

Medi-Cal Rx Monthly Bulletin

November 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 Medi-Cal Rx Contract Drugs List
- 2. <u>Changes to the Medi-Cal Rx Contract Drugs List Over-the-Counter Drugs and Cough/Cold Preparations</u>
- 3. Changes to the Medi-Cal Rx Pharmacy Reimbursable Physician Administered Drugs
- 4. Updates to the Medi-Cal Rx Provider Manual
- 5. 30-Day Countdown: Phase IV, Lift 4: End of Transition Policy
- 6. How to Resolve Reject Code 76 Plan Limitations Exceeded
- 7. <u>90-Day Countdown: Medi-Cal Managed Care Plan Transition</u>
- 8. Updates to Enteral Nutrition Prescription Requirements
- 9. Enteral Nutrition Shortages
- 10. Now Available: Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form
- 12. COVID-19 Antigen Over-the-Counter Test Coverage Updates, Effective November 1, 2023
- 13. <u>Medical Supplies: Future Changes to Continuous Glucose Monitoring Systems Coverage</u>
 <u>Criteria and Prior Authorization Bundling</u>
- 14. Diabetic Supplies: Updates to the Quantity and Fill Limitations for Diabetic Testing Supplies
- 15. <u>Diabetic Supplies: Updates to the Dexcom G7® Continuous Glucose Monitoring Sensor Package Size Description, Effective October 1, 2023</u>

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 November 1, 2023.

Drug Name	Description	Effective Date
Abacavir Sulfate/Lamivudine/ Zidovudine	Effective December 1, 2023: Labeler restriction removed.	November 1, 2023
Ciprofloxacin HCL/ Dexamethasone	Labeler restriction removed from otic suspension.	November 1, 2023
Crotamiton	Labeler restriction added.	November 1, 2023
Dolutegravir	Effective December 1, 2023: Labeler restriction removed for 10 mg and 25 mg tablets.	November 1, 2023
Elranatamab-bcmm	Added to CDL with labeler restriction.	November 1, 2023
Fluticasone Propionate	Effective December 1, 2023: Labeler restriction removed from oral inhaler without chlorofluoro-carbons as the propellant and oral powder for inhalation.	November 1, 2023
Fosamprenavir Calcium	Effective December 1, 2023 : Labeler restriction removed.	November 1, 2023
Ivermectin	Restriction removed.	November 1, 2023
Maraviroc	Effective December 1, 2023: Labeler restriction removed for 25 mg and 75 mg tablets.	November 1, 2023
Naloxegol Oxalate	Labeler restriction updated.	November 1, 2023
Niraparib and Abiraterone Acetate	Added to CDL with labeler restriction.	November 1, 2023
Simvastatin	Restriction removed from 80 mg tablets.	November 1, 2023
Talquetamab-tgvs	Added to CDL with labeler restriction.	November 1, 2023

2. Changes to the Medi-Cal Rx Contract Drugs List – Over-the-Counter Drugs and Cough/Cold Preparations

The below changes have been made to the <u>Medi-Cal Rx Contract Drugs List – Over-the-Counter Drugs and Cough/Cold Preparations</u> posted to the Medi-Cal Rx Web Portal, effective November 1, 2023.

Drug Name	Description	Effective Date
Fluticasone Propionate	Package size restriction removed from nasal spray.	November 1, 2023
Guaifenesin/ Dextromethorphan	Additional dosage form (tablet) added to CDL with age restriction.	November 1, 2023
Naloxone	Added to the CDL with labeler restriction.	November 1, 2023

