



**Gold Coast
Health Plan**SM
A Public Entity

Pharmacy Newsletter

DECEMBER 2019

Q1 2020

Table of Contents

SECTION 1: A Message from the Gold Coast Health Plan (GCHP) Pharmacy Director 3

SECTION 2: Notice: Changes to Pharmacy Prior Authorization Request Process 4

SECTION 3: Influenza Update 5

SECTION 4: Health Services Tobacco Cessation Program 7

SECTION 5: Formulary Changes 9

SECTION 6: Alerts from the U.S. Food and Drug Administration (FDA): FDA New Drug Approvals,
Drug Safety Labeling Changes, Drug Shortages, FDA Drug Safety Communications 10

A Message from the Gold Coast Health Plan Pharmacy Director



Anne Freese

Gold Coast Health Plan's (GCHP) Pharmacy Newsletter is designed to help providers stay current on updates to the Plan's formulary, new drug approvals, and safety labeling changes.

GCHP's goal is to provide all medically-necessary pharmaceuticals in the most economical way possible. The Plan's formulary was developed by the Pharmacy & Therapeutics (P & T) Committee. It is reviewed and updated quarterly due to advances in therapeutic treatment regimens and newly-approved products by the U.S. Food and Drug Administration (FDA).

GCHP wants to ensure that all drugs are available to its members when the drugs are indicated. To help manage drug utilization, the formulary employs several mechanisms: Step therapy protocols, prior authorizations, quantity limits, and age restrictions. Any drug that is limited or is not listed may be available via prior authorization.

At GCHP, we know that our providers are interested in providing the best care possible to their patients and the Plan's 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,

A handwritten signature in black ink, appearing to read 'Anne Freese', written in a cursive style.

Anne Freese, Pharm.D.
Director of Pharmacy

Notice: Changes to Pharmacy Prior Authorization Request Process

OptumRx will soon retire the current fax number used to submit pharmacy prior authorization requests for GCHP. THE CURRENT NUMBER, 1-800-527-0531, WILL BE RETIRED ON DEC. 31.

The new fax number for submitting prior authorization requests to OptumRx is 1-844-403-1029 and is currently in effect.

Phoned in requests are also still being accepted. To request a prior authorization by telephone, you may reach the OptumRx Prior Authorization team at 1-855-297-2870.

Electronic submission is also available and allows providers to:

- Spend more time with patients by reducing paperwork.
- Receive faster electronic decisions.
- Efficiently create renewals from previously submitted requests.
- Securely protect patient health information.

To submit an electronic prior authorization (ePA), [click here](#).

For more information, contact the OptumRx Prior Authorization team at 1-855-297-2870.

Influenza Season¹ Update

The Centers for Disease Control and Prevention (CDC) recently published its annual report: “[Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices – United States, 2019-20 Influenza Season.](#)” The CDC recommends annual influenza vaccination for everyone 6 months of age and older with any licensed, influenza vaccine that is appropriate for the recipient’s age and health status (IIV, RIV4, or LAIV4) with no preference expressed for any one vaccine over another. [Click here](#) for more information about the upcoming 2019-2020 flu season.

Antiviral Medications Recommended for Treatment and Chemoprophylaxis of Influenza¹

Drug	Activity Against	Use and Age Recommendations	Not Recommended for Use in	GCHP Coverage
Oseltamivir	Influenza A and B	Treatment: Any age	N/A	Generic oseltamivir with the following limits: <ul style="list-style-type: none"> • 75 mg: 10 caps / 30 days • 45 mg: 10 caps / 30 days • 30 mg: 20 caps / 30 days • Suspension: 180 ml / 30 days
		Chemoprophylaxis: 3 months of age or older	N/A	
Inhaled Zanamivir	Influenza A and B	Treatment: 7 years of age and older	People with underlying respiratory disease.	Relenza is covered up to one inhaler per month.
		Chemoprophylaxis: 5 years of age and older		
Intravenous Peramivir	Influenza A and B	Treatment: 2 years of age and older	N/A	Not covered.
		Chemoprophylaxis: Not recommended	N/A	
Oral Baloxavir	Influenza A and B	Treatment: 12 years of age and older	N/A	Xofluza is covered up to two doses per year (four capsules).
		Chemoprophylaxis: Not recommended	N/A	

Office Preparation Steps

These tips can help you protect your practice this flu season.

1. Refresh Diagnostic Skills

Promote influenza awareness in your practice to ensure staff recognizes the signs of flu. Rapid recognition is essential in managing influenza with antiviral therapy.^{2,3} Often, the onset of influenza is sudden. Fever, muscle aches, chills, and extreme tiredness are common symptoms and help differentiate influenza from other common respiratory viral infections, such as a cold.⁴

2. Make Time for Telephone Triage

Develop a practice protocol for telephone triage that will enable your office to:

- Prioritize visits for patients by severity of illness.
- Identify patients who are candidates for antiviral therapy.
- Assess if patients are taking over-the-counter medications for symptomatic relief.

3. Plan for Prompt Initiation of Treatment

Establish over the phone if a patient may be an appropriate candidate for antiviral treatment. Since early initiation is essential for treating influenza with antivirals, it is important to see the patient as soon as possible.^{2,3}

References:

1. Centers for Disease Control and Prevention. Influenza Antiviral Medications: Summary for Clinicians. <http://www.cdc.gov/flu/professionals/antivirals/summary-clinicians.htm>. Updated November 29, 2019. Accessed December 10, 2019
2. Centers for Disease Control and Prevention. Influenza symptoms and the Role of Laboratory Diagnostics. <http://www.cdc.gov/flu/professionals/diagnosis/labrolesprocedures.htm>. Updated December 9, 2011. Accessed October 2, 2014.
3. Centers for Disease Control and Prevention. Rapid Diagnostic Testing for Influenza: Information for Health Care Professionals. <http://www.cdc.gov/flu/professionals/diagnosis/rapidclin.htm>. Updated August 27, 2013. Accessed October 2, 2014.
4. National Institute of Allergy and Infectious Diseases. Is It a Cold or the Flu? Updated August 2014. Accessed October 2, 2014.

Health Services Tobacco Cessation Program

Gold Coast Health Plan's (GCHP) Health Education Department has launched an exciting new Tobacco Cessation Program. The department will follow up with members who have recently received prescriptions for nicotine replacement products and Chantix and provide resources and tips to encourage them to remain on track. The department will also be in contact with pharmacists and doctor's offices as a collaborative effort to help Plan members permanently stop smoking. For more information, contact GCHP's Health Education Department at 1-805-437-5718 or HealthEducation@goldchp.org. [Click here](#) for additional resources.

Save the Date! Register today for the Upcoming "Basic Tobacco Intervention Skills Certification Program"

GCHP invites medical and allied health care professionals to attend the "Basic Tobacco Intervention Skills Certification Program." The workshop will be held on Wednesday, Feb. 5, 2020 from 1 p.m. to 5 p.m. Pre-registration is required.

For more information, please contact GCHP's Health Education Department at 1-805-437-5718 or HealthEducation@goldchp.org.

Nicotine Dependence Treatment Continuing Education and Certification Program
Earn Certification to utilize evidence-based nicotine dependence interventions to help save a life!



Be A Lifesaver!

Evidence-based interventions that encourage quitting and prevent youth smoking continue to be underutilized.
 — a Report of the Surgeon General, 2014

WORKSHOP Basic Tobacco Intervention Skills Certification Program for Medical & Allied Health Professionals

Date Wednesday, February 5th, 2020

Time 1:00PM – 5:00PM

Location Ventura County Public Health
 2240 E. Gonzales Rd., Suite 200
 Oxnard, CA 93036

REGISTER TODAY!

This continuing education program teaches the pathophysiology of nicotine addiction, and utilizes case studies, audiovisual aids, and return practice demonstrations to equip point of care providers with information along with methods and techniques to prevent and/or treat nicotine dependence.

Instructed by Isabel Gómez, MPH
 HCA Training & Education Assistant
 Tobacco Education & Prevention Program

Pre-registration is **REQUIRED** please call 201-STOP (7867) or email callitquits@ventura.org
 Workshops is free – Certification/CEU fee is \$85.00



The Facts About
Juul E-Cigarettes

What is Juul?

Juul is a brand of e-cigarette that has skyrocketed in popularity among teens across the United States. Educators report an alarming level of Juul use in middle and high schools.

- A sleek, high tech e-cigarette that looks like USB flash drive and charges in a computer.
- Available in sweet flavors including mango, fruit and mint.
- Small enough to fit in a closed hand.
- A "Juul Pod" contains as much nicotine as a pack of cigarettes.
- Teens often refer to Juul use as "Juuling."
- Juul now has over 70% of the e-cigarette market.

What are the health risks of using Juul?

Juul is putting kids at risk of nicotine addiction and threatens to reverse decades of progress in reducing youth tobacco use.

- Juul use exposes kids to nicotine, which is highly addictive. More than 60% of young people who use Juul don't realize the product always contain nicotine.
- Nicotine can harm adolescent brain development, affecting attention, learning and susceptibility to addiction.
- E-cigarette use increases teens' likelihood of ever using regular cigarettes.

Visit tobaccofreekids.org/juul or truthinitiative.org to learn more.



Health Alert: Outbreak of Lung Injury Associated with E-Cigarette Use, Vaping

Health officials have reported an outbreak of serious vaping-related lung diseases. The number of vaping-related deaths continues to rise. Tobacco use, primarily the use of e-cigarettes or vaping devices, is a growing problem in the U.S., especially among younger populations.

The California Smokers' Helpline provides free services for help with smoking and vaping cessation. To order educational materials in English and Spanish, click here. For more information, call:

- English: 1-800-NO-BUTTS (1-800-662-8887)
- Spanish: 1-800-45-NO-FUME (1-800-456-6386)

New Tobacco Cessation Resource

The California Smokers' Helpline offers postcards that promote free Nicotine Replacement Therapy (NRT). To order these free materials, available in English and Spanish, click here or contact GCHP's Health Education Department for assistance at 1-805-437-5718 or HealthEducation@goldchp.org.

You Can Quit Smoking. We Can Help!



Doubles Your Chance of Quitting for Good

Enroll today for one-on-one support from caring, trained professionals. Services are available in English, Spanish, Chinese, Korean and Vietnamese. We have lots of tools to help you!

TELEPHONE COUNSELING
SELF-HELP MATERIALS
TEXT MESSAGING PROGRAM
FREE NICOTINE PATCHES*

*Free patches for qualified callers who are pregnant or have children under age 5, made possible by funding from First 5 California.

Hours
 Mon thru Fri, 7 am-9 pm and Sat, 9am-5pm

Call Today!


CALIFORNIA SMOKERS' HELPLINE
1-800-NO-BUTTS
(1-800-662-8887)
 Enroll Online
www.nobutts.org
[Facebook.com/nobutts.org](https://www.facebook.com/nobutts.org)
[Twitter.com/1800NOBUTTS](https://twitter.com/1800NOBUTTS)
[Instagram/1800NOBUTTS](https://www.instagram.com/1800NOBUTTS)

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Formulary Changes

The following changes to GCHP's formulary are effective January 1, 2020:

Additions

Drug	Formulary Status / Change
VYNDAMAX (<i>tafamidis</i>)	Added to formulary with PA.
DUAKLIR PRESSAIR (<i>aclidinium bromide; formoterol fumarate dihydrate</i>)	Added to formulary.
RYBELSUS (<i>semaglutide</i>)	Added to formulary with step therapy requirement.
TURALIO (<i>pexidartinib hydrochloride</i>)	Added to formulary with PA.
ROZLYTREK (<i>entrectinib</i>)	Added to formulary with PA.
INREBIC (<i>fedratinib hydrochloride</i>)	Added to formulary with PA.
WAKIX (<i>pitolisant hydrochloride</i>)	Added to formulary with PA.
NOURIANZ (<i>istradefylline</i>)	Added to formulary with PA.
TRIKAFTA (<i>elexacaftor, tezacaftor, ivacaftor; ivacaftor</i>)	Added to formulary with PA.

