Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

Q4 2023

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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.

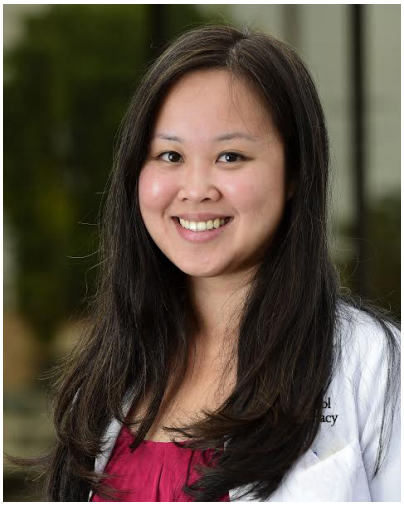
Director of Pharmacy Services
Lily Yip, Pharm.D.

Chief Medical Officer:
Felix Nuñez, MD

Editor-in-Chief:
Susana Enriquez-Euyoque

Copy Editor:
Calley Griffith

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

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.

Hormonal Contraceptives

Please note, Medi-Cal Rx will only pay for hormonal contraceptives when written as an 84-day supply. If a beneficiary attempts to fill less than 84 days at a time, the claim will reject. Please submit all prescriptions for hormonal contraceptives as no less than an 84-day supply to prevent confusion and unnecessary rejections.

Physician Administered Drugs (PADs)

Medi-Cal Rx no longer provides coverage for most physician administered drugs (PADs) that are only approved to be administered under medical supervision. This includes, but is not limited to, drugs such as Prolia and Xolair. If a PAD is prescribed, the provider's office will need to purchase the medication and bill Gold Coast Health Plan (GCHP) directly for the product. For additional information related to this policy, please see the Medi-Cal Rx Billing Policy for Physician Administered Drugs on the Medi-Cal Rx website. However, Medi-Cal Rx does cover a very limited list of Pharmacy Reimbursable Physician Administered Drugs.

Enteral Nutrition

Effective Nov. 9, 2023, PA requirements will be reinstated for all enteral nutrition orders due to the retirement of the Transition Policy for members 22 years of age and older. Submission of a new PA will be required effective Nov. 9, 2023. Medi-Cal Rx has a separate PA process for enteral nutrition. You may access this form by clicking on the Enteral Nutrition Prior Authorization Request form link or you can find it in the Medi-Cal Rx portal.

Cost Ceiling Prior Authorizations

As of Sept. 22, 2023, Medi-Cal Rx reinstated cost ceiling claim edits for members 22 years of age and older. Reject Code 78 was reinstated for all therapeutic drug classes with some exclusions. The updated policy will apply when a point of service (POS) pharmacy claim exceeds the dollar claim amount threshold as specified in the table below. Claims will reject for Reject Code 78.

Cost Ceiling Limits	
Drug / Product	**Cost Ceiling**
Over-the-counter (OTC)	$50/claim
Generic	$1,000/claim
Single and Multi-Source Brand	$4,000/claim
High-Cost Generics and Brands*	$14,000/claim
Claims over the Cost Ceiling Maximum for each category will trigger Reject Code 78 and will require a PA or a real-time override by the Medi-Cal Rx Customer Service Center (CSC).	

* Drugs / products in this category include generic and brand drugs not in the Generic or Single and Multi-Source Brand categories, where the claim threshold amount is equal to or greater than $14,000.

What pharmacy providers and prescribers need to do:
Reject Code 78 requires approval of an override with clinician review to receive a paid claim. Providers should perform the following steps:

1. Consider prescribing a less costly therapy, if clinically appropriate.
2. If a change in therapy is not appropriate,
   a. Contact the Medi-Cal Rx Customer Service Center (CSC) at 1-800-977-2273 for consideration of a real-time override; or
   b. Submit a PA request via one of the approved Medi-Cal Rx PA submission methods.

Please see the 30-Day Countdown: Reinstatement of Cost Ceiling and PAs for Enteral Nutrition and Specific Standard Therapeutic Classes bulletin on the Medi-Cal Rx website.

Quantity Limit (QL) Requirements

Effective Oct. 13, 2023, claims are now subject to the edit for Reject Code 76 – Plan Limitations Exceeded. This change applies to new start claims for all ages and refill claims only for members 22 years of age and older. If you encounter a Quantity Limit (QL) rejection, please review the CDL to determine the quantity limits. If these limits are inappropriate, you must request a PA for approval.

Note: If a claim rejects due to quantity limitations exceeding a 100-day supply for drugs / products, a PA is not reviewable for coverage consideration as it must meet this limitation of up to and including a 100-day supply (except U.S. Food and Drug Administration [FDA]-approved self-administered hormonal contraceptives [this includes transdermal patches and vaginal rings in addition to oral dosage forms] and sodium fluoride products / drops / solutions).

For more information, please review the following bulletins:

- 30-Day Countdown: Phase IV, Lift III: Reinstatement of Reject Code 76: Plan Limitations Exceeded
- How to Resolve Reject Code 76 – Plan Limitations Exceeded
- Effective Oct. 13, 2023, Medi-Cal Rx Will Reinstate Quantity Restriction Edits

Updates on the Reinstatement Process and Retirement of the Transition Policy

As of Aug. 4, 2023, Medi-Cal Rx started a series of lifts impacting claim utilization management (UM) edits. The first set of claim edits included the following NCPDP Reject Codes:

- Reject Code 60 – Product / Service Not Covered for Patient Age
  - » Medi-Cal Rx will reinstate age limit UM requirements on claims for beneficiaries 22 years of age and older. Reject Code 60 will be reinstated for claims of all standard therapeutic classes (STCs) except enteral nutrition products (including, but not limited to, to the Code I restriction listed in the Medi-Cal Rx Contract Drugs List [CDL]).
- Reject Code 61 – Product / Service Not Covered for Patient Gender
  - » Medi-Cal Rx will reinstate gender UM requirements on claims for beneficiaries 22 years of age and older. Reject Code 61 will be reinstated for claims of all STCs.
  - » Claims submitted for Medi-Cal, California Children's Services (CCS), and Genetically Handicapped Persons Program (GHPP) beneficiaries will not be impacted by Reject Code 61.
  - » Claims submitted for Family Planning, Access, Care, and Treatment (Family PACT) beneficiaries will be impacted by Reject Code 61.

