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:

Target drugs in the Prior Authorization Requirement for Select Drugs (PARSD) policy have prerequisites on the formulary with similar efficacy and safety profiles. The policy is designed to apply prior authorization to target drugs that have prerequisites that are more cost effective.

Definition:

1. Target: the drug to which the prior authorization is applied
2. Prerequisite: the alternative drugs(s) that must be used prior to approving the target drug

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 (i,e., cosmetic); and
3. ONE of the following:
    a. Inadequate response or inability to tolerate the alternative(s) listed; or
    b. The medication is requested for the treatment of stage IV, advanced metastatic cancer or a severe adverse health condition experienced as a result of stage IV, advanced metastatic cancer

Authorization duration: 2 years

Target	Prerequisite(s)	Category
Mitigare ®, Colcrys®, Gloperba®	colchicine tablets	Anti-gout
Febuxostat (Uloric®)	generic allopurinol	Anti-gout
Daytrana®, amphetamine ER 1.25mg/ml suspension [Adzenys® ER], Adzenys XR-ODT®, Dyanavel XR®, Mydayis®, Cotempla®, Evekeo ODT, Azstarys™	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®, Methylphenidate ER [Aptensio®], Jornay PM®, Adhansia XR®	Generic methylphenidate	ADHD
Qelbree™	ONE of the following: generic atomoxetine, generic guanfacine ER, generic clonidine ER	ADHD
Atacand [HCT]®, Avapro [Avalide]®, Cozaar [Hyzaar]®, Diovan [HCT] ®, Micardis [HCT]®, Exforge [HCT]®, Twynsta®, Benicar [HCT]®, Azor®, Tribenzor®, Edarbi®, Edarbyclor®, Tekturna [HCT]®,	3 generic angiotensin receptor blockers or combinations (e.g., losartan, olmesartan, valsartan, etc.)	Angiotensin II receptor antagonists
Vasotec®, Zestril®, Prinivil®, Altace®, Accupril®, Lotrel®	3 generic angiotensin-converting enzyme (ACE) inhibitors (e.g., lisinopril, enalapril)	ACE-Inhibitors
Lamictal®	generic lamotrigine	anticonvulsants
Keppra ®, Elepsia™ XR	generic levetiracetam	anticonvulsants
Briviact®, Xcopri®	generic levetiracetam OR continuation of therapy with the requested drug	anticonvulsants
Lyrica®	Generic pregabalin	anticonvulsants
Wellbutrin XL®, Prozac®, Lexapro®, Zoloft®, Effexor XR®, Aplenzin®, bupropion ER 450mg [Forfivo® XL], Pristiq®	3 generic antidepressants (e.g., citalopram, venlafaxine, bupropion, sertraline, etc.)	Antidepressants
Topamax® [sprinkle]	topiramate	Anticonvulsants
Trokendi XR®, topiramate ER [Qudexy XR®]	generic topiramate	Anticonvulsants
Fetzima®, 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 therapy with requested agent for a minimum of 2 weeks	Antidepressants
Cymbalta®, Drizalma®	Duloxetine	Antidepressants
Fortamet®	2 generic metformin products	Anti-diabetics
Mytesi®	HIV therapy and ONE of the following: loperamide or diphenoxylate/ atropine	Antidiarrheal
Abilify Mycite®, Vraylar®, Fanapt®, Latuda®, Rexulti®, Caplyta™, Secuado®, Lybalvi™	2 generic antipsychotic agents (e.g., aripiprazole, paliperidone, quetiapine, risperidone, etc.) OR continuation of therapy with requested medication	antipsychotics
Abilify®, Saphris®, Invega®	2 generic antipsychotic agents (e.g., aripiprazole, paliperidone, quetiapine, risperidone, etc.)	antipsychotics
Valtrex®	generic valacyclovir	Antivirals
Ativan®, Valium®, Xanax®, Klonopin®, Loreev™ XR	3 generic benzodiazepines (e.g., lorazepam, diazepam, alprazolam, clonazepam, etc.)	Benzodiazepine
Inderal LA®, Tenormin®, Tenoretic®, Kapspargo™	3 generic beta blockers (e.g., propranolol, atenolol, metoprolol, etc.)	Beta blockers
Penicillamine [Cuprimine®], Trientine/Clovique [Syprine®]	Depen®	Chelating agents
Adlyxin®	ONE of the following: Trulicity®, Byetta®, Bydureon®, Victoza®, Rybelsus® or Ozempic®	Anti-diabetics
Xultophy	Soliqua	Anti-diabetics

Symlin®	Insulin within 180 days	Anti-diabetics
Non-preferred diabetic testing supplies (test strips and meters)	One Touch®	Anti-diabetics
Nesina®, Oseni®, Kazano®, Tradjenta®, Jentadueto®	Januvia® or Janumet® AND Onglyza® or Kombiglyze®	Anti-diabetics
Duetact®	Generic pioglitazone-glimepiride	Anti-diabetic
Qtern®, Steglatro™, Steglujan™, Segluromet™, Invokana®, Invokamet® [XR]	One of the following: Jardiance®, Synjardy® [XR], Glyxambi® or Trijardy® XR AND One of the following: Farxiga® or Xigduo® XR	Anti-diabetics
Humulin®, Humalog® (insulin lispro), Apidra®, Admelog®, Lyumjev®, Fiasp®	One of the following: Novolin® or Novolog®	Anti-diabetics
Basaglar®, Levemir®, Tresiba®, Semglee®	One of the following: Lantus®, Toujeo®,	Anti-diabetics
Gonal-F®, Gonal-RFF®	Follistim AQ®	Fertility
Lipitor®, Crestor®, Livalo®, Vytorin® Zypitamag®, Ezallor®, Zocor®, Roszet®	3 generic HMG CoA reductase inhibitors (e.g., simvastatin, atorvastatin, rosuvastatin, pravastatin, etc.)	HMG Co A reductase inhibitors
Niaspan®	Generic niacin	Cholesterol lowering agents
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
Lubiprostone [Amitiza®]	Lactulose solution and ONE of the following: Linzess® or Symproic®	IBS
Trulance ®, Zelnorm®	Both of the following: lactulose solution and Linzess®	IBS
Motegrity®	Linzess®	IBS
Extavia®, Rebif [Rebidose] ®, Mavenclad®, Ponvory®	2 of the following: Avonex®, Betaseron®, glatiramer (Copaxone®, Glatopa®), Tecfidera®, Plegridy®, Vumerity®, Bafiertam®, dimethyl fumarate, Kesimpta® OR continuation of therapy with the requested agent	MS
Tecfidera®	Dimethyl fumarate AND one of the following: Vumerity® or Bafiertam®	MS
Conzip®, Qdolo®	2 generic tramadol products	Narcotic analgesic
Anaprox DS®, naproxen sodium ER [Naprelan CR®], Naprosyn®, EC-Naprosyn®, Celebrex®, Arthrotec®, Daypro®, Mobic®, Zipsor®, Fenoprofen, Fenortho™, Nalfon®, Qmiiz™ ODT, Relafen [DS®], indomethacin [Tivorbex®], Meloxicam [Vivlodex®], diclofenac [Zorvolex®], Ketoprofen 25mg caps, Cataflam®	3 generic prescription strength NSAIDS (e.g., ibuprofen, naproxen, diclofenac, celecoxib, meloxicam, etc.)	NSAIDs
Butalbital/APAP 25/325mg tablet [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™, Xelpros®, Rocklatan®, Travatan Z®	ONE of the following generics: latanoprost, bimatoprost, travoprost AND Lumigan®	Ophthalmic prostaglandins
Bromsite®, Ilevro®, Nevanac®	Both of the following: Prolensa® and one generic (diclofenac, flurbiprofen, ketorolac)	Ophthalmic NSAIDs
Cequa™	Restasis®	Misc. ophthalmic agents

Toviaz®, Gemtesa®	Both of the following: Myrbetriq® AND 2 generic alternatives (e.g., solifenacin, oxybutynin, tolterodine, etc.)	Overactive bladder agents
Vesicare®, Vesicare LS®	Generic solifenacin	Overactive bladder agents
Xadago®	generic rasagiline and selegiline	Parkinson's disease
Rytary®	generic carbidopa/ levodopa	Parkinson's disease
Ongentys®	Generic entacapone	Parkinson's disease
Durlaza®	aspirin	Platelet inhibitors
ProAir Digihaler®, Proventil®, Albuterol [Ventolin®], Xopenex®	albuterol HFA	Pulmonary
Alvesco®, Asmanex®, Qvar®, Armonair®	Two of the following: Arnuity Ellipta®, Flovent Diskus/ HFA®, Pulmicort Flexhaler®	Pulmonary
Dulera®, AirDuo®	ONE of the following: Breo Ellipta®, Symbicort® or Advair® Diskus/HFA	Pulmonary
Utibron Neohaler®, Bevespi Aerosphere®, Duaklir®	ONE of the following: Anoro Ellipta®, Stiolto Respimat®	Pulmonary
Tudorza® Lonhala Magnair®, Seebri®, Yupelri™	ONE of the following: Spiriva® or Incruse® Ellipta	Pulmonary
Pancreaze®, Pertzye®, Viokace®	Both of the following: Creon® and Zenpep®	Pancreatic enzymes
Finacea®, Zilxi®	Soolantra®	Rosacea
Rhofade®	Mirvaso®	Rosacea
Noritate®	Soolantra® or Mirvaso®	Rosacea
Metaxalone [Skelaxin®], Soma®, Zanaflex®, Cyclobenzaprine ER [Amrix ER®], Lorzone®, Orphenadrine w aspirin & Caffeine [Norgesic Forte®, Orphengesic tab forte®]	2 generic skeletal muscle relaxants (e.g., carisoprodol, tizanidine, cyclobenzaprine, chlorzoxazone 500mg, etc.)	Skeletal muscle relaxants
Ozobax™	Generic baclofen tablets	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
Doxepin [Silenor®], Belsomra®, Dayvigo™	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®, doxycycline hyclate [Targadox®], Minocycline ER [Ximino®]**, Seysara™**; doxycycline hyclate 80mg ER	2 generic alternatives (e.g., doxycycline, minocycline, tetracycline)	Tetracyclines
Absorica [LD] ®	2 of the following: Amnesteem®, Claravis®, Myorisan®, Zenatane®	Acne agents
Duobrii®	Generic tazarotene cream and generic halobetasol	Topical steroid
Proctocort®	Hydrocortisone suppositories	Topical steroids
Eucrisa®	One of the following: one generic topical steroid (e.g., triamcinolone, clobetasol, halobetasol, etc.) or one generic topical calcineurin inhibitor	Dermatological agents
Elidel®	One generic topical steroid (e.g., triamcinolone, clobetasol, halobetasol, etc.) or generic tacrolimus	Dermatological agents
Protopic®	generic tacrolimus	Dermatological agents

Tazorac®, tazarotene [Fabior®]	Tazarotene	Topical acne agents
Differin®, Retin-A®, Retin-A micro®, Atralin®, Altreno™ Aklief®, Adapalene pad 0.1%, Arazlo®	2 generic topical vitamin A derivative products	Topical acne agents
Amzeeq®, Cleocin T®, Evoclin foam®, Dapsone gel 7.5% [Aczone gel® 7.5%], Aczone gel® 5%, Azelex® cream®, Clindagel®	2 generic, topical antibiotic or topical antibiotic combination products	Topical acne agents
Acanya®, Benzaclin gel®, Benzaclin pump®, Benzamycin gel®, Benzamycinpak gel®, Clindamycin/benzoyl peroxide 1% / 5%, Veltin gel®, Ziana®	One of the following: Epiduo® Forte or Onexton®	Topical acne agents
Winlevi®	One generic topical vitamin A derivative product AND one generic topical antibiotic/topical antibiotic combination product	Topical acne agents
Noxafil	Generic posaconazole	Antiinfectives
ZMax®	generic azithromycin	Antiinfectives
Zyvox	generic linezolid	Antiinfectives
Bethkis®, Kitabis®, Tobi® Nebulizer solution	Generic tobramycin nebulizer solution	Anti-infective
Nuvessa™, Cleocin® ovules, Cleocin® cream	ONE of the following: generic metronidazole gel or generic clindamycin cream	Anti-infective
Solosec®	Generic metronidazole	Anti-infective
Lidoderm® patches, Ztlido™	generic lidocaine patch	Topical anesthetics
Loprox®, Extina®, Oxistat®, Ecoza®, Xolegel®, luliconazole [Luzu®], mico-zn-petro [Vusion®], Ertaczo®, sulconazole [Exelderm®], oxiconazole	2 generic, prescription strength, topical antifungals (e.g., ketoconazole, , ciclopirox, etc.)	Topical antifungal
Carac®	Fluorouracil 0.5% topical cream	Topical antineoplastics
Clobex®, Olux/ Olux E®, Ultravate®, Topicort®, Kenalog®, Luxiq®, clocortolone pivalate [Cloderm®], Desowen®, flurandrenolide [Cordran®, Nolix®], Derma-smoothe®, Synalar®, Cutivate®, Locoid®, Locoid Lipocream®, Halog®, Desonate®, Verdeso®, Capex®, Pandel®, Sernivo®, halobetasol propionate [Lexette®], Bryhali®; diflorasone diacetate [Apexicon E®, Psorcon®], triamcinolone ointment 0.05% /Tritocin [Trianex®], Impeklo ™	3 prescription strength, generic topical steroids	Topical steroid
Wynzora®	BOTH of the following: calcipotriene AND one of the following: Taclonex ointment, Taclonex suspension, calcipotrienebetamethasone ointment, calcipotriene suspension, Enstilar	psoriasis agents
Relistor ®, Movantik®	BOTH of the following: Symproic® and lactulose solution	Opioid induced constipation
Rayaldee®	generic calcitriol	Vitamin D analog
Brand prenatal vitamins	3 generic prenatal vitamins (various)	Vitamins, prenatal
Levothyroxine [Tirosint®], Thyquidity™	Generic levothyroxine	Thyroid replacement
Actiq®, fentanyl citrate (Fentora®), Abstral®, Lazanda®, Subsys®	Generic oral transmucosal fentanyl citrate	TIRF
Zohydro®, Arymo® ER, Morphabond®	Two generic opioid analgesics or documentation of a history of or a potential	Opioid analgesics

	for drug abuse for individual or a member of the individual's household	
Duragesic®, Dilaudid®, MS Contin®, Kadian®, Roxicodone®, Oxaydo®, Opana®, Percocet®, Norco®, Xodol®, Exalgo®, Demerol®, Actiq®, Methadose ®, Tylenol #3 ®, Tylenol #4®, Hycet®, Ultracet®, Ultram®, Fioricet® with codeine, Fiorinal® with codeine	Generic equivalent of requested brand	Opioid analgesics
Benzhydrocodone/Acetaminophen (Apadaz®)	Generic Hydrocodone/Acetaminophen and generic oxycodone/acetaminophen	Opioid analgesics
Primlev®, Prolate®, Oxycodone/Acetaminophen 2.5-300mg, 5-300mg, 10-300mg, Nalocet 2.5-300mg	Generic oxycodone/acetaminophen	Opioid analgesics
Oxycontin®, Oxycodone ER, Hysingla®	Xtampza® ER	Opioid analgesics
Ursodiol [Reltone™]	Generic ursodiol capsule	Gallstone agents
Xepi™, Altabax®	mupirocin	Impetigo agents
lactulose packet [Kristalose® packet]	lactulose solution	Laxative
Buphenyl tablet	generic sodium phenylbutyrate tablet	Metabolic modifiers
DDAVP	generic desmopressin acetate nasal spray	Posterior pituitary hormones
Pepcid	Two of the generics: famotidine, nizatidine, cimetidine, ranitidine	H2- Antagonists
Zileuton ER [Zyflo CR®]	Generic montelukast	Leukotriene modifiers
Zerviate™, Bepreve®, Lastacaft®	Two of the following generics: azelastine, cromolyn sodium, epinastine), olopatadine	Allergic conjunctivitis
Oxtellar XR®	generic oxcarbazepine	Anticonvulsants
Aptiom®	Three generic anticonvulsants OR continuation of therapy with Aptiom®	Anticonvulsants
Tegretol®, Tegretol XR®, Carbatrol®	generic carbamazepine	Anticonvulsants
Neurontin®	Generic gabapentin	Anticonvulsants
Felbatol®	Generic felbamate	Anticonvulsants
Zonegran®	Generic zonisamide	Anticonvulsants
Trileptal®	Generic oxcarbazepine	Anticonvulsants
Glucagen®, Zegalogue®	ONE of the following: Glucagon®, Baqsimi®, Gvoke®	Glucagon agents
Cardizem CD®, Conjupri®, Norvasc®	3 generic calcium channel blockers (e.g., amlodipine, diltiazem, nifedipine, verapamil, etc.)	Calcium channel blockers
Pamelor®	3 generic tricyclic antidepressants (e.g., nortriptyline, amitriptyline, imipramine, etc.)	Tricyclic antidepressants
Asacol HD®	Generic mesalamine HD	Gastrointestinal agent
Lotronex®	Generic alosetron	Gastrointestinal agent
Gimoti™****	Generic oral metoclopramide	Gastrointestinal agent
Dexchlorpheniramine/Ryclora®	BOTH of the following generics (desloratadine, carbinoxamine/Ryvent®)	Antihistamines
Uceris®, Entocort EC®	Generic oral budesonide	Corticosteroid
Ortikos®	Generic budesonide cap 3mg DR (Entocort EC®)	Systemic glucocorticoid
Moviprep®, Plenvu®, Osmoprep®,	Suprep® or Clenpiq®	Bowel prep agents
Golytely®, Nulytely®	PEG-3350 oral solution	Bowel prep agents
Cialis®, Viagra®, Levitra® (vardenafil), Staxyn® (vardenafil), Stendra®	One of the following: sildenafil or tadalafil AND no concurrent use of nitrate	Erectile dysfunction agent
Alkindi®	One generic oral corticosteroid {e.g., hydrocortisone, methylprednisolone)	Corticosteroid

Intrarosa®, Femring®, Vagifem®, Estrace cream®	Generic estradiol vaginal cream or vaginal tablet	Hormone replacement therapy
Sensipar®	Generic cinacalcet	Antiparathyroid agent

**Solodyn®, Minolira™, Seysara™, Ximino® are approved for maximum of 84 days/180 days (authorization duration is 84 days)

***Levemir® and Tresiba® do not require prior authorization for members under 6 years of age

****Gimoti™ is approved for maximum of 56 days/180 days (authorization duration is 56 days)

Black Box Warning as shown in the drug Prescribing Information:
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 miligrams per day, and often involve more than one acetaminophen-containing products.

Acne Agents

Absorica®, Absorica LD™

a) Pregnancy Category X: Causes birth defects: Absorica™, Absorica LD™ 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™, Absorica LD™ 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™, Absorica LD™ 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. CNS stimulants, including Focalin and Ritalin LA, other methylphenidate-containing products, and amphetamines, 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.

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

a. Abuse and dependence: CNS stimulants, other amphetamine-containing products, and methylphenidate, have a high potential for abuse and dependence. Administration of amphetamines for prolonged periods of time may lead to drug dependence and must be avoided. 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 prescribed 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.

Qelbree®

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

Antihypertensives

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

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®, Altace®, Accupril®, Lotrel®

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.

Sabril®

a. Sabril® can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, Sabril® also can damage the central retina and may decrease visual acuity. The onset of vision loss from Sabril® is unpredictable, and can occur within weeks of starting treatment or sooner, or at any time after starting treatment, even after months or years. Symptoms of vision loss from Sabril® are unlikely to be recognized by patients or caregivers before vision loss is severe. Vision loss of milder severity, while often unrecognized by the patient or caregiver, can still adversely affect function. The risk of vision loss increases with increasing dose and cumulative exposure, but there is no dose or exposure known to be free of risk of vision loss. Vision assessment is recommended at baseline (no later than 4 weeks after starting Sabril®), at least every 3 months during therapy, and about 3 to 6 months after the discontinuation of therapy. Once detected, vision loss due to Sabril® is not reversible. It is expected that, even with frequent monitoring, some patients will develop severe vision loss. Consider drug discontinuation, balancing benefit and risk, if vision loss is documented. Risk of new or worsening vision loss continues as long as Sabril® is used. It is possible that vision loss can worsen despite discontinuation of Sabril®. Because of the risk of vision loss, Sabril® should be withdrawn from patients with refractory complex partial seizures who fail to show substantial clinical benefit within 3 months of initiation and within 2-4 weeks of initiation for patients with infantile spasms, or sooner if treatment failure becomes obvious. Patient response to and continued need for Sabril® should be periodically reassessed. Sabril® should not be used in patients with, or at high risk of, other types of irreversible vision loss unless the benefits of treatment clearly outweigh the risks. Sabril® should not be used with other drugs associated with serious adverse ophthalmic effects such as retinopathy or glaucoma unless the benefits clearly outweigh the risks. Use the lowest dosage and shortest exposure to Sabril® consistent with clinical objectives.

Tegretol®, Tegretol XR®, Carbatrol®

a. Serious and sometimes fatal dermatologic reactions, including Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been reported during treatment with Tegretol®, Tegretol XR®. These reactions are estimated to occur in 1 to 6 per 10,000 new users in countries with mainly Caucasian populations, but the risk in some Asian countries is estimated to be about 10 times higher. Studies in patients of Chinese ancestry have found a strong association between the risk of developing SJS/TEN and the presence of HLA-b*1502, an inherited allelic variant of the HLