Gold Coast Health Plan℠
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Pharmacy Newsletter

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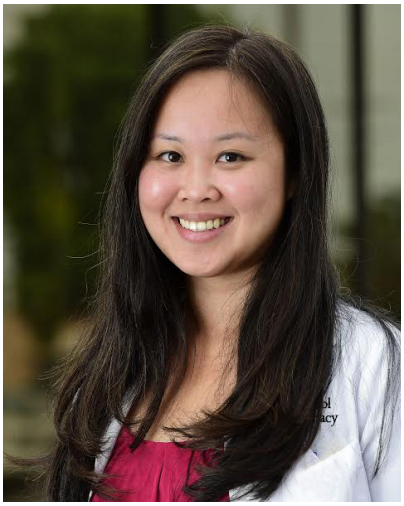
A Message from the Gold Coast Health Plan Director of Pharmacy Services



Lily Yip, Pharm.D., APh, CDCES, BCACP

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,

Lily Yip, Pharm.D., APh, CDCES, BCACP
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. On March 25, 2024, all Magellan Medicaid Administration (MMA) Medi-Cal Rx email addresses transitioned to the Prime Therapeutics domain "@primetherapeutics.com." The updated Medi-Cal Rx education and outreach inbox is now MediCalRxEducationOutreach@primetherapeutics.com.

Medi-Cal Rx - Updated Drug Lookup Tool

The Drug Lookup Tool, located on the Medi-Cal Rx website, has been updated to be more user friendly. You can now use this tool to look up drugs by brand or generic and it will list the National Drug Code (NDC) and all dosages available in the marketplace. You can also use this tool to determine if a prior authorization (PA) is required or if there are any Code 1 restrictions. There is also a link to CoverMyMeds to submit an electronic prior authorization (ePA). For instructions on how to use this feature, click here.

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 on a monthly basis. Below is a list of the most recent changes to the Contract Drug List for Medi-Cal Rx.

Drug Name	Description	Effective Date
Bosutinib	Additional formulation (capsules) added to CDL with labeler restriction.	April 1, 2024
Brinzolamide	Labeler code 00065 removed.	April 1, 2024
Brinzolamide / Brimonidine Tartrate	Labeler code 00078 removed.	April 1, 2024
Ciprofloxacin Hydrochloride / Hydrocortisone	Labeler code 00065 removed.	April 1, 2024
Copanlisib	End-dated.	April 1, 2024
Dapagliflozin Propanediol / Metformin HCL Extended Release	Additional strength (2.5 mg/1000 mg) added to CDL. Labeler restriction added to drug.	April 1, 2024
Edaravone	Added to CDL with labeler restriction.	April 1, 2024
Empagliflozin	Labeler restriction added.	April 1, 2024
Fosfomycin	Added to CDL.	April 1, 2024
Glucagon (R-DNA Origin)	Labeler code 00002 removed.	April 1, 2024
Glycopyrrolate and Formoterol Fumarate	Labeler restriction added.	April 1, 2024
Ipratropium Bromide and Albuterol Sulfate	Labeler restriction added to inhaler.	April 1, 2024

Drug Name	Description	Effective Date
Lenvatinib	Additional strength (12 mg/ day) added to CDL with labeler restriction.	April 1, 2024
Mobocertinib	End-dated.	April 1, 2024
Perampanel	Labeler restriction added to tablets and suspension.	April 1, 2024
Tetracycline	Tablets end-dated.	April 1, 2024
Tobramycin with Dexamethasone	Labeler code 00065 removed from ophthalmic ointment.	April 1, 2024
Travoprost	Labeler code 00065 removed.	May 1, 2024
Cabergoline	Added to CDL.	May 1, 2024
Doxycycline Monohydrate	75 mg capsules end-dated	May 1, 2024
Hydrocortisone	Additional formulation (suppository) added to CDL.	May 1, 2024
Ibrutinib	560 mg tablets end-dated.	May 1, 2024
Insulin Aspart	Labeler restriction added.	May 1, 2024
Insulin Aspart Protamine Suspension / Insulin Aspart (rDNA Origin)	Labeler restriction added.	May 1, 2024
Lithium Carbonate	Additional strengths (150 mg capsule and 450 mg ER tablet) added to CDL.	May 1, 2024
Minoxidil	Added to CDL.	May 1, 2024
Mirtazapine	Additional strength (7.5 mg) added to CDL.	May 1, 2024
Omacetaxine Mepesuccinate	End-dated.	May 1, 2024
Penicillin G Benzathine	Additional formulation (powder for injection) added to CDL.	May 1, 2024
Progesterone	Additional formulation (capsules, micronized) added to CDL.	May 1, 2024
Saquinavir Mesylate	End-dated.	May 1, 2024
Saxagliptin / Metformin HCL Extended-Release	Labeler restriction removed.	May 1, 2024
Selenium Sulfide	Added to CDL.	May 1, 2024
Alendronate Sodium / Cholecalciferol	Labeler code 00006 removed.	June 1, 2024

Drug Name	Description	Effective Date
Epinephrine	Quantity limit removed from auto-injector.	June 1, 2024
Evolocumab	**Effective July 1, 2024:** Single-dose Pushtronex system end-dated.	June 1, 2024
Ganciclovir	Quantity limit removed from ophthalmic gel.	June 1, 2024
Granisetron Hydrochloride	Quantity limit removed from tablets.	June 1, 2024
Iloperidone	Labeler code 00078 removed. Additional formulation (titration pack) added to CDL.	June 1, 2024
Nystatin / Triamcinolone	Added to CDL.	June 1, 2024
Oxybutynin	Labeler code 52544 removed.	June 1, 2024
Pralsetinib	**Effective July 1, 2024:** Labeler code 72064 removed.	June 1, 2024
Risperidone	Additional formulation (oral disintegrating tablets) added to CDL.	June 1, 2024
Smallpox / Mpox Vaccine	Added to CDL with age restriction.	June 1, 2024
Saxagliptin HCL	Labeler restriction removed.	June 1, 2024

Medi-Cal Rx: Coverage Guidelines for Covered Medical Supplies

See below for a quick reference guide listing some of the commonly prescribed medical supplies for diabetes, hypertension, and/or asthma that are covered under the pharmacy benefit. Any prior authorizations (Pas) that are required, quantity limits, and billing notes are also listed below.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Alcohol Prep Pads	No	200 per 30-day period.	None

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Blood glucose test strips for blood glucose monitor **(*change effective Oct. 5, 2023)**	No	Quantity limits are based upon documented insulin usage and are restricted to up to six test strips per day. Up to 600 test strips per 100 days for insulin users or up to 100 test strips per 100 days for non-insulin users; Code I for diabetes diagnosis and insulin or non-insulin user must be documented on the prescription and is subject to audit. ***Policy was updated to allow up to six per day for pregnancy-related diabetes diagnoses.**	Code I Restriction for a diabetes diagnosis and insulin usage. Provider must document on the electronic or written prescription the beneficiary is an insulin user or non-user. ***For pregnancy-related diabetes diagnoses, the member can continue to receive up to six per day of both test strips and lancets during the pregnancy and up to 12 months postpartum.**
Blood pressure monitoring devices for personal home use	No	One monitoring device every five years.	Code I diagnosis of any ICD-10-CM diagnosis code that justifies medical necessity for cardiovascular monitoring for a chronic condition or on a regular basis; documentation in the electronic file or on the prescription is required. Wrist personal blood pressure monitoring devices are not a Medi-Cal Rx benefit.
Blood pressure cuff for use with home BP device	No	One cuff per 365 days.	Code I diagnosis of any ICD-10-CM diagnosis code that justifies medical necessity for cardiovascular monitoring for a chronic condition or on a regular basis; documentation in the electronic file or on the prescription is required. Wrist cuffs are not a Medi-Cal Rx benefit.
Blood ketone test or reagent strip	No	10 per claim and no more than three claims in a 90-day period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Control solution for blood glucose monitor	No	One every 365-day period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.
Disposable insulin delivery devices	Yes	PA required.	• For Omnipod systems, 10 pods every 30 days with a maximum of a 90-days-supply. • For V-Go Series, 30 pods every 30 days with a maximum of a 90-day supply.
Inhaler, Assist Devices (spacer, bag, or reservoir, with or without mask, for use with metered dose inhaler)	No	Two per 365-day period.	None.
Lancets	No	Quantity limits are based upon documented insulin usage and are restricted to up to six lancets per day. Up to 600 lancets per 100 days for insulin users or up to 100 lancets per 100 days for non-insulin users; Code 1 for diabetes diagnosis and insulin or non-insulin user must be documented on the prescription and is subject to audit.	Code I Restriction for a diabetes diagnosis and insulin usage. Provider must document on the electronic or written prescription the beneficiary is an insulin user or non-user.
Lancing Device	No	One every 365-day period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.
Peak flow meters, non-electronic	No	One per 365-day period.	None.
Pen needles **(*change effective Jan. 1, 2024)**	No	***Limited to six pen needles per day and a maximum of four fills every 100 days.**	None.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Self-monitoring blood glucose monitor (glucometer)	No	One glucometer every five-year period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.
Syringe, Insulin U-500 **(*change effective Jan. 1, 2024)**	No	***Limited to three syringes per day and a maximum of four fills every 100 days.**	Code I Restriction for use with Insulin, Regular, U-500 only.
Syringes, insulin, any size **(*change effective Jan. 1, 2024)**	No	***Limited to six syringes per day and a maximum of four fills every 100 days.**	None.
Therapeutic continuous glucose monitor (CGM)	Yes	PA required.	Refer to the List of Contracted Continuous Glucose Monitoring (CGM) Systems for product-specific coverage restrictions.

