Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

Q1 2026

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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 Lily Yip, at lyip@goldchp.org or 1-805-437-5873.

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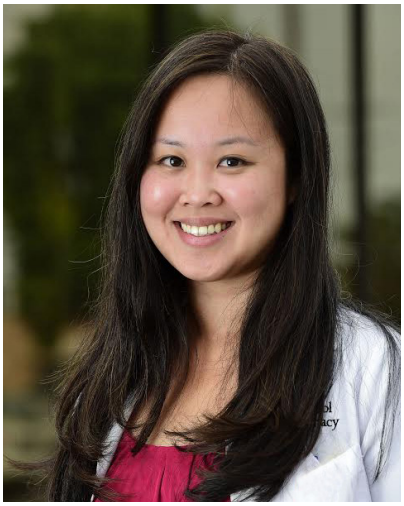
A Message from the Gold Coast Health Plan Director of Pharmacy



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

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates related to the use of medications and pharmacy services and benefits for GCHP members. The newsletter includes information and updates regarding the pharmacy benefit for our new Medicare Advantage plan, Gold Coast Health Plan Total Care Advantage (HMO D-SNP) for our GCHP members who are eligible for both Medicare and Medi-Cal, as well as information about the Medi-Cal pharmacy benefit, which is managed by Medi-Cal Rx for Medi-Cal members.

Our goal is to equip providers with the information necessary to safely prescribe medications and to ensure members have access to all necessary pharmacy benefits and services through Medi-Cal Rx, or Total Care Advantage. We are available to help any members or providers 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., MBA, APh, CDCES, BCACP, CPHQ
Director of Pharmacy

Where to Safely Dispose of Unused Medications

You can now search the California Board of Pharmacy website for local locations to 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.

Total Care Advantage (HMO D-SNP) Updates – New Medicare Advantage Plan

Gold Coast Health Plan (GCHP) introduced a Medicare Advantage Dual Eligible Special Needs Plan for members who have both Medicare and Medi-Cal (Medi-Medi members) on Jan. 1, 2026.

Gold Coast Health Plan Total Care Advantage (HMO D-SNP) Part B Drugs

Medicare Part B covers physician-administered drugs (PADs) and biologics that are typically provided in a clinical setting (in-office, outpatient infusion centers). This includes chemotherapy infusions, IV infusions, and most injectable medications that are NOT self-administered. Certain preventive vaccines are also covered under Part B, including influenza, COVID-19, hepatitis B, and pneumococcal vaccines. In addition, Part B covers diabetic testing supplies, continuous glucose monitors (CGMs), durable medical equipment (DME), and drugs and biologics related to end stage renal disease (ESRD).

Part B Physician Administered Drugs (PADs) - Medical Benefit (managed by Gold Coast Health Plan)

Part B medications are billed under the medical benefit. Gold Coast Health Plan (GCHP) will review prior authorization requests for some drugs that are administered at a physician's office. For a list of the Medicare Part B Drugs that require prior authorization and review for approval, please check the Total Care Advantage Medicare Part B Drug List. This list is updated quarterly in alignment with guidance and direction received by the Centers for Medicare & Medicaid Services (CMS) and the GCHP Pharmacy and Therapeutics (P&T) Committee.

To avoid delays or denials, providers should submit a completed prior authorization request with all necessary clinical documentation. You may submit prior authorization requests for Part B electronically on the Provider Portal (preferred) or manually by completing and faxing a Prior Authorization Treatment Request Form. Claims may be delayed or denied until the required information is received to establish medical necessity. PADs that are billed on a medical claim are the responsibility of GCHP.

*NOTE: Prior authorization requests are subject to CMS-mandated turnaround times (TATs). Standard requests will be reviewed within **72 hours** from receipt of request. Expedited requests will be reviewed within **24 hours** from receipt of request; however, a request should ONLY be deemed expedited if waiting the standard 72-hour TAT could jeopardize the member's life, health, or ability to regain maximum function.

Total Care Advantage – Pharmacy Benefit (Part D)

Medicare Part D covers outpatient prescription drugs that are typically self-administered, including oral medications, inhalers, self-administered injectables and maintenance medications for chronic conditions. All adult vaccines recommended by ACIP are also covered under Part D.

Most of the members will pay a copay for their medications under Medicare Part D. The amount they have to pay depends on their Low-Income Subsidy (LIS) level (also called Extra Help) which is dependent on a member's income and resources. Members can have a LIS level of 1, 2, or 3. Depending on which level they are assigned by the Social Security Administration, their co-pays would be defined as follows:

LIS Level	Generic Copay	Brand Copay
Level 1	$5.10	$12.65
Level 2	$1.60	$4.90
Level 3	$0	$0

Over-the-counter medications are NOT covered under Part D; however, certain OTC products may be covered under Medi-Cal Rx. For list of covered Part D medications, refer to the Total Care Advantage 2026 Formulary or myPrime website (online searchable formulary).

Part D medications are dispensed through contracted retail and mail-order pharmacies; prescriptions may be filled for up to a 100-day supply for maintenance medications. A list of contracted pharmacies can be found on the GCHP website or by visiting the myPrime website.

GCHP has contracted with Prime Therapeutics as the Pharmacy Benefit Manager (PBM) for the Part D pharmacy benefit for Total Care Advantage members. Prime Therapeutics is responsible for processing Part D pharmacy claims, some Part B pharmacy claims, and diabetic testing supplies (DTS) and continuous glucose monitors (CGMs) billed by pharmacies.

*NOTE: these medications and supplies may be subject to co-pays.

Medications covered by our Part D formulary that may require additional supporting documentation will require a Prior Authorization; drugs not covered on the TCA Part D Formulary will require a Formulary Exception. Both prior authorizations and formulary exceptions should be submitted to Prime. All other forms can be found on the myPrime website.

Total Care Advantage: Part B Drugs/Products managed by Prime Therapeutics under Pharmacy Benefit

- Diabetic testing supplies including continuous glucose monitors (CGMs)
- Nebulizer solutions for at home use (e.g. albuterol, budesonide)
- Oral anti-nausea drugs related to cancer
- Transplant/immunosuppressive drugs

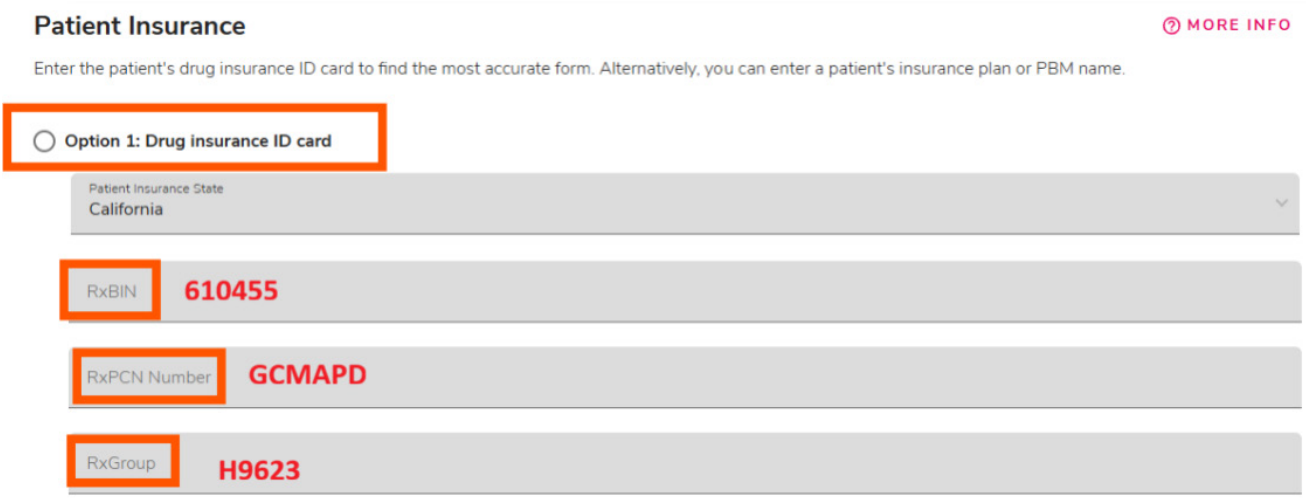
Preferred Diabetes Testing Supplies Manufacturers: *Abbott* and *Ascensia*	
Glucose Monitoring Systems (meter, tests strips, lancets)	Freestyle Lite Freestyle Freedom Lite Freestyle Precision Neo Freestyle Optium Neo Precision Xtra Contour Next EZ Contour Next GEN Contour Next ONE
Continuous Glucose Monitors (sensors, receiver, transmitter)	Dexcom G6 Dexcom G7 Freestyle Libre 2 PLUS Freestyle Libre 3 PLUS

ALL other brands of diabetic testing supplies/CGMs will require prior authorization submitted to Prime Therapeutics.

Total Care Advantage – Submitting Coverage Determination (CD) or Prior Authorization (PA) Requests

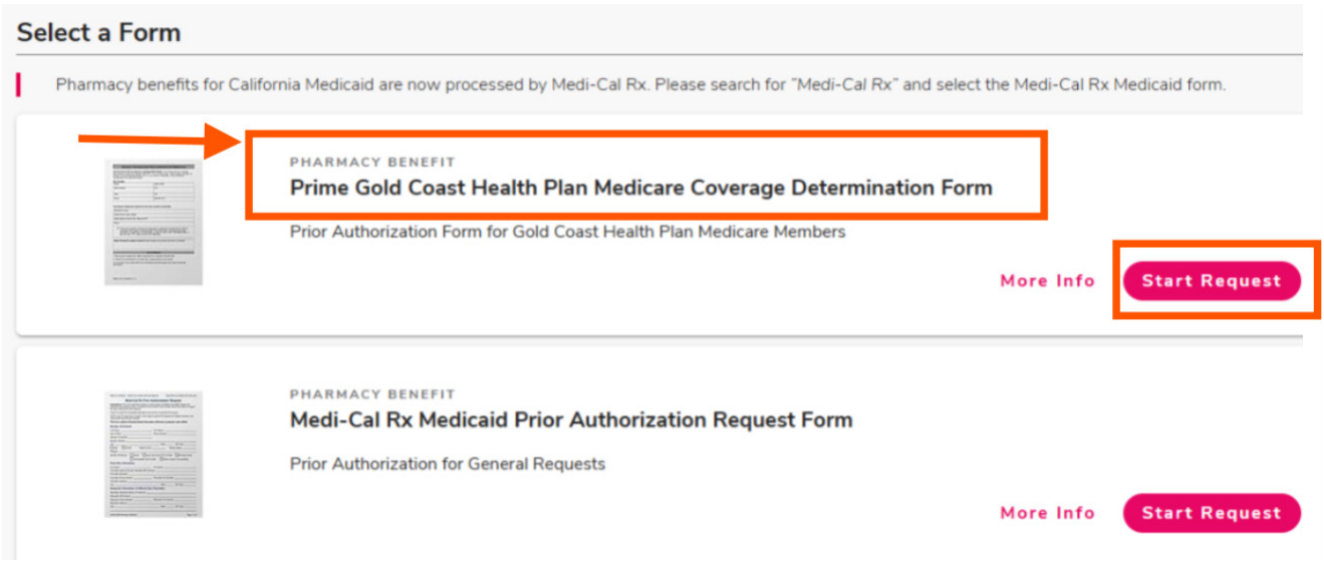
You can submit Prior Authorizations electronically using CoverMyMeds. For Total Care Advantage members – please use one of the two options below to ensure that the appropriate insurance information is entered:

- **Option 1:** Entering the **RxBIN 610455, RxPCN GCMAPD, RxGroup H9623** (which will take you directly to the Prime Gold Coast Health Plan Medicare Coverage Determination Form), or



- **Option 2:** When manually searching for the insurance plan or PBM name, enter **"California"** as the state, enter **"Gold Coast"** as the plan name, and selecting the **"Prime Gold Coast Health Plan Medicare Coverage Determination Form"** and not the Medi-Cal Rx Medicaid Prior Authorization Request Form (which is for Medi-Cal members only)

  - » **Search result will return 2 Forms. Select Prime Gold Coast Health Plan Medicare Coverage Determination Form**
- **Retain CMM Key# to follow up**



Prime Therapeutics Member Services can be reached directly at **1-855-681-7966**, 24/7 to assist with any questions or issues regarding pharmacy claims or prior authorizations.

Providers may also call Prime Therapeutics directly at **1-877-277-5449 – option 3** to submit Prior Authorizations for Part D verbally over the phone.

For more information regarding pharmacy services, please check the GCHP pharmacy website. For additional questions, the GCHP Pharmacy Team can be reached at 1-805-437-5738 or by email at Pharmacy@goldchp.org.

Medi-Cal Rx Updates

Medi-Cal Rx Updated Drug Lookup Tool

The Drug Lookup Tool, located on the Medi-Cal Rx website, has been updated to be more user friendly. You can now use this tool to look up drugs by brand or generic and it will list the 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.

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, or email 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.

Requirement for Provider Enrollment in Medi-Cal

- Individual Prescribers must be enrolled in Medi-Cal using their Type 1 National Provider Identifier (NPI) in order for pharmacy claims to be processed and paid effective **June 26, 2026**
- Verify Medi-Cal Provider enrollment status using Enrolled Fee-for-Service (FFS) Providers list on the California Health and Human Services Open Data Portal
- If the Type 1 NPI is not found on the Enrolled Fee-for-Service (FFS) Provider List, submit an application with the DHCS Provider Application and Validation for Enrollment
- For more information, visit Reminder: Requirement for Provider Enrollment in Medi-Cal

ICD-10-CM Diagnosis Code on Pharmacy Claims

- Effective fall 2026, ICD-10-CM diagnosis code(s) will be required for pharmacy claim adjudication. Please include ICD-10-CM Diagnosis code on all prescriptions.
- Apply to all pharmacy claims submitted on and after the implementation date, including claims for refills.
- For more information, visit Reminder: Include ICD-10-CM Diagnosis Codes on Pharmacy Claims

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
Blinatumomab	PA Required.	Jan. 1, 2026
Dulaglutide	Diagnosis restriction added.	Jan. 1, 2026
Gemcitabine HCL	Additional formulation (multi-dose vials) added to CDL with LR.	Jan. 1, 2026
Liraglutide (Saxenda)	Removed from CDL.	Jan. 1, 2026
Semaglutide (Wegovy)	Removed from CDL.	Jan. 1, 2026
Tirzepatide (Zepbound)	Removed from CDL.	Jan. 1, 2026
Tralokinumab-ldrm	Added to CDL with AL, LR, QL, and diagnosis restrictions.	Jan. 1, 2026
Amivantamab and Hyaluronidase-lpuj	Added to CDL with LR.	Feb. 1, 2026
Brinzolamide	Effective March 1, 2026: Removed LR 00078.	Feb. 1, 2026
Denileukin Diftitox-cxdl	Added to CDL with LR.	Feb. 1, 2026
Estrogens, Conjugated	Additional strength (0.45 mg) added to CDL.	Feb. 1, 2026
Estrogens, Conjugated and Medroxyprogesterone Acetate	Additional strengths (0.3 mg-1.5 mg and 0.45 mg-1.5 mg) added to CDL.	Feb. 1, 2026
Mepolizumab	Added to CDL with LR, QL, and diagnosis restrictions.	Feb. 1, 2026
Mirikizumab-mrkz	Added to CDL with AL, LR, QL, and diagnosis restrictions.	Feb. 1, 2026
Nystatin/Triamcinolone	Additional formulation (ointment) added to CDL.	Feb. 1, 2026
Sevabertinib	Added to CDL with LR.	Feb. 1, 2026

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.

Medi-Cal Rx Contracted Mail Order Pharmacy FAQs:

Frequently Asked Questions	Gojji Pharmacy	Burts Pharmacy
1. Medi-Cal Rx contracted Pharmacies with mail order service available to GCHPMembers	Gojji Pharmacy (909) 693-3376 www.gojji.com NPI 1790045292	Burts Pharmacy (805) 498-6675 https://burtsrx.com NPI 1235255886
2. What other languages are available?	Interpreter service including Spanish	Multilanguage including Spanish
3. Are they able to ship controlled medications?	No	No
4. Are they able to ship insulin or other refrigerated medications?	Yes	No
5. Do they provide tracking service for the shipment?	Yes, upon request	Yes
6. Is same day shipping available?	No	Yes

Frequently Asked Questions	Gojji Pharmacy	Burts Pharmacy
7. Do they handle specialty drugs?	No	Yes
8. Do they provide compounded medications?	No	Yes
9. Do they notify the member when the shipment goes out?	Yes, if the Member agrees to SMS	Yes

Medi-Cal 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.

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 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 (i.e., J-Code) requiring a PA must be submitted as a Prior Authorization Treatment Request Form to GCHP to be considered for coverage under the medical benefit. For the most part, PADs are covered under the medical benefit and billed by the provider on a medical claim to GCHP. The provider will need to purchase the drugs from their wholesaler, distributor, or manufacturer (or another internal process at their site of practice) and then administer to the member and later bill GCHP for reimbursement.

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

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

For the most part, PADs that require 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.

Key Updates from 2026 ADA Standards of Diabetes Care

1. Improving Care and Population Health

- Align approaches to diabetes management with evidence-based care models. These models emphasize person-centered team care, integrated long-term treatment approaches to diabetes and comorbidities, and ongoing collaborative communication and goal setting among all team members and with people with diabetes.
- Health systems should adopt a culture of continuous quality improvement, implement benchmarking programs, and engage interprofessional teams to support sustainable and scalable process changes to improve quality of care and health outcomes.

2. Diagnosis and Classification

- Diagnose diabetes based on A1C or plasma glucose criteria. Plasma glucose criteria include either fasting plasma glucose (FPG), 2-h plasma glucose (2-h PG) during a 75-g oral glucose tolerance test (OGTT), or random glucose accompanied by classic hyperglycemic symptoms or crises.
- Screen for presymptomatic type 1 diabetes by testing autoantibodies against insulin (IA), glutamic acid decarboxylase (GAD), islet antigen 2 (IA-2), or zinc transporter 8 (ZnT8).
- Autoantibody-based screening for presymptomatic type 1 diabetes should be offered to those with a family history of type 1 diabetes or otherwise known elevated genetic risk.
- Individuals with positive screening results for one or more islet autoantibodies should be evaluated for stage 3 (overt) type 1 diabetes (using A1C, urinalysis, and/or plasma glucose), which would require prompt clinical management and education.
- Individuals with multiple confirmed islet autoantibodies and without overt type 1 diabetes have a high risk for progression to stage 3 type 1 diabetes and should be referred to a specialized center for metabolic staging, education, and consideration of prevention trials or approved treatments (e.g., teplizumab).
- People starting cancer treatment with immune checkpoint inhibitors (ICIs), including anti-PD-1 or anti-PDL-1 therapy (e.g., nivolumab, pembrolizumab, avelumab), phosphoinositidylinositol 3- kinase α (PI3Kα) inhibitors (e.g., alpelisib, inavolisib), or mammalian target of rapamycin (mTOR) inhibitors (e.g., everolimus), should be educated regarding risks, symptoms, and signs of hyperglycemia and hyperglycemic crises.
- In people treated with ICIs, fasting or random plasma glucose should be tested before initiating treatment, during each visit, or if symptoms and signs of hyperglycemia develop during or after treatment cessation.
- In people treated with PI3Kα inhibitors, fasting or random plasma glucose and A1C should be tested before initiating treatment, and random plasma glucose should be tested weekly for the first 2 weeks of treatment and then every 4 weeks during treatment. Consider testing A1C every 3 months during treatment.
- In people treated with mTOR inhibitors, fasting or random plasma glucose should be tested before starting and at each visit throughout the duration of treatment. Consider testing A1C every 3 months during treatment.

3. Prevention and Delay of Diabetes and Comorbidities

- Refer adults with overweight or obesity at high risk of type 2 diabetes to a diabetes prevention program to achieve and maintain a weight reduction of at least five to seven percentof initial body weight through a healthy reduced-calorie eating pattern and ≥150 min/week of moderate-intensity physical activity.
- Prescribe an evidence-based eating pattern (e.g., Mediterranean, low carbohydrate) to individuals with prediabetes to prevent type 2 diabetes.

- Metformin for the prevention of type 2 diabetes should be considered in adults at high risk of type 2 diabetes, as typified by the Diabetes Prevention Program, especially those aged 25 to 59 years with BMI ≥35 kg/m2, higher fasting plasma glucose (e.g., ≥110 mg/dL [≥6 mmol/L]), and higher A1C (e.g., ≥6.0% [≥42 mmol/mol]), and in individuals with prior gestational diabetes mellitus.
- Consider using metformin to prevent hyperglycemia in high-risk individuals treated with a phosphatidylinositol 3-kinase α (PI3Kα) inhibitor (e.g., alpelisib and inavolisib).
- Consider using metformin to prevent hyperglycemia in high-risk individuals treated with high-dose glucocorticoids.
- Pharmacotherapy (e.g., for weight management, minimizing the progression of hyperglycemia, and cardiovascular risk reduction) should be considered to support person-centered care goals.

4. Comprehensive Medical Evaluation and Comorbidity Assessment

- Consider osteoporosis drug therapy in older adults with diabetes who are at increased risk of fracture, including those with low bone mineral density (T-score ≤–2.5), history of fragility fracture, or elevated Fracture Risk Assessment Tool score (≥3% for hip fracture or ≥20% for major osteoporotic fracture).
- Treatment may be considered for adults with diabetes with a T-score between –2.0 and –2.5 in the presence of additional risk factors for fracture.
- In adults with type 2 diabetes, Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD), and overweight or obesity, consider using a glucagon-like peptide 1 receptor agonist (GLP-1 RA) with demonstrated benefits in Metabolic Dysfunction-Associated Steatohepatitis (MASH) or a dual glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA with potential benefits in MASH for the treatment of obesity as an adjunctive therapy to lifestyle interventions for weight loss.
- In adults with type 2 diabetes and biopsy-proven MASH or those at high risk for liver fibrosis (based on noninvasive tests), a GLP-1 RA is preferred for glycemic management due to beneficial effects on MASH.

5. Facilitating Positive Health Behaviors

- Use behavioral strategies (e.g., motivational interviewing, goal setting, problem solving) to support diabetes self-management education and support (DSMES) and engagement in behaviors known to optimize health-related quality of life and outcomes.
- Provide culturally and socially appropriate DSMES responsive to personal preferences and needs in group or individual settings.
- Provide an overweight or obesity treatment plan based on their nutrition, physical activity, and behavioral health status for all people with overweight or obesity, aiming for at least five to seven percent weight loss.
- Counsel and regularly monitor individuals pursuing intentional weight loss to ensure adequate nutritional intake, with particular attention to preventing protein insufficiency and micronutrient deficiencies.
- Use the updated International Diabetes Federation along with Diabetes and Ramadan International Alliance comprehensive prefasting risk assessment to generate a risk score for the safety of religious fasting. Provide fasting-focused education to minimize risks.
- Evaluate baseline physical activity and sedentary time for all people with diabetes and those at risk for diabetes. For people who do not meet activity guidelines, encourage an increase in physical activities above baseline with the goal of meeting activity guidelines.
- Ask people with diabetes routinely about the use of tobacco or vape products. Advise complete avoidance of tobacco and vaping. For individuals who use these products, provide or refer for combination treatment consisting of tobacco and/or vape product(s) cessation counseling and pharmacologic therapy.
- Screen for diabetes distress at least annually in people with diabetes, caregivers, and family members, and repeat screening when treatment goals are not met, at transitional times, and/or in the presence of diabetes complications.
- Screen for anxiety symptoms at least annually in people with diabetes.

- Screen individuals at high risk for hypoglycemia or with severe and/or frequent hypoglycemia for fear of hypoglycemia at least annually and when clinically appropriate.

6. Glycemic Goals, Hypoglycemia and Crises

- First aid kits should include oral glucose for use in treating hypoglycemia.

7. Diabetes Technology

- When prescribing a continuous glucose monitoring (CGM) device, ensure that people with diabetes and caregivers are offered initial and ongoing training and education as indicated by individual circumstances.
- When prescribing an automated insulin delivery (AID) system, people with diabetes and their caregivers must receive education on how to use and troubleshoot the system. This education should occur at regular intervals as needed. Education should include utilization of the integrated system and its data, including uploading or sharing data to monitor and adjust therapy.
- Children and adolescents should be supported at school in the use of diabetes technology, such as CGM systems, CSII, connected insulin pens, and AID systems.
- Consider early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's needs and preferences.
- Use of CGM is recommended at diabetes onset and anytime thereafter for children, adolescents, and adults with diabetes who are on insulin therapy.
- CGM recommended at diagnosis and thereafter for patients with insulin therapy, at hypoglycemia risk, or who may benefit, with emphasis on training.
- AID systems are the preferred insulin delivery method over MDI, CSII, and sensor-augmented pumps in people with type 1 diabetes, adults with type 2 diabetes.

8. Obesity and Weight Management for the Prevention and Treatment of Diabetes

- Screen for overweight and obesity using BMI annually. To confirm excess adiposity, additional assessments of body fat using anthropometric assessments (e.g., waist-to-hip ratio) or direct measurements (e.g., dual-energy X-ray absorptiometry, bioelectrical impedance analysis) could be considered where available/feasible.
- Counsel and regularly monitor individuals pursuing intentional weight loss to ensure adequate nutritional intake, with particular attention to preventing protein insufficiency and micronutrient deficiencies.
- Whenever clinically appropriate, engage other care team members to minimize use of weight-promoting medications for treatment of other conditions among adults with diabetes and obesity.
- Individualize the dose and the dose titration approach of obesity pharmacotherapy to balance effectiveness, health benefits, and tolerability; the optimal treatment dose may not be the maximum approved dose.
- In people with diabetes not reaching weight treatment goals, modify or intensify treatment with additional approaches, including structured lifestyle management programs, metabolic surgery and additional or alternative pharmacologic agents.
- Apply obesity management strategies used in the general adult population, including GLP-1 RA–based therapy and metabolic surgery, to adults with type 1 diabetes who have obesity (BMI ≥30.0 kg/m2 , or ≥27.5 kg/m2 in Asian American individuals). Shared decision-making should inform individualized care.

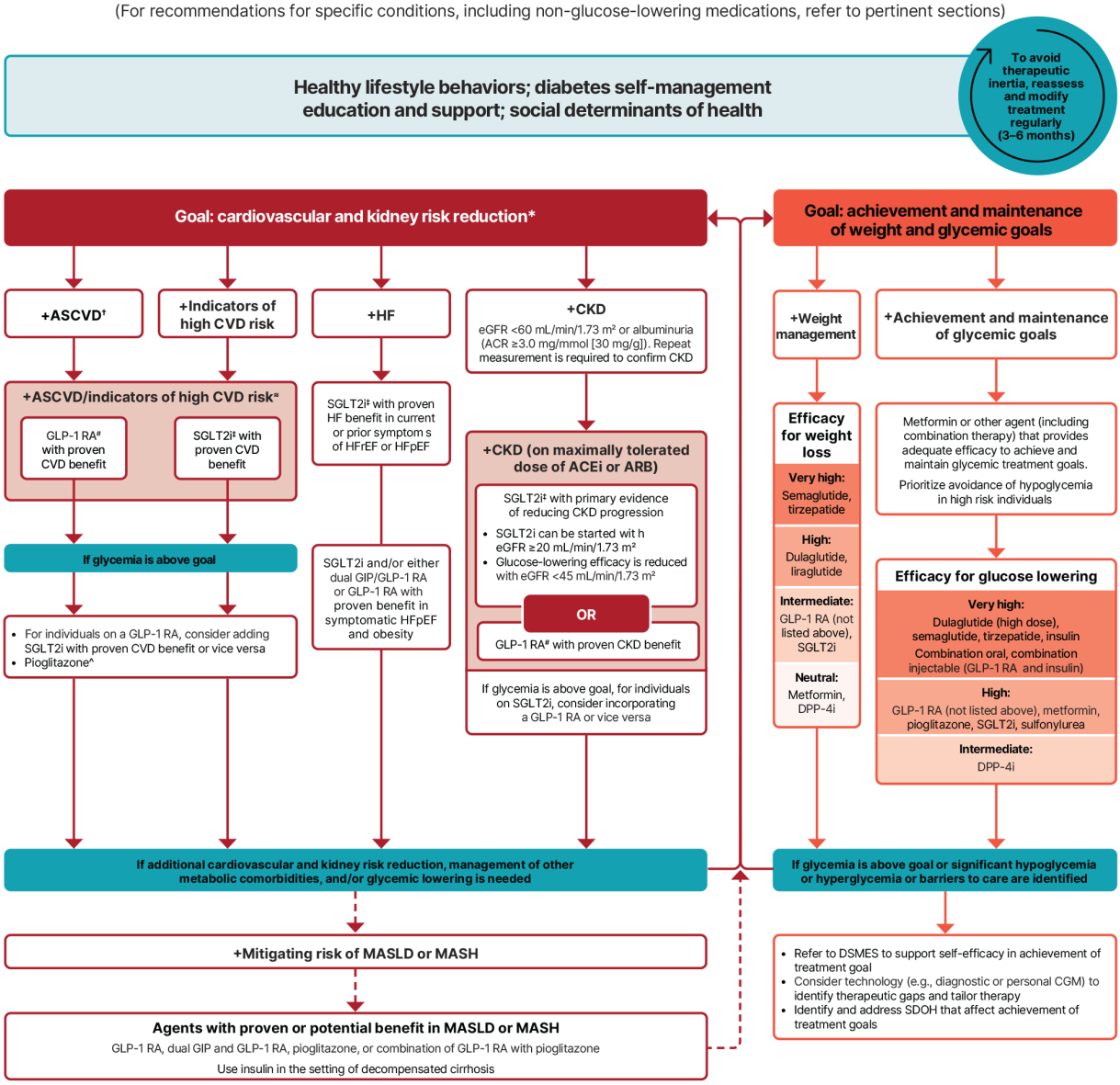
9. Pharmacologic Approaches to Glycemic Treatment

- In adults with type 2 diabetes, obesity, and symptomatic heart failure with preserved ejection fraction (HFpEF), the glucose-lowering treatment plan should include a dual glucose dependent insulinotropic polypeptide (GIP) and GLP-1 RA with demonstrated benefits for HF-related symptoms and reduction in HF events (irrespective of A1C).
- In adults with type 2 diabetes and advanced CKD (eGFR < 30 mL/min/1.73m2), a GLP-1 RA is preferred for glycemic management due to lower risk of hypoglycemia and for cardiovascular event reduction.

