

## Medi-Cal Rx Monthly Bulletin

#### September 1, 2022

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.

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- 5. <u>Now Active Reinstatement of Reject Code 88</u>
- 6. Code 1 Documentation and Postponement of Implementation of Reject Code 80
- <u>Update: Implementation of Phase I, Wave III Reinstatement of Prior Authorizations for</u> <u>11 Drug Classes</u>
- 8. <u>Electronic Claims Agreement Submission Deadline Extended</u>
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- 12. Inappropriate Treatment Delays and Denials for HIV PrEP and PEP

## 1. Changes to the Contract Drugs List

The below changes have been made to the *Contract Drugs List*, effective September 1, 2022.

For more information, see the <u>Contract Drugs List</u> on the Medi-Cal Rx Web Portal.

Drug Name	Description	Effective Date
Adapalene	Added to CDL.	September 1, 2022
Ammonium lactate	Added to CDL.	September 1, 2022
Clobazam	Removed age restriction and diagnosis restriction.	September 1, 2022
Clonazepam	Additional formulation (ODT tablets) added.	September 1, 2022
Dasiglucagon HCl	Updated quantity limit restriction and removed labeler restriction.	September 1, 2022
Felbamate	Added to CDL with restriction.	September 1, 2022
Glucagon	Updated quantity limit restriction.	September 1, 2022
Indomethacin	Additional formulation (suspension) added with a restriction.	September 1, 2022
Influenza Virus Vaccine	Additional strength (240 mcg /0.7ml) added.	September 1, 2022
Ipratropium Bromide	Added to CDL.	September 1, 2022
Mycophenolate Mofetil	Additional formulation (suspension) added with restriction.	September 1, 2022
Olopatadine HCL	Removed labeler code restriction (00065).	September 1, 2022
Posaconazole	Added to CDL with restriction.	September 1, 2022
Rufinamide	Added to CDL with restriction.	September 1, 2022
Salicylic Acid	Added to CDL.	September 1, 2022
Sirolimus	Additional formulation (solution) added with restriction.	September 1, 2022
Topiramate	Additional formulation (solution) added with restriction.	September 1, 2022
Voriconazole	Added to CDL with restriction.	September 1, 2022

# 2. Changes to the Contract Drugs List – Over-the-Counter Drugs

The below changes have been made to the <u>Contract Drugs List – Over-the-Counter Drugs</u>, effective September 1, 2022.

For more information, see the <u>Contract Drugs List – Over-the-Counter Drugs</u> on the Medi-Cal Rx Web Portal.

Drug Name	Description	Effective Date
Docusate sodium	Additional formulation (liquid) added.	September 1, 2022
Ferrous Sulfate	Additional formulation (solution) added.	September 1, 2022
Fexofenadine	Additional formulation (suspension) and strengths (30 mg and 60 mg) added.	September 1, 2022
Loratadine	Removed age restriction.	September 1, 2022
Multivitamins	Added to CDL with restriction.	September 1, 2022
Poly-Vi-Sol	Added to CDL with restriction.	September 1, 2022
Poly-Vi-Sol with Iron	Added to CDL with restriction.	September 1, 2022
Vitamin D3	Additional strength (5000 units) added.	September 1, 2022
(Cholecalciferol)		

### 3. Changes to the Family PACT Formulary

The below changes have been made to the Family Planning, Access, Care and Treatment (Family PACT) Pharmacy Formulary.

For more information, see the <u>Family PACT Pharmacy Formulary</u> on the Medi-Cal Rx Web Portal.

Drug Name	Description	Effective Date
Moxifloxacin	Prior authorization restriction removed.	August 15, 2022

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

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

For more information, see the <u>Medi-Cal Rx Provider Manual</u> Version 1.17 on the Medi-Cal Rx Web Portal.

Section	Update Description	Effective Date
Section 3.6 – Medi-Cal Rx Website	<ul> <li>Removed the word "therapeutic" from verbiage related to Continuous Glucose Monitoring (CGM) systems</li> </ul>	September 1, 2022
Section 4.6.13 – Medical Supply Reimbursement	<ul> <li>Removed the word "therapeutic" from verbiage related to Continuous Glucose Monitoring (CGM) systems</li> </ul>	September 1, 2022
Section 8.2.1 – Long-Term Care Claims Processing	<ul> <li>Removed the word "therapeutic" from verbiage related to Continuous Glucose Monitoring (CGM) systems</li> </ul>	September 1, 2022
Section 12.3.5 – Specialty Infant Products Criteria	<ul> <li>Added the following verbiage: <ul> <li>"Extensively Hydrolyzed Specialty Infant"</li> </ul> </li> <li>Added additional criteria for approval of Extensively Hydrolyzed Specialty Infant (EH) products with probiotics: <ul> <li>"the beneficiary must meet all of the criteria listed below. Product- specific criteria may also apply"</li> <li>"Have a current diagnosis of CMPA or intolerance to breast milk or regular infant formula"</li> <li>"Have a birth weight greater than 1000 grams; and the formula is not used in the prevention of a chronic or acute disease or condition"</li> </ul> </li> <li>Removed the following verbiage from the criteria for approval of Extensively</li> </ul>	September 1, 2022

Section	Update Description	Effective Date
	<ul> <li>Hydrolyzed Specialty Infant (EH) products with probiotics:</li> <li>"Born full term (between 37 and 42 weeks)"</li> <li>Added additional criteria for approval for amino based (100 percent) products with probiotics:</li> <li>"Have a birth weight greater than 1000 grams."</li> <li>"The formula is not used in the prevention of a chronic or acute disease or condition."</li> <li>Removed the following verbiage from the criteria for approval of amino based (100 percent) products with probiotics:</li> <li>"Born full term (between 37 and 42 weeks)"</li> </ul>	
Section 13.0 – Medical Supplies	<ul> <li>Removed the word "therapeutic" from verbiage related to Continuous Glucose Monitoring (CGM) systems</li> </ul>	September 1, 2022
Section 13.4 – Diabetic Supplies – Continuous Glucose Monitoring (CGM) Systems	<ul> <li>Removed the word "Therapeutic" from Section Heading</li> <li>Removed the word "therapeutic" from verbiage related to Continuous Glucose Monitoring (CGM) systems</li> <li>Updated verbiage of first paragraph to the following: <ul> <li>"Continuous Glucose Monitors may be covered by Medi-Cal Rx with an approved PA meeting the established criteria."</li> </ul> </li> </ul>	September 1, 2022

Section	Update Description	Effective Date
Section	<ul> <li>Update Description</li> <li>Updated verbiage under bullets of Billing Requirements to the following: <ul> <li>"Quantity, frequency, and age restrictions apply. Please refer to the list of Covered Continuous Glucose Monitoring (CGM) Systems for product-specific criteria and restrictions."</li> <li>"Claim quantities are limited to twenty-five (25)within three (3) months documentation of ongoing therapeutic CGM use, and a current or new PA request for a therapeutic CGM. This restriction does not apply to non-therapeutic CGM systems."</li> </ul> </li> <li>Updated verbiage under bullets of Prior Authorization Requirements for CGM to the following: <ul> <li>"For therapeutic CGM and beneficiariesusing Point-of-Care diabetic supplies would not be eligible for approval of therapeutic CGM since it replaces"</li> <li>"For therapeutic CGM and beneficiaries residing in a LTC facility</li> </ul> </li> </ul>	Effective Date
Section 15.1.2 – Medical Supplies Dispensing Quantity Limitations	<ul> <li>setting"</li> <li>Removed the word "therapeutic" from verbiage related to Continuous Glucose Monitoring (CGM) systems</li> </ul>	September 1, 2022
Section 15.1.3 – Controlled Substance Policy	<ul> <li>Renamed heading from "Opioid Management" to "Controlled Substance Policy"</li> </ul>	September 1, 2022

