Gold Coast Health Plan℠
A Public Entity

Pharmacy Newsletter

Q1 2024

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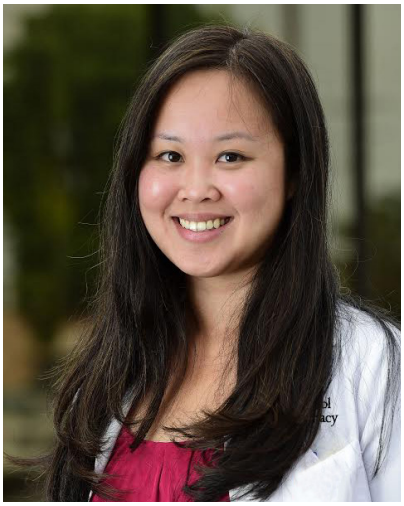
A Message from the Gold Coast Health Plan Director of Pharmacy Services



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 the pharmacy benefit, which is managed by Medi-Cal Rx.

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

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

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

Sincerely,

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

Medi-Cal Rx Updates

Updated Drug Lookup Tool

The Drug Lookup Tool located on the Medi-Cal Rx website has been updated to be more user friendly. You can now use this tool to look up drugs by their brand or generic names. 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 PA (ePA). For instructions on how to use this feature, click here.

Physician Administered Drugs (PADs)

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

Enteral Nutrition

As of Nov. 9, 2023, prior authorization (PA) requirements were reinstated for all enteral nutrition orders due to the retirement of the Transition Policy for members 22 years of age and older. Submission of a new PA is now required. Medi-Cal Rx has a separate PA process and specific PA form for enteral nutrition. You may access this form by clicking on the Enteral Nutrition PA Request Form link or you can find it in the Medi-Cal Rx portal.

Medical Foods

Medical foods do not meet the definition of Covered Outpatient Drugs according to Section 1927(d)(2) of the Social Security Act §1927. Medical foods are not treated as prescribed drugs and are not a covered Medi-Cal benefit. The state Department of Health Care Services (DHCS) considers semi-solid, solid, pureed specialty food items, and oral supplements as medical foods. As of Jan. 1, 2024, pharmacy claims for medical foods will no longer be reimbursed by Medi-Cal Rx, except for the following special populations with an approved prior authorization (PA) request:

- Early and Periodic Screening, Diagnostic, and Treatment (EPSDT)
- California Children's Services (CCS)
- Genetically Handicapped Persons Program (GHPP)

Enteral nutrition formula is, and will remain, a covered Medi-Cal Rx benefit, restricted to coverage criteria, PA requests, and the List of Contracted Enteral Nutrition Products. Refer to the Medi-Cal Rx Provider Manual for specific enteral nutrition formula coverage information.

Medical Supplies

Only some medical supplies are a partial Medi-Cal Rx benefit. Disposable outpatient medical supplies not found on the lists located on the Contract Drugs & Covered Products Lists page are not a benefit of Medi-Cal Rx. However, these non-listed medical supplies may be a benefit when billed on a medical / institutional claim to GCHP.

GCHP is obligated to provide access to non-listed or excluded Medi-Cal Rx medical supplies to their members via a medical claim. GCHP will review medical claims to determine if the medical supply is a Medi-Cal Rx non-covered or excluded product. Providers should not be instructed to bill Medi-Cal Rx for non-listed or excluded Medi-Cal Rx medical supplies.

Some products are restricted from coverage by state law. Medical supplies provided in renal dialysis centers and medical supplies that are commonly used in providing Skilled Nursing Facility- and Intermediate Care Facility-levels of care are included in the all-inclusive rate, billable under the medical benefit and are not separately billable. Solid and semi-solid foods are excluded from coverage.

Specific Medi-Cal benefits should be billed on a medical claim through the California Medicaid Management Information Systems (CA-MMIS) fiscal intermediary. The following medical supplies are covered Fee-for-Service Medi-Cal benefits and should be billed on a medical claim via a Healthcare Common Procedure Coding System (HCPCS) code on a CMS-1500 Claim Form through CA-MMIS or through GCHP:

- Incontinence supplies
- Ostomy supplies
- Wound care supplies
- Tracheostomy supplies
- Respiratory supplies
- Enteral feeding supplies
- Durable Medical Equipment (DME) supplies
- Other medical supplies commonly billed by HCPCS code (refer to the Medical Supplies Billing Codes, Units, and Quantity Limits List)

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

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

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

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

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

Drug Name	Description	Effective Date
Abacavir Sulfate / Lamivudine / Zidovudine	Labeler restriction removed.	Dec. 1, 2023
Ciprofloxacin HCL / Dexamethasone	Labeler restriction removed from otic suspension.	Nov. 1, 2023
Crotamiton	Labeler restriction added.	
Dolutegravir	Labeler restriction removed for 10 mg and 25 mg tablets.	Dec. 1, 2023

Drug Name	Description	Effective Date
Elranatamab-bcmm	Added to CDL with labeler restriction.	Nov. 1, 2023
Fluticasone Propionate	Labeler restriction removed from oral inhaler without	Dec. 1, 2023
Fosamprenavir Calcium	chlorofluoro-carbons as the propellant and oral powder for inhalation.	
Ivermectin	Labeler restriction removed.	Nov. 1, 2023
Maraviroc	Restriction removed.	Dec. 1, 2023
Naloxegol Oxalate	Labeler restriction removed for 25 mg and 75 mg tablets.	Nov. 1, 2023
Niraparib and Abiraterone	Labeler restriction updated.	
Acetate	Added to CDL with labeler restriction.	
Simvastatin	Restriction removed from 80 mg tablets.	
Talquetamab-tgvs	Added to CDL with labeler restriction.	
Aprepitant	Diagnosis restriction removed from 40 mg capsules.	Dec. 1, 2023
Atomoxetine HCL	Diagnosis restriction removed.	
Buprenorphine	Diagnosis restriction removed from sublingual tablets and transdermal patch. Quantity limit restriction updated for transdermal patch.	
Buprenorphine / Naloxone	Diagnosis restriction removed from sublingual tablets and sublingual films.	
Clonidine HCL	Diagnosis restriction removed from 12-hour tablets.	
Dornase Alfa	Diagnosis restriction removed.	
Entecavir	Diagnosis restriction removed.	
Flurazepam	Diagnosis restriction removed.	
Ganciclovir	Diagnosis restriction removed from ophthalmic gel.	
Guanfacine	Diagnosis restriction removed from extended-release tablets.	

Drug Name	Description	Effective Date
Lidocaine	Additional dosage form (patches) added to CDL.	Dec. 1, 2023
Momelotinib	Added to CDL with labeler restriction.	
Paliperidone	Added to CDL.	
Peginterferon Alfa-2A	Diagnosis restriction removed.	
Polatuzumab Vedotin-Piiq	Additional strength (30 mg) added to CDL with labeler restriction.	
Posaconazole	Additional formulation (delayed-release tablets) added to CDL.	
Ramelteon	Diagnosis and quantity limit restrictions removed.	
Ribavirin	Diagnosis restriction removed.	
Riluzole	Diagnosis restriction removed.	
Temazepam	Diagnosis restriction removed.	
Tiagabine HCL	Diagnosis restriction removed.	
Vaccines	Updated with age restriction.	
Voriconazole	Additional formulation (tablets) added to CDL.	
Zolpidem Tartrate	Diagnosis restriction removed.	
Glucagon (synthetic)	Prefilled auto-injector, syringe, and single-dose vial / syringe kit enddated.	Jan. 1, 2024
Baclofen	Additional formulation (solution) added to CDL. Additional formulation (oral granule packets) added to CDL with labeler restriction. **Effective Feb. 1, 2024:** Oral suspension end-dated.	
Crizotinib	Additional formulation (pellets in capsules) added to CDL with labeler restriction.	
Entrectinib	Additional formulation (oral pellets) added to CDL with labeler restriction.	