- In adults with type 2 diabetes, metabolic dysfunction–associated steatotic liver disease (MASLD), and overweight or obesity, consider using a GLP-1 RA with demonstrated benefits in metabolic dysfunction–associated steatohepatitis (MASH) or a dual GIP and GLP-1 RA with potential benefits in MASH for glycemic management and as an adjunctive therapy to interventions for weight loss.
- In adults with type 2 diabetes and biopsy-proven MASH or those at high risk for liver fibrosis (based on noninvasive tests), a GLP-1 RA is preferred for glycemic management due to beneficial effects on MASH.
- Use of continuous glucose monitoring (CGM) is recommended at diabetes onset and anytime thereafter for adults with diabetes who are on insulin therapy.
- Automated insulin delivery systems should be offered to all adults with type 1 and 2 diabetes on insulin depending on the person's or caregiver's needs and preferences.
- Individuals who develop hyperglycemia during treatment with immunotherapy (including anti-PD-1 or anti-PD-L1 therapy, e.g., nivolumab, pembrolizumab, or avelumab) should be assessed for the immediate need for initiation of insulin therapy due to the potential risk of diabetic ketoacidosis while additional testing is completed to determine if hyperglycemia is related to immunotherapy-associated diabetes. Close monitoring, education, and dose adjustment are needed if insulin is started.
- Consider metformin as the first line treatment of hyperglycemia due to mTOR inhibitors, phosphoinositide 3-kinase (PI3K) inhibitors that affect the α isoform (e.g., alpelisib and inavolisib). Use of insulin should be reserved for severe hyperglycemia and hyperglycemic crises due to its potential impact on the efficacy of PI3K inhibitors.
- In adults with post transplantation diabetes mellitus (PTDM) or preexisting type 2 diabetes, insulin is preferred for the management of hyperglycemia in the postoperative setting. A DPP-4 inhibitor can be considered for mild hyperglycemia.

Use of glucose-lowering medications in the management of type 2 diabetes

(For recommendations for specific conditions, including non-glucose-lowering medications, refer to pertinent sections)



* In people with HF, CKD, established CVD, or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be made irrespective of attainment of glycemic goal.

† ASCVD: Defined differently across CVOTs but all included individuals with established CVD (e.g., MI, stroke, and arterial revascularization procedure) and variably included conditions such as transient ischemic attack, unstable angina, amputation, and symptomatic or asymptomatic coronary artery disease. Indicators of high risk: While definitions vary, most comprise ≥55 years of age with two or more additional risk factors (including obesity, hypertension, smoking, dyslipidemia, or albuminuria).

≈ A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high risk CVD. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. See text for details.

For GLP-1 RAs, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke, and kidney end points in individuals with T2D with established or high risk of CVD. One kidney outcome trial demonstrated benefit in reducing persistent eGFR reduction and CV death for a GLP-1 RA in individuals with CKD and T2D.

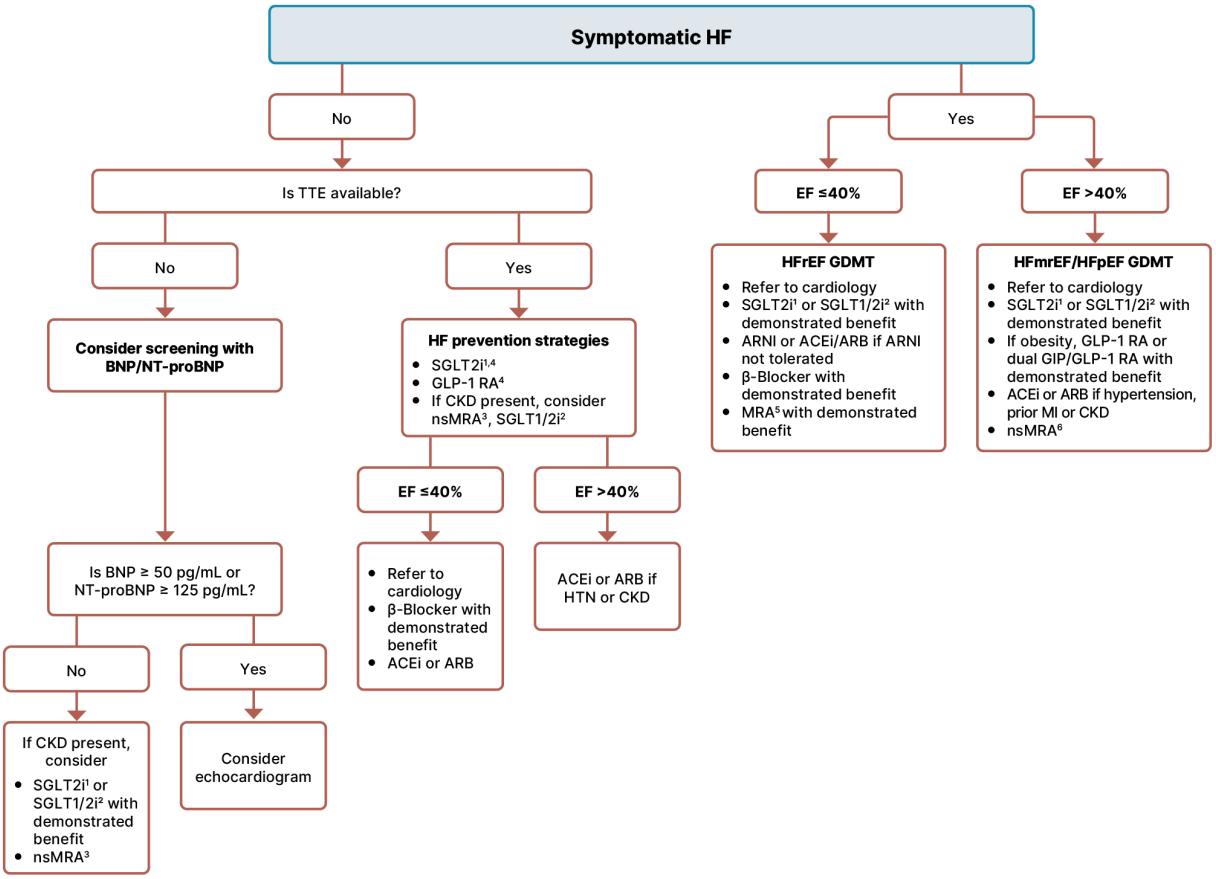
‡ For SGLT2is, CV and kidney outcomes trials demonstrate their efficacy in reducing the risks of composite MACE, CV death, all-cause mortality, MI, HHF, and kidney outcomes in individuals with T2D and established or high risk of CVD.

^ Low-dose pioglitazone may be better tolerated and similarly effective as higher doses.

Figure 9.4—Use of glucose-lowering medications in the management of type 2 diabetes. The left side of the algorithm prioritizes mitigation of diabetes-related complications and end-organ effects, while the right side addresses weight and glucose management goals. ACEi, angiotensin-converting enzyme inhibitor; ACR, albumin-to-creatinine ratio; ARB, angiotensin receptor blocker; ASCVD, atherosclerotic cardiovascular disease; CGM, continuous glucose monitoring; CKD, chronic kidney disease; CV, cardiovascular; CVD, cardiovascular disease; CVOT, cardiovascular outcomes trial; DPP-4i, dipeptidyl peptidase 4 inhibitor; DSMES, diabetes self-management education and support; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide 1 receptor agonist; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; HHF, hospitalization for heart failure; MACE, major adverse cardiovascular events; MASH, metabolic dysfunction-associated steatohepatitis; MASLD, metabolic dysfunction-associated steatotic liver disease; MI, myocardial infarction; SDOH, social determinants of health; SGLT2i, sodium–glucose cotransporter 2 inhibitor; T2D, type 2 diabetes. Adapted from Davies et al. (90).

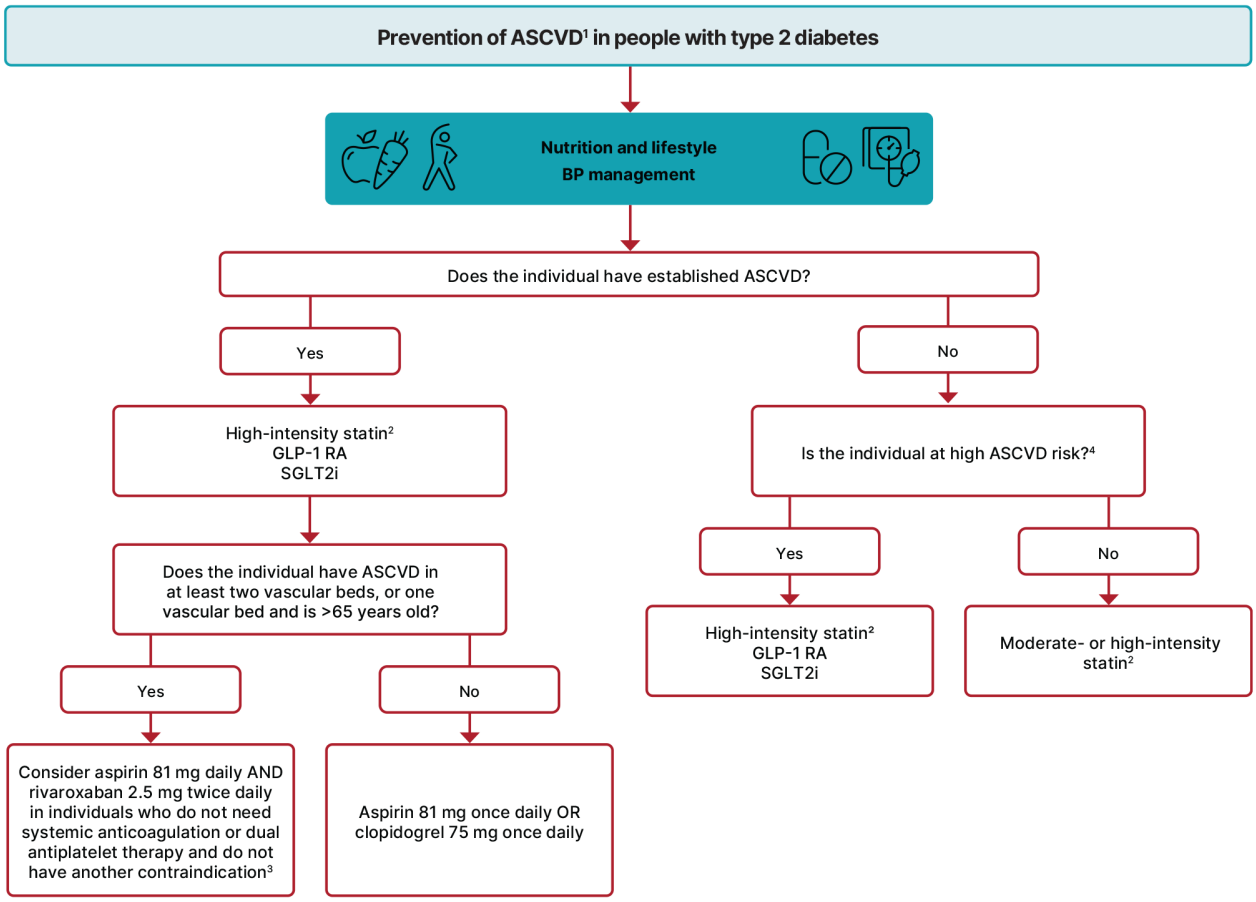
10. Cardiovascular Disease and Risk Management