Note, this is not an all-inclusive list and information is subject to change per Medi-Cal Rx. For a complete list of covered medical supplies under the pharmacy benefit and the most up-to-date information, click here. For a complete list of all the contracted and covered products, click here.

Changes to the Contracted Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs for Medi-Cal Rx

View the Contracted Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs for Medi-Cal Rx spreadsheet on the Medi-Cal Rx Web Portal for the most recent changes.

Blood pressure monitoring devices and cuffs not on this list can be covered through medical benefit. For medical benefit coverage for Blood Pressure Monitors and Cuffs, please find a contracted durable medical equipment (DME) vendor listed in Gold Coast Health Plan Provider Directory (DME pg. 213) then send the order to the DME vendor.

The following pharmacies have confirmed they are able to order the covered blood pressure monitors and can bill Medi-Cal Rx:

Pharmacy Name	Address	Phone Number
Seena Pharmacy	3901 Las Posas Road #101, Camarillo, CA 93010-1501	1-805-419-2686
Medical Plaza Pharmacy	1700 North Rose Avenue, Suite 140, Oxnard, CA 93030-3790	1-805-981-3366
Stan's Drugs	3001 Saviers Road, Oxnard, CA 93033-5312	1-805-486-2678
OMAC Pharmacy	901 West 7TH Street, Oxnard, CA 93030-6755	1-805-486-2688
Simi Pharmacy	1357 East Los Aneles Avenue, Suite C, Simi Valley, CA 93065-2805	1-805-582-7474

Find A Pharmacy

To find the nearest pharmacy where prescriptions can be picked up, use the Medi-Cal Rx Find a Pharmacy tool. Medi-Cal members can now pick up their prescriptions at Costco Pharmacies. Costco Membership is not required to access their pharmacy. Please review the state Department of Health Care Services (DHCS) press release.

Physician Administered Drugs (PADs) and Prior Authorization (PA) 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 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, the Physician Administered Injectables List has been re-titled to Physician Administered Drugs List. The list has also been updated. We will continue to update this list. Please use the GCHP's List of Services Requiring Prior Authorizations (see list of Physician Administered Drugs) for the most updated list.

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 PA, 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 state Medi-Cal FFS for authorization consideration and reimbursement for both pharmacy and medical claims.

Advisory Committee on Immunization Practices (ACIP) Recommendation Update

Advisory Committee on Immunization Practices (ACIP) approved the following recommendation at the June 26-28, 2024, meeting:

- **RSV Vaccines**
  - » ACIP recommends adults 75 years of age and older receive a single dose of RSV vaccine.
  - » ACIP recommends adults 60-74 years of age and older who are at increased risk of severe RSV disease receive a single dose of RSV vaccine.

- **COVID-19 Vaccines**
  - » ACIP recommends 2024-2025 COVID-19 vaccines as authorized or approved by the FDA in persons 6 months of age and older.

- **Pneumococcal Vaccines**
  - » ACIP recommends PCV21 (CAPVAXIVE™) as an option for adults 19 years of age and older who currently have a recommendation to receive a dose of PCV.

For more information on ACIP recommendations, please click here.

Antipsychotics and Antidepressants

Antipsychotics

First Generation Antipsychotics

Medication	Daily Dose Range	Comments
Chlorpromazine (Thorazine)	50-800 mg	Sedation, anticholinergic, hypotension.
Thioridazine (Mellaril)	50-800 mg	
Loxapine (Loxitane)	20-250 mg	Moderate sedation, moderate extrapyramidal symptoms.
Perphenazine (Trilafon)	8-64 mg	
Fluphenazine (Prolixin)	2.5-20 mg	Less sedation, extrapyramidal symptoms (EPS).
Haloperidol (Haldol)	2.5-20 mg	
Pimozide (Orap)	0.5-4 mg	
Thiothixene (Navane)	5-60 mg	
Trifluoperazine (Stelazine)	2-20 mg	

Second Generation Antipsychotics

Medication	Daily Dose Range	Comments
Aripiprazole (Abilify)	2.5-30 mg	Akathisia: fewer metabolic effects.
Asenapine (Saphris)	Tablet: 5-20 mg Patch: 3.8-7.6 mg	Fewer metabolic effects.
Brexpiprazole (Rexulti)	20-250 mg	Akathisia; increased triglycerides.
Cariprazine (Vraylar)	1.5-6 mg	Nausea, insomnia, EPS.
Clozapine (Clozaril, Fazacio)	1.5-6 mg	Constipation, sedation, most metabolic side effects, sialorrhea, myocarditis, requires ANC monitoring.
Iloperidone (Fanapt)	50-900 mg	Increased prolactin, weight gain, dizziness.
Lumateperone	4-24 mg	Sedation, headache, nausea.
Lurasideone (Latuda)	42 mg	Akathisia, fewer metabolic side effects.
Olanzapine (Zyprexa)	20-160 mg	Metabolic side effects, sedation.
Paliperidone (Invega)	5-30 mg	Increased prolactin, EPS.
Pimavanserin (Nuplazid)	3-12 mg	For Parkinson disease psychosis.
Quetiapine (Seroquel)	34 mg	Sedation, orthostatic hypotension.
Risperidone (Risperdal)	200-800 mg	Increased prolactin, EPS.
Ziprasidone (Geodon)	0.5-6 mg	Less metabolic effects.

- Second generation antipsychotics are associated with increased risk of metabolic syndrome including hypertension, dyslipidemia, diabetes, obesity, and coronary heart disease. Metabolic syndrome is associated with up to a sixfold increase in the risk of type 2 diabetes and death from coronary artery disease.
- Routine monitoring of weight, body mass index (BMI), waist circumference, blood pressure, fasting glucose or hemoglobin A1C and fasting lipids are recommended to reduce the risk of antipsychotic-induced metabolic syndrome.

Metabolic Monitoring Parameters and Frequency

Parameter	Adult Patients	Pediatric Patients
Height, Weight, BMI	Baseline, then every four weeks for the first 12 weeks, then every three months.	Baseline, then every four weeks for the first 12 weeks, then every three months.
Waist circumference	Baseline, then annually.	N/A
Blood pressure, pulse; fasting blood glucose or HbA1C; lipids	Baseline, then 12 weeks, then annually.	Baseline, then three months, then every six months.

- The diagnosis of Metabolic Syndrome is defined as meeting three or more of the following five categories:

Parameter	Adult Patients
Waist Circumference	Men: >/= 40 in (102 cm); Women: >/= 35 in (88 cm)
Blood Pressure*	Systolic >/= 130 mmHg or Diastolic >/= 85 mmHg
Fasting Plasma Glucose*	>/= 100 mg/dL
Triglyceride*	>150 mg/dL
HDL	Men < 40 mg/dL; Women < 50 mg/dL

**Also positive if measurement in normal range and receiving treatment for that indication.*

Metabolic Monitoring for Children and Adolescents on Antipsychotics (APM) Measure

- Antipsychotics increases a child's risk for developing serious metabolic health complications and are associated with poor cardiometabolic outcomes in adulthood.
- Definition – the percentage of patients 1-17 years of age who had two or more antipsychotic prescriptions and had metabolic testing.
- Measure Tips
  - » Order a blood glucose or HbA1C and lipid panel annually. Consider checking at annual checkup to reduce additional visits.
  - » Measure baseline lipid profiles, fasting blood glucose level and body mass index.

Antipsychotics and Opioids

- The Federal Drug Administration (FDA) issued a black box warning about the combined use of opioids and antipsychotics due to risks of respiratory depression in 2016.
- Avoid use of prescription opioid cough medication.
- If the combined use is clinically necessary, consider limiting the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect.

- Warn patients and caregivers about the risk of slowed or difficult breathing and/or sedation, and the associated signs and symptoms.
- Consider prescribing opioid reversal agent such as naloxone nasal spray (i.e., Narcan).

Antidepressants

Selective Serotonin Reuptake Inhibitors (SSRIs)

- Can take anywhere between four to 12 weeks to reach their full effect, with initial response likely in the first two to six weeks. Sudden cessation of SSRIs can lead to discontinuation syndrome, consisting of flu-like symptoms, sleep disturbance, imbalance, tremors, dizziness, electric-shock sensations, agitation, and confusion.
- Common initial side effects are headaches, nausea, gastrointestinal effects (constipation, diarrhea, vomiting). These effects are usually mild and tend to dissipate in one to two weeks. Some individuals experience an initial increase in anxiety. This, too, tends to improve over time. Sexual dysfunction may occur. The most common types of dysfunctions are delayed ejaculation and anorgasmia.

Medication	Daily Dose Range	Comments
Citalopram* (Celexa)	10 – 40 mg	Well tolerated; QTc prolongation and FDA warning for abnormal heart rhythms; fewer drug interactions.
Escitalopram (Lexapro)	5 – 20 mg	Well tolerated; QTc prolongation; fewer drug interactions.
Fluoxetine (Prozac)	10 – 80 mg	Most activating (insomnia, diarrhea, initial increase in anxiety); more drug interactions; least likely to cause discontinuation syndrome; QTc prolongation.
Fluvoxamine (Luvox)	50 – 300 mg	Most sedating.
Paroxetine (Paxil)	10 – 60 mg (immediate release) 12.5 – 62.5 mg (controlled release)	Sedating; anticholinergic effects; drug interactions; short half-life.
Sertraline (Zoloft))	50 – 200 mg	Slightly activating; fewer drug interactions.
Vilazodone (Viibryd)	10 – 40 mg	Nausea, anorexia, diarrhea.

Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)

- The effects on serotonin and norepinephrine reuptake are dose dependent. SNRIs should not be stopped abruptly due to discontinuation syndrome.
- Common side effects are diaphoresis, dizziness, headache, and nausea. Nausea tends to diminish over time and the medication may be better tolerated with food. Sexual dysfunction is common.
- All are associated with elevated blood pressure due to norepinephrine effects. Blood pressure should be evaluated prior to initiating SNRIs, and their use should be avoided in individuals with uncontrolled hypertension.

Medication	Daily Dose Range	Comments
Desvenlafaxine	50 – 100 mg	Monitor blood pressure
Duloxetine (Cymbalta)	60 – 120 mg	Monitor blood pressure; avoid in chronic liver disease or those with substantial alcohol use.

Medication	Daily Dose Range	Comments
Levomilnacipran (Fetzima)	40 – 80 mg	Orthostatic hypotension; monitor blood pressure.
Venlafaxine (Effexor)	75-375 mg (immediate) 75 – 225 mg (extended release)	Sexual dysfunction; QTc prolongation; monitor blood pressure.

Tricyclic Antidepressants (TCAs)

- Secondary amines have greater affinity for the norepinephrine transporter, while tertiary amines have greater affinity for the serotonin transporter. In general, secondary amine TCAs are better tolerated than tertiary amines.
- Commonly cause sedation, weight gain, sexual dysfunction and anticholinergic effects including blurry vision, urinary retention, dry mouth, constipation, cognitive impairment, and delirium. They should be used with caution in individuals with a history of glaucoma. TCAs should not be stopped abruptly due to discontinuation syndrome.
- Contraindicated in individuals with a recent myocardial infarction. They should be used cautiously in individuals with cardiovascular disease or family history of sudden death. They are also known to cause orthostatic hypotension, tachycardia, and right bundle branch block.
- ECG monitoring should be performed at baseline and as clinically indicated when TCAs are used in children, in adults over the age of 40, and in those with cardiovascular disease.

Medications	Daily Dose Range	Comments
Amitriptyline (Elavil)	50 – 300 mg	Tertiary; active metabolite is nortriptyline.
Clomipramine (Anafranil)	25 – 250 mg	Tertiary.
Desipramine (norpramin)	25 – 300 mg	Secondary.
Doxepin	150 – 300 mg	Tertiary; lower doses used for insomnia.
Imipramine	50 – 300 mg	Tertiary; active metabolite is desipramine.
Nortriptyline (Pamelor)	25 – 150 mg	Secondary.
Protriptyline	10 – 60 mg	Secondary.

Bupropion (Wellbutrin)

- Norepinephrine-dopamine reuptake inhibitor.
- Can lower the seizure threshold and therefore is contraindicated in anyone who is prone to seizures, including individuals with a known seizure disorder, those with eating disorders or those withdrawing from alcohol or sedative-hypnotics.
- Can take four – 12 weeks for full antidepressant effect.
- Daily dose range is 100 – 450 mg for immediate release (IR), 150 – 400 mg for sustained release (SR), 150 – 450 mg for extended release (XL).
- Common side effects include insomnia, anxiety, headache and increase in sweating. It is less likely to cause sexual side effects compared to SSRIs.

Mirtazapine (Remeron)

- Inhibits alpha2 receptors which result in increased release of serotonin and norepinephrine. Also, antagonizes serotonin receptors 5HT2, 5HT3, and the histamine receptor, H1.
- Can take four – 12 weeks for full antidepressant effect.
- Daily dose range is 15 – 45 mg.

- Common side effects are increased appetite, weight gain, and sedation. It is less likely to cause sexual side effects compared to SSRIs.

Vortioxetine (Trintellix)

- Inhibits serotonin reuptake by inhibiting 5HT transporter.
- Daily dose range is 5 – 20 mg. Dose should be adjusted for CYP2D6 poor metabolizers or who are taking strong CYP2D6 inhibitors or inducers.
- Doses > 15 mg per day should be tapered down to 10 mg for one week prior to discontinuation.
- Common side effects include nausea, dizziness, headache, diarrhea, dry mouth, constipation, vomiting, flatulence, pruritus, abnormal dreams, and sexual dysfunction.

Esketamine (Spravato)

- Non-competitive N-methyl D-aspartate receptor antagonist for the treatment of treatment-resistant depression in adults, in conjunction with an oral antidepressant.
- Only available through a restricted Risk Evaluation and Mitigation Strategy (REMS) program because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse.
- Prescribers, patients, pharmacies, and health settings must all be registered within the REMS program to assure that all program requirements are met.
- Intranasal spray.
- Common side effects include sedation, blood pressure changes, dissociation, perceptual changes, impaired attention and reaction speed and impaired ability to drive. It carries a risk of abuse and misuse and is a schedule III-controlled substance. It can cause suicidal thoughts and behaviors in adolescents and young adults.

Brexanolone (Zulresso)

- Indicated for the treatment of postpartum depression in patients15 years of age and older.
- Precise mechanism of action is unknown, but it is thought to fall in the class of GABA-A modulators.
- Only available through a restricted REMS program that requires it to be administered as a continuous intravenous infusion at a certified health care facility under the close supervision of a health care provider.

Antidepressants Use in Children and Adolescents

Antidepressants with FDA approval for use in children and adolescents

Medication	Daily Dose Range	Age	Comments
Clomipramine (Anafranil)	25 – 200mg (or 3mg/kg, whichever is smaller)	10 years of age and older	Obsessive compulsive disorder (OCD)
Duloxetine (Cymbalta)	30 – 120 mg	7 years of age and older	Generalized anxiety disorder (GAD)
Escitalopram (Lexapro)	5 – 20 mg	12 years of age and older	Major depressive disorder (MDD)
Fluoxetine (Prozac)	10 – 60 mg	7 years of age and older	MDD, OCD
Fluvoxamine (Luvox)	25 – 300 mg	8 years of age and older	OCD
Sertraline (Zoloft)	25 – 200 mg	6 years of age and older	OCD

- For most, the full antidepressant effect is not seen until four – six weeks or longer.
- For children, start at the lowest possible dose and increase slowly.
- Children and families should be informed of the possible risks and side effects of medication and consent for medication must be signed by parents or guardians.
- **FDA recommended monitoring parameters for children and adolescents starting SSRI medication.**

Month One	Seen once per week for the first four weeks. Some contacts may be by phone if deemed safe by prescriber. Telehealth appointments are reasonable if in-person visits are not an option and patient can tolerate them.
Month Two	Seen every two weeks. One contact may be by phone if determined safe by prescriber.
Month three - 12	Seen every one to three months if symptoms and dose stable. May be more frequent if clinically indicated.
Month 12 and beyond	After 12 months of medication, treatment symptom re-assessment should be performed. If symptom free and no previous depressive episodes or extenuating clinical circumstances, consider possibility of medication taper if safe and clinically indicated.

