

Pharmacy Policy Bulletin

Title: Prior Authorization Requirements for Select Drugs

Policy #: Rx.01.202

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 selected drugs with generic and/or therapeutic alternatives as provided under the member's prescription drug benefit.

▸ Description:

The Prior Authorization Requirements for Select Drugs is designed to expedite and automate access to certain medications that require prior authorization (PA) by using information available in the member's prescription drug benefit claim history. If the prerequisite drug(s) is (are) in the claim history, the requested medication will be available at the point of sale without having their prescriber submit a PA request. If there is no history of the prerequisite drug(s) in a member's claim history, a PA request will be required per the standard process.

Definitions:

- A. Target: the medication to which the prior authorization is applied
- B. Prerequisite: the alternative medication(s) that must be used prior to approving the target medication

▸ Policy:

A medication with an alternative or alternatives will be approved when ALL of the following are met:

1. FDA or compendia approved indication; and
2. Request is not for an excluded benefit (ie cosmetic); and

3. Inadequate response or inability to tolerate the alternative(s) listed

Target	Prerequisite(s)	Category
Colcrys®, Mitigare ®	colchicine	Anti-gout
Uloric®	generic allopurinol	Anti-gout
Daytrana®, Adzenys® ER, Adzenys XR-ODT®, Dyanavel XR®, Mydayis®, Cotempla®	2 generic ADHD stimulants (e.g. methylphenidate, amphetamines, etc)	ADHD
Concerta® Dexedrine® spansule Desoxyn® Metadate CD® Ritalin LA® Focalin XR® Adderall®, Kapvay®, Intuniv®, Strattera®	generic equivalent of requested brand	ADHD
Quillichew®, Quillivant®, Aptensio®	Generic methylphenidate	ADHD
Atacand [HCT]®, Avapro [Avalide]®, Cozaar [Hyzaar]®, Diovan [HCT] ®, Micardis [HCT]®, Exforge [HCT]®, Twynsta®, Benicar [HCT]®, Azor®, Tribenzor®, Edarbi®, Edarbyclor®, Tekturna [HCT]®, Byvalson®	3 generic angiotensin receptor blockers or combinations (e.g. losartan, olmesartan, valsartan, etc)	Angiotensin II receptor antagonists
Vasotec®, Zestril®, Prinivil®	3 generic angiotensin-converting enzyme (ACE) inhibitors (e.g. lisinopril, enalapril)	ACE-Inhibitors
Lamictal®	generic lamotrigine	anticonvulsants
Keppra ®	generic levetiracetam	anticonvulsants
Briviact®	generic levetiracetam OR continuation of therapy with Briviact®	anticonvulsants
Wellbutrin XL®, Prozac®, Lexapro®, Zoloft®, Effexor XR®, Aplenzin®	3 generic antidepressants (e.g. citalopram, venlafaxine, bupropion, sertraline, etc)	Antidepressants
Topamax® [sprinkle]	topiramate	Anticonvulsants
Fetzima®, Pristiq®, Khedezla®, Viibryd®	3 generic antidepressants (e.g. citalopram, venlafaxine, bupropion, sertraline, etc) OR continuous therapy with requested agent for a minimum of 2 weeks	Antidepressants
Trintellix®	2 generic antidepressants (e.g. citalopram, venlafaxine, bupropion, sertraline, etc) OR continuous	Antidepressants