- If it can be safely attained, the on-treatment blood pressure goal is <130/80 mmHg; a systolic blood pressure goal <120 mmHg should be encouraged in individuals with high cardiovascular or kidney risk.
- In nonpregnant people with diabetes and hypertension, either an ACE inhibitor or ARB is recommended for those with moderately increased albuminuria (UACR 30–299 mg/g creatinine) B and is strongly recommended for those with severely increased albuminuria (UACR ≥300 mg/g creatinine) and/or estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m2 to maximally tolerated dose to prevent the progression of kidney disease and reduce cardiovascular events.
- Monitor for drop in eGFR and for increase in serum potassium levels at initiation and periodically as clinically appropriate when ACE inhibitors, ARBs, and mineralocorticoid receptor antagonists (MRAs) are used. Monitor for hypokalemia when diuretics are used at routine visits and seven to14 days after initiation or after a dose change and periodically as clinically appropriate.
- In individuals receiving statin therapy, the addition of fibrate, niacin, or dietary supplements containing n-3 fatty acids is not recommended as they do not provide additional cardiovascular risk reduction.
- In people with type 2 diabetes and established ASCVD or multiple risk factors for ASCVD, or CKD, a GLP-1 RA with demonstrated cardiovascular benefit is recommended to reduce the risk of cardiovascular events.
- In individuals with type 2 diabetes and asymptomatic (stage B) heart failure or with high risk of or established cardiovascular disease, treatment with an SGLT inhibitor with proven heart failure prevention benefit or a GLP-1 RA with heart failure prevention benefit is recommended to reduce the risk of hospitalization for heart failure.
- In adults with type 2 diabetes, obesity, and symptomatic heart failure with preserved ejection fraction (HFpEF), the treatment plan should include a dual GIP/GLP-1 RA or a GLP-1 RA with demonstrated benefit for reduction in heart failure events.
- In individuals with diabetes and symptomatic stage C heart failure with ejection fraction >40%, a nonsteroidal MRA with proven benefit in reducing worsening heart failure events is recommended. A nonsteroidal MRA should not be used with an MRA.



1. SGLT2i parameters: if eGFR ≥ 20 mL/min/1.73 m²
2. SGLT1/2i can be used as an alternative to SGLT2i if eGFR ≥ 30 mL/min/1.73 m²
3. If UACR ≥ 30mg/g, K+<5.0 mEq/L (< 5.0 mmol/L)
4. The absolute benefit of SGLT2i and GLP-1RA in preventing symptomatic HF will be greatest among those at the highest absolute risk.
5. If eGFR ≥30 mL/min/1.73 m², K+<5.0 mEq/L (< 5.0 mmol/L)
6. If eGFR ≥25 mL/min/1.73 m², K+<5.0 mEq/L (< 5.0 mmol/L)

Figure 10.5—Overview of recommendations for the prevention and treatment of symptomatic heart failure in people with diabetes. ACEi, ACE inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; BNP, B-type natriuretic peptide; NT-proBNP, N-terminal pro-B–type natriuretic peptide; CKD, chronic kidney disease; CVD, cardiovascular disease; EF, ejection fraction; eGFR, estimated glomerular filtration rate; GDMT, guideline-directed medical therapy; GIP/GLP-1 RA, glucose-dependent insulinotropic polypeptide and glucagon-like peptide-1 receptor agonist; GLP-1 RA, glucagon-like peptide-1 receptor agonist; HF, heart failure; HFmrEF, heart failure with mildly reduced ejection fraction; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; HTN, hypertension; MI, myocardial infarction; MRA, mineralocorticoid receptor antagonist; nsMRA, nonsteroidal mineralocorticoid receptor antagonist; SGLT1/2i, sodium–glucose cotransporter 1 and 2 inhibitor; SGLT2i, sodium–glucose cotransporter 2 inhibitor; TTE, transthoracic echocardiography; UACR, urine albumin-to-creatinine ratio.



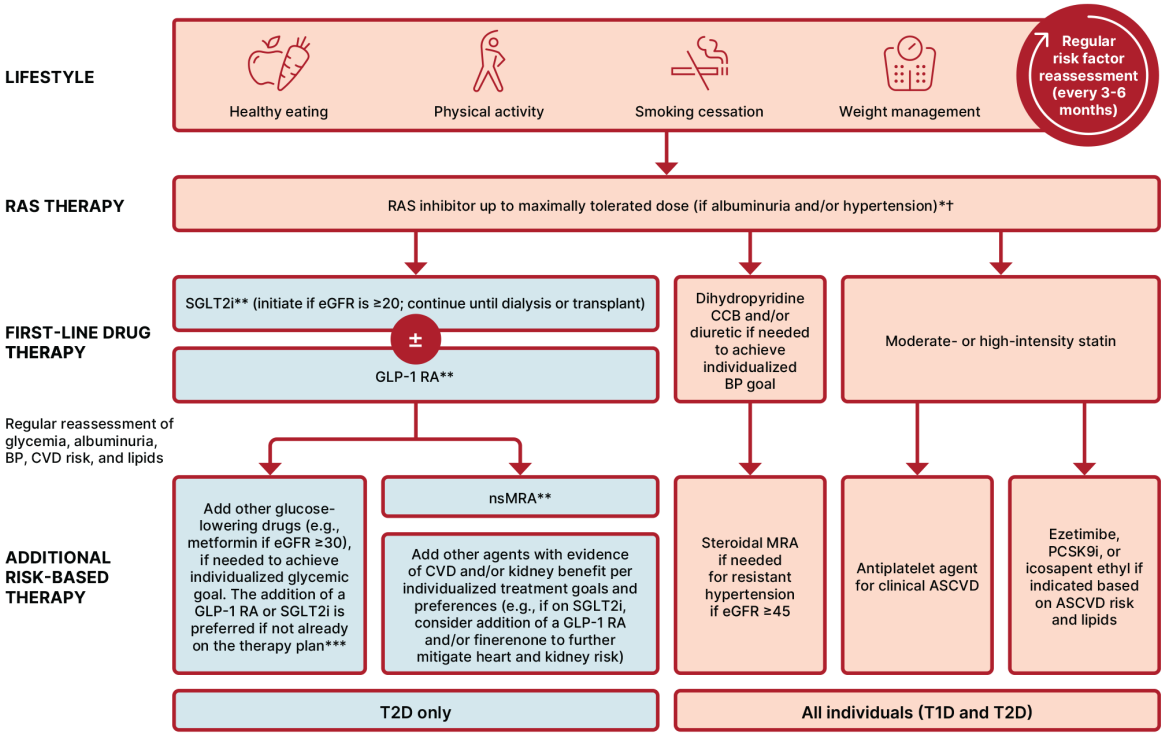
1. ASCVD is defined as a history of an acute coronary syndrome or myocardial infarction, angina, coronary heart disease with or without revascularization, other arterial revascularization, stroke, or peripheral artery disease assumed to be atherosclerotic in origin.
2. Non-statins with demonstrated benefit should be considered in those with statin intolerance.
3. Consider low-dose rivaroxaban in people with atherosclerotic disease in at least two vascular beds, or in one bed and are older than 65 years, who do NOT have an increased risk of bleeding, recent (<1 year) stroke, renal failure, LVEF <30%, or need for dual antiplatelet therapy or systemic anticoagulation.
4. Individuals at high risk for ASCVD include those with end-organ damage such as left ventricular hypertrophy or retinopathy or with multiple CV risk factors (e.g., older age, hypertension, smoking, dyslipidemia, CKD, and obesity).

Figure 10.6—Approach to prevent ASCVD in people with type 2 diabetes. ASCVD, atherosclerotic cardiovascular disease; BP, blood pressure; CKD, chronic kidney disease; CV, cardiovascular; GLP-1 RA, glucagon-like peptide 1 receptor agonist; LVEF, left ventricle ejection fraction; SGLT2i, sodium–glucose cotransporter 2 inhibitor.

11. Chronic Kidney Disease and Risk Management

- To reduce CKD progression and cardiovascular events in people with CKD and albuminuria, a nonsteroidal MRA that has been shown to be effective in clinical trials is recommended (if eGFR is ≥25 mL/min/1.73 m2). Potassium levels should be monitored one month after initiation.
- Simultaneous initiation of an SGLT2 inhibitor and a nonsteroidal MRA (finerenone) can be considered in adults with type 2 diabetes and UACR ≥100 mg/g with eGFR 30–90 mL/min/1.73 m2 on a reninangiotensin system inhibitor due to evidence of safety and beneficial effects on albuminuria.
- Kidney-protective medications that are potentially harmful in pregnancy should be avoided in sexually active individuals of childbearing potential who are not using reliable contraception and, if used, should be switched prior to conception to kidney-protective medications considered safer during pregnancy.
- Individuals with eGFR <20 mL/min/1.73 m2 and not on dialysis can be safely continued on SGLT2 inhibitors to reduce the risk of CKD progression and for cardiovascular benefits.

- Individuals on dialysis can be safely initiated or continued on GLP1–based therapy that is not dependent on kidney clearance to reduce cardiovascular risk and mortality.



*The majority of participants in SGLT2i, GLP-1 RA and nsMRA kidney outcome trials were receiving background optimized RAS inhibitor therapy.
**With demonstrated benefit in this population
***Glucose-lowering efficacy of GLP-1 RAs is preserved at low eGFR; glucose-lowering efficacy of SGLT2i is diminished at lower eGFR.

Figure 11.2—Holistic approach for improving outcomes in people with diabetes and CKD. Icons presented indicate the following benefits: BP cuff, BP lowering; glucose meter, glucose lowering; heart, cardioprotection; kidney, kidney protection; scale, weight management. eGFR is presented in units of mL/min/1.73 m^2. †ACEi or ARB (at maximal tolerated doses) should be first-line therapy for hypertension when albuminuria is present. Otherwise, dihydropyridine calcium channel blocker or diuretic can also be considered; all three classes are often needed to attain BP targets. †Finerenone is currently the only nsMRA with proven clinical kidney and cardiovascular benefits. ACEi, angiotensin-converting enzyme inhibitor; ACR, albumin-to-creatinine ratio; ARB, angiotensin receptor blocker; ASCVD, atherosclerotic cardiovascular disease; BP, blood pressure; CCB, calcium channel blocker; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide 1 receptor agonist; HTN, hypertension; MRA, mineralocorticoid receptor antagonist; nsMRA, nonsteroidal mineralocorticoid receptor antagonist; PCSK9i, proprotein convertase subtilisin/kexin type 9 inhibitor; RAS, renin-angiotensin system; SGLT2i, sodium–glucose cotransporter 2 inhibitor; T1D, type 1 diabetes; T2D, type 2 diabetes.