Strategies for Addressing Treatment Resistance

- Medication adherence – Poor medication adherence can impact the efficacy of antidepressant medication. Careful evaluation is recommended in all cases of less-than expected treatment response.
- Maximizing the dose – Maximize the dose after determining that medication adherence is not a significant problem if the patient is able to tolerate the current dose and has shown some response after a reasonable trial at the current dose.
- Switching antidepressant – If the patient cannot tolerate current antidepressant due to side effects or when there is little to no response after a reasonable trial despite attempts to maximize the dose. Switch can be within the same family or to another family of antidepressant medication. Cross titration is not necessary when switching within the family of SSRIs.
- Antidepressant augmentation – Adding a non-antidepressant medication to the treatment regimen with the goal of improving antidepressant response. Considered in patients who have partially responded to the current antidepressant medication, have maximized its dose and in whom switching is contraindicated or not clinically appropriate. Current antipsychotic medications approved by the FDA as add on therapy in major depressive disorder include aripiprazole, brexpiprazole, and quetiapine ER. The combination medication, olanzapine / fluoxetine, is FDA approved for treatment resistant depression.
- Antidepressant combination therapy - Combining two antidepressant medications that each have a different mechanism of action is the final strategy to address treatment resistance. Some combination therapies that have evidence of efficacy include SSRIs/SNRIs with mirtazapine, and SSRIs/SNRIs with bupropion. Consider in patients who have partially responded to the current antidepressant medication, have maximized its dose and in whom switching is contraindicated or not clinically appropriate.

Chronic Disease Self-Management Program (CDSMP)

Gold Coast Health Plan (GCHP) offers free Chronic Disease Self-Management Program (CDSMP) workshops to members over 18 years of age with a chronic health condition, such as arthritis, diabetes, heart disease, depression, obesity, pain and more.

For more information, please review the CDSMP flyer (available in English and Spanish) and share with GCHP members.

Free Workshop for Gold Coast Health Plan Members

Chronic Disease Self-Management Program

Gold Coast Health Plan (GCHP) offers free Chronic Disease Self-Management Program (CDSMP) workshops to members over the age of 18 with a chronic health condition. A chronic health condition is one that lasts for a long time, such as arthritis, diabetes, heart disease, depression, obesity, pain and more. The workshop can teach you how to control and manage your symptoms.

Workshops will be held once a week for six weeks. Members can choose between a virtual or telephonic workshop. The virtual workshop is 2.5 hours each week, and the telephonic workshop is 30 minutes each week.

In the workshop, you will learn about:

- Making a weekly action plan
- Healthy eating
- Physical activity and exercise
- Medication usage

Participants will get:

- "Living a Healthy Life with Chronic Conditions" book
- Class handouts
- Relaxation CD
- Refillable water bottle
- Backpack
- Lunch bag

Sign up now for CDSMP workshops to gain the self-confidence to take charge of your health.

Call the Health Education Department at **1-805-437-5718**, Monday through Friday, 8 a.m. to 5 p.m. (except holidays). If you use a TTY, cal **711**. You can also email **HealthEducation@goldchp.org**. For more information, visit the GCHP website, **www.goldcoasthealthplan.org**.

Gold Coast Health Plan℠
A Public Entity

Taller gratis para miembros de Gold Coast Health Plan

Programa Tomando Control de su Salud

Gold Coast Health Plan (GCHP) ofrece talleres gratis de Tomando Control de su Salud (CDSMP, por sus siglas en inglés) para miembros mayores de 18 años con una condición médica crónica. Una condición médica crónica es la que dura mucho tiempo, como artritis, diabetes, enfermedades cardíacas, depresión, obesidad, dolor y muchas más. El taller puede enseñarle cómo controlar y manejar sus síntomas.

Los talleres se harán una vez a la semana durante seis semanas. Los miembros pueden elegir entre un taller virtual o por teléfono. El taller virtual es de 2.5 horas por semana y el taller por teléfono es de 30 minutos por semana.

En el taller aprenderá sobre:

- Cómo hacer un plan de acción semanal
- La alimentación saludable
- La actividad física y el ejercicio
- El uso de medicamentos

Los participantes recibirán:

- El libro "Tomando control de su salud"
- Folletos de la clase
- CD de relajación
- Botella de agua recargable
- Mochila
- Bolsa del almuerzo

Regístrese ahora al taller Tomando Control de su Salud para ganar confianza en sí mismo y hacerse cargo de su salud.

Llame al Departamento de Educación para la Salud al **1-805-437-5718**, de lunes a viernes, de **8 a.m.** a **5 p.m.** (excepto días festivos). Si usa un TTY, llame al **711**. También puede enviar un correo electrónico a **HealthEducation@goldchp.org**. Para más información, visite el sitio web de GCHP, **www.goldcoasthealthplan.org**.

Gold Coast Health Plan℠
A Public Entity

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
- U.S. 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

FDA New Drug Approvals

This is a list of new drugs recently approved by the FDA. This is only a subset of all drugs that were approved and include all 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
ZEVTERA	*ceftobiprole medocaril sodium*	INTRAVENOUS POWDER	Indicated for the treatment of: • Adult patients with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis, • Adult patients with acute bacterial skin and skin structure infections (ABSSSI), and • Adult and pediatric patients (3 months to less than 18 years of age) with community-acquired bacterial pneumonia (CABP).
XROMI	*hydroxyurea*	ORAL SOLUTION	Indicated to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients6 months to less than 2 years of age with sickle cell anemia with recurrent moderate to severe painful crises.
ENTRESTO SPRINKLE	*sacubitril; valsartan*	COATED PELLETS; ORAL CAPSULE; PELLETS; ORAL CAPSULE	Indicated: • To reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. Benefits are most clearly evident in patients with left ventricular ejection fraction (LVEF) below normal. • For the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.
SELARSDI	*ustekinumab-aekn*	INJECTABLE	Indicated for the treatment of: Adult patients with: • Moderate to severe plaque psoriasis (PSO) who are candidates for phototherapy or systemic therapy. • Active psoriatic arthritis (PSA). Pediatric patients 6 years of age and older with: • Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy. • Active PSA.

Brand Name	Generic Name	Dosage Form	Summary of Indication
LUMISIGHT	*pegulicianine*	INJECTABLE	Indicated for fluorescence imaging in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery.
REZENOPY	*naloxone hydrochloride*	NASAL SPRAY	For the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adult and pediatric patients.
ANKTIVA	*nogapendekin alfa inbakicept-pmln*	INTRAVESICAL SOLUTION	Indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
OJEMDA	*tovorafenib*	ORAL TABLET; ORAL SUSPENSION	Indicated for the treatment of patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.
PIVYA	*Pivmecillinam hydrochloride*	ORAL TABLET	Indicated for the treatment of female patients 18 years of age and older with uncomplicated urinary tract infections caused by susceptible isolates of E. coli, Proteus mirabilis, and Staphylococcus saprophyticus.
XOLREMDI	*Mavorixafor*	ORAL CAPSULE	Indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.
IMDELLTRA	*tarlatamab-dlle*	INJECTABLE	Indicated for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.
YESAFILI	*aflibercept-jbvf*	NJECTABLE	Indicated for the treatment of patients with: • Neovascular (wet) age-related macular degeneration (amd) • Macular edema following retinal vein occlusion (rvo) • Diabetic macular edema (dme) • Diabetic retinopathy (dr)

Brand Name	Generic Name	Dosage Form	Summary of Indication
OPUVIZ	*aflibercept-yszy*	INJECTABLE	Indicated for the treatment of patients with: • Neovascular (wet) age-related macular degeneration (amd) • Macular edema following retinal vein occlusion (rvo) • Diabetic macular edema (dme) • Diabetic retinopathy (dr)
BKEMV	*eculizumab-aeeb*	INJECTABLE	Indicated for: • The treatment of patients with paroxysmal nocturnal hemoglobinuria (pnh) to reduce hemolysis. • The treatment of patients with atypical hemolytic uremic syndrome (ahus) to inhibit complement-mediated thrombotic microangiopathy.
RYTELO	*imetelstat sodium*	INTRAVENOUS POWDER	Indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring four or more red blood cell units over eight weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).
IQIRVO	*elafibranor*	ORAL TABLET	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.
SOFDRA	*sofpironium*	TOPICAL GEL	Indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.
PIASKY	*crovalimab-akkz*	INJECTABLE	Indicated for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg.

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
KESIMPTA *(ofatumumab)*	Contraindications	KESIMPTA is contraindicated in patients with: • Active HBV infection. • History of hypersensitivity to ofatumumab or life-threatening injection-related reaction to KESIMPTA. Hypersensitivity reactions have included anaphylaxis and angioedema.
RYLAZE *(asparaginase erwinia chrysanthemi (recombinant)-rywn)*	Contraindications	RYLAZE is contraindicated in patients with: • History of serious hypersensitivity reactions to Erwinia asparaginase, including anaphylaxis. • History of serious pancreatitis during previous asparaginase. • History of serious thrombosis during previous asparaginase therapy. • History of serious hemorrhagic events during previous asparaginase. • Severe hepatic impairment.
BESREMI *(ropeginterferon alfa-2b-njft)*	Contraindications	BESREMi is contraindicated in patients with: • Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt. • Hypersensitivity to interferons including interferon alfa-2b or any of the inactive ingredients of BESREMi. • Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment. • History or presence of active serious or untreated autoimmune disease. • History of transplantation and receiving immunosuppressant agents.
TIVDAK *(tisotumab vedotin-tftv)*	Boxed Warning	Conduct an ophthalmic exam, including an assessment of ocular symptoms, visual acuity, and slit lamp exam of the anterior segment of the eye prior to initiation of TIVDAK, prior to every cycle for the first nine cycles, and as clinically indicated.
ESMOLOL HYDROCHLORIDE	Contraindications	Esmolol hydrochloride is contraindicated in patients with: • Severe sinus bradycardia, heart block greater than first degree, sick sinus syndrome: May precipitate or worsen bradycardia resulting in cardiogenic shock and cardiac arrest. • Decompensated heart failure: May worsen heart failure and cause cardiogenic shock. • Concomitant use of IV cardiodepressant calcium-channel antagonists (e.g., verapamil): May cause cardiovascular collapse. • Hypersensitivity reactions, including anaphylaxis, to esmolol or any of the inactive ingredients of the product (cross-sensitivity between beta-blockers is possible).

Drug	Type of Change	Change
ETICOVO *(etanercept-ykro)*	Contraindications	ETICOVO is contraindicated in patients with sepsis.
CADUET *(amlodipine besylate; atorvastatin calcium)*	Contraindications	CADUET is contraindicated in patients with: • Acute liver failure or decompensated cirrhosis. • Hypersensitivity to amlodipine, atorvastatin or any excipients in CADUET. Hypersensitivity reactions, including anaphylaxis, angioneurotic edema, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported.
RETACRIT *(epoetin alfa-epbx)*	Boxed Warning	Chronic Kidney Disease: In controlled trials, patients with chronic kidney disease (CKD) experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered.
APTIVUS *(tipranavir)*	Warnings and Precautions	Importance of Co-administration with Ritonavir APTIVUS must be co-administered with ritonavir and food to achieve the desired antiviral effect. Failure to administer APTIVUS with ritonavir and food may result in a loss of efficacy of tipranavir.
BRUKINSA *(zanubrutinib)*	Warnings and Precautions	Hepatotoxicity, including Drug-induced Liver Injury Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including BRUKINSA.

Drug Shortages

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

Drug Product	Affected Manufacturers	Summary
REGRANEX *(becaplermin)* topical gel	• Smith & Nephew	Smith & Nephew has Regranex 0.01% topical gel in 15-gram tubes on back order and the company estimates a release date in July 2024.
Hydrocodone bitartrate and Acetaminophen oral tablet 10 mg / 325 mg; 5 mg / 325 mg; 7.5 mg / 325 mg; 5 mg / 300 mg; 10 mg / 300 mg; 7.5 mg / 300 mg	• Amneal • Camber • Eywa • KVK-Tech • Major • Mallinckrodt • Rhodes	• Amneal did not provide a reason for the shortage. • Camber discontinued hydrocodone and acetaminophen tablets. • Eywa has hydrocodone and acetaminophen tablets available to contracted customers. • KVK-Tech states the shortage is due to regulatory delays. • Major did not provide a reason for the shortage. • Mallinckrodt refuses to provide availability information. • Rhodes did not provide a reason for the shortage. The products with 300 mg of acetaminophen have been discontinued. **Estimated Resupply Dates** • Amneal has hydrocodone 5 mg / 325 mg tablets in 100-count bottles on allocation. The 10 mg / 325 mg tablets in 500-count and 1,000-count bottles on back order and the company cannot estimate a release date. • KVK-Tech has hydrocodone 7.5 mg / 325 mg tablets in 500-count bottles and 10 mg / 325 mg tablets in 500-count and 1,000-count bottles on back order and the company cannot estimate a release date. • Major has hydrocodone 5 mg / 325 mg, 7.5 mg / 325 mg, and 10 mg / 325 mg tablets in 100-count unit-dose packages on back order and the company cannot estimate a release date. • Rhodes has all presentations on back order and the company cannot estimate a release date.
SAXENDA *(liraglutide)*	• Novo Nordisk	Novo Nordisk has Saxenda on shortage due to increased demand. There is insufficient supply for usual ordering.
Asmanex HFA *(mometasone furoate)* 50 mcg/actuation Asmanex Twisthaler (mometasone furoate) 220 mcg/actuation	• Organon	Organon states customer demand for Asmanex HFA and Asmanex Twisthaler has increased due to the discontinuation of Flovent HFA and Flovent Diskus in late-2023. Organon has Asmanex Twisthalers 220 mcg in 60-count on back order and the company estimates a release date in mid-July 2024. Amanex HFA 50 mcg inhaler is on back order and the company estimates a release date in early-July 2024.

Drug Product	Affected Manufacturers	Summary
Oxycodone Hydrochloride Immediate-Release Tablets 15 mg; 30 mg; 5 mg; 10 mg; 20 mg	• Alvogen Amneal • Camber • KVK-Tech • Major • Mallinckrodt • Rhodes	• Alvogen did not provide a reason for the shortage. • Amneal did not provide a reason for the shortage. The company discontinued oxycodone 30 mg tablets in 500-count bottles in January 2024. • Camber discontinued oxycodone immediate-release tablets. • KVK-Tech has oxycodone immediate-release tablets available. • Major did not provide a reason for the shortage. • Mallinckrodt refuses to provide availability information. • Rhodes did not provide a reason for the shortage. **Estimated Resupply Dates** • Alvogen has all oxycodone immediate-release products on allocation. • Amneal has all oxycodone immediate-release tablets on back order and the company cannot estimate a release date. • Major has oxycodone 5 mg tablets in 100-count unit-dose packages on back order and the company estimates a release date in early-August 2024. • Rhodes has oxycodone 10 mg tablets in 100-count unit-dose packages available in limited supply.
Dexmethylphenidate Extended-Release Capsules 10 mg; 20 mg; 35 mg; 15 mg; 25 mg; 30 mg; 40 mg; 5 mg	• Amneal • Camber • Lannett • Novartis • Par • Sandoz • Sun Pharma • Teva	• Amneal did not provide a reason for the shortage. • Camber discontinued dexmethylphenidate extended-release capsules. • Lannett did not provide a reason for the shortage. • Novartis divested Focalin XR capsules to Sandoz. • Par did not provide a reason for the shortage. • Sandoz has Focalin XR capsules available. • Sun Pharma discontinued dexmethylphenidate extended-release capsules. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Amneal has dexmethylphenidate 10 mg, 20 mg, and 35 mg extended-release capsules on intermittent back order and the company is releasing supplies as they become available. • Lannett has all dexmethylphenidate 5 mg, 10 mg, 15 mg, and 20 mg extended-release capsules on back order and the company cannot estimate a resupply date. • Par has dexmethylphenidate 5 mg, 10 mg, 15 mg, 25 mg, 35 mg, and 40 mg extended-release capsules on back order and the company cannot estimate a release date. • Teva has dexmethylphenidate 10 mg, 25 mg, and 40 mg extended-release capsules on intermittent back order and the company is releasing supplies as they become available.

Drug Product	Affected Manufacturers	Summary
Lisdexamfetamine Dimesylate Capsules 10 mg; 20 mg; 30 mg; 40 mg; 50 mg; 60 mg; 70 mg	• Alvogen • Amneal • Hikma • Lannett • Mallinckrodt • Mylan • Rhodes • Solco • Sun Pharma • Takeda	• Alvogen has lisdexamfetamine capsules on shortage due to regulatory delays. • Amneal has lisdexamfetamine capsules on shortage due to an issue with the active ingredient. • Hikma has lisdexamfetamine capsules on shortage due to an issue with the active ingredient. • Lannett did not provide a reason for the shortage. • Mallinckrodt does not provide information on drug shortages. • Mylan has lisdexamfetamine capsules available. • Rhodes launched lisdexamfetamine 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules in March 2024. The 10 mg and 20 mg capsules have not been launched and the company cannot estimate a release date. • Solco has lisdexamfetamine capsules on shortage due to an issue with the active ingredient. • Sun Pharma has lisdexamfetamine capsules on shortage due to regulatory delays. • Takeda has Vyvanse available. **Estimated Resupply Dates** • Alvogen has lisdexamfetamine 20 mg, 30 mg, 60 mg, and 70 mg capsules available in limited supply. The 10 mg, 40 mg and 50 mg capsules are on back order and the company cannot estimate a release date. • Amneal has lisdexamfetamine capsules on back order and the company cannot estimate a release date. • Hikma has lisdexamfetamine 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules on allocation. • Lannett has lisdexamfetamine 10 mg, 20 mg, 30 mg, and 40 mg capsules on allocation. Lisdexamfetamine 50 mg, 60 mg, and 70 mg capsules are on back order and the company cannot estimate a release date. • Rhodes has all lisdexamfetamine on back order and the company cannot estimate a release date. • Solco has lisdexamfetamine capsules on back order and the company cannot estimate a release date. • Sun Pharma has all lisdexamfetamine presentations on back order and the company estimates additional product will be available in late-June 2024.

Drug Product	Affected Manufacturers	Summary
Methylphenidate Extended-Release Oral Presentations 30 mg; 10 mg; 20 mg; 40 mg; 60 mg; 50 mg; 15 mg; 18 mg; 27 mg; 36 mg; 54 mg;	• Acella • Adlon • Amneal • Aytu • Camber • Ironhorse • Janssen • KVK-Tech • Lannett • Mallinckrodt • Patriot • Rhodes • Sandoz • Sun Pharma • Teva • Trigen • Tris Pharma • Vertical • XLCare	• Acella was not available to provide information. • Adlon discontinued Adhansia XR in July 2022. • Amneal discontinued the extended-release tablets in March 2023. The company has the extended-release (CD) capsules available. • Aytu BioPharma has Cotempla XR-ODT extended-release oral disintegrating tablets available. Cotempla is dose equivalent to methylphenidate hydrochloride extended-release (CD) capsules. • Camber discontinued methylphenidate extended-release tablets. • Ironhorse has Jornay PM available. • Janssen has Concerta extended-release tablets available. • KVK-Tech was not available to provide information. • Lannett did not provide a reason for the shortage. Lannett is shipping most presentations to forecast. • Mallinckrodt has all presentations available. • Patriot discontinued methylphenidate extended-release tablets (authorized generic) in January 2023. • Rhodes has Aptensio XR capsules available. • Sandoz has methylphenidate (LA) capsules and Ritalin LA capsules available. • Sun Pharma discontinued methylphenidate extended-release tablets. • Teva states the reason for the delay is manufacturing delay. Teva has the extended-release (LA) capsules temporarily unavailable. Teva discontinued the 40 mg, 50 mg, and 60 mg extended-release (CD) capsules in December 2023. • Trigen has methylphenidate extended-release tablets available. • Tris Pharma has Quillichew ER chewable tablets and Quillivant XR liquid available. • Vertical has Relexxii tablets available. • XLCare has methylphenidate extended-release tablets on shortage because the company is awaiting DEA allocation for active ingredient. **Estimated Resupply Dates** • Lannett has methylphenidate 54 mg extended-release tablets on back order and the company cannot estimate a release date. The 30 mg extended-release (CD) capsules are on intermittent back order and the company is releasing supplies as they become available. • Teva has methylphenidate 18 mg, 27 mg, 36 mg, and 54 mg extended-release tablets on intermittent back order and the company is releasing supplies as they become available. Teva has 10 mg extended-release (CD) capsules on intermittent back order and has 20 mg extended-release (CD) capsules on back order. Teva cannot estimate a release date for the 20 mg extended-release (CD) capsules.

Drug Product	Affected Manufacturers	Summary
		• The 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg extended-release (XR) capsules are on intermittent back order and the company is releasing supplies as they become available. The 50 mg and 60 mg extended-release (XR) capsules are intermittent back order and the company is releasing product as it becomes available. • XLCare has methylphenidate extended-release tablets on back order and the company cannot estimate a release date.
Oxymorphone Immediate-Release Tablets 5 mg; 10 mg	• Camber • Hikma • KVK-Tech	• Camber discontinued oxymorphone tablets in early 2024. • Hikma did not provide a reason for the shortage. • KVK-Tech has oxymorphone on shortage due to DEA quotas. **Estimated Resupply Dates** • KVK-Tech has oxymorphone 5 mg immediate-release tablets on back order and the company cannot estimate a release date. • Hikma has oxymorphone 5 mg and 10 mg tablets on back order and the company cannot estimate a release date.
Isosorbide Mononitrate Immediate-Release Tablets 10 mg; 20 mg	• Teva	Teva did not provide a reason for the shortage. Teva is the sole supplier of isosorbide mononitrate immediate-release tablets. **Estimated Resupply Dates** Teva has isosorbide mononitrate 10 mg and 20 mg immediate-release tablets on back order and the company cannot estimate a release date.
Minoxidil 2.5 mg Tablets	• Sun Pharma • Par • Teva	• Sun Pharma did not provide a reason for the shortage. • Par has minoxidil available. • Teva did not provide a reason for the shortage. • Minoxidil 10 mg tablets are not affected by the shortage. **Estimated Resupply Dates** Teva has minoxidil 2.5 mg tablets on intermittent back order and the company is releasing supplies as they become available.
Moxifloxacin Tablets 400 mg	• Major • Rising Pharmaceuticals • Aurobindo	• Major did not provide a reason for the shortage. Major has updated the NDC numbers recently. • Rising did not provide a reason for the shortage. • Teva has moxifloxacin tablets available. • Aurobindo refuses to provide availability information. **Estimated Resupply Dates** • Major has moxifloxacin 400 mg tablets in unit-dose packaging on back order and the company estimates a release date in late-June 2024. • Rising has moxifloxacin 400 mg tablets in 30-count bottles on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Naltrexone Tablets 50 mg	• Accord • Avet • Mallinckrodt • Major • Sun Pharma • Tagi Pharma	• Accord did not provide a reason for the shortage. • Avet did not provide a reason for the shortage. • Mallinckrodt refuses to provide availability information. • Major did not provide a reason for the shortage. • Sun Pharma did not provide a reason for the shortage. • Tagi Pharma did not provide a reason for the shortage. • Information from a few additional suppliers is forthcoming. • There is insufficient supply for usual ordering. **Estimated Resupply Dates** • Accord has naltrexone 50 mg tablets on intermittent back order and the company is releasing supplies as they become available. • Avet has naltrexone 50 mg tablets on back order and the company cannot estimate a release date. • Major has naltrexone 50 mg tablets in 30-count unit-dose packages on back order and the company estimates a release date in mid-July 2024. • Sun Pharma has naltrexone 50 mg tablets on back order and the company is releasing supplies as they become available. • Tagi Pharma has naltrexone 50 mg tablets on back order and the company is releasing supplies as they become available.
Nystatin Oral Suspension	• 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). • There is insufficient supply for usual ordering. **Estimated Resupply Dates** • 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 and 473 mL bottles on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Amphetamine Extended-Release Oral Presentations 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg	• Amneal • Aytu BioPharma • Camber • Lannett • Mallinckrodt • Par Pharmaceuticals • Prasco • Rhodes • Sandoz • Sun Pharma • Shire • Teva • Tris Pharma	• Amneal did not provide a reason for the shortage. • Aytu BioPharma has Adzenys XR oral disintegrating tablets available. • Camber discontinued amphetamine mixed salts extended-release capsules. • Lannett did not provide a reason for the shortage. Lannett updated the NDC numbers recently. • Mallinckrodt refuses to provide availability information. • Par Pharmaceuticals has discontinued amphetamines mixed salts extended-release capsules. • Prasco has discontinued amphetamine mixed salts extended-release capsules authorized generic because Shire is no longer supplying the company with product. Inventory is being distributed until remaining supply is depleted. • Rhodes did not provide a reason for the shortage. • Sandoz has discontinued amphetamine mixed salts extended-release capsules. • Sun Pharma has discontinued amphetamines mixed salts extended-release capsules. • Shire has Adderall XR and Mydayis extended-release capsules available. • Teva did not provide a reason for the shortage. • Tris Pharma has Dynavel XR tablets and suspension available. **Estimated Resupply Dates** • Amneal has amphetamine 5 mg, 20 mg, and 25 mg extended-release capsules on back order and the company cannot estimate a release date. • Lannett has amphetamine 5 mg extended-release capsules on intermittent back order and the company is releasing supplies as they become available. • Rhodes has amphetamine extended-release capsules on back order and the company cannot estimate a release date. • Teva has amphetamine 15 mg, 20 mg, and 30 mg extended-release capsules on intermittent back order and the company is releasing supplies as they become available.

Drug Product	Affected Manufacturers	Summary
Amphetamine Mixed Salts, Immediate-Release Tablets 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg 5 mg, 7.5 mg	• Alvogen • Aurobindo • Camber • Elite Laboratories • Epic Pharma • Lannett • Mallinckrodt • Rhodes • Sandoz • Solco Healthcare • Teva • Mylan • Zydus	• Alvogen has all presentations available to contracted customers. • Aurobindo refuses to provide availability information. • Camber discontinued amphetamine mixed salts immediate-release tablets. • Elite Laboratories has amphetamine mixed salts immediate-release tablets available. • Epic Pharma has amphetamine mixed salts immediate-release tablets available. • Lannett has amphetamine mixed salts immediate-release tablets available. • Mallincrodt did not provide a reason for the shortage. • Rhodes did not provide a reason for the shortage. • Sandoz has amphetamine mixed salts immediate-release tablets available. • Solco Healthcare discontinued amphetamine mixed salts immediate-release tablets. • Teva did not provide a reason for the shortage. • Mylan and Zydus have discontinued amphetamine mixed salt immediate-release tablets. **Estimated Resupply Dates** • Mallinckrodt has most amphetamine mixed salts tablets on intermittent back order and the company is releasing supplies as they become available. • Rhodes has all presentations on back order and the company cannot estimate a release date. • Teva has amphetamine mixed salts 10 mg and 30 mg immediate-release tablets on back order and the company estimates a release date of mid-July 2024. The 15 mg immediate-release tablets are also on back order and the company estimates a release date of late-August 2024.
Epinephrine Auto-Injectors 0.15 mg/0.3 mg, 03 mg/0.3 ml	• Amneal • Kaleo • Mylan (Viatris) • US WorldMeds, LLC • Teva	• Amneal has epinephrine auto-injectors available. • Kaleo has Auvi-Q available only through specific distributors. • Mylan did not provide a reason for the shortage of EpiPen and EpiPen Jr. • Teva did not provide a reason for the shortage. • In March 2022, certain lots of Symjepi were recalled due to potential clogging of the needle. US Worldmeds, LLC states the shortage is due to ongoing issues related to the recall. **Estimated Resupply Dates** • Mylan has EpiPen and EpiPen Jr auto-injectors on back order and the company cannot estimate a release date. • Teva has epinephrine auto-injectors on intermittent back order and the company is releasing supplies as they become available. • US WorldMeds, LLC has Symjepi auto-injectors on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Methylphenidate Immediate-Release Tablets 5 mg, 10 mg, 20 mg	• Accord • Amneal • Camber • KVK-Tech • Mallinckrodt • Novartis • Sandoz • Solco Healthcare • Sun Pharma • XLCare	• Accord states the reason for the shortage is active ingredient delay. • Amneal has all marketed presentations available. • Camber discontinued methylphenidate immediate-release tablets. • KVK-Tech has methylphenidate immediate-release tablets on allocation due to meeting DEA quota. • Mallinckrodt refuses to provide availability information. • Novartis divested Ritalin tablets to Sandoz. • Sandoz did not provide a reason for the shortage. • Solco Healthcare did not provide a reason for the shortage. • Sun Pharma has methylphenidate immediate-release tablets on shortage due to regulatory issues. • XLCare states the reason for the shortage is active ingredient delay. **Estimated Resupply Dates** • Accord has all presentations on back order and the company cannot estimate a release date. • KVK-Tech has all presentations on allocation. • Sandoz has Ritalin 10 mg tablets on back order and the company cannot estimate a release date. • Solco Healthcare has all presentations on allocation. • Sun Pharma has methylphenidate 10 mg and 20 mg immediate-release tablets on back order and the company cannot estimate a release date.
Oxycodone Hydrochloride and Acetaminophen Tablets 10 mg/325 mg, 5 mg/325 mg, 7.5 mg/325 mg, 2.5 mg/325 mg	• Amneal • Camber • Endo • KVK-Tech • Major • Mallinckrodt • Par • Rhodes	• Amneal did not provide a reason for the shortage. • Camber discontinued their oxycodone and acetaminophen presentations. • Endo has Percocet available. • KVK-Tech is awaiting DEA quota approval for active ingredient. • Major did not provide a reason for the shortage. • Mallinckrodt was not available to provide information. • Par has Endocet available. • Rhodes oxycodone and acetaminophen presentations available. **Estimated Resupply Dates** • Amneal has all oxycodone and acetaminophen products on allocation. • KVK-Tech has oxycodone and acetaminophen 10 mg / 325 mg tablets in 100-count and 500-count bottles on intermittent back order and the company is releasing supplies as they become available. The 5 mg / 325 mg in the 100-count and 500-count bottles and 7.5 mg / 325 mg tablets in 100-count bottles are on long-term back order and the company cannot estimate a release date. • Major has oxycodone and acetaminophen 5 mg / 325 mg tablets, 7.5 mg / 325 mg tablets, and 10 mg / 325 mg in 100 count unit-dose packages on back order and the company estimates a release date of early-August 2024.

Drug Product	Affected Manufacturers	Summary
TRULICITY (dulaglutide) Injection 3 mg/0.5ml, 4.5 mg/0.5 ml	• Lilly USA • Trulicity	• Lilly USA did not provide a reason for the shortage. • Trulicity 0.75 mg/0.5 ml and 1.5 mg/0.5 ml are available. **Estimated Resupply Dates** • Lilly USA has Trulicity 3 mg/0.5 mL and 4.5 mg/0.5 mL on intermittent back order and the company is releasing supplies as they become available.
WEGOVY (semaglutide) Injection 0.25 mg/0.5 ml, 0.5 mg/0.5 ml, 1 mg/0.5 ml	• Novo Nordisk	• Novo Nordisk has Ozempic available. Novo Nordisk discontinued Ozempic 0.25 mg and 0.5 mg dose strength in the 2 mg/1.5 mL presentation. • Novo Nordisk has Wegovy on shortage due to increased demand. The company has taken measures to increase production capacity; however, the supply is not anticipated to meet patient demand for the 0.25 mg, 0.5 mg, and 1 mg dose strengths. Additional product supply information can be found here. **Estimated Resupply Dates** Novo Nordisk has Wegovy 0.25 mg/0.5 mL, 0.5 mg/0.5 mL, and 1 mg/ 0.5 mL prefilled pens available in limited supply.

FDA 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
06/26/2024	Potassium Chloride Extended Release 750mg Capsules, 100 count and 500 count	American Health Packaging on behalf of BluePoint Laboratories is voluntarily recalling 21 batches of Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K, to the consumer level. The product is being recalled because of failed dissolution. Risk Statement: The failed dissolution of potassium chloride extended-release capsules may cause high potassium levels, also known as hyperkalemia, which can result in irregular heartbeat that can lead to cardiac arrest. For patients who require chronic use of potassium chloride extended-release oral capsules, especially in those patients with underlying comorbidities or conditions that cause altered excretory mechanisms for potassium such as hypertension, heart failure, or renal dysfunction, there is a reasonable probability of developing hyperkalemia that may lead to a range of severity of adverse events from being asymptomatic to more severe potential life threatening adverse events of hyperkalemia, such as cardiac arrythmias, severe muscle weakness, and death. To date, the firm has not received any reports of hyperkalemia or serious adverse events from spontaneous sources related to this recall. Potassium Chloride Extended-Release Capsules are used for the treatment of patients with low potassium (hypokalemia) and are packaged in bottles of 100-count (NDC 68001-396-00) and 500-count (NDC 68001-396-03) capsules. The Potassium Chloride Extended-Release Capsules being recalled were distributed nationwide to wholesale, distributor, and retail outlets.	American Health Packaging	100-count - NDC: 68001-396-00 Batch #: • 17221738 exp. 07/31/2024 • 17222494 exp. 10/31/2024 • 17230533 exp. 01/31/2025 • 17232208 exp. 09/30/2025 500-count NDC: 68001-396-03 Batch #: • 17221823 exp. 07/31/2024 • 17221830 exp. 07/31/2024 • 17221831 exp. 08/31/2024 • 17230248 exp 12/31/2024 • 17230253 exp. 12/31/2024 • 17230271 exp. 12/31/2024 • 17230796 exp. 02/28/2025 • 17230820 exp. 02/28/2025 • 17230825 exp. 03/31/2025 • 17230833 exp. 03/31/2025 • 17230840 exp. 03/31/2025 • 17231537 exp. 06/30/2025 • 17231540 exp. 06/30/2025 • 17231719 exp. 06/30/2025 • 17231737 exp. 06/30/2025 • 17232111 exp. 09/30/2025 • 17232164 exp. 09/30/2025

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
06/25/2024	Potassium Chloride Extended Release 750mg Capsules, 100 count and 500 count	Glenmark Pharmaceuticals Inc., USA, Mahwah, NJ is voluntarily recalling 114 batches of Potassium Chloride Extended-Release Capsules, USP (750 mg) 10 mEq K, to the consumer level. The product is being recalled because of failed dissolution. Risk Statement: The failed dissolution of potassium chloride extended-release capsules may cause high potassium levels, also known as hyperkalemia, which can result in irregular heartbeat that can lead to cardiac arrest. For patients who require chronic use of potassium chloride extended-release oral capsules, especially in those patients with underlying comorbidities or conditions that cause altered excretory mechanisms for potassium such as hypertension, heart failure, or renal dysfunction, there is a reasonable probability of developing hyperkalemia that may lead to a range of severity of adverse events from being asymptomatic to more severe potential life threatening adverse events of hyperkalemia such as cardiac arrythmias, severe muscle weakness, and death. To date, the firm has not received any reports of hyperkalemia or serious adverse events from spontaneous sources related to this recall. Potassium Chloride Extended-Release Capsules are used for the treatment of patients with low potassium (hypokalemia) and are packaged in bottles of 100-count (NDC 68462-357-01) and 500-count (NDC 68462-357-05) capsules. The Potassium Chloride Extended-Release Capsules being recalled were distributed nationwide to wholesale, distributor, and retail outlets.	Glenmark Pharmaceuticals, Inc.	100-count - NDC: 68462-357-01: Batch #: • 17221393 exp. 06/2024 • 17221403 exp. 06/2024 • 17221405 exp. 06/2024 • 17221503 exp. 06/2024 • 17221508 exp. 06/2024 • 17221567 exp. 07/2024 • 17221566 exp. 07/2024 • 17221719 exp. 07/2024 • 17221731 exp. 07/2024 • 17221891 exp. 08/2024 • 17221892 exp. 08/2024 • 17221900 exp. 08/2024 • 17221992 exp. 08/2024 • 17222022 exp. 08/2024 • 17222056 exp. 09/2024 • 17222043 exp. 09/2024 • 17222068 exp. 09/2024 • 17222079 exp. 09/2024 • 17222099 exp. 09/2024 • 17222103 exp. 09/2024 • 17222114 exp. 09/2024 • 17222119 exp. 09/2024 • 17222188 exp. 09/2024 • 17222199 exp. 09/2024 • 17222209 exp. 09/2024 • 17222200 exp. 09/2024

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
				• 17222265 exp. 10/2024 • 17222269 exp. 10/2024 • 17222527 exp. 11/2024 • 17222530 exp. 11/2024 • 17222583 exp. 11/2024 • 17222586 exp. 11/2024 • 17230051 exp. 11/2024 • 17230075 exp. 11/2024 • 17230067 exp. 11/2024 • 17230074 exp. 12/2024 • 17230221 exp. 12/2024 • 17230468 exp. 01/2025 • 17230479 exp. 01/2025 • 17230553 exp. 01/2025 • 17230543 exp. 01/2025 • 17230561 exp. 01/2025 • 17230619 exp. 02/2025 • 17230624 exp. 02/2025 • 17230879 exp. 03/2025 • 17230890 exp. 03/2025 • 17230918 exp. 03/2025 • 17230984 exp. 03/2025 • 17230996 exp. 03/2025 • 17231002 exp. 03/2025 • 17231081 exp. 03/2025 • 17231102 exp. 04/2025 • 17231135 exp. 04/2025 • 17231329 exp. 04/2025

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
				• 17231369 exp. 05/2025 • 17231513 exp. 05/2025 • 17231516 exp. 06/2025 • 17231713 exp. 06/2025 • 17231909 exp. 07/2025 • 17231903 exp. 07/2025 • 17231943 exp. 08/2025 • 17232166 exp. 09/2025 • 17232179 exp. 09/2025 500-count - NDC: 68462-357-05 • 17221489 exp. 06/2024 • 17221504 exp. 06/2024 • 17221530 exp. 06/2024 • 17221561 exp. 07/2024 • 17221579 exp. 07/2024 • 17221568 exp. 07/2024 • 17221702 exp. 07/2024 • 17221704 exp. 07/2024 • 17221898 exp. 08/2024 • 17221993 exp. 08/2024 • 17222029 exp. 08/2024 • 17222300 exp. 10/2024 • 17222304 exp. 10/2024 • 17222278 exp. 10/2024 • 17222609 exp. 10/2024 • 17222395 exp. 10/2024 • 17222589 exp. 11/2024

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
				• 17222605 exp. 11/2024 • 17222613 exp. 11/2024 • 17230186 exp. 12/2024 • 17230192 exp. 12/2024 • 17230213 exp. 12/2024 • 17230278 exp. 12/2024 • 17230399 exp. 12/2024 • 17230406 exp. 01/2025 • 17230412 exp. 01/2025 • 17230427 exp. 01/2025 • 17230444 exp. 01/2025 • 17230453 exp. 01/2025 • 17230495 exp. 01/2025 • 17230574 exp. 02/2025 • 17230585 exp. 02/2025 • 17230608 exp. 02/2025 • 17230629 exp. 02/2025 • 17230883 exp. 03/2025 • 17230921 exp. 03/2025 • 17231087 exp. 04/2025 • 17231339 exp. 04/2025 • 17231360 exp. 05/2025 • 17231711 exp. 06/2025 • 17231745 exp. 06/2025 • 17231819 exp. 07/2025 • 17231820 exp. 07/2025 • 17231936 exp. 07/2025 • 17231957 exp. 07/2025

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
				• 17231998 exp. 08/2025 • 17232012 exp. 08/2025 • 17232110 exp. 09/2025 • 17232114 exp. 08/2025 • 17232119 exp. 09/2025 • 17232343 exp. 09/2025
04/23/2024	Sapropterin Dihydrochloride Powder for Oral Solution 100 mg	Dr. Reddy's Laboratories Ltd. along with its subsidiaries (together referred to as "Dr. Reddy's"), announced that it is voluntarily recalling six lots of Sapropterin Dihydrochloride Powder for Oral Solution 100 mg to the consumer level due to powder discoloration in some packets leading to decreased potency. The issue was discovered during an accelerated stability test in addition to customer complaints. Risk Statement: Reduced efficacy of the product would result in elevated Phenylalaninemia (Phe) levels in patients. Chronically elevated Phe levels in infants and children are likely to cause permanent neurocognitive deficits, including permanent and irreversible intellectual disability, developmental delay, and seizures. Furthermore, elevated Phe levels during pregnancy, especially in early gestation, are associated with microcephaly and congenital heart disease. Dr. Reddy's Laboratories Inc. has not received any reports of adverse events related to this recall to date.	Dr. Reddy's Laboratories Inc	Javygtor™ (Sapropterin) Dihydrochloride) Powder for Oral Solution 100 mg: NDC: 43598-097-30 Lot numbers: • T2202812 exp. 07/2025 • T2204053 exp. 10/2025 • T2300975 exp. 02/2026 • T2300976 exp. 02/2026 • T2304356 exp. 08/2026 Sapropterin Dihydrochloride Powder for Oral Solution 100 mg NDC: 43598-477-30 • Lot number: T2200352 exp. 12/2024

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
04/01/2024	Atovaquone Oral Suspension, USP 750mg/5mL	AvKARE, LLC. is voluntarily recalling lot # AW0221A of Atovaquone Oral Suspension, USP 750mg/5mL to the Consumer / User level, due to the potential Bacillus cereus contamination in the product found during stability testing at a 3rd party lab. 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 endocarditis and necrotizing soft tissue infections. To date, AvKARE has not received any reports of adverse events related to this recall. Atovaquone Oral Suspension, USP is indicated for prevention and treatment of Pneumocystis jiroveci pneumonia (PCP) in adults and children 13 years of age and older who cannot tolerate other medicines, such as trimethoprim-sulfamethoxazole. Atovaquone Oral Suspension, USP was distributed between March 18, 2024, through March 21, 2024, nationwide to wholesalers. The product is packaged in a carton. The identified NDC # associated with the product is 50268-086-12, UPC # 5026808612 and the affected lot# is AW0221A with an expiration date of Aug. 2025.	AvKARE, LLC	• NDC: 50268-086-12 • Lot #: AW0221A exp. 08/2025

Gold Coast Health Plan℠
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Pharmacy Newsletter

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