3. Changes to the Medi-Cal Rx 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 November 1, 2023.

Drug Name	Description	Effective Date
Agalsidase Beta	Added to Pharmacy Reimbursable	November 1, 2023
	Physician Administered Drugs with	
	prior authorization required.	
Alglucosidase Alfa	Added to Pharmacy Reimbursable	November 1, 2023
	Physician Administered Drugs with	
	prior authorization required.	
Avalglucosidase Alfa-ngpt	Added to Pharmacy Reimbursable	November 1, 2023
	Physician Administered Drugs with	
	prior authorization required.	
Cerliponase Alfa	Added to Pharmacy Reimbursable	November 1, 2023
	Physician Administered Drugs with	
	prior authorization required.	
Cipaglucosidase Alfa-atga	Added to Pharmacy Reimbursable	November 1, 2023
	Physician Administered Drugs with	
	prior authorization required.	
Elosulfase Alfa	Added to Pharmacy Reimbursable	November 1, 2023
	Physician Administered Drugs with	
	prior authorization required.	

Drug Name	Description	Effective Date
Galsulfase	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Idursulfase	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Imiglucerase	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Laronidase	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Olipudase Alfa-rpcp	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Pegunigalsidase Alfa-iwxj	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Taliglucerase Alfa	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Velaglucerase Alfa	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 1, 2023
Vestronidase Alfa-vjbk	Added to Pharmacy Reimbursable Physician Administered Drugs with prior authorization required.	November 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 12.0.

Updates

Section	Update Description	Effective Date
Section 4.4 – Paper Claim(s)	Added language regarding claims with "inner" and "outer" NDCs.	November 1, 2023
Section 4.4.1 – Missing Price (NEW!)	Added language regarding the policy of "inner" and "outer" NDCs.	November 1, 2023

Section	Update Description	Effective Date
Section 12.0 – Enteral Nutrition Products	Updated language pertaining to eligibility requirements.	November 1, 2023
Section 12.3 – Prescription Requirements	Updated signature requirements for prescriptions.	November 1, 2023
Section 12.4 – Documentation Requirements	Refined language pertaining to required and optional documentation.	November 1, 2023
Section 13.0 – Medical Supplies	Language refined.	November 1, 2023
Section 13.1 – Diabetic Supplies – Test Strips and Lancets	 Documentation requirements have been updated. Quantity and frequency limits for test strips and lancets have been updated. 	November 1, 2023
Section 13.2 – Diabetic Supplies – Self-Monitoring Blood Glucose Systems (Glucometers), Control Solutions, and Lancing Devices	 Language removed regarding Code I. Added language pertaining to documentation of pregnancy-related diabetes. 	November 1, 2023
Section 13.3 – Diabetic Supplies – Disposable Insulin Delivery Devices	 Language refined. Billing requirements refined. Prior authorization (PA) requirements refined. 	November 1, 2023
Section 13.4 – Diabetic Supplies – Continuous Glucose Monitoring (CGM) Systems	 Language refined. Billing requirements updated. PA requirements updated. Initial authorization requirements updated. Reauthorization requirements updated. Refill requirements updated. 	November 1, 2023
Section 17.3 – OTC COVID-19 Antigen Test Kits	 Language refined. Removed language pertaining to coverage criteria. Removed language of Code I restriction. 	November 1, 2023
Section 17.3.1 – OTC COVID-19 Antigen Test Kits Reimbursement	Refined language pertaining to billing and dispensing of OTC tests.	November 1, 2023

Section	Update Description	Effective Date
Section 17.5 – Commercial COVID-19 Vaccines (NEW!)	 Added information outlining benefit guidelines for monovalent commercial COVID-19 vaccines. 	November 1, 2023
Section 17.5.1 – Commercial COVID-19 Vaccines Administration Reimbursement (NEW!)	 Added language regarding reimbursement for commercial COVID-19 vaccines. 	November 1, 2023
Appendix C – Aid Codes	Updated language for Aid Code 76 and Aid Code M9.	November 1, 2023

5. 30-Day Countdown: Phase IV, Lift 4: End of Transition Policy

Background

The purpose of this alert is to notify pharmacy providers and prescribers that on November 10, 2023, Phase IV, Lift 4 (P4/L4) will be implemented for members 22 years of age and older.

P4/L4 will:

 Retire the Transition Policy for all pharmacy benefits for members 22 years of age and older.

Note: Members 21 years of age and younger will not be impacted at this time.

- Reinstate prior authorization (PA) requirements for all therapies for standard therapeutic classes (STCs) 68, 86, and 87, which includes enteral nutrition products.
- Reinstate Brand Medically Necessary (BMN) PA requirements for all claims.

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

What Pharmacy Providers and Prescribers Need to Know

PA requirements will be reinstated for all therapies for STCs 68, 86, and 87 for members 22 years of age and older.

Phase IV, Lift 4 (P4/L4) Drug Classes *		
Protein Lysates (STC 68)	Infant Formulas (STC 86)	Electrolytes and Miscellaneous Nutrients (STC 87)

^{*} STC refers to the Standard Therapeutic Classification number.

- Enteral nutrition products are included within STCs 68, 86, and 87.
- Members 21 years of age and younger will not be impacted at this time.

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 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, or 87, pharmacy providers and prescribers should prepare for the 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 <u>Prior Authorization Submission Reminders</u> alert and the <u>Medi-Cal Rx Provider Manual</u> 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).

Reinstatement of BMN PAs for DAW 1

What Pharmacy Providers and Prescribers Need to Know

Claims submitted with a dispense as written (DAW) code of DAW 1 for a brand, multisource product, when the product is not subject to a labeler restriction for the brand drug, will deny for BMN PA requirements. This will be reinstated for claims for members 22 years of age and older.

Note: Claims submitted for brand, multisource drugs that do not have a Maximum Allowable Ingredient Cost (MAIC) or Federal Upper Limit (FUL) price type will not deny for BMN PA requirements.

What Pharmacy Providers and Prescribers Need to Do

If a member is 22 years of age and older and DAW 1 must be submitted on a claim where the product is not labeler restricted and is a multisource brand, pharmacy providers and prescribers should:

• Refer to the <u>Contract Drugs & Covered Products List</u> page on the <u>Medi-Cal Rx Web Portal</u> for labeler code information.

- Submit a BMN PA request via one of the approved Medi-Cal Rx PA submission methods.
- Refer to the <u>Prior Authorization Submission Reminders</u> alert and the <u>Medi-Cal Rx Provider</u> <u>Manual</u> for more information on submitting a PA.

Resources

- Reject Code 80 (Diagnosis) Implementation Date Postponed
- <u>90-Day Countdown: Reinstatement of Prior Authorization Requirements for Enteral Nutrition</u> <u>Products for Members 22 Years of Age and Older</u>
- <u>30-Day Countdown: Reinstatement of Cost Ceiling and Prior Authorization for Enteral Nutrition and Specific Standard Therapeutic Classes</u>
- <u>Medi-Cal Rx Enteral Nutrition Frequently Asked Questions (FAQs)</u>
- Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form
- Prior Authorization Submission Reminders
- Refer to the Reinstatement Spotlight published weekly on the <u>Bulletins & News</u> page.
- <u>Dispense as Written (DAW), Brand Medically Necessary (BMN), and Reimbursement Frequently Asked Questions (FAQs)</u>

6. How to Resolve Reject Code 76 – Plan Limitations Exceeded

Background

The purpose of this alert is to assist providers in resolving Reject Code 76. On September 13, 2023, the <u>30-Day Countdown: Phase IV, Lift III: Reinstatement of Reject Code 76: Plan Limitations Exceeded</u> alert announced the reinstatement of **Reject Code 76 – Plan Limitations Exceeded**.

What Pharmacy Providers and Prescribers Need to Know

Beginning October 13, 2023, claims will be subject to the edit for Reject Code 76. Many of these Quantity Limits (QLs) are outlined in the lists located on the Contract Drugs & Covered Products Lists page. Claims will also be subject to QLs based on U.S. Food and Drug Administration (FDA)-approved or medically accepted maximum daily doses and length of therapy of a particular dose to ensure safe and effective medication use.

