Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

Q1 2025

MARCH 2025

www.goldcoasthealthplan.org

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

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

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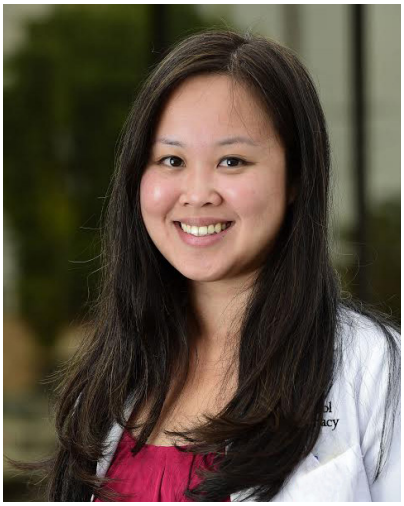
A Message from the Gold Coast Health Plan Director of Pharmacy Services



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

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

Our goal is to equip providers with the information necessary to safely prescribe medications and to ensure members have access to all necessary pharmaceutical services through Medi-Cal Rx. We are available to help all 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., APh, CDCES, BCACP
Director of Pharmacy Services

Medi-Cal Rx Updates

Pediatric Integration of Members 21 Years of Age and Younger

Medi-Cal Rx reinstated claim edits and prior authorization (PA) requirements for members 21 years of age and younger on Jan. 31, 2025, for new start drugs / products. Continuation of therapy claims will be implemented on April 25, 2025. 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 on claim and PA request requirements, refer to the Medi-Cal Rx Provider Manual. For more information on reinstatement of Pediatric Integration, go to the Education & Outreach page and select "Pediatric Integration."

California Children's Services Paneled Providers

On Jan. 31, 2025, Medi-Cal Rx implemented the California Children's Services (CCS) Panel Authority policy for CCS Paneled Providers who are physicians or certified nurse practitioners and enrolled in Medi-Cal. CCS Panel Authority enables CCS Paneled Providers to prescribe for members 20 years of age and younger without submitting a PA request for Medi-Cal Rx covered drugs / products, with some exceptions.

Maximum Quantity Limits for Enteral Nutrition Products

On Jan. 31, 2025, Medi-Cal Rx implemented a maximum quantity limit (QL) for contracted infant enteral nutrition products, including specialty infant formulas, based on a maximum daily caloric limit of up to 800 calories / day for a maximum of a 31-day supply.

Daily caloric requirements will be assessed during the PA request review. Maximum daily caloric limits based on feeding status, age, and product type are as follows:

- Up to 2,000 calories / day for members who are tube fed.
- Up to 1,200 calories / day for members who are orally fed and 22 years of age and older.
- Up to 1,000 calories / day for members who are orally fed and 21 years of age and younger.
- Up to 800 calories / day for members receiving infant formula.

Please use the updated enteral nutrition PA form, Medi-Cal Rx Enteral Nutrition Prior Authorization Request Form. For additional information, please refer to the Enteral Nutrition Products section in the Medi-Cal Rx Provider Manual.

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 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, email at MediCalRxEducationOutreach@magellanhealth.com. Agents are available 24 hours a day, seven days a week, 365 days a year.

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

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

Changes to the Contract Drugs List (CDL) 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
Somatropin (Nutropin AQ NuSpin)	End-dated.	Oct. 1, 2024
Adalimumab-fkjp	Added to CDL with diagnosis, quantity, and labeler restrictions.	Oct. 1, 2024
Atovaquone-Proguanil HCL	Added to CDL.	Oct. 1, 2024
Crotamiton	Labeler restriction removed.	Oct. 1, 2024
Glucagon (R-DNA Origin)	Labeler restriction removed.	Oct. 1, 2024
Imetelstat	Added to CDL with labeler restriction.	Oct. 1, 2024
Lazertinib	Added to CDL with labeler restriction.	Oct. 1, 2024
Mefloquine HCL	Added to CDL.	Oct. 1, 2024
Segesterone Acetate and Ethinyl Estradiol	Additional labeler code (68308) restriction added.	Oct. 1, 2024
Selpercatinib	Additional formulation (tablets) added to CDL with prior authorization required.	Oct. 1, 2024
Tislelizumab-jsgr	Added to CDL with labeler restriction.	Oct. 1, 2024
Tirzepatide (Zepbound)	Added to CDL with diagnosis, quantity, and labeler restrictions.	Oct. 1, 2024
Vaccines	Added new vaccines, updated / removed age restrictions.	Oct. 1, 2024
Vorasidenib	Added to CDL with prior authorization required.	Oct. 1, 2024
Valbenazine Tosylate	Added to CDL with age, diagnosis, and labeler restrictions.	Oct. 1, 2024
Apremilast	Additional strength (20 mg tablet) added to CDL with diagnosis and labeler restrictions.	Nov. 1, 2024

Drug Name	Description	Effective Date
Atezolizumab Hyaluronidase-tqjs	Added to CDL with labeler restriction.	Nov. 1, 2024
Desonide	Added to the CDL.	Nov. 1, 2024
Dexlansoprazole	Effective Dec. 1, 2024: End-dated.	Nov. 1, 2024
Imetelstat	Labeler restriction removed. Prior authorization requirement added.	Nov. 1, 2024
Isosorbide Mononitrate	Additional formulation (tablets) added to CDL.	Nov. 1, 2024
Glatiramer Acetate	Added to CDL with labeler restriction.	Nov. 1, 2024
Nebivolol	Added to the CDL.	Nov. 1, 2024
Paroxetine HCL	Additional formulation (controlled release tablets) added to CDL.	Nov. 1, 2024
Selpercatinib	Labeler restriction added and prior authorization requirement removed from tablets.	Nov. 1, 2024
Travoprost	Labeler restriction removed.	Nov. 1, 2024
Clobetasol Propionate	Additional package size (60 gm) added to the CDL for cream and ointment.	Dec. 1, 2024
Deutetrabenazine	PA requirement removed for Tardive Dyskinesia.	Dec. 1, 2024
Glucagon (synthetic)	Effective Jan. 1, 2025: Labeler restriction (LR) added.	Dec. 1, 2024
Roflumilast	Added to the CDL with quantity limit (QL) restriction.	Dec. 1, 2024
Brentuximab Vedotin	Added to CDL with LR.	Jan. 1, 2025
Ciprofloxacin HCL/Hydrocortisone	Additional LR (66758) added.	Jan. 1, 2025
Deutetrabenazine	Additional formulations (extended-release tablets and titration kit) added to CDL with restrictions.	Jan. 1, 2025
Diflunisal	Effective Feb. 1, 2025: End-dated.	Jan. 1, 2025
Enfortumab Vedotin-ejfv	Added to CDL with LR.	Jan. 1, 2025
Glucagon (synthetic)	Additional formulations (prefilled auto-injector, prefilled syringe, and single-dose vial kit) added to CDL with QL restriction.	Jan. 1, 2025
Inavolisib	Added to CDL with LR.	Jan. 1, 2025

Drug Name	Description	Effective Date
Polyethylene Glycol 3350/Sodium Sulfate/Potassium Chloride/ Magnesium Sulfate/Sodium Chloride	Added to CDL with LR.	Jan. 1, 2025
Pramipexole Dihydrochloride	Additional strengths (2.25 mg and 3.75 mg) added to the CDL for extended-release tablets.	Jan. 1, 2025
Repotrectinib	Additional strength (160 mg) added to the CDL with LR.	Jan. 1, 2025
Secnidazole	LR removed.	Jan. 1, 2025
Sodium Sulfate/Potassium Chloride/Magnesium Sulfate	Added to CDL with LR.	Jan. 1, 2025
Sotorasib	Additional strength (240 mg) added to the CDL with LR.	Jan. 1, 2025
Tisotumab Vedotin-tftv	PA requirement removed. LR added.	Jan. 1, 2025
Tucatinib	Added to CDL with LR.	Jan. 1, 2025
Zolbetuximab-clzb	Added to CDL with LR.	Jan. 1, 2025
Brinzolamide	Additional labeler restriction (LR) added.	Feb. 1, 2025
Imatinib Mesylate	Additional formulation (oral solution) added with LR.	Feb. 1, 2025
Revumenib	Added to the CDL with LR.	Feb. 1, 2025
Topotecan HCL	LR removed from capsules.	Feb. 1, 2025
Zanidatamab-hrii	Added with prior authorization (PA) restriction.	Feb. 1, 2025

Changes to the Medi-Cal Rx Contract Drugs List (CDL) Over- the-Counter Drugs and Cough / Cold Preparations Rx

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

Drug Name	Description	Effective Date
Cetirizine HCL	Age restriction removed.	Oct. 1, 2024
Fexofenadine	Age restriction removed.	Oct. 1, 2024
Levocetirizine Dihydrochloride	Age restriction removed.	Oct. 1, 2024
Loratadine	Age restriction removed.	Oct. 1, 2024

Changes to the List of Contracted Enteral Nutrition Products, Effective Jan. 1, 2025

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 Jan. 1, 2025.

