Gold Coast Health Plan℠
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Pharmacy Newsletter

Q4 2024

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The Pharmacy Newsletter is published quarterly for the provider community of Gold Coast Health Plan by the Communications Department.

Information in the Pharmacy Newsletter comes from a wide range of medical experts. If you have any questions regarding its content, please contact GCHP's Director of Pharmacy Services Lily Yip, at lyip@goldchp.org or 1-805-437-5873.

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A Message from the Gold Coast Health Plan Interim Director of Pharmacy Services

Yoonhee Kim

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates related to the use of medications for GCHP members and to stay current with all the updates related to the pharmacy benefit which is now managed by Medi-Cal Rx.

Our goal is to equip providers with the information necessary to safely prescribe medications and to ensure members have access to all necessary pharmaceutical services through Medi-Cal Rx. We are available to help any members or provider as needed.

At GCHP, we know that our providers are interested in providing the best care possible to their patients and our members. We value the role you play in the well-being of our community.

If you have any questions, please feel free to contact me.

Sincerely,

Yoonhee Kim, Pharm.D., APh
Interim Director of Pharmacy Services

Medi-Cal Rx Updates

Prime Therapeutics acquired Magellan Rx in 2023. As a result, there has been a migration of Medi-Cal Rx applications to the new Prime Therapeutics platforms. As of March 25, 2024, all Magellan Medicaid Administration (MMA) Medi-Cal Rx email addresses have transitioned to the Prime Therapeutics domain "@primetherapeutics.com." The updated Medi-Cal Rx Education and Outreach Inbox is now MediCalRxEducationOutreach@primetherapeutics.com.

Changes to the Contract Drugs List (CDL) for Medi-Cal Rx

View the Medi-Cal Rx Contract Drugs List (CDL) on the Medi-Cal Rx Web Portal for the most recent changes to the prescription and over-the-counter drugs lists. Revisions and/or deletions are made monthly. Below is a list of the most recent changes to the CDL for Medi-Cal Rx.

Drug Name	Description	Effective Date
Baricitinib	Added to CDL with diagnosis and labeler restriction.	July 1, 2024
Bismuth Subcitrate Potassium / Metronidazole / Tetracycline HCL	Labeler restriction removed.	July 1, 2024
Contraceptives	Quantity limit updated on tablets, vaginal ring, and transdermal patches.	July 1, 2024
Insulin Lispro Protamine 50% and Insulin Lispro 50%	Vial end-dated.	July 1, 2024
Loteprednol Etabonate / Tobramycin	Labeler restriction added.	July 1, 2024
Methadone HCL	Added to CDL.	July 1, 2024
Nitazoxanide	Added to CDL.	July 1, 2024
Quetiapine Fumarate	Additional strength (150 mg) added to CDL.	July 1, 2024
Tovorafenib	Added to CDL with prior authorization required.	July 1, 2024
Vortioxetine Hydrobromide	Labeler restriction added.	July 1, 2024
Adapalene	Additional strength (0.3% gel) added to CDL.	Aug. 1, 2024
Adapalene / Benzoyl Peroxide	Added to CDL.	Aug. 1, 2024
Asciminib Hydrochloride	Additional strength (100 mg) added to CDL.	Aug. 1, 2024
Betamethasone Dipropionate	Additional formulation (lotion) added to CDL.	Aug. 1, 2024
Betamethasone / Propylene Glycol	Added to CDL.	Aug. 1, 2024
Betamethasone Valerate	Added to CDL.	Aug. 1, 2024

Drug Name	Description	Effective Date
Clindamycin Phosphate / Benzoyl Peroxide	Additional strength (1.2% / 5%) and size (1% / 5%, 25-gram container) added to CDL.	Aug. 1, 2024
Duvelisib	Labeler code 71779 removed.	Aug. 1, 2024
Fluoxetine HCL	Additional strengths (20 mg and 60 mg tablet) added to CDL.	Aug. 1, 2024
Nogapendekin Alfa Inbakicept-pmln	Added to CDL with prior authorization required.	Aug. 1, 2024
Pralsetinib	Labeler code 71332 added.	Aug. 1, 2024
Tacrolimus	Additional formulation (ointment) added to CDL.	Aug. 1, 2024
Tarlatamab-dlle	Added to CDL with labeler restriction.	Aug. 1, 2024
Ciclopirox	Additional formulation (solution) added to CDL.	Sept. 1, 2024
Famciclovir	Added to CDL.	Sept. 1, 2024
Isotretinoin	Added to CDL.	Sept. 1, 2024
Levothyroxine Sodium	Additional strengths (37.5 mcg, 44 mcg, 62.5 mcg capsules) added to CDL.	Sept. 1, 2024
Methylphenidate HCL	Additional formulation (solution) added to CDL with diagnosis and Controlled Substance Policy restriction.	Sept. 1, 2024
Naloxone HCL	Labeler restriction removed from intranasal spray 4 mg/0.1 ml.	Sept. 1, 2024
Praziquantel	Added to CDL.	Sept. 1, 2024
Sodium Fluoride	Additional formulation (paste) added to CDL.	Sept. 1, 2024
Somatropin (Nutropin AQ NuSpin)	**Effective October 1, 2024**: End-dated	Sept. 1, 2024

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

View the Medi-Cal Rx Contract Drugs List – Over-the-Counter Drugs and Cough / Cold Preparations on the Medi-Cal Rx Web Portal for the most recent changes to the prescription and over-the-counter drugs lists. Revisions and/or deletions are made monthly. Below is a list of the most recent changes to the Contract Drug List for Medi-Cal Rx.

Drug Name	Description	Effective Date
Acetaminophen	Additional strength (650 mg suppository) added to CDL.	Aug. 1, 2024
Carboxymethylcellulose sodium	Added to CDL.	Sept. 1, 2024
Docosanol	Added to CDL.	Sept. 1, 2024
Glycerin	Added to CDL.	Sept. 1, 2024
Naloxone HCL	Labeler restriction removed.	Sept. 1, 2024
Sodium Phosphate, Mono Dibasic	Added to CDL.	Sept. 1, 2024

Changes to the List of Contracted Enteral Nutrition Products, Effective Oct. 1, 2024

The List of Contracted Enteral Nutrition Products (List) spreadsheet has been updated on the Medi-Cal Rx Web Portal. View the web portal for the most recent changes. Below is a list of the most recent changes, effective Oct. 1, 2024.