QLs may be administered as a quantity over time or a maximum daily dose. Quantity over time is based on dosing guidelines over a rolling time period. Maximum daily dose (maximum quantity per day) is based on maximum number of units of the drug allowed per day. Refer to the specific manufacturer's prescribing information for additional details.

What Pharmacy Providers and Prescribers Need to Do

To resolve Reject Code 76, pharmacy providers and prescribers should:

- 1. Consult the following resources:
 - Contract Drugs Lists & Covered Products Lists page on the Medi-Cal Rx Web Portal
 - Specific manufacturer's prescribing information
 - FDA-approved dosing
- 2. If resubmission of the claim to meet QLs is not appropriate, a prior authorization (PA) is required for coverage consideration. Point-of-sale (POS) overrides are not available.
- 3. When applicable, submit a PA request via one of the five approved Medi-Cal Rx PA submission methods:
 - CoverMyMeds®
 - Medi-Cal Rx Secured Provider Portal
 - NCPDP P4 Transaction
 - Fax
 - U.S. Mail

7. 90-Day Countdown: Medi-Cal Managed Care Plan Transition

Background

The purpose of this alert is to inform pharmacy providers and prescribers of the upcoming changes among Medi-Cal managed care plans (MCPs) in 2024. On September 1, 2023, the Department of Health Care Services (DHCS) provided "go-live" decisions to all Medi-Cal MCPs scheduled to assume operations on January 1, 2024. Under the new MCP contract, all MCPs are required to advance health equity, quality, access, accountability, and transparency. These new contracts will serve approximately 99 percent of all Medi-Cal members and are part of California's transformation of Medi-Cal to ensure members can access the care they need to live healthier lives.

What Pharmacy Providers and Prescribers Need to Know

As part of this transformation, some Medi-Cal MCPs will change on January 1, 2024. These changes require approximately 1.2 million Medi-Cal members in 21 counties to transition to a new health plan. In select counties, Medi-Cal members will have the ability to select from more than one MCP. Refer to the table in the <u>Medi-Cal Managed Care Plans by County (as of 2023 and 2024)</u> document located on the DHCS website for additional information.

• Pharmacy providers should anticipate little change, except members may belong to a new health plan.

Pharmacy providers must use the member's Beneficiary Identification Card (BIC) to submit a claim. Claims billed with the MCP plan ID number will be denied.

More information and communications will be shared as Medi-Cal Rx continues to support pharmacy providers and prescribers during the MCP Transition.

Refer to the <u>Medi-Cal Managed Care Plan Transition</u> page on the DHCS website or the <u>MCP</u> Transition tab on the Medi-Cal Rx Web Portal for current details.

8. Updates to Enteral Nutrition Prescription Requirements

Background

The purpose of this alert is to notify prescribers of the following updates to the Medi-Cal Rx prescription requirements for enteral nutrition products.

- Medi-Cal Rx now allows additional prescriber types to place enteral nutrition orders.
- The height and weight documentation requirement is no longer required on the prior authorization (PA) submission.

All other enteral nutrition prescription and PA requirements remain in place.

What Pharmacy Providers and Prescribers Need to Know

Medi-Cal Rx has modified the prescription requirement for enteral nutrition therapy orders. Effective September 22, 2023, the member's physician, nurse practitioner, clinical nurse specialist, or physician assistant may submit the enteral nutrition orders. Additionally, the height and weight documentation requirement is no longer required. However, this information may assist in determination of cases where additional consideration for quantity limit review is needed.

Updated Enteral Nutrition Prescription Requirements:

- A written or electronic prescription signed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant is required for authorization of all enteral nutrition products.
- The prescriber's full name, address, and telephone number must be clearly supplied if not preprinted on the prescription form.

PA Documentation Requirements:

- Medical diagnosis code related to the product requested.
- Optional: height (length) and weight.

- 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.
- Clinical documentation to support request for non-listed ICD-10 diagnosis, when applicable.