  Note: The state Department of Health Care Services (DHCS) removed current gender UM requirements for all Medi-Cal Rx claims except for Family PACT.
- Reject Code 606 – Brand Drug / Specific Labeler Code Required
  - » Medi-Cal Rx will reinstate labeler code UM requirements on brand, multisource drugs where the brand name is less costly than the therapeutically equivalent (AB-rated) generic alternatives for beneficiaries 22 years of age and older.

- Code I labeler restrictions can be found in the CDL, as well as in the supplemental message returned upon claim adjudication.
- The following table provides examples of brand, multisource drugs impacted by the labeler restriction:

Example of Impacted Brand, Multisource Drugs			
Advair	Diclegis	Natroba	Symbicort
Alphagan P 0.15	Enemeez mini	Nesina	Travatan Z
Azopt	Flovent	Pentasa	Xulane Patch
Butrans	Kazano	Pradaxa	
Ciprodex Otic	Lotemax	Saphris	
Combigan	Narcan	Suboxone	

Note: DHCS will continue to evaluate the cost of these brand, multisource drugs and their generic equivalents on a quarterly basis. As generic equivalents become the least costly slternative, labeler code UM requirements will be modified.

For more information, click here.

As of Sept. 22, 2023, PA requirements are now reinstated for new starts for enteral nutrition for beneficiaries 22 years of age or older. The List of Contracted Enteral Nutrition Products are listed here. Coverage criteria for enteral nutrition is detailed in Section 12 of the Medi-Cal Rx Provider Manual. Use the Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form when submitting a PA. For more information regarding the PA requirements, review this bulletin. For more information regarding the Medi-Cal Rx Reinstatement, visit the Medi-Cal Rx Education & Outreach page.

As of Nov. 10, 2023, Reject Code 80 – Diagnosis Code Submitted Does Not Meet Drug Coverage Criteria will be reinstated for members 22 years of age and older. For auditing purposes, the Code I diagnosis restrictions can be met by:

- Diagnosis code in the acceptable range is found in the member's medical profile; or
- Diagnosis code in the acceptable range is submitted on the claim; or
- Pharmacy verifies and documents that use of product meets the Code I restriction by populating a submission clarification code (SCC) with "07" or
- A valid PA is on file.

There will also be a reinstatement of PA requirements for DAW 1 claims. If the medication is not subject to a labeler restriction for the brand drug per the Contract Drugs List, the claim will deny for brand, multisource product (BMN) PA requirements. Providers will need to consider changing the medication to an alternative or submit a BMN PA request. For more information, review this bulletin.

Additional resources:

- Medi-Cal Rx Reinstatement
- Medi-Cal Rx Phase Reinstatement Frequently Asked Questions (FAQs) page
- Medi-Cal Rx Approved NDC List
- Medi-Cal Rx Drug Lookup Tool

General Medi-Cal Rx Information

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.

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. Agents are available 24 hours a day, seven days a week, 365 days a year.

To submit a PA or appeals for a pharmacy claim to Medi-Cal Rx, please fax 1-800-869-4325. This information sheet contains important information regarding how to submit a PA 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.

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

Changes to the Contract Drugs List (CDL)

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
Amlodipine Besylate	Additional formulation (oral solution) added to CDL with age restriction.	July 1, 2023
Carglumic acid	Added to CDL with labeler restriction.	July 1, 2023
Clarithromycin	Diagnosis restrictions removed from tablets and liquid.	July 1, 2023
Dabrafenib	Additional formulation (tablets for oral suspension) added to CDL with labeler restriction.	July 1, 2023
Doxycycline Hyclate	Quantity limit restrictions removed from tablets (20 mg).	July 1, 2023
Efavirenz	Labeler restriction removed from capsules (50 mg and 200 mg).	July 1, 2023
Ketoprofen	Diagnosis restriction and formulation (tablets) removed.	July 1, 2023
Methotrexate	Additional formulation (single dose autoinjector) added to CDL with labeler restriction.	July 1, 2023
Mitotane	Added to CDL with labeler restriction.	July 1, 2023
Ofloxacin	Diagnosis restriction removed.	July 1, 2023
Sodium phenylbutyrate	Added to CDL with labeler restriction.	July 1, 2023

Drug Name	Description	Effective Date
Trametinib	Additional formulation (reconstituted solution) added to CDL with labeler restriction.	July 1, 2023
Varenicline Tartrate	Quantity limit restriction removed.	July 1, 2023
Brompheniramine Maleate with Pseudoephedrine HCL and Dextromethorphan	Age restriction added.	Aug. 1, 2023
Cetirizine HCL	Age restriction added to liquid (1 mg/1 ml) formulation.	Aug. 1, 2023
Donepezil HCL	Diagnosis restriction removed.	Aug. 1, 2023
Epcoritamab-bysp	Added to CDL with labeler restriction.	Aug. 1, 2023
Galantamine Hydrobromide	Diagnosis restriction removed from capsules. Additional formulations (oral solution and tablets) added to CDL.	Aug. 1, 2023
Guaifenesin with Codeine	Age restriction added.	Aug. 1, 2023
Hydrocodone and Acetaminophen	Age restriction removed from oral solution.	Aug. 1, 2023
Insulin Aspart	Labeler restriction removed.	Aug. 1, 2023
Insulin Aspart Protamine Suspension / Insulin Aspart, (rDNA Origin)	Labeler restriction removed.	Aug. 1, 2023
Levocetirizine Dihydrochloride	Age restriction added.	Aug. 1, 2023
Lurasidone Hydrochloride	Labeler restriction removed.	Aug. 1, 2023
Olopatadine HCL	Age restriction added to ophthalmic solution.	Aug. 1, 2023
Promethazine with Codeine	Age restriction updated.	Aug. 1, 2023
Promethazine with Phenylephrine and Codeine	Age restriction updated.	Aug. 1, 2023
Rivastigmine	Diagnosis restriction removed from transdermal system and capsules.	Aug. 1, 2023
Ciprofloxacin HCL and Dexamethasone	Labeler restriction (00065) removed from otic suspension.	Sept. 1, 2023
Cyclophosphamide	Additional formulation (vials) added to CDL.	Sept. 1, 2023
Emtricitabine and Tenofovir Disoproxil Fumarate	Labeler restriction removed.	Sept. 1, 2023

Drug Name	Description	Effective Date
Glofitamab-gxbm	Added to CDL with labeler restriction.	Sept. 1, 2023
Glucagon	Labeler restriction removed from nasal spray.	Sept. 1, 2023
Niraparib	Additional formulation (tablets) added to CDL with labeler code restriction.	Sept. 1, 2023
Ozanimod Hydrochloride	Additional strength (0.23 mg x 4, 0.46 mg x 3, 0.92 mg x 21 starter kit) added to CDL with age, diagnosis, and labeler restriction.	Sept. 1, 2023
Talazoparib	Additional strengths (0.1 mg and 0.35 mg) added to CDL with labeler restriction.	Sept. 1, 2023
Abrysvo (Respiratory Syncytial Virus Vaccine)	Added to CDL with restriction.	Oct. 1, 2023
Alogliptin	Labeler restriction removed.	Nov. 1, 2023
Arexvy (Respiratory Syncytial Virus Vaccine, Adjuvanted)	Added to CDL with restriction.	Oct. 1, 2023
Arsenic Trioxide	Labeler restriction removed.	Nov. 1, 2023
Bortezomib	Labeler restriction removed.	Nov. 1, 2023
Fulvestrant	Labeler restriction removed.	Nov. 1, 2023
Leuprolide Acetate Additional strength (six-month Syringe Kit 45 mg)	Added to CDL with diagnosis and labeler restriction.	Oct. 1, 2023
Quizartinib	Added to CDL with labeler restriction.	Oct. 1, 2023
Tobramycin Additional formulation (inhalation powder)	added to CDL with diagnosis and labeler restriction.	Oct. 1, 2023

Pharmacy Benefit for COVID-19

Reminder: COVID-19 vaccinations, treatments, and self-test at-home kits are covered by Medi-Cal Rx until Sept. 30, 2024. Members are able to pick up eight tests (four kits for two tests / kit) per 30 days. Member will need a prescription from a pharmacist or provider for each dispensing and no refills are allowed. Please review this bulletin for more information.

The new COVID vaccines are currently available and covered under Medi-Cal Rx, for beneficiaries 19 years and older. For members 6 months through 18 years of age, coverage of the vaccine will be available only through the Vaccines for Children (VFC) program. Products remain federally funded. To locate an eligible provider, click here or call 1-877-243-8832. Claims submitted to Medi-Cal Rx for members 6 months to 18 years of age will be rejected with Reject Code 60 – Product / Service Not Covered for Patient Age. Please review the Reimbursement for New Commercial COVID-19 Vaccines bulletin on the Medi-Cal Rx website for additional details.

Over The Counter at Home COVID-19 Tests

Effective Nov. 1, 2023, pharmacy providers are required to have one-on-one documented contact (in-person, telehealth, or phone) with the member or caregiver prior to dispensing COVID-19 over the counter (OTC) EUA tests. The member / caregiver must request the pharmacy provider dispense the COVID-19 OTC EUA tests; autofill is not permitted.

Items dispensed without a valid, documented request will be denied as not reasonable or necessary and are subject to post-adjudication audit review by DHCS.

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

For more details related to this change, click here.

For more information regarding vaccinations / treatments, check the CDL. For more information about covered self-test at-home COVID-19 test kits, review this list.

Pharmacy Benefit for RSV Vaccines

Effective Oct. 1, 2023, Medi-Cal Rx will cover the two new adult respiratory syncytial virus (RSV) vaccines based on their FDA approved indications.

Arexvy (GSK adjuvanted RSV vaccine) is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older.

Abrysvo (Pfizer RSV vaccine) is indicated for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age. It is also indicated for active immunization for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

For more information, review this bulletin.