12. Retinopathy, Neuropathy and Foot Care

- Implement strategies to help people with diabetes reach blood pressure and lipid goals to reduce the risk or slow the progression of diabetic retinopathy.
- Gabapentinoids, serotonin norepinephrine reuptake inhibitors, tricyclic antidepressants, and sodium channel blockers are recommended as initial pharmacologic treatments for neuropathic pain in diabetes. Combinations of these medications can provide additional relief of neuropathic pain. Opioids, including tramadol and tapentadol, should not be used for neuropathic pain treatment in diabetes given the potential for adverse events except in rare circumstances.

13. Older Adults

- Recommend continuous glucose monitoring (CGM) for older adults with type 1 diabetes and type 2 diabetes on insulin therapy to improve glycemic outcomes, reduce hypoglycemia, and reduce treatment burden.
- The on-treatment blood pressure goal for most older adults with diabetes is <130/80 mmHg when it can be achieved safely, A and more a relaxed blood pressure goal (e.g., <140/90 mmHg) may be used for people with poor health, limited life expectancy, or high risk for adverse effects of hypertensive therapy.

- Recommend healthful eating with adequate protein intake (at least 0.8 g/kg body weight/day) for older adults with diabetes to maintain and potentially higher, individualized amounts to regain lean body mass and function.
- Recommend healthful eating with adequate protein intake (at least 0.8 g/kg body weight/day) for older adults with diabetes to maintain and potentially higher, individualized amounts to regain lean body mass and function.

14. Children and Adolescents

- Provide individualized medical nutrition therapy for children and adolescents with prediabetes or diabetes, emphasizing key nutrition principles (i.e., more non-starchy vegetables, whole fruits, legumes, whole grains, nuts and seeds, and low-fat dairy products and less sugar-sweetened beverages, sweets, meat, refined grains, and processed or ultra processed foods), B as an essential component of the overall treatment plan.
- Monitor carbohydrate intake, whether by carbohydrate counting or experience-based estimation, as a key component to optimizing glycemic and weight management for children and adolescents with diabetes.
- Diabetes care teams should implement transition preparation programs beginning in early adolescence and, at the latest, at least one year before the anticipated transfer from pediatric to adult health care.

15. Management of Diabetes in Pregnancy

- Recommend CGM to pregnant individuals with type 1 diabetes. In conjunction with aims to achieve traditional pre- and postprandial glycemic goals, CGM can reduce the risk for large-for-gestational-age infants and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes.
- In pregnant individuals with diabetes and chronic hypertension, a blood pressure threshold <140/90 mmHg is recommended for initiation and titration of therapy for better pregnancy outcomes.
- In most circumstances, lipid lowering medications should be stopped prior to conception and avoided in sexually active individuals of childbearing potential with diabetes who are not using reliable contraception. In some circumstances (familial hypercholesterolemia, severe hypertriglyceridemia, prior atherosclerotic cardiovascular disease event), lipid lowering therapy may be continued when the benefits outweigh risks.

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
JASCAYD	NERANDOMILAST	Indicated for the treatment of idiopathic pulmonary fibrosis in adult patients.	Oct. 7, 2025
LYNKUET	ELINZANETANT	Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause	Oct. 10, 2025
BLENREP	BELANTAMAB MAFODOTIN-BLMF	Indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent.	Oct. 27, 2025
AVTOZMA	TOCILIZUMAB-ANOH	Indicated for treatment of: **Rheumatoid Arthritis (RA)** • Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs). Giant Cell Arteritis (GCA). • Adult patients with giant cell arteritis. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** • Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. **Systemic Juvenile Idiopathic Arthritis (SJIA).** • Patients 2 years of age and older with active systemic juvenile idiopathic arthritis. **Cytokine Release Syndrome (CRS).** • Adults and pediatric patients 2 years of age and older with chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome.	

Brand Name	Generic Name	Indication	Date Available
		Coronavirus Disease 2019 (COVID-19). • Hospitalized adult patients with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).	
HYRNUO	SEVABERTINIB	Indicated for the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. This indication is approved under accelerated approval based on objective 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.	Nov. 19, 2025
VOYXACT	SIBEPRENLIMAB-SZSI	Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether VOYXACT slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.	Nov. 25, 2025
RYBREVANT FASPRO	AMIVANTAMAB AND HYALURONIDASE-LPUJ	Indicated for treating advanced metastatic non-small cell lung cancer (NSCLC) with specific Epidermal Growth Factor Receptor (EGFR) gene mutations, used alone or with other drugs like lazertinib or chemotherapy, depending on the mutation type (exon 19 deletions, exon 21 L858R, or exon 20 insertions) and prior treatments, targeting cancers that have spread or can't be removed surgically.	Dec. 18, 2025

Brand Name	Generic Name	Indication	Date Available
EXDENSUR	DEPEMOKIMAB-ULAA	Indicated for add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older. **Limitations of Use:** Not for relief of acute bronchospasm or status asthmaticus.	Dec. 19, 2025
ENOBY	DENOSUMAB-QBDE	Indicated for treatment: of postmenopausal women with osteoporosis at high risk for fracture to increase bone mass in men with osteoporosis at high risk for fracture of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.	Jan. 7, 2026
XTRENBO	DENOSUMAB-QBDE	Indicated for treatment: of postmenopausal women with osteoporosis at high risk for fracture to increase bone mass in men with osteoporosis at high risk for fracture of glucocorticoid-induced osteoporosis in men and women at high risk for fracture. to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.	Jan. 7, 2026
KYGEVVI	DOXECITINE; DOXRIBTIMINE	Indicated for the treatment of thymidine kinase 2 deficiency (TK2d) in adults and pediatric patients with an age of symptom onset on or before 12 years.	Jan. 12, 2026
REDEMPLO	PLOZASIRAN	Indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).	Jan. 12, 2026
MYQORZO	AFICAMTEN	Indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (OHCM) to improve functional capacity and symptoms.	Jan. 12, 2026

Brand Name	Generic Name	Indication	Date Available
ZYCUBO	COPPER HISTIDINATE	Indicated for the treatment of Menkes disease in pediatric patients. **Limitations of Use:** ZYCUBO is not indicated for the treatment of Occipital Horn Syndrome.	Jan. 30, 2026
YARTEMLEA	NARSOPLIMAB	Indicated for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).	Feb. 3, 2026

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
Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications	FDA Requests Removal of Suicidal Behavior and Ideation Warning from Glucagon-Like Peptide-1 Receptor Agonist (GLP-1 RA) Medications FDA is requesting that drug application holders remove information regarding the risk of suicidal ideation and behavior (SI/B) from the labeling of glucagon-like peptide-1 receptor agonist (GLP-1 RA) medications that currently include such language. The affected products are Saxenda (liraglutide), Wegovy (semaglutide), and Zepbound (tirzepatide). This action follows a comprehensive FDA review that found no increased risk of SI/B associated with the use of GLP-1 RA medications. Saxenda, Wegovy, and Zepbound are each approved for weight reduction in people with obesity or overweight. At the time of the original FDA approvals, the labeling for each of these products included information in the Warnings and Precautions section about the potential risk of SI/B. Similar information about SI/B is also included in the labeling of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or studied for weight loss. Labeling for GLP-1 RA medications that are approved to improve glycemic (blood sugar) control or other complications in patients with type 2 diabetes mellitus does not currently include information on the risk of SI/B. This FDA action will ensure consistent messaging across the labeling for all FDA-approved GLP-1 RA medications. FDA found no increased risk of SI/B with the use of GLP-1 RA medications and is requesting the removal of this Warning and Precaution from the prescribing information for the GLP-1 RA medications (Saxenda, Wegovy, and Zepbound) that include such language. Health care professionals should be prepared to discuss with patients that FDA has found no increased risk after conducting a comprehensive review of the available data.

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
CAPLYTA (lumateperone tosylate)	Contraindications	CAPLYTA is contraindicated in patients with history of hypersensitivity reaction to lumateperone or any components of CAPYLTA. Reactions have included pruritus, rash (e.g. allergic dermatitis, papular rash, and generalized rash), and urticaria.
COMETRIQ (cabozantinib s-malate)	Warnings and Precautions	COMETRIQ can cause severe and fatal cardiac failure. Cardiac failure occurred in 0.9% of patients treated with COMETRIQ as a single agent. Median time to onset of cardiac failure was 76 days. Consider baseline and periodic evaluations of left ventricular ejection fraction. Monitor for signs and symptoms of cardiovascular events. Withhold and resume at a reduced dose upon recovery or permanently discontinue COMETRIQ depending on the severity.
EPKINLY (epcoritamab-bysp)	Boxed Warning	CYTOKINE RELEASE SYNDROME AND IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME Cytokine release syndrome (CRS), including serious or fatal reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.
FLOWTUSS (guaifenesin-hydrocodone bitartrate)	Boxed Warning	Neonatal Opioid Withdrawal Syndrome FLOWTUSS is not recommended for use in pregnant women *[see Use in Specific Populations (8.1)]*. Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.
GAVRETO (pralsetinib)	Boxed Warning	WARNING: SERIOUS INFECTIONS, INCLUDING OPPORTUNISTIC INFECTIONS GAVRETO may increase the risk for serious infections, including bacterial, fungal, viral and opportunistic infections, which can lead to hospitalization or death. Withhold, reduce the dose or permanently discontinue GAVRETO based on severity.
HYCOFENIX (guaifenesin-hydrocodone bitartrate-pseudoephedrine hcl)	Boxed Warning	Neonatal Opioid Withdrawal Syndrome HYCOFENIX is not recommended for use in pregnant women. Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Drug	Type of Change	Change
IMDELLTRA (tarlatamab-dlle)	Contraindications	WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving IMDELLTRA. Initiate IMDELLTRA using the step- up dosing schedule to reduce the incidence and severity of CRS. Withhold IMDELLTRA until CRS resolves or permanently discontinue based on severity. Neurologic toxicity and immune effector cell-associated neurotoxicity syndrome (ICANS), including life-threatening or fatal reactions, can occur in patients receiving IMDELLTRA. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment and treat promptly. Withhold IMDELLTRA until ICANS resolves or permanently discontinue based on severity.
NEXPLANON (etonogestrel)	Boxed Warning	WARNING: RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION and REMOVAL • Improper insertion of NEXPLANON increases the risk of complications. • Proper training prior to first use of NEXPLANON can minimize the risk of improper NEXPLANON insertion. Because of the risk of complications due to improper insertion and removal NEXPLANON is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the NEXPLANON REMS.
OBREDON (guaifenesin-hydrocodone bitartrate)	Boxed Warning	Neonatal Opioid Withdrawal Syndrome OBREDON is not recommended for use in pregnant women. Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery
PHENERGAN VC W/CODEINE (codeine phosphate; phenylephrine hcl; promethazine hcl)	Boxed Warning	Neonatal Opioid Withdrawal Syndrome Promethazine HCl, Phenylephrine HCl and Codeine Phosphate Oral Solution is not recommended for use in pregnant women. Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery
PHENERGAN W/CODEINE (codeine phosphate; promethazine hcl)	Boxed Warning	Neonatal Opioid Withdrawal Syndrome Promethazine HCl and Codeine Phosphate Oral Solution is not recommended for use in pregnant women. Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery
QOLIANA (brimonidine tartrate)	Contraindications	4.1 Neonates and Infants (Pediatric Patients Younger than 2 Years Old) Brimonidine tartrate ophthalmic solution, 0.15 percent is contraindicated in neonates and infants (pediatric patients younger than 2 years old).