Removals

Drug	Formulary Status / Change
Viibryd (<i>vilazodone hydrochloride</i>)	Generic now available. Brand name removed from formulary.
Soolantra (<i>ivermectin</i>)	Generic now available. Brand name removed from formulary.
Dyrenium (<i>triamterene</i>)	Generic now available. Brand name removed from formulary.
Halog (<i>halcinonide</i>)	Generic now available. Brand name removed from formulary.



FDA Alerts

FDA New Drug Approvals

This is a list of new drugs approved by the FDA. This is only a subset of all drugs that were approved and include all first-time approvals and any other significant drug approvals. [Click here](#) to access the FDA's website.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
GVOKE HYOPEN	Glucagon	Solution; Subcutaneous	Antihyperglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes 2 years of age and older.
GVOKE PFS	Glucagon	Solution; Subcutaneous	Antihyperglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes 2 years of age and older.
IBSRELA	Tenapanor Hydrochloride	Tablet; Oral	Sodium / hydrogen exchanger 3 (NHE3) inhibitor indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults.
OZOBAX	Baclofen	Solution: Oral	OZOBAX is a gamma-aminobutyric acid (GABA-ergic) agonist indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. OZOBAX may also be of some value in patients with spinal cord injuries and other spinal cord diseases. Limitations of Use OZOBAX is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.
RYBELSUS	Semaglutide	Tablet; Oral	Glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use <ul style="list-style-type: none"> • Not recommended as first-line therapy for patients inadequately controlled on diet and exercise (1, 5.1). • Has not been studied in patients with a history of pancreatitis (1, 5.2). • Not indicated for use in patients with type 1 diabetes mellitus or treatment of diabetic ketoacidosis (1).
HEMADY	Dexamethasone	Tablet; Oral	Corticosteroid indicated in combination with other antimyeloma products for the treatment of adults with multiple myeloma.
AKLIEF	Trifarotene	Cream; Topical	Retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
REYVOW	Lasmiditan Succinate	Tablet; Oral	<p>Serotonin (5-HT) 1F receptor agonist indicated for the acute treatment of migraines with or without aura in adults.</p> <p>Limitations of Use REYVOW is not indicated for the preventive treatment of migraines.</p>
SECUADO	Asenapine	System; Transdermal	Atypical antipsychotic indicated for the treatment of adults with schizophrenia.
AMZEEQ	Minocycline Hydrochloride	Aerosol, Foam; Topical	<p>Tetracycline-class drug indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older.</p> <p>Limitations of Use This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, AMZEEQ should be used only as indicated.</p>
TRIKAFTA (COPACKAGED)	Elexacaftor, Ivacaftor, Tezacaftor; Ivacaftor	Tablet; Oral	<p>TRIKAFTA is a combination of ivacaftor, a CFTR potentiator, tezacaftor, and elexacaftor indicated for the treatment of cystic fibrosis (CF) in patients 12 years of age and older who have at least one F508del mutation in the CFTR gene.</p> <p>If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation.</p>
VUMERITY	Diroximel Fumarate	Capsule, Delayed Release; Oral	VUMERITY is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease in adults.
IBRANCE	Palbociclib	Tablet; Oral	<p>Kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:</p> <ul style="list-style-type: none"> • An aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men (1); or • Fulvestrant in patients with disease progression following endocrine therapy.