Continuous Glucose Monitors (CGMs) Coverage Update

Medi-Cal Rx will expand their coverage criteria for continuous glucose monitors (CGMs). CGM coverage criteria will be updated as follows:

- Once approved, CGM authorizations will be for a period of one year, initiating on the date of approval. Each fill can be up to a 90-day supply.
- CGM coverage will be limited to prescribing by an endocrinologist, a primary care provider (physician [MD or DO]), nurse practitioner (NP), clinical nurse specialist (CNS), physician assistant (PA), or a certified nurse midwife (APRN-CNM), or other licensed health care practitioner with experience in diabetes management.
- Will require diagnosis of either insulin-dependent diabetes (type 1, type 2 or history of problematic hypoglycemia) or gestational diabetes.
- Will require HbA1c value measured within eight months of the date of the request to be documented on the PA request.
- Will have stringent authorization and reauthorization guidelines based on diagnosis.

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

Please review Medical Supplies: Future Changes to Continuous Glucose Monitoring Systems Coverage Criteria and Prior Authorization Bundling and 30-Day Countdown: Changes to Continuous Glucose Monitoring Systems Coverage Criteria and Prior Authorization Bundling for additional information.

Coverage Guidelines for Covered Medical Supplies

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 DHCS press release.

Physician Administered Drugs and Prior Authorization Requests

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 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 must 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 bill GCHP for reimbursement.

For a list of PADs that require a Prior Authorization Treatment Request Form, please use the GCHP's List of Services Requiring Prior Authorization. This list allows providers to look at specific physician administered drug codes that require PA.

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. 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.

Drug Use Review (DUR) Educational Articles

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

Disclaimer: These articles are the result of analyses carried out by the Global Medi-Cal DUR Program and are not official DHCS policies.

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

- 2023 Immunization Update: COVID-19, Influenza, RSV, HepB, Pneumococcal, HPV, Polio, Mpox, and MMR - November 2023
- No Added Benefit from Concomitant Use of GLP-1 Agonists and DPP-4 Inhibitors - August 2023
- New Resources Available for Perinatal Mental Health Conditions - August 2023
- Updated Guidance by the CDC and FDA for Prescribing Opioids - June 2023
- FDA Approves First Over-the-Counter Naloxone Nasal Spray - June 2023

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

Update to the Asthma Guidelines

The Global Initiative for Asthma (GINA) recently published the 2023 GINA Report, which provides the latest updates regarding the Global Strategy for Asthma Management and Prevention.

Terminology Definitions:

- Reliever – For symptom relief, or before exercise or allergen exposure.
- Controller – Mostly used for ICS-containing treatment.
- Maintenance Treatment – Regularly scheduled treatment.
- Anti-Inflammatory Reliever (AIR) – Provides rapid symptom relief, plus a small dose of ICS (e.g., ICS-formoterol, ICS-SABA), to reduce the risk of exacerbations compared with using a SABA reliever.
- Maintenance and Reliever Therapy (MART) – A low dose of ICS-formoterol is used as the patient's maintenance treatment, plus whenever needed for symptom relief.

Personalized asthma management:

Assess

- Confirmation of diagnosis if necessary
- Symptom control and modifiable risk factors
- Comorbidities
- Inhaler technique and adherence
- Patient (and parent / caregiver) preferences and goals

Adjust

- Treatment of modifiable risk factors and comorbidities
- Non-pharmacological strategies
- Asthma medications (adjust down / up / between tracks)
- Education & skills training

Review

- Symptoms
- Exacerbations
- Side-effects
- Lung function
- Comorbidities
- Patient (and parent / caregiver) satisfaction

Assessing a Patient with Asthma

- Asthma control – assess both symptom control and risk factors.
- Assess multimorbidity.
- Treatment issues.

Assessment of symptom control and future risk

- Assessment of symptom control.
- Risk factors for poor asthma outcomes.

How to investigate uncontrolled asthma in primary care

- Watch patient using their inhaler(s). Discuss adherence and barriers to use.
  - » Review inhaler technique and correct any errors; recheck frequently.
  - » Confirm the diagnosis of asthma.
  - » If lung function normal during symptoms, consider halving ICS dose and repeating lung function after two to three weeks.
- Remove potential risk factors. Assess and manage comorbidities.
  - » Adults / adolescents: switch to GINA Track 1 if available.
  - » Check for risk factors or inducers such as smoking, beta-blockers, NSAIDs, allergen exposure.
  - » Check for comorbidities such as rhinitis, obesity, GERD, depression / anxiety.
- Consider treatment step-up.
  - » Use shared decision-making and balance potential benefits and risk.
- Refer to a specialist or severe asthma clinic.
  - » If asthma still uncontrolled after three to six months on Step 4 treatment, refer for expert / advice. Refer earlier is asthma symptoms severe or doubts about diagnosis.

Personalized Asthma Management Guidelines

Adults & adolescents 12+ years

Track 1: The reliever is as-needed low-dose ICS-formoterol. This is the preferred approach recommended by GINA for adults and adolescents, based on strong evidence that it reduces the risk of severe exacerbations compared with regimens with SABA as reliever with similar symptom control, and the simplicity of treatment.

When a patient at any treatment step has asthma symptoms, they use low-dose combination ICS-formoterol for symptom relief.

In Steps 3-5, patients also take combination ICS-formoterol as their daily maintenance treatment. This is called Maintenance and Reliever Therapy (MART).

ICS-formoterol should not be used as the reliever by patients taking any other (non-formoterol) ICS-LABA or ICS-LABA-LAMA.

	Preferred Controller Choice	Reliever
Step 1	As-needed-only low dose ICS-formoterol	As-needed low-dose ICS-formoterol
Step 2		
Step 3	Low dose maintenance ICS-formoterol	
Step 4	Medium dose maintenance ICS-formoterol	
Step 5	Add-on LAMA. Refer for assessment of phenotype. Consider high dose maintenance ICS-formoterol (eg +/-anti-IgE, anti-IL5/5R, anti-IL4Ro, anti-TSLP)	

Track 2: The reliever is as-needed SABA or ICS-SABA. This is an alternative approach when Track 1 is not possible or is not preferred by a patient who has stable asthma and no exacerbations on their current therapy.

In Step 1, the patient takes a SABA and a low-dose ICS together for symptom relief when symptoms occur, either in a combination inhaler, or with the ICS taken right after the SABA.

In Steps 2-5, a SABA or combination ICS-SABA is used for symptom relief, and the patient also takes maintenance ICS-containing medication every day.

Before prescribing a SABA reliever, consider whether the patient is likely to be adherent with their ICS-containing therapy, otherwise they will be exposed to SABA-only treatment and a higher risk of exacerbations.

During ongoing treatment, treatment can be stepped up or down along one track, using the same reliever at each step, or it can be switched between tracks, according to the individual patient's needs.

Before stepping up, check for common problems such as incorrect inhaler technique, poor adherence, and environmental exposures, and confirm that the symptoms are due to asthma.

	Preferred Controller Choice	Other controller options	Reliever
Step 1	Take ICS whenever SABA taken		As-needed ICS-SABA or as-needed SABA
Step 2	Low dose maintenance ICS	Low dose ICS whenever SABA taken, or daily LTRA, or add HDM SLIT	
Step 3	Low dose maintenance ICS-LABA	Medium dose ICS, or add LTRA, or add HDM SLIT	
Step 4	Medium / high dose maintenance ICS-LABA	Add LAMA or LTRA or HDM SLIT, or switch to high dose ICS	
Step 5	Add-on LAMA. Refer for assessment of phenotype. Consider high dose maintenance ICS-LABA (eg +/- anti-IgE, anti-IL4Ro, anti-IL5/5R, anti-TSLP)	Add azithromycin (adults) or LTRA. As last resort consider adding low dose OCS but consider side-effects	

Children 6-11 years of age

	Preferred Controller Choice	Other controller options	Reliever
Step 1	Low dose ICS is taken whenever SABA is taken	Consider daily low dose ICS	As-needed SABA (or ICS-formoterol reliever in MART in Steps 3 and 4)
Step 2	Daily low dose inhaled corticosteroid (ICS)	Daily leukotriene receptor antagonist (LTRA) or low dose ICS taken whenever SABA taken.	
Step 3	Low dose ICS-LABA or medium dose ICS or very low dose ICS-formoterol maintenance and reliever (MART)	Low dose ICS + LTRA	
Step 4	Medium dose ICS-LABA, or low dose ICS-formoterol maintenance and reliever therapy (MART). Refer for expert advice.	Add tiotropium or LTRA	
Step 5	Refer for phenotypic assessment +/- higher dose ICS-LABA or add-on therapy (eg anti-IgE, anti-IL4Ro, anti-IL5)	As last resort, consider add-on low dose OCS, but consider side effects	

Children 5 years of age and younger

	Preferred Controller Choice	Other controller options	Reliever
Step 1	Insufficient evidence for daily controller	Consider intermittent short course ICS at onset of viral illness	As-needed short-acting beta2-agonist
Step 2	Daily low dose inhaled corticosteroid (ICS)	Daily LTRA or intermittent short course of ICS at onset of respiratory illness	
Step 3	Double low dose ICS	Low dose ICS + LTRA, consider specialist referral	
Step 4	Continue controlled & refer for specialist assessment	Add LTRA, or increase ICS frequency, or add intermittent ICS	

Prescription Tips for Symbicort

- In adults, adolescents and children 6-11 years of age, MART with ICS-formoterol reduced risk of severe exacerbations compared with same or higher dose of ICS or ICS-LABA, with similar symptom control.
- Patients prescribed ICS-formoterol as their reliever (with or without maintenance ICS-formoterol) should take one inhalation of their ICS-formoterol reliever whenever needed for symptom relief. If necessary, an extra dose can be taken a few minutes later. Additional doses are taken when symptoms recur, even if this is within four hours.
- The maximum total recommended dose in any single day for adults and adolescents is 12 inhalations for budesonide-formoterol (total 72 mcg formoterol [54 mcg delivered dose]) and 8 inhalations for budesonide-formoterol in children and for beclomethasone-formoterol in adults (48 mcg formoterol [36 mcg delivered dose]). This is the maximum total of as-needed doses and maintenance doses, if used.

An example of a Single Inhaler Maintenance and Reliever Therapy (SMART) Asthma Action Plan from the Allergy & Asthma Network can be viewed here.

List of Medications for Asthma Management

Here is a list of the currently covered medications used in the treatment of asthma that is covered by Medi-Cal Rx (as of Sept. 1, 2023 and subject to change). They are listed under the Autonomic Drugs: Anti-Asthmatics therapeutic category.

You can also use the Medi-Cal Rx Drug Lookup tool to find out if a medication requires a prior authorization and/or if there are Code I restrictions that need to be met.

Managed Care Accountability Set (MCAS) Quality Measure – Asthma Medication Ratio (AMR)

GCHP monitors and reports the Managed Care Accountability Set (MCAS) performance measures to assess and improve clinical quality of care. MCAS is based on the Centers for Medicare and Medicaid Services Child and Adult Core Set Measures, which includes National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) measures. All state Medi-Cal Managed Care Plans are required to annually report these measures to DHCS.

The Asthma Medication Ratio (AMR) measures the percentage of members 5 to 64 years of age who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year.

For more information regarding the AMR and other MCAS measures, visit the GCHP website.