Drug Name	Description	Effective Date
Fezolinetant	Added to CDL with labeler restriction.	Jan. 1, 2024
Fruquintinib	Added to CDL with labeler restriction.	
Lasmiditan Succinate	**Effective Feb. 1, 2024:** Tablets end-dated.	
Perampanel	Labeler restriction removed.	
Rivaroxaban	Additional strength (2.5 mg) added to CDL with labeler restriction.	
Triptorelin Pamoate	Additional formulation (kit) added to CDL with labeler restriction.	

Diabetes Supplies Updates

As of Jan. 1, 2024:

- The list of Contracted Self-Monitoring Blood Glucose Systems (Glucometers) has been updated to add **True Metrix Air Self-Monitoring Blood Glucose Meter**. For a complete list, click here.
- The OneTouch Verio Test Strips, **100-Strip Box**, is no longer covered by Medi-Cal Rx. The **50-Strip Box** and **25-Strip Box** are covered. For more details, click here.

Pharmacy Benefit for COVID-19

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

Commercial COVID-19 Vaccine Coverage for Children

COVID-19 vaccines are now covered under Medi-Cal Rx for beneficiaries 3 years of age and older. For members 6 months to 3 years of age, coverage of the vaccine will be available only through the Vaccines for Children (VFC) program. Products remain federally funded. To locate an eligible provider, visit https://eziz.org/ or call **1-877-243-8832**.

Claims submitted to Medi-Cal Rx for members under 3 years of age will be rejected with Reject Code 60 – Product / Service Not Covered for Patient Age. Please review the Commercial COVID-19 Vaccine Coverage for Children bulletin on the Medi-Cal Rx website for additional details.

Over The Counter At-Home COVID-19 Tests

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

Items dispensed without a valid, documented request will be denied as not reasonable or necessary and are subject to a post-adjudication audit review by the state Department of Health Care Services (DHCS).

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

Please click here for more details related to this change.

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

Medi-Cal Rx: Coverage Guidelines for Covered Medical Supplies

See below for a quick reference guide listing some of the commonly prescribed medical supplies for diabetes, hypertension, and/or asthma that are covered under the pharmacy benefit. Any PAs that are required, quantity limits, and billing notes are also listed below.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Alcohol Prep Pads	No	200 per 30-day period	None
Blood glucose test strips for blood glucose monitor **(*change effective Oct. 5, 2023)**	No	Quantity limits are based upon documented insulin usage and are restricted to up to six test strips per day. Up to 600 test strips per 100 days for insulin users or up to 100 test strips per 100 days for non-insulin users; Code I for diabetes diagnosis and insulin or non-insulin user must be documented on the prescription and is subject to audit. ***Policy was updated to allow up to six per day for pregnancy-related diabetes diagnoses**	Code I Restriction for a diabetes diagnosis and insulin usage. The provider must document on the electronic or written prescription the beneficiary is an insulin user or non-user. ***For pregnancy-related diabetes diagnoses, the member can continue to receive up to six per day of both test strips and lancets during the pregnancy and up to 12 months postpartum**
Blood pressure monitoring devices for personal home use	No	One monitoring device every five years.	Code I diagnosis of any ICD-10-CM diagnosis code that justifies medical necessity for cardiovascular monitoring for a chronic condition or on a regular basis; documentation in the electronic file or on the prescription is required. Wrist Personal Blood Pressure Monitoring Devices are not a Medi-Cal Rx benefit.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Blood pressure cuff for use with home BP device	No	One cuff per 365 days.	Code I diagnosis of any ICD-10-CM diagnosis code that justifies medical necessity for cardiovascular monitoring for a chronic condition or on a regular basis; documentation in the electronic file or on the prescription is required. Wrist cuffs are not a Medi-Cal Rx benefit.
Blood ketone test or reagent strip	No	10 per claim and no more than three claims in a 90-day period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.
Control solution for blood glucose monitor	No	One every 365-day period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.
Disposable insulin delivery devices	Yes	PA required	a) For Omnipod systems, 10 pods every 30 days with a maximum of a 90-days-supply. b) For V-Go Series, 30 pods every 30 days with a maximum of a 90-days-supply.
Inhaler, Assist Devices (spacer, bag or reservoir, with or without mask, for use with metered dose inhaler)	No	Two per 365-day period.	None
Lancets	No	Quantity limits are based upon documented insulin usage and are restricted to up to six lancets per day. Up to 600 lancets per 100 days for insulin users or up to 100 lancets per 100 days for non-insulin users; Code 1 for diabetes diagnosis and insulin or non-insulin user must be documented on the prescription and is subject to audit.	Code I Restriction for a diabetes diagnosis and insulin usage. The provider must document on the electronic or written prescription the beneficiary is an insulin user or non-user.

Product	Prior Authorization Required? Y/N	Quantity Limits Without Prior Authorization	Billing Notes
Lancing Device	No	One every 365-day period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.
Peak flow meters, non-electronic	No	One per 365-day period.	None
Pen needles (*change effective Jan. 1, 2024)	No	***Limited to six pen needles per day and a maximum of four fills every 100 days**	None
Self-monitoring blood glucose monitor (glucometer)	No	One glucometer every five-year period.	Code I Restriction for recipients being treated by a physician for a diabetes diagnosis documented in their medical records.
Syringe, Insulin U-500 (*change effective Jan. 1, 2024)	No	***Limited to three syringes per day and a maximum of four fills every 100 days**	Code I Restriction for use with Insulin, Regular, U-500 only.
Syringes, insulin, any size (*change effective Jan. 1, 2024)	No	***Limited to six syringes per day and a maximum of four fills every 100 days**	None
Therapeutic continuous glucose monitor (CGM)	Yes	PA required.	Refer to the List of Contracted Continuous Glucose Monitoring (CGM) Systems for product-specific coverage restrictions.

Note, this is not an all-inclusive list and information is subject to change per Medi-Cal Rx. For a complete list of covered medical supplies under the pharmacy benefit and the most up-to-date information, click here. And for a complete list of all the contracted and covered products, click here.

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 press release from the state Department of Health Care Services (DHCS) on this topic.

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

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

GCHP maintains risk for PADs and with few exceptions, these medications are not billable under the California Medi-Cal pharmacy benefit program (Medi-Cal Rx). Certain PAD drugs require prior authorization (PA) to ensure medical necessity prior to receiving the drug therapy. Any request for a PAD medication (administered at a provider's office or infusion / hospital facility) via Procedure Code (i.e., J-Code) requiring a PA must be submitted using the PA 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.

For a list of PADs that require submission of a PA Treatment Request Form, please refer to GCHP's List of Services Requiring PA (see list of injectables on page 5). This list allows providers to look at specific PAD codes that require PA.

Completing a PA 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 State of CA Medi-Cal FFS for authorization consideration and reimbursement for both pharmacy and medical claims.

Drug Use Review (DUR) Educational Articles

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

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

The following educational article has been recently published since the last GCHP Pharmacy Newsletter:

- Alternatives to Diphenhydramine for Older Adults - January 2024

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

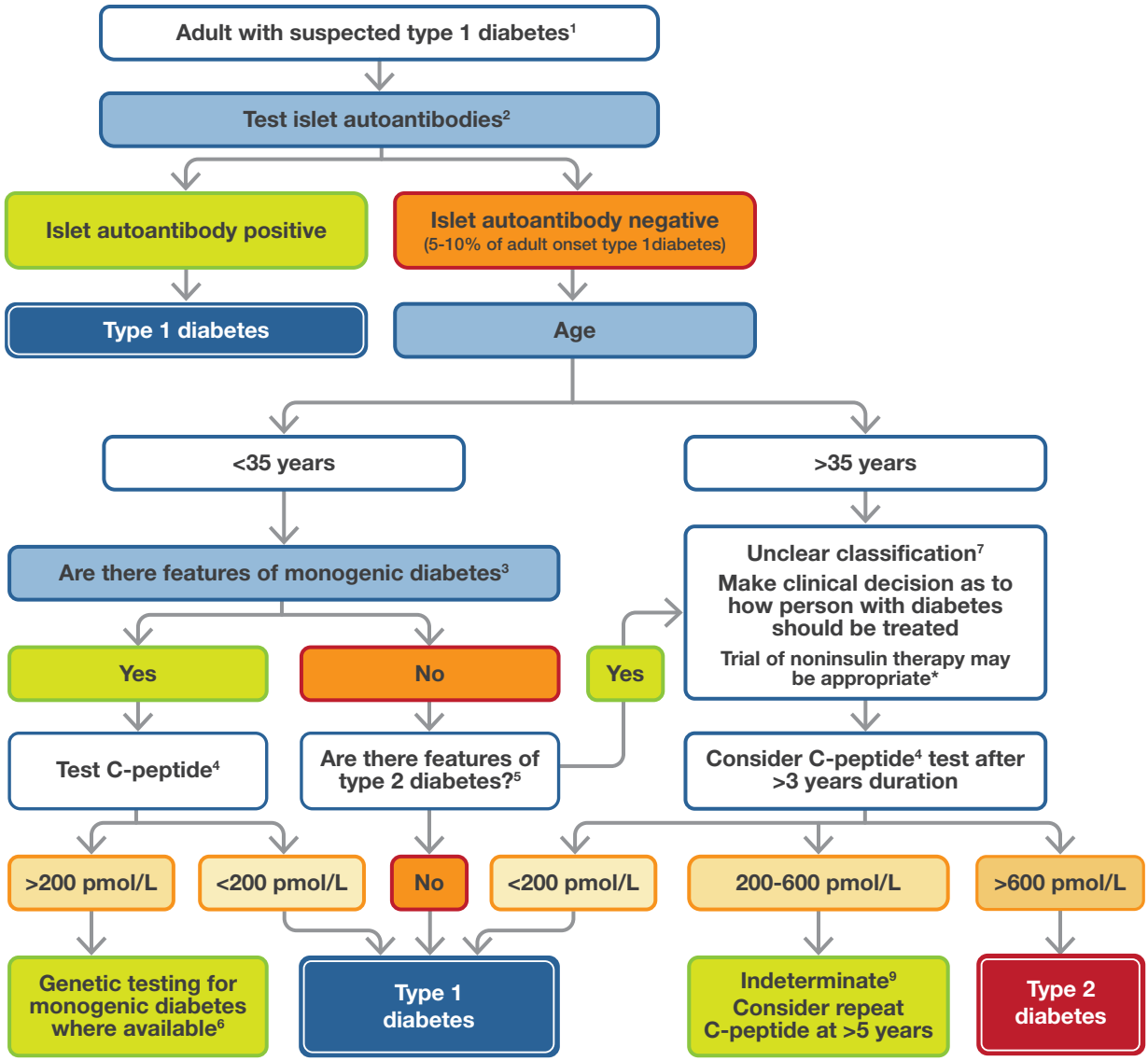
Summary of Revisions: Standards of Care in Diabetes – 2024

The American Diabetes Association recently published the updated Standards of Care in Diabetes-2024 guidelines. A summary of the revisions is provided below.

Investigating for Type 1 Diabetes

- Misdiagnosis is common and can occur in ~40% of adults with new type 1 diabetes.
- Incidence and prevalence of type 1 diabetes are increasing.
- Screening for presymptomatic type 1 diabetes may be done by detection of autoantibodies to insulin, glutamic acid decarboxylase (GAD), islet antigen 2 (IA-2), or zinc transporter 8 (ZnT8).
- Standardized islet autoantibody tests are recommended for classification of diabetes in adults who have phenotypic risk factors that overlap with those for type 1 diabetes (e.g., younger age at diagnosis, unintentional weight loss, ketoacidosis, or short time to insulin treatment).
- Use AABBCC approach:
  - Age < 35 years old
  - Autoimmunity: Personal or family history of autoimmune disease or polyglandular autoimmune syndromes
  - Body habitus: BMI < 25 kg/m2
  - Background: Family history of type 1 diabetes
  - Control: Level of glucose control on noninsulin therapies
  - Comorbidities: Treatment with immune checkpoint inhibitors for cancer can cause acute autoimmune type 1 diabetes.

Flow chart for investigation of suspected type 1 diabetes in newly diagnosed adults, based on date from white European populations



Role of Certain Medications that can Increase the Risk of Pre-Diabetes and Type 2 Diabetes

- Consider screening people for prediabetes or diabetes if on medications such as
  - » Glucocorticoids
  - » Statins: May increase the risk of diabetes in people at high risk of developing type 2 diabetes
  - » Thiazide diuretics,
  - » Some HIV medications:
    - PIs (protease inhibitors): Associated with insulin resistance and may also lead to apoptosis of pancreatic B-cells,
    - NRTIs (nucleoside / nucleotide reverse transcriptase inhibitors): Affect fat distribution, which is associated with insulin resistance
  - » Second-generation antipsychotic medications: e.g., olanzapine, clozapine, quetiapine, or risperidone. Screen at baseline, 12-16 weeks after initiation, then annually.

Immunizations: Added RSV for adults over 60

- The U.S. Food and Drug Administration (FDA) approved the vaccines for prevention of RSV (respiratory syncytial virus)-associated lower respiratory tract disease in adults aged ≥ 60 years in 2023.
- On June 21, 2023, Advisory Committee on Immunization Practices (ACIP) voted to recommend that adults ≥ 60 years ***may*** receive a single dose of an RSV vaccine, using shared decision-making.
- Adults ≥ 60 years with diabetes are at high risk for severe RSV disease and would most likely benefit from the vaccination.

Diabetes-Specific Risk Factors for Fracture (Bone Health)

- Age-specific fracture risk is significantly increased in people with type 1 or type 2 diabetes in both sexes, with a 34% increase in fracture risk compared with those without diabetes.
- Fracture risk should be assessed in older adults with diabetes as a part of a routine care.
- Monitor bone mineral density using dual-energy X-ray absorptiometry of high-risk older adults with diabetes age >65 years and younger individuals with diabetes and multiple risk factors every 2-3 years.
- Daily Calcium + vitamin D supplementation should be recommended for those at risk for fracture.
- Antiresorptive medications and osteoanabolic agents should be considered for people with diabetes who have low bone mineral density with a T-score ≤-2.0 or have experienced fragility fractures.
- To reduce the risk of falls and fractures, prioritize use of glucose-lowering medications that are associated with low risk of hypoglycemia to avoid falls.