Section	Update Description	Effective Date
Section 15.8 – Physician Administered Drugs (PAD)	<ul> <li>Added the following verbiage:         <ul> <li>"A Physician Administered Drug (PAD)typically administered to a beneficiary and billedin locations that include, but are not limited to, physician's offices, clinics, and hospitals, and are not self- administered by a beneficiary or caregiver."</li> </ul> </li> <li>Updated reference of "Medi-Cal Rx website" to "Medi-Cal Rx Web Portal"</li> <li>Added the following verbiage:         <ul> <li>"NOTE: PADs not listed on the Pharmacy Reimbursable Physician- Administered Drugs list will reject with either NCPDP EC 70 – Product/Service Not Covered or NCPDP EC 816 – Drug Benefit Exclusion, may be covered by Medical. Claims that reject with NCPDP EC 70 must be billed to the beneficiary's medical plan. Claims that reject with NCPDP EC 816 will return the following supplemental message: "Pharmacy Drug Benefit Exclusion. Exception for pharmacy benefit approval may be considered via PA request. May be covered as a medical benefit." Claims should be submitted via the beneficiary's medical insurance, but may, under some circumstances, be submitted to Medi-Cal Rx for a PA review and determination."</li> </ul></li></ul>	September 1, 2022

Section	Update Description	Effective Date
Section 17.0 – COVID-19 Vaccine Coverage, Reimbursement, and OTC Antigen Test Kits	<ul> <li>Update Description</li> <li>Added the following NDCs to Table 17.0-1: COVID-19 Billable NDCs and Maximum Quantity Limitations: <ul> <li>80777028005   Moderna COVID BIV Boostr (Unap)</li> <li>80777028099   Moderna COVID BIV Boostr (Unap)</li> <li>80631010010   Novavax COVID19 Vac. Adj (Unapp)</li> <li>80631010001   Novavax COVID19 Vac. Adj (Unapp)</li> <li>80631010001   Novavax COVID19 Vac. Adj (Unapp)</li> </ul> </li> <li>Added the following verbiage: <ul> <li>A diagnosis code is recommended but is not required to be included on the claim.</li> </ul> </li> <li>Deleted the following verbiage: <ul> <li>NOTE: A diagnosis code is recommended but is not required to be included on the claim.</li> </ul> </li> <li>Deleted the following verbiage under "For Pfizer-BioNTech COVID-19 or Pfizer Booster Dose(s):"</li> <li>Effective for dates of service on or after November 19, 2021, the FDA amended the Emergency Use Authorization (EUA) for the Pfizer- BioNTech coronavirus disease 2019 (COVID-19) Vaccine to allow for the administration of a booster dose to individuals 18 years of age and older who received their second dose of a primary vaccination series at least six</li> </ul>	Effective Date September 1, 2022

•	Added the following verbiage:
	<ul> <li>Effective for dates of service on or</li> </ul>
	after November 19, 2021:
•	The FDA amended the Emergency Use
	Authorization (EUA) for the Pfizer-
	BioNTech coronavirus disease 2019
	(COVID-19) Vaccine to allow for the
	administration of a booster dose to
	individuals 18 years of age and older
	who received their second dose of a
	primary vaccination series at least six
	months ago.
	Deleted the following verbiage under
	"For Moderna COVID-19 Booster
	Dose(s):"
	<ul> <li>Effective for dates of service on or</li> </ul>
	after March 29, 2022, booster doses
	are available to beneficiaries who
	meet the following criteria:
•	Eligible individuals include:
	<ul> <li>Individuals aged 50 years and older.</li> </ul>
	<ul> <li>Individuals aged 18 years and older</li> </ul>
	who have undergone solid organ
	transplantation, or who are living
	with conditions that are considered
	to have an equivalent level of
	immunocompromised at least
	4 months after receipt of a first
	booster dose of any authorized or
	approved COVID-19 vaccine. – Individuals who were administered a
	J&J or Janssen COVID-19 Vaccine for
	both primary dose and booster
	dose.