Tips on how to improve the AMR measure:

- Consider a 90-day supply and three refills (use auto refill) for all controller medications.
- Consider a 30-day supply and no more than one - two refills for rescue inhaler (to alert you that your patient may require an evaluation for asthma symptoms and management).
- Avoid using auto refill at the pharmacy for rescue medications which should be used only as needed.
- If you receive a refill request from the pharmacy, check with the member to see if they really need the refill for the inhaler before approving the request. This is an opportunity to bring the member back in for a follow up appointment to assess their asthma control or also prevent the member from getting multiple unnecessary auto-refills of rescue inhaler medication. These members can be evaluated by telemedicine visits if appropriate and applicable.
- Evaluate patients with asthma diagnosis and use guidelines to step up or down on therapy and ensure that patients are only using rescue inhalers as needed and being prescribed and maintained on controller medications, if appropriate.
- Assess inhaler technique.
- Check on patient's understanding of difference between controller versus rescue inhaler.
- Develop / update / review asthma action plan.
- Ensure adherence to controller medication to prevent asthma symptoms and flare ups.
- If a patient needs two inhalers (for home and school / work / etc.), try to write a prescription for a quantity of two inhalers filled at the same time to count as one dispensing event.

For helpful patient education resources regarding asthma inhaler education, see the list below:

- GCHP Health Education website
- GCHP Health Library website
- American Lung Association – Asthma website
- NIH NHLBI Asthma Resources for Patients and Caregivers

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
ELREXFIO	ELRANATAMAB	SOLUTION; INJECTION	Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.
AKEEGA	NIRAPARIB; ABIRATERONE ACETATE	ORAL TABLET	Indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (brcam) metastatic castration-resistant prostate cancer (mcrpc). Select patients for therapy based on an FDA-approved test for AKEEGA.
TALVEY	TALQUETAMAB-TGVS	INJECTABLE	Indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody.
VANFLYTA	QUIZARTINIB	ORAL TABLET	Indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test.
NGENLA	SOMATROGON-GHLA	INJECTABLE	Indicated for treatment of pediatric patients 3 years of age and older who have growth failure due to inadequate secretion of endogenous growth hormone.
RYSTIGGO	ROZANOLIXIZUMAB-NOLI	INJECTABLE; SUBCUTANEOUS	Indicated for the treatment of generalized myasthenia gravis (gmg) in adult patients who are anti-acetylcholine receptor (achr) or antimuscle-specific tyrosine kinase (musk) antibody positive.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
LITFULO	RITLECITINIB TOSYLATE	ORAL CAPSULE	Indicated for the treatment of severe alopecia areata in adults and adolescents 12 years of age and older.
COLUMVI	GLOFITAMAB-GXBM	INJECTABLE	Indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy.
BRIXADI	BUPRENORPHINE	INJECTION, EXTENDED RELEASE; SUBCUTANEOUS	Indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine.
YUFLYMA	ADALIMUMAB-AATY	INJECTABLE	Indicated for: • Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PSA) • Ankylosing Spondylitis (AS) • Crohn's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps) • Hidradenitis Suppurativa (HS)
OPVEE	NALMEFENE	NASAL SPRAY	Indicated for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients 12 years of age and older, as manifested by respiratory and/or central nervous system depression.
ZEJULA	NIRAPARIB TOSYLATE	ORAL TABLET	Indicated for: • Maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy. • For the maintenance treatment of adult patients with deleterious or selected deleterious germline brca-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. • Select patients for therapy based on an fda-approved companion diagnostic for ZEJULA.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ZAVZPRET	ZAVEGEPANT HYDROCHLORIDE	NASAL SPRAY	Indicated for the acute treatment of migraine with or without aura in adults.
SKYCLARYS	OMAVELOXOLONE	ORAL CAPSULE	Indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years of age and older.
LEQEMBI	LECANEMAB-IRMB	INJECTABLE	Indicated for the treatment of approval based on reduction in amyloid beta plaques observed in patients treated with LEQEMBI.
BENDAMUSTINE HYDROCHLORIDE (Baxter Healthcare)	BENDAMUSTINE HYDROCHLORIDE	SOLUTION; INTRAVENOUS	Indicated for: • Treatment of adult patients with chronic lymphocytic leukemia (CLL). • Indolent b-cell non-hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
IYUZEH	LATANOPROST	OPHTHALMIC SOLUTION	Indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
IDACIO	ADALIMUMAB-AACF	INJECTABLE; SUBCUTANEOUS	Indicated for: • Rheumatoid arthritis (RA) • Juvenile idiopathic arthritis (JIA) • Psoriatic arthritis (PSA) • Ankylosing spondylitis (AS) • Crohn's disease (CD) • Ulcerative colitis (UC) • Plaque psoriasis (Ps)
STIMUFEND	PEGFILGRASTIM-FPGK	SOLUTION; INJECTION	Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
XENPOZYME	OLIPUDASE ALFA-RPCP	INJECTABLE	Indicated for treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.
CUVRIOR	TRIENTINE TETRAHYDROCHLORIDE	ORAL TABLET	Indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
HADLIMA	ADALIMUMAB-BWWD (BIOSIMILAR TO HUMIRA)	INJECTABLE	Indicated for: • Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PSA) • Ankylosing Spondylitis (AS) • Adult Chron's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps)
HYRIMOZ	ADALIMUMAB-ADAZ (BIOSIMILAR TO HUMIRA)	INJECTABLE	Indicated for: • Rheumatoid Arthritis (RA) • Juvenile Idiopathic Arthritis (JIA) • Psoriatic Arthritis (PSA) • Ankylosing Spondylitis (AS) • Adult Chron's Disease (CD) • Ulcerative Colitis (UC) • Plaque Psoriasis (Ps)

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's website.