When submitting PAs for enteral nutrition products via fax or U.S. Mail, Medi-Cal Rx recommends utilizing the new <u>Medi-Cal Rx</u> <u>Enteral Nutrition Prior Authorization Request Form</u>.

9. Enteral Nutrition Shortages

Background

On September 7, 2023, Abbott Nutrition announced the continuation of enteral nutrition product shortages. The purpose of this alert is to remind pharmacy providers and prescribers what actions can be taken for members who may be impacted by these shortages.

The enteral nutrition coverage policy was temporarily updated in the *Product Interchangeability* section of the *Medi-Cal Rx Provider Manual* allowing substitutions of contracted enteral nutrition products without the need for a new prior authorization (PA). As a result, this policy will continue and allow for interchangeability among contracted enteral nutrition products which are therapeutically equivalent. Interchange between non-therapeutically equivalent products will require a submission of a PA. For example, specialized diabetic products are interchangeable, but a specialized diabetic product is not interchangeable with a specialized hepatic product.

Prescription requirements remain unchanged. Pharmacy providers and prescribers must meet all prescription requirements, as previously mentioned, when interchanging products.

What Pharmacy Providers and Prescribers Need to Know

To qualify for interchangeability, the following criteria applies and must be documented, either physically or electronically, in the member's file:

- The substituted product must be a contracted enteral nutrition product on the <u>List of Contracted Enteral Nutrition Products</u> published on the <u>Medi-Cal Rx Web Portal</u>.
- The substituted product must be in the same category and must have the same published product use as the original product (refer to the manufacturer's website for specific

- details). Refer to the *Enteral Nutrition Products* section of the *Medi-Cal Rx Provider Manual* for more detailed coverage information.
- The substituted product must be the same kcal/gram, milliliter, or each as the original product. The product substituted must have the same product-specific criteria as the original product. Refer to the <u>List of Contracted Enteral Nutrition Products</u> for product-specific criteria.
- The pharmacy provider must document:
 - The substitution necessity; and
 - The date of the substitution; and
 - The original Rx number for the original product is now unavailable; and
 - The number of refills remaining on the prescription.

Once the prescription is filled with the substituted product, the pharmacy provider will notify the prescriber that a substitution has been made due to a lack of available formula due to shortages or recalls. This notification will inform the prescriber of the updated product currently being administered to the member and allow the prescriber to review, evaluate, and order a change to the enteral nutrition therapy if desired.

- » Claims submitted for the same date of service (DOS) for additional flavors of the enteral nutrition product will deny with Reject Code 83 – Duplicate Paid/Captured Claim.
- » For assistance, refer to the alert titled <u>NCPDP Reject Code 83 Duplicate Paid/Captured Claim</u>.

Affected Products List

For a list of affected enteral nutrition products, view the <u>Abbott Inventory Update: Nutrition Products</u>.

Resources

The following additional resources are available regarding enteral nutrition substitutions:

- Medi-Cal Rx Provider Manual
- <u>Enteral Nutrition Update: Temporary Interchange of Equivalent Contracted Enteral Nutrition</u> <u>Products Due to Recent Formula Recall</u>
- <u>Medi-Cal Rx Policy for Requesting Alternative Medical Supplies or Enteral Nutrition Products</u>
 <u>Due to Supply Shortages</u>
- <u>Enteral Nutrition Updates: Interchange of Equivalent Contracted Enteral Nutrition Product and Specialty Infant Authorization Term Limit</u>
- List of Contracted Enteral Nutrition Products
- Medi-Cal Rx Billing Tips
- NCPDP Reject Code 83 Duplicate Paid/Captured Claim

10. Now Available: Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form

Background

The purpose of this alert is to notify pharmacy providers and prescribers that Medi-Cal Rx has created a new prior authorization (PA) form for enteral nutrition products, which will be available for use beginning September 22, 2023.

Medi-Cal Rx created the <u>Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form</u> to reduce the administrative burden for pharmacy providers and prescribers when submitting a PA for enteral nutrition products via fax or U.S. Mail. The new form includes designated sections to gather product information, route of administration, and clinical justification.

Implementation of this new form reflects the Department of Health Care Services' (DHCS) commitment to better prepare pharmacy providers and prescribers for the reinstatement of PA requirements.

What Pharmacy Providers and Prescribers Need to Know

The <u>Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form</u> is the preferred form when submitting an enteral nutrition PA request via fax or U.S. Mail. However, pharmacy providers and prescribers may continue to utilize any of the five approved PA submission methods to submit PA requests for enteral nutrition products, including:

- CoverMyMeds®
- Medi-Cal Rx Secured Provider Portal
- NCPDP P4 transaction
- Fax
- U.S. Mail

Refer to the section titled *Prior Authorization Overview, Request Methods, and Adjudication* in the <u>Medi-Cal Rx Provider Manual</u> for more information on PA submission.

- » PA submissions for enteral nutrition products will not be accepted prior to September 22, 2023.
- Members 21 years of age and younger are currently exempt and will not be impacted prior to 2024.

What Pharmacy Providers and Prescribers Need to Do

• When submitting PAs for enteral nutrition products via fax or U.S. Mail, Medi-Cal Rx recommends utilizing the new <u>Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form</u>.

- Beginning September 22, 2023, enteral nutrition PA requirements will change. Continue to review the <u>List of Contracted Enteral Nutrition Products</u> to determine if the requested product is covered.
- Review the *Enteral Nutrition Products* section in the <u>Medi-Cal Rx Provider Manual</u> to ensure prescription requirements, billing requirements/limitations, and documentation requirements are met.
- Prepare to submit PAs for enteral nutrition products for members 22 years of age and older:
 - All new start orders for enteral nutrition therapy for members 22 years of age and older will require a PA as of September 22, 2023. PAs for renewing orders for members 22 years of age and older may also be submitted beginning on this date, in advance of retirement of the Transition Policy.

Resources

- Medi-Cal Rx Provider Manual
- <u>List of Contracted Enteral Nutrition Products</u>
- <u>Enteral Nutrition for Members 22 Years of Age and Older: New Start Prior Authorization</u> Reminders
- <u>90-Day Countdown: Reinstatement of Prior Authorization Requirements for Enteral Nutrition Claims for Members 22 Years of Age and Older</u>

11. Respiratory Syncytial Virus (RSV) Vaccines Arexvy™ and Abrysvo™ Now on the Contract Drugs List

Effective October 1, 2023, Arexvy and Abrysvo are included on the <u>Medi-Cal Rx Contract Drugs</u> <u>List</u> and available without a prior authorization (PA), but restricted to the U.S. Food and Drug Administration (FDA) indications.

- **Arexvy** is indicated for active immunization for the prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.
- **Abrysvo** is indicated for active immunization of pregnant individuals at 32 to 36 weeks gestational age for the prevention of lower respiratory tract disease caused by RSV in infants from birth to 6 months. It is also indicated for active immunization for the prevention of lower respiratory tract disease caused by RSV in individuals 60 years of age and older.

12. COVID-19 Antigen Over-the-Counter Test Coverage Updates, Effective November 1, 2023

On February 9, 2023, the U.S. Department of Health and Human Services (HHS) issued <u>Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap</u> which stated that the federal Coronavirus 2019 (COVID-19) public health emergency (PHE) ended on May 11, 2023.

Over-the-Counter (OTC) Emergency Use of Authorization (EUA) U.S. Food and Drug Administration (FDA)-authorized, self-administered COVID-19 antigen test kits will remain a Medi-Cal Rx covered pharmacy benefit, subject to utilization controls and board of pharmacy prescription billing requirements. No changes will occur to the benefit status until October 1, 2024, prior to which the Department of Health Care Services (DHCS) will review the benefit to determine appropriate continuation and coverage criteria. Continue to refer to the Medi-Cal Rx Bulletins & News page for updated information.

