



**Gold Coast
Health Plan** SM
A Public Entity

Pharmacy Newsletter

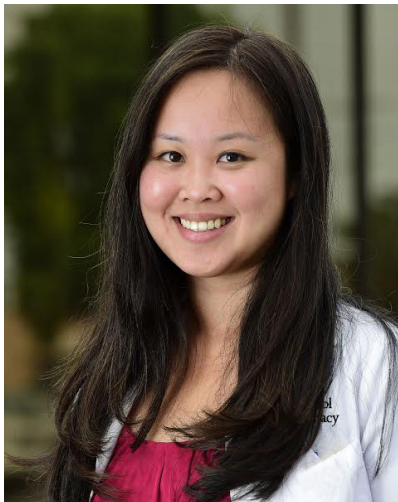
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A Message from the Gold Coast Health Plan Clinical Programs Pharmacist



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
Clinical Programs Pharmacist

Medi-Cal Rx: Changes to Diabetic Blood Glucose Test Strips and Lancets Coverage

Beginning July 1, 2023, the coverage for diabetic testing supplies will be updated as follows:

- Maximum days supply allowed will be updated from a 90-day supply maximum to allow up to a 100-day supply per claim.
- **Code 1 restrictions will be applied.**
- Must document diagnosis of diabetes on prescription.
- Must document if patient is insulin or non-insulin dependent on prescription.
- Quantity restrictions will be changed as follows:
 - » For **insulin dependent** beneficiaries:
 - Documentation by the provider on the prescription the beneficiary is using insulin;
AND
 - Limited to up to six per day of blood glucose test strips and up to six per day of lancets;
AND
 - A maximum quantity of up to 600 (612 if using the Accu-Chek® Fastclix Lancets) of each product in 100 days.
 - » For non-insulin dependent beneficiaries:
 - Documentation by the provider on the prescription the beneficiary is not using insulin;
AND
 - Limited to one per day of blood glucose test strips and one per day of lancets;
AND
 - A maximum of up to 100 of each product in 100 days.

A prior authorization (PA) showing medical necessity will be required for quantities over the published allowances or non-diabetic diagnoses.

[Click here](#) for more information or visit the Medi-Cal Rx website for all updates.

Member Out-of-Pocket Reminder

Unless a Medi-Cal beneficiary is eligible for Medicare or has a share of cost (SOC) to meet, they should never pay out-of-pocket for their prescription medications. If you discover that a member has been paying out-of-pocket for their prescribed medications, please notify Gold Coast Health Plan (GCHP) immediately at 1-888-301-1228. If a member is asked to pay out-of-pocket due to a prescription not being covered, please submit a prior authorization (PA) request to Medi-Cal Rx or work with the member and pharmacy to change the medication to something that is listed on the Medi-Cal Rx Contract Drugs List or the Medi-Cal Rx Approved NDC List.

If a member has paid out-of-pocket for a medication, they may be eligible for reimbursement if all of the following applies:

- Member received a Medi-Cal covered product on a date they were Medi-Cal eligible. This includes the evaluation time frame starting the date they applied for Medi-Cal until the date their Medi-Cal card was issued, the three-month retroactive period (if applicable), and any time during the post approval period that the member was covered.
- Someone paid out-of-pocket for a covered prescription item.
- After the member received their Medi-Cal card, they produced their benefit card to the pharmacy, and the pharmacy did not reimburse them.

If you discover a member has been paying out-of-pocket for their prescription medications, please direct them to the [DHCS website](#) for information related to direct member reimbursement.

For more information or to file a claim, please direct the member to call 1-916-403-2007 or write to Medi-Cal at:

California Department of Health Care Services / Beneficiary Services Center
P.O. Box 138008
Sacramento, CA 95813-8008

Medi-Cal Rx Updates

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 NDC and all dosages available in the marketplace. You can also use this tool to determine if a prior authorization (PA) 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](#).

Updates on the Reinstatement of PA and Phasing Out of the Transition Policy for Medi-Cal Rx

As of Feb. 24, 2023, PA requirements have been reinstated for all therapeutic drug classes except for enteral nutrition products for beneficiaries 22 years of age or older. As of June 23, 2023, all lifts to the transition policy that allowed beneficiaries 22 years of age or older to continue their medications based on historical paid claims data or a grandfathered PA that was approved prior to Medi-Cal Rx have been completed. If a beneficiary 22 years of age or older needs to continue therapy for a medication that requires a PA in any therapeutic drug class, except for enteral nutrition products, it will require a new prior authorization to be submitted or the provider may consider an alternative therapy that's covered in the Contract Drugs List (CDL).

Additional resources include [Frequently Asked Questions \(FAQs\)](#) related to the transition and a [Medi-Cal Rx webinar](#) explaining the transition lift.

The state Department of Health Care Services (DHCS) has enabled extended duration / multi-year PAs for up to five years for certain maintenance medications used for chronic conditions. Qualified prescriptions in the classes below have been automatically extended.

Extended Duration PA Maintenance Drug Classes*			
Anti-depressants	Glaucoma agents	Asthma inhalers	Anti-hypertensives
Anti-lipemic agents	Oncology agents	Diabetes medications	Anti-psychotic agents
Antiviral agents	Anti-convulsants	Hormone agents	Cardiovascular agents
Coronary vasodilators	Anti-Parkinson's agents	Rheumatoid Arthritis agents	Diuretics
Multiple Sclerosis agents			

*Not all maintenance drug classes are listed.

For more information related to this change, [click here](#).

At this time, these changes will not affect beneficiaries under the age of 22. Reinstating PAs for beneficiaries 21 years of age and younger and all enteral nutrition products to begin no sooner than July 2023. For more information regarding the Medi-Cal Rx Reinstatement, visit the [Medi-Cal Rx Education and Outreach page](#).

Additional resources:

- [How to Prepare for Retirement of the Transition Policy](#)
- [Medi-Cal Rx Approved NDC List](#)

General Medi-Cal Rx Information

All pharmacy claims and PA requests should be submitted to Medi-Cal Rx. For pharmacy billing, claims will process under: **BIN 022659, PCN 6334225, Group MEDICALRX.**

For assistance regarding a pharmacy claim or PA, please contact the Medi-Cal Rx Customer Service Center via phone at 1-800-977-2273, email at MediCalRxEducationOutreach@magellanhealth.com or chat [here](#). Agents are available 24 hours a day, seven days a week, 365 days a year.

To submit a PA or appeal for a pharmacy claim to Medi-Cal Rx, please fax 1-800-869-4325. [This information sheet](#) contains all of the important information regarding how to submit a prior authorization or an appeal for a pharmacy claim to Medi-Cal Rx. You may also visit the [Medi-Cal Rx Communication page](#) for any upcoming bulletins and news.

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. Most recent changes made are effective June 1, 2023. Below is a list of the most recent changes to the CDL for Medi-Cal Rx.

Drug Name	Description	Effective Date
Adagrasib	Added to CDL with restriction.	April 1, 2023
Aztreonam Lysine	Removed Code I restriction.	April 1, 2023
Elacestrant	Added to CDL with restriction.	April 1, 2023
Fesoterodine Fumarate	Removed Code I restriction.	April 1, 2023
Mercaptopurine	Additional formulation (oral suspension) added to CDL.	April 1, 2023
Mirvetuximab soravtansine-gynx	Added to CDL with restriction.	April 1, 2023
Nevirapine	Labeler restriction removed (liquid).	April 1, 2023
Pirtobrutinib	Added to CDL with restriction.	April 1, 2023
Somatropin (Genotropin)	Added to CDL with restriction.	April 1, 2023
Somatropin (Genotropin MiniQuick)	Added to CDL with restriction.	April 1, 2023
Somatropin (Norditropin FlexPro)	Added to CDL with restriction.	April 1, 2023
Tagraxofusp-erzs	Added to CDL with restriction.	April 1, 2023
Tobramycin	Removed Code I restriction.	April 1, 2023
Ulipristal Acetate	Updated Code I restriction.	April 1, 2023
Apalutamide	Additional strength (240 mg) added with restriction.	May 1, 2023
Buspirone	Additional strength (7.5 mg) added.	May 1, 2023
Calaspargase pegol-mknl	Added to CDL with restriction.	May 1, 2023
Canagliflozin	Added to CDL with restriction.	May 1, 2023
Clobetasol Propionate	Additional formulation (shampoo) added to CDL.	May 1, 2023
Cyclosporine	Added to CDL with restriction.	May 1, 2023
Efavirenz	Labeler restriction removed (600 mg tablets).	May 1, 2023
Estradiol	Additional formulation (vaginal cream) added to CDL.	May 1, 2023
Insulin Lispro	Labeler restriction updated (3 ml vial).	May 1, 2023
Insulin Regular, Human	Added to CDL.	May 1, 2023

Drug Name	Description	Effective Date
Linaclotide	Added to CDL with restriction.	May 1, 2023
Mifepristone	Added to CDL.	May 1, 2023
Norethindrone / Ethinyl Estradiol / Iron	Additional strength (1.5 mg-30 mcg) added with restriction.	May 1, 2023
Omega-3 Acid Ethyl Esters	Added to CDL.	May 1, 2023
Pegaspargase	Diagnosis and prior authorization restriction added.	May 1, 2023
Sotorasib	Additional strength (320 mg) added with restriction.	May 1, 2023
Acalabrutinib	Effective July 1, 2023: 100 mg capsules end dated.	June 1, 2023
Alitretinoin	Restriction updated to prior authorization required.	June 1, 2023
Azithromycin	Labeler code restriction (17478) removed from ophthalmic solution.	June 1, 2023
Bupropion HCL	Restrictions removed on sustained release tablets.	June 1, 2023
Colistimethate	Added to CDL.	June 1, 2023
Cytarabine	Available strengths updated.	June 1, 2023
Insulin Glargine-YFGN	Labeler restriction added.	June 1, 2023
Porfimer Sodium	Restriction updated to prior authorization required.	June 1, 2023
Retifanlimab-DLWR	Added to CDL with prior authorization restriction.	June 1, 2023
SMOFlipid	Added to CDL.	June 1, 2023
Thyroid, Pork	Additional strength (16.25 mg) added.	June 1, 2023

Medi-Cal Rx: Pharmacy Benefit for COVID-19

Reminder: COVID-19 vaccinations, treatments, and self-test at-home kits are covered until Sept. 30, 2024.

For more information regarding vaccinations / treatments, view the [CDL](#). For more information about self-test at-home kits, review this [list](#).

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 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	
Blood glucose test strips for blood glucose monitor (*change effective July 1, 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.	*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.
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.
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.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Disposable insulin delivery devices	Yes	PA required	a. For Omnipod systems, 10 pods every 30 days with a maximum of a 90-days-supply. b. For V-Go Series, 30 pods every 30 days with a maximum of a 90-days-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 (*change effective July 1, 2023)	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	No	200 per 30-day period.	None.
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, with needle (non-insulin)	No	200 per 30-day period.	None.
Syringe, Insulin U-500	No	100 per 30-day period.	Code I Restriction for use with Insulin, Regular, U-500 only.
Syringes, insulin, any size	No	200 per 30-day period.	None.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Therapeutic continuous glucose monitor (CGM)	Yes	PA required. One Receiver / Reader every 365 days. One Transmitter every 90 days. Up to three Sensors every 30 days (based upon the specific manufacturer's recommended use)	Refer to the List of Covered Therapeutic 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](#).

Find A Pharmacy

To find the nearest pharmacy where prescriptions can be picked up, use the [Med-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 the pharmacy. Please review the state Department of Health Care Services (DHCS) [press release](#).

The [Medi-Cal Rx Website](#) contains the most accurate, up-to-date information related to prescription benefits. The website includes an overview and background information, frequently asked questions (FAQs), [Bulletins & News](#), [Contract Drugs List \(CDL\)](#), [Provider Manual](#) and other helpful information. Please bookmark this website today and sign up for the [Medi-Cal Rx Subscription Services](#).

For assistance regarding a pharmacy claim or PA, please contact the Medi-Cal Rx Customer Service Center at 1-800-977-2273. Agents are available 24 hours a day, seven days a week, 365 days a year.

For pharmacy billing, claims will process under: **BIN 022659, PCN 6334225, Group MEDICALRX.**

For assistance regarding submitting a PA or appeal for a pharmacy claim to Medi-Cal Rx, please fax to 1-800-869-4325.

If you need further assistance, contact the GCHP Pharmacy Department at 1-805-437-5738 or email at Pharmacy@goldchp.org.

Medi-Cal Rx: Controlled Substances Policy

All controlled drug products, including opioids (DEA Schedule 2-5) will have a maximum day supply of 35 days. Any claims submitted for more than 35 days will require a prior authorization (PA).

NOTE: The above supply limitation does not apply to new-start opioid prescriptions, new-start benzodiazepine prescriptions, or buprenorphine products. PAs will be required for all intramuscular, intravenous, and subcutaneous injectable forms of opioids.

NOTE: This limit does not apply to buprenorphine products indicated for pain or addiction. New-start opioid claims will be restricted to a seven-day supply or a maximum quantity per fill of 30 solid dosage units (each) or 240mL for liquids.

NOTE: New start is defined as absence of paid claims for opioids in the beneficiary's history within the prior 90 days. (Cough preparations containing opioids are excluded from this look back.)

Subsequent fills will be restricted to a 35-day supply.

NOTE: Subsequent fills / Chronic Use is defined as the presence of paid claims for opioids in the beneficiary's history within the prior 90 days. (Cough preparations containing opioids are excluded from this lookback.)

Claims submitted for new-start and subsequent fill for opioids will be restricted to the following maximum daily quantity limits:

Maximum Quantity Per Day Limit(s) New-Start and Subsequent Fill(s)	
Dosage Form	Allowable Daily Limit
Solid Dosage Forms	8 each
Liquid Dosage Forms	60mL
Transdermal Dosage Forms	1 each
NOTE: These limits do not apply to buprenorphine products.	

Claims submitted for *subsequent fills* for opioids will be restricted to the following maximum quantities **per fill**:

Maximum Quantity Per Fill Subsequent Fill(s)	
Dosage Form	Allowable Per Fill Limit
Solid Oral – Immediate Release	120 each
Solid Oral – Extended-Release	90 each
Oral Liquids	180mL
Parenterals	100mL
Transdermal Dosage Forms	10 each
NOTE: These limits do not apply to buprenorphine products.	

Utilization Management Types

Code	Description
AL	Age limit: age parameters must be met.
LR	Labeler restriction: claim must reflect indicated labeler code for claim to pay.
QL	Quantity limit: claim will reject if defined quantity limits are exceeded.

For more information, please review the [Medi-Cal Rx Contract Drugs List](#).

Reinstatement of the Medi-Cal Rx Controlled Substance Policy on Buprenorphine Products

As of June 1, 2023, Buprenorphine products for pain or addiction no longer have the option to be filled for an up to 100-day supply without a PA. All Buprenorphine products will now follow the Controlled Substance Policy as documented in the [Medi-Cal Rx Contract Drugs List \(CDL\)](#). As of June 1, 2023, all Buprenorphine products have a maximum day supply of 35 days, with new starts restricted to a seven-day supply.