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (Ndc)	Changes
POA Pharma; Nexus Patient Services LLC (Distributor)	PKU Easy Microtabs Plus, 6 x 100 g bottles, unflavored, 600 g Caloric Density: 3.39	50059034007	Added to the List.
Kate Farms, Inc.	Kate Farms Standard 1.4, strawberry, 325 ml Caloric Density: 1.40	11112003080	Added to the List.
Ajinomoto Cambrooke, Inc.	KetoVie 3:1, unflavored, 30 x 250 ml Caloric Density: 1.05	24359050404 (new)	Update to NDC.
Ajinomoto Cambrooke, Inc.	KetoVie 3:1 unflavored, 30 x 250 ml	24359050403	Will be deleted from the List on **Jan. 1, 2025**.
Nutricia North America	GlutarAde GA-1 Amino Acid Blend, powder, unflavored, 454 g	00847075000	Will be deleted from the List on **Jan. 1, 2025**.
Nutricia North America	PhenylAde Amino Acid Blend, powder, unflavored, 454 g	00847095000	Will be deleted from the List on **Jan. 1, 2025**.
Nutricia North America	PhenylAde GMP Mix, powder, original unflavored, 16 x 33.3 g packets	49735014116	Will be deleted from the List on **Jan. 1, 2025**.
Nutricia North America	PhenylAde GMP Mix, powder, vanilla, 16 x 33.3 g packets	49735018304	Will be deleted from the List on **Jan. 1, 2025**.

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (Ndc)	Changes
Nutricia North America	PhenylAde MTE Amino Acid Blend, powder, unflavored, 30 x 12.8 g sachets	00847095964	Will be deleted from the List on **Jan. 1, 2025**.
Nutricia North America	a TYR Lophex GMP Mix-In, unflavored, 20 x 12.5 g powder	49735015757	Will be deleted from the List on **Jan. 1, 2025**.

Note: Product addition or inclusion on the List does not guarantee supply nor individual specific coverage. Products deleted from the List will no longer be reimbursable, even with an approved prior authorization (PA) request, on or after the effective date of deletion.

Changes to Family PACT formulary

Below are the most recent changes to the Medi-Cal Rx Family Planning, Access, Care, and Treatment Pharmacy Formulary, that has been posted to the Medi-Cal Rx Web Portal as of Oct. 1, 2024. View the web portal for the most updated list.

Drug Name	Description	Effective Date
Etonogestrel and Ethinyl Estradiol	Quantity Limit (QL) updated.	June 1, 2024
Levonorgestrel and Ethinyl Estradiol	QL updated.	June 1, 2024
Norelgestromin and Ethinyl Estradiol	QL updated.	June 1, 2024

Reminder: Quantity Limit Restrictions for Anti-Obesity Preparations

Wegovy (semaglutide) and Saxenda (liraglutide) are restricted to a maximum quantity of one carton per dispensing and one dispensing every 28 days. Claims submitted in which the quantity or day supply exceeds the values mentioned will deny Reject Code 76 – Plan limitations exceeded. If resubmission of the claim to meet Code I restrictions is not appropriate, a prior authorization (PA) request is required for coverage consideration.

Drug	Drug Quantity / Days' Supply
Wegovy (Semaglutide)	
0.25 mg/0.5 ml	2 ml/28 days
0.5 mg/0.5 ml	2 ml/28 days
1 mg/0.5 ml	2 ml/28 days
1.7 mg/0.75 ml	3 ml/28 days
2.4 mg/0.75 ml	3 ml/28 days
Saxenda (Liraglutide)	
18 mg/3 ml	15 ml/28 days

For product-specific QLs and utilization management (UM) information, refer to the UM Type and Code I columns in the Medi-Cal Rx Contract Drugs List.

Deactivation of Pharmacy Override Code 55555

Medi-Cal Rx will be deactivating pharmacy override code "55555," which allowed pharmacies to manually override items that typically require PA based on previous usage. Effective Oct. 18, 2024, a prior authorization request will now be required where a "55555" override code was previously used. The deactivation of this code affects all drugs / products for all members in all age groups.

To prepare for the deactivation of override code "55555," it is recommended that pharmacy providers and prescribers:

1. Review the Contract Drugs & Covered Products Lists page on the Medi-Cal Rx Web Portal for covered drugs / products and coverage restrictions.
2. When applicable, submit a PA request with rationale to establish medical necessity to address the Medi-Cal Rx claim UM edit.

For more information related to this change, please view the Deactivation of Override Code "55555" for All Drugs/ Products – Medi-Cal Rx Program Integrity Update on the Medi-Cal Rx Bulletins and News page.

Where to Safely Dispose of Unused Medications

You can now search the CA Board of Pharmacy website for local locations where anyone can dispose of unused medications. Pharmacies may offer two types of drug take-back services: on-site collection bins and/or envelopes for mailing back unused medications. This search tool only offers locations that are registered with the Board of Pharmacy.

COVID-19 Updates

COVID-19 Antigen Over-the-Counter Test Coverage Updates, Effective Oct. 1, 2024

Effective Oct. 1, 2024, quantity restrictions for over-the-counter (OTC) self-administered

COVID-19 antigen tests, which test for diagnosis of a current infection with SARS-CoV-2 (the virus that causes COVID-19), will be updated to allow for **four tests (or two kits for two tests / kit) per 30-day period** *per member*. Medi-Cal Rx restricts coverage to the tests found on the List of Contracted COVID-19 Antigen Over-the-Counter Tests. The coverage of these test will remain as a Medi-Cal Rx pharmacy benefit as per the following criteria listed in the Medi-Cal Rx Provider Manual:

- Restricted to up to four tests total (two kits for two tests / kit) per member per 30 days, currently on the List of Contracted COVID-19 Antigen Over-the-Counter Tests, 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
- 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
- No refills allowed; the member would need to obtain a new prescription for each dispensing; AND
- The member / caregiver must request the pharmacy provider dispense the COVID-19 OTC EUA tests; autofill is not permitted.