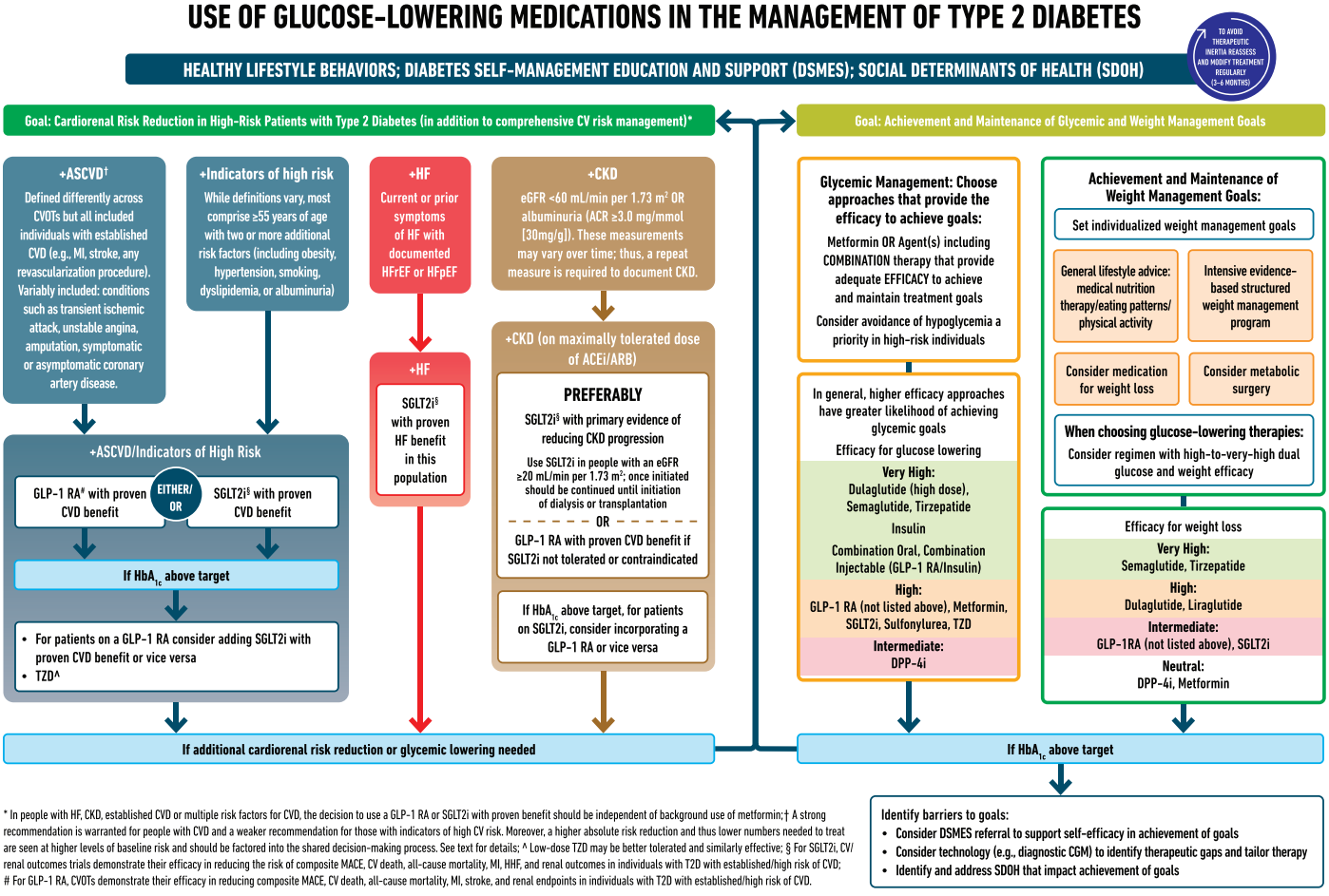
Continuous Glucose Monitors (CGMs)

- CGM should be offered in:
  - Type 1 diabetes early in the disease, even at time of diagnosis
  - Adults with diabetes on multiple daily injections (MDI) or continuous subcutaneous infusion insulin (CSII)
  - Adults with diabetes on basal insulin
  - Youth with type 1 diabetes on MDI or CSII
  - Youth with type 2 diabetes on MDI or CSII
- Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in the successful use of devices.
- Patients should be educated on potential interfering substances and other factors that may affect accuracy.

Pharmacologic Approaches to Glycemic Treatment

- For adults with type 1 diabetes:
  - Early use of CGM is recommended.
  - Automated insulin delivery system should be considered.
  - Insulin treatment plan and insulin-taking behavior should be reevaluated at regular intervals (e.g., every 3-6 months).
- For adults with type 2 diabetes:
  - Consider the effects on cardiovascular and renal comorbidities; effectiveness; hypoglycemic risk; impact on weight, cost and access; risk for adverse reactions and tolerability; and individual preferences.
  - Consider approaches that support weight management goals.
- For adults with established or high risk of atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease:
  - With established or high risk of atherosclerotic cardiovascular disease, heart failure and/or CKD (chronic kidney disease), the treatment plan should include agents that reduce cardiovascular and kidney disease risk [e.g., SGLT2i (sodium-glucose cotransporter 2 inhibitor) and/or GLP-1 RA (glucagon-like peptide 1 receptor agonist)]
  - With heart failure, an SGLT-2 inhibitor is recommended.
  - With CKD with eGFR 20-60 mL/min/1.73m2, SGLT2i is recommended but the glycemic benefits are reduced at eGFR < 45 mL/min/1.73m2.
  - With advanced CKD with eGFR < 30 mL/min/1.73m2, GLP-1 RA is preferred for glycemic management due to lower risk of hypoglycemia and for cardiovascular event reduction.

- GLP-1 RA or dual GIP (glucose-dependent insulinotropic polypeptide)/GLP-1 RA agents are preferred to insulin.
- When insulin is used, combination therapy with GLP-1RA or dual GIP/GLP-1RA is recommended for greater glycemic effectiveness as well as beneficial effects on weight and hypoglycemia risk.



Cardiovascular Disease and Risk Management

- Consider screening for coronary artery disease in any of the following:
  - Atypical cardiac symptoms
  - Signs or symptoms of associated vascular disease including carotid bruits, transient ischemic attack, stroke, claudication, or PAD
  - Electrocardiogram abnormalities
- Consider screening adults with diabetes for heart failure by measuring B-type natriuretic peptide (BNP) or N-terminal pro-BNP (NT-proBNP), since adults with diabetes are at increased risk for the development of asymptomatic cardiac structural or functional abnormalities or symptomatic heart failure.
- Screening for PAD with ankle-brachial index testing is recommended in asymptomatic individuals with diabetes and age >50 years, microvascular disease in any location, or foot complications or any end-organ damage from diabetes.

Chronic Kidney Disease and Risk Management

- Assess urinary albumin (e.g., spot urinary albumin-to-creatine ration [UACR]) and estimated glomerular filtration rate (eGFR) at least annually in people with type 1 diabetes with duration of >5 years and in all people with type 2 diabetes.

- Monitor urinary albumin and eGFR 1-4 times per year depending on the stage of the kidney disease in people with established chronic kidney disease (CKD).

Older Adults

- Screening for early detection of mild cognitive impairment or dementia should be performed for adults 65 years of age or older at the initial visit, annually and as appropriate since older adults with diabetes are at higher risk of cognitive decline and institutionalization.
- Older adults with type 1 diabetes, CGM is recommended to reduce hypoglycemia.
- Older adults with type 2 diabetes on insulin therapy, consider CGM to improve glycemic outcomes and reduce hypoglycemia.
- Episodes of hypoglycemia should be ascertained and addressed at routine visits since older adults with diabetes have a greater risk of hypoglycemia especially when treated with hypoglycemic agents (e.g., sulfonylureas, meglitinides, & insulin).

Children and Adolescents

- Youth with overweight / obesity and type 2 diabetes and their families should be provided with developmentally and culturally appropriate comprehensive lifestyle programs that are integrated with diabetes management to achieve at least a 7-10% decrease in excess weight.
- Elicit a smoking history at initial and follow-up diabetes visits; discourage smoking in youth who do not smoke and encourage smoking cessation in those who do smoke.
- Electronic cigarette use should be discouraged.

Management of Diabetes in Pregnancy

- Glycemic Goals in Pregnancy
  - » Fasting, pre- and post-prandial blood glucose monitoring are recommended in individuals with diabetes in pregnancy to achieve optimal glucose levels. Glucose goals are fasting plasma glucose <95 mg/dL (<5.3 mmol/L) and either 1-h postprandial glucose <140 mg/dL (<7.8 mmol/L) or 2-h postprandial glucose <120 mg/dL (<6.7 mmol/L).
  - » Due to increased red blood cell turnover, A1C is slightly lower during pregnancy in people with and without diabetes. Ideally, the A1C goal in pregnancy is <6% (<42 mmol/mol) if this can be achieved without significant hypoglycemia, but the goal may be relaxed to <7% (<53 mmol/mol) if necessary to prevent hypoglycemia.
  - » When used in addition to pre- and post-prandial blood glucose monitoring, continuous glucose monitoring (CGM) can help to achieve the A1C goal in diabetes and pregnancy.
  - » CGM is recommended in pregnancies associated with type 1 diabetes. When used in addition to blood glucose monitoring, achieving traditional pre- and post-prandial goals, real-time CGM can reduce the risk for large-for-gestational age infants and neonatal hypoglycemia in pregnancy complicated by type 1 diabetes.
- Management of Gestational Diabetes Mellitus
  - » Lifestyle behavior change is an essential component of management of gestational diabetes mellitus (GDM) and may suffice as treatment for many individuals. Insulin should be added if needed to achieve glycemic goals.
  - » Insulin is the preferred medication for treating hyperglycemia in GDM. Metformin and glyburide, individually or in combination, should not be used as first-line agents, as both cross the placenta to the fetus. Other oral and noninsulin injectable glucose-lowering medications lack long-term safety data.
  - » Metformin, when used to treat polycystic ovary syndrome and induce ovulation, should be discontinued by the end of the first trimester.
  - » Telehealth visits used in combination with in-person visits for pregnant people with GDM can improve outcomes compared with standard in-person care alone.
- For more information, click here.

Contract Drugs List (CDL) per Medi-Cal Rx

Here is a comprehensive list of all the pharmacologic agents that can be used in the management of diabetes. The ones that are marked with an asterisk (*) indicate that a prior authorization (PA) is required to be reviewed for medical necessity by Medi-Cal Rx. If a medication is not listed on the Contract Drugs List (CDL), the medication is currently not covered / preferred by Medi-Cal Rx. However, you can still try to submit a PA to justify medical necessity for approval, if appropriate.

To access the complete and most up-to-date Contract Drugs List, click here.

Therapeutic Drug Class	Generic Name (Brand Name)	Strength / Package Size
Biguanides	Metformin (Glucophage)	IR: 500 mg, 850 mg, 1000 mg ER: 500 mg, 750 mg, 1000 mg Solution, Oral: 100 mg/ml
Sulfonylureas	Glimepiride (Amaryl)	1 mg, 2 mg, 4 mg
	Glipizide (Glucotrol)	IR: 5 mg 10 mg ER: 2.5 mg, 5 mg, 10 mg
	Glyburide (Glynase)	IR: 1.25 mg, 2.5 mg, 5 mg Micronized: 1.5 mg, 3 mg, 6 mg
Thiazolidinedione	Pioglitazone (Actos)	15 mg, 30 mg, 45 mg
a-Glucosidase inhibitors	Acarbose (Precose)	25 mg, 50 mg, 100 mg
	Miglitol (Glyset)	25 mg, 50 mg, 100 mg
Meglitinides	Nateglinide (Starlix)	60 mg, 120 mg
	Repaglinide (Prandin)*	0.5 mg, 1 mg, 2 mg
DPP-4 Inhibitors	Alogliptin (Nesina)	6.25 mg, 12.5 mg, 25 mg
	Saxagliptin (Onglyza)	2.5 mg, 5 mg
	Linagliptin (Tradjenta)	5 mg
	Sitagliptin (Januvia)	25 mg, 50 mg, 100 mg
SGLT2 Inhibitors	Ertugliflozin (Steglatro)*	5 mg, 15 mg
	Dapagliflozin (Farxiga)	5 mg, 10 mg
	Canagliflozin (Invokana)	100 mg, 300 mg
	Empagliflozin (Jardiance)	10 mg, 25 mg

Therapeutic Drug Class	Generic Name (Brand Name)	Strength / Package Size
GLP-1 Receptor Agonists	Exenatide (Byetta) Exenatide ER (Bydureon BCise)	250mcg/ml, 1.2ml, 250mcg/ml, 2.4ml ER: 2mg/pen, 0.85ml
	Dulaglutide (Trulicity)	0.75 mg/0.5 ml, 1.5 mg/0.5 ml, 3 mg/0.5 ml, 4.5 mg/0.5 ml
	Semaglutide (Ozempic)	0.25-0.5 mg/dose (2mg/1.5 ml), 0.25-0.5mg/dose (2mg/3ml), 1 mg/dose (2mg/1.5 ml), 1 mg/dose (4mg/3 ml), 2 mg/dose (8mg/3 ml)
	Semaglutide oral tab (Rybelsus)	3 mg, 7 mg, 14 mg
	Liraglutide (Victoza)	18 mg/3ml
GLP-1/GIP dual agonist	Tirzepatide (Mounjaro)*	2.5 mg/0.5 mL (0.5 mL); 5 mg/0.5 mL (0.5 mL); 7.5 mg/0.5 mL (0.5 mL); 10 mg/0.5 mL (0.5 mL); 12.5 mg/0.5 mL (0.5 mL); 15 mg/0.5 mL (0.5 mL)
Dopamine-2 agonist	Bromocriptine (Cycloset)*	0.8 mg
Amylin mimetic	Pramlintide (Symlin)	60 Pen injector: 1.5 ml 120 Pen injector: 2.7 ml

Therapeutic Drug Class	Generic Name (Brand Name)	Strength / Package Size
Combinations	Alogliptin / metformin HCL (Kazano)	12.5 mg/500 mg, 12.5 mg/1000 mg
	Alogliptin / pioglitazone (Oseni)	12.5 mg/15 mg, 12.5 mg/30 mg, 12.5 mg/45 mg, 25 mg/15 mg, 25 mg/30 mg, 25 mg/45 mg
	Dapagliflozin / metformin HCL ER (Xigduo XR)	5 mg/500 mg, 5 mg/1000 mg, 10 mg/500 mg, 10 mg/1000 mg
	Empagliflozin / linagliptin (Glyxambi)	10 mg/5 mg, 25 mg/5 mg
	Empagliflozin / linagliptin / metformin (Trijardy XR)	5mg/2.5mg/1000 mg, 10mg/5mg/1000 mg, 12.5mg/2.5mg/1000 mg, 25mg/5mg/1000 mg
	Empagliflozin / metformin (Synjardy, Synjardy XR)	IR: 5 mg/500 mg, 5 mg/1000 mg, 12.5 mg/500 mg, 12.5 mg/1000 mg ER: 5 mg/1000 mg, 10 mg/1000 mg, 12.5 mg/1000 mg, 25 mg/1000 mg
	Glipizide / metformin HCL (Metaglip)	2.5 mg/250 mg, 2.5 mg/500 mg, 5 mg/500 mg
	Glyburide / metformin HCL (Glucovance)	1.25 mg/250 mg, 2.5 mg/500 mg, 5 mg/500 mg
	Linagliptin / metformin HCL (Jentadueto, Jentadueto XR)	IR: 2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg ER: 2.5 mg/1000 mg, 5 mg/1000 mg
	Pioglitazone / glimepiride (Duetact)	30 mg/2 mg, 30 mg/4 mg
	Pioglitazone / metformin HCL (Actoplus Met)	15 mg/500 mg, 15 mg/850 mg
	Saxagliptin / metformin HCL (Kombiglyze XR)	2.5 mg /1,000 mg, 5 mg/500 mg, 5 mg /1,000 mg
	Sitagliptin / metformin HCL (Janumet, Janumet XR)	IR: 50 mg/500 mg, 50 mg/1000 mg ER:50 mg/500 mg, 50 mg/1000 mg, 100 mg/1000 mg

Therapeutic Drug Class	Generic Name (Brand Name)	Strength / Package Size
Insulin	Injection, concentrated, USP (rDNA Origin) regular (Humulin R U-500)	Vial: 500 units/ml, 20 ml Prefilled pen: 500 units/ml, 3ml x 2
	Insulin Glargine (rDNA Origin) (Lantus)	Vial: 100 units/ml, 10 ml Prefilled pen: 100 units/ml, 3 ml x 5
	Insulin Glargine-YFGN (Semglee)	Vial: 100 units/ml, 10 ml Prefilled pen: 100 units/ml, 3 ml x 5
	Insulin Aspart (Novolog)	Cartridge: 100 units/ml, 3 ml x 5 Vial: 100 units/ml, 10 ml Prefilled pen: 100 units/ml, 3 ml x 5
	Insulin Aspart (niacinamide) (Fiasp)	Cartridge: 100 units/ml, 3 ml x 5 Vial: 100 units/ml, 10 ml Prefilled pen: 100 units/ml, 3 ml x 5
	Insulin Aspart Protamine Suspension / Insulin Aspart, (rDNA Origin) (Novolog Mix)	Vial: 100 units/ml, 10 ml Prefilled pen: 100 units/ml, 3 ml x 5
	Insulin Degludec (Tresiba)	Vial: 100 units/ml Prefilled pen: 100 units/ml, 3 ml x 5 or 200 units/ml, 3 ml x 3
	Insulin Detemir (rDNA Origin) (Levemir)	Vial: 100 units/ml Prefilled pen: 100 units/ml, 3 ml x 5
	Insulin Lispro (rDNA Origin) (Humalog)	Cartridge: 100 units/ml, 3 ml x 5 Vial: 100 units/ml, 3ml or 10 ml Prefilled pen: 100 units/ml, 3 ml x 5
	Insulin Lispro Protamine / Insulin Lispro (rDNA Origin) (Humalog Mix)	Vial: 100 units/ml, 10 ml Prefilled pen: 100 units/ml, 3 ml x 5

Note: Those marked with an asterisk (*) indicate that a PA is required: the PA list is subject to change at any time.