Drug	Type of Change	Change
DROXIA *(hydroxyurea)* *HYDREA (hydroxyurea)*	Boxed Warnings	WARNING: MYELOSUPPRESSION AND MALIGNANCIES **Myelosuppression:** DROXIA may cause severe myelosuppression. Do not give if bone marrow function is markedly depressed. Monitor blood counts at baseline and throughout treatment. Interrupt treatment and reduce dose as necessary. **Malignancies:** DROXIA is carcinogenic. Advise sun protection and monitor patients for malignancies.
EVAMIST *(estradiol)*	Boxed Warning	WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, PROBABLE DEMENTIA, BREAST CANCER, and UNINTENTIONAL SECONDARY EXPOSURE TO ESTROGEN.
EZALLOR SPRINKLE *(rosuvastatin calcium)*	Contraindications	Contraindicated in acute liver failure or decompensated cirrhosis.
GANIRELIX ACETATE *(ganirelix acetate)*	Contraindications	Known hypersensitivity to Ganirelix Acetate or to any of its components including dry natural rubber / latex.
LEQEMBI *(lecanemab-irmb)*	Contraindications	LEQEMBI is contraindicated in patients with serious hypersensitivity to lecanemab-irmb or to any of the excipients of LEQEMBI. Reactions have included angioedema and anaphylaxis.
MOUNJARO *(tirzepatide)*	Contraindications	Contraindicated in patients with: • A personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). • Known serious hypersensitivity to tirzepatide or any of the excipients in MOUNJARO. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with MOUNJARO.
OMEPRAZOLE AND CLARITHROMYCIN AND AMOXICILLIN *(amoxicillin; clarithromycin; omeprazole)*	Contraindications	Coadministration of OMECLAMOX-PAK with lurasidone is contraindicated since it may result in an increase in lurasidone exposure and the potential for serious adverse reactions.
RIFADIN *(rifampin)* RIMACTANE *(rifampin)*	Contraindications	Rifampin is contraindicated in patients receiving lurasidone. Concomitant use of lurasidone with strong CYP3A4 inducers (e.g., rifampin) decreased the exposure of lurasidone compared to the use of lurasidone alone.

Drug	Type of Change	Change
RIFATER *(isoniazid; pyrazinamide; rifampin)*	Contraindications	RIFATER, which contains rifampin, is contraindicated in patients who are also receiving: • Ritonavir-boosted saquinavir due to an increased risk of severe hepatocellular toxicity. • Atazanavir, darunavir, fosamprenavir, saquinavir, or tipranavir due to the potential of rifampin to substantially decrease plasma concentrations of these antiviral drugs, which may result in loss of antiviral efficacy and/or development of viral resistance. • Praziquantel since therapeutically effective blood levels of praziquantel may not be achieved. In patients receiving RIFATER who need immediate treatment with praziquantel, alternative agents should be considered. However, if treatment with praziquantel is necessary, RIFATER should be discontinued four weeks before administration of praziquantel. Treatment with RIFATER can then be restarted one day after completion of praziquantel treatment. • Lurasidone: Concomitant use of lurasidone with strong CYP3A4 inducers (e.g., rifampin) decreased the exposure of lurasidone compared to the use of lurasidone alone.
ZETIA *(ezetimibe)*	Contraindications	Contraindicated when used in combination with a statin, fenofibrate, or other LDL-C lowering therapy, ZETIA is contraindicated in patients for whom a statin, fenofibrate, or other LDL-C lowering therapy are contraindicated.

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
Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%	• Akorn • Hikma • Wockhardt	• Akorn ceased operations in February 2023. • Hikma did not provide a reason for the shortage. • Wockhardt did not provide a reason for the shortage. **Estimated Resupply Dates** • 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	• Winthrop did not provide a reason for the shortage. **Estimated Resupply Dates** • Winthrop has 0.5 mcg, 1 mcg, and 2.5 mcg capsules on allocation.
Collagenase Ointment	• Smith & Nephew	• Smith & Nephew did not provide a reason for the shortage. **Estimated Resupply Dates** • Smith & Nephew has Santyl ointment on intermittent back order and the company is releasing supplies as they become available.
Fluocinolone Acetonide Shampoo	• Galderma	• Galderma did not provide a reason for the shortage. **Estimated Resupply Dates** • Galderma has Capex 0.01% shampoo on long-term back order and the company cannot estimate a release date.
Nystatin Topical Powder	• Padagis	• Padagis did not provide a reason for the shortage. **Estimated Resupply Dates** • Padagis has nystatin topical powder in 15-gram and 60-gram bottles on allocation and the company estimates this will continue through October 2023. Padagis has nystatin topical powder in 30 gram bottles on intermittent back order and the company is allocating supplies as they become available.
Diazepam Oral Solution	• Hikma • Lannett	• Hikma did not provide a reason for the shortage. • Lannett discontinued diazepam oral solution in January 2022. **Estimated Resupply Dates** • Hikma has diazepam 5 mg/mL 30 mL bottles on allocation.

Drug Product	Affected Manufacturers	Summary
Guanfacine Hydrochloride Tablets	• Amneal • Mylan • Teva	• 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. **Estimated Resupply Dates** • 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 mid-September 2023.
Isradipine Capsules	• Epic Pharma • Teva	• Epic Pharma has discontinued isradipine capsules. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Teva has isradipine 2.5 mg and 5 mg capsules in 100 count bottles on back order and the company estimates a release date of late-August 2023.
Varenicline tablets (Chantix)	• Pfizer	• Pfizer has Chantix on shortage due to a manufacturing delay to evaluate the active ingredient of the product. Pfizer has recalled all presentations of Chantix. More information on the recall can be found here. • The generic presentations are not affected by this shortage. **Estimated Resupply Dates** • Pfizer has Chantix on back order and the company cannot estimate a release date.
Fluorometholone Ophthalmic Ointment	• Allergan (AbbVie)	• Allergan did not provide a reason for the shortage. They are the sole suppliers of fluorometholone ointment. • Fluorometholone ophthalmic suspension is not affected by this shortage. **Estimated Resupply Dates** • Allergan has FML ophthalmic ointment on long-term back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Budesonide Suspension for Inhalation	• Amneal • AstraZeneca • Cipla • Lupin • Nephron • Sandoz • Teva	• Amneal has discontinued budesonide inhalation suspension. • 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 did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Cipla has all presentations on allocation. • Nephron is shipping budesonide inhalation suspension regularly to wholesalers. Wholesalers are allocating supplies. Nephron has product available for direct orders. • Sandoz has all budesonide inhalation suspension presentations temporarily unavailable. • Teva has all budesonide inhalation suspension presentations on back order and the company estimates a release date in early- to mid-September 2023. • Lupin has budesonide 0.5 mg/2 mL with five single-dose ampules per pouch on allocation.
Calcitriol Oral Solution	• Hikma • Rising • Sun Pharma	• Hikma did not provide a reason for the shortage. • Rising did not provide a reason for the shortage. • Sun Pharma did not provide a reason for the shortage. **Estimated Resupply Dates** • Hikma has calcitriol 1 mcg/mL oral solution in 15 mL bottles on allocation. • Rising has calcitriol 1 mcg/mL oral solution in 15 mL bottles on back order and the company estimates a release date in late-August 2023. • Sun Pharma has calcitriol 1 mcg/mL oral solution in 15 mL bottles on back order and the company cannot estimate a release date.
Tedizolid Oral Tablets	• Merck	• Nabriva is transitioning the distribution of Sivextro tablets back to Merck as Nabriva winds down company operations. **Estimated Resupply Dates** • Merck estimates Sivextro 200 mg tablets in 30 count bottles and six-count blister packs will be available in late-August 2023. Wholesalers are distributing remaining Sivextro tablets (distributed by Nabriva) until inventory is depleted.

Drug Product	Affected Manufacturers	Summary
Testosterone 2% Topical Gel	• Endo • Par • Teva	• Endo did not provide a reason for the shortage. • Par did not provide a reason for the shortage. • Teva did not provide a reason for the shortage. **Estimated Resupply Dates** • Endo has Fortesta 10 mg/0.5 gram topical gel in 60 gram metered-dose canisters on back order and the company cannot estimate a release date. • Par has testosterone 10 mg/0.5 gram topical gel in 60 gram metered-dose canisters on intermittent back order and the company is releasing supplies as they become available. • Teva has testosterone 10 mg/0.5 gram topical gel in 60 gram metered-dose canisters on intermittent back order and the company is releasing supplies as they become available.
Ribavirin Inhalation	• Bausch • Cameron • Zydus	• Bausch Health did not provide a reason for the shortage. Bausch Health discontinued the authorized generic in October 2022. • Cameron Pharmaceuticals was not available to provide information. • Zydus did not provide a reason for the shortage. **Estimated Resupply Dates** • Bausch Health has Virazole inhalation 6 gram powder for solution on long-term back order and the company cannot estimate a release date. • Zydus has ribavirin inhalation 6 gram powder for solution available with short expiration dating. The company estimates additional product will be available in the second half of 2023.
Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution	• OCuSOFT • Altaire	• Altaire has recalled several medications due concerns over lack of sterility assurance. More information can be found here. • OCuSOFT discontinued Flucaine in January 2020. **Estimated Resupply Dates** • Altaire has fluorescein / proparacaine 5 mL bottles on back order and the company cannot estimate a resupply date.

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 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.

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
July 7, 2023	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation)	Failure to deliver the recommended dose.	Cipla	**NDC: 69097-142-60** **Batch #:** IB20045 IB20055 IB20056 IB20057 IB20059 IB20072
July 31, 2023	Tydemy (Drospirenone, Ethinyl Estradiol and Levomefolate Calcium Tablets 3 mg/0.03 mg/0.451 mg and Levomefolate Calcium Tablets 0.451 mg) oral contraceptive	Out of specification results.	Lupin Pharmaceuticals, Inc.	**NDC: 68180-904-71 (1 Blister of 28 tablets each)** **Lot #:** L200183 **68180-904-73 (3 Blister of 28 tablets each)** **Lot #:** L201560
Aug. 31, 2023	Digoxin Tablets USP, 0.125 mg and 0.25 mg	Label mix-up	Marlex Pharmaceuticals, Inc.	**Digoxin 0.125mg Tablet - NDC: 10135-0747-01** **Lot#:** E3810 **Digoxin 0.25mg Tablet - NDC 10135-0748-01** **Lot#:** E3811
Sept. 11, 2023	Sandimunne Oral Solution (cyclosporine oral solution, USP) 100 mg/mL	Crystal formation, which could potentially result in incorrect dosing.	Novartis	**NDC: 00078-0110-22** **Lot #:** FX001691

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Pharmacy Newsletter

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For additional information, contact the
Pharmacy Department at 1-805-437-5738.
Gold Coast Health Plan
711 East Daily Drive, Suite 106, Camarillo, CA 93010
www.goldcoasthealthplan.org