For further details and information, refer to Section 17.3 – OTC COVID-19 Antigen Test Kits of the Medi-Cal Rx Provider Manual.

COVID-19 Vaccines Update

As of August 22, 2024, the U.S. Food and Drug Administration (FDA) has approved and granted emergency use authorization for updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2, to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death. In early June, the FDA advised manufacturers of licensed and authorized COVID-19 vaccines that the COVID-19 vaccines (2024-2025 formula) should be monovalent JN.1 vaccines. Based on the further evolution of SARS-CoV-2 and a rise in cases of COVID-19, the agency subsequently determined and advised manufacturers that the preferred JN.1-lineage for the COVID-19 vaccines (2024-2025 formula) is the KP.2 strain, if feasible. The mRNA COVID-19 vaccines have been updated with this formula, as recommended by the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC).

The updated mRNA COVID-19 KP.2 strain vaccines include:

- Comirnaty (by Pfizer-BioNTech), approved for individuals 12 years of age and older.
- Spikevax (by Moderna), approved for individuals 12 years of age and older.
- Moderna COVID-19 Vaccine, EUA for individuals 6 months through 11 years of age.
- Pfizer-BioNTech COVID-19 Vaccine, EUA for individuals 6 months through 11 years of age.

Of note, on August 30, 2024, the FDA also granted emergency use authorization (EUA) for an updated version of the Novavax COVID-19 vaccine. It includes a monovalent (single) component that corresponds to the Omicron variant JN.1 strain of SARS-CoV-2 and is authorized for use in individuals 12 years of age and older. For additional information on the COVID-19 dosing schedule, refer to the COVID-19 Vaccine Timing 2024-25.

Medi-Cal Rx continues to cover COVID-19 and other vaccines. For a full list of vaccines, visit the Medi-Cal Rx Contract Drug List. For additional information, refer to the section titled *COVID-19 Vaccines, OTC Antigen Test Kits, and Therapeutics: Coverage and Reimbursements* in the Medi-Cal Rx Provider Manual.

Pemgarda™ (pemivibart) Now a Medi-Cal Rx Benefit

Effective March 28, 2024, Pemgarda™ is available to Medi-Cal Rx members as a pharmacy benefit contingent upon an approved PA request. Pemgarda is indicated for the pre-exposure prophylaxis of COVID-19 in certain adults and adolescents (12 years of age and older weighing at least 88 lb. [40 kg]) who are moderately or severely immunocompromised and are unlikely to mount an adequate immune response to the COVID-19 vaccination. Pre-exposure prophylaxis helps prevent COVID-19 but does not take the place of vaccination in people who are eligible to receive an updated COVID-19 vaccine.

Physician Administered Drugs and Prior Authorization Requests

This section serves as a reminder that Physician Administered Drugs (PADs) include all infused, injectable drugs provided or administered to a member that is billed by a provider on a medical claim by a Procedure Code (i.e., J-Code). These providers include, but are not limited to, physician offices, clinics, outpatient infusion centers, and hospitals.

Gold Coast Health Plan (GCHP) maintains risk for PADs, and with few exceptions, these medications are not billable under the California Medi-Cal pharmacy benefit program (Medi-Cal Rx). Certain PAD drugs require prior authorization (PA) to ensure medical necessity prior to receiving the drug therapy. Any request for a PAD medication (administered at a provider's office or infusion/hospital facility) via Procedure Code (i.e., J-Code) requiring a PA must be submitted as a Prior Authorization Treatment Request Form to Gold Coast Health Plan (GCHP) to be considered for coverage under the medical benefit. For the most part, PADs are covered under the medical benefit and billed by the provider on a medical claim to GCHP. The provider will need to purchase the drugs from their wholesaler, distributor, or manufacturer (or another internal process at their site of practice) and then administer to the member and later bill GCHP for reimbursement.

Effective Feb. 20, 2024, Physician Administered Injectables List has been re-titled to Physician Administered Drugs (PADs) List and the list has been updated. We will continue to update this list. Please use GCHP's List of Services Requiring Prior Authorizations (see list of Physician Administered Drugs) for the most updated list. You can also find the PAD list and the Prior Authorization Treatment Request Form in the Medical Drug Benefit section located on the GCHP website, under Pharmacy Services for Providers.

Completing a Prior Authorization Treatment Request Form will help expedite the claims processing. If you do not obtain approval, your claims may be delayed or denied until we receive the information needed to establish medical necessity.

For the most part, PADs that require prior authorization, are not billable under Medi-Cal Rx as a pharmacy benefit. The only PADs that are potentially reimbursable under Medi-Cal Rx are included in this list.

As a reminder, all pharmacy benefits billed on a pharmacy claim have transitioned to Medi-Cal Rx and are no longer the responsibility of GCHP. In addition, there are some classes of medications that are carved out of the GCHP benefit and are to be reviewed / billed to the California Medi-Cal FFS for authorization consideration and reimbursement for both pharmacy and medical claims.

Drug Use Review (DUR) Educational Articles

The purpose of this educational intervention component of Drug Use Review (DUR) is to improve the quality and cost-effectiveness of prescribing and dispensing practices for Medi-Cal recipients. Educational interventions include ongoing dissemination of information through the Medi-Cal provider bulletin process about clinically important, drug-specific therapy problems.

Disclaimer: These articles are the result of analyses carried out by the Global Medi-Cal DUR Program and are not official state Department of Health Care Services (DHCS) policies.

The following educational articles have been recently posted since the last pharmacy newsletter:

- Screening, Diagnosis, and Treatment of Chronic Hepatitis C Virus Infection - September 2024
- Risks of Concomitant Statin Therapy with Gemfibrozil - August 2024
- Aspirin for Primary Prevention of Cardiovascular Disease - May 2024

These articles and copies of previous newsletters are available on the GCHP website.

Safe Opioid Utilization and Management: A Guide for Prescribers

Opioids continue to play a critical role in the management of acute and cancer-related pain. However, due to their potential for misuse, addiction, and serious adverse effects, opioid prescribing requires a thorough, evidence-based approach. Prior to initiating opioid therapy, health care providers should evaluate the patient's medical condition and pain management needs, considering non-opioid alternatives when appropriate. Responsible prescribing of opioids also includes mitigating the patient's risk for opioid misuse and overdose with strategies such as, but not limited to, managing opiate use disorder, prescribing opioid reversal agents, and assessing risks associated with the concomitant use of antipsychotics, benzodiazepines, and gabapentin.