The following criteria apply for coverage of these tests as a Medi-Cal Rx pharmacy benefit:

- Restricted for the diagnostic condition of suspected COVID-19 (Code I Restriction); and,
- Restricted to up to 8 tests total (4 kits with 2 tests per kit), currently on the <u>List of Covered Emergency Use of Authorization (EUA) COVID-19 Antigen Tests</u>, per 30 days, per member, where only 1-test-per-kit, or 2-tests-per-kit billing codes (11-digit NDC-like number) are reimbursable, and kits cannot be broken and must be dispensed whole; and,
- No refills allowed. The member would need to obtain a new prescription for each dispensing; and,
- Dispensed from a Medi-Cal Rx pharmacy provider, written (or electronic equivalent) on a prescription signed by a licensed prescriber or a pharmacist; and,
- **(New, effective November 1, 2023)** Pharmacy providers are required to have one-on-one documented contact (in-person, telehealth, or phone) with the member or caregiver prior to dispensing COVID-19 OTC EUA tests; and,
- (New, effective November 1, 2023) The member/caregiver must request the pharmacy provider dispense the COVID-19 OTC EUA tests; autofill is not permitted. Items dispensed without a valid, documented request will be denied as not reasonable or necessary and are subject to post-adjudication audit review by DHCS.

Note: Prior authorization (PA) requests for quantities outside the allowed amounts will be denied unless ordered or administered by a pharmacy provider following an individualized clinical assessment with appropriate medical necessity demonstrated.

To receive a test or test kit, the member must be eligible for Medi-Cal on the date of service (DOS). The *COVID-19 Vaccines, OTC Antigen Test Kits, and Therapeutics: Coverage and Reimbursements* section of the *Medi-Cal Rx Provider Manual* will be updated at a later time on the Medi-Cal Rx Web Portal with additional coverage and reimbursement information.

For the most current information regarding Medi-Cal's COVID-19 response, see the <u>COVID-19</u> <u>Medi-Cal Response</u> page on the Medi-Cal Providers website. For questions concerning the discontinuation of specific COVID-19 benefits, email DHCS at <u>COVID19Apps@dhcs.ca.gov</u>.

13. Medical Supplies: Future Changes to Continuous Glucose Monitoring Systems Coverage Criteria and Prior Authorization Bundling

Medi-Cal Rx is in the process of modifying the system for the coverage criteria for continuous glucose monitoring (CGM) systems as outlined in this alert. A subsequent alert will be published once the system changes have been implemented. The purpose of this alert is to provide advance notice of the upcoming changes.

The coverage criteria for CGM systems will be updated as follows:

Life of the Prior Authorization (PA) Approval:

• CGM initial authorization and subsequent reauthorizations will be for a period of one year, initiating on the date of approval. Each fill can be up to a 90-day supply.

Prescriber Requirement:

• CGM coverage is limited to prescribing by an endocrinologist, a primary care provider (physician [MD or DO]), nurse practitioner (NP), clinical nurse specialist (CNS), physician assistant (PA), or a certified nurse midwife (APRN-CNM), or other licensed healthcare practitioner with experience in diabetes management.

Diagnosis Requirement:

- A diagnosis of either diabetes or gestational diabetes:
 - Diabetes (Type 1 or Type 2) and one of the following other criteria:
 - Insulin-dependence based on regular insulin claim history in the past year or other documentation of regular insulin use; or
 - History of problematic hypoglycemia with documentation demonstrating recurrent (more than one) level 2 hypoglycemic events (glucose <54 mg/dL [3.0 mmol/L]) that persist despite attempts to adjust medication(s) and/or modify the diabetes treatment plan within the past year.
 - Gestational Diabetes:
 - Restricted to approval for the duration of the pregnancy and 12 months postpartum; and
 - Estimated and/or actual date of delivery must be included on the request.

Hemoglobin A1c (HbA1c) Requirement:

 A HbA1c value measured within eight months of the date of the request is documented on the PA request.

