Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

Q2 2025

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www.goldcoasthealthplan.org

Table of Contents

SECTION 1. Message from the Gold Coast Health Plan (GCHP) Director of Pharmacy Services 3
SECTION 2. Medi-Cal Rx Updates 4
SECTION 3. Safe Disposable of Unused Medications.....10
SECTION 4. State Department of Health Care Services (DHCS) Vaccines for Children (VFC) Pharmacy Pilot Program.....11
SECTION 5. Partial Benefit Products / Drugs 12
SECTION 6. Rite Aid Pharmacy Closures 13
SECTION 7. Physician Administered Drugs (PAD) and Prior Authorization (PA) Requests 14
SECTION 8. Drug Use Review (DUR) Educational Articles 15
SECTION 9: COVID-19 Update 16
SECTION 10. Hyperlipidemia Management 17
SECTION 11. Alerts from the U.S. Food and Drug Administration (FDA): FDA New Drug Approvals, Drug Safety Labeling Changes, Drug Shortages, Drug Safety Communications, Drug Recalls 23

PN Q2 2025

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

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

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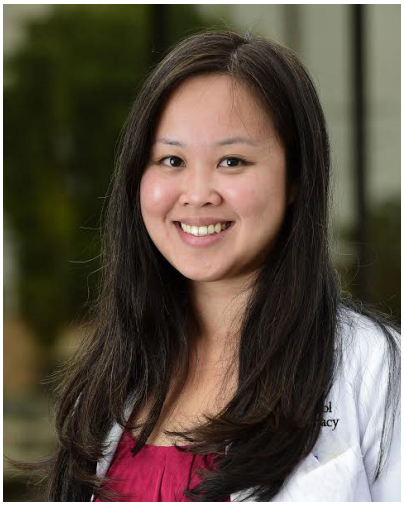
A Message from the Gold Coast Health Plan Director of Pharmacy Services



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

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

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

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

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

Sincerely,

Lily Yip, Pharm.D., APh, CDCES, BCACP
Director of Pharmacy Services

Medi-Cal Rx Updates

Pediatric Integration of Members 21 Years of Age and Younger

Medi-Cal Rx has completed implementation of Pediatric Integration by reinstating prior authorization (PA) requirements for new and continuation of therapy claims for members 21 years of age and younger. This means that all claims for new and continuing therapies will be subject to all utilization management (UM) edits, including PA requirements, as applicable per Medi-Cal policy. Pharmacy providers and prescribers may proactively submit PA requests up to 100 days in advance of new start therapy or PA expiration for members 21 years of age and younger. For more information, please refer to the Education & Outreach page on the Medi-Cal Rx Web Portal and select "Pediatric Integration."

Medi-Cal Rx Updated Drug Lookup Tool

The Drug Lookup Tool, located on the Medi-Cal Rx website, has been updated to be more user friendly. You can now use this tool to look up drugs by brand or generic and it will list the National Drug Code (NDC) and all dosages available in the marketplace. You can also use this tool to determine if a 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.

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 email at Pharmacy@goldchp.org.

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

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

Drug Name	Description	Effective Date
Bortezomib	Additional formulation (single dose vial) added to CDL with PA restriction.	March 1, 2025
Datopotamab Deruxtecan-dlnk	Added to CDL with LR.	March 1, 2025
Docetaxel	Additional formulation (solution for injection) added to CDL with LR.	March 1, 2025

Drug Name	Description	Effective Date
Glucagon (synthetic)	LR added to prefilled auto-injector, prefilled syringe, and single-dose vial kit.	March 1, 2025
Nivolumab and Hyaluronidase-nvhy	Added to CDL with LR.	March 1, 2025
Pemetrexed Dipotassium	Added to CDL with LR.	March 1, 2025
Vaccines	Additional vaccines added to CDL.	March 1, 2025
Bendamustine HCL	Additional LR (71225) added.	April 1, 2025
Diroximel Fumarate	Effective May 1, 2025: End-dated.	April 1, 2025
Dupilumab	Added to CDL with diagnosis, quantity, and labeler restrictions.	April 1, 2025
Nilotinib	Additional formulation (tablets) added to CDL with LR.	April 1, 2025
Somatrogon-ghla	Added to CDL with age, diagnosis, and labeler restrictions.	April 1, 2025
Tirzepatide (Mounjaro)	Added to CDL with diagnosis, quantity, and labeler restrictions.	April 1, 2025
Zenocutuzumab-zbco	Added to CDL with PA restriction.	April 1, 2025
Dalfampridine	Added to CDL with age and diagnosis restrictions.	May 1, 2025
Dimethyl Fumarate	Added to CDL with age and diagnosis restrictions.	May 1, 2025
Diphtheria/Tetanus Toxoids/ Acellular Pertussis/Inactivated Poliovirus Vaccine	Additional strength (15-48-5-62/0.5 ml vial) added to CDL.	May 1, 2025
Lebrikizumab-lbkz	Added to CDL with age, diagnosis, labeler, and quantity restrictions.	May 1, 2025
Maraviroc	Effective June 1, 2025: 25 mg and 75 mg tablets end-dated.	May 1, 2025
Mirvetuximab Soravtansine-gynx	PA restriction removed. LR added.	May 1, 2025
Rotavirus Vaccine	Additional dosage form (reconstituted suspension) added to CDL.	May 1, 2025
Secnidazole	Effective June 1, 2025: LR added.	May 1, 2025
Teriflunomide	Added to CDL with age and diagnosis restrictions.	May 1, 2025
Abiraterone Acetate	Labeler restriction (LR) removed from film-coated tablets.	June 1, 2025

Drug Name	Description	Effective Date
Bendamustine HCL	Additional LR (24338) added to the CDL.	June 1, 2025
Cyclophosphamide	LR added to vials	June 1, 2025
Darunavir	LR removed from 600 mg and 800 mg tablets.	June 1, 2025
Diazepam	Age restriction updated for nasal spray. Effective May 1, 2025: Code I package size limit updated for nasal spray.	May 1, 2025
Dupilumab	Additional diagnosis codes added to the Medi-Cal Rx Diagnosis Crosswalk.	June 1, 2025
Exenatide	LR removed from pre-filled injectable pens.	June 1, 2025
Loteprednol Etabonate	LR removed from 0.5% ophthalmic suspension	June 1, 2025
Naloxone HCL	Effective July 1, 2025: 5 mg/0.5 ml syringe 2-pack end-dated.	July 1, 2025
Revumenib	Additional strength (25 mg) added to the CDL with LR.	June 1, 2025
Zolbetuximab-clzb	Additional strength (300 mg) added to the CDL with LR.	June 1, 2025

Changes to the Medi-Cal Rx List of Contracted Continuous Glucose Monitoring (CGM) Systems

View the Medi-Cal Rx List of Contracted Continuous Glucose Monitoring (CGM) Systems on the Medi-Cal Rx Web Portal for the most recent changes. Revisions and/or deletions are made on a monthly basis. Below is a list of the most recent changes to the CDL for Medi-Cal Rx. View the web portal for the most recent changes. Below is a list of the most recent changes, effective March 1, 2025.

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (NDC)	Changes
Abbott	FreeStyle LIBRE 2 Plus Sensor kit, 1 each	57599083500	Added effective July 1, 2025 with PA

Changes to the Medi-Cal Rx List of Contracted Diabetic Testing Supplies

View the Medi-Cal Rx List of Contracted Diabetic Testing Supplies on the Medi-Cal Rx Web Portal for the most recent changes. Revisions and/or deletions are made on a monthly basis. Below is a list of the most recent changes to the CDL for Medi-Cal Rx. View the web portal for the most recent changes. Below is a list of the most recent changes, effective March 1, 2025.

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (NDC)	Changes
Abbott	MediSense Glucose & Ketone Control Solution (High/Low, 2 vials)	57599013901	QL to 1 every 90-day period added effective July 1, 2025
Abbott	MediSense Glucose & Ketone Control Solution (Mid only)	57599031201	QL to 1 every 90-day period added Effective July 1, 2025
Arkray USA	GLUCOCARD Shine Control Solution (Level 1)	08317540005	QL to 1 every 90-day period added effective July 1, 2025
Arkray USA	GLUCOCARD Expression Control Solution	08317570005	QL to 1 every 90-day period added effective July 1, 2025
ForaCare, Inc.	Control Solution (GDH), normal 1	16042001200	QL to 1 every 90-day period added effective July 1, 2025
ForaCare, Inc.	Control Solution (GDH), normal 1	98939000206	QL to 1 every 90-day period added effective July 1, 2025
ForaCare, Inc.	Control Solution Ketone, Level 1	16042001313	QL to 1 every 90-day period added effective July 1, 2025
Medline Industries, Inc.	Control Solution EvenCare G2	84389010254	QL to 1 every 90-day period added effective July 1, 2025
Omnis Health, LLC	Embrace WAVE™ Control Solution-Low	94030000223	QL to 1 every 90-day period added effective July 1, 2025
Omnis Health, LLC	Embrace TALK™ Control SolutionLow	94030000287	QL to 1 every 90-day period added effective July 1, 2025
Roche Diabetes Care, Inc.	Accu-Chek Aviva Control Solution	65702010710	QL to 1 every 90-day period added effective July 1, 2025
Roche Diabetes Care, Inc.	Accu-Chek Guide Control Solution	65702010710	QL to 1 every 90-day period added effective July 1, 2025

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (NDC)	Changes
Simple Diagnostics	Clever Choice Control Solution	98302000103	QL to 1 every 90-day period added effective July 1, 2025
Trividia Health, Inc.	True Metrix Control Solution 1	56151145001	QL to 1 every 90-day period added effective July 1, 2025
Trividia Health, Inc.	True Metrix Control Solution 2	56151145002	QL to 1 every 90-day period added effective July 1, 2025
Trividia Health, Inc.	True Metrix Control Solution 3	56151145003	QL to 1 every 90-day period added effective July 1, 2025

QL = Quantity Limit

Changes to the Medi-Cal Rx List of Contracted Disposable Insulin Delivery Devices

View the Medi-Cal Rx List of Contracted Disposable Delivery Devices on the Medi-Cal Rx Web Portal for the most recent changes. Revisions and/or deletions are made on a monthly basis. Below is a list of the most recent changes to the CDL for Medi-Cal Rx. View the web portal for the most recent changes. Below is a list of the most recent changes, effective March 1, 2025.

Product Label Name	Changes
Omnipod 5 Libre 2 Plus G6 Intro Kit (10 pods + Controller)	Added effective July 1, 2025. PA required.
Omnipod 5 Libre 2 Plus G6 Pods (five pods)	Added effective July 1, 2025. PA required.

Changes to the Medi-Cal Rx List of Contracted COVID-19 Antigen Tests

View the Medi-Cal Rx List of Contracted COVID-19 Antigen Tests on the Medi-Cal Rx Web Portal for the most recent changes. Revisions and/or deletions are made on a monthly basis. Below is a list of the most recent changes to the CDL for Medi-Cal Rx. View the web portal for the most recent changes. Below is a list of the most recent changes, effective March 1, 2025.

Manufacturer	Description	Effective Date
Innova Medical Group	Advin COVID-19 Antigen Test @Home (one test per kit) NDC 60010003312	Deleted effective June 1, 2025
Innova Medical Group	Advin COVID-19 Antigen Test @Home (two tests per kit) NDC 60010003310	Deleted effective June 1, 2025

Changes to the List of Contracted Enteral Nutrition Products

The List of Contracted Enteral Nutrition Products spreadsheet has been updated on the Medi-Cal Rx Web Portal. View the web portal for the most recent changes. Below is a list of the most recent changes, effective March 1, 2025.

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (NDC)	Changes
Kate Farms, Inc.	Kate Farms Pediatric Peptide 1.0, strawberry, 250ml	11112003131	Added effective April 1, 2025
Nestlé HealthCare Nutrition	Vivonex Pediatric, unflavored, 6 x 400g canisters	45291050766	Added effective May 1, 2025
Abbott Nutrition	EleCare Junior 400g, Unflavored, powder	70074068628	Added effective July 1, 2025
Abbott Nutrition	EleCare Junior, Vanilla, 400g 6CT powder	70074068631	Added effective July 1, 2025

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

Changes to Family PACT formulary Below are the most recent changes to the Medi-Cal Rx Family Planning, Access, Care, and Treatment Pharmacy Formulary, that has been posted to the Medi-Cal Rx Web Portal as of March 1, 2025. View the web portal for the most updated list.

Manufacturer	Description	Effective Date
Secnidazole	Effective June 1, 2025: LR updated.	May 1, 2025

Find A Pharmacy

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

Where to Safely Dispose of Unused Medications

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

State Department of Health Care Services (DHCS) Vaccines for Children (VFC) Pharmacy Pilot Program

The state Department of Health Care Services (DHCS) is collaborating with the California Department of Public Health (CDPH) on the Vaccines for Children (VFC) Pharmacy Pilot Program. DHCS will reimburse Medi-Cal enrolled pharmacy providers who provide immunization services under the VFC Program to VFC-eligible Medi-Cal members. My Turn Vaccine Locator is available to find vaccine providers (including pharmacies enrolled in VFC) in a given coverage area.

The VFC Program helps families by providing vaccines at no cost to medical providers who serve eligible children from birth through 18 years of age. The Centers for Disease Control and Prevention (CDC) contracts with vaccine manufacturers to buy vaccines at reduced rates. Enrolled providers order federally funded vaccines through their state VFC Program and receive routine vaccines (including influenza) at no cost.

Partial Benefit Drugs / Products

Certain products/drugs may be covered by either the Medi-Cal Rx Pharmacy benefit or the Gold Coast Health Plan (GCHP) Medical benefit, as they are considered partial benefits under Medi-Cal such as

- Enteral Nutritional Products
- Continuous Glucose Monitors (CGMs)
- Blood Pressure Monitors

For coverage by **GCHP for medical benefits**:

- **Enteral Nutritional Products and CGMs** - Prior Authorization (PA) must be submitted for review by GCHP's Utilization Management (UM) department. You can submit the PA using the Prior Authorization Treatment Request Form and fax it to 855-883-1552, or through GCHP's NTT Provider Portal.
- **Blood Pressure Monitors** - send a prescription to a contracted durable medical equipment (DME) vendor. The vendor can bill GCHP under medical benefit using form CMS-1500. For a list of contracted DME vendors, refer to the GCHP Provider Directory.

For coverage by **Medi-Cal Rx Pharmacy benefit**:

- **Enteral Nutritional Products** – Submit a PA for one of the Contracted Enteral Nutrition Products. Once PA has been approved send a prescription to a pharmacy.
- **CGMs** – submit a PA for one of the Contracted Continuous Glucose Monitoring Systems. Once PA has been approved send a prescription to a pharmacy.
- **Blood Pressure Monitors** – send a prescription to a pharmacy for one of the Contracted Personal Blood Pressure Monitoring Devices and Blood Pressure Cuffs. One monitor is covered every five years.

Peak Flow Meters and Inhaler Assistive Devices (e.g., spacers) are fully carved-out to Medi-Cal Rx pharmacy benefit and covered. Please submit a prescription to a participating pharmacy for dispensing.

Coverage limits are as follows:

- One Peak Flow Meter per 365 days.
- Two Inhaler Assistive Devices (e.g., spacers) per 365 days.

If additional quantities are medically necessary beyond these limits, a prior authorization (PA) request must be submitted to Medi-Cal Rx. The request should include clinical justification for exceeding the standard coverage limits.

Rite Aid Pharmacy Closures

Rite Aid filed for bankruptcy in October 2023, resulting in the closure of several locations nationwide. On May 5, 2025, Rite Aid filed for bankruptcy again and is in the process of selling assets including prescriptions, to other pharmacies.

In response, the California Department of Consumers Affairs and the California State Board of Pharmacy released a Joint Statement on May 5, 2025. The statement urges prescribers to be responsive to pharmacists' outreach regarding prescription refills and to proactively work with patients to find alternative pharmacies. The closures are expected to significantly affect timely access to prescriptions, particularly in communities where Rite Aid was the primary pharmacy.

For details about when a specific Rite Aid store will be closing, please contact the store directly. Some Rite Aid locations plan to transfer members' prescriptions to other pharmacies. To avoid disruption in access to therapy, pharmacy providers and prescribers should encourage members to contact their Rite Aid pharmacy to determine if they need to transfer their prescriptions or if that pharmacy location will transfer their prescriptions for them.

Prescriptions at a Rite Aid location can be transferred to any pharmacy that is contracted with Medi-Cal Rx. To find a participating pharmacy, click here.

For further details and guidance, please refer to the Medi-Cal Rx Rite Aid Closure Guidance for Providers.

Physician Administered Drugs or Medical Drug Benefit and Prior Authorization Requests

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

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 PADs 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 will need to purchase the drugs from their wholesaler, distributor, or manufacturer (or another internal process at their site of practice) and then administer to the member and later bill GCHP for reimbursement.

Please use GCHP's List of Services Requiring Prior Authorizations (see list of PADs for the most updated list). You can also find the PAD list and the Prior Authorization Treatment Request Form in the Medical Drug Benefit section located on the GCHP website, under Pharmacy Services for Providers.

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

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

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

Drug Use Review (DUR) Educational Articles

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

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

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

- 2024 Immunization Update: COVID-19, Influenza, RSV, Pneumococcal, Polio, Meningococcal, HiB, HepB, and Mpox - February 2025
- Measles Vaccination Prevents Outbreaks, Protects Californians - April 2025

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

COVID-19 Updates

New Paxlovid Dosing Regimen for Severe Renal Impairment

A new dose regimen of Paxlovid is available for the treatment of mild to moderate COVID-19 in patients who have severe renal impairment (eGFR < 30 mL/min, including those who require hemodialysis). For patients with severe renal impairment, Paxlovid should be taken as follow:

1. Day one: Take 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) ONCE.
2. Days two through five: Take 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet) ONCE.
3. On hemodialysis days, Paxlovid should be administered after hemodialysis.

Hyperlipidemia Management

2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients with Chronic Coronary Disease (CCD)

1. Risk Assessment and Stratification
   - Use risk-based approach for treatment intensity and follow-up
   - Incorporate coronary artery calcium (CAC) score, lipoprotein(a), and high-sensitivity C-reactive protein
   - Emphasis on social determinants of health, comorbidities, and frailty

2. Lifestyle Modifications
   - Smoking cessation
   - Heart-healthy diet (e.g., Mediterranean, or DASH)
   - Regular physical activity (> 150 min/week moderate aerobic activity)
   - Weight management
   - Psychosocial support and stress management

3. Lipid Management
   - High-intensity statin therapy is first-line
   - Goal: > 50% LDL-C reduction and LDL-C < 55 mg/dL for very high-risk patients
   - Consider ezetimibe or PCSK9 inhibitors if LDL goal is not met
   - For triglycerides > 150 mg/dL, consider icosapent ethyl in select patients

Table 10. Very High-Risk* of Future ASCVD Events

Definition of Very-High Risk
History of multiple or major ASCVD events
OR
One major ASCVD event **and** ≥ high-risk conditions
Major ASCVD Events
Recent ACS (within the past 12 mo)
History of MI (other than recent ACS events listed above)
History of ischemic stroke
Symptomatic peripheral artery disease (history of claudication with ABI <0.85, or previous revascularization or amputation)[5]
High-Risk Conditions
Age ≥65y
Familial hypercholesteralemia†

Definition of Very-High Risk
History of previous coronary artery bypass graft surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
Diabetes
Hypertension
Chronic kidney disease (eGFR, 15-59 mL/min/1.73m2)[15,29]
Current tobacco smoking
Persistently elevated LDL-C ≥100mg/dL despite maximally tolerated statin therapy and ezetimbe
History of congestive heart failure

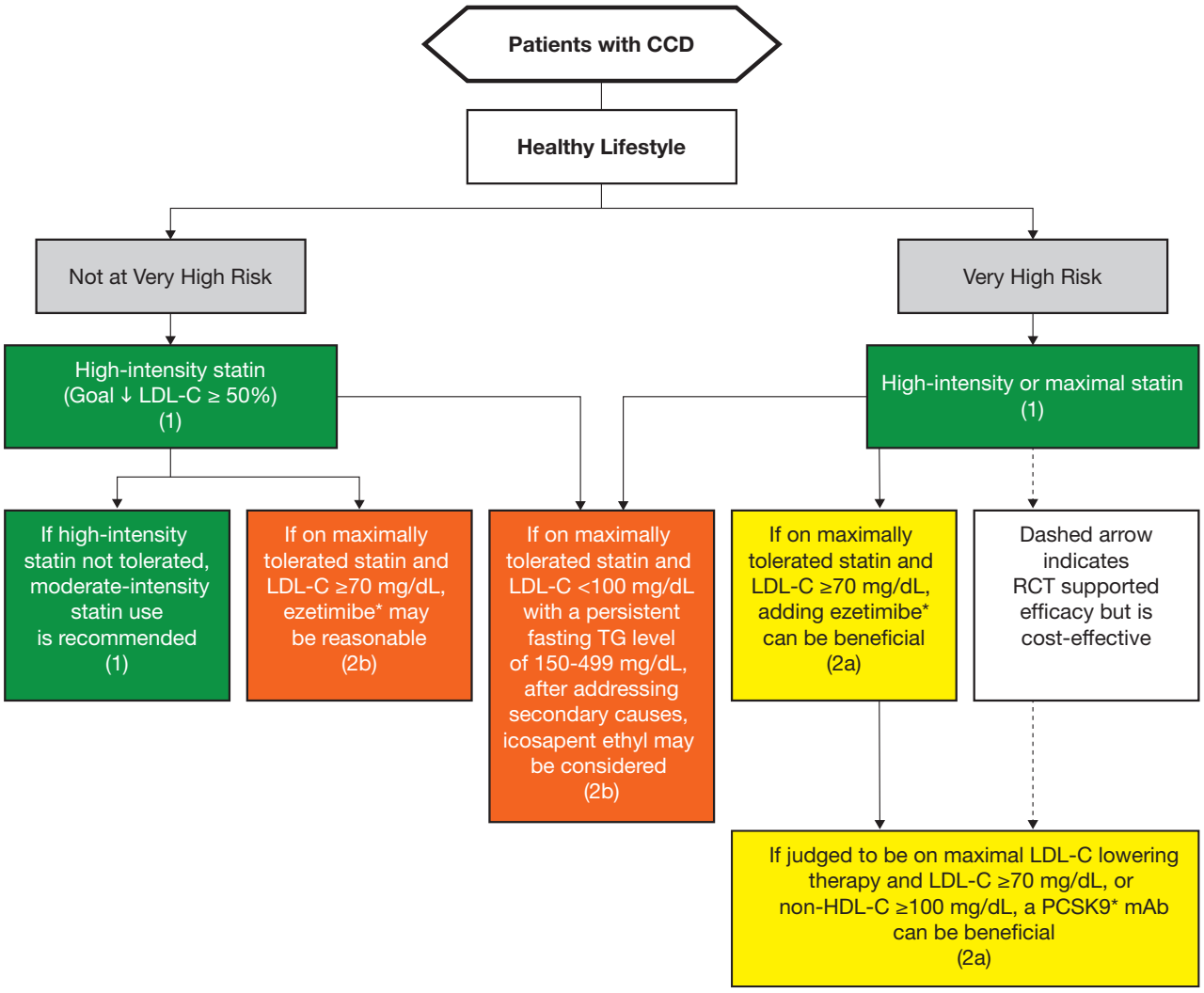
* Very high-risk includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.

† Management of patients with familial hypercholesteralemia often requires combination lipid lowering therapy and referral to a lipid specialist, and possibly lipoprotein apheresis. [54 29]

ABI indicates ankle brachial index; ACS acute coronary syndrome; ASCVD, atherosclerotic cardiovascular disease; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; LDL-C, low-density lipoprotein cholestral; and MI, myocardial infarction.

Modified with permission from Grundy SM et al.[42] Copyright 2019 American Heart Association, Inc. and American College of Cardiology Foundation.

Figure 8. Lipid Management in Patients With CCD



Colors correspond to Class of Recommendation in Table 3. Very high-risk includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions (Table 10). * Only when ezetimibe and PCSK9 mAb are deemed insufficient or not tolerated should bempedoic acid or inclisiran (in place of PCSK9 mAb) be considerd to further reduce LDL-C levels. The effect of bempedoic acid and inclisiran on MACE is being evaluated. LDL-C indicates low-density lipoprotein cholesterol; HDL-C, high-density lipprotein cholestrol, PCSK9 mAb, PCSK9 monoclonal antibody; RCT, randomized controlled trial; and TG, triglycerides. Adapted with permission from Grundy SM, et al.[42] Copyright © 2019 American Heart Association, Inc., and American College of Cardiology Foundation.

2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease

- Attention to ASCVD risk factors beginning early in life
- Adults 20 to 39 years of age with moderately high LDL-C (> 160 mg/dL) or very high LDL-C (> 190 mg/dL) – initiate drug therapy
- Adults 40 to 75 years of age with very high LDL (> 90mg/dL) – initiate high intensity statin

- Adults 40 to 75 years of age with Diabetes mellitus – initiate moderate to high intensity statin
  - » Risk enhancers
    - › Long duration (>/= 10 years for type 2 DM, or >/= 20 years for type 1 DM)
    - › Nephropathy – albuminuria and/or eGFR < 60mL/m2/1.73m2
    - › Retinopathy
    - › Neuropathy
    - › Peripheral arterial disease (ABI < 0.9)
- Adults 40 to 75 years with LDL-C > 70 - < 190 mg/dL without diabetes mellitus, assess ASCVD risk
  - » ASCVD Risk Estimator Plus
    - › Low risk (<5%) – unlikely to benefit from statin
    - › Borderline risk (5-7.5%) – unclear if they will benefit. Further testing may be undertaken to identify subclinical atherosclerosis
    - › Intermediate risk (7.5-20%) – possible that they will benefit. Further imaging may be undertaken to identify subclinical atherosclerosis. Risk-enhancing factors may be used to refine risk.
    - › High risk (>/= 20%) - initiate statin

Table 1: ASCVD Risk Enhancers

- Family history of premature ASCVD
- Primary hypercholestrolemia
- Chronic kidney disease
- Metabolic syndrome
- Conditions specific to women (e.g. preeclampsia, premature menopause)
- Chronic inflammatory conditions (especially rheumatoid arthritis, psoriasis, HIV)
- Ethnicity (e.g. south Asian ancestry)

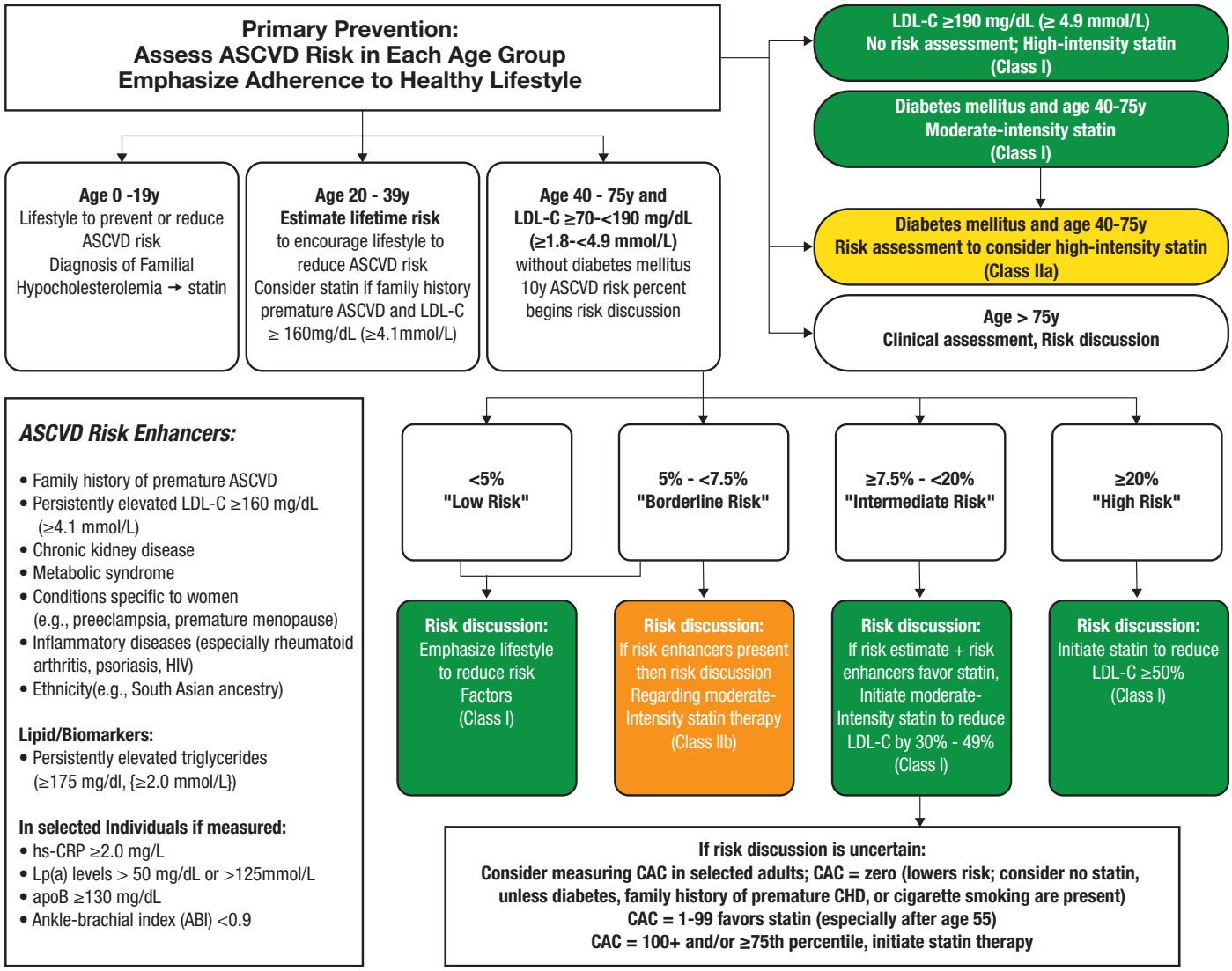
Lipid / Biomarkers:

- Persistently elevated triglycerides (≥175mg/dL)

in selected individuals if measured:

- hsCRP≥2mg/dL
- Lp(a) levels ≥50mg/dL or ≥125 nmo/L
- ApoB levels ≥130mg/dL
- Ankle-brachial index <0.9

Figure 3. Primary prevention



Colors correspond to Class of Recommendation in Table 1. ABI indicates ankle-brachial index; apoB, apolipoprotein B; ASCVD, atherosclerotic cardiovascular disease; CAC, coronary artery calcium; CHD, coronary heart disease; HIV, human immunodeficiency virus; hs-CRP, high-sensitivity C-reactive protein; LDL-C, low-density lipoprotein cholesterol; and Lp(a), lipoprotein (a). Reproduced with permission from Grundy et al.[54 3-1]

Medi-Cal Rx Covered Statin Therapy:

High Intensity (> 50%)	Moderate Intensity (30-49%)	Low Intensity (< 30%)
Atorvastatin 40-80 mg	Atorvastatin 10-20 mg	Simvastatin 10 mg
Rosuvastatin 20-40 mg	Rosuvastatin 5-10 mg	Pravastatin 10-20 mg
	Simvastatin 20-40 mg	Lovastatin 20 mg
	Pravastatin 40-80 mg	
	Lovastatin 40 mg	

Non-Statin Therapies - For individuals who cannot tolerate statins or who need additional LDL-C lowering:

- **Ezetimibe:** Often added to statin therapy if the target LDL level isn't achieved.
- **PCSK9 inhibitors:** (e.g., evolocumab, alirocumab) for individuals at high risk of cardiovascular events who need additional lipid lowering.
- **Bempedoic acid (Nexletol):** An alternative to statins for those who are statin-intolerant.

Drug Name	Dosage Form	Usual Dose	Medi-Cal Rx Coverage Status
Evolocumab (Repatha)	140 mg/dL Auto-Injector 140 mg/dL Prefilled Syringe 420 mg/3.5 mL Cartridge	140 mg SQ Q2weeks or 420 mg SQ once monthly	Covered but limited to ≥ 10 years of age #2 syringes or #1 kit per 28 days
Ezetimibe (Zetia)	10 mg Tablet	10 mg PO QD	Covered
Omega-3 fatty acids oral (Lovaza)	1 gram Capsule	4 g PO QD or 2 g PO BID	Covered
Alirocumab (Praluent)	75 mg/mL, 150 mg/dL Auto-Injector	75 - 150 mg Q2 weeks or 300mg Q4 weeks	PA with Medi-Cal Rx
Evinacumab (Evkeeza)	345 mg/2.3 mL, 1200 mg/8 mL IV Solution	15 mg/kg IV Q4 weeks	• PA with Medi-Cal Rx • GCHP medical benefit with PA
Bempedoic acid (Nexletol)	180 mg Tablet	180 mg PO QD	PA with Medi-Cal Rx
Inclisiran (Leqvio)	284 mg/1.5 mL Prefilled Syringe	284 mg SQ initially, again at 3 months then Q6months	• PA with Medi-Cal Rx • GCHP medical benefit with PA
Icosapent ethyl (Vascepa)	0.5 gm, 1gm Capsule	2 gm PO BID with meals	• PA with Medi-Cal Rx
Lomitapide (Juxtapid)	5 mg, 10mg, 20mg, 30mg Capsule	5 – 60 mg PO QD	• PA with Medi-Cal Rx

PA – Prior Authorization

FDA Alerts

New to Marketplace Drugs

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

Brand Name	Generic Name	Indication	Date Available
YESINTEK	USTEKINUMAB-KFCE	Indicated for the treatment of: Adult patients with: • Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy. • Active psoriatic arthritis (PsA). • Moderately to severely active Crohn's disease (CD). • Moderately to severely active ulcerative colitis. Pediatric patients 6 years and older with: • Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy. • Active psoriatic arthritis (PsA).	Jan. 22, 2025
STEQEYMA	USTEKINUMAB-STBA	Indicated for the treatment of: Adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy. Active psoriatic arthritis (PsA). Moderately to severely active Crohn's disease (CD). Moderately to severely active ulcerative colitis. Pediatric patients 6 years and older with: moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy.	Jan. 27, 2025
SOFDRA	SOFPIRONIUM	Indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.	Feb. 10, 2025

Brand Name	Generic Name	Indication	Date Available
AXTLE	PEMETREXED DIPOTASSIUM	Indicated: • In combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous NSCLC. • As a single agent for the maintenance treatment of patients with locally advanced or metastatic, non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. • As a single agent for the treatment of patients with recurrent, metastatic non-squamous, NSCLC after prior chemotherapy. Limitations of Use: Pemetrexed for Injection is not indicated for the treatment of patients with squamous cell, non-small cell lung cancer. • Initial treatment, in combination with cisplatin, of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.	Feb. 10, 2025
TRYNGOLZA (AUTOINJECTOR)	OLEZARSEN SODIUM	Indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).	Feb. 18, 2025
XROMI	HYDROXYUREA	Indicated to reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients aged 6 months of age to less than 2 years of age with sickle cell anemia with recurrent moderate to severe painful crises.	Feb. 20, 2025
OTULFI	USTEKINUMAB-AAUZ	Indicated for the treatment of: Adult patients with: • Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy. • Active psoriatic arthritis (PsA). • Moderately to severely active Crohn's disease (CD). • Moderately to severely active ulcerative colitis. Pediatric patients 6 years of age and older with: • Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy. • Active psoriatic arthritis (PsA).	Feb. 21, 2025

Brand Name	Generic Name	Indication	Date Available
ROMVIMZA	VIMSELTINIB	Indicated for treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.	Feb. 24, 2025
PREVYMIS	LETERMOVIR	Indicated for: • Prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). • Prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).	Feb. 25, 2025
OPDIVO QVANTIG	NIVOLUMAB; HYALURONIDASE-NVHY	Indicated for the treatment of: Renal Cell Carcinoma (RCC) adult patients with intermediate or poor risk advanced RCC, as a first-line treatment following combination treatment with intravenous nivolumab and ipilimumab.	March 4, 2025
DATROWAY	DATOPOTAMAB DERUXTECAN-DLNK	Indicated for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.	March 4, 2025
JOURNAVX	SUZETRIGINE	Indicated for the treatment of moderate to severe acute pain in adults.	March 4, 2025
GOMEKLI	MIRDAMETINIB	Indicated for the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.	March 4, 2025
NIKTIMVO	AXATILIMAB-CSFR	Indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.	March 4, 2025

Brand Name	Generic Name	Indication	Date Available
BKEMV	ECULIZUMAB-AEEB	Indicated for: • The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. • The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Limitation of Use BKEMV is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).	March 5, 2025
ALHEMO	CONCIZUMAB-MTCI	Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with: hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors hemophilia B (congenital factor IX deficiency) with FIX inhibitors.	March 11, 2025
EVRYSDI	RISDIPLAM	Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.	March 11, 2025
NEFFY	EPINEPHRINE	Indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater.	March 11, 2025
RALDESY	TRAZODONE HYDROCHLORIDE	Indicated for the treatment of major depressive disorder (MDD) in adults.	March 18, 2025
LUMISIGHT	PEGULICIANINE	Indicated for fluorescence imaging in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery.	March 18, 2025
FLYRCADO	FLURPIRIDAZ F-18	Indicated for positron emission tomography (PET) myocardial perfusion imaging (MPI) under rest or stress (pharmacologic or exercise) in adult patients with known or suspected coronary artery disease (CAD) to evaluate for myocardial ischemia and infarction.	March 18, 2025
QFITLIA	FITUSIRAN INJECTION	Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors.	March 28, 2025

Brand Name	Generic Name	Indication	Date Available
ZUNVEYL	BENZGALANTAMINE	Indicated for the treatment of mild to moderate dementia of the Alzheimer's type in adults. The recommended starting dosage is 5 mg twice a day (10 mg/day) by mouth.	March 31, 2025
VANRAFIA	ATRASENTAN	Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether VANRAFIA slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.	April 28, 2025
LIVMARLI	MARALIXIBAT CHLORIDE	Indicated for: • The treatment of cholestatic pruritus in patients 3 months of age and older with Alagille syndrome (ALGS). • The treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitations of Use: LIVMARLI is not recommended in a subgroup of PFIC type 2 patients with specific ABCB11 variants resulting in nonfunctional or complete absence of bile salt export pump (BSEP) protein.	May 5, 2025
IMAAVY	NIPOCALIMAB-AAHU	Indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-musclespecific tyrosine kinase (MuSK) antibody positive.	May 20, 2025

Brand Name	Generic Name	Indication	Date Available
EMRELIS	TELISOTUZUMAB VEDOTIN-TLLV	Indicated for the treatment of adult patients with locally advanced or metastatic non-squamous cell lung cancer (NSCLC) with high c-Met protein overexpression [>50% of tumor cellswith strong (3+) staining], as determined by FDA-approved test, who have received a prior systemic therapy. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).	May 14, 2025

Drug Safety Labeling Changes

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

Drug	Type of Change	Change
BAQSIMI *(glucagon)*	Contraindications	BAQSIMI is contraindicated in patients with: • Pheochromocytoma because of the risk of substantial increase in blood pressure. • Insulinoma because of the risk of hypoglycemia • Prior hypersensitivity reaction to glucagon or to any of the excipients in BAQSIMI. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.
BRISDELLE *(paroxetine mesylate)*	Boxed Warning Contraindications	WARNING: SUICIDAL THOUGHTS AND BEHAVIORS Selective serotonin reuptake inhibitors (SSRIs) increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term trials for the treatment of major depressive disorder and other psychiatric disorders. Because BRISDELLE is an SSRI, closely monitor BRISDELLE-treated patients closely for emergence of suicidal thoughts and behaviors. BRISDELLE is not approved for use in any psychiatric condition or in pediatric and young adult patients. BRISDELLE is contraindicated in patients: Taking pimozide because of risk of QT prolongation with known hypersensitivity (e.g., anaphylaxis, angioedema, Stevens-Johnson syndrome) to paroxetine or to any of the inactive ingredients in BRISDELLE. Who are or become pregnant because menopausal VMS does not occur during pregnancy and BRISDELLE may cause fetal harm.
BYLVAY *(odevixibat)*	Contraindications	IBAT inhibitors, including BYLVAY, are contraindicated in patients with prior or active hepatic decompensation events (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).
CLOZARIL *(clozapine)*	Boxed Warning	WARNING: SEVERE NEUTROPENIA; ORTHOSTATIC HYPOTENSION, BRADYCARDIA, AND SYNCOPE; SEIZURE; MYOCARDITIS, PERICARDITIS, AND CARDIOMYOPATHY; INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS Myocarditis, Pericarditis, Cardiomyopathy and Mitral Valve Incompetence

Drug	Type of Change	Change
		Fatal myocarditis and cardiomyopathy have occurred with CLOZARIL treatment. Discontinue CLOZARIL and obtain a cardiac evaluation upon suspicion of these reactions. Generally, patients with CLOZARIL-related myocarditis or cardiomyopathy should not be rechallenged with CLOZARIL. Consider the possibility of myocarditis, pericarditis, or cardiomyopathy if chest pain, tachycardia, palpitations, dyspnea, fever, flu-like symptoms, hypotension, or ECG changes occur.
DEPAKOTE *(divalproex sodium)*	Contraindications	Depakote is contraindicated in patients: • With hepatic disease or significant hepatic dysfunction. • Known to have mitochondrial disorders caused by mutations in mitochondrial DNA polymerase (POLG; e.g., Alpers-Huttenlocher Syndrome) and children under two years of age who are suspected of having a POLG-related disorder • With known hypersensitivity to divalproex sodium, sodium valproate, or valproic acid. Reactions have included multiorgan hypersensitivity, serious dermatologic reactions, and angioedema. • With known urea cycle disorders. • Being treated for prophylaxis of migraine headaches who are pregnant or in women of childbearing potential who are not using effective contraception
EZALLOR SPRINKLE *(rosuvastatin calcium)*	Contraindications	EZALLOR SPRINKLE is contraindicated in patients with: Acute liver failure or decompensated cirrhosis Hypersensitivity to rosuvastatin or any excipients in EZALLOR SPRINKLE. Hypersensitivity reactions, including rash, pruritus, urticaria, and angioedema, have been reported with EZALLOR SPRINKLE.
FINTEPLA *(fenfluramine hydrochloride)*	Boxed Warning	FINTEPLA can cause valvular heart disease and pulmonary arterial hypertension.
GEODON *(ziprasidone hydrochloride)*	Contraindications	Ziprasidone is contraindicated in patients taking, or within 14 days of stopping, MAOIs (including the MAOIs linezolid and intravenous methylene blue) because of an increased risk of serotonin syndrome.
GVOKE HYPOPEN *(glucagon)*	Contraindications	GVOKE and GVOKE VialDx are contraindicated in patients with: Prior hypersensitivity reaction to glucagon or to any of the excipients in GVOKE or GVOKE VialDx. Serious hypersensitivity reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension. GVOKE VialDx for use as a diagnostic aid is also contraindicated in patients with glucagonoma because of risk of hypoglycemia.

Drug	Type of Change	Change
GVOKE PFS *(glucagon)*	Contraindications	GVOKE and GVOKE VialDx are contraindicated in patients with: Prior hypersensitivity reaction to glucagon or to any of the excipients in GVOKE or GVOKE VialDx. Serious hypersensitivity reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension. GVOKE VialDx for use as a diagnostic aid is also contraindicated in patients with glucagonoma because of risk of hypoglycemia.
LETAIRIS *(ambrisentan)*	Boxed Warning	Letairis is contraindicated for use during pregnancy because it may cause major birth defects if used by pregnant patients, based on studies in animals. Therefore, for females of reproductive potential, exclude pregnancy before the initiation of treatment with Letairis. Advise use of effective contraception before initiation, during treatment, and for one month after treatment with Letairis. When pregnancy is detected, discontinue Letairis as soon as possible.
OPSUMIT *(macitentan)*	Boxed Warning	OPSUMIT is contraindicated for use during pregnancy because it may cause fetal harm based on animal data. Therefore, for females of reproductive potential, exclude pregnancy before the start of treatment with OPSUMIT. Advise use of effective contraception before the initiation of treatment, during treatment, and for one month after stopping treatment with OPSUMIT. When pregnancy is detected, discontinue OPSUMIT as soon as possible.
OPSYNVI *(macitentan-tadalafil)*	Boxed Warning	OPSYNVI is contraindicated for use during pregnancy because it may cause fetal harm based on animal data. Therefore, for females of reproductive potential, exclude pregnancy before the start of treatment with OPSYNVI. Advise use of effective contraception before the initiation of treatment, during treatment, and for one month after stopping treatment with OPSYNVI. When pregnancy is detected, discontinue OPSYNVI as soon as possible.
PAXLOVID (COPACKAGED) *(nirmatrelvir; ritonavir)*	Contraindications	Drugs that are strong CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance. PAXLOVID cannot be started immediately after discontinuation of any of the following medications due to the delayed offset of the recently discontinued CYP3A inducer. Anticancer drugs: apalutamide, enzalutamide.

Drug	Type of Change	Change
PRIMAQUINE *(primaquine phosphate)*	Contraindications	Known hypersensitivity reactions to primaquine phosphate, other 8-aminoquinolones, or to any component in Primaquine phosphate Tablets. Breastfeeding by a lactating woman when the infant is found to be G6PD deficient or if G6PD status is unknown.
SOLODYN *(minocycline hydrochloride)*	Contraindications	SOLODYN is contraindicated in patients with history of a hypersensitivity reaction to any of the tetracyclines.
TRYVIO *(aprocitentan)*	Boxed Warning	WARNING: EMBRYO–FETAL TOXICITY • TRYVIO is contraindicated for use during pregnancy because it may cause fetal harm if used by pregnant patients. Therefore, in patients who can become pregnant, exclude pregnancy prior to initiation of TRYVIO. • Advise use of effective contraception before the start of TRYVIO, during treatment and for one month after stopping treatment. • When pregnancy is detected, discontinue TRYVIO as soon as possible.
TYENNE *(tocilizumab-aazg)*	Boxed Warning	Reported infections include: Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients, except those with COVID-19, should be tested for latent tuberculosis before TYENNE use and during therapy. Treatment for latent infection should be initiated prior to TYENNE use.
TYGACIL *(tigecycline)*	Contraindications	TYGACIL is contraindicated for use in patients who have known hypersensitivity to tigecycline or to any of the excipients.
VERSACLOZ *(clozapine)*	Boxed Warning	WARNING: SEVERE NEUTROPENIA; ORTHOSTATIC HYPOTENSION, BRADYCARDIA, AND SYNCOPE; SEIZURE; MYOCARDITIS, PERICARDITIS, AND CARDIOMYOPATHY; INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS Myocarditis, Pericarditis, Cardiomyopathy and Mitral Valve Incompetence Fatal myocarditis and cardiomyopathy have occurred with clozapine treatment. Discontinue VERSACLOZ and obtain a cardiac evaluation upon suspicion of these reactions. Generally, patients with VERSACLOZ-related myocarditis or cardiomyopathy should not be rechallenged with VERSACLOZ. Consider the possibility of myocarditis, pericarditis, or cardiomyopathy if chest pain, tachycardia, palpitations, dyspnea, fever, flu-like symptoms, hypotension, or ECG changes occur.

Drug	Type of Change	Change
VFEND *(voriconazole)*	Contraindications	Coadministration of VFEND with finerenone is contraindicated since it may result in significant increases in finerenone exposure and the potential for serious adverse reactions.
ZILBRYSQ *(zilucoplan sodium)*	Boxed Warning	WARNING: SERIOUS MENINGOCOCCAL INFECTIONS ZILBRYSQ, a complement inhibitor, increases the risk of serious infections caused by Neisseria meningitidis. Life- threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life- threatening or fatal if not recognized and treated early. Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ZILBRYSQ, unless the risks of delaying therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination against meningococcal bacteria in patients receiving a complement inhibitor. For additional guidance on the management of the risk of serious infections caused by meningococcal bacteria. Patients receiving ZILBRYSQ are at increased risk for invasive disease caused by Neisseria meningitidis, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected. Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

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	Communication Summary
Cetirizine or levocetirizine (Zyrtec, Xyzal, and other trade names)	The U.S. Food and Drug Administration (FDA) is warning that patients stopping the oral allergy medicines cetirizine (Zyrtec) or levocetirizine (Xyzal) after long-term use may experience rare but severe itching. These medicines are available in prescription and over-the-counter (OTC) forms. The itching, also called pruritus, has been reported in patients who used these medicines daily, typically for at least a few months and often for years. Patients did not experience itching before starting the medicines. Reported cases were rare but sometimes serious, with patients experiencing widespread, severe itching that required medical intervention. As a result, we are revising the prescription cetirizine and levocetirizine prescribing information to include a new warning about this risk. We will subsequently request that manufacturers add a warning about pruritus to the Drug Facts Label of the OTC versions

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 American Society of Health-System Pharmacists (ASHP) Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Morphine Oral Solution	Hikama	**Products Affected – Description** • Morphine oral solution, Hikma, 10 mg/5 mL, 100 mL bottle, 1 count, NDC 00054-0237-49 • Morphine oral solution, Hikma, 10 mg/5 mL, 500 mL bottle, 1 count, NDC 00054-0237-63 • Morphine oral solution, Hikma, 20 mg/5 mL, 100 mL bottle, 1 count, NDC 00054-0238-49 • Morphine oral solution, Hikma, 20 mg/5 mL, 500 mL bottle, 1 count, NDC 00054-0238-63 • Morphine oral solution, Hikma, 20 mg/mL, 120 mL bottle, 1 count, NDC 00054-0517-50 • Morphine oral solution, Hikma, 20 mg/mL, 15 mL bottle, 1 count, NDC 00054-0517-41 • Morphine oral solution, Hikma, 20 mg/mL, 30 mL bottle, 1 count, NDC 00054-0517-44 **Reason for the Shortage** Hikma did not provide a reason for the shortage. **Available Products** None. **Estimated Resupply Dates** Hikma has morphine 10 mg/5 mL 100 mL and 500 mL bottles on back order and the company estimates a release date of mid- to late-June 2025. The 20 mg/mL 15 mL bottles are on back order and the company estimates a release date of late-May 2025. The 20 mg/5mL 100 mL and 500 mL bottles and 20 mg/mL 30 mL and 120 mL bottles are on allocation.
Fluorescein Sodium Ophthalmic Strips	Amcon Labs	**Products Affected - Description** • GloStrips, Amcon Labs, 1 mg, ophthalmic strips 100-count, NDC 51801-0009-40 **Reason for the Shortage** • Amcon Labs are reformulating their previous presentation. **Available Products** None **Estimated Resupply Dates** • Amcon Labs has an estimated relaunch date of early-September 2025.

Drug Product	Affected Manufacturers	Summary
Oxymorphone Immediate-Release Tablets	• Camber • Hikma • KVK-Tech	**Products Affected - Description** • Oxymorphone immediate release tablet, Camber, 10 mg, bottle, 100-count, NDC 31722-0930-01 - discontinued • Oxymorphone immediate release tablet, Camber, 5 mg, bottle, 100-count, NDC 31722-0929-01 - discontinued • Oxymorphone immediate release tablet, Hikma, 10 mg, bottle, 100-count, NDC 00054-0284-25 • Oxymorphone immediate release tablet, Hikma, 5 mg, bottle, 100-count, NDC 00054-0283-25 • Oxymorphone immediate release tablet, KVK-Tech, 10 mg, bottle, 100-count, NDC 10702-0071-01 • Oxymorphone immediate release tablet, KVK-Tech, 5 mg, bottle, 100-count, NDC 10702-0070-01 **Reason for the Shortage** • Camber discontinued oxymorphone tablets in early 2024. • Hikma did not provide a reason for the shortage. • KVK-Tech has oxymorphone on shortage due to DEA quotas. **Available Products** None. **Estimated Resupply Dates** • Hikma has oxymorphone 5 mg and 10 mg tablets on allocation. • KVK-Tech has oxymorphone 5 mg and 10 mg immediate-release tablets on back order and the company cannot estimate a release date.
Azithromycin Powder for Oral Suspension Packets	• Pfizer • Mylan (Vitaris)	**Products Affected** • Zithromax oral powder for suspension, Pfizer, 1 gram, packet, 3 count, NDC 00069-3051-75 • Zithromax oral powder for suspension, Pfizer, 1 gram, packet, 10 count, NDC 00069-3051-07 - discontinued • Azithromycin oral powder for suspension, Mylan (Viatris), 1 gram, packet, 3 count, NDC 59762-3051-02 - discontinued • Azithromycin oral powder for suspension, Mylan (Viatris), 1 gram, packet, 10 count, NDC 59762-3051-01 - discontinued **Reason for the Shortage** • In May 2024, Mylan (Viatris) discontinued azithromycin oral powder for suspension in 1-gram packets. • Pfizer has Zithromax oral powder for suspension 1-gram packets in 3 count on shortage due to manufacturing delays. In June 2024, the company stopped marketing Zithromax oral powder for suspension 1 gram packets in 10 count. • Pfizer is the sole supplier of azithromycin oral powder for suspension packets.

Drug Product	Affected Manufacturers	Summary
		Available Products None. **Estimated Resupply Dates** • Pfizer has Zithromax oral powder for suspension in 1 gram packets on back order and the company cannot estimate a release date.
Propranolol Hydrochloride Oral Solution	Hikma	**Products Affected - Description** • Propranolol hydrochloride oral solution, Hikma, 20 mg/5 mL, 500 mL bottle, strawberry-mint flavor, NDC 00054-3727-63 • Propranolol hydrochloride oral solution, Hikma, 40 mg/5 mL, 500 mL bottle, strawberry-mint flavor, NDC 00054-3730-63 **Reason for the Shortage** • Hikma did not provide a reason for the shortage. • Pierre Fabre's Hemangeol oral solution is not affected by this shortage. **Available Products** None. **Estimated Resupply Dates** • Hikma has propranolol 20 mg/5 mL in 500 mL bottles and 40 mg/5 mL in 500 mL bottles on back order and the company estimates a release date of early-May 2025 for the 20 mg/5 mL 500 mL bottles and late-April 2025 for the 40 mg/5 mL 500 mL bottles.
Penicillin G Benzathine/Penicillin G Procaine	Pfizer	**Products Affected - Description** • Bicillin C-R intramuscular suspension for injection, Pfizer, 1,200,000 units (600,000 units penicillin G benzathine/600,000 units penicillin G procaine), 2 mL prefilled syringe, 10 count, NDC 60793-0600-10 • Bicillin C-R intramuscular suspension for injection, Pfizer, 1,200,000 units (600,000 units penicillin G benzathine/600,000 units penicillin G procaine), 2 mL pediatric prefilled syringe, 10 count, NDC 60793-0601-10 • Bicillin C-R 900/300 intramuscular suspension for injection, Pfizer, 1,200,000 units (900,000 units penicillin G benzathine/300,000 units penicillin G procaine), 2 mL pediatric prefilled syringe, 10 count, NDC 60793-0602-10 **Reason for the Shortage** • Pfizer has Bicillin-CR on shortage due to increased demand and manufacturing delays. Pfizer is allocating resources towards manufacturing Bicillin-LA due to increased syphilis infection rates. A Dear Healthcare Professional Letter can be found here.

Drug Product	Affected Manufacturers	Summary
		Available Products • There is insufficient supply for usual ordering. **Estimated Resupply Dates** Pfizer has Bicillin-CR 1,200,000 units adult 2 mL syringes and 1,200,000 units pediatric 2 mL syringes on back order and the company estimates a release date of December 2028. The Bicillin-CR (900/300) 2 mL syringes are on back order and the company estimates a release date of December 2028.
Mercaptopurine Tablets	• Hikma • Mylan (Viatris) • Quinn	**Products Affected – Description** • Mercaptopurine tablet, Hikma, 50 mg, bottle, 25 count, NDC 00054-4581-11 • Mercaptopurine tablet, Hikma, 50 mg, bottle, 250 count, NDC 00054-4581-27 • Mercaptopurine tablet, Mylan (Viatris), 50 mg, bottle, 25 count, NDC 00378-3547-52 - discontinued • Mercaptopurine tablet, Mylan (Viatris), 50 mg, bottle, 250 count, NDC 00378-3547-25 - discontinued • Mercaptopurine tablet, Quinn Pharmaceuticals, 50 mg, bottle, 25 count, NDC 69076-0913-02 • Mercaptopurine tablet, Quinn Pharmaceuticals, 50 mg, bottle, 250 count, NDC 69076-0913-25 **Reason for the Shortage** • Hikma did not provide a reason for the shortage. • Viatris discontinued mercaptopurine 50 mg tablets in 25 count bottles in March 2025. • Quinn has mercaptopurine tablets on shortage due to manufacturing issues. The company has temporarily discontinued mercaptopurine 50 mg tablets. **Available Products** None. **Estimated Resupply Dates** • Hikma has mercaptopurine 50 mg tablets in 25 count and 250 count bottles on allocation. • Quinn has temporarily discontinued mercaptopurine 50 mg tablets in 25 count and 250 count bottles and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Varenicline Tablets (Chantix)	Pfizer	**Products Affected - Description** • Chantix oral tablet, Pfizer, 0.5 mg, bottle, 56 count, NDC 00069-0468-56 • Chantix oral tablet, Pfizer, 0.5 mg/1 mg, starting month box 0.5 mg = 11 tablets/1 mg = 42 tablets; 53 count, NDC 00069-0471-03 • Chantix oral tablet, Pfizer, 1 mg, bottle, 56 count, NDC 00069-0469-56 • Chantix oral tablet, Pfizer, 1 mg, continuing month box 56 count, NDC 00069-0469-03 **Reason for the Shortage** • 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. **Available Products** None. **Estimated Resupply Dates** • Pfizer has Chantix on back order and the company cannot estimate a release date. **Implications for Patient Care** • FDA is allowing temporary importation Apo-Varenicline (varenicline tartrate) from Apotex in Canada. More information on ordering the product from Apotex through a distributor or wholesaler can be found here. **Safety** • Abrupt discontinuation of varenicline has been associated with increased irritability and sleep disturbances, suggesting varenicline may produce mild physical dependence.

Drug Product	Affected Manufacturers	Summary
Megestrol Tablets (Megace)	• Major • Strides • Teva	**Products Affected - Description** • Megestrol acetate oral tablet, Major, 40 mg, unit-dose blister pack, 100-count, NDC 00904-7236-61 • Megestrol acetate oral tablet, Strides Pharma, 20 mg, bottle, 100-count, NDC 64380-0158-01 • Megestrol acetate oral tablet, Strides Pharma, 40 mg, bottle, 100-count, NDC 64380-0159-01 • Megestrol acetate oral tablet, Strides Pharma, 40 mg, bottle, 500-count, NDC 64380-0159-03 • Megestrol acetate oral tablet, Teva, 20 mg, bottle, 100-count, NDC 00555-0606-02 • Megestrol acetate oral tablet, Teva, 40 mg, bottle, 100-count, NDC 00555-0607-02 **Reason for the Shortage** • Major, Strides, and Teva did not provide a reason for the shortage. **Available Products** None. **Estimated Resupply Dates** • Strides has megestrol acetate 20 mg tablets in 100-count bottles and 40 mg tablets in 100-count and 500-count bottles on back order and the company estimates a release date of June 2025. • Major has megestrol acetate 40 mg tablets in unit-dose packs on back order and the company estimates a release date of mid-June 2025. • Teva has megestrol acetate 20 mg tablets in 100-count and 40 mg tablets in 100-count bottles on back order and the company estimates a release date of mid-July 2025.
Ibrexafungerp Tablets (Brexafemme)		**Products Affected - Description** Brexafemme oral tablet, Scynexis, 150 mg, unit-dose blister pack, 4-count, NDC 75788-0115-04 **Reason for the Shortage** Scynexis recalled Brexafemme tablets in September 2023 due to a potential for cross-contamination. **Available Products** None. **Estimated Resupply Dates** Scynexis has Brexafemme temporarily unavailable, and the company cannot estimate when the product will return to the market.

Drug Product	Affected Manufacturers	Summary
Dronabinol Capsules (Marinol)		**Products Affected - Description** • Dronabinol oral capsule, Ascend, 10 mg, bottle, 60 count, NDC 67877-0755-60 • Dronabinol oral capsule, Ascend, 2.5 mg, bottle, 60 count, NDC 67877-0753-60 • Dronabinol oral capsule, Ascend, 5 mg, bottle, 60 count, NDC 67877-0754-60 • Dronabinol oral capsule, Major, 2.5 mg, unit-dose blister pack, 100 count, NDC 00904-7144-61 • Dronabinol oral capsule, Major, 5 mg, unit-dose blister pack, 30 count, NDC 00904-7145-04 • Dronabinol oral capsule, Rhodes, 10 mg, bottle, 60 count, NDC 42858-0869-06 • Dronabinol oral capsule, Rhodes, 2.5 mg, bottle, 60 count, NDC 42858-0867-06 • Dronabinol oral capsule, Rhodes, 5 mg, bottle, 60 count, NDC 42858-0868-06 **Reason for the Shortage** • Ascend has dronabinol capsules on shortage due to regulatory issues. • Major did not provide a reason for the shortage. • Rhodes has dronabinol capsules on shortage due to manufacturing delays. **Available Products** There is insufficient supply for usual ordering **Estimated Resupply Dates** • Ascend has dronabinol capsules in limited supply. • Major has dronabinol capsules on back order and the company estimates a release date in mid-June 2025. • Rhodes has dronabinol capsules on long-term back order and the company cannot estimate a release date.
Doxazosin Extended Release Tablet (Cardura XL)	Mylan (Viatris)	**Products Affected - Description** • Cardura XL oral extended release tablet, Mylan (Viatris), 4 mg, bottle, 30 count, NDC 58151-0078-93 • Cardura XL oral extended release tablet, Mylan (Viatris), 8 mg, bottle, 30 count, NDC 58151-0079-93 **Reason for the Shortage** In December 2024, Viatris recalled certain lots of Cardura XL 4 mg and 8 mg tablets due to out of specification results of an impurity during stability testing. **Available Products** None **Estimated Resupply Dates** Viatris has Cardura XL 4 mg and 8 mg tablets on back order and the company estimates a release date of mid- to late-June 2025.

Drug Product	Affected Manufacturers	Summary
Peginterferon Alfa-2a Injection (Pegasys)	Summit SD	**Products Affected - Description** • Pegasys subcutaneous solution for injection, Summit SD, 180 mcg/0.5 mL, 0.5 mL prefilled syringe, four syringes in a monthly convenience pack, NDC 82154-0451-04 • Pegasys subcutaneous solution for injection, Summit SD, 180 mcg/mL, 1 mL single dose vial, NDC 82154-0449-01 **Reason for the Shortage** Summit SD is the distributor of Pegasys in the US. Pharma& manufactures Pegasys and is working to expand bio-manufacturing capabilities at the manufacturing plant. **Available Products** None. **Estimated Resupply Dates** Summit SD has Pegasys 180 mcg/mL 1 mL vials and 180 mcg/0.5 mL prefilled syringes on allocation. The company expects supply to become more limited through 4th quarter 2025. The company estimates additional product will be available in the first half of 2026.

Drug Recalls

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

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
Feb. 14, 2025	Potassium Chloride Injection, 20 mEq and Potassium Chloride Injection, 10 mEq	Bags of POTASSIUM CHLORIDE Inj. 20 mEq have incorrect overwrap labels which state POTASSIUM CHLORIDE Inj. 10 mEq.	ICU Medical	NDC 0990-7074-26 Lot #1023172 (exp Jan. 31, 2026) NDC 0990-7075-26 Lot # 1023172 (exp Jan. 31, 2026) NDC 0990-7075-26 Lot #1023172 (exp Jan. 31, 2026)
Feb. 25, 2025	Phenylephrine 40 mg Added to 0.9% Sodium Chloride 250 mL in 250 mL	The product is being recalled because CAPS was notified by their raw material supplier of the detection of visible black particulate matter in a single sealed vial of Phenylephrine Hydrochloride.	CAPS	NDC 71285-6092-1 Lot # 37-928390 (exp March 3, 2025) NDC 71285-6092-1 Lot # 37-928796 (exp March 9, 2025) NDC 71285-6092-1 Lot # 37-928839 (exp March 10, 2025)
March 13, 2025	Levetiracetam in Sodium Chloride Injection	Mislabeling of infusion bag	Dr. Reddy's Laboratories Ltd	NDC 43598-635-52 Lot A1540076 (exp August 2026) NDC 43598-636-52 Lot #A1540076 (exp August 2026) NDC 43598-636-10 Lot #A1540076 (exp August 2026)
4/18/2025	Ropivacaine HCl Injection 500mg/100mL	Product may contain an inert fiber identified as polypropylene fibers from the IV bag	Amneal Pharmaceuticals LLC	NDC 70121-17343 Lot #AL240003 (exp January 2026) Lot #AL240004 (exp January 2026)

Gold Coast Health Plan℠
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Pharmacy Newsletter

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For additional information, contact the
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