Opioid Use Disorder Management

Effective management of opioid use disorder (OUD) is key to safe opioid prescribing. Factors associated with an increased risk in prescription or opioid misuse include, prior history of another substance use disorder, such as nicotine or alcohol use disorder and mental health disorders like pain-related anxiety and post-traumatic stress disorder.

OUD is a chronic condition and should be treated with medications approved for opioid use disorder (MOUD). MOUD is the first line treatment for OUD with clinical goals of safely and effectively reducing or stopping the use of opioids. MOUD includes the following FDA-approved medications that have shown efficacy.

1. Methadone: A long-acting opioid agonist, methadone reduces cravings and withdrawal symptoms by activating opioid receptors at a controlled, steady rate. Methadone up to 100 mg/day is associated with higher retention in treatment and fewer withdrawal symptoms. While methadone does not have a ceiling effect, high doses of methadone can pose a risk of overdose if used beyond an individual's tolerance or when combined with alcohol or sedatives. The recommended approach for methadone as OUD therapy is to start at a low dose and titrate up.
2. Buprenorphine: A partial opioid agonist, buprenorphine has a ceiling effect, limiting its potential for misuse and overdose. It is used to treat withdrawal and helps reduce cravings while minimizing the euphoric effects typical of full opioid agonists. Transmucosal buprenorphine formulations combined with naloxone are the most common mode of MOUD therapy. According to the SAMHSA, the maximum recommended dose for the first day is 8 mg of buprenorphine, while most patients stabilize at doses between 8 and 16 mg, which is then continued as maintenance therapy.
3. Naltrexone: An opioid antagonist, naltrexone blocks the euphoric effects of opioids and is particularly suitable for patients who have completed detoxification. Naltrexone is not an opioid, not addictive, and works by preventing relapse through receptor blockade. For opioid use disorder, naltrexone can be started at a lower dose of 25 mg once daily for a few days and then increased to 50 mg once daily.

As of December 2022, the MAT (Mainstreaming Addiction Treatment) Act has eliminated the DATA-Waiver (X-Waiver) program. All DEA-registered practitioners with Schedule III authority may now prescribe buprenorphine for OUD and SAMHSA (Substance Abuse and Mental Health Services Administration) encourages them to do so. MOUD products currently available on the Medi-Cal Rx Contract Drugs List are listed in Table 1.

Table 1. Medication for Opioid Use Disorders Available on the Medi-Cal Rx Contract Drugs List

Drug and Dosage Form	Strength	UM type
Methadone Tablets	5mg, 10mg	Quantity limit, Max day supply: 35
Buprenorphine Sublingual Tablets	2mg, 8 mg	Quantity limit, Max day supply: 35, Daily dosage limit: 32 mg

Drug and Dosage Form	Strength	UM type
Buprenorphine Transdermal Patch	5 mcg/hour, 7.5 mcg/hour, 10 mcg/hour, 15 mcg/hour, 20 mcg/hour	Quantity limit, Max day supply: 35
Buprenorphine / Naloxone Sublingual Tablets	2 mg/0.5 mg, 8 mg/2 mg, 0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg/0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg	Quantity limit, Max day supply: 35
Buprenorphine / Naloxone Sublingual Film	2 mg/0.5mg, 4 mg/1 mg, 8 mg/2 mg, 12 mg/3 mg	Quantity limit, Max day supply: 35
Naltrexone HCL Tablets	50 mg	

For further information of OUD treatment, visit Medications for Substance Use Disorders - SAMHSA. Patients can also be enrolled into treatment programs near them found on the Opioid Treatment Program Directory.

Overdose Reversal Agents

According to data published on the California Opioid Overdose Surveillance Dashboard, the age-adjusted opioid-related overdose death rate continues to rise. Risk factors for opioid misuse, addiction, and overdose include high cumulative dose from all sources of opioids (such as multiple prescriptions, providers or unprescribed sources), concomitant medications with respiratory depressant effects and certain comorbid conditions (Table 2).

Table 2. Risk factors that increase opioid-induced respiratory depression

Category	Risk Factors
Opioid Use	• ≥ 90 morphine milligram equivalents (MME)/day). • ≥ 4 overlapping opioid prescriptions • Long-acting opioid use. • Injectable opioid use. • Recent period of opioid abstinence. • Excessive doses when switching opioids. • Opioid prescriptions from multiple prescribers. • Opioid prescriptions filled at multiple pharmacies.
Behavioral Health	• Mental health disorder history (undiagnosed or undertreated). • Past substance use or dependence. • Concurrent use of benzodiazepines or sedatives. • Actively taking an antidepressant. • Using an opioid with CNS depressants combined with alcohol. • Using opioids prescribe.
Comorbid Conditions	• Liver, lung, or renal disease. • Respiratory condition (i.e., asthma, sleep apnea).

Overdose reversal medications are safe and effective life-saving tools that play a critical role in a science-based approach to the drug overdose crisis. Current overdose reversal medications — including naloxone (Narcan®, Kloxxado®, Zimhi®, ReVive®) and nalmefene (Opvee®) — are approved to reverse overdoses caused by opioids. Naloxone is a short acting medication that attaches to opioid receptors and reverses the effects of opioids. Nalmefene works in a similar mechanism of action, however it has a five-fold higher binding affinity for opioid receptors and a longer-acting ability. Longer acting antagonists are anticipated to cause longer lasting withdrawal symptoms and potentially cause more harm. As a result, in September 2023, the American College of Medical Toxicology (ACMT) and American Academy of Clinical Toxicology (AACT) recommended naloxone remain the preferred first-line agent until more clinical data supports routine use of Nalmefene.

Naloxone prescriptions can also be written directly to third party individuals who might be likely to witness and assist a person at risk of an opioid overdose. Naloxone products currently available on the Medi-Cal Rx Contract Drugs List are listed in Table 3.

