cal Rx diabetic testing supply and will be deleted from the <u>List of Contracted Diabetic Test Strips and Lancets</u>. Claims for this billing code will reject on and after January 1, 2024, even with an approved PA, as stated in the alert titled <u>Updates to Diabetic Testing Supplies, Effective July 1, 2023</u>.

Recommencement of Pharmacy Retroactive Claim Adjustments: Publication of Updated Frequently Asked Questions (FAQs)

What Pharmacy Providers Need to Know

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 (DOS) 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 remind pharmacies that retroactive claim adjustments will recommence at the end of August 2023, with recoupments set to begin in October 2023.

Medi-Cal Rx has published an updated support document, <u>*Pharmacy Retroactive Claims</u></u> <u><i>Adjustment Frequently Asked Questions (FAQs)*</u>, with additional information about the process and available resources.</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 accounts receivable (AR) cancellations in early 2024.

What Pharmacy Providers Need to Do

- Review the July 31, 2023 alert titled <u>Recommencement of Pharmacy Retroactive Claim</u> <u>Adjustments in August 2023</u>, for an overview of the recoupment effort.
- Read the updated *Pharmacy Retroactive Claim Adjustments Frequently Asked Questions* (*FAQs*). Included in the FAQs are the following:
 - Overview of the reprocessing effort
 - Background of AAC
 - Claim adjustment and AR recoupment schedule
 - Claim adjustment reprocessing specifics

- AR recoupment specifics
- Contact information
- Beginning in late August 2023, access the Medi-Cal Remittance Advice Details (RADs)/835 files, available through the <u>Medi-Cal Provider Portal</u>, to review the detail of the claims adjusted and the total adjustment for that iteration.

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

All adjustments will appear on RAD forms with **Code 0812: Covered Outpatient Drug Retroactive Payment Adjustment**.

- Beginning in late October 2023, access the Medi-Cal Rx RADs/835 files, available from the Medi-Cal Rx Finance Portal accessible via the <u>Medi-Cal Rx Provider Portal</u>, to review the AR recoupments.
- In early 2024, monitor for notification of AR cancellations for those pharmacies meeting the requirements of AB 179, Statutes of 2022, which allowed DHCS to forego the recoupment of overpayments from independent pharmacies.

15. Maximum Allowable Ingredient Cost 30-Day Pharmacy Provider Notice

What Pharmacy Providers Need to Know

The Department of Health Care Services (DHCS) has contracted with Magellan Medicaid Administration, LLC (MMA), who contracts with Mercer Government Human Services Consulting (Mercer), part of Mercer Health and Benefits LLC, to establish and maintain a Maximum Allowable Ingredient Cost (MAIC) program for generic pharmaceutical drugs.

Rates are effective October 1, 2023, and have been posted to the Mercer Medi-Cal Rx website no later than September 1, 2023.

What Pharmacy Providers Need to Do

• Refer to the Mercer Medi-Cal Rx website for MAIC rate lists, MAIC program information, Frequently Asked Questions (FAQs), and contact information. To request a review of a MAIC rate for a specific drug, submit a request using the <u>Medi-Cal Rx Maximum Allowable Ingredient Cost (MAIC) Price Research Request Form</u> found on the <u>Mercer Medi-Cal Rx website</u> and the <u>Medi-Cal Rx Web Portal</u>.

Note: All required fields on the form must be completed. Providers will be contacted for supporting documentation or other information, as necessary.

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 <u>MediCalRxEducationOutreach@magellanhealth.com</u>.