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
TALICIA	Omeprazole Magnesium; Amoxicillin; Rifabutin	Capsule, Delayed Release; Oral	<p>TALICIA is a three-drug combination of omeprazole, a proton pump inhibitor, amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial, indicated for the treatment of <i>Helicobacter pylori</i> infection in adults.</p> <p>To reduce the development of drug-resistant bacteria and maintain the effectiveness of TALICIA and other antibacterial drugs, TALICIA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.</p>
ZIEXTENZO	Pegfilgratim-Bmez	Injectable; Injection	<p>Leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.</p> <p>Limitations of Use ZIEXTENZO is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.</p>
ABSORICA LD	Isotretinoin	Capsule; Oral	<p>ABSORICA and ABSORICA LD are retinoids indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater.</p> <p>Because of significant adverse reactions associated with its use, ABSORICA and ABSORICA LD are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.</p> <p>Limitations of Use: If a second course of ABSORICA / ABSORICA LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15- to 20-week course of therapy.</p>
BRUKINSA	Zanubrutinib	Capsule; Oral	<p>Kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.</p> <p>This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p>

Brand Name	Generic Name	Dosage Form	Summary of Indication and Mechanism of Action
ABRILADA	Adalimumab-afzb	Injectable; Injection	<p>ABRILADA is a tumor necrosis factor (TNF) blocker indicated for treatment of:</p> <p>Rheumatoid Arthritis (RA) (1.1): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA.</p> <p>Juvenile Idiopathic Arthritis (JIA) (1.2): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 4 years of age and older.</p> <p>Psoriatic Arthritis (PsA) (1.3): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.</p> <p>Ankylosing Spondylitis (AS) (1.4): Reducing signs and symptoms in adult patients with active AS.</p> <p>Adult Crohn's Disease (CD) (1.5): Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab products.</p> <p>Ulcerative Colitis (UC) (1.6): Inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP). The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers.</p> <p>Plaque Psoriasis (Ps) (1.7): The treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.</p>



FDA Safety Labeling Changes

This section includes new safety labeling changes or updated boxed warnings or contraindications. [Click here](#) to access this information on the FDA's website.

Drug	Type of Change	Change
PAXIL CR (<i>paroxetine hydrochloride</i>)	Boxed Warning	WARNING: SUICIDAL THOUGHTS AND BEHAVIORS Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors.
THALITONE (<i>chlorthalidone</i>)	Contraindications	THALITONE is contraindicated in patients with anuria or hypersensitivity to chlorthalidone or other sulfonamide-derived drugs.
BIAXIN (<i>clarithromycin</i>) BIAXIN XL (<i>clarithromycin</i>)	Contraindications	Lomitapide, Lovastatin, and Simvastatin Concomitant administration of BIAXIN with lomitapide is contraindicated due to potential for markedly increased transaminases. Concomitant administration of BIAXIN with HMG-CoA reductase inhibitors (statins) that are extensively metabolized by CYP3A4 (lovastatin or simvastatin) is contraindicated, due to the increased risk of myopathy, including rhabdomyolysis.
ZEGERID (<i>omeprazole; sodium bicarbonate</i>)	Contraindications	ZEGERID is contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticaria. Proton pump inhibitors (PPIs), including ZEGERID, are contraindicated in patients receiving products containing rilpivirine.
CYCLOPHOSPHAMIDE	Contraindications	CYCLOPHOSPHAMIDE capsules are contraindicated in patients with: <ul style="list-style-type: none"> • A history of severe hypersensitivity reactions to CYCLOPHOSPHAMIDE, any of its metabolites, or to other components of the product. Anaphylactic reactions including death have been reported with CYCLOPHOSPHAMIDE. Cross-sensitivity with other alkylating agents can occur. • In patients with urinary outflow obstruction.
MAVYRET (<i>glecaprevir; pibrentasvir</i>)	Contraindications	MAVYRET is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation. MAVYRET is contraindicated with atazanavir or rifampin.

Drug	Type of Change	Change
CRYSVITA (burosumab-twza)	Contraindications	<p>CRYSVITA is contraindicated:</p> <ul style="list-style-type: none"> • In concomitant use with oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol) due to the risk of hyperphosphatemia. • When the serum phosphorus is within or above the normal range for age. • In patients with severe renal impairment or end stage renal disease because these conditions are associated with abnormal mineral metabolism.
INVOKANA (canagliflozin)	Boxed Warning And Contraindications	<p>Boxed Warning: WARNING: LOWER LIMB AMPUTATION</p> <p>An increased risk of lower limb amputations associated with INVOKANA use versus placebo was observed in CANVAS (5.9 vs 2.8 events per 1000 patient-years) and CANVAS-R (7.5 vs 4.2 events per 1000 patient-years), two large, randomized, placebo-controlled trials in patients with type 2 diabetes who had established cardiovascular disease (CVD) or were at risk for CVD.</p> <p>Amputations of the toe and midfoot were most frequent; however, amputations involving the leg were also observed. Some patients had multiple amputations, some involving both limbs.</p> <p>Before initiating, consider factors that may increase the risk of amputation, such as a history of prior amputation, peripheral vascular disease, neuropathy, and diabetic foot ulcers.</p> <p>Monitor patients receiving INVOKANA for infection, new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue if these complications occur.</p> <p>Contraindications:</p> <ul style="list-style-type: none"> • Serious hypersensitivity reaction to INVOKANA, such as anaphylaxis or angioedema. • Patients with severe renal impairment (eGFR < 30 mL/min/1.73 m²) who are being treated for glycemic control. • Patients on dialysis.

Drug	Type of Change	Change
MAXALT (rizatriptan benzoate) MAXALT-MLT (rizatriptan benzoate)	Contraindications	MAXALT is contraindicated in patients with: Concurrent administration or recent discontinuation (i.e., within two weeks) of a MAO-A inhibitor. Hypersensitivity to rizatriptan or any of the excipients (angioedema and anaphylaxis seen).
ARYMO ER (morphine sulfate)	Boxed Warning	WARNING: ADDICTION, ABUSE, and MISUSE: RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a REMS for these products [see Warnings and Precautions (5.2)]. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to health care providers. Health care providers are strongly encouraged to complete a REMS-compliant education program, counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products, emphasize to patients and their caregivers the importance of reading the medication guide every time it is provided by their pharmacist, and consider other tools to improve patient, household and community safety.
FETZIMA (levomilnacipran hydrochloride)	Boxed Warning	Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. FETZIMA is not approved for use in pediatric patients.
ADDYI (flibanserin)	Boxed Warning	Interaction with Alcohol The use of ADDYI and alcohol together close in time increases the risk of severe hypotension and syncope. Counsel patients to wait at least two hours after consuming one or two standard alcoholic drinks before taking ADDYI at bedtime or to skip their ADDYI dose if they have consumed three or more standard alcoholic drinks that evening.
XOFLUZA (baloxavir marboxil)	Contraindications	XOFLUZA is contraindicated in patients with a history of hypersensitivity to baloxavir marboxil or any of its ingredients. Serious allergic reactions have included anaphylaxis, angioedema, urticaria and erythema multiforme.

Drug	Type of Change	Change
LIVALO (<i>pitavastatin calcium</i>)	Contraindications	Known hypersensitivity to pitavastatin or any inactive ingredient in LIVALO. Hypersensitivity reactions including angioedema, rash, pruritus, and urticaria have been reported with LIVALO.
ULTOMIRIS (<i>ravulizumab-cwvz</i>)	Contraindications	ULTOMIRIS is contraindicated in: Patients who are not currently vaccinated against <i>Neisseria meningitidis</i> , unless the risks of delaying ULTOMIRIS treatment outweigh the risks of developing a meningococcal infection.
LILETTA (<i>levonorgestrel</i>)	Contraindications	LILETTA is contraindicated when one or more of the following conditions exist: <ul style="list-style-type: none"> • Pregnancy. • For use as post-coital contraception (emergency contraception). • Congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity and would be incompatible with correct IUS placement. • Acute pelvic inflammatory disease (PID) or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy. • Infected abortion in the past three months. • Known or suspected uterine or cervical neoplasia. • Known or suspected breast cancer or other hormone-sensitive cancer, now or in the past. • Uterine bleeding of unknown etiology. • Untreated acute cervicitis or vaginitis, including bacterial vaginosis, known chlamydial or gonococcal cervical infection, or other lower genital tract infections until infection is controlled. • Acute liver disease or liver tumor (benign or malignant). • Conditions associated with increased susceptibility to pelvic infections. • A previously inserted IUS that has not been removed. • A history of hypersensitivity reaction to any component of LILETTA. Reactions may include rash, urticaria, and angioedema.
HUMATROPE (<i>somatropin recombinant</i>)	Contraindications	HUMATROPE is contraindicated in patients with: <ul style="list-style-type: none"> • Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin. • Active malignancy.
ERYTHROMYCIN (<i>erythromycin lactobionate</i>)	Contraindications	ERYTHROMYCIN is contraindicated in patients with known hypersensitivity to this antibiotic. ERYTHROMYCIN is contraindicated in patients taking terfenadine or astemizole, cisapride, pimozide, ergotamine, or dihydroergotamine.