Table 3. Naloxone Products on the Medi-Cal Rx Contract Drugs List

Drug and Dosage Form	Strength	Note
Naloxone HCL Injection	0.4 mg/ml 1.0 mg/ml	
Naloxone HCL Intranasal Spray	4 mg/0.1 ml 8 mg/0.1 ml*	*Restricted to NDC labeler code 55467 for 8 mg/0.1 ml intranasal spray only.
Naloxone HCL Syringe, two-pack	5 mg/0.5 ml*	*Restricted to NDC labeler code 78670 for 5 mg/0.5 ml syringe only.

Refer to the Substance Abuse and Mental Health Administration's (SAMHSA) Opioid Overdose Prevention Toolkit to educate patients, caregivers, and the community about the benefits of having naloxone readily available, the different forms and how to use them.

Side Effects of Antipsychotics and Benzodiazepines with Opioids

In 2021, nearly 14% of overdose deaths involving opioids also involved benzodiazepines, a commonly prescribed sedative. As a result, the Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioids for Pain recommends that clinicians use particular caution when prescribing benzodiazepines concurrently with opioids and consider whether benefits outweigh risks. Key adverse effects of combining these medications include

- Severe Sedation: significant increase in the risk of falls, motor vehicle accidents, and other accidents due to impaired alertness.
- Respiratory Depression: suppressed respiratory function even at therapeutic doses.
- Orthostatic Hypotension: Orthostatic hypotension is exacerbated when antipsychotics are used with opioids, increasing the risk of fainting and falls.

Given these risks, it is recommended to take the following steps to minimize harm according to the FDA:

1. **Assess Risk:** Evaluate the patient's overall health status, history of substance use disorder, and comorbidities prior to initiating or continuing therapy that combines opioids with antipsychotics or benzodiazepines.
2. **Educate Patients:** Clearly inform patients about the risks of combining these medications, emphasizing the importance of strict adherence to the prescribed dosages.
3. **Frequent Monitoring:** Regularly assess patients for signs of CNS depression, including respiratory function and mental alertness. Increased follow-up visits, as well as tools like urine drug screens, may be warranted for high-risk patients.
4. **Reduce Polypharmacy:** Whenever possible, explore non-pharmacologic therapies or non-opioid pharmacologic alternatives to reduce the reliance on multiple CNS depressants.

If risks are determined to outweigh benefits of continuing opioids for pain and benzodiazepine therapy at current dosages, please consider gradually tapering benzodiazepines because abrupt withdrawal may cause rebound effects.

Concomitant Use of Gabapentin and Opioids

Gabapentin and opioids are both commonly prescribed for pain, the likelihood of co-prescription is high, and concerns have been raised about the risks of concomitant therapy. A recent study published in 2017 found that patients who took both medications were at an increased risk of opioid-related overdose compared to those on opioids alone.

The study concluded that the combination of gabapentin and opioids led to a 49% higher risk of opioid-related death compared to opioids alone. The study's findings support the existence of a life-threatening drug–drug interaction between gabapentin and opioids of additive respiratory depression. When combined, opioids prolong the gastrointestinal transit and increases gabapentin bioavailability. Patients with underlying respiratory issues, older age, or higher opioid doses are at the greatest risk.

Please consider the necessity of gabapentin in patients taking opioids and closely monitor for signs of respiratory depression. If co-prescription is deemed necessary, consider closely monitoring the patients and adjusting the opioid dose accordingly.

Conclusion

Safe opioid prescribing requires a patient-centered approach that balances effective pain management with the risks of opioid misuse and overdose. By using appropriate medications for OUD, incorporating reversal agents like naloxone and monitoring for dangerous drug interactions, healthcare providers can mitigate the risks associated with opioid therapy while supporting their patients' pain management needs. For more information and resources, please visit Preventing Opioid Overdose and Medications for Opioid Use Disorder.

Prior Authorization (PA) Overview and tips

Certain medications require prior authorization (PA) before coverage can be applied. The provider should contact Medi-Cal Rx to initiate a PA. Medi-Cal Rx allows requests to be initiated via the following methods:

- NCPDP P4 – Request Only
- Medi-Cal Rx Provider Portal
- CoverMyMeds
- Fax
- United States (US) Mail

Please note that phone requests are not accepted, and members cannot initiate a PA for themselves.

To make the most of your request, the following tips may be useful in facilitating an authorization:

- **Check the CDL** before writing a new prescription. If the drug is not listed, it will require a PA.
- **Review Code I restrictions.** If the medication is listed on the CDL, but has restrictions noted in the "Code I" column, you should document the required information on the prescription hard copy and the pharmacy can override at point of service. **If the patient does not meet the code I restriction indicated on the CDL, a PA will be required.**
- **Consider switching to a covered alternative drug** if the medication you are considering requires authorization. In most cases, Medi-Cal Rx will require a trial of covered medications before approving a drug not listed on the CDL.
- **Request an authorization** if switching to a covered alternative is not an option.
- **Be specific in your request** by including all relevant information in your original PA request. It is always best to include all the following details for the best outcome:
  - Drug name, strength, quantity, and directions.
  - Indicate BOTH the ICD-10 diagnosis code and description of the code.
  - Document prior treatment history.
  - Prescriber rationale. Be specific. If patient has experienced adverse effects, allergies, or other toxicities, you should document this in your request.
  - If continuation of therapy, be sure to document the date patient starting using the medication and include detriments of discontinuing or changing the medication.

If a PA is denied, you may submit an appeal to Medi-Cal Rx. Providers have 180 days from denial date to request an appeal.

FDA Alerts

New to Marketplace Drugs

This information is a list of new drugs recently available in the marketplace. This is only a subset of all drugs that were approved and includes first-time approvals and any other significant drug approvals. Click here to access this information on the FDA website.

Brand Name	Generic Name	Dosage Form	Summary of Indication
FLUMIST	*Influenza Vaccine Live*	INTRANASAL	Indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B for 2 through 49 years of age. Contains a weakened form of live influenza virus strains and is sprayed in the nose. FLUMIST may be administered by a health care provider or by the vaccine recipient or a caregiver who is 18 years of age or older.
YORVIPATH	*Palopegteriparatide*	INJECTION	Indicated for the treatment of hypoparathyroidism in adults.
EBGLYSS	*lebrikizumab-lbkz*	INJECTION	Indicated for the treatment of adult and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. EBGLYSS can be used with or without topical corticosteroids.
OHTUVAYRE	*Ensifentrine*	INHALATION SUSPENSION	Indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.
KISUNLA	*Donanemab-azbt*	INJECTION	Indicated for the treatment of Alzheimer's disease. Treatment with KISUNLA should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

Brand Name	Generic Name	Dosage Form	Summary of Indication
VOQUEZNA	*Vonoprazan fumarate*	ORAL TABLET	Indicated: • For healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. • To maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. • For the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults. • In combination with amoxicillin and clarithromycin for the treatment of helicobacter pylori (h. Pylori) infection in adults. • In combination with amoxicillin for the treatment of h. Pylori infection in adults.
VORANIGO	*Vorasidenib*	ORAL TABLET	Indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection.
LIVDELZI	*Seladelpar lysine*	ORAL CAPSULE	Indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.
LAZCLUZE	*Lazertinib*	ORAL TABLET	Indicated in combination with amivantamab for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.
TEVIMBRA	*Tislelizumab-jsgr*	INJECTION; SOLUTION	Indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.
VAFSEO	*Vadadustat*	ORAL TABLET	Indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

Brand Name	Generic Name	Dosage Form	Summary of Indication
MYHIBBIN	*Mycophenolate mofetil*	ORAL SUSPENSION	Indicated for the prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart or liver transplants, in combination with other immunosuppressants.
ONYDA XR	*Clonidine hydrochloride*	ORAL SUSPENSION, EXTENDED RELEASE	Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy or as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older.
VIGAFYDE	*Vigabatrin*	ORAL SOLUTION	Indicated as monotherapy for the treatment of infantile spasms in pediatric patients 1-month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Drug Safety Labeling Changes

This section includes new safety labeling changes or updated boxed warnings or contraindications. Click here to access this information on the FDA website.

Drug	Type of Change	Change
ALESSE *(ethinyl estradiol; levonorgestrel)*	Boxed Warning Contraindications	WARNING: CIGARETTE SMOKING AND SERIOUS CARDIOVASCULAR EVENTS Cigarette smoking increases the risk of serious cardiovascular events from combined oral contraceptives (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs, including ALESSE, are contraindicated in women who are over 35 years of age and smoke. Contraindications: Combination oral contraceptives should not be used in women with any of the following conditions: • Headaches with focal neurological symptoms or migraine with aura Women with migraine. • Known or suspected carcinoma of the breast or personal history of breast cancer. • Known or suspected estrogen- or progesterone-sensitive malignancy.
ANTARA (MICRONIZED) *(fenofibrate)*	Contraindications	Antara is contraindicated in the following conditions: • Severe renal impairment, including those with end-stage renal disease (ESRD) and those receiving dialysis. • Hypersensitivity to fenofibric acid, fenofibrate, or any of the excipients in Antara. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with fenofibrate.
CEREZYME *(imiglucerase)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
COPIKTRA *(duvelisib)*	Boxed Warning	WARNING: TREAMENT-RELATED MORTALITY AND SERIOUS TOXICITIES: • Infections, Diarrhea or Colitis, Cutaneous Reactions, and Pneumonitis. • Treatment-related mortality occurred in 15% of COPIKTRA-treated patients.

Drug	Type of Change	Change
ELELYSO *(taliglucerase alfa)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS • Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
ESTRASORB *(estradiol hemihydrate)*	Boxed Warning	**Cardiovascular Disorders and Probable Dementia** Only daily oral 0.625 mg CE was studied in the estrogen-alone substudy of the WHI. Therefore, the relevance of the WHI findings regarding adverse cardiovascular events and dementia to lower CE doses, other routes of administration, or other estrogen-alone products is not known. Without such data, it is not possible to definitively exclude these risks or determine the extent of these risks for other products. Discuss with your patient the benefits and risks of estrogen-alone therapy, taking into account her individual risk profile. **Breast Cancer** Only daily oral 0.625 mg CE and 2.5 mg MPA were studies in the estrogen plus progestin substudy of the WHI. Therefore, the relevance of the WHI findings regarding adverse cardiovascular events, dementia and breast cancer to lower CE plus other MPA does, other routes of administration, or other estrogen plus progestogen product is not known. Without such data, it is not possible to definitively exclude these risks or determine the extent of these risks for other products. Discuss with your patient the benefits and risks of estrogen plus progestogen therapy, taking into account her individual risk profile.
FABRAZYME *(agalsidase beta)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
FILSPARI *(sparsentan)*	Boxed Warning	Hepatotoxicity Some Endothelin Receptor Antagonists (ERAs) have caused elevations of aminotransferases, hepatotoxicity, and liver failure. In clinical studies, elevations in aminotransferases (ALT or AST) of at least three-times the Upper Limit of Normal (ULN) have been observed in up to 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.
FOSRENOL *(lanthanum carbonate)*	Contraindications	Contraindicated in patients with: • Hypersensitivity to FOSRENOL or to any ingredient in the formulation. • Bowel obstruction, including ileus and fecal impaction.

Drug	Type of Change	Change
FUROSCIX *(furosemide)*	Contraindications	FUROSCIX is contraindicated in patients with anuria. FUROSCIX is contraindicated in patients with a history of hypersensitivity to furosemide, any component of the FUROSCIX formulation, or medical adhesives.
INREBIC *(fedratinib hydrochloride)*	Boxed Warning	WARNING: ENCEPHALOPATHY INCLUDING WERNICKE'S Serious and fatal encephalopathy, including Wernicke's, has occurred in patients treated with INREBIC. Wernicke's encephalopathy is a neurologic emergency. Assess thiamine levels in all patients prior to starting INREBIC. Do not start INREBIC in patients with thiamine deficiency, replete thiamine prior to treatment initiation. While on treatment, all patients should receive prophylaxis with daily oral thiamine and should have thiamine levels assessed as clinically indicated. If encephalopathy is suspected, immediately discontinue INREBIC and initiate parenteral thiamine. Monitor until symptoms resolve or improve and thiamine levels normalize.
KANUMA *(sebelipase alfa)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
LACTATED RINGER'S IN PLASTIC CONTAINER *(calcium chloride; potassium chloride; sodium chloride; sodium lactate)*	Contraindications	Lactated Ringer's Injection, USP is contraindicated in: • Newborns (under 28 days of age) receiving concomitant treatment with ceftriaxone, even if separate infusion lines are used due to the risk of fatal ceftriaxone-calcium salt precipitation in the neonate's bloodstream. • Patients older than 28 days, including adults, ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Lactated Ringer's Injection, USP through the same infusion line (e.g., via a Y-connector). If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.
NAGLAZYME *(galsulfase)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
PROGLYCEM *(diazoxide)*	Contraindications	PROGLYCEM is contraindicated in patients with Functional hypoglycemia.

Drug	Type of Change	Change
STRENSIQ *(asfotase alfa)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy.
TOFIDENCE *(tocilizumab-bavi)*	Boxed Warning	If a serious infection develops, interrupt TOFIDENCE until the infection is controlled. Reported infections include: • Active tuberculosis, which may present with pulmonary or extrapulmonary disease. • Patients, except those with COVID-19, should be tested for latent tuberculosis before TOFIDENCE use and during therapy.
VPRIV *(velaglucerase alfa)*	Boxed Warning	WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement and after extended duration of therapy.
FEXINIDAZOLE	Contraindication	FEXINIDAZOLE Tablets are contraindicated in patients with severe hepatic impairment.
GANIRELIX ACETATE	Contraindications	Ganirelix Acetate Injection is contraindicated under the following conditions: • Known hypersensitivity to Ganirelix Acetate or to any of its components including dry natural rubber / latex which may be contained in the rigid needle shield. • Known hypersensitivity to GnRH or any other GnRH analog. • Known or suspected pregnancy.

Drug Shortages

This section documents drug shortages that were updated in the past 30 days that affect the prescription benefit for GCHP. Click here to access this information on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Bacitracin ophthalmic ointment, 500 unit/gram, 3.5-gram tube	• Padagis	Padagis temporarily discontinued bacitracin ophthalmic ointment in July 2024 and the company cannot estimate when product will be available again.
Combipatch (estradiol and norethindrone acetate transdermal system) 0.05/0.14 mg/day 0.05/0.25 mg/day	• Noven	Noven did not provide a reason for the shortage. Noven has Combipatch 0.05/0.14 mg/day and 0.05/0.25 mg/day transdermal systems on back order and the company estimates a release date of late-September 2024. The company provides a local pharmacy locater number that is available for all of their brand name products. This general number is 800-420-2719.
Trihexyphenidyl hydrochloride oral solution 2 mg/5 mL (0.4 mg/mL) 473 mL bottle	• Pharmaceutical Associates, Inc.	Pharmaceutical Associates (PAI) did not provide a reason for the shortage. Pharmaceutical Associates is the sole supplier of trihexyphenidyl oral solution. The oral tablets are not affected by this shortage. Pharmaceutical Associates has trihexyphenidyl oral solution on back order and the company cannot estimate a release date.
Nystatin oral suspension 100,000 unit/mL 473 mL bottle 60 mL bottle	• Leading Pharma • Pharmaceutical Associates • Wockhardt	• Leading Pharma did not provide a reason for the shortage. • Pharmaceutical Associates did not provide a reason for the shortage. • Wockhardt discontinued nystatin suspension and the company is distributing remaining inventory (short-dated). Nystatin oral suspension, Pharmaceutical Associates, Inc., 100,000 unit/mL, 473 mL bottle, NDC 00121-1045-16 is currently available. • Leading Pharma has nystatin 100,000 unit/mL suspension in 60 mL and 473 mL bottles on allocation. • Pharmaceutical Associates has nystatin 100,000 unit/mL suspension in 60 mL sizes on back order and the company cannot estimate a release date.
Udenyca *(Pegfilgrastim-cbqv)* subcutaneous injection 6mg/0.6 mL prefilled syringe single-dose auto injection	• Coherus Biosciences	• Coherus has Udenyca on shortage due to third-party manufacturing constraints related to labeling and packaging of the product. The company estimates supplies will be depleted by mid-October 2024. Supplies are expected to gradually become available again starting in early-November 2024. • There is insufficient supply for usual ordering.

Drug Product	Affected Manufacturers	Summary
Zirabev *(Bevacizumab-bvzr)* injection, 25mg/mL 16 mL vial 4 mL vial	• Pfizer	• Pfizer has Zirabev on shortage due to manufacturing delays. Pfizer has Zirabev 25 mg/mL 4 mL vials on allocation. The 16 mL vials are expected to be depleted in September and the company estimates a release date of late-November 2024. Both presentations are on a Medical Reserve for emergency requests. • There is insufficient supply for usual ordering.
Depo-Estradiol *(Estradiol Cypionate)* intramuscular oil Injection, 5mg/ml 5 mL vial	• Pfizer	• Pfizer has Depo-Estradiol on shortage due to manufacturing delays. They are sole suppliers, and the company estimates a release date of October 2024.
Simulect *(Basiliximab)* Injection 10 mg vial 20 mg vial	• Novartis	• Novartis has Simulect on shortage due to manufacturing delays. Novartis has Simulect 10 mg and 20 mg vials on intermittent back order and the company is releasing product as it becomes available. • There is insufficient supply for usual ordering.

Drug Recalls

This section includes drug recalls that have been reported by the FDA this quarter. Click here to view this information on the FDA website. Click company name under Company column below for full alert.