Drug Use Review (DUR) Educational Articles

The purpose of the 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 policies of the state Department of Health Care Services (DHCS).

The following educational articles that have been posted since the beginning of the year:

- [Clinical Review: Management of Acute Postpartum Pain - May 2023](#)
- [Risks to Patients Exposed to Xylazine in Illicit Drugs - January 2023](#)
- [Improving the Quality of Care: Treatment of Latent Tuberculosis Infection - January 2023](#)
- [2022 Immunization Update: Mpox, HepB, Influenza, COVID-19, Pneumococcal, Zoster - January 2023](#)
- [Removal of DATA-Waiver \(X-Waiver\) Requirement - January 2023](#)

These articles and copies of previous newsletters are available on the GCHP [website](#).

Update to the Centers for Disease Control and Prevention (CDC) Opioid Guidelines

The Centers for Disease Control and Prevention (CDC) has provided [2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain](#), which is intended to be a clinical tool to help providers and members work together to make patient-centered decisions about pain management.

The guideline is intended to help providers:

- Improve communication with patients about the benefits and risks of pain treatments, including opioid therapy for pain.
- Improve the safety and effectiveness of pain treatment.
- Mitigate pain.
- Improve function and quality of life for patients with pain.
- Reduce the risks associated with opioid pain therapy (including opioid use disorder, overdose, and death).

The clinical practice guideline includes [12 recommendations](#) for clinicians providing pain care for outpatients 18 years of age or older with acute pain (duration less than one month), subacute pain (duration of one to three months), or chronic pain (duration of more than three months). These recommendations are grouped into four areas of consideration: Determining whether or not to initiate opioids for pain, deciding duration of initial opioid prescription and conducting follow-up, selecting opioids and determining opioid dosages, and assessing risk and addressing potential harms of opioid use. These recommendations do not apply to pain management related to sickle cell disease, cancer-related pain treatment, palliative care, or end-of-life care.

Highlighted recommendations listed in the clinical practice guidelines include:

- Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient.
- Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks.
- When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release and long-acting (ER/LA) opioids.
- When opioids are initiated for opioid-naïve patients with acute, subacute, or chronic pain, clinicians should prescribe the lowest effective dosage.
- Unless there are indications of a life-threatening issue, such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), opioid therapy should not be discontinued abruptly, and clinicians should not rapidly reduce opioid dosages from higher dosages.
- Clinicians should evaluate benefits and risks with patients within one to four weeks of starting opioid therapy for subacute or chronic pain or of dosage escalation. Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients.
- Clinicians should use caution when prescribing opioid pain medication and benzodiazepines concurrently and consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants.
- Clinicians should offer or arrange treatment with evidence-based medications to treat patients with opioid use disorder.
- Detoxification on its own, without medications for opioid use disorder, is not recommended for opioid use disorder because of increased risks for resuming drug use, overdose, and overdose death.

Chronic Disease Self-Management Program

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, call **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
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FDA Alerts

FDA New Drug Approvals

This information is a list of new drugs 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 the FDA's website.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
DAYBUE	<i>Trofinetide</i>	Oral Solution	Indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.
ZYNYZ	<i>Retifanlimab-Dlwr</i>	Iv Injectable	Indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma.
JOENJA	<i>Leniolisib Phosphate</i>	Oral Tablet	Indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.
QALSODY	<i>Tofersen</i>	Intrathecal Solution	Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.
TRIKAFTA (COPACKAGED)	<i>Elexacaftor, Ivacaftor, Tezacaftor; Ivacaftor</i>	Oral Granules	Indicated for the treatment of cystic fibrosis (CF) in patients 2 years of age and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on in vitro data
ABILIFY ASIMTUFII	<i>Aripiprazole</i>	Intramuscular Suspension, Extended Release	Indicated: <ul style="list-style-type: none"> • For the treatment of schizophrenia in adults. • As maintenance monotherapy treatment of bipolar I disorder in adults.
UZEDY	<i>Risperidone</i>	Subcutaneous Suspension, Extended Release	Indicated for the treatment of schizophrenia in adults.
SYMBICORT AEROSPHERE	<i>Budesonide; Formoterol Fumarate</i>	Inhalation Aerosol, Metered	Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

FDA 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's website.