Drug	Type of Change	Change
PROVOCHOLINE <i>(methacholine chloride)</i>	Boxed Warnings and Contraindications	<p>Boxed Warning: WARNING: SEVERE BRONCHOCONSTRICTION</p> <p>Severe bronchoconstriction can result from PROVOCHOLINE administration (including the lowest dose). The use of PROVOCHOLINE is contraindicated in pediatric and adult patients with baseline FEV1 <60% predicted or adults with FEV1 <1.5 L. Because of the potential for severe bronchoconstriction, the use of PROVOCHOLINE in patients with clinically apparent asthma or wheezing is not recommended.</p> <p>Emergency equipment and medication should be immediately available to treat acute respiratory distress. If severe bronchoconstriction occurs, reverse immediately with a rapid-acting inhaled bronchodilator agent.</p> <p>If baseline spirometry is not performed or measured inaccurately, the initial FEV1 may be underestimated. In this situation, decreases in FEV1 may not be detected after administration of escalating PROVOCHOLINE doses, which may result in administration of unnecessary higher doses and an increased risk for excessive bronchoconstriction.</p> <p>Contraindications: PROVOCHOLINE is contraindicated in the following situations:</p> <p>Hypersensitivity to methacholine or other parasympathomimetic agents. Reactions have included rash, itching / swelling (especially of the face / tongue / throat), severe dizziness, trouble breathing.</p> <p>Baseline FEV1 <60% predicted (adults or pediatric patients) or <1.5 L (adults).</p>



Drug Shortages

This section documents drug shortages that were updated in the past 30 days that affect the prescription benefit for GCHP. [Click here](#) to access this information on the ASHP Resource Center's website.

Drug Product	Affected Manufacturers	Summary
Gentamicin Sulfate Ophthalmic Ointment	Akorn	Akorn has Gentak ophthalmic ointment on shortage due to manufacturing delays. Gentamicin ophthalmic solutions are not affected by this shortage.
Flurazepam Capsules	Mylan	Mylan did not provide a reason for the shortage. They are the sole suppliers of flurazepam. Estimated resupply dates: Mylan has flurazepam 15 mg and 30 mg capsules on back order and the company estimates a release date of early- to mid-December 2019.
Sodium Polystyrene Sulfonate Oral or Rectal Suspension	CMP Pharma Perrigo Hikma	<ul style="list-style-type: none"> • CMP Pharma reports that increased demand has led to a shortage of raw material required to manufacture the products. They are using available powder to manufacture the suspension. • Perrigo has temporarily discontinued their Kionex suspension and sodium polystyrene sulfonate (sorbitol-free) suspension. They cannot estimate when these products will be manufactured again. • Hikma is not currently marketing sodium polystyrene sulfonate suspension. <p>Estimated resupply dates: CMP Pharma has SPS Suspension on allocation and the company is shipping supplies regularly.</p>

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	Communications Summary
IBRANCE (<i>palbociclib</i>) KISQALI (<i>ribociclib</i>) VERZENIO (<i>abemaciclib</i>)	FDA warns about rare but severe lung inflammation with IBRANCE, KISQALI, and VERZENIO for breast cancer.



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