Drug	Type of Change	Change
ZOVIRAX (acyclovir)	Contraindications	ZOVIRAX is contraindicated in patients who have had a demonstrated clinically significant hypersensitivity reaction [e.g., anaphylaxis, severe cutaneous adverse reactions (SCARs)] to acyclovir, valacyclovir, or any component of the formulation.
VALTREX (valacyclovir hydrochloride)	Contraindications	VALTREX is contraindicated in patients who have had a demonstrated clinically significant hypersensitivity reaction [e.g., anaphylaxis, severe cutaneous adverse reactions (SCARs)] to valacyclovir, acyclovir, or any component of the formulation
RIFADIN (rifampin)	Contraindications	Rifampin is contraindicated in patients who are also receiving atazanavir, darunavir, fosamprenavir, saquinavir, tipranavir, cabotegravir, fostemsavir and lenacapavir (see prescribing information for SUNLENCA) due to the potential of rifampin to substantially decrease plasma concentrations of these antiviral drugs, which may result in decreased antiviral efficacy and/or development of viral resistance.
TUZISTRA XR	Boxed Warning	Neonatal Opioid Withdrawal Syndrome TUZISTRA XR is not recommended for use in pregnant women. Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.
XTRELUS (guaifenesin; hydrocodone bitartrate)	Boxed Warning	Neonatal Opioid Withdrawal Syndrome Xtrelus is not recommended for use in pregnant women. Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.
METHADONE HYDROCHLORIDE (methadone hcl) METHADOSE (methadone hcl)	Boxed Warning	Managing Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants Concomitant use with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, is a risk factor for respiratory depression and death. • Reserve concomitant prescribing of benzodiazepines or other CNS depressants in patients in methadone treatment to those for whom alternatives to benzodiazepines or other CNS depressants are inadequate. Follow patients for signs and symptoms of respiratory depression and sedation. If the patient is visibly sedated, evaluate the cause of sedation and consider delaying or omitting daily methadone dosing.

Drug	Type of Change	Change
VFND (voriconazole)	Contraindications	• VFEND is contraindicated in patients with known hypersensitivity to voriconazole or its excipients. There is no information regarding cross-sensitivity between VFEND and other azole antifungal agents. Refer to the prescribing information for other azole antifungal agents. • Concomittant use of VFEND with the interacting drugs described and listed below in this section are a guide and not considered a comprehensive list of all possible drugs that may be contraindicated with VFEND. 1. Concomitant use of VFEND is contraindicated with drugs that are highly dependent on CYP3A4 for metabolism, and for which elevated plasma concentrations are associated with serious and/or life-threatening reactions: • Eplerenone • Voclosporin 2. Concomitant use of VFEND is contraindicated with drugs and herbal products that induce CYP2C19, CYP2C9, and/or CYP3A4 and for which significantly reduced voriconazole plasma concentrations may be associated with loss of efficacy: • Carbamazepine • Efavirenz Concomitant use with efavirenz dosages of 400 mg every 24 hours or higher is contraindicated. • Long-acting barbiturates • Rifabutin • Rifampin • Ritonavir Concomitant use with high-dose ritonavir (400 mg every 12 hours) is contraindicated. Concomitant use with low-dose ritonavir (100 mg every 12 hours) should be avoided, unless an assessment of the benefit/risk to the patient justifies the use of VFEND • St. John's Wort
AFREZZA (insulin recombinant human)	Contraindications	AFREZZA is contraindicated: • In patients with a previous severe hypersensitivity reaction to any regular human insulin product or any of the inactive ingredients in AFREZZA. Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with AFREZZA
XIMINO (minocycline hydrochloride)	Contraindications	XIMINO is contraindicated in patients with a history of a hypersensitivity reaction to any of the tetracyclines
BIJUVA (estradiol; progesterone)	Contraindications	BIJUVA is contraindicated in women with any of the following conditions: • Abnormal genital bleeding of unknown etiology

Drug	Type of Change	Change
CENESTIN (estrogens, conjugated synthetic a)	Boxed Warning Contraindications	WARNING: ENDOMETRIAL CANCER WITH UNOPPOSED ESTROGEN IN WOMEN WITH A UTERUS There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. Adding a progestogen to estrogen-only therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Perform adequate diagnostic measures, including directed or random endometrial sampling when indicated, to rule out malignancy in menopausal women with abnormal genital bleeding of unknown etiology Contraindications CENESTIN is contraindicated in women with any of the following conditions: • Abnormal genital bleeding of unknown etiology
CONCERTA (methylphenidate hydrochloride)	Contraindications	CONCERTA is contraindicated in patients: Known to be hypersensitive to methylphenidate or other components of CONCERTA. Hypersensitivity reactions, such as angioedema and anaphylactic reactions, have been reported in patients treated with CONCERTA. Receiving concomitant monoamine oxidase inhibitors (MAOIs), and within 14 days following discontinuation of treatment with a MAO inhibitor because of the risk of a hypertensive crisis
DIVIGEL (estradiol)	Contraindications	Divigel is contraindicated in women with any of the following conditions: Abnormal genital bleeding of unknown etiology
ESTRING (estradiol)	Contraindications	ESTRING is contraindicated in women with any of the following conditions: 1. Abnormal genital bleeding with unknown etiology.
GIMOTI (metoclopramide hydrochloride)	Boxed Warning	WARNING: TARDIVE DYSKINESIA • Metoclopramide, including GIMOTI, can cause tardive dyskinesia (TD), a potentially irreversible serious movement disorder. In patients treated with metoclopramide, including GIMOTI, the risk of developing TD increases with duration of treatment and total cumulative. • GIMOTI is contraindicated in patients with a history of TD. • Use GIMOTI for the shortest duration of treatment and periodically reassess the need for continued treatment. • Immediately discontinue GIMOTI in patients who develop signs or symptoms of TD. • Avoid a total duration of treatment with metoclopramide products, including GIMOTI, for longer than 12 weeks. If longer-term use is unavoidable, routinely monitor for signs and symptoms of TD.

Drug	Type of Change	Change
PROMETRIUM (progesterone)	Contraindications	PROMETRIUM is contraindicated in women with any of the following conditions: Hypersensitivity to its ingredients. PROMETRIUM Capsules contain peanut oil and is contraindicated in patients allergic to peanuts. Abnormal genital bleeding of unknown etiology.
REGLAN (metoclopramide hydrochloride)	Boxed Warning	WARNING: TARDIVE DYSKINESIA • Metoclopramide, including Reglan, can cause tardive dyskinesia (TD), a potentially irreversible serious movement disorder. In patients treated with metoclopramide, including Reglan, the risk of developing TD increases with duration of treatment and total cumulative dosage. • Reglan is contraindicated in patients with a history of TD. • Use Reglan for the shortest duration of treatment and periodically reassess the need for continued treatment. • Immediately discontinue Reglan in patients who develop signs or symptoms of TD. • In patients with symptomatic, documented gastroesophageal reflux, the maximum duration of Reglan treatment is 12 weeks. • In patients with diabetic gastroparesis, avoid a total duration of treatment with metoclopramide products, including Reglan tablets, for longer than 12 weeks. If longer term use is unavoidable, routinely monitor for signs and symptoms of TD.

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
Isocarboxazid Tablets	• Lifsa Pharma	**Products Affected** • Marplan oral tablet, Lifsa Pharma, 10 mg, bottle, 100 count, NDC 30698-0032-01 **Reason for the Shortage:** • Lifsa Pharma is now manufacturing Marplan. The company estimates that product will be available in the first quarter of 2026. **Available Products:** • There are no presentations available **Estimated Resupply Dates** • Lifsa Pharma estimates Marplan 10 mg tablets will be available in the first quarter of 2026.
Azithromycin Injection	• Pfizer • Eugia • Fresenius Kabi • Sagent • Slate Run Pharmacuticals • Sun Pharma	**Products Affected:** • Zithromax intravenous lyophilized powder for injection, Pfizer, 500 mg, vial, 10 count, NDC 00069-3150-83 - discontinued • Azithromycin intravenous lyophilized powder for injection, Eugia US, 500 mg, vial, 10 count, NDC 55150-0174-10 • Azithromycin intravenous lyophilized powder for injection, Fresenius Kabi, 500 mg, vial, 10 count, NDC 63323-0398-10 • Azithromycin intravenous lyophilized powder for injection, Sagent, 500 mg, vial, 10 count, NDC 25021-0180-10 • Azithromycin intravenous lyophilized powder for injection, Slate Run Pharmaceuticals, 500 mg, vial, 10 count, NDC 70436-0019-82 • Azithromycin intravenous lyophilized powder for injection, Sun Pharma, 500 mg, vial, 10 count, NDC 62756-0512-44

Drug Product	Affected Manufacturers	Summary
		Reason for the Shortage: • Eugia did not provide a reason for the shortage. • Fresenius Kabi did not provide a reason for the shortage. • Sagent did not provide a reason for the shortage. • Slate Run Pharma has azithromycin on allocation due to increased demand. • Sun Pharma has azithromycin on shortage due to manufacturing delays from lack of active ingredient. • Pfizer discontinued Zithromax in January 2026. **Available Products:** • There is insufficient supply for usual ordering **Estimated Resupply Dates:** • Eugia has azithromycin 500 mg vials on intermittent back order and the company is releasing product as it becomes available. • Fresenius Kabi has azithromycin 500 mg vials on back order and the company estimates a release date of late-January 2026. • Sagent has azithromycin 500 mg vials on back order and the company estimates a release date of June 2026. • Slate Run Pharma has azithromycin 500 mg vials on allocation. • Sun Pharma has azithromycin 500 mg vials available in limited supply.
Moxifloxacin Injection	• Fresenius Kabi • Mylan Institutional (Viatris)	**Products Affected:** • Moxifloxacin injection, Fresenius Kabi, 400 mg/250 mL, premixed bag, 12 count, NDC 63323-0850-74 - discontinued • Moxifloxacin injection, Mylan Institutional (Viatris), 400 mg/250 mL, premixed bag, 12 count, NDC 67457-0323-25 **Reason for the Shortage:** • Fresenius Kabi recently discontinued moxifloxacin injection. • Viatris did not provide a reason for the shortage. They are sole suppliers of moxifloxacin injection. **Available Products:** • There are no presentations available **Estimated Resupply Dates:** • Viatris has moxifloxacin 400 mg/250 mL premixed bags on back order and the company estimates a release date of late-November 2026.

