Pharmacy Policy Bulletin

Title: Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

Policy #: Rx.01.76

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for medications that have quantity limits as provided under the member's prescription drug benefit. Applicable medications may not be appropriate for members when prescribed in quantities above quantity level limits. Quantities exceeding the quantity level limits may create safety concerns or inappropriate utilization issues. Medications subject to quantity level limits are reviewed by the Pharmacy and Therapeutics (P&T) Committee.

Description:

Quantity limits are designed to allow a sufficient supply of medication based upon FDA-approved or medically accepted maximum daily doses and length of therapy of a particular drug. Quantity limits may be expressed as quantity over time or maximum daily dose. Additionally, there are some medications to which a limit on the days' supply is applied.

A. Quantity over time: This quantity limit is based on dosing guidelines over a rolling time period, usually 30 days.
B. Maximum daily dose (maximum quantity per day): This quantity limit is based on maximum number of units of the drug allowed per day.
C. Days' supply limit: This limits the numbers of days of therapy in a defined time period. Maximum daily dose applies to days' supply limits.

Refer to the specific manufacturer's prescribing information for additional details.

Quantity limits for opioids and stimulants are included in their respective opioid and stimulant policies.

Quantity limits apply to some drugs to achieve dose optimization, which is a utilization management strategy that encourages consolidation of medication regimen to the lowest number of units when medically appropriate. The goal of dose optimization is to reduces pill burden and waste. Exceptions may be made when medical necessity is established such as dose titration, inability to swallow larger pills or the requested dose is not commercially available. For example, when a medication is available in tablets of 10mg and 20mg strengths, with a maximum dose 20mg per day; the quantity limit in place will favor the 20mg tablet once daily over two tablets of the 10mg strength once daily. However, if the individual is unable to swallow the 20mg tablet due to its size; an exception may be made to allow two tablets of the 10mg strength per day.

Policy:

General quantity limit criteria

Quantity limit requests are approved when ONE of the following is met: (drug specific criteria below).

A. Requests that exceed the cumulative daily dose, dose frequency, or duration of therapy approved or recommended by the FDA or as stated in accepted compendia[1] are considered off-label and are reviewed per Off-Label Use policy, OR

B. Requests that do not exceed the cumulative daily dose, dose frequency or duration of therapy approved or recommended by the FDA or as stated in accepted compendia[1]: A quantity limit exceeding those listed in the following table is approved when ONE of the following is met:
    1. Documentation of the inability to reach the requested dose with higher strengths of commercially available dosage forms due to member specific characteristics (i.e., inability to swallow larger pills, malabsorption, presence of a feeding tube, etc.); or
    2. The requested dose is not commercially available; or
    3. The requested dose is used for titration or loading-dose purposes (one-time authorization)

[1] Please refer to the Off-Label Use policy for definition of accepted compendia

Authorization duration: 2 years

Drug specific quantity limit criteria:

Belumosudil (Rezurock™) specific criteria:

A quantity limit exceeding that listed is approved when BOTH of the following are met:

1. One of the following:
    a. Member is taking a strong CYP3A4 inducer; or
    b. Member is on a proton pump inhibitor; and
2. Quantity requested does not exceed 2 per day

Authorization duration: 2 years

Icatibant (Firazyr®) specific criteria:

A quantity limit exceeding those listed is approved when BOTH of the following criteria are met:

1. The total dose does not exceed FDA approved maximum dose; and
2. ONE of the following:
    a. For Hereditary Angioedema (HAE)Types I and II: documentation of an inadequate response or inability to tolerate C1 inhibitor replacement therapy (e.g., Cinryze®, Berinert®); or
    b. For HAE non-Type I or II: documentation of medical necessity

Authorization duration: 2 years

Acute migraine Agents specific criteria:

An increased quantity of a migraine agent is approved when there is a diagnosis of acute treatment of migraine headache and all of the following inclusion criteria are met:

1. Trial of prophylactic treatment with one of the following: beta blocker, calcium channel blocker, tricyclic antidepressant, valproic acid, cyproheptadine calcitonin gene-related peptide receptor antagonist (CGRP) indicated for prophylaxis (e.g., Erenumab [Aimovig™], fremanezumab [Ajovy™] or galcanezumab [Emgality™] 120mg/ml) or topiramate; and
2. Requested quantity does not exceed the manufacturer-recommend maximum doses; and
3. The member has been examined by a neurologist within the past three years.

Authorization duration: 2 years

Proton pump inhibitor specific criteria:

Increased quantity limits of proton pump inhibitors are approved when ONE of the following is met:

1. Pathological hypersecretory condition including Zollinger-Ellison syndrome; or
2. Barrett's esophagus; or
3. Upper gastrointestinal bleed (gastric or duodenal); or
4. Inadequate response to once daily proton pump inhibitor therapy with ONE of the following:
    a. Gastroesophageal reflux disease (GERD) with nocturnal symptoms; or
    b. GERD or erosive esophagitis for member less than 11 years old; or
    c. Laryngopharyngeal reflux; or
    d. Treatment for the eradication of H pylori with triple therapy (duration of therapy will be limited to 14 days)

Authorization duration: 2 years

Doxycycline DR (Doryx DR®) 200mg specific criteria

A quantity limit exceeding those listed is approved when ONE of the following criteria are met:

1. Diagnosis of acne and inadequate response or inability to tolerate 2 generic alternatives (e.g., doxycycline, minocycline, tetracycline); or
2. Other diagnosis approved by the FDA or as stated in accepted compendia are considered off-label and are reviewed per Off-Label policy

Authorization duration: 2 years

Smoking Cessation Agents specific criteria:

Additional days' supply of bupropion (Zyban®), Varenicline (Chantix®, Apo-varenicline) and Nicotine Replacements (Nicotine gum, patches, inhalers, and spray) are approved when all the following are met:

1. One month has passed since last treatment failure with any product indicated for smoking cessation; and
2. Member is enrolled in a Smoking Cessation Program (in person or online); and
3. Member is currently a smoker

Authorization duration: 6 months

Epinephrine pens/ auto-injectors

A quantity limit exceeding those listed may be considered with documentation that a member needs an additional supply based on medical necessity (where additional doses or storage at additional locations are required).

Authorization duration**:** 6 months

Lofexidine (Lucemyra®)

Criteria for approving more than two 14-day supplies:

Lofexidine (Lucemyra®): An exception for increased days' supply is approved when there is documentation that lofexidine (Lucemyra®) will be used concurrently with comprehensive addiction care (this includes participation in nonpharmacological interventions such as drug abuse counseling, self-help programs, behavioral therapy, or other psychosocial services)

Authorization duration: 6 months

Caplacizumab-yhdp (Cablivi®)

Criteria for approving more than 30-day supply per 365 days:

Caplacizumab-yhdp (Cablivi®): Additional quantities will be approved when the total duration of therapy does not exceed 58 doses after the last plasma exchange.

Authorization duration: 30 days

Black Box Warning as shown in the drug Prescribing Information:
Antivirals/Anti-infective

Truvada® (emtricitabine and tenofovir disoproxil fumarate), tenofovir, Viread® (tenofovir disoproxil fumarate)

A. Severe acute exacerbations of hepatitis B virus (HBV) have been reported in HBV-infected patients who have discontinued Truvada® and tenofovir. Hepatic function should be monitored closely in HBV-infected patients who discontinue Truvada® and tenofovir. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Truvada® (emtricitabine and tenofovir disoproxil fumarate)

TRUVADA used for HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and at least every 3 months during use. Drug resistant HIV-1 variants have been identified with the use of TRUVADA for HIV-1 PrEP following undetected acute HIV-1 infection. Do not initiate TRUVADA for HIV-1 PrEP if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed. Tenofovir

A. Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including VIREAD, in combination with other antiretrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogs to any patient with known risk factors for liver disease; however, cases have also been reported in patients with no known risk factors. Treatment with VIREAD should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

Strattera®

A. Suicidal ideation in children and adolescents: increases the risk of suicidal ideation in short-term studies in children and adolescents with ADHD. Anyone considering the use in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behavior. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Strattera® is approved for ADHD in pediatric and adult patients. Strattera® is not approved for major depressive disorder. Pooled analyses of short-term (6 to 18 weeks) placebo-controlled trials in children and adolescents (a total of 12 trials involving over 2200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving Strattera® compared to placebo. The average risk of suicidal ideation in patients receiving Strattera® was 0.4% (5/1357 patients), compared to none in placebo-treated patients (851 patients). No suicides occurred in these trials.

Impavido®

A. Impavido® may cause fetal harm. Fetal death and teratogenicity occurred in animals administered Impavido® at doses lower than the recommended human dose. Do not administer Impavido® to pregnant women. Obtain a serum or urine pregnancy test in females of reproductive potential prior to prescribing Impavido®.
B. Females of reproductive potential should be advised to use effective contraception during Impavido® therapy and for 5 months after therapy.

Fluoroquinolones (Baxdela®)

A. Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together including:
    a. Tendinitis and tendon rupture
    b. Peripheral neuropathy
    c. Central nervous system effects
B. Discontinue immediately and avoid the use of fluoroquinolones in patients who experience any of these serious adverse reactions.
    a. Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid fluoroquinolones in patients with known history of myasthenia gravis.

Quinine sulfate (Qualaquin®)

A. QUALAQUIN use for the treatment or prevention of nocturnal leg cramps may result in serious and life-threatening hematologic reactions, including thrombocytopenia and hemolytic uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP). Chronic renal impairment associated with the development of TTP has been reported. The risk associated with QUALAQUIN use in the absence of evidence of its effectiveness in the treatment or prevention of nocturnal leg cramps outweighs any potential benefit.

Levoketoconazole (Recorlev®)

A. Cases of hepatotoxicity with fatal outcome or requiring liver transplantation have been reported with oral ketoconazole. Some patients had no obvious risk factors for liver disease. RECORLEV is associated with serious hepatotoxicity. Evaluate liver enzymes prior to and during treatment.
B. RECORLEV is associated with dose-related QT interval prolongation. QT interval prolongation may result in life-threatening ventricular dysrhythmias such as torsades de pointes. Perform ECG prior to and during treatment.

Antidepressants

Prozac® Weekly™

A. Suicidal thoughts and behaviors: antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increased. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 and older.
B. In patients of all ages who are started in antidepressant therapy, monitor closely for worsening and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.
C. Not approved for use in children less than 7 years of age.

Attention Deficit Hyperactivity Disorder (ADHD)

Qelbree™

A. In clinical trials, higher rates of suicidal thoughts and behavior were reported in pediatric patients treated with Qelbree than in patients treated with placebo. Closely monitor for worsening and emergence of suicidal thoughts and behaviors.

Contraceptives

NuvaRing®, Xulane®, Annovera®, Twirla®

A. Cigarette smoking and serious cardiovascular events: cigarette smoking increases the risk of serious cardiovascular events from combination hormonal contraceptive (CHC) use. This risk increases with age, particularly in women over 35 years of age and with the number of cigarettes smoked. For this reason, CHCs should not be used by women who are over 35 years of age and smoke.

Xulane®

A. Risk of venous thromboembolism: the risk of VTE among women aged 15-44 who used the patch compared to women who used several different oral contraceptives was assessed in five U.S. epidemiologic studies using electronic healthcare claims data. The relative risk estimates ranged from 1.2 to 2.2; one of the studies found a statistically significant increased relative risk of VTE for current users.
B. Pharmacokinetic profile of ethinyl estradiol: the PK profile for the patch is different from the PK profile for oral contraceptives in that it has a higher steady state concentration and a lower peak concentration. Area under the time-concentration curve (AUC) and average concentration at steady state (Css) for EE are approximately 60% higher in women than compared with women using an oral contraceptive containing 35 mcg of EE. In contrast, the peak concentration (Cmax) for EE is approximately 25% lower in women using the patch. It is not known whether there are changes in the risk of serious adverse events based on the differences in PK profiles of EE in women using norelgestromin and ethinyl estradiol transdermal system compared with women using oral contraceptives containing 30–35 mcg of EE. Increased estrogen exposure may increase the risk of adverse events, including VTE.

Depo-Provera®

A. Loss of bone mineral density: women may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible. It unknown if use during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life. It should not be used as a long-term birth control method (i.e., longer than 2 years) unless other birth control methods are considered inadequate.

Diabetic Supplies/Drugs

Rybelsus™

Warning: Risk of Thyroid C-Cell Tumors

In rodents, semaglutide causes thyroid C-cell tumors. It is unknown whether semaglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as the human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined.

Semaglutide is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors.

Migraine Agents

Butorphanol tartrate NS

A. Exposes patients and others to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient’s risk prior to prescribing and monitor all patients regularly for the development of these behaviors and conditions.
B. Serious, life-threatening, or fatal respiratory depression may occur with use. Monitor for respiratory for respiratory depression, especially during initiation or following a dose increase.
C. Accidental exposure, especially by children, can result in fatal overdose.
D. Prolonged use during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts.
E. Interactions with drugs affecting cytochrome P450 isoenzymes: the concomitant use of butorphanol tartrate NS with all cytochrome P450 3A4 inhibitors may result in an increase in butorphanol plasma concentrations, which could increase or prolong adverse reactions and potentially fatal respiratory depression. Discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in butorphanol concentration. The effects of concomitant use or discontinuation of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol or codeine are complex and requires careful consideration of the effects on the parent drug and the active metabolite.

F. Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Migranal®, Trudhesa™

A. Serious and/or life-threatening peripheral ischemia has been associated with the co-administration of dihydroergotamine with potent CYP 3A4 inhibitors including protease inhibitors and macrolide antibiotics. Because CYP 3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of these medications is contraindicated.

Treximet® (sumatriptan/naproxen)

A. May cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. TREXIMET® is contraindicated in the setting of coronary artery bypass graft.
B. NSAID containing products cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events

Miscellaneous agents

Flector® patch, Zipsor®, Sprix®, Licart™, Elyxyb™

A. Cardiovascular thrombotic events: NSAIDs cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. It is contraindicated in the setting of coronary artery bypass graft surgery.
B. Gastrointestinal bleeding, ulceration, and perforation: NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Entresto™

A. Fetal toxicity: when pregnancy is detected, discontinue as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

Oxandrin®

A. Peliosis hepatis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, has been reported in patients receiving androgenic anabolic steroid therapy. These cysts are sometimes present with minimal hepatic dysfunction, but at other times they have been associated with liver failure. They are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops. Withdrawal of drug usually results in complete disappearance of lesions. Liver cell tumors are also reported. Most often these tumors are benign and androgen-dependent, but fatal malignant tumors have been reported. Withdrawal of drug often results in regression or cessation of progression of the tumor. However, hepatic tumors associated with androgens or anabolic steroids are much more vascular than other hepatic tumors and may be silent until life-threatening intra-abdominal hemorrhage develops. Blood lipid changes that are known to be associated with increased risk of atherosclerosis are seen in patients treated with androgens or anabolic steroids. These changes include decreased high-density lipoproteins and sometimes increased low-density lipoproteins. The changes may be very marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease.

Xyrem®, Xywav™

A. Central nervous system depression: Xyrem and Xywav are CNS depressants. Clinically significant respiratory depression and obtundation may occur in patients treated with Xyrem and Xywav at recommended doses. Many patients who received Xyrem and Xywav during clinical trials in narcolepsy were receiving central nervous system stimulants.
B. Misuse and abuse: Xyrem and Xywav are sodium salt of gamma hydroxybutyrate (GHB). Abuse of GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. Because of because of the risks of CNS depression, abuse, and misuse, it is available only through a restricted distribution program called the Xyrem and Xywav REMS Program, using the central pharmacy that is specially certified. Prescribers must enroll in the program.

Bevyxxa®

A. Epidural or spinal hematomas may occur in patients treated with betrixaban who are receiving neuraxial anesthesia or undergoing spinal puncture. The risk of these events may be increased by the use of in-dwelling epidural catheters or the concomitant use of medical products affecting hemostasis. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.

Verquvo® (vericiguat)

A. Embryo-fetal toxicity
    a. Do not administer Verquvo® to a pregnant female because it may cause fetal harm.
    b. Females of reproductive potential: Exclude pregnancy before the start of treatment. To prevent pregnancy, females of reproductive potential must use effective forms of contraception during treatment and for one month after stopping treatment.

Lupkynis™ (voclosporin)

A. Malignancies and serious infections
    a. Increased risk for developing serious infections and malignancies with Lupkynis or other immunosuppressants that may lead to hospitalization or death.

Opzelura™ (ruxolitinib)

Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving Janus kinase inhibitors for inflammatory conditions. Higher rate of all-cause mortality, including sudden cardiovascular death have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Lymphoma and other malignancies have been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Higher rate of MACE (including cardiovascular death, myocardial infarction, and stroke) has been observed in patients treated with Janus kinase inhibitors for inflammatory conditions. Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with Janus kinase inhibitors for inflammatory conditions.

Sedative Hypnotics

Estazolam, Flurazepam HCL, Restoril®, Halcion®, Nayzilam®, Valtoco®

A. Concomitant use of benzodiazepines and opioids: may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and duration to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

Nayzilam®, Valtoco®

A. The use of benzodiazepines, including Nayzilam, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing Nayzilam and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
B. Although Nayzilam is indicated only for intermittent use if used more frequently than recommended, abrupt discontinuation or rapid dosage reduction of Nayzilam may precipitate acute withdrawal reactions, which can be life-threatening. For patients using Nayzilam more frequently than recommended, to reduce the risk of withdrawal reactions, use a gradual taper to discontinue Nayzilam.

Zolpidem, Ambien ®, Ambien CR ®, Zolpimist®, Intermezzo®, Edluar®, (eszoplicone) Lunesta®, (zaleplon) Sonata®

A. Complex Sleep Behaviors: Complex sleep behaviors including sleepwalking, sleep driving, and engaging in other activities while not fully awake have been reported following use of the above agents. Some of these events have resulted in serious injuries, including death. Discontinue use immediately if a patient experiences a complex sleep behavior.

Camzyos™ (mavacamten)

A. CAMZYOS can cause heart failure due to systolic dysfunction.
B. Echocardiogram assessments of left ventricular ejection fraction (LVEF) required before and during CAMZYOS use.
C. Initiation in patients with LVEF <55% not recommended. Interrupt if LVEF <50% or if worsening clinical status.
D. Certain CYP450 inhibitors and inducers are contraindicated in patients taking CAMZYOS because of an increased risk of heart failure.
E. CAMZYOS is available only through a restricted program called the CAMZYOS REMS Program.

Smoking Cessation Products

Bupropion hydrochloride (oral tablet/extended release tablet)

A. Suicidality and antidepressant drugs: although it is not indicated for the treatment of depression, it contains the same active ingredient as the antidepressant medication Wellbutrin®. Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term trials. These trials did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in subjects over age 24; there was a reduction in risk with antidepressant use in subjects aged 65 and older. In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

Miscellaneous

Gimoti™

A. Tardive Dyskinesia: Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage. Discontinue Gimoti in patients who develop signs or symptoms of TD. Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the risk of developing TD with longer-term use.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are off-Label Use policy or cosmetic are benefit contract exclusions for all products of the Company.

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Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Medication	Maximum Quantity per day	Quantity limit per rolling 30 days, unless otherwise specified (tablets, capsules, mL)	
ADHD Agents			
Atomoxetine HCL (Strattera®) 10mg, 18mg, 25mg, 40mg	2	60	
Atomoxetine HCL (Strattera®) 60mg, 80mg, 100mg	1	30	

Clonidine HCL (Kapvay®) 0.1mg	4	120	
Guanfacine HCL (Intuniv ER®) 1mg, 2mg, 3mg, 4mg tablet	1	30	
Viloxazine (Qelbree™) 100 mg	1	30	
Viloxazine (Qelbree™) 150 mg, 200 mg	2	60	
Antiemetics			
Aprepitant (Emend®) 80mg	NA	8	
Aprepitant (Emend®) 40mg	NA	2	
Aprepitant (Emend®) 125mg	NA	4	
Aprepitant (Emend®) trifold pack	NA	4 packs	
Antidepressant			
Fluoxetine (Prozac weekly®)	NA	4	
Anti-Seizure Agents			
Diazepam (Valtoco®) nasal spray	NA	5 boxes (10 units)	
Midazolam (Nayzilam®) nasal spray	NA	5 boxes (10 single dose spray units)	
Antivirals/Antiinfectives			
Acyclovir (Sitavig®)		2/30	
Baloxavir marboxil (Xofluza™) Therapy Packs 2 x 20mg (40mg dose) 2 x 40mg (80mg dose)	NA	2 tablets (1 box)/28 days	
Baloxavir marboxil (Xofluza™) therapy packs 1 x 40mg (40mg dose) 1 x 80mg (80mg dose)	NA	1 tablet/28 days	
Mebendazole (Emverm®)	NA	6/21 days	
Fidaxomicin (Dificid®) tablets	NA	20/10 days	
Fidaxomicin (Dificid®) suspension	NA	136 ml per 10 days	
Isavuconazonium (Cresemba®) capsule	NA	68	
Ibrexafungerp (Brexafemme®)	NA	4/28 days	
Lefamulin (Xenleta™)	NA	10 tablets for 5 days	
Linezolid (Zyvox®) tablet 600mg	NA	56 tablets per 28 days	
Linezolid (Zyvox®) oral suspension 100mg/5ml	NA	1680 ml per 28 days	

Delafloxacin (Baxdela®) tablet 450mg	NA	28 tablets per 14 days	
Omadacycline (Nuzyra®) tablet 150mg	NA	30 tablets per 14 days	
Minocycline ER (Solodyn®, Minolira™, Ximino®)	NA	84 days' supply per 180 days	
Nitazoxanide (Alinia®) tablet	NA	12 tablets per 6 days	
Nitazoxanide (Alinia®) suspension	NA	300ml per 6 days	
Oseltamivir (Tamiflu®) 6mg/ml	NA	180mL (3 bottles) per Rx	
Oseltamivir (Tamiflu®) 30mg	NA	20 per Rx	
Oseltamivir (Tamiflu®) 45mg, 75mg	NA	10 per Rx	
Posaconazole (Noxafil®) 100mg tab	NA	93	
Posaconazole (Noxafil®) 40mg/1ml oral suspension	20 ml	NA	
Quinine sulfate (Qualaquin®)	NA	60 capsule per 10 days	
Rifamycin tablet delayed release 194 mg (Aemcolo™)	NA	12 tablets per 30 days	
Sarecycline (Seysara™)	NA	84 days' supply per 180 days	
Tedizolid phosphate (Sivextro®)	NA	6 per 6 days	
Tenofovir 300mg (Viread®)	1	30	
Truvada® 200mg-300mg (emtricitabine/tenofovir disoproxil fumarate)	1	30	
Penciclovir (Denavir®)	NA	5 grams	
Zanamivir (Relenza®)	NA	1 Diskhaler per Rx	
Rifaximin (Xifaxan® 200mg)	NA	9/ 90days	
Acyclovir cream (Zovirax®)	NA	5g	
Acyclovir ointment (Zovirax®)	NA	30g	
Doxycycline DR (Doryx DR®) 200mg	1	7 days’ supply per 30 days	
Miltefosine (Impavido®)	NA	84 per 28 days	
Bowel Prep Kits			
Peg 3350-electrolyte (Nulytely, Trilyte, Golytely)	NA	2 kits/year (8000ml)	
Peg-prep kits	NA	2 kits/year	
Contraceptives			
Diaphragm	NA	1 per year	
Ethinyl estradiol/etonogestrel (Nuvaring®)	NA	1per 28 days	
Ethinyl estradiol/norelgestromine (Xulane patch®, Zafemy®)	NA	3	
Ethinyl estradiol/segesterone acetate (Annovera®)	NA	1 per 365 days	
Condoms	NA	15	

Levonorgestrel 1.5mg (My Way®, Next Choice®, One Dose®, Plan B one-step®)	NA	3	
Levonorgestrel-ethinyl estradiol TD patch weekly (Twirla®)	NA	3	
Medroxyprogesterone acetate (Depo-Provera®)	NA	1 per 90 days	
Ulipristal (Ella®)	NA	3	
Diabetic Supplies/Drugs			
Blood glucose monitor	NA	2 per year	
Diabetic test strips	NA	200	
Freestyle Libre® reader; Dexcom® receiver	NA	2 per year	
Dexcom® transmitters	NA	4 per year	
Guardian® transmitters	NA	2 per year	
Freestyle Libre® 14-day sensor, Freestyle Libre® 2 sensor, Freestyle Libre® kit 3 sensor	NA	2 per 28 days	
Freestyle Libre® 10-day sensor	NA	3 per 30 days	
Dexcom G4, G5, G6, G7 sensor	NA	4 per 28 days	
Guardian sensor, Enlite sensor	NA	5 per 30 days	
Insulin injecting device (e.g., Novopen®)	NA	2 per year	
Insulin syringes and pen needles	NA	200	
Lancets	NA	200	
Insulin products	2mL	60	
Rybelsus™	1	30	
Erectile Dysfunction			
Alprostadil (Caverject®, IFE-PG20)	NA	8 per 30 days	
Alprostadil (Edex®, Muse®)	NA	8 per 30 days	
Avanafil (Stendra®)	NA	8 per 30 days	
Sildenafil (Viagra®)	NA	8 per 30 days	
Tadalafil (Cialis®) 2.5mg, 5mg	1	30	
Tadalafil (Cialis®) 10mg, 20mg	NA	8	
Vardenafil (Levitra®, Staxyn®)	NA	8	
Injectable Fertility			
Follitropin Beta (Follistim AQ®) 75 unit vial	NA	60	
Follitropin Beta (Follistim AQ®) 150 unit vial	NA	30	
Follitropin Beta (Follistim AQ®) 300 unit cartridge	NA	15	
Follitropin Beta (Follistim AQ®) 600 unit cartridge	NA	8	

Follitropin Beta (Follistim AQ®) 900 unit cartridge	NA	5	
Follitropin Alfa (Gonal-F®) 450 units vial	NA	10	
Follitropin Alfa (Gonal-F®) 1050 units vial	NA	5	
Follitropin Alfa (Gonal-F RFF®) 300/0.5ml pen injector	NA	15	
Follitropin Alfa (Gonal-F RFF®) 450/0.75ml pen injector	NA	10	
Follitropin Alfa (Gonal-F RFF®) 900/1.5ml pen injector	NA	5	
Follitropin Alfa (Gonal-F RFF®) 75 unit vial	NA	60	
Menotropins (Menopur®)75 units vial	NA	180	
Migraine Agents			
Atogepant (Qulipta™)	1	30	
Eletriptan (Relpax®) 20mg, 40mg	NA	12	
Butorphanol nasal spray	NA	10	
Dihydroergotamine (Migranal®)	NA	8	
Dihydroergotamine mesylate HFA (Trudhesa™)	NA	12/28 days	
Emgality 100mg/ml	NA	9 injections/ 180 days	
Frovatriptan (Frova®) 2.5mg	NA	18	
Lasmiditan (Reyvow™) 50mg	NA	4	
Lasmiditan (Reyvow™) 100mg	NA	8	
Naratriptan (Amerge®) 1mg, 2.5mg	NA	9	
Rimegepant (Nurtec ODT®)	NA	18	
Rizatriptan (Maxalt® and Maxalt MLT®) 5mg and 10mg	NA	12	
Sumatriptan (Imitrex®) 4mg injections	NA	14 kits (28 injections)	
Sumatriptan (Imitrex®) 6mg injections	NA	9 kits (18 injections)	
Sumatriptan (Imitrex®) 5mg/actuation nasal spray	NA	36	
Sumatriptan (Imitrex®) 20mg/actuation nasal spray	NA	18	
Sumatriptan (Imitrex®) 6mg/0.5ml subcutaneous cartridge/pen injection	NA	9ml	
Sumatriptan (Imitrex®) 4mg/0.5ml subcutaneous cartridge/pen injection	NA	14ml	
Sumatriptan (Imitrex®) 25mg, 50mg, 100mg	NA	18	

Sumatriptan (Onzetra Xsail®) nasal	NA	16	
Sumatriptan (Tosymra®)	NA	12 single dose nasal sprays	
Sumatriptan/Naproxen (Treximet®) 85mg/500mg	NA	18	
Sumatriptan (Zembrace symtouch®) 3mg/0.5mL	NA	8	
Ubrogepant (Ubrelvy™)	NA	16	
Zolmitriptan (Zomig®, Zomig ZMT®) 2.5mg, 5mg	NA	9	
Zolmitriptan (Zomig®) 2.5mg, 5mg nasal spray	NA	9	
Miscellaneous			
Alpelisib (Vijoice®) 250mg	2	60	
Alpelisib (Vijoice®) 50mg, 125mg	1	30	
Acrivastine & pseudoephedrine (Semprex D®	4	14 days	
Asciminib (Scemblix®) 20 mg	2	60	
Avapritinib (Ayvakit™)	1	30	
Baclofen suspension (Fleqsuvy ®)	16 ml	480 ml	
Belumosudil (Rezurock™)	1	30	
Bremelanotide (Vyleesi™)	NA	8	
Budesonide (Tarpeyo™)	4	120	
Caplacizumab-yhdp (Cablivi®)	1 kit (11mg)	30 days' supply per 365 days	
Celecoxib (Elyxyb™)	4.8 ml	144 ml	
Cenegermin-BKBJ (Oxervate™)	2	60	
Cyclosporine (Restasis®)	2	60	
Cyclosporine (Verkazia®)	4	120	
Cysteamine (Cystaran®) 0.44% ophthalmic solution	NA	4 bottles/30 days	
Cysteamine (Cystadrops®)	NA	20/28 days	
Diclofenac (Flector®) patch	2	60	
Diclofenac (Licart®) patch	1	30	
Diclofenac potassium (Zipsor®)	4	120	

Doxepin 5% cream (Prudoxin®, Zonalon®)	NA	45g/ 90 days	
Epinephrine pens/auto-injectors (Epi-Pen®, Auvi-Q®, Symjepi™)	NA	3 twin packs (6 injections) per 180 days	
Gimoti®	NA	56 days' supply per 180 days	
Glycopyrrolate (Dartisla ODT™)	4	120	
Glycopyrronium (Qbrexza™)	1	30	
Icatibant (Firazyr® 30mg/3ml syringe)	NA	27mL	
Ketorolac tromethamine (Sprix®)	NA	5	
Levoketoconazole (Recorlev®)	8	240	
Lidocaine (Lidoderm®, Ztlido™) patch	3	90	
Maribavir (Livtencity™)	4	224/56 days	
Mavacamten (Camzyos™)	1	30	
Migalastat (Galafold®)	NA	14 tablets per 28 days	
Naloxone (Zimhi™)	NA	3 ml (6 units)	
Naloxone (Evzio®)	NA	4 (1.6mL)	
Naloxone (Narcan®)	NA	6	
Naloxone (Kloxxado™)	NA	6	
Oxandrolone 2.5mg	8	30 days/180 days	
Oxandrolone 10mg	2	30 days/180 days	
Osilodrostat (Isturisa®) 1mg	8	240	
Osilodrostat (Isturisa®) 5mg	2	60	
Osilodrostat (Isturisa®) 10mg	6	180	
Oteseconazole (Vivjoa™)	N/A	18 tablets per 180 days	
Pitolisant (Wakix®) 4.45mg	2	60	
Pitolisant (Wakix®) 17.8mg	2	NA	
Ruxolitinib (Opzelura™)	NA	240 grams/28 days	
Sacubitril/valsartan (Entresto®)	2	60	
Sodium oxybate (Xyrem®), calcium, magnesium, potassium and sodium oxybates (Xywav™)	18	540	
Betrixaban (Bevyxxa®)	NA	42 days' supply/180 days	
Lofexidine (Lucemyra™)	16	480	Two 14 days' supply in 365 days
Apomorpine (Kynmobi™)	5	NA	
Vericiguat (Verquvo®)	1	30	
Varenicline (Tyrvaya™)	NA	8.4ml (2 bottles)	
Voclosporin (Lupkynis™)	6	180	
Multiple sclerosis agents			
Dalfampridine (Ampyra®)	2	60	

Interferon beta-1a (Avonex®)	NA	4	
Interferon beta-1a (Rebif/Rebif Rebidose®)	NA	12	
Interferon beta-1b (Betaseron®)	NA	15	
Interferon beta-1b (Extavia®)	NA	15	
Glatiramer acetate (Copaxone® 20mg)	1	30	
Glatiramer acetate (Copaxone® 40mg)	NA	12	
Peginterferon beta-1a (Plegridy®)	NA	1mL per 28 days	
Osteoporosis Agents			
Alendronate 70mg/75ml solution	NA	300mL per 28 days	
Alendronate (Fosamax® and Binosto®) 35mg, 70mg	NA	4 per 28 days	
Alendronate with Vitamin D (Fosamax plus D®) 70mg/2.8ml, 70mg/5.6ml	NA	4 per28 days	
Ibandronate (Boniva®) 150mg	NA	1	
Risedronate sodium (Actonel® and Atelvia®) 35mg	NA	4 per28 days	
Risedronate sodium (Actonel®) 150mg	NA	1 per30 days	
Proton Pump Inhibitor			
Dexlansoprazole (Dexilant®)	2	60	
Esomeprazole magnesium (Nexium®) and strontium capsules	2	60	
Esomeprazole magnesium (Nexium®) packet	1	30	
Lansoprazole (Prevacid®)	2	60	
Lansoprazole (Prevacid®) solu-tab	1	30	
Omeprazole (Prilosec®)	2	60	
Omeprazole/sodium bicarbonate (Zegerid®) packets	1	30	
Prilosec 2.5mg pak	1	30	
Pantoprazole sodium (Protonix®)	2	60	
Pantoprazole sodium (Protonix®) packet	1	30	
Rabeprazole (Aciphex®)	2	60	
Rabeprazole (Aciphex®) sprinkle	1	30	
Sedative Hypnotics			
Daridorexant (Quviviq™)	1	30	
Estazolam	1	30	
Eszopiclone (Lunesta®) 1mg	2	60	

Eszopiclone (Lunesta®) 2mg, 3mg	1	30	
Flurazepam HCL	1	30	
Lemborexant (Dayvigo™)	1	30	
Ramelteon (Rozerem®)	1	30	
Suvorexant (Belsomra®)	1	30	
Tasimelteon (Hetlioz®)	1	30	
Temazepam (Restoril®)	1	30	
Triazolam (Halcion®)	1	30	
Zaleplon	1	30	
Zolpidem (Zolpimist®)	NA	7.7ml (1 pump)	
Zolpidem tartrate (Ambien®, Ambien CR®, Edluar®, Intermezzo®)	1	30	
Smoking Cessation Products			
Bupropion HCL	2	60	180 cumulative days' supply per 365 days
Nicotine gum/inhaler/lozenges	10	300	
Nicotine nasal spray (Nicotrol® NS)	NA	80ml per 30 days	
Nicotine patches	1	30	
Varenicline (Chantix®, Apo-varenicline)	2	60	
Bronchodilator Inhalers			
Albuterol sulfate (Proair HFA, Proair Respiclick, Proair Digihaler, Ventolin HFA, Proventil HFA)	NA	2 inhalers per 30 days	
Levalbuterol tartrate (Xopenex HFA)	NA	2 inhalers per 30 days	

Cross References:

Acute Seizure Activity Agents Rx.01.226
Applicable Age Edits Rx.01.2
Belimumab (Benlysta®)/Voclosporin (Lupkynis™) Rx.01.203
Belumosudil (Rezurock™) Rx.01.256
Budesonide (Tarpeyo™) Rx.01.262
Cenegermin-bkbj (Oxervate) Rx.01.217
Continuous Glucose Monitor Rx.01.218
Cushing's Disease Agents Rx.01.132
Cyclosporine (Verkazia®) Rx.01.263
Cysteamine-containing products Rx.01.136
Diclofenac Products Rx.01.155
Dalfampridine (Ampyra) Rx.01.122
Epinephrine Pen Policy Rx.01.142
Off-Label Use Policy Rx.01.33
Fabry Disease Agents Policy Rx.01.2012
Glycopyrronium Topical (Qbrexza™) policy Rx.01.2014
Glycopyrrolate (Dartisla ODT™) Rx.01.264
Heart Failure Agents Rx.01.174
Hereditary Angioedema Agents Rx.01.109
Hypoactive Sexual Desire Disorder (HSDD) Agents Policy Rx.01.177
Insulin policy
Mavacamten (Camzyos™) Rx.01.265
Migraine and Headache Agents Rx.01.251
Naloxone Rx.01.167
Oncology agents Rx.01.67

Opioid policy Rx.01.197
Oral Anti-infective Agents Rx.01.66
Oteseconazole (Vivjoa™) Rx.1.272
Prior Authorization of Select Drugs Rx.01.202
Proton Pump Inhibitors Rx.01.75
Ruxolitinib (Opzelura™) Rx.01.258
Sleep Agents Rx.01.84
Sodium oxybate (Xyrem®)/Calcium, Magnesium, Potassium and Sodium Oxybates (Xywav™) Rx.01.124

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