Drug	Type of Change	Change
AMONDYS 45 (casimersen)	Contraindications	AMONDYS 45 is contraindicated in patients with known hypersensitivity to casimersen or to any of the inactive ingredients. Instances of hypersensitivity, including angioedema and anaphylaxis, have occurred in patients receiving AMONDYS 45.
CLINOLIPID 20%	Contraindications	The use of CLINOLIPID is contraindicated in patients with the following: <ul style="list-style-type: none"> • Known hypersensitivity to egg, soybean, peanut or to any of the active or inactive ingredients in CLINOLIPID. • Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride >1,000 mg/dL).
CLOZARIL (clozapine)	Boxed Warning	Orthostatic hypotension, bradycardia, syncope, and cardiac arrest have occurred with CLOZARIL treatment. The risk is highest during the initial titration period, particularly with rapid dose escalation. These reactions can occur with the first dose, with doses as low as 12.5 mg per day, or when restarting patients who have had even a brief interruption in treatment with CLOZARIL. Initiate treatment at 12.5 mg once or twice daily; titrate slowly; and use divided dosages to minimize risk. Use CLOZARIL cautiously in patients with cardiovascular or cerebrovascular disease or conditions predisposing to hypotension (e.g., dehydration, use of antihypertensive medications).
FETZIMA (levomilnacipran hydrochloride)	Contraindications	FETZIMA is contraindicated: <ul style="list-style-type: none"> • In patients with hypersensitivity to levomilnacipran, milnacipran HCl, or to any excipient in the formulation. • With the use of Monoamine Oxidase Inhibitors (MAOIs) intended to treat psychiatric disorders with FETZIMA or within seven days of stopping treatment with FETZIMA is contraindicated because of an increased risk of serotonin syndrome.
UBRELVY		UBRELVY is contraindicated with concomitant use of strong CYP3A4 inhibitors.
VESANOID	Boxed Warning	WARNING: EMBRYO-FETAL TOXICITY and DIFFERENTIATION SYNDROME <ul style="list-style-type: none"> • VESANOID can cause embryo-fetal loss and malformations when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Females of reproductive potential must have a negative pregnancy test before initiating.

Drug	Type of Change	Change
KABIVEN IN PLASTIC CONTAINER (amino acids; calcium chloride; dextrose; magnesium sulfate; potassium chloride; sodium acetate; sodium glycerophosphate; soybean oil)	Contraindications	The use of KABIVEN is contraindicated in: <ul style="list-style-type: none"> • Neonates (28 days of age or younger) 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 with known hypersensitivity to egg, soybean, peanut or any of the active or inactive ingredients in KABIVEN. • Patients with severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentration >1,000 mg/dL).
LIPIODOL (ethiodized oil)	Contraindications	Lipiodol hysterosalpingography is contraindicated in pregnancy, acute pelvic inflammatory disease, marked cervical erosion, endocervicitis and intrauterine bleeding, in the immediate pre- or postmenstrual phase, and within 30 days of curettage or conization or patients with known or suspected reproductive tract neoplasia due to the risk of peritoneal spread of neoplasm.
ORGOVYX (relugolix)	Contraindications	ORGOVYX is contraindicated in patients with severe hypersensitivity to relugolix or to any of the product components.
PERIKABIVEN IN PLASTIC CONTAINER (amino acids; calcium chloride; dextrose; magnesium sulfate; potassium chloride; sodium acetate; sodium glycerophosphate; soybean oil)	Contraindications	The use of PERIKABIVEN is contraindicated in: <ul style="list-style-type: none"> • Neonates (28 days of age or younger) 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 with known hypersensitivity to egg, soybean, peanut or any of the active or inactive ingredients in PERIKABIVEN. • Patients with severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentration >1,000 mg/dL).
QULIPTA (atogepant)	Contraindications	QULIPTA is contraindicated in patients with a history of hypersensitivity to atogepant or any of the components of QULIPTA. Reactions have included anaphylaxis and dyspnea.
SOGROYA (somapacitan-beco)	Contraindications	SOGROYA is contraindicated in patients with: <ul style="list-style-type: none"> • Acute critical illness after open-heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure because of the risk of increased mortality with use of pharmacologic doses of SOGROYA. • Hypersensitivity to SOGROYA or any of its excipients. Systemic hypersensitivity reactions have been reported post marketing with somatropin. • Pediatric patients with closed epiphyses. • Active malignancy. • Active proliferative or severe non-proliferative diabetic retinopathy. • Pediatric patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea or have severe respiratory impairment due to risk of sudden death.

Drug	Type of Change	Change
VERSACLOZ (clozapine)	Boxed Warning	Orthostatic hypotension, bradycardia, syncope, and cardiac arrest have occurred with clozapine treatment. The risk is highest during the initial titration period, particularly with rapid dose escalation. These reactions can occur with the first dose, with doses as low as 12.5 mg per day, or when restarting patients who have had even a brief interruption in treatment with Versacloz. Initiate treatment at 12.5 mg once or twice daily; titrate slowly; and use divided dosages to minimize risk. Use VERSACLOZ cautiously in patients with cardiovascular or cerebrovascular disease or conditions predisposing to hypotension (e.g., dehydration, use of antihypertensive medications).

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
Guanfacine Hydrochloride Tablets	Amneal Teva	<ul style="list-style-type: none"> Amneal did not provide a reason for the shortage. Mylan discontinued guanfacine tablets in June 2021. Teva did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Amneal has guanfacine 1 mg and 2 mg tablets on back order and the company cannot estimate a release date. Teva has guanfacine 1 mg and 2 mg tablets on back order and the company estimates a release date of late-June 2023.
Budesonide Suspension for Inhalation	Amneal AstraZeneca Cipla Lupin Nephron Sandoz Teva	<ul style="list-style-type: none"> Amneal did not provide a reason for the shortage. AstraZeneca states Pulmicort Respules are available. Cipla did not provide a reason for the shortage. Lupin did not provide a reason for the shortage. Nephron is prioritizing the production of albuterol inhalation solution. Sandoz was not available to provide information. Teva did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Amneal has budesonide 0.25 mg/2 mL inhalation suspension in limited supply. Cipla has all presentations available in limited supply. Lupin has budesonide 0.5 mg / 2 mL inhalation suspension in 30-count (five ampules per foil pouch) on intermittent back order and the company is allocating supplies as they become available. Nephron has all presentations on intermittent back order and the company is releasing supplies as they become available. Teva has budesonide 0.25 mg/2 mL (NDC 00093-6815-55) inhalation suspension in 30-count ampules in individual pouches on back order with an estimated release date in early- to mid-June 2023. All other presentations are on back order and the company estimates a release date in late-June 2023.

Drug Product	Affected Manufacturers	Summary
Dexmethylphenidate Extended Release Capsules	Amneal Camber Lannett Par Sun Pharma Teva	<ul style="list-style-type: none"> • Amneal did not provide a reason for the shortage. • Camber did not provide a reason for the shortage. • Lannett has dexmethylphenidate extended-release capsules available. • Novartis has Focalin XR capsules available. • Par did not provide a reason for the shortage. • Sun Pharma did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> • Amneal has dexmethylphenidate 5 mg and 35 mg extended-release capsules available with short expiration dating. The 10 mg and 30 mg extended-release capsules are on back order and the company cannot estimate a release date. • Camber has all presentations on back order and the company cannot estimate a release date. • Par has dexmethylphenidate 15 mg, 20 mg, 30 mg, and 40 mg extended-release capsules on back order and the company cannot estimate a release date. • Sun Pharma has all presentations on back order and the company cannot estimate a release date. • Teva has dexmethylphenidate 5 mg, 10 mg, 15 mg and 25 mg extended-release capsules on intermittent back order and the company is releasing supplies as they become available. The 20 mg and 40 mg extended-release capsules are on back order and the company estimates a release date in early-August 2023.
Hydroxyurea capsules (Droxia)	H2-Pharma	<ul style="list-style-type: none"> • H2-Pharma is in the process of changing NDC numbers over after the product was divested from Bristol Myers Squibb. • Generic products are not affected, however there are no generic equivalents for hydroxyurea 200 mg, 300 mg, and 400 mg capsules. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> • H2-Pharma has Droxia 200 mg, 300 mg, and 400 mg capsules on back order and the company estimates a release date in late-June to early-July 2023.

Drug Product	Affected Manufacturers	Summary
Albuterol sulfate and Ipratropium Bromide Inhalation Solution	Cipla Ritedose Sun Pharma	<ul style="list-style-type: none"> • Cipla has albuterol and ipratropium inhalation solution available. • Mylan has albuterol and ipratropium inhalation solution available. • Nephron is shipping albuterol and ipratropium inhalation solution regularly. • Ritedose has albuterol and ipratropium inhalation solution on allocation due to increased demand. • Sun Pharma did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> • Ritedose has albuterol and ipratropium inhalation solution on allocation. • Sun Pharma has albuterol and ipratropium inhalation solution on back order and the company estimates a release date in late-June 2023.
Amphetamine Mixed Salts, Immediate-Release Tablets	Alvogen Aurobindo Camber Lannett Mallincrodt Rhodes	<ul style="list-style-type: none"> • Alvogen did not provide a reason for the shortage. • Aurobindo refuses to provide availability information. • Camber states the company is awaiting DEA quota review / approval. • Lannett has amphetamine mixed salts immediate-release tablets available. • Mallincrodt refuses to provide availability information. • Rhodes did not provide a reason for the shortage. • Sandoz is prioritizing amphetamine mixed salts immediate-release tablets to current customers. • Solco has amphetamine mixed salts immediate-release tablets available. • Teva did not provide a reason for the shortage. • Mylan and Zydus have discontinued amphetamine mixed salt immediate-release tablets. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> • Alvogen has all presentations on back order and the company estimates a release date in June 2023. • Camber has all presentations on back order and the company cannot estimate a release date. • Lannett has amphetamine mixed salts 7.5 mg immediate-release tablets on back order and the company cannot estimate a release date. • Rhodes has amphetamines mixed salts 10 mg, 20 mg, and 30 mg immediate-release tablets on back order and the company estimates a release date in July 2023. • Teva has Adderall 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg immediate-release tablets on back order and the company estimates a release date in early-July 2023. • Teva has amphetamine mixed salts 5 mg, 10 mg, 12.5 mg, 15 mg, and 30 mg immediate-release tablets on intermittent back order and the company is releasing supplies as they become available. The 7.5 mg and 20 mg tablets are on back order and the company estimates a release date of late-July 2023 for the 7.5 mg tablets and mid- to late-August 2023 for the 20 mg tablets.

Drug Product	Affected Manufacturers	Summary
Amphetamine Extended-Release Oral Presentations	Camber Lannett Mallincrodt Shire	<ul style="list-style-type: none"> Amneal did not provide a reason for the shortage. Aytu BioPharma has Adzenys XR oral disintegrating tablets available. Camber did not provide a reason for the shortage. Lannett did not provide a reason for the shortage. Mallincrodt refuses to provide availability information. Par has discontinued amphetamines mixed salts extended-release capsules. Prasco has amphetamine mixed salts extended-release capsules available for contracted customers. Rhodes has amphetamine mixed salts extended-release capsules available. Sandoz is prioritizing amphetamine mixed salts extended-release capsules to current customers. Sun Pharma has discontinued amphetamines mixed salts extended-release capsules. Shire did not provide updated availability information for Adderall XR or Mydayis extended-release capsules. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Amneal has all presentations on back order and the company cannot estimate a release date. Camber has all presentations on back order and the company cannot estimate a release date. Lannett has amphetamine 25 mg extended-release capsules on back order and the company cannot estimate a release date. Teva has amphetamine 15 mg, 25 mg, and 30 mg extended-release capsules on intermittent back order and the company is releasing supplies as they become available. The 5 mg, 10 mg, and 20 mg capsules are on back order and the company estimates a release date in late-July 2023.
Isoniazid Tablets	Mylan Teva Marlex	<ul style="list-style-type: none"> Mylan did not provide a reason for the shortage. Teva did not provide a reason for the shortage. Marlex did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Marlex has isoniazid 300 mg tablets in 30-count and 100-count bottles on long-term back order and the company cannot estimate a release date. Mylan has isoniazid 300 mg tablets in 100-count unit-dose packages on back order and the company estimates a release date of mid- to late-July 2023. Teva has isoniazid 100 mg tablets on back order and the company estimates a release date in mid-June 2023. The 300 mg tablets in 30-count bottles are on back order and the company estimates a release date in mid-July 2023. The 300 mg tablets in 100-count bottles are on back order with an estimated release date in mid- to late-June 2023.

Drug Product	Affected Manufacturers	Summary
Ibuprofen Oral Suspension (Prescription Products Only)	Teva Taro	<ul style="list-style-type: none"> Teva discontinued ibuprofen 100 mg/5 mL oral suspension in early-2023. Taro did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Taro has ibuprofen 100 mg/5 mL oral suspension 120 mL and 473 mL bottles on backorder and the company cannot estimate a resupply date.
Amoxicillin Oral Presentations	Aurobindo Hikma Sandoz Teva	<ul style="list-style-type: none"> Aurobindo refuses to provide availability information. Hikma is allocating amoxicillin to current customers to meet the planned contracted demand. Rising has amoxicillin capsules and tablets available. Sandoz did not provide a reason for the shortage. Teva did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Hikma has all amoxicillin oral presentations on allocation for current customers only. Sandoz has amoxicillin 125 mg/5 mL 100 mL bottles, 200 mg/5 mL 100 mL bottles, and 875 mg tablets in 100-count on back order and the company cannot estimate a release date. All other presentations are available in limited supply. Teva has amoxicillin 200 mg/5 mL 50 mL, 75 mL, and 100 mL bottles on back order and the company estimates a release date of mid-June 2023. The 250 mg/5 mL 80 mL, 100 mL, and 150 mL bottles are on back order and the company estimates a release date of mid-June 2023. The 400 mg/5 mL 50 mL, 75 mL, and 100 mL bottles are on back order and the company estimates a release date of mid-June 2023. The 500 mg tablets are on back order and the company estimates a release date of mid-July 2023. The 875 mg tablets are on back order and the company estimates a release date of late-July 2023. The 125 mg chewable tablets are on back order and the company estimates a release date of mid-July 2023. The 250 mg chewable tablets are on back order and the company estimates a release date of mid-June 2023. The 250 mg capsules in 100-count and 500-count are on back order and the company estimates a release date of mid-July 2023. The 500 mg capsules in 50-count and 500-count are on back order and the company estimates a release date of mid-June 2023 for the 50-count bottles and mid-July 2023 for the 500-count bottles.

Drug Product	Affected Manufacturers	Summary
Norditropin Flexpro (somatropin) Injection	Novo Nordisk	<ul style="list-style-type: none"> Novo Nordisk has Norditropin FlexPro prefilled pens on intermittent back order and the company is releasing supplies as they become available. Other somatropin injection products do not appear to be affected by this shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Novo Nordisk has Norditropin FlexPro prefilled pens on intermittent back order and the company is releasing supplies as they become available.
Clonazepam Oral Tablets	Accord H2-Pharma Solco Teva	<ul style="list-style-type: none"> Accord has clonazepam tablets on back order due to a manufacturing issue. H2-Pharma has brand name Klonopin available. Solco was not available to provide updated information. Teva did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Accord has all clonazepam tablet presentations on back order and the company cannot estimate a release date. Teva has clonazepam 0.5 mg, 1 mg, and 2 mg presentations on back order and the company estimates a release date in mid-June 2023.
Acetylcysteine Oral and Inhalation Solution	American Regent Arbor Fresenius Kabi Pfizer Roxane Labs	<ul style="list-style-type: none"> American Regent had acetylcysteine oral and inhalation solution on shortage due to manufacturing delays. They are not currently marketing the 200 mg/mL 30 mL vials. Arbor discontinued Cetylev effervescent tablets in April 2019. Fresenius Kabi has acetylcysteine oral and inhalation solution on shortage due to manufacturing delays at their contract manufacturing site. Pfizer has acetylcysteine oral and inhalation solution on shortage due to increased demand. Roxane Labs discontinued acetylcysteine oral and inhalation solution in April 2014. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> American Regent has acetylcysteine 100 mg/mL 4 mL vials and 200 mg/mL 4 mL vials available in limited supply. Fresenius Kabi has acetylcysteine 100 mg/mL 4 mL, 10 mL, and 30 mL vials on back order and the company estimates a release date of mid-June 2023. The 200 mg/mL 4 mL, 10 mL, and 30 mL vials are on back order and the company estimates a release date of mid-June 2023. Pfizer has acetylcysteine 100 mg/mL 30 mL vials are on back order and the company estimates a release date of July 2023. The 200 mg/mL 30 mL vials are on back order and the company estimates a release date of July 2023.

Drug Product	Affected Manufacturers	Summary
Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%	Akorn Hikma Wockhardt	<ul style="list-style-type: none"> Akorn ceased operations in February 2023. Hikma did not provide a reason for the shortage. Wockhardt did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Hikma has viscous lidocaine 2% in 100 mL bottles on allocation. Wockhardt has viscous lidocaine 2% in 100 mL bottles on back order and the company cannot estimate a release date.
Doxercalciferol Capsules	Winthrop	<ul style="list-style-type: none"> Winthrop did not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Winthrop has 0.5 mcg, 1 mcg, and 2.5 mcg capsules on allocation.
Methotrexate Injection	Accord Fresenius Kabi Pfizer Teva Hikma	<ul style="list-style-type: none"> Accord has methotrexate injection on shortage due to manufacturing delays. Fresenius Kabi has methotrexate injection on back order due to increased demand. Pfizer has methotrexate injection on back order due to increased demand. Teva did not provide a reason for the shortage. Hikma has methotrexate injection on back order due to increased demand. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> Accord has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL preservative-free vials on back order and the company cannot estimate a release date. Fresenius Kabi has methotrexate 25 mg/mL 10 mL preservative-free vials on back order and the company estimates a release date of mid- to late-July 2023. The 1 gram lyophilized powder vials are on back order and the company estimates a release date of mid- to late-July 2023. Hikma has methotrexate 25 mg/mL 2 mL preservative-free vials on allocation. The 1 gram lyophilized powder vials are on allocation. Pfizer has methotrexate 25 mg/mL 2 mL vials and 40 mL preservative-free vials available in limited supply. Teva has methotrexate 25 mg/mL 2 mL, 10 mL, and 40 mL preservative-free vials on allocation.

FDA Drug Safety Communications

This section includes drug alerts that were released in the last three months by the FDA that affect the prescription benefit for GCHP. [Click here](#) to access this information on the FDA's website.

Drug	Communications Summary
Copiktra (<i>duvelisib</i>)	<p>The U.S. Food and Drug Administration (FDA) is warning that results from a clinical trial show a possible increased risk of death with Copiktra (duvelisib) compared to another medicine to treat a chronic blood cancer called leukemia and a lymphoma, a cancer found in the lymph nodes. The trial also found Copiktra was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood.</p>
Opioids	<p>FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use.</p> <p>As part of its ongoing efforts to address the nation's opioid crisis, the FDA is making several updates to the prescribing information of opioid pain medicines to provide additional guidance on the use of these powerful medicines. Opioid pain medicines are an important treatment option when used as prescribed; however, they also have serious risks, including misuse and abuse, addiction, overdose, and death.</p> <p>Although there has been a substantial overall decrease in the number of dispensed prescriptions for opioid pain medicines, overdose deaths involving prescription opioids have remained steady. Data also suggest that:</p> <ul style="list-style-type: none">• Many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine, although the dose and duration of treatment needed to adequately manage pain will vary based on the underlying cause and individual patient factors.• Patients who use opioid pain medicines after surgery often have unused tablets, which may pose a risk of accidental use, misuse and abuse, addiction, and overdose, including by children and teenagers.• Extended-release/long-acting (ER/LA) opioid pain medicines have unique risks and should be used only for those with severe and persistent pain.

Drug	Communications Summary
Stimulants	<p>The FDA updating warnings to improve the safe use of prescription stimulants used to treat Attention-Deficit / Hyperactivity Disorder (ADHD) and other conditions.</p> <p>To address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the FDA is requiring updates to the Boxed Warning and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information for some prescription stimulants does not provide up-to-date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.</p> <p>Prescription stimulants can be an important treatment option for disorders for which they are indicated. However, even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse. Misuse and abuse, also called nonmedical use, can include taking your own medicine differently than prescribed or using someone else's medicine. For this reason, sharing prescription stimulants with those for whom they are not prescribed is an important concern and a major contributor to nonmedical use and addiction. Misuse and abuse of prescription stimulants can result in overdose and death, and this risk is increased with higher doses or unapproved methods of taking the medicine such as snorting or injecting.</p>



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