Reauthorization Requirement:

Documentation that the member continues to meet CGM PA coverage criteria (see above);
 and

- The member has been seen and evaluated by the prescriber annually, either in-person or virtually through video or telephone conferencing with documentation of:
 - The date of the most recent visit; and
 - The member is using the device as prescribed; and
 - The member is maintaining clinical HbA1c targets defined by the prescriber.

In the future, PA requests will approve all CGM components for the prescribed system within the same authorization. Medi-Cal Rx will inform providers when bundling of PAs for CGM systems are allowed under one authorization.

Currently, the Medi-Cal Rx PA policy for CGM system components allows one PA per requested and contracted billing code/NDC. This 1-to-1 relation ensures tracking for the PA review process and under normal circumstances works appropriately. However, for CGM, this process is creating barriers to access and repetitive work for providers and prescribers. At a future date, for CGM systems with complementary components (example, sensor plus transmitter plus reader), one PA will apply to all components of the CGM system requested by the provider.

More information concerning the bundling process will be published prior to implementation.

14. Diabetic Supplies: Updates to the Quantity and Fill Limitations for Diabetic Testing Supplies

The quantity and fill limitations for diabetic test strips and lancets have been updated to allow up to six per day for pregnancy-related diabetes diagnoses. The *Medi-Cal Rx Provider Manual* will be updated to reflect these changes at a later time.

- A maximum of up to 600 (612 if using the Accu-Chek® Fastclix Lancets) of each product in 100 days (up to 6 test strips and up to 6 lancets, per day) for:
 - A member with a diabetes diagnosis and using insulin; or
 - A member with a pregnancy-related diabetes diagnosis, and up to 12 months postpartum.
- A maximum of up to 100 of each product in 100 days (1 test strip and 1 lancet per day) for a member with a diabetes diagnosis and not using insulin.
- Contracted diabetic lancets and test strips are restricted to members being treated by a prescriber for a diabetes diagnosis or pregnancy-related diabetes diagnosis, documented in their medical records.
- The following must be documented on the prescription, either written or documented electronically in the member's electronic file:
 - The diagnosis; and
 - A description of the item prescribed; and
 - The specific frequency of testing ("as needed" or "PRN" are not acceptable); and
 - The member is an insulin user or a non-insulin user.
 - For pregnancy-related diabetes diagnoses, the member can continue to receive up to 6 per day of both test strips and lancets during the pregnancy and up to 12 months postpartum.

Note: Documentation of the expected or actual delivery date is required.

Coverage is restricted to contracted products found on the <u>List of Contracted Diabetic Test</u> <u>Strips and Lancets</u> which can be found on the <u>Medi-Cal Rx Provider Portal</u> by visiting the <u>Forms & Information</u> page.

Product addition or inclusion on the *List* does not guarantee supply or individual specific coverage.

15. Diabetic Supplies: Updates to the Dexcom G7® Continuous Glucose Monitoring Sensor Package Size Description, Effective October 1, 2023

Effective October 1, 2023, the <u>List of Contracted Continuous Glucose Monitoring (CGM) Systems</u> has been updated on the <u>Medi-Cal Rx Web Portal</u> to update the package size for Dexcom G7 sensors from "3 each" to "1 each." A prior authorization (PA) is required for coverage. Quantity and frequency limits apply. The published maximum acquisition cost (MAC)/maximum allowable product cost (MAPC) price is for each sensor.

Product Label Name	Billing Code (11-digit NDC-like number)	MAC/MAPC per each
Dexcom G7 Sensor, 1 each	08627007701	118.3300

The contractors have guaranteed Medi-Cal Rx providers may purchase, upon request, covered products at or below the MAC for dispensing to eligible Medi-Cal Rx members. Providers can locate MAC price suppliers by calling manufacturer phone numbers referenced in the *List* on the Medi-Cal Rx Web Portal.

Note: Product addition or inclusion on the *List* does not guarantee supply or 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.

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.