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (Ndc)	Changes
Ajinomoto Cambrooke, Inc.	KetoVie 3:1 unflavored, 30 x 250 ml	24359050403	Removed from list effective Jan. 1, 2025.
Nutricia North America	GlutarAde GA-1 Amino Acid Blend, powder, unflavored, 454 g	00847075000	Removed from list effective Jan. 1, 2025.
Nutricia North America	PhenylAde Amino Acid Blend, powder, unflavored, 454 g	00847095000	Removed from list effective Jan. 1, 2025.
Nutricia North America	PhenylAde GMP Mix, powder, original unflavored, 16 x 33.3 g packets	49735014116	Removed from list effective Jan. 1, 2025.
Nutricia North America	PhenylAde GMP Mix, powder, vanilla, 16 x 33.3 g packets	49735018304	Removed from list effective Jan. 1, 2025.
Nutricia North America	PhenylAde MTE Amino Acid Blend, powder, unflavored, 30 x 12.8 g sachets	00847095964	Removed from list effective Jan. 1, 2025.
Nutricia North America	a TYR Lophex GMP Mix-In, unflavored, 20 x 12.5 g powder	49735015757	Removed from list effective Jan. 1, 2025.
Nestlé HealthCare Nutrition; 1-888-240-2713	COMPLEAT® Pediatric Peptide 1.0 Cal, Vegetable & Fruit Medley 24 x 250mL carton	43900037040	Added to list effective Jan. 1, 2025.
Nestlé HealthCare Nutrition; 1-888-240-2713	COMPLEAT® Peptide 1.0 Cal, Vegetable & Fruit Medley 24 x 250mL carton	43900047337	Added to list effective Jan. 1, 2025.
Nutricia North America; 1-800-365-7354	Neocate Syneo Junior, unflavored, 400g, powder	49735010099	Added to list effective Jan. 1, 2025.
Kate Farms, Inc.; 1-805-845-2446	Kate Farms Kids Nutrition 1.0, Vanilla, 250 mL	11112003119	Added to list effective Jan. 1, 2025.
Kate Farms, Inc.; 1-805-845-2446	Kate Farms Kids Nutrition, Chocolate, 250 mL	11112003121	Added to list effective Jan. 1, 2025.
Kate Farms, Inc.; 1-805-845-2446	Kate Farms Kids Nutrition, Strawberry, 250ml	11112003123	Added to list effective Jan. 1, 2025.
Nestlé HealthCare Nutrition; 1-888-240-2713	COMPLEAT® Original 1.5, Fruit Medley 24 x 250 mL carton	43900083732	Added to list effective Jan. 1, 2025.

Manufacturer	Product Label Name	Medi-Cal 11-Digit Billing Number (Ndc)	Changes
Nestlé HealthCare Nutrition; 1-888-240-2713	COMPLEAT® Pediatric Original 1.5 Fruit Medley 24 x 250 mL carton	43900063763	Added to list effective Jan. 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.

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.

Safe Disposal 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.

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.

COVID-19 Updates

COVID-19 Vaccines

- Everyone 6 months of age and older should get the 2024-2025 COVID-19 vaccine.
- For those 65 years of age and older, two doses of any 2024-2025 COVID-19 vaccine six months apart are recommended. While it is recommended to get 2024-2025 COVID-19 vaccine doses six months apart, the minimum time is two months apart, which allows flexibility to get the second doses prior to typical COVID-19 surges, travel, life events and health care visits.

CDC Recommended COVID-19 Vaccines

Three vaccines are available for use in the United States. There is no preference for one vaccine over the other when more than one vaccine is recommended for an age group.

Vaccine	Recommended for:
2024 – 2025 Moderna COVID-19 Vaccine	Everyone 6 months and older
2024 – 2025 Pfizer-BioNTech COVID-19 Vaccine	Everyone 6 months and older
2024 – 2025 Novavax COVID-19 Vaccine	Everyone ages 12 years and older

For additional information on the COVID-19 dosing schedule, refer to the COVID-19 Vaccine Timing 2024-25.

Medi-Cal Rx continues to cover COVID-19 and other vaccines. For a full list of vaccines, visit the Medi-Cal Rx Contract Drug List (CDL). For additional information, refer to the section titled "COVID-19 Vaccines, OTC Antigen Test Kits, and Therapeutics: Coverage and Reimbursements" in the Medi-Cal Rx Provider Manual.

Physician Administered Drugs (PAD) and Prior Authorization (PA) Requests

Physician Administered Drugs (PADs) include all infused, injectable drugs provided or administered to a member who 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), then administer to the member and later bill GCHP for reimbursement.

Please use GCHP's List of Services Requiring Prior Authorization (see list of Physician Administered Drugs) for the most up-to-date 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: The following article is a result of analyses carried out by the Global Medi-Cal DUR Program and is not official state Department of Health Care Services (DHCS) policy.

The following educational article has been recently posted since the last pharmacy newsletter:

- Drug-Drug Interaction: Amlodipine with Simvastatin or Lovastatin - October 2024

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

Summary of Revisions: Standards of Care in Diabetes – 2025

The American Diabetes Association recently published the updated Standards of Care in Diabetes-2025 guidelines. A summary of the revisions is provided below.

- **Prevention or Delay of Diabetes and Associated Comorbidities**
  - Consider metformin for the prevention of type 2 diabetes in adults at high risk of type 2 diabetes, especially those aged 25–59 years with BMI >35 kg/m2, higher fasting plasma glucose (e.g., >110 mg/dL), and higher A1C (e.g., >6.0%), and in individuals with prior gestational diabetes mellitus.
  - Long-term use of metformin may be associated with vitamin B12 deficiency; consider periodic assessment of vitamin B12 level in metformin treated individuals, especially in those with anemia or peripheral neuropathy.
  - Teplizumab-mzwv (Tzield) infusion to delay the onset of symptomatic type 1 diabetes (stage 3) should be discussed with selected individuals aged >8 years with stage 2 type 1 diabetes.

- **Assessment of Comorbidities**
  - Autoimmune Diseases
    - Screen people with type 1 diabetes for autoimmune thyroid disease soon after diagnosis and thereafter at repeated intervals if clinically indicated.
    - Adults with type 1 diabetes should be screened for celiac disease in the presence of gastrointestinal symptoms, signs, laboratory manifestations, or clinical suspicion suggestive of celiac disease.
  - Assess for disability at the initial visit and for decline in function at each subsequent visit in people with diabetes.
  - Sexual Dysfunction
    - In men with diabetes or prediabetes, inquire about sexual health (e.g., low libido and erectile dysfunction [ED]). If symptoms and/or signs of hypogonadism are detected (e.g., low libido, ED, and depression), screen with a morning serum total testosterone level.
    - In men with diabetes or prediabetes, screen for ED, particularly in those with high cardiovascular risk, retinopathy, cardiovascular disease, chronic kidney disease, peripheral or autonomic neuropathy, longer duration of diabetes, depression, and hypogonadism, and in those who are not meeting glycemic goals.
    - In women with diabetes or prediabetes, inquire about sexual health by screening for desire (libido), arousal, and orgasm difficulties, particularly in those who experience depression and/or anxiety and those with recurrent urinary tract infections.
    - In postmenopausal women with diabetes or prediabetes, screen for symptoms and/or signs of genitourinary syndrome of menopause, including vaginal dryness and dyspareunia.
    - Immunization
    - Provide routinely recommended vaccinations for children and adults with diabetes as indicated by age as shown in Table 4.3.