Section	Update Description	Effective Date
	NOTE: Booster doses of the Moderna	
	COVID19 Vaccine are limited to a half-	
	dose (0.25 mL) of the primary series.	
	• NOTE: The following NDCs are limited	
	to booster doses only:	
	<ul> <li>NDC: 80777027505 (MODERNA COVID-19 BOOSTER)</li> </ul>	
	<ul> <li>NDC: 80777027599 (MODERNA COVID-19 BOOSTER)</li> </ul>	
	Added the following verbiage:	
	<ul> <li>Effective for dates of service on or after November 19, 2021</li> </ul>	
	• The U.S. FDA amended the EUA for the	
	Moderna COVID-19 Vaccine to allow for	
	the administration of a booster dose to	
	individuals 18 years of age and older	
	who received their second dose of a	
	primary vaccination series at least six	
	months ago.	
	<ul> <li>Effective for dates of service on or</li> </ul>	
	after March 29, 2022, booster doses	
	are available for beneficiaries who meet the following criteria:	
	Eligible individuals include:	
	<ul> <li>Individuals aged 50 years and older.</li> </ul>	
	<ul> <li>Individuals aged 18 years and older</li> </ul>	
	who have undergone solid organ	
	transplantation, or who are living	
	with conditions that are considered	
	to have an equivalent level of	
	immunocompromised at least	
	4 months after receipt of a first booster dose of any authorized or	
	approved COVID-19 vaccine.	

Section	Update Description	Effective Date
	<ul> <li>Individuals who were administered a Janssen COVID-19 vaccine for both primary dose and booster dose.</li> <li>Heterologous COVID-19 Booster Dose(s):         <ul> <li>COVID-19 Booster Dose for Immunocompromised:</li> </ul> </li> <li>Added Table 17.0-5: COVID-19 Vaccine Age Limitations for DOS on or after 06/17/2022</li> <li>Added Table 17.0-6: COVID-19 Vaccine Age Limitations for DOS on or after 07/13/2022</li> </ul>	
17.1 – Pediatric COVID-19 Vaccine Coverage	<ul> <li>Added the following verbiage: <ul> <li>Effective for dates of service on or after June 17, 2022, the FDA authorized the use of the Moderna and Pfizer-BioNTech COVID-19 vaccines for children 6 months of age and up.</li> </ul> </li> <li>For Pfizer-BioNTech COVID-19 Vaccines <ul> <li>The FDA amended the EUA to include use of the vaccine in children 6 months through 4 years of age.</li> <li>The vaccine is administered as a 3 dose primary series (3 mg/ 0.2 mL).</li> <li>The first and second doses should be separated by 3 weeks (21 days).</li> <li>The second and third doses should be separated by 8 weeks (56 days).</li> </ul> </li> <li>For Moderna COVID-19 Vaccines <ul> <li>The FDA amended the EUA to include use of the vaccine in children the separated by 8 weeks (56 days).</li> </ul> </li> </ul>	September 1, 2022

Section	Update Description	Effective Date
Section	<ul> <li>The vaccine is administered as a 2 dose primary series.</li> <li>The first and second doses should be separated by at least one month (28 days).</li> <li>A third primary series dose may be administered at least one month (28 days) following the second dose for individuals in this age group who have been determined to have certain kinds of immunocompromise.</li> <li>NOTE: For the following ages, the doses are limited to the following:</li> <li>Individuals aged 6 months to 5 years: 25 mcg</li> <li>Individuals aged 6 to 11 years: 50 mcg</li> <li>Individuals aged 12 to 17 years: 100 mcg</li> <li>Added the following NDCs to Table 17.1-1: COVID-19 Pediatric Billable NDCs and Maximum Quantity Limitations</li> </ul>	Effective Date

### 5. Now Active – Reinstatement of Reject Code 88

#### What is Happening?

Effective July 22, 2022—claim edits for Drug Utilization Review (DUR) requirements are in effect. Specifically, claims may now reject for National Council for Prescription Drug Programs (NCPDP) **Reject Code 88 – Drug Utilization Review Reject Error** for DUR alerts such as drug-drug interactions, high dose, early refill, etc.

#### **Next Steps**

Providers can learn how to avoid and resolve claim rejections for DUR claim edits by referring to the Medi-Cal Rx billing guidelines in the <u>NCPDP Reject Code 88 DUR Reference Guide</u> along with <u>Appendix A: Reject Code 88 DUR: Service Codes Scenarios</u>.