Drug Product	Affected Manufacturers	Summary
Conjugated Estrogens Injection	• Pfizer	**Products Affected:** • Premarin lyophilized powder for injection, Pfizer, 25 mg vial, 1 count, NDC 00046-0749-05 **Reason for the Shortage:** • Pfizer has Premarin injections on shortage due to manufacturing delays. **Available Products:** • There are no presentations available **Estimated Resupply Dates:** • Pfizer has Premarin 25 mg vials on back order and the company estimates a release date of April 2026.
Lanreotide Acetate Injection	• Ipsen • Exelan	**Products Affected:** • Somatuline Depot subcutaneous injection, Ipsen Biopharmaceuticals, 120 mg/0.5 mL, prefilled syringe, NDC 15054-1120-04 • Lanreotide acetate subcutaneous injection, Exelan Pharmaceuticals, 120 mg/0.5 mL, prefilled syringe, NDC 76282-0720-67 **Reason for the Shortage:** • Cipla was not available to provide updated information. • Exelan did not provide a reason for the shortage. • Ipsen Biopharmaceuticals did not provide a reason for the shortage of Somatuline Depot. **Available Products:** • Somatuline Depot subcutaneous injection, Ipsen Biopharmaceuticals, 60 mg/0.2 mL, prefilled syringe, NDC 15054-1060-04 • Somatuline Depot subcutaneous injection, Ipsen Biopharmaceuticals, 90 mg/0.3 mL, prefilled syringe, NDC 15054-1090-04 **Estimated Resupply Dates:** • Exelan has lanreotide 120 mg/0.5 mL prefilled syringes on back order and the company cannot estimate a release date. • Ipsen has Somatuline Depot 120 mg/0.5 mL prefilled syringes on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Colchicine Oral Liquid	Gloperba	**Products Affected:** • Gloperba oral liquid, Scilex Pharmaceuticals, 0.6 mg/5 mL, 150 mL bottle, NDC 69557-0222-0 **Reason for the Shortage:** • Scilex did not provide a reason for the shortage. They are the sole supplier of colchicine oral liquid. **Available Products:** • There are no presentations available. **Estimated Resupply Dates:** • Scilex pharmaceuticals has Gloperba 0.6 mg/5 mL liquid in 150 mL bottles on backorder and the company cannot estimate a resupply date.
Disopyramide Phosphate Controlled-Release Capsules	Pfizer	**Products Affected:** • Norpace CR oral extended release capsule, Pfizer, 100 mg, bottle, 100 count, NDC 00025-2732-31 • Norpace CR oral extended release capsule, Pfizer, 150 mg, bottle, 100 count, NDC 00025-2742-31 **Reason for the Shortage:** • Pfizer has Norpace CR on shortage due to manufacturing delays. They are sole suppliers. • Norpace IR is available. **Available Products:** • There are no presentations available. **Estimated Resupply Dates:** • Pfizer has Norpace CR 100 mg and 150 mg capsules on back order with an estimated release date of May 2026.
Mesalamine Extended-Release Capsules	Sun Pharma	**Products Affected:** • Mesalamine oral capsule, Sun Pharma, 500 mg, bottle, 120 count, NDC 63304-0089-13 **Reason for the Shortage:** • Sun Pharma did not provide a reason for the shortage. **Available Products:** • Pentasa oral capsule, Takeda, 250 mg, bottle, 240 count, NDC 54092-0189-81 • Pentasa oral capsule, Takeda, 500 mg, bottle, 120 count, NDC 54092-0191-12 **Estimated Resupply Dates:** • Sun Pharma has mesalamine extended-release 500 mg capsules in 120 count bottles on back order and the company cannot estimate a resupply date.

Drug Product	Affected Manufacturers	Summary
Penicillin G Benzathine	Pfizer	**Products Affected:** • Bicillin L-A intramuscular suspension for injection, Pfizer, 1,200,000 units, 2 mL syringe, 10 count, NDC 60793-0701-10 • Bicillin L-A intramuscular suspension for injection, Pfizer, 2,400,000 units, 4 mL syringe, 10 count, NDC 60793-0702-10 • Bicillin L-A intramuscular suspension for injection, Pfizer, 600,000 units, 1 mL syringe, 10 count, NDC 60793-0700-10 **Reason for the Shortage:** • Pfizer has Bicillin-LA on shortage due to increased demand. Pfizer is allocating resources towards manufacturing adult Bicillin-LA presentations due to increased syphilis infection rates. Once current supplies of the pediatric Bicillin-LA vials are depleted it is unclear when more product will be manufactured. A Dear Healthcare Professional Letter can be found at: https://www.fda.gov/media/169427/download. **Available Products:** • Lentocilin intramuscular powder for solution for injection, Mark Cuban Cost Plus Drug Company (MCCPDC), 1,200,000 units, 1,200,000 unit vial of powder/4 mL 1.5 percent lidocaine for injection in ampules vial, 1 count, NDC 84383-0110-01. **Estimated Resupply Dates:** • Pfizer has Bicillin-LA 1,200,000 unit syringes and 2,400,000 unit syringes intermittent back order with weekly releases. The 600,000 unit syringes are on back order and the company estimates a release date of December 2026. Pfizer continues to offer emergency supply via the Medical Request Process for patients with the highest medical necessity.
Peginterferon Alfa-2a	??	**Products Affected:** • Pegasys subcutaneous solution for injection, Summit SD, 180 mcg/0.5 mL, 0.5 mL prefilled syringe, 4 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 - discontinued **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. To streamline operations and simplify the production process, Pharma& is only manufacturing the prefilled syringes. The company is no longer manufacturing the vial formulation.

Drug Product	Affected Manufacturers	Summary
		Available Products: • There is insufficient supply for usual ordering **Estimated Resupply Dates:** • Pharma& states the most recent batch of Pegasys 180 mcg/0.5 mL prefilled syringes has cleared regulatory approval and the company estimates a release date of mid- to late-February 2026. Pharma& estimates this batch will last through mid-2026. **Alternative Agents & Management:** • Ropeginterferon alfa-2b-njft (Besremi) is a preferred alternative in patients with both low-risk (symptomatic) and high-risk polycythemia vera (PV) in the NCCN Clinical Practice Guidelines in Oncology. This information can be found at https://www.besremihcp.com/.
Fluocinolone Acetonide Intravitreal Implant	Ani Pharmaceuticals	**Products Affected:** • Yutiq intravitreal implant, Ani Pharmaceuticals, 0.18 mg prefilled syringe, 1 count, NDC 68611-0180-01. **Reason for the Shortage:** • Ani Pharmaceuticals did not provide a reason for the shortage. **Available Products:** • Iluvien intravitreal implant, Ani Pharmaceuticals, 0.19 mg prefilled syringe, 1 count, NDC 68611-0190-02. **Estimated Resupply Dates:** • Ani Pharmaceuticals has Yutiq 0.18 mg intravitreal implant on long term back order and the company cannot estimate a resupply date. **Implications for Patient Care:** • Fluocinolone acetonide intravitreal implant is used for patients with chronic non-infectious uveitis affecting the posterior segment of the eye. • Iluvien is also used for specific patients with diabetic macular edema. **Alternative Agents & Management:** • Both Yutiq 0.18 mg and Iluvien 0.19 mg deliver fluocinolone acetonide at an initial rate of 0.25 mcg/day for 36 months. • Bausch Health has Retisert 0.59 mg available, which delivers fluocinolone acetonide at an initial rate of 0.6 mcg/day in the first month and a steady-state rate of 0.3-0.4 mcg/day for 30 months. • Retisert is surgically implanted into the posterior segment of the eye via an incision, while Iluvien and Yutiq are injected into the vitreous cavity.

Drug Product	Affected Manufacturers	Summary
Ibandronate Sodium Intravenous Solution	Apotex Eugia	**Products Affected:** • Ibandronate sodium intravenous solution for injection, Apotex, 1 mg/mL, 3 mL prefilled syringe, NDC 60505-6097-00 • Ibandronate sodium intravenous solution for injection, Eugia US, 1 mg/mL, 3 mL prefilled syringe, NDC 55150-0191-83 **Reason for the Shortage:** • Apotex did not provide a reason for the shortage. • Eugia did not provide a reason for the shortage. **Available Products:** • There is insufficient supply for usual ordering **Estimated Resupply Dates:** • Apotex has ibandronate 1 mg/mL 3 mL prefilled syringes on back order and the company estimates a release date of late-February 2026. • Eugia has ibandronate 1 mg/mL 3 mL prefilled syringes on intermittent back order and the company is releasing supplies as they become available.
Mercaptopurine Tablets	Hikma Mylan (Viatris) Quinn Pharmaceuticals	**Products Affected:** • 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:** • There is insufficient supply for usual ordering **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
Chlorothiazide Oral Suspension	Bausch Health	**Products Affected:** • Diuril oral suspension, Bausch Health, 250 mg / 5 mL 237 mL bottle, NDC 65649-0311-12 **Reason for the Shortage:** • Bausch Health did not provide a reason for the shortage. **Available Products:** • There are no products available. **Estimated Resupply Dates:** • Bausch Health has Diuril oral suspension in 237 mL bottle on back order and the company cannot estimate a release date.

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
Nov. 7, 2025	Famotidine Injection, USP 20 mg per 2 mL	Out-of-specification endotoxin results	Fresenius Kabi USA, LLC	63323-739-11 63323-739-12 Lot 6133156 EXP Aug. 2026 Lot 6133194 EXP Aug. 2026 Lot 6133388 EXP Oct. 2026

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