Pharmacologic Agents Used to Treat Hypoglycemia

Therapeutic Drug Class	Generic Name (Brand Name)	Strength / Package Size
Hypoglycemia Antidote	Glucagon (R-DNA Origin) (Glucagon Emergency Kit)	1 mg/vial
	Glucagon (synthetic) • Baqsimi (nasal powder) • Gvoke (prefilled auto-injector, prefilled syringe) • GlucaGen HypoKit (single-dose vial, syringe kit)	Nasal Powder: 3 mg Prefilled Auto-Injector: 0.5 mg/0.1ml, 1.0 mg/0.2 ml Prefilled Syringe: 0.5 mg/0.1 ml, 1.0 mg/0.2 ml Single-dose vial / syringe kit: 1 mg/0.2 ml
	Dasiglucagon HCL (Zegalogue)	Single Dose Auto-injector or Single Dose Prefilled Syringe: 0.6 mg/0.6 ml

Note: The CDL is subject to change at any time. Medi-Cal Rx typically makes updates at the beginning of every month.

Diabetes vs. Chronic Weight Management FDA Indications for GLP-1 RA & GIP / GLP-1 RA

Note: Only certain GLP-1 RA's and GIP / GLP-1 RA are **FDA approved** for chronic weight management.

FDA Approved for Type 2 Diabetes		FDA Approved for Chronic Weight Management	
Drug Name	**Usual Dose**	**Drug Name**	**Usual Dose**
Dulaglutide (Trulicity)	0.75 mg SC once weekly. Titrate dose every four weeks up to maximum of 4.5 mg once weekly	------	------
Exenatide IR (Byetta)	5 mcg SC twice daily. Titrate dose after one month up to 10 mcg twice daily	------	------
Exenatide ER (Bydureon BCise)	2 mg SC every seven days	------	------
Liraglutide **(Victoza)**	0.6mg SC once daily. Titrate dose every seven days up to maximum of 1.8 mg daily.	Liraglutide **(Saxenda)**	0.6 mg SC once daily. Titrate dose every seven days up to maximum of 3 mg daily.
Semaglutide **(Ozempic)**	0.25 mg SC once weekly. Titrate dose every four weeks up to maximum of 2 mg once weekly.	Semaglutide **(Wegovy)**	0.25 mg SC once weekly. Increase dose every four Titrate dose up to maximum of 2.4 mg once weekly.

FDA Approved for Type 2 Diabetes		FDA Approved for Chronic Weight Management	
Drug Name	**Usual Dose**	**Drug Name**	**Usual Dose**
Semaglutide oral (Rybelsus)	3 mg by mouth once daily. Titrate dose every 30 days up to maximum of 14 mg daily.	------	------
Tirzepatide **(Mounjaro*)**	2.5 mg SC once weekly. Titrate dose every four weeks up to maximum of 15 mg once weekly.	Tirzepatide **(Zepbound*)**	2.5 mg SC once weekly. Titrate dose every four weeks up to maximum of 15 mg once weekly.

***Note:** PA is required to justify medical necessity, per Medi-Cal Rx.

Chronic Disease Self-Management Program

Gold Coast Health Plan (GCHP) offers free Chronic Disease Self-Management Program (CDSMP) workshops to members over 18 years of age with a chronic health condition, such as arthritis, diabetes, heart disease, depression, obesity, pain and more.

For more information, please review the CDSMP flyer (available in English and Spanish) and share it with GCHP members.

Free Workshop for Gold Coast Health Plan Members

Chronic Disease Self-Management Program

Gold Coast Health Plan (GCHP) offers free Chronic Disease Self-Management Program (CDSMP) workshops to members over the age of 18 with a chronic health condition. A chronic health condition is one that lasts for a long time, such as arthritis, diabetes, heart disease, depression, obesity, pain and more. The workshop can teach you how to control and manage your symptoms.

Workshops will be held once a week for six weeks. Members can choose between a virtual or telephonic workshop. The virtual workshop is 2.5 hours each week, and the telephonic workshop is 30 minutes each week.

In the workshop, you will learn about:

- Making a weekly action plan
- Healthy eating
- Physical activity and exercise
- Medication usage

Participants will get:

- "Living a Healthy Life with Chronic Conditions" book
- Class handouts
- Relaxation CD
- Refillable water bottle
- Backpack
- Lunch bag

Sign up now for CDSMP workshops to gain the self-confidence to take charge of your health.

Call the Health Education Department at **1-805-437-5718**, Monday through Friday, 8 a.m. to 5 p.m. (except holidays). If you use a TTY, cal **711**. You can also email **HealthEducation@goldchp.org**. For more information, visit the GCHP website, **www.goldcoasthealthplan.org**.

Gold Coast Health Plan℠
A Public Entity

Taller gratis para miembros de Gold Coast Health Plan

Programa Tomando Control de su Salud

Gold Coast Health Plan (GCHP) ofrece talleres gratis de Tomando Control de su Salud (CDSMP, por sus siglas en inglés) para miembros mayores de 18 años con una condición médica crónica. Una condición médica crónica es la que dura mucho tiempo, como artritis, diabetes, enfermedades cardíacas, depresión, obesidad, dolor y muchas más. El taller puede enseñarle cómo controlar y manejar sus síntomas.

Los talleres se harán una vez a la semana durante seis semanas. Los miembros pueden elegir entre un taller virtual o por teléfono. El taller virtual es de 2.5 horas por semana y el taller por teléfono es de 30 minutos por semana.

En el taller aprenderá sobre:

- Cómo hacer un plan de acción semanal
- La alimentación saludable
- La actividad física y el ejercicio
- El uso de medicamentos

Los participantes recibirán:

- El libro "Tomando control de su salud"
- Folletos de la clase
- CD de relajación
- Botella de agua recargable
- Mochila
- Bolsa del almuerzo

Regístrese ahora al taller Tomando Control de su Salud para ganar confianza en sí mismo y hacerse cargo de su salud.

Llame al Departamento de Educación para la Salud al **1-805-437-5718**, de lunes a viernes, de **8 a.m.** a **5 p.m.** (excepto días festivos). Si usa un TTY, llame al **711**. También puede enviar un correo electrónico a **HealthEducation@goldchp.org**. Para más información, visite el sitio web de GCHP, **www.goldcoasthealthplan.org**.

Gold Coast Health Plan℠
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Prior Authorization Overview and Tips

Certain medications require prior authorization (PA) before coverage can be applied. The provider should contact Medi-Cal Rx to initiate a PA. Medi-Cal Rx allows requests to be initiated via the following methods:

- NCPDP P4 – Request Only
- Medi-Cal Rx Provider Portal
- CoverMyMeds
- Fax
- U.S. Mail

Note: Phone requests are not accepted, and members cannot initiate a PA for themselves.