Table 4.3—Highly recommended immunizations for adults with diabetes (from the Advisory Committee on Immunization Practices and Centers for Disease Control and Prevention)

Vaccine	Recommended ages	Schedule	GRADE evidence type*	References
COVID-19	All people 6 months of age and older	Current initial vaccination and boosters		Centers for Disease Control and Prevention, Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States (318)
Hepatitis B	Adults with diabetes aged <60 years; for adults aged ≥60 years, hepatitis B vaccine may be administered at the discretion of the treating clinician based on the person's likelihood of acquiring hepatitis B infection			Weng et al., Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2022 (19)
Influenza	All people with diabetes advised to receive a trivalent influenza vaccine and not to receive live attenuated influenza vaccine	Annual		Centers for Disease Control and Prevention, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season (22)
Pneumonia (PPSV23 [Pneumovax])	19–64 years of age, vaccinate with Pneumovax	One dose is recommended for those who previously received PCV13; if PCV15 was used, follow with PPSV23 ≥1 year later; PPSV23 is not indicated after PCV20; adults who received only PPSV23 may receive PCV15 or PCV20 ≥1 year after their last dose	2	Centers for Disease Control and Prevention, Updated Recommendations for Prevention of Invasive Pneumococcal Disease Among Adults Using the 23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23) (24,319)
	≥65 years of age	One dose is recommended for those who previously received PCV13; if PCV15 was used, follow with PPSV23 ≥1 year later; PPSV23 is not indicated after PCV20; adults who received only PPSV23 may receive PCV15 or PCV20 ≥1 year after their last dose	2	Falkenhorst et al., Effectiveness of the 23-Valent Pneumococcal Polysaccharide Vaccine (PPV23) Against Pneumococcal Disease in the Elderly: Systematic Review and Meta-analysis (24,320)
PCV20 or PCV15	Adults 19–64 years of age with an immunocompromising condition (e.g., chronic renal failure), cochlear implant, or cerebrospinal fluid leak	One dose of PCV15 or PCV20 is recommended by the Centers for Disease Control and Prevention		Kobayashi et al., Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2022 (24, 321)
	Adults 19–64 years of age, immunocompetent	For those who have never received any pneumococcal vaccine, the Centers for Disease Control and Prevention recommends one dose of PCV15 or PCV20		
	≥65 years of age, immunocompetent, have shared decision-making discussion with health care professionals	One dose of PCV15 or PCV20; PCSV23 may be given ≥8 weeks after PCV15; PPSV23 is not indicated after PCV20		
RSV	Older adults ≥60 years of age with diabetes appear to be a risk group	Adults aged ≥75 years and those aged ≥60 years and at high risk may receive a single dose of an RSV vaccine		Centers for Disease Control and Prevention, CDC Recommends RSV Vaccine for Older Adults (25)
Tetanus, diphtheria, pertussis (Tdap)	All adults; pregnant individuals should have an extra dose	Booster every 10 years	2 for effectiveness, 3 for safety	Havers et al., Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, 2019 (322)

Table 4.3—Continued

Vaccine	Recommended ages	Schedule	GRADE evidence type*	References
Zoster	≥50 years of age	Two-dose Shingrix, even if previously vaccinated	1	Dooling et al., Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines (323)

For a comprehensive list of vaccines, refer to the Centers for Disease Control and Prevention web site at cdc.gov/vaccines/. Advisory Committee on Immunization Practices recommendations can be found at cdc.gov/vaccines/acip/recommendations. GRADE, Grading of Recommendations Assessment, Development, and Evaluation; PCV13, 13-valent pneumococcal conjugate vaccine; PCV15, 15-valent pneumococcal conjugate vaccine; PCV 20, 20-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine. *Evidence type: 1, randomized controlled trials (RCTs) or overwhelming evidence from observational studies; 2, RCTs with important limitations or exceptionally strong evidence from observational studies; 3, observational studies or RCTs with notable limitations; 4, clinical experience and observations, observational studies with important limitations, or RCTs with several major limitations.

- Bone Health
  - Assess fracture risk in older adults with diabetes as a part of routine care.
  - Consider the potential adverse impact on skeletal health when selecting pharmacological options to lower glucose levels in people with diabetes. Avoiding medications with a known association with higher fracture risk (e.g., thiazolidinediones and sulfonylureas) is recommended, particularly for those at elevated risk for fractures.
  - Antiresorptive medications and osteoanabolic agents should be recommended for older adults with diabetes who are at higher risk of fracture, including those with low bone mineral density with a T-score < -2.0, history of fragility fracture, or elevated Fracture Risk Assessment Tool score (>3% for hip fracture or >20% for major osteoporotic fracture).

Table 4.4—Diagnostic assessment

Individuals who should receive BMD testing
People aged ≥65 years
Postmenopausal women and men aged ≥50 years with history of adult-age fracture or with diabetes–specific risk factors: • Frequent hypoglycemic events • Diabetes duration >10 years • Diabetes medications: insulin, thiazolidinediones, sulfonylureas • A1C >8% • Peripheral or autonomic neuropathy, retinopathy, nephropathy • Frequent falls • Glucocorticoid use

- Metabolic Dysfunction
  - Screen adults with type 2 diabetes or with prediabetes, particularly those with obesity or other cardiometabolic risk factors or established cardiovascular disease, for their risk of having or developing cirrhosis related to metabolic dysfunction–associated steatohepatitis (MASH) using a calculated fibrosis-4 index (FIB-4) (derived from age, ALT, AST, and platelet), even if they have normal liver enzymes.
  - Adults with diabetes or prediabetes with persistently elevated plasma aminotransferase levels for >6 months and low FIB-4 should be evaluated for other causes of liver disease.
  - Adults with type 2 diabetes or prediabetes with a FIB-4 >1.3 should have additional risk stratification by liver stiffness measurement with transient elastography, or, if unavailable, the enhanced liver fibrosis (ELF) test.
  - Refer adults with type 2 diabetes or prediabetes at higher risk for significant liver fibrosis (i.e., as indicated by FIB-4, liver stiffness measurement, or ELF) to a gastroenterologist or hepatologist for further evaluation and management.
  - Adults with type 2 diabetes or prediabetes, particularly with overweight or obesity, who have metabolic dysfunction-associated steatotic liver disease (MASLD) should be recommended lifestyle changes using an

interprofessional approach that promotes weight loss, ideally within a structured nutrition plan and physical activity program for cardiometabolic benefits and histological improvement.

- In adults with type 2 diabetes, MASLD, and overweight or obesity, consider using a glucagon-like peptide 1 (GLP-1) receptor agonist (RA) or a dual glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA for the treatment of obesity with potential benefits in MASH 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), pioglitazone, a GLP-1 RA, or a dual GIP and GLP-1 RA is preferred for glycemic management because of potential beneficial effects on MASH.
- Combination therapy with pioglitazone plus GLP-1 RA can be considered for the treatment of hyperglycemia in adults with type 2 diabetes with biopsy proven MASH or those at high risk of liver fibrosis (identified with noninvasive tests) because of potential beneficial effects on MASH.
- For consideration of treatment with a thyroid hormone receptor-b agonist in adults with type 2 diabetes or prediabetes with MASLD with moderate (F2) or advanced (F3) liver fibrosis on liver histology, or by a validated imaging-based or blood-based test, refer to a gastroenterologist or hepatologist with expertise in MASLD management.
- In adults with type 2 diabetes and MASLD, use of glucose-lowering therapies other than pioglitazone or GLP-1 RAs may be continued as clinically indicated, but these therapies lack evidence of benefit in MASH.
- Insulin therapy is the preferred agent for the treatment of hyperglycemia in adults with type 2 diabetes with decompensated cirrhosis.
- Statin therapy is safe in adults with type 2 diabetes and compensated cirrhosis from MASLD and should be initiated or continued for cardiovascular risk reduction as clinically indicated. In people with decompensated cirrhosis, statin therapy should be used with caution, and close monitoring is needed, given limited safety and efficacy data.