#### **Questions?**

For claims or prior authorization assistance, 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 a year.

You can also submit questions via email to Medi-Cal Rx Education & Outreach at <u>MediCalRxEducationOutreach@magellanhealth.com</u>.

## 6. Code 1 Documentation and Postponement of Implementation of Reject Code 80

#### What Providers Need to Know

Code 1 drugs are restricted to certain medical conditions or specific circumstances. If the prescribed medication is subject to Code 1 restriction, providers are obligated to document the meeting of Code 1 restrictions and to keep that information readily available.

The Department of Health Care Services (DHCS) recently updated the alert titled, "<u>Update:</u> <u>Postponement of Implementation of NCPDP Reject Code 80</u>," originally published on July 12, 2022, to provide additional clarification. Claims submitted to Medi-Cal Rx will <u>not</u> be edited for a diagnosis code (NCPDP Reject Code 80) as planned to begin July 22, 2022.

Providers are reminded of their obligation to document the meeting of Code 1 restrictions and to keep that information readily available. However, if the diagnosis does not meet the Code 1 criteria, prior authorization (PA) will not be required until such time as reinstatement of Medi-Cal Rx PA processes for the drug dispensed have been fully implemented. Claims for the medication may be submitted without an approved PA.

#### What Providers Need to Do

- Review the updated Medi-Cal Rx alert <u>Update: Postponement of Implementation of NCPDP</u> <u>Reject Code 80</u>.
- Refer to the <u>Medi-Cal Rx Contract Drugs List</u> to identify medications with Code 1 requirements.

## Update: Implementation of Phase I, Wave III -Reinstatement of Prior Authorizations for 11 Drug Classes

#### What is Happening?

On May 31, 2022, the Department of Health Care Services (DHCS) announced a proposed plan for reinstatement of claim edits and prior authorizations (PAs), as well as the phasing out of the Transition Policy for Medi-Cal Rx. DHCS presented a three-phase plan that includes reinstatement of PAs for new start medications based upon drug classes. This approach allows providers to initiate PAs on a gradual basis while DHCS continues to grandfather prescriptions with historical claims or PAs.

Phase I, Wave III requires providers to submit PAs for new start medications in 11 identified drug classes (see the appendix in the proposed <u>Reinstatement Plan</u>). Please note the following modifications:

 Wave III, which was previously targeted for late August, will be implemented on September 16, 2022 to allow for the September updates to the Contract Drugs List (CDL) to take effect, as well as additional time for provider readiness and education, and analysis of the impact of Phase I, Wave I.

- New prescriptions for beneficiaries 21 years of age and under, for medications within the 11 drug classes, are excluded. Specifically, new start prescriptions for children and youth within these 11 drug classes will not be subject to PA reinstatement.
  - Note: Medi-Cal Rx product-specific coverage criteria for enteral nutrition products and medical supplies products have not changed or been waived. For prescriptions requiring a PA that do not have an approved PA (or a historical claim) on file, PA requirements will remain in place.

#### What is the Rationale for These Decisions?

Feedback from stakeholder engagement has been critical to the design of the reinstatement plan. Over the course of the past six weeks, DHCS reviewed written feedback and participated in multiple meetings with stakeholder groups including those representing beneficiaries, pharmacies, and prescribers. DHCS has committed to a measured approach for implementation of each phase and wave; postponement of Phase I, Wave III enables Med-Cal Rx to further assess impacts and identify opportunities to improve provider awareness via communication and coordination.

DHCS also recognizes that providers of specialty pediatric services have been significantly impacted by the transition to Medi-Cal Rx. Exclusion of the population 21 years of age and under from Phase I, Wave III prevents additional administrative obligation at this time.

#### Next Steps

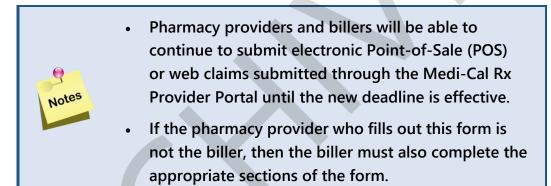
Medi-Cal Rx will issue more detailed information in the coming weeks. In the meantime, providers are encouraged to prepare for reinstatement of PAs for the 11 drug classes in Phase I, Wave III.