	therapy with requested agent for a minimum of 2 weeks	
Fortamet®	2 generic metformin products	Anti-diabetics
Mytesi®	HIV therapy and ONE of the following: loperimide or diphenoxylate/ atropine	Antidiarrheal
Abilify®, Saphris®, Vraylar®, Fanapt®, Latuda®, Invega®, Rexulti®	2 generic antipsychotic agents (e.g. aripirazole, paliperidone, quetiapine, risperidone, etc) OR continuation of therapy with requested medication	antipsychotics
Valtrex®	generic valacyclovir	Antivirals
Ativan®, Valium®, Xanax®	3 generic benzodiazepines (e.g. lorazepam, diazepam, alprazolam, etc)	Benzodiazepine
Inderal LA®, Tenormin®, Tenoretic®, Kapspargo™	3 generic beta blockers (e.g. propranolol, atenolol, metoprolol, etc)	Beta blockers
Cuprimine®, Syprine®	Depen®	Chelating agents
Beyaz®, Safyral®, Minastrin 24 FE®	3 generic oral contraceptives	Contraceptives
Adlyxin®	ONE of the following: Trulicity®, Byetta®, Bydureon®, Victoza®, or Ozempic®	Anti-diabetics
Soliqua®, Xultophy®	ONE of the following: Trulicity®, Byetta®, Bydureon®, or Victoza® AND ONE of the following: Lantus®, Levemir®, Toujeo®, or Tresiba®	Anti-diabetics
Symlin®	Insulin within 180 days	Anti-diabetics
Non-preferred diabetic test strips	One test strip from Ascensia (ie Breeze, Contour) and one test strip from Abbott (ie FreeStyle, Precision)	Anti-diabetics
Nesina®, Oseni®, Kazano®, Tradjenta®, Jentaduet®	Januvia® or Janumet® AND Onglyza® or Kombiglyze®	Anti-diabetics
Farxiga®, Xigduo XR®, Qtern®, Steglatro™, Steglujan™, Segluromet™	ONE of the following: Invokana®, Invokamet®, Jardiance®, or Synjardy®	Anti-diabetics
Humulin®, Humalog®, Apidra®, Admelog®	One of the following: Novolin® or Novolog®	Anti-diabetics
Basaglar®	two of the following: Lantus®, Levemir®, Toujeo®, Tresiba®	Anti-diabetics
Bravelle®, Follistim®	Gonal-F	Fertility
Lipitor®, Crestor®, Livalo®, Vytorin® Zypitamag®	3 generic HMG CoA reductase inhibitors (e.g. simvastatin, atorvastatin, rosuvastatin, pravastatin, etc)	HMG Co A reductase inhibitors
Lovaza®	Omega-3-acid ethyl esters	Cholesterol lowering agents
Zetia®	generic ezetimibe	Cholesterol lowering agents

Vecamyl®	2 generic antihypertensives in different classes	Hypertension
Viberzi®	One antidiarrheal medication (e.g. loperamide) AND one antispasmodic (e.g. dicyclomine, etc)	IBS
Amitiza®, Relistor®, Trulance®	lactulose and ONE of the following: Linzess® or Movantik®	IBS
Extavia®, Rebif [Rebidose] ®,	2 of the following: Avonex®, Betaseron®, Copaxone®, Glatopa®, Tecfidera®, Plegridy® OR continuation of therapy with the requested agent	MS
Conzip®	2 generic tramadol products	Narcotic analgesic
Anaprox DS®, Naprelan CR®, Naprosyn®, EC-Naprosyn®, Celebrex®, Arthrotec®, Daypro®, Mobic®, Zipsor®, Fenoprofen, Fenortho™, Nalfon®	3 generic NSAIDS (e.g. ibuprofen, naproxen, diclofenac, celecoxib, meloxicam, etc)	NSAIDs
Allzital®, Butalbital/APAP 50/300mg tabs/caps	Butalbital/APAP 50/325mg tabs	Non-Narcotic Analgesic
Vanatol S®, Vanatol LQ®	Butalbital/APAP/Caffeine 50/325mg/40mg tabs OR caps	Non-Narcotic Analgesic
Zioptan®, Vyzulta™, Rescula®, Rhopressa®	ONE of the following generics: latanoprost, bimatoprost, travoprost AND ONE of the following: Lumigan® or Travatan Z®	Ophthalmic prostaglandins
Toviaz®	ONE of the following: Vesicare® or Myrbetriq® AND 2 generic alternatives (e.g. oxybutinin, tolterodine, etc)	Overactive bladder agents
Xadago®	generic rasagiline and selegiline	Parkinson's disease
Rytary®	generic carbidopa/ levodopa	Parkinson's disease
Durlaza®	aspirin	Platelet inhibitors
Proventil®, Ventolin®, Xopenex®	ProAir®	Pulmonary
Flovent Diskus/ HFA*®, Alvesco®, Pulmicort Flexhaler®, Aerospan®, Arnuity Ellipta®, AirDuo®, Armonair®	Asmanex® or Qvar®	Pulmonary
Dulera®	ONE of the following: Breo Ellipta®, Symbicort® or Advair® Diskus/HFA	Pulmonary
Utibron Neohaler®, Bevespi Aerosphere®	ONE of the following: Anoro Ellipta®, Stiolto Respimat®	Pulmonary