Diagnostic Algorithm for the Prevention of Cirrhosis in People With Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)

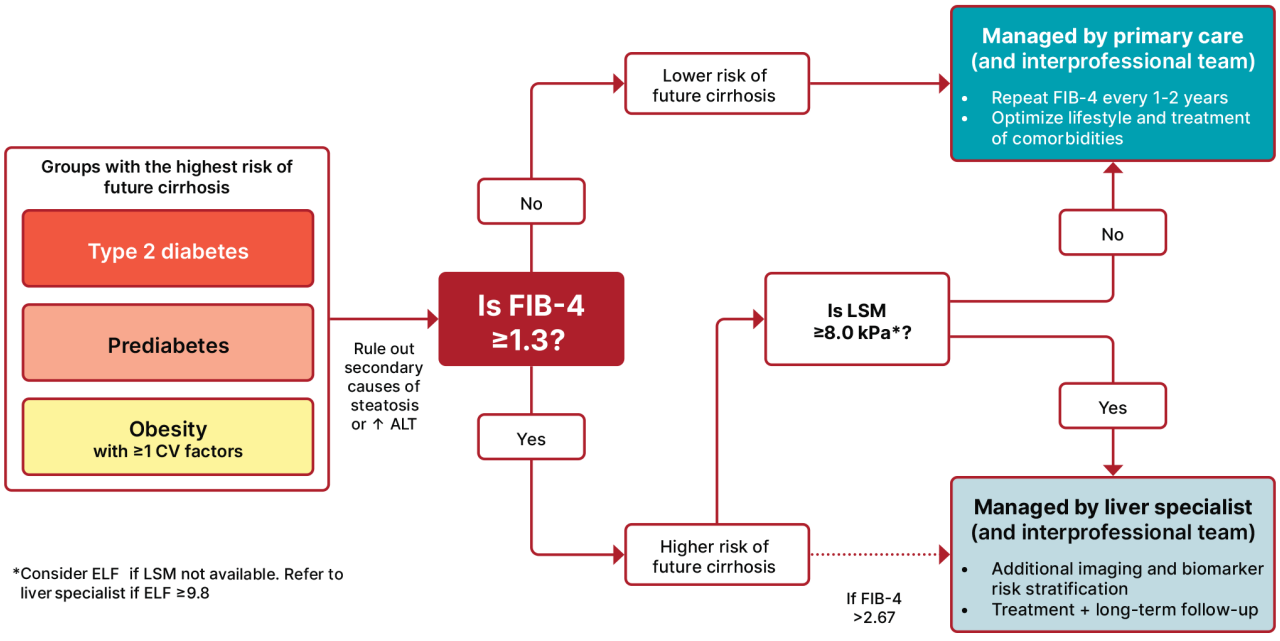
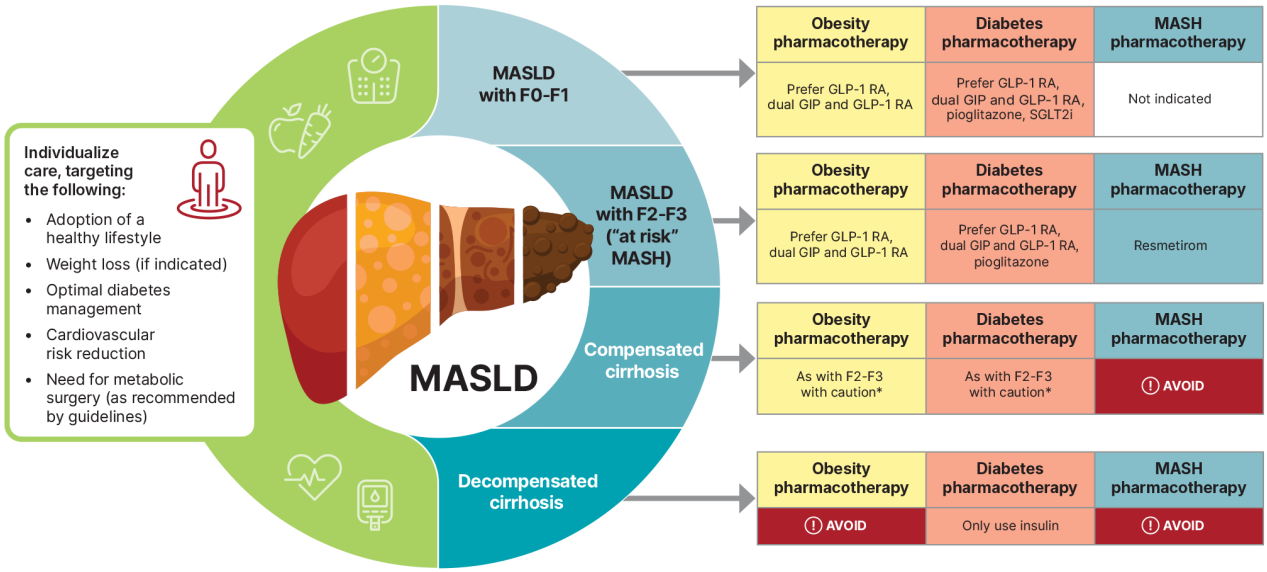


Figure 4.2—Diagnostic algorithm for risk stratification and the prevention of cirrhosis in individuals with metabolic dysfunction–associated steatotic liver disease (MASLD). CV, cardiovascular; ELF, enhanced liver fibrosis test; FIB-4, fibrosis-4 index; LSM, liver stiffness measurement, as measured by vibration-controlled transient elastography. *In the absence of LSM, consider ELF a diagnostic alternative. If ELF ≥9.8, an individual is at high risk of metabolic dysfunction–associated steatohepatitis with advanced liver fibrosis (≥F3–F4) and should be referred to a liver specialist.

Metabolic Dysfunction–Associated Steatotic Liver Disease (MASLD) Treatment Algorithm



*Individualized care and close monitoring needed in compensated cirrhosis given limited safety data available.

Figure 4.3—Metabolic dysfunction–associated steatotic liver disease (MASLD) treatment algorithm. F0-F1, no to minimal fibrosis; F2-F3, moderate fibrosis; F4, cirrhosis; GIP, glucose-dependent insulinotropic polypeptide; GLP-1 RA, glucagon-like peptide 1 receptor agonist; MASH, metabolic dysfunction–associated steatohepatitis; SGLT2i, sodium–glucose cotransporter 2 inhibitor.

- **Diabetes Technology**
  - » Consider potential interference of medications and substances on glucose levels measured by blood glucose meters.

Table 7.2—Common interfering substances and/or conditions that affect glucose meters (for inpatient and outpatient use)

Substance or condition	Effects on glucose values measured by blood glucose meters
Maltose*	Falsely higher blood glucose values
Galactose	Falsely higher blood glucose values
Xylose	Falsely higher blood glucose values
N-Acetylcysteine†	Falsely higher blood glucose values
Acetaminophen	Falsely higher blood glucose values at low blood glucose levels
Dopamine	Falsely higher blood glucose values at low blood glucose levels
Furosemide	Falsely lower blood glucose values
Vitamin C	Falsely lower or higher blood glucose values
Uric acid	Falsely higher blood glucose values at very low or very high glucose levels
Hematocrit (high)	Falsely lower blood glucose values
Hematocrit (low)	Falsely higher blood glucose values

*Unmodified glucose dehydrogenase method only. †Glucose dehydrogenase monitors using pyrroloquinoline quinone cofactor (GDH/PQQ).

Table 7.3—Continuous glucose monitoring devices

Type of CGM	Description
rtCGM	CGM systems that measure and display glucose levels continuously
isCGM with and without alarms	CGM systems that measure glucose levels continuously but require scanning for visualization and storage of glucose values
Professional CGM	CGM devices that are placed on the person with diabetes in the health care professional's office and worn for a discrete period of time (generally 7–14 days). Data may be blinded or visible to the person wearing the device. The data are used to assess glycemic patterns and trends. Unlike rtCGM and isCGM devices, these devices are clinic-based and not owned by the person with diabetes.
Over-the-counter CGM	CGM devices called biosensors, which measure glucose continuously and display the levels at various times, have insights rather than alarms and are indicated for people with prediabetes or with diabetes not on insulin.