- Share this information with vendors, business partners, and staff who need to know about the upcoming change.
- Review Section 14.0 Prior Authorization Overview, Request Methods, and Adjudication of the <u>Medi-Cal Rx Provider Manual</u>.
- Assess business processes and workflows to ensure successful submission of PAs.
- Continue to monitor the Medi-Cal Rx Web Portal as additional alerts and bulletins are published.

## 8. Electronic Claims Agreement – Submission Deadline Extended

Pursuant to the alert published December 13, 2021 ("<u>Medi-Cal Rx Electronic Claims</u> <u>Agreement</u>"), and the latest reminder alert ("<u>Two-Week Reminder: Electronic Claims</u> <u>Agreement – Submission Deadline Extended to July 31, 2022</u>") published July 15, 2022, Medi-Cal Rx has extended the deadline for all participating Medi-Cal Rx pharmacy providers and billers to submit a <u>Medi-Cal Rx Telecommunications Provider and Biller</u> <u>Application/Agreement Form</u> (DHCS 6500) to continue submitting electronic claims without interruption.

## Stakeholders will be notified at least 60 days prior to the new extended deadline submission date.



#### Instructions for Pharmacy Providers and Billers

- 1. Download and print the Medi-Cal Rx Telecommunications Provider and Biller Application/Agreement Form (DHCS 6500).
- For pharmacy chain administrators completing the Medi-Cal Rx Telecommunications Provider and Biller Application/Agreement Form (for Electronic Claims Submission [DHCS 6500]) on behalf of several National Provider Identifiers (NPIs) where the Contact Information and Biller Information are the same, the Medi-Cal Rx Telecommunications Provider and Biller Application/Agreement Form – Supplemental Form (For Electronic Claims Submission) (DHCS 6500-A) can be used. The DHCS 6500-A is supplemental to the DHCS 6500 and does not replace the DHCS 6500.
  - a. If you have already submitted a DHCS 6500 for each individual NPI within your pharmacy chain, it is not required for you to submit a DHCS 6500-A.

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- 3. Complete the form in **blue ink** and verify that all information is correct.
- 4. Return the form with an original signature to the following address:

Medi-Cal Rx Customer Service Center ATTN: Billing Agreement Processing P.O. Box 610 Rancho Cordova, CA 95741-0610

#### Note: Your completed application must be received by the extended deadline.

#### **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.

## 9. Enteral Nutrition Updates to the List of Covered Enteral Nutrition Products, Effective September 1, 2022, and December 1, 2022

The <u>List of Covered Enteral Nutrition Products</u> has been updated on the <u>Medi-Cal Rx Web</u> <u>Portal</u>. The effective date of the additions (Tab 1 on the Excel List) is September 1, 2022, and the effective date of the deletions (Tab 2 on the Excel List) is December 1, 2022. Please refer to the Excel list and the column titled "Effective Date of Change" for the specific dates of changes.

Effective September 1, 2022, the following additions or updates have occurred:

#### Ajinomoto Cambrooke, Inc.

Product Label Name	Medi-Cal 11- Digit Billing Number (NDC)	Description of Change
Enū Nutritional Shake, creamy chocolate, 250 mL tetra x 24 case	24359032324	Added
Enū Nutritional Shake, vanilla creme, 250 mL tetra x 24 case	24359032224	Added

Product Label Name	Medi-Cal 11- Digit Billing Number (NDC)	Description of Change
Glytactin 15 PE Bettermilk powder, orange cream, 40 g x 30 Packets	24359050801	Updated package size, caloric density, protein per gram, and Maximum Allowable Cost (MAC) per gram
Glytactin 15 PE Bettermilk powder, original, 40 g x 30 Packets	24359035001	Updated package size, caloric density, protein per gram, and MAC per gram
Glytactin 15 PE Bettermilk powder, strawberry cream, 40 g x 30 Packets	24359050901	Updated package size, caloric density, protein per gram, and MAC per gram
KetoVie 4:1, chocolate, 30 x 250 mL	24359050103	Updated caloric density
KetoVie 4:1 Plant-based Protein, vanilla, 250 mL tetra x 30 case	24359060303	Added
KetoVie 4:1, unflavored, 250 mL tetra x 30 case	24359050603	Added
KetoVie 4:1, vanilla, 30 x 250 mL	24359050203	Updated caloric density

## Kate Farms, Inc.

Product Label Name	Medi-Cal 11- Digit Billing Number (NDC)	Description of Change
Kate Farms Glucose Support 1.2, vanilla, 250 mL	11112003066	Added
Kate Farms Renal Support 1.8, vanilla, 250 mL	11112003064	Added

## 10. COVID-19 Vaccine: Single Booster Dose for Children Ages 5-11

Effective for dates of service on or after May 17, 2022, the United States Food and Drug Administration (FDA) amended the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine. This amendment authorizes the administration of a single booster dose to individuals from ages 5 through 11. The Centers for Disease Control and Prevention (CDC) recommends a booster of Pfizer-BioNTech vaccine for:

- Most children, at least 5 months after the final dose in the primary series.
- Children who are moderately or severely immunocompromised, at least 3 months after the final dose in the primary series.

# 11. Coming Soon: COVID-19 Vaccine for Children 6 Months and Up

Effective for dates of service on or after June 17, 2022, the U.S. Food and Drug Administration (FDA) amended the Emergency Use Authorizations (EUAs) for the Pfizer-BioNTech and Moderna COVID-19 Vaccines.

#### Pfizer-BioNTech COVID-19 Vaccine

The FDA amended the EUA to include use of the vaccine in individuals 6 months through 4 years of age.

#### Moderna COVID-19 Vaccine

The FDA amended the EUA to include use of the vaccine in individuals 6 months through 17 years of age.

The Department of Health Care Services (DHCS) is aggressively pursuing the necessary system and operational changes required to enable successful claims adjudication for administration of the Pfizer-BioNTech and Moderna COVID-19 Vaccines for this age range.

Medi-Cal will announce when the claims adjudication system is prepared to appropriately adjudicate submitted claims as well as any additional instruction providers should utilize when billing. Until then, providers are advised to administer the primary vaccination series to eligible children, based on recommendations from the FDA and Centers for Disease Control and Prevention, and hold the claim submission until further notice.

For the most current information regarding Medi-Cal's COVID19 response, see the <u>COVID19 Medi-Cal Response page</u> on the Medi-Cal Provider website.

## 12. Inappropriate Treatment Delays and Denials for HIV PrEP and PEP

The Department of Health Care Services (DHCS) has recently learned of inappropriate treatment delays and denials for HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) used to prevent seroconversion to HIV. These incidents have negatively impacted beneficiary health.

In most of the investigated cases, the cause for delay/denial of a service was a lack of information/understanding related to the scope of benefits and/or claims processes involved with billing for the service. DHCS also received reports that some providers shared information with beneficiaries that was misleading, incorrect, or false regarding when prior authorization (PA) is/is not required for HIV medications. DHCS wishes to clarify/remind providers that **HIV medications for both PrEP and PEP are a Medi-Cal benefit when deemed medically necessary.** 

It is the responsibility of pharmacy providers, medical providers, and ancillary staff to be fully informed about the scope of benefits and the proper submission of claims for HIV prevention and treatment medications.

These medications do not require a PA when used as a preventative regimen for persons at risk of acquiring HIV PrEP or for PEP treatment. DHCS wants to ensure timely access to these critical medications.

Although there may be a Code 1 (diagnosis code) restriction for HIV medications, pharmacists are encouraged to override using Submission Clarification Code 7 within the scope of their professional discretion, and/or consider suspected exposure to HIV as an HIV diagnosis for the purposes of claims submission. Diagnosis codes indicating potential exposure to the HIV virus are sufficient documentation of diagnoses meeting the Code 1 requirements. Examples would include diagnosis codes related to sticks from sharp objects that may be contaminated with HIV, encounters with body fluids from a person that may have the HIV virus, or potential transmission through unprotected sexual encounters.