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
Sept. 26, 2024	Oxbryta *(voxelotor)*	Pfizer Inc., the manufacturer of Oxbryta, announced it is voluntarily withdrawing the medication from the market, ceasing distribution, and discontinuing all active clinical trials and expanded access programs for Oxbryta because recent data indicate the benefit of Oxbryta does not outweigh the risks for the sickle cell patient population. The data suggest an imbalance in vaso-occlusive crises and fatal events which require further assessment.	Pfizer	All lots
Sept. 23, 2024	Veklury® *(remdesivir)* for Injection 100 mg/vial	Gilead Sciences, Inc. (Nasdaq: GILD) today announced it is issuing a voluntary recall of one lot of Veklury® (remdesivir) for Injection 100 mg/vial, to the consumer level. Gilead received a customer complaint and confirmed the presence of a glass particle in the vial during the company's investigation. Risk Statement: The administration of an injectable product that contains glass particles may result in local irritation or swelling in response to the foreign material. The glass particulate can potentially travel through the blood vessels to various organs and block blood vessels in the heart, lungs or brain, which can cause stroke and even lead to death.	Gilead	NDC: 61958-2901-02 Lot #: 47035CFA Exp: 11/2025

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
Sept. 18, 2024	Atovaquone Oral Suspension, 750 mg/mL	Bionpharma Inc. is voluntarily recalling (1) single Batch (2310083) of Atovaquone Oral Suspension, 750mg per mL to the consumer level. The product was manufactured by CoreRx, Inc. in Clearwater, FL and distributed by Bionpharma Inc. The product was found to be contaminated with Cohnella bacteria. Risk Statement: In the population most at risk, immunocompromised population, there is a reasonable probability that microbial contamination of Atovaquone Oral Suspension can result in disseminated, life threatening infections such as inflammation of the heart and permanent damage to soft tissue.	BionPharma	NDC: 69452-252-87 Lot #: 2310083 Exp: 9/2025
Aug. 8, 2024	0.9% Sodium Chloride for Injection USP 1000 mL in E3 containers	B. Braun Medical Inc. (B. Braun) is voluntarily recalling two (2) lots of 0.9% Sodium Chloride for Injection USP 1000 mL in E3 containers within the U.S. to the consumer level. The voluntary recall has been initiated due to the potential for particulate matter and fluid leakage of the respective containers. The affected batches were inadvertently released to the market prior to the completion of the required acceptance activities for embedded particulate matter which may result in leakage.	B Braun	NDC: 0264-7800-09 Lot #: J2L763 Exp: 3/31/2025 Lot #: J2L764 Exp: 3/31/2025
Aug. 6, 2024	Heparin Sodium in 0.9% Sodium Chloride Injection, 2,000 units per 1,000 mL	Baxter International Inc. (NYSE:BAX) is voluntarily recalling one lot of Heparin Sodium in 0.9% Sodium Chloride Injection to the consumer level due to the potential for elevated endotoxin levels based on issues related to the bacterial endotoxin test specific to lot number N008235. Use of heparin with higher than acceptable endotoxin levels may lead to significant adverse health consequences ranging from febrile reactions to toxic shock, multi-organ failure and death.	Baxter	NDC: 0338-0433-04 Lot #: N008235 Exp: 8/31/2024

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
July 24. 2024	Acetaminophen 250mg; Aspirin 250mg; Caffeine 65mg tablets – 100ct bottles	Aurobindo Pharma USA, Inc. on behalf of AuroHealth, Issues Voluntary Nationwide Recall of one (1) Lot of Healthy Living Over the Counter (OTC) Migraine Relief: Acetaminophen 250mg; Aspirin 250mg; Caffeine 65mg Tablets, Due to Missing Manufacturer Label Aurobindo Pharma USA, Inc., on behalf of AuroHealth, is voluntarily recalling one lot of Healthy Living Migraine Relief, Acetaminophen 250mg, Aspirin (NSAID) 250mg & Caffeine 65mg tablets, to the consumer level as sold through Amazon to known within the US market due to the product missing the manufacturer label.	Healthy Living	NDC: 58602-882-21 Lot #: AC2523005A Exp: 6/2025
July 22, 2024	Hikma brand Acetaminophen Injection USP, 1,000 mg per 100 mL (10 mg/mL)	Hikma Pharmaceuticals PLC (Hikma, Group) announced that its subsidiary Hikma Pharmaceuticals USA, Inc. is extending its voluntary recall of one lot of Acetaminophen Injection, 1000mg/100mL, (10mg/mL) to the consumer/user level. The product is being recalled due to the potential presence of a bag labelled Dexmedetomidine HCL Injection (400mcg/100mL) inside the overwrap that is labelled Acetaminophen Injection, 1000mg/100mL, (10mg/mL). If the provider does not identify the drug inside the acetaminophen overwrap as dexmedetomidine and administers the drug to a patient, there are multiple potential adverse outcomes that may result including varying degrees of sedation, bradypnea, bradycardia, hypertension, and hypotension or more serious and potentially life-threatening outcomes.	Hikma	NDC: 0143-9386-10 and 0143-9386-01 Lot #: 24070381 Exp: 9/2025

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
July 17, 2024	Clonazepam Orally Disintegrating Tablets, USP 0.25 mg 60-count carton Clonazepam Orally Disintegrating Tablets, USP 0.125 mg 60-count carton	Endo, Inc (OTCQX: NDOI) ("Endo"), announced that one of its operating subsidiaries, Endo USA, Inc., is voluntarily recalling one lot of Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.25 mg tablets, which may also appear as Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.125 tablets 60-count pack to the consumer level. The product lot is being recalled due to mislabeling where an incorrect strength appears on the cartons of some packs to show the product strength as 0.125 mg and not 0.25 mg due to an error at a third-party packager. The blister strips inside the product pack reflect the correct strength of 0.25 mg. Risk Statement: Children and adults who are inadvertently prescribed a two-fold overdose of clonazepam would be at risk for the adverse effects of significant sedation, dizziness, ataxia, and confusion. There is reasonable probability for significant, possibly life-threatening, respiratory depression especially for patients with concomitant pulmonary disease, patients who have prescribed dosing near maximal dosing, and patients also taking other medications that could cause additional respiratory depression.	Par Pharmaceutical	The product is packaged in cartons of 60 tablets; the package labels feature the product name, strength, lot number, and expiration date, and the National Drug Code (NDC) number 49884-307-02; impacted units will display the NDC code 49884-306-02. This recall impacts the following product lot: Clonazepam Orally Disintegrating Tablets, USP 0.25 mg 60-count carton Lot #: 550147301 Exp: 8/2026 Clonazepam Orally Disintegrating Tablets, USP 0.125 mg 60-count carton Lot #: 550147301 Exp: 8/2026

Gold Coast Health Plan℠
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Pharmacy Newsletter

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For additional information, contact the
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