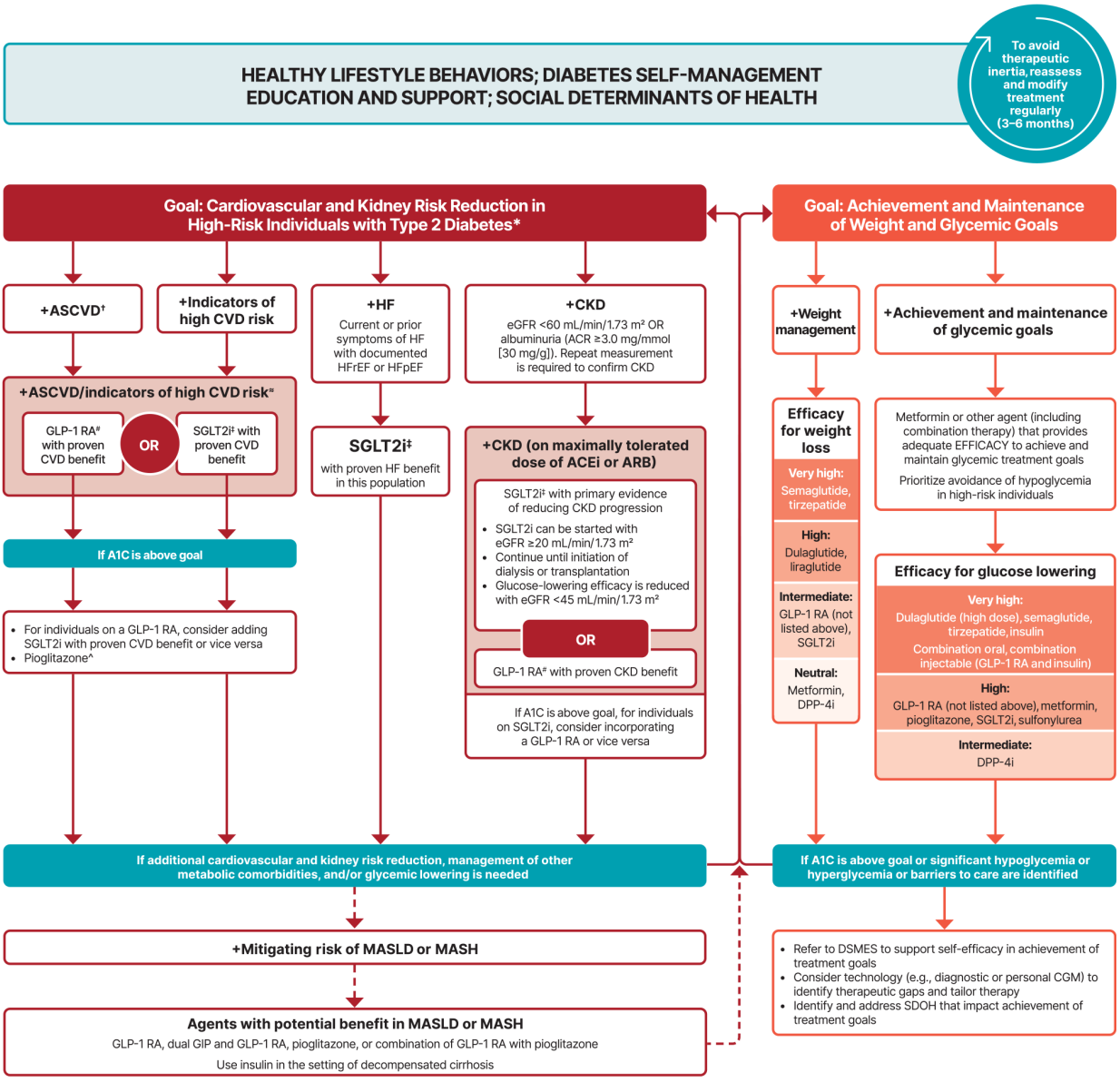
CGM, continuous glucose monitoring; isCGM, intermittently scanned CGM; rtCGM, real-time CGM.

- **Obesity and Weight Management for the Preventions and Treatment of Type 2 Diabetes**
  - » Screen people with diabetes and obesity who have lost significant weight for malnutrition, especially those who have undergone metabolic surgery and those treated with weight management pharmacologic therapy.
  - » Weight management pharmacotherapy indicated for chronic therapy should be continued beyond reaching weight loss goals to maintain the health benefits. Sudden discontinuation of weight management pharmacotherapy often results in weight gain and worsening of cardiometabolic risk factors.
  - » If post-metabolic surgery hypoglycemia is suspected, clinical evaluation should exclude other potential disorders contributing to hypoglycemia, and management should include education, medical nutrition therapy with a registered dietitian nutritionist experienced in post–metabolic surgery hypoglycemia, and medication treatment, as needed. In individuals with post-metabolic surgery hypoglycemia, use continuous glucose monitoring to improve safety.

- **Pharmacologic Approaches to Glycemic Treatment**
  - » Adults with Type 1 Diabetes
    - Treat most adults with type 1 diabetes with continuous subcutaneous insulin infusion or multiple daily doses of prandial (injected or inhaled) and basal insulin.
    - Early use of continuous glucose monitoring is recommended for adults with type 1 diabetes to improve glycemic outcomes and quality of life and to minimize hypoglycemia.
  - » Adults with Type 2 Diabetes
    - In adults with type 2 diabetes and established or high risk of atherosclerotic cardiovascular disease, the treatment plan should include medications with demonstrated benefits to reduce cardiovascular events (e.g., glucagon-like peptide 1 receptor agonist [GLP-1 RA] and/or sodium-glucose cotransporter 2 [SGLT2] inhibitor) for glycemic management and comprehensive cardiovascular risk reduction (irrespective of A1C).
    - o In adults with type 2 diabetes who have heart failure (HF) (with either reduced or preserved ejection fraction), an SGLT2 inhibitor is recommended for both glycemic management and prevention of HF hospitalizations (irrespective of A1C).
    - In adults with type 2 diabetes and symptomatic heart failure with preserved ejection fraction (HFpEF) and obesity, a GLP-1 RA with demonstrated benefits for both glycemic management and reduction of HF related symptoms (irrespective of A1C) is recommended.
    - In adults with type 2 diabetes who have CKD (with confirmed estimated glomerular filtration rate [eGFR] 20-60 mL/min/1.73 m2 and/or albuminuria), an SGLT2 inhibitor or GLP-1 RA with demonstrated benefit in this population should be used for both glycemic management (irrespective of A1C) and for slowing progression of CKD and reduction in cardiovascular events. The glycemic benefits of SGLT2 inhibitors are reduced at eGFR < 45 mL/min/1.73m2.
    - In adults with type 2 diabetes, metabolic dysfunction-associated steatotic liver disease (MASLD), and overweight or obesity, consider using a GLP-1 RA or a dual glucose-dependent insulinotropic polypeptide (GIP) and GLP-1 RA with potential benefits in metabolic dysfunction-associated steatohepatitis (MASH) for glycemic management and as an adjunctive to healthy 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), pioglitazone, a GLP-1 RA, or a dual GIP and GLP-1 RA is preferred for glycemic management due to potential beneficial effects on MASH.
  - Concurrent use of dipeptidyl peptidase 4 (DPP-4) inhibitors with a GLP-1 RA or a dual GIP and GLP-1 RA is not recommended due to lack of additional glucose lowering beyond that of a GLP-1 RA alone.
  - In adults with type 2 diabetes and no evidence of insulin deficiency, a GLP-1 RA, including a dual GIP and GLP-1 RA, is preferred to insulin.
- Use of compounded products that are not approved by the FDA is not recommended due to uncertainty about their content and resulting concerns about safety, quality, and effectiveness.
- If a glucose-lowering medication is unavailable (e.g., in shortage), it is recommended to switch to a different FDA-approved medication with similar efficacy, as clinically appropriate.
- Upon resolution of the unavailability (e.g., shortage), reassess the appropriateness of resuming the original FDA-approved medication.
- Individuals with diabetes of childbearing potential should be counseled on contraception options and the impact of some glucose-lowering medications on contraception efficacy.
- Educate individuals with diabetes who are at risk for developing diabetic ketoacidosis and/or follow a ketogenic eating pattern and who are treated with SGLT inhibitors on the risks and signs of ketoacidosis and methods of risk mitigation management and provide them with appropriate tools for accurate ketone measurement (i.e., serum b-hydroxybutyrate).

Use of Glucose-Lowering Medications in the Management of Type 2 Diabetes



* 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 background use of metformin or A1C.

† 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 9.3—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. (89).

- **Cardiovascular Disease and Risk Management**
  - » Blood pressure should be measured at every routine clinical visit, or at least every six months. Individuals found to have elevated blood pressure without a diagnosis of hypertension (systolic blood pressure 120–129 mmHg and diastolic blood pressure).
  - » ACE inhibitors, angiotensin receptor blockers, MRAs, direct renin inhibitors, and neprilysin inhibitors should be avoided in sexually active individuals of childbearing potential who are not using reliable contraception and are contraindicated in pregnancy.
  - » In most circumstances, lipid lowering agents should be stopped prior to conception and avoided in sexually active individuals of childbearing potential who are not using reliable contraception.
  - » In individuals with ASCVD or other cardiovascular risk factors on a statin with managed LDL cholesterol but elevated triglycerides (150–499 mg/dL [1.7–5.6 mmol/L]), the addition of icosapent ethyl can be considered to reduce cardiovascular risk.
  - » In individuals with type 2 diabetes, obesity, and symptomatic heart failure with preserved ejection fraction, therapy with a GLP-1 RA with demonstrated benefit for reduction of heart failure-related symptoms, physical limitations, and exercise function is recommended.
  - » In individuals with type 2 diabetes, obesity, and symptomatic heart failure with preserved ejection fraction, therapy with a GLP-1 RA with demonstrated benefit for reduction of heart failure-related symptoms, physical limitations, and exercise function is recommended.

- **Chronic Kidney Disease and Risk Management**
  - » To reduce cardiovascular risk and kidney disease progression in people with type 2 diabetes and CKD, a glucagon-like peptide 1 agonist with demonstrated benefit in this population is recommended.
  - » Potentially harmful antihypertensive medications 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 antihypertensive medications considered safer during pregnancy.
  - » For people with non-dialysis-dependent stage G3 or higher CKD, protein intake should be 0.8 g/kg body weight per day, as for the general population. For individuals on dialysis, protein intake of 1.0-1.2 g/kg/day should be considered since protein energy wasting is a major problem for some individuals on dialysis.

Table 11.1—Reasons to consider nondiabetic kidney diseases in a person with chronic kidney disease and diabetes

- Type 1 diabetes duration <5 years
- Active urine sediment (e.g., containing red blood cells or cellular casts)
- Chronically well-managed blood glucose
- Rapidly declining eGFR
- Rapidly increasing or very high UACR or urine protein/creatinine level
- No retinopathy in a person with type 1 diabetes

Information adapted from Liang et al. (129). eGFR, estimated glomerular filtration rate; UACR, urine albumin-to-creatinine ratio.

- **Older Adults**
  - » Older adults with diabetes who are otherwise healthy with few, and stable coexisting chronic illnesses and intact cognitive and functional status should have lower glycemic goals (such as A1C < 7.0-7.5% and/or time in range [TIR] 70-180 mg/dL of ~70% and time below range < 70 mg/dL of < 4% if CGM is used).

Table 13.1—Framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes

Characteristics and health status of person with diabetes	Rationale	Reasonable A1C goal*	Reasonable CGM goals	Fasting or preprandial glucose	Bedtime glucose	Blood pressure	Lipids
Healthy (few coexisting chronic illnesses, intact cognitive and functional status)	Longer remaining life expectancy	<7.0–7.5% (<53–58 mmol/mol)	TIR 70–180 mg/dL (3.9–10.0 mmol) of ~70%, and TBR <70 mg/dL (3.9 mmol/L) of <4%)	80–130 mg/dL (4.4–7.2 mmol/L)	80–180 mg/dL (4.4–10.0 mmol/L)	<130/80 mmHg	Statin, unless contraindicated or not tolerated
Complex/intermediate (multiple coexisting chronic illnesses† or two or more ADL impairments or mild to moderate cognitive impairment)	Variable life expectancy. Individualize goals, considering: • Severity of comorbidities • Cognitive and functional limitations • Frailty • Risk-to-benefit ratio of diabetes medications • Individual preference	<8.0% (<64 mmol/mol)	TIR 70–180 mg/dL (3.9–10.0 mmol) of ~50% and TBR <70 mg/dL (3.9 mmol/L) of <1%	90–150 mg/dL (5.0–8.3 mmol/L)	100–180 mg/dL (5.6–10.0 mmol/L)	<130/80 mmHg	Statin, unless contraindicated or not tolerated
Very complex/poor health (LTC or end-stage chronic illnesses‡ or moderate to severe cognitive impairment or two or more ADL impairments)	Limited remaining life expectancy makes benefit minimal	Avoid reliance on A1C; glucose management decisions should be based on avoiding hypoglycemia and symptomatic hyperglycemia		100–180 mg/dL (5.6–10.0 mmol/L)	110–200 mg/dL (6.1–11.1 mmol/L)	<140/90 mmHg	Consider likelihood of benefit with statin

This table represents a consensus framework for considering treatment goals for glycemia, blood pressure, and dyslipidemia in older adults with diabetes. The characteristic categories are general concepts. Not every individual will clearly fall into a particular category. Consideration of individual and care partner preferences, care partner engagement, abilities, and resources is an important aspect of treatment individualization. Additionally, an individual's health status and preferences may change over time. ADL, activities of daily living; CGM, continuous glucose monitoring; LTC, long-term care; TBR, time below range; TIR, time in range. *A lower A1C goal may be set for an individual if achievable without recurrent or severe hypoglycemia or undue treatment burden. †Coexisting chronic illnesses are conditions serious enough to require medications or lifestyle management and may include arthritis, cancer, heart failure, depression, emphysema, falls, hypertension, incontinence, stage 3 or worse chronic kidney disease, myocardial infarction, and stroke. "Multiple" means at least three, but many individuals may have five or more (77). ‡The presence of a single end-stage chronic illness, such as stage 3–4 heart failure or oxygen-dependent lung disease, chronic kidney disease requiring dialysis, or uncontrolled metastatic cancer, may cause significant symptoms or impairment of functional status and significantly reduce life expectancy. Adapted from Kirkman et al. (3).

- **Children and Adolescents**
  - » Youth and their parents or caregivers should be educated on strategies to prevent hypoglycemia during, after, and overnight following physical activity and exercise. Treatment for hypoglycemia should be accessible before, during, and after engaging in activity.
  - » Less stringent A1C goals (such as < 7.5%) may be appropriate for youth who cannot articulate symptoms of hypoglycemia; have hypoglycemia unawareness; lack advanced insulin delivery technology and/or CGM; cannot check blood glucose regularly; or have nonglycemic factors that increase A1C (e.g., high glycators).
  - » Consider age-approved statins, in addition to medical nutritional therapy (MNT) and lifestyle changes, for youth with type 1 diabetes who have LDL cholesterol >130 mg/dL.
  - » If diabetes screening is normal, repeat screening at a minimum of two-year intervals or more frequently if BMI is increasing.
  - » Consider setting an A1C goal of <6.5% for most children and adolescents with type 2 diabetes who have a low risk of hypoglycemia. For those at higher risk of hypoglycemia, A1C goals should be individualized as clinically appropriate.
  - » Advise all youth with diabetes not to use cannabis recreationally in any form.

- **Management of Diabetes in Pregnancy**
  - » Individuals with preexisting diabetes who are planning a pregnancy or who have become pregnant should be counseled on the risk of development and/or progression of diabetic retinopathy. Dilated eye examinations should occur ideally before pregnancy as well as in the first trimester, and then pregnant individuals should be monitored every trimester and for one year postpartum as indicated by the degree of retinopathy and as recommended by the eye care health care professional.
  - » Continuous glucose monitoring (CGM) can help to achieve glycemic goals (e.g., time in range, time above range) and A1C goal in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy.
  - » CGM metrics may be used in combination with blood glucose monitoring to achieve optimal pre- and postprandial glycemic goals.

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	Dosage Form	Summary of Indication
RETEVMO	*Selpercatinib*	Oral Tablet	Indicated for the treatment of: • Adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion. • Adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation. • Adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion. • Adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options.
ZITUVIMET XR	*Metformin Hydrochloride; Sitagliptin*	Oral Tablet, Extended Release	A biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
AQNEURSA	*Levacetylleucine*	For Oral Suspension	Indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighing ≥15 kg.
DANZITEN	*Nilotinib Tartrate*	Oral Tablet	Indicated for the treatment of: • Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. • Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib.
REVUFORJ	*Revumenib Citrate*	Oral Tablet	Indicated for the treatment of relapsed or refractory acute leukemia with a lysine methyltransferase 2A gene (KMT2A) translocation in adult and pediatric patients 1 year of age and older.