To make the most of your request, the following tips may be useful in facilitating an authorization:

- **Check the CDL** before writing a new prescription. If the drug is not listed, it will require a PA.
- **Review Code 1 restrictions** If the medication is listed on the CDL but has restrictions noted in the "Code 1" column, you should document the required information on the prescription hard copy and the pharmacy can override at point of service. **If the patient does not meet the code 1 restriction indicated on the CDL, a PA will be required.**
- **Consider switching to a covered alternative drug** if the medication you are considering requires PA. In most cases, Medi-Cal Rx will require a trial of covered medications before approving a drug not listed on the CDL.
- **Request a PA** if switching to a covered alternative is not an option.
- **Be specific in your request** by including all relevant information in your original PA request. It is always best to include all the following details for the best outcome:
  - Drug name, strength, quantity, and directions
  - Indicate BOTH the ICD-10 diagnosis code and description of the code
  - Document prior treatment history
  - Prescriber rationale. Be specific. If the patient has experienced adverse effects, allergies, or other toxicities, you should document this in your request.
  - If continuation of therapy, be sure to document the date patient starting using the medication and include detriments of discontinuing or changing the medication.

If a PA is denied, you may submit an appeal to Medi-Cal Rx. Providers have 180 days from the denial date to request an appeal.

FDA Alerts

FDA New Drug Approvals

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

Brand Name	Generic Name	Dosage Form	Summary of Indication
ZITUVIMET	*Sitagliptin; metformin hydrochloride*	Oral tablet	Combination of sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (hcl), a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
DEFENCATH	*Taurolidine and heparin sodium*	Injectable	Combination of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC).
AUGTYRO	*Repotrectinib*	Oral capsule	Kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).
TRUQAP	*Capivasertib*	Oral tablet	Kinase inhibitor indicated, in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with one or more PIK3CA / AKT1 / PTEN-alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.
RYZNEUTA	*Efbemalenograstim alfa-vuxw*	Injectable	Leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
OGSIVEO	*Nirogacestat*	Oral tablet	Gamma secretase inhibitor indicated for adult patients with progressing desmoid tumors who require systemic treatment.

Brand Name	Generic Name	Dosage Form	Summary of Indication
ALVAIZ	*Eltrombopag choline*	Oral tablet	Thrombopoietin receptor agonist indicated for the treatment of: • Thrombocytopenia in adult and pediatric patients 6 years of age and older with persistent or chronic immune thrombocytopenia (itp) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. • Thrombocytopenia in adult patients with chronic hepatitis c to allow the initiation and maintenance of interferon-based therapy. • Adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.
PHYRAGO	*Dasatinib*	Oral tablet	Kinase inhibitor indicated for the treatment of: • Newly diagnosed adults with philadelphia chromosome-positive (ph+) chronic myeloid leukemia (cml) in chronic phase. • Adults with chronic, accelerated, or myeloid or lymphoid blast phase ph+ cml with resistance or intolerance to prior therapy including imatinib. • Adults with philadelphia chromosome-positive acute lymphoblastic leukemia (ph+ all) with resistance or intolerance to prior therapy.
FABHALTA	*Iptacopan hydrochloride*	Oral capsule	Complement Factor B Inhibitor; Complement Inhibitor indicated for Paroxysmal nocturnal hemoglobinuria
AVZIVI	*Bevacizumab-tnjn*	Injectable	Antineoplastic Agent, Monoclonal Antibody; Antineoplastic Agent, Vascular Endothelial Growth Factor (VEGF) Inhibitor; Vascular Endothelial Growth Factor (VEGF) Inhibitor indicated for: • Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment. • Metastatic colorectal cancer, in combination with fluoropyrimidineirinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.

Brand Name	Generic Name	Dosage Form	Summary of Indication
			• Unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment. • Recurrent glioblastoma in adults. • Metastatic renal cell carcinoma in combination with interferon alfa. • Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan. • Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than two prior chemotherapy regimens.
IWILFIN	*Eflornithine*	Oral tablet	Ornithine decarboxylase inhibitor indicated to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.
ZORYVE	*Roflumilast*	Topical foam	Phosphodiesterase 4 inhibitor indicated for seborrheic dermatitis.
WAINUA	*Eplontersen sodium*	Injectable	Transthyretin-directed antisense oligonucleotide indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis.
ZELSUVMI	*Berdazimer*	Topical gel	Nitric oxide (NO)-releasing agent indicated for molluscum contagiosum (MC).

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
PROVAYBLUE *(methylene blue)*	Boxed Warning	**WARNING: SEROTONIN SYNDROME WITH CONCOMITANT USE OF SEROTONERGIC DRUGS AND OPIOIDS** PROVAYBLUE® may cause serious or fatal serotonergic syndrome when used in combination with serotonergic drugs and opioids. Avoid concomitant use of PROVAYBLUE® with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), monoamine oxidase inhibitors (MAOIs) and opioids.
LYSODREN *(mitotane)*	Boxed Warning	**WARNING: ADRENAL CRISIS IN THE SETTING OF SHOCK, SEVERE TRAUMA OR INFECTION** Patients treated with LYSODREN are at increased risk for developing adrenal crisis in the setting of shock, severe trauma or infection that may lead to death.
ASPARLAS *(calaspargase pegol-mknl)*	Contraindications	ASPARLAS is contraindicated in patients with: • History of serious hypersensitivity reactions, including anaphylaxis, to pegylated L-asparaginase therapy • History of serious pancreatitis during previous L-asparaginase • History of serious thrombosis during previous L-asparaginase therapy • History of serious hemorrhagic events during previous L-asparaginase therapy • Severe hepatic impairment
LESCOL XL *(fluvastatin sodium)*	Contraindications	LESCOL XL is contraindicated in patients with acute liver failure or decompensated cirrhosis.
IXIFI *(infliximab-qbtx)* RENFLEXIS *(infliximab-abda)*	Contraindications	The use of IXIFI at doses >5 mg/kg is contraindicated in patients with moderate or severe heart failure.
LYSODREN *(mitotane)*	Boxed Warning	**WARNING: ADRENAL CRISIS IN THE SETTING OF SHOCK, SEVERE TRAUMA OR INFECTION** Patients treated with LYSODREN are at increased risk for developing adrenal crisis in the setting of shock, severe trauma or infection that may lead to death. If shock, severe trauma or infection occurs or develops, temporarily discontinue LYSODREN and administer exogenous steroids. Monitor patients closely for infections and instruct patients to contact their physician immediately if injury, infection, or any other concomitant illness occurs.

Drug	Type of Change	Change
METAXALONE	Contraindications	The use of Metaxalone Tablets, 640 mg is contraindicated in patients with: • Known hypersensitivity to any components of this product. • Known tendency for drug-induced, hemolytic, or other anemias. • Severe renal or hepatic impairment.
PROLIA *(denosumab)*	Boxed Warning	**WARNING: SEVERE HYPOCALCEMIA IN PATIENTS WITH ADVANCED KIDNEY DISEASE** • Patients with advanced chronic kidney disease (eGFR <30 mL/min/1.73 m2), including dialysis-dependent patients, are at greater risk of severe hypocalcemia following Prolia administration. Severe hypocalcemia resulting in hospitalization, life-threatening events and fatal cases have been reported. • The presence of chronic kidney disease-mineral bone disorder (CKD-MBD) markedly increases the risk of hypocalcemia in these patients. • Prior to initiating Prolia in patients with advanced chronic kidney disease, evaluate for the presence of CKD-MBD. Treatment with Prolia in these patients should be supervised by a health care provider with expertise in the diagnosis and management of CKD-MBD.
SOTYLIZE *(sotalol hydrochloride)*	Contraindications	For the treatment of AFIB / AFL or ventricular arrhythmias, SOTYLIZE is contraindicated in patients with: • Baseline QT interval 450 msec. • Sinus bradycardia, sick sinus syndrome, second- and third-degree AV block, unless a functioning pacemaker is present. • Congenital or acquired long QT syndromes. • Cardiogenic shock or decompensated heart failure.

Drug Shortages

This section documents drug shortages that were updated in the past 30 days that affect the prescription benefit for Medi-Cal Rx. Click here to access this information on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Emgality *(galcanezumab-gnlm)*	Lilly	Lilly has Emgality on shortage due to increased demand. **Estimated Resupply Dates** Lilly has all Emgality presentations on intermittent back order and the company is releasing product as it becomes available.
Asmanex HFA *(mometasone furoate)*	Organon	Reason for the Shortage • Organon did not provide a reason for the shortage of Asmanex HFA. • Organon states Asmanex Twisthaler powder inhalers remain available. Available Products • Asmanex HFA inhalation aerosol, Organon, 100 mcg/actuation (120 metered actuations), 13 grams, metered dose inhaler, 1 count, NDC 78206-0112-01 • Asmanex HFA inhalation aerosol, Organon, 200 mcg/actuation (120 metered actuations), 13 grams, metered dose inhaler, 1 count, NDC 78206-0113-01 **Estimated Resupply Dates** Organon has Asmanex HFA 50 mcg/actuation inhalers on back order and the company estimates a release date in mid-Feb. 2024.
Levemir *(insulin detemir)*	NovoNordisk	Reason for the Shortage NovoNordisk is transitioning insulin detemir out of the U.S. market. **Estimated Resupply Dates** NovoNordisk is discontinuing insulin detemir. The Levemir FlexPens are expected to be depleted by April 2024. The Levemir vials are expected to be depleted by Dec. 2024.

Drug Product	Affected Manufacturers	Summary
Novolog *(insulin aspart)*	Novo Nordisk	Reason for the Shortage Novo Nordisk did not provide a reason for the shortage. The company did not provide availability information on Relion products. Available Products • Fiasp subcutaneous injection, Novo Nordisk, 100 units/mL, 10 mL multiple dose vial, 1 count, NDC 00169-3201-11 • Fiasp Flextouch subcutaneous injection, Novo Nordisk, 100 units/mL, 3 mL pen, 5 count, NDC 00169-3204-15 • Fiasp Penfill subcutaneous injection, Novo Nordisk, 100 units/mL, 3 mL pen, 5 count, NDC 00169-3205-15 • Insulin Aspart Penfill subcutaneous injection, Novo Nordisk, 100 units/mL, 3 mL pen, 5 count, NDC 73070-0102-15 • Novolog Flexpen subcutaneous injection, Novo Nordisk, 100 units/mL, 3 mL pen, 5 count, NDC 00169-6339-10 • Novolog Penfill subcutaneous injection, Novo Nordisk, 100 units/mL, 3 mL pen, 5 count, NDC 00169-3303-12 • Insulin Aspart subcutaneous injection, Novo Nordisk, 100 units/mL, 10 mL multiple dose vial, 1 count, NDC 73070-0100-11 **Estimated Resupply Dates** Novo Nordisk has insulin aspart Flexpens on intermittent back order and the company is releasing supplies as they become available. Novolog 10 mL vials are also on back order and the company estimates a release date of late-Jan. 2024.
Beyfortus *(nirsevimab-alip)*	Sanofi-Pasteur	Reason for the Shortage Sanofi-Pasteur has Beyfortus on shortage due to demand exceeding supply. Available Products There are no presentations available. **Estimated Resupply Dates** Sanofi-Pasteur has Beyfortus 50 mg/0.5 mL syringes and 100 mg/1 mL syringes on back order and the company cannot estimate a release date.

FDA Drug Safety Communications

This section includes drug alerts that were released in the last three months by the FDA that affect the Medi-Cal Rx prescription benefit. Click here to access any new and up to date information on the FDA website.

Drug	Communication Summary
Prolia *(denosumab)*	Based on a completed FDA review of available information, it has been concluded that the osteoporosis medicine Prolia (denosumab) increases the risk of severe hypocalcemia, very low blood calcium levels, in patients with advanced chronic kidney disease (CKD), particularly patients on dialysis. Severe hypocalcemia appears to be more common in patients with CKD who also have a condition known as mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia, severe hypocalcemia resulted in serious harm, including hospitalization, life-threatening events, and death. As a result, the FDA has revised Prolia prescribing information to include a new Boxed Warning, the FDA's most prominent warning, communicating this increased risk. Severe hypocalcemia can be asymptomatic or may present with symptoms that include confusion; seizures; irregular heart rhythm; fainting; face twitching; uncontrolled muscle spasms; or weakness, tingling, or numbness in parts of the body.
Glucagon-like Peptide-1 Receptor Agonists (GLP-1 RAs) **Adlyxin** *(lixisenatide)* **Bydureon BCise** *(exenatide)* **Byetta** *(exenatide)* **Mounjaro** *(tirzepatide)* **Ozempic** *(semaglutide)* **Rybelsus** *(semaglutide)* **Saxenda** *(liraglutide)* **Soliqua** *(lixisenatide and insulin glargine)* **Trulicity** *(dulaglutide)* **Victoza** *(liraglutide)* **Wegovy** *(semaglutide)* **Xultophy** *(liraglutide and insulin degludec)* **Zepbound** *(tirzepatide)*	The FDA has been evaluating reports of suicidal thoughts or actions in patients treated with medication in the glucagon-like peptide-1 receptor agonists (GLP-1 Ras) class. These medicines are used to treat people with type 2 diabetes or to help those with obesity or overweight to lose weight. The preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions. The FDA has conducted detailed reviews of reports of suicidality presented in the FDA Adverse Event Reporting System (FAERS) over the course of several months. Due to limited information and the possibility that the events could potentially be influenced by other factors, it was determined that the information reported did not demonstrate a clear relationship with the use of GLP-1 RAs. Likewise, the FDA concluded that the reviews of clinical trials, including large outcome and observational studies, did not indicate a solid relation with the use of GLP-1 Ras and the occurrence of suicidal thoughts or actions. However, because of the small number of suicidal thoughts or actions observed in both people using GLP-1 RAs and in the comparative control groups, they cannot definitively rule out that a small risk may exist; therefore, the FDA is continuing to investigate this issue. **Patients** should not stop taking GLP-1 RAs without first consulting their health care professional, as stopping these medicines may worsen their condition. Patients should talk to their health care professional if they have questions or concerns. They should tell their health care professional if they experience new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Patients should call or text 988 or go to the website at https://988lifeline.org/External Link Disclaimer, which provides free support for people in distress 24 hours a day, seven days a week. The current prescribing information for the GLP-1 RAs approved to treat patients with obesity or overweight contains information about the risk of suicidal thoughts and actions. This information is also included in the labels of other types of weight loss medicines and is based on reports of such events observed with a variety of older medicines used or tested for weight loss.

Drug	Communication Summary
Keppra, Keppra XR, Elepsia XR, Spritam *(levetiracetam)* **Onfi, Sympazan** *(clobazam)*	The FDA is warning that the antiseizure medicines levetiracetam (Keppra, Keppra XR, Elepsia XR, Spritam) and clobazam (Onfi, Sympazan), can cause a rare but serious reaction that can be life-threatening if not diagnosed and treated quickly. This reaction is called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). It may start as a rash but can quickly progress, resulting in injury to internal organs, the need for hospitalization, and even death. As a result, the FDA is requiring warnings about this risk to be added to the prescribing information and patient Medication Guides for these medicines. This hypersensitivity reaction to these medicines is serious but rare. DRESS can include fever, rash, swollen lymph nodes, or injury to organs including the liver, kidneys, lungs, heart, or pancreas.

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 the company name under the 'Company' column below to see the full alert.

Date	Drug Name	Recall Summary	Company	NDCs and Lot Numbers
11/24/2023	Sandimmune® Oral Solution (Cyclosporine Oral Solution, USP), 100 mg/mL	Novartis is conducting a voluntary nationwide recall at the consumer level of two lots of its Sandimmune® Oral Solution (cyclosporine oral solution, USP), 100 mg/mL in the U.S. due to crystal formation observed in some bottles, which could potentially result in incorrect dosing.	Novartis	0078-0110-22 Lot #: FX001500 (exp 09/2024) Lot #: FX001582 (exp 09/2024)

Gold Coast Health Plan℠
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For additional information, contact the
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