Tudorza® Lonhala Magnair®	ONE of the following: Spiriva® or Incruse® Ellipta	Pulmonary
Finacea®	Soolantra®	Rosacea
Rhofade®	Mirvaso®	Rosacea
Noritrate®	Soolantra® or Mirvaso®	Rosacea
Skelaxin®, Soma®, Zanaflex®, Amrix ER®, Lorzone®	2 generic skeletal muscle relaxants (e.g. metaxolone, carisoprodol, tizanidine, cyclobenzaprine, chlorzoxazone, etc)	Skeletal muscle relaxants
Restoril®, Halcion®, Doral®	2 generic benzodiazepines indicated for sleep (e.g. temazepam, triazolam, quazepam, estazolam, etc)	Sleep agents
Ambien® 5mg [CR 6.25mg], Lunesta® 1mg, 2mg, Sonata®	2 generic sleep aids (e.g. zolpidem, eszopiclone, zaleplon, etc)	Sleep agents
Silenor®, Belsomra®	Two of the following: eszopiclone, zaleplon, zolpidem	Sleep agents
Nuvigil®, Provigil®	generic modafinil or armodafinil	Sleep agents
Acticlate®, Adoxa®, Avidoxy, Doryx DR®, Minocin®, Minolira™**, Monodox®, Solodyn®**, Vibramycin®, Targadox®, Ximino®	2 generic alternatives (e.g. doxycycline, minocycline, tetracycline)	Tetracyclines
Absorica®	2 of the following: Amnesteem®, Claravis®, Myorisan®, Zenatane®	Acne agents
Proctocort®	Hydrocortisone suppositories	Topical steroids
Eucrisa®	One generic topical steroid (e.g. triamcinolone, clobetasol, halobetasol, etc)	Dermatological agents
Elidel®	One generic topical steroid (e.g. triamcinolone, clobetasol, halobetasol, etc) or generic tacrolimus	Dermatological agents
Protopic®	generic tacrolimus	Dermatological agents
Differin®, Retin-A®, Retin-A micro®, Atralin®, Altreno™	2 generic topical vitamin A derivative products	topical acne agents
Cleocin T®, Benzaclin gel®, Duac gel®, Benzamycin gel®, Evoclin foam®, Aczone gel®, Veltin gel®, Azelex® cream®, Benzaclin pump®, Onexton gel w/ pump®, Benzamycinpak gel®, Clindagel®, Acanya®, Ziana®, Clindamycin/benzoyl peroxide 1% / 5%, Aktipak™	2 generic, topical antibiotic or topical antibiotic combination products	topical acne agents
ZMax®	generic azithromycin	Antiinfectives
Lidoderm® patches, Ztlido™	generic lidocaine patch	Topical anesthetics

Loprox®, Extina®, Oxistat®, Ecoza®, Xolegel®, Luzu®, Vusion®, Ertaczo®, Exelderm®	2 generic, prescription strength, topical antifungals (e.g. ketoconazole, oxiconazole, ciclopirox, etc)	Topical antifungal
Carac®	Fluorouracil 0.5% topical cream	Topical antineoplastics
Clobex®, Olux/ Olux E®, Vanos®, Ultravate®, Topicort®, Kenalog®, Luxiq®, Cloderm®, Desowen®, Cordran®, Derma-smoothe®, Synalar®, Cutivate®, Locoid®, Locoid Lipocream®, Halog®, Desonate®, Verdeso®, Capex®, Pandel®, Sernivo®	3 prescription strength, generic topical steroids	Topical steroid
Enstilar®, Taclonex®, Taclonex® suspension	generic calcipotriene/ betamethasone or generic calcipotriene plus generic betamethasone	Topical steroid
Symproic®	Movantik®	Opioid induced constipation
Royaldee®	generic calcitriol	Vitamin D analog
Brand prenatal vitamins	3 generic prenatal vitamins (various)	Vitamins, prenatal
Tirosint®	Generic levothyroxine	Thyroid replacement
Actiq®, Fentora®, Abstral®, Lazanda®, Subsys®	Generic oral transmucosal fentanyl citrate	TIRF
Hysingla® ER, Zohydro®, Arymo® ER, Embeda®, Morphabond®	Two generic opioid analgesics or documentation of a history of or a potential for drug abuse for individual or a member of the individual's household	Opioid analgesics
Duragesic®, Dilaudid®, MS Contin®, Kadian®, AVINza®, Roxicodone®, Opana®, Percocet®, Norco®, Xodol®, Exalgo®, Vicoprofen®, Ibudone®, Demerol®, Actiq®, Dolophine®, Methadose®, Tylenol #3®, Tylenol #4®, Hycet®, Ultracet®, Ultram®, Fioricet® with codeine, Fiorinal® with codeine	Generic equivalent of requested brand	Opioid analgesics
Oxycontin®, Oxycodone ER	Xtampza® ER	Opioid analgesics
Xepi™, Altabax®	mupirocin	Impetigo agents

*Flovent HFA does not require prior authorization for members under 12 years of age

**Solodyn®, Minolira™ are approved for maximum of 84 days/180 days

Black Box Warning:

Acetaminophen-containing agents

Hepatotoxicity

Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen-containing products.

Acne Agents

Absorica®

- A. Causes birth defects: Absorica™ must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking Absorica™ in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Absorica™ is available only through a restricted program called the iPLEDGE program. Prescribers, patients, pharmacies, and distributors must enroll in the program.

ADHD stimulants

Daytrana®, Concerta®, Metadate® CD, Ritalin LA®, Focalin®,

A. Drug dependence: should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Adzenys® ER, Adzenys XR-ODT™, Dyanavel® XR, Dexedrine®, Adderall®, QuilliChew ER™, Quillivant XR®, Aptensio XR™, Cotempla®

- a. Abuse and dependence: CNS stimulants, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy
- b. Particular attention should be paid to subjects obtaining amphetamines for non-therapeutic use or distribution to others, and the drugs should be described sparingly.
- c. Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events.

Desoxyn®

- a. Methamphetamine has a high potential for abuse. It should thus be tried only in weight reduction programs for patients in whom alternative therapy has been ineffective. Administration of methamphetamine for prolonged periods of time in obesity may lead to drug dependence and must be avoided. Particular attention should be paid to the possibility of subjects obtaining methamphetamine for non-therapeutic use or distribution to others,

and the drugs should be prescribed or dispensed sparingly. Misuse of methamphetamine may cause sudden death and serious cardiovascular adverse events.

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.

Antihypertensives

Atacand HCT®, Avapro®, Cozaar®, Diovan HCT®, Micardis® HCT, HCT, Exforge HCT®, Twynsta®, Benicar HCT®, Azor®, Tribenzor®, Edarbi®, Edarbyclor®, Tekturna HCT®, Byvalson™

- 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.

Angiotensin-converting enzyme (ACE) inhibitors

Vasotec®, Zestril®, Prinivil®

- A. When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. The use of ACE inhibitors during the second and third trimesters of pregnancy has been associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function. In a published retrospective epidemiological study, infants whose mothers had taken an ACE inhibitor drug during the first trimester of pregnancy appeared to have an increased risk of major congenital malformations compared with infants whose mothers had not undergone first trimester exposure to ACE inhibitor drugs. The number of cases of birth defects is small and the findings of this study have not yet been repeated. When pregnancy is detected, discontinue ACEi as soon as possible.

Anticonvulsants

Lamictal®

- A. Serious skin rashes: rashes requiring hospitalization and discontinuation of treatment. The incidence of these rashes, which have included Stevens-Johnson syndrome, is approximately 0.3%

to 0.8% in pediatric patients (aged 2 to 17 years) and 0.08% to 0.3% in adults. One rash-related death was reported in a prospectively followed cohort of 1,983 pediatric patients (aged 2 to 16 years) with epilepsy taking Lamictal® as adjunctive therapy. In worldwide postmarketing experience, rare cases of toxic epidermal necrolysis and/or rash-related death have been reported in adult and pediatric patients, but their numbers are too few to permit a precise estimate of the rate. Other than age, there are as yet no factors identified that are known to predict the risk of occurrence or the severity of rash caused by Lamictal®. There are suggestions, yet to be proven, that the risk of rash may also be increased by (1) coadministration of Lamictal® with valproate (includes valproic acid and divalproex sodium), (2) exceeding the recommended initial dose of Lamictal® or (3) exceeding the recommended dose escalation for Lamictal®. However, cases have occurred in the absence of these factors. Nearly all cases of life-threatening rashes caused by Lamictal® have occurred within 2 to 8 weeks of treatment initiation. However, isolated cases have occurred after prolonged treatment (e.g., 6 months). Accordingly, duration of therapy cannot be relied upon as means to predict the potential risk heralded by the first appearance of a rash. Although benign rashes are also caused by Lamictal®, it is not possible to predict reliably which rashes will prove to be serious or life threatening. Accordingly, Lamictal® should ordinarily be discontinued at the first sign of rash, unless the rash is clearly not drug related. Discontinuation of treatment may not prevent a rash from becoming life threatening or permanently disabling or disfiguring.

Antidepressants

Wellbutrin XL®, Prozac®, Lexapro®, Zoloft®, Effexor XR®, Fetzima™, Trintellix®, Pristiq®, Khedezla™, Viibryd®, Aplenzin®

- a. Suicidality and antidepressant drugs: 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 increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction on risk with antidepressant use in patients 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.
- b. Prozac® is not approved for use in children less than 7 years of age.
- c. Lexapro® is not approved for use in pediatric patients less than 12 years of age.
- d. Fetzima™, Pristiq®, & Khedezla™ are not approved for use in pediatric patients.
- e. Trintellix® & Viibryd® have not been evaluated for use in pediatric patients.
- f. Aplenzin®: Serious neuropsychiatric reactions have occurred in patients taking bupropion for smoking cessation.

Anti-diabetics

Fortmet®, Kazano®, Jentadueto®, Xigduo® XR, Segluromet™

A. Lactic acidosis: postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (greater than 5 mmol/L), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio; and metformin plasma levels generally greater than 5 mcg/mL. Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with

contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high risk groups are provided in the Full Prescribing Information. If metformin-associated lactic acidosis is suspected, immediately discontinue the drug and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.

Xultophy®, Ozempic®

- a. Risk of thyroid C-cell tumors: carcinogenicity of albiglutide could not be assessed in rodents, but other glucagon-like peptide-1 (GLP-1) receptor agonists have caused thyroid C-cell tumors in rodents at clinically relevant exposures. Human relevance of GLP-1 receptor agonist induced C-cell tumors in rodents has not been determined. It is unknown whether these agents cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. Liraglutide, one of the components of Xultophy®, causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Xultophy® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined
- b. Xultophy® and Ozempic® are 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 with the use and inform them of the symptoms of thyroid tumors (e.g., mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound monitoring is of uncertain value for early detection of MTC in patients.

Symlin®

- a. Severe hypoglycemia: use with insulin increases the risk of severe hypoglycemia, particularly in patients with type 1 diabetes. When severe hypoglycemia occurs, it is seen within 3 hours following a Symlin® injection. Serious injuries may occur if severe hypoglycemia occurs while operating a motor vehicle, heavy machinery or while engaging in other high-risk activities. Appropriate patient selection, careful patient instruction, and insulin dose reduction are critical elements for reducing this risk.

Oseni®

- a. Congestive heart failure: thiazolidinediones, including pioglitazone, which is a component of Oseni®, cause or exacerbate congestive heart failure in some patients. After initiation of Oseni® and after dose increase, monitor patients carefully for signs and symptoms of heart failure (e.g., excessive, rapid weight gain, dyspnea and/or edema). If heart failure develops, it should be managed according to current standards considered. It is not recommended in patients with symptomatic heart failure. Initiation of Oseni® in patients with established New York Heart Association (NYHA) Class III or IV heart failure is contraindicated.

Antipsychotics

Abilify®, Saphris®, Vraylar™, Latuda®, Rexulti™

- a. Increased mortality in elderly patients with dementia-related psychosis: elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of

death. They are not approved for the treatment of patients with dementia-related psychosis. 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 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. 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.

- b. Latuda® is not approved for use in pediatric patients.
- c. The safety and efficacy of Rexulti™ have not been established in pediatric patients.

Fanapt®, Invega®

- a. Increased mortality in elderly patients with dementia-related psychosis: Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analysis of seventeen placebo-controlled trials (modal duration 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. They are not approved for the treatment of patients with Dementia-Related Psychosis.

Benzodiazepines

Ativan®, Valium®, Xanax®

- a. Risks from concomitant use with opioids: 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 durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.

Chelating agents

Curprimine®

- a. Physicians planning to use penicillamine should thoroughly familiarize themselves with its toxicity, special dosage considerations, and therapeutic benefits. Penicillamine should never be used casually. Each patient should remain constantly under the close supervision of the physician. Patients should be warned to report promptly any symptoms suggesting toxicity.

Contraceptives

Beyaz™, Safyral™, Minastrin® 24 FE

- a. Cigarette smoking and serious cardiovascular events: cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) USE. The risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke.

Dermatological agents

Elidel®, Protopic®

- a. Long-term Safety of Topical Calcineurin Inhibitors has not been established. Although a causal relationship has not been established, rare cases of malignancy (e.g., skin and lymphoma) have been reported in patients treated with topical calcineurin inhibitors

IBS

Trulance™

- a. Risk of serious dehydration in pediatric patients: contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Avoid use of in patients 6 years to less than 18 years of age. The safety and effectiveness of Trulance™ have not been established in patients less than 18 years of age.

Narcotic analgesics

ConZip®, Ultram®, Ultracet®

- a. Addiction abuse and misuse: 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. Life-threatening respiratory depression: 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 ingestion: accidental exposure, especially by children, can result in fatal overdose.
- d. Neonatal opioid withdrawal syndrome: 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 effects of concomitant use or discontinuation of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol 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.

NSAIDs

Anaprox[®] DS, Naprelan[®] CR, Naprosyn[®], EC-Naprosyn[®], Celebrex[®], Arthrotec[®], Daypro[®], Mobic[®], Volatren[®] XR, Zipsor[®]

- a. Cardiovascular risk: NSAIDs 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. Naproxen as Naprosyn[®], EC-Naprosyn[®], Anaprox[®], Anaprox[®] DS or Naprosyn[®] suspension is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery.
- b. Gastrointestinal risk: NSAIDs 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.

Opioid Analgesics

1. Respiratory depression: TIRFs (Actiq[®], Abstral[®], Fentora[®], Subsys[®]), Lazanda[®], Duragesic[®], Hydromorphone (Dilaudid, Exalgo[®]), Morphine Sulfate: Arymo[™] ER, Avinza[®], Kadian[®], and MS Contin[®], Morphabond ER[®], Opana ER[®], Oxycodone (Oxycontin[®]), Zohydro ER[™] (hydrocodone ER),

- a. Fatal respiratory depression has occurred in patients treated with the above listed opioid products, including following use in opioid-intolerant patients and improper dosing. Be sure to monitor for sign and symptoms of respiratory depression, especially during initiation of the drugs. The substitution of fentanyl sublingual/buccal for any other fentanyl product may result in fatal overdose. Because of the risk of respiratory depression, fentanyl products are contraindicated for use as an as-needed analgesic, or in the management of acute or postoperative pain, including headache/migraine and in opioid-intolerant patients. In addition, the concomitant use of fentanyl sublingual with CYP3A4 inhibitors may result in an increase in fentanyl plasma concentrations and may cause potentially fatal respiratory depression.

For hydromorphone and ER products like morphine ER, oxycodone ER, hydrocodone ER, tapentadol ER, and oxymorphone ER products, instruct patients to swallow a whole tablet. Crushing, chewing, snorting, or dissolving tablets can cause rapid release and absorption that could lead to fatal overdose and even death. Note: Avinza[®] capsule contents may be sprinkled on applesauce and swallowed without chewing¹⁹. Hydromorphone is a potent Schedule II controlled opioid agonist. Schedule II opioid agonists have the highest potential for abuse and risk of producing respiratory depression. Alcohol, other opioids, and CNS depressants (sedative-hypnotics) potentiate the respiratory depressant effects of hydromorphone, increasing the risk of respiratory depression that might result in death.

2. Medication errors: TIRFs (Actiq[®], Abstral[®], Fentora[®], Subsys[®]), Lazanda[®]

Substantial differences exist in the pharmacokinetic profile of fentanyl sublingual/buccal compared with other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose. When prescribing, do not convert patients on a mcg-

per-mcg basis from any other fentanyl products to fentanyl sublingual/buccal. When dispensing, do not substitute a fentanyl sublingual/buccal prescription for other fentanyl products.

3. Addiction and Abuse potential: TIRFs (Actiq[®], Abstral[®], Fentora[®], Subsys[®]), Lazanda[®], Duragesic[®], Hydromorphone (Dilaudid, Exalgo[®]), Morphine Sulfate: Arymo[™] ER, Avinza[®], Kadian[®], and MS Contin[®], Morphabond ER[®], Opana ER[®], Oxycodone (Oxycontin[®]), Zohydro ER[™] (hydrocodone ER),

All opioid analgesics regardless of formulation are classified as Schedule II controlled substance, with high abuse liability. They expose patients and drug users to the risk of opioid addiction, abuse, and misuse, which can lead to overdose and death. Diversion, addiction, and abuse potential should be considered when prescribing or dispensing opioid analgesics. Providers must monitor all patients regularly for the development of these behaviors or conditions. Due to the risk for misuse, abuse, addiction, and overdose, some products such as fentanyl sublingual/buccal is available only through a restricted program required by the Food and Drug Administration, called a Risk Evaluation and Mitigation Strategy (REMS). Under the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, outpatients, health care providers who prescribe to outpatients, pharmacies, and distributors must enroll in the program. Further information is available at <http://www.TIRFREMSaccess.com> or by calling 1-866-822-1483.

4. Cytochrome P450 3A4 interaction: TIRFs (Actiq[®], Abstral[®], Fentora[®], Subsys[®]), Lazanda[®], Duragesic[®], Oxycodone (Oxycontin[®]), Zohydro ER[™] (hydrocodone ER)

The concomitant use of fentanyl, oxycodone ER and hydrocodone ER with all cytochrome P450 3A4 (CYP3A4) inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Monitor patients receiving oxycodone ER and any CYP3A4 inhibitor or inducer.

5. Accidental exposure: Duragesic[®], Hydromorphone (Dilaudid, Exalgo[®]), Morphine Sulfate: Arymo[™] ER, Avinza[®], Kadian[®], MS Contin[®], Morphabond ER[®], Opana ER[®], Oxycodone (Oxycontin[®]), Zohydro ER[™],

Deaths due to a fatal overdose of the above listed opioid analgesics have occurred when children and adults were accidentally exposed to the drugs. Strict adherence to the recommended handling and disposal instructions is of the utmost importance to prevent accidental exposure. Accidental ingestion of even 1 dose, especially in children, can result in a fatal overdose and death.

6. Neonatal opioid withdrawal syndrome:

Prolonged use of opioid analgesics especially **Duragesic[®], Hydromorphone (Exalgo[®]), Morphine Sulfate: Arymo[™] ER, Avinza[®], Kadian[®], and MS Contin[®], Morphabond ER[®], Opana ER[®] (tapentadol ER, and oxymorphone ER), Zohydro ER[™], Oxycodone (Oxycontin[®])** 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. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

7. Exposure to heat: Duragesic[®](31)

Exposure of the fentanyl application site and surrounding area to direct external heat sources, such as heating pads or electric blankets, heat or tanning lamps, sunbathing, hot baths, saunas, hot

tubs, and heated water beds may increase fentanyl absorption and has resulted in fatal overdose of fentanyl and death. Patients wearing fentanyl systems who develop fever or increased core body temperature due to strenuous exertion are also at risk for increased fentanyl exposure and may require an adjustment in the dose of fentanyl to avoid overdose and death.

8. Interaction with alcohol: Morphine Sulfate: Avinza[®], Kadian[®], and MS Contin[®], Opana ER[®], Zohydro ER[™], Oxycodone (Oxycontin[®])

When using with alcohol, all opioid analgesic products have the potential to cause excessive sedation and may increase blood concentration of certain opioids like tapentadol, oxymorphone, and morphine. This could lead to fatal overdose and death. Instruct patients to avoid alcoholic beverages or use prescription or nonprescription products that contain alcohol while taking opioid analgesics.

9. Information about oral morphine and oxycodone solution: Morphine Sulfate: Avinza[®], Kadian[®], and MS Contin[®], Oxycodone (Oxycontin[®])

Morphine oral solution is available in 10 mg per 5 mL, 20 mg per 5 mL, and 100 mg per 5 mL (20 mg/mL) concentrations. The 100 mg per 5 mL (20 mg/mL) concentration is indicated for use in opioid-tolerant patients only. Take care when prescribing and administering morphine oral solution to avoid dosing errors due to confusion between different concentrations and between milligrams and milliliters, which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. Keep morphine oral solution out of the reach of children. In case of accidental ingestion, seek emergency medical help immediately.

Oxycodone concentrated oral solution is available as a 20 mg/mL concentration and is indicated for use in opioid-tolerant patients only. Take care when prescribing and administering oxycodone concentrated oral solution to avoid dosing errors due to confusion between milligram and milliliter, and other oxycodone solutions with different concentrations, which could result in accidental overdose and death. Take care to ensure the proper dose is communicated and dispensed. Keep oxycodone out of the reach of children. In case of accidental ingestion, seek emergency medical help immediately.

10. Risks from Concomitant Use with Benzodiazepines or other CNS Depressants: Arymo[™] ER, Morphabond ER[®]

Concomitant use of opioid with benzodiazepines or other CNS depressants may result in profound sedation, respiratory depressions, coma, and death.

Pulmonary

Advair[®], Airduo[™], Utibron[™] Neohaler[®], Bevespi Aerosphere[™], Trelegy Ellipta[®]

- a. Asthma-related death: Long-acting beta2-adrenergic agonists (LABA), such as salmeterol or valenterol, one of the active ingredients, increase the risk of asthma-related death. Data from a large placebo-controlled US trial that compared the safety of salmeterol with placebo added to usual asthma therapy showed an increase in asthma-related deaths in subjects receiving salmeterol (13 deaths out of 13,176 subjects treated for 28 weeks on salmeterol versus 3 deaths out of 13,179 subjects on placebo). Currently available data are

inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe this for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use this for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.

- b. The safety and efficacy of Utibron™ Neohaler®, Bevespi Aerospherre™, Trelegy Ellipta® in patients with asthma have not been established. They are not indicated in the treatment of asthma.

Sleep agents

Restoril™, Halcion®, Doral®,

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.

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 experimental/investigational 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.

Refer to table above

▾ **Cross References:**

N/A

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