Brand Name	Generic Name	Dosage Form	Summary of Indication
ZIIHERA	*Zanidatamab-Hrii*	Injectable	Indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC).
ATTRUBY	*Acoramidis Hydrochloride*	Oral Tablet	Indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.
IMKELDI	*Imatinib Mesylate*	Oral Solution	Indicated for the treatment of: • Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy. • Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). • Pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy. • Adult patients with myelodysplastic/ myeloproliferative diseases (MDS/ MPD) associated with platelet-derived growth factor receptor (PDGFR) gene re-arrangements. • Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown. • Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRα fusion kinase (mutational analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRα fusion kinase negative or unknown. • Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

Brand Name	Generic Name	Dosage Form	Summary of Indication
			• Patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). • Adjuvant treatment of adult patients following resection of Kit (CD117) positive GIST.
BIZENGRI	*Zenocutuzumab-Zbco*	Injection	Indicated for the treatment of: • Adults with advanced, unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. • Adults with advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.
CRENESSITY	*Crinecerfont*	Oral Capsule	Indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).
CRENESSITY	*Crinecerfont*	Oral Solution	Indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH).
NEMLUVIO	*Nemolizumab-Ilto*	Injectable	Indicated for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
ALYFTREK	*Deutivacaftor; Tezacaftor; Vanzacaftor Calcium*	Oral Tablet	Indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years of age and older who have at least one F508del mutation or another responsive mutation in the CFTR gene.

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
TURALIO *(pexidartinib hydrochloride)*	Boxed Warning	**WARNING: HEPATOTOXICITY** TURALIO can cause serious and potentially fatal liver injury, including vanishing bile duct syndrome. Monitor liver tests prior to initiation of TURALIO and at specified intervals during treatment. Withhold and dose reduce or permanently discontinue TURALIO based on severity of hepatotoxicity. Monitoring and prompt cessation of TURALIO may not eliminate the risk of serious and potentially fatal liver injury. TURALIO is available only through a restricted program called the TURALIO Risk Evaluation and Mitigation Strategy (REMS) Program.
LEQEMBI *(lecanemab-irmb)*	Boxed Warning	Serious intracerebral hemorrhages > 1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy to a patient being treated with LEQEMBI.
MYCOBUTIN *(rifabutin)*	Contraindications	MYCOBUTIN capsules are contraindicated in patients who have had clinically significant hypersensitivity to rifabutin or to any other rifamycins. MYCOBUTIN capsules are contraindicated in patients being treated with cabotegravir / rilpivirine prolonged-release injectable suspension.
REYATAZ *(atazanavir sulfate)*	Contraindications	When co-administered with drugs that are strong inducers of CYP3A due to the potential for loss of therapeutic effect and development of resistance.
VEOZAH *(fezolinetant)*	Boxed Warning	**WARNING: RISKS OF HEPATOTOXICITY** Hepatotoxicity has occurred with the use of VEOZAH in the post marketing setting. Perform hepatic laboratory tests prior to initiation of treatment to evaluate for hepatic function and injury. Do not start VEOZAH if either aminotransferase is greater than or equal to two times the upper limit of normal (ULN) or if the total bilirubin is greater than or equal to two times ULN for the evaluating laboratory. Perform follow-up hepatic laboratory testing monthly for the first three months, at six months, and nine months of treatment.

Drug	Type of Change	Change
		Advise patients to discontinue VEOZAH immediately and seek medical attention including hepatic laboratory tests if they experience signs or symptoms that may suggest liver injury (new onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, or abdominal pain). Discontinue VEOZAH if transaminase elevations are > five times ULN, or if transaminase elevations are > three times ULN and the total bilirubin level is > two times ULN. If transaminase elevations > three times ULN occur, perform more frequent follow-up hepatic laboratory tests until resolution.
LUMIZYME *(alglucosidase alfa*	Boxed Warning	**Hypersensitivity Reactions Including Anaphylaxis** Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Initiate LUMIZYME in a health care setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue LUMIZYME and immediately initiate appropriate medical treatment, including use of epinephrine. Inform patients of the symptoms of life-threatening hypersensitivity reactions, including anaphylaxis and to seek immediate medical care should symptoms occur.
COPAXONE, GLATOPA *(glatiramer acetate)*	Boxed Warning	The risk of a rare but serious allergic reaction called anaphylaxis. Anaphylaxis can occur at any time, from as early as after the first dose or after doses administered years after starting the medicine. New recommendations for patients and health care professionals about the critical importance of quickly recognizing and treating symptoms of anaphylaxis was added.
ABRYSO *(respiratory syncytial virus vaccine)*	Warnings and Precautions	Guillain Barré Syndrome. The results of a post marketing observational study suggest an increased risk of Guillain Barré syndrome during the 42 days following vaccination with ABRYSVO.
AREXVY *(respiratory syncytial virus vaccine, adjuvanted)*	Warnings and Precautions	Guillain Barré Syndrome. The results of a post marketing observational study suggest an increased risk of Guillain Barré syndrome during the 42 days following vaccination with AREXVY.

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
OCALIVA *(obeticholic acid)*	**Serious liver injury being observed in patients without cirrhosis taking Ocaliva (obeticholic acid) to treat primary biliary cholangitis.** Based on its review of post market clinical trial data, the U.S. Food and Drug Administration (FDA) identified cases of serious liver injury among patients being treated for primary biliary cholangitis (PBC) with Ocaliva (obeticholic acid) who did not have cirrhosis of the liver. PBC patients with advanced cirrhosis were previously notified they were at risk of serious liver injury when taking Ocaliva and the prescribing information was updated to restrict its use in these patients. FDA's review of this required clinical trial found that some cases of liver injury in patients without cirrhosis resulted in liver transplant. This risk was notably higher for patients taking Ocaliva compared with a placebo, a pill without any active medicine. FDA restricted the use of Ocaliva in patients who have PBC with advanced cirrhosis of the liver in 2021 because it can cause serious harm in those patients, adding a new Contraindication to the Ocaliva prescribing information and patient Medication Guide. However, our recent review of case reports submitted to FDA found that some patients with PBC and advanced cirrhosis were still taking the medicine despite these restrictions.

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
Xifaxan (rifaximin) 200mg tablets	• Bausch Health	Bausch Health has Xifaxan 200 mg tablets on allocation. Orders are being monitored and allocated according to the demand for its labeled use of the treatment of travelers' diarrhea. **Available Products** • Xifaxan oral tablet, Bausch Health, 550 mg, bottle, 60 count, NDC 65649-0303-02. • Xifaxan oral tablet, Bausch Health, 550 mg, unit-dose carton 42 count, NDC 65649-0303-04. • Xifaxan oral tablet, Bausch Health, 550 mg, unit-dose carton, 60 count, NDC 65649-0303-03.
Theophylline 24-Hour Extended Release Capsules and Tablets 100 mg, 400 mg and 600 mg	• Endo Pharmaceuticals • Rhodes	• Endo did not provide a reason for the shortage of Theo-24 100 mg capsules. • Rhodes did not provide a reason for the shortage of theophylline 400 mg extended-release tablets. Rhodes discontinued the 600 mg extended-release tablets in May 2024 due to a business decision. • Glenmark has theophylline 24-hour extended-release tablets available. The company is reviewing orders. **Available Products** • Theo-24 extended-release capsule, Endo Pharmaceuticals, 200 mg, bottle, 100-count, NDC 52244-0200-10. • Theo-24 extended-release capsule, Endo Pharmaceuticals, 300 mg, bottle, 100-count, NDC 52244-0300-10. • Theo-24 extended-release capsule, Endo Pharmaceuticals, 400 mg, bottle, 100-count, NDC 52244-0400-10. • Theophylline extended-release tablet, Glenmark, 400 mg, bottle, 100 count, NDC 68462-0380-01. • Theophylline extended-release tablet, Glenmark, 600 mg, bottle, 100-count, NDC 68462-0356-01. **Estimated Resupply Dates** Endo has Theo-24 100 mg capsules on back order and the company cannot estimate a release date. Rhodes has theophylline 400 mg extended-release tablets on back order and the company cannot estimate a release date.

Drug Product	Affected Manufacturers	Summary
Lidocaine Hydrochloride Oral Topical Solution (Viscous) 2%	• Akorn • Hikma • Morton Grove Pharmaceutical • Wockhardt	• Akorn ceased operations in February 2023. • Chartwell launched viscous lidocaine oral solution in late-2023. • Hikma did not provide a reason for the shortage. • Morton Grove Pharmaceutical stopped production at its plant in Morton Grove, IL. Lidocaine 2% viscous oral topical solution was transitioned to Wockhardt. • Wockhardt has discontinued lidocaine 2% viscous oral topical solution. **Available Products** Viscous Lidocaine oral solution, Chartwell, 2%, 100 mL bottle, one-count, NDC 62135-0712-42. **Estimated Resupply Dates** Hikma has viscous lidocaine 2% in 100 mL bottles on allocation.
Azithromycin Powder for Oral Suspension Packets 1 gram packet	• Pfizer • Mylan (Vitaris)	**Products Affected** • Zithromax oral powder for suspension, Pfizer, one-gram, packet, three count, NDC 00069-3051-75 • Zithromax oral powder for suspension, Pfizer, one-gram, packet, 10 count, NDC 00069-3051-07 – discontinued. • Azithromycin oral powder for suspension, Mylan (Viatris), one-gram, packet, three count, NDC 59762-3051-02 discontinued. • Azithromycin oral powder for suspension, Mylan (Viatris), one-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 one-gram packets. • Pfizer has Zithromax oral powder for suspension one-gram packets in three-count on shortage due to manufacturing delays. In June 2024, the company stopped marketing Zithromax oral powder for suspension one-gram packets in 10-count. • Pfizer is the sole supplier of azithromycin oral powder for suspension packets. **Available Products** None. **Estimated Resupply Dates** No release date.

Drug Product	Affected Manufacturers	Summary
Dorzolamide ophthalmic solution 2%	• Bausch Health • Leading • Micro Labs • Sandoz	**Reason for the Shortage** • Bausch Health did not provide a reason for the shortage. • Leading did not provide a reason for the shortage. • Micro Labs did not provide a reason for the shortage. • Sandoz did not provide a reason for the shortage. **Estimated Resupply Dates** • Bausch Health has 2% dorzolamide 10 mL bottles on allocation. • Leading has 2% dorzolamide 10 mL bottles on back order and the company cannot estimate a release date. • Micro Labs has 2% dorzolamide 10 mL bottles on allocation. • Sandoz has 2% dorzolamide 10 mL bottles on back order and the company cannot estimate a release date.
BCG Live Intravesical	• Merck	**Reason for the Shortage** Because of increased global demand, and as the only source of BCG Live (Intravesical) in the United States and many other countries, Merck anticipates supply constraints for Tice BCG in 2019. To minimize disruption to patient care and address the current imbalance between supply and increased global demand, Tice BCG will be under allocation when demand exceeds production plans and available inventory. **Estimated Resupply Dates** Merck has Tice BCG on allocation.
Bicillin-LA (penicillin G benzathine) IM suspension for injection 600,000 units	• Pfizer	**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 here. **Available Products** • 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. • 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% lidocaine for injection in ampules vial, one-count, NDC 84383-0110-01. • Extencilline intramuscular powder for solution for injection, Provepharm, 1,200,000 units, 20 mL vial of powder/5 mL water for injection in ampules vial, 10-count, NDC 81284-0521-01.

Drug Product	Affected Manufacturers	Summary
		• Extencilline intramuscular powder for solution for injection, Provepharm, 2,400,000 units, 20 mL vial of powder/5 mL water for injection in ampules vial, 10-count, NDC 81284-0522-01. **Estimated Resupply Dates** Pfizer estimates a release date of June 2025.

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
Dec. 23, 2024	PROGRAF *(tacrolimus)* 0.5mg ASTAGRAF XL *(tacrolimus extended-release)* capsules 0.5mg	Astellas Pharma US, Inc. (Head of US Commercial: Michael Petroutsas, "Astellas") is voluntarily recalling one lot of PROGRAF® 0.5mg (tacrolimus) and one lot of ASTAGRAF XL® 0.5mg (tacrolimus extended-release) capsules to the consumer level. These products are being recalled because bottles may contain empty capsules.	Astellas	PROGRAF® (tacrolimus) 0.5 mg capsules, 100 capsules per bottle NDC: 0469-0607-73 Lot #: 0E3353D Exp.: 03/2026 ASTAGRAF XL® (tacrolimus extended-release capsules) 0.5 mg capsules, 30 capsules per bottle NDC: 0469-0647-73 Lot #: 0R3092A Exp.: 03/2026

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
Dec. 20, 2024	Adrenalin® Chloride Solution *(EPINEPHrine nasal solution, USP)* 30mg/30mL (1mg/mL) 30 mL vials	Endo, Inc (OTCQX: NDOI) ("Endo"), announced that one of its operating subsidiaries, Endo USA, Inc., is voluntarily recalling all lots within expiry of Adrenalin® Chloride Solution (EPINEPHrine nasal solution, USP) 30mg/30mL (1mg/mL) 30 mL vials, to the consumer level. This product, which pre-dates the 1938 Federal Food, Drug & Cosmetic Act, was never submitted for approval by the FDA, and as such, is an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. In addition, FDA has determined the product to be misbranded with a misleading label similar in appearance to the FDA-approved drug product Adrenalin® (epinephrine injection, USP) (1mg/mL) 30mL vial, also produced by Endo USA, Inc. Both products are distributed to hospitals and health care systems for use by health care professionals. The similarity in labeling makes it difficult to distinguish between the non-sterile topical and sterile injectable product which can lead to potential administration errors. This recall does not include the approved Adrenalin® (epinephrine injection, USP) (1mg/mL) 30mL vial	Par Pharmaceutical	Adrenalin® Chloride Solution (EPINEPHrine Nasal Solution, USP) for topical application 30mg/30mL (1mg/mL) NDC: 42023-103-01 Lot #: 42023-103-01 Exp.: 03/26 Lot #: 79637 Exp.: 11/2025 Lot #: 77776 Exp.: 07/2025 Lot #: 74716 Exp.: 05/2025 Lot #: 71835 Exp.: 01/2025 Lot #: 72916 Exp.: 01/2025

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
Dec. 20, 2024	Clonazepam Orally Disintegrating Tablets, USP (C-IV)	Endo, Inc. (OTCQX: NDOI) ("Endo") announced that one of its operating subsidiaries, Endo USA, Inc., is expanding its previously announced voluntary recall of Clonazepam Orally Disintegrating Tablets, USP (C-IV) due to potential product carton strength mislabeling. Specifically, Endo's ongoing investigation has identified the possibility that the Clonazepam product lots listed below contain a limited number of cartons printed with the incorrect strength and National Drug Code (NDC) code due to an error by a third-party packager. The blister strips and tablets inside the product pack reflect the correct strength for the lot.	Par Pharmaceutical	Clonazepam ODT, USP (C-IV) 2mg NDC: 49884-310-02 Lot #: 550176501 Exp.: /022027 Lot #: 550176601 Exp.: 02/2027 Clonazepam ODT, USP (C-IV) 0.125mg NDC: 49884-306-02 Lot #: 550174101 Exp.: 02/2027 Clonazepam ODT, USP (C-IV) 0.25mg NDC: 49884-307-02 Lot #: 550142801 Exp.: 08/2026 Lot #: 550142901 Exp.: 08/2026 Lot #: 550143001 Exp.: 08/2026 Lot #: 550143101 Exp.: 08/2026 Lot #: 550143201 Exp.: 08/2026 Lot #: 550143301 Exp.: 08/2026 Lot #: 550143401 Exp.: 08/2026 Lot #: 550147201 Exp.: 08/2026 Lot #: 550147401 Exp.: 08/2026 Clonazepam ODT, USP (C-IV) 1mg NDC: 49884-309-02 Lot #: 550145201 Exp.: 08/2026 Lot #: 550175901 Exp.: 02/2027 Lot #: 550176001 Exp.: 02/2027 Lot #: 550176201 Exp.: 2/2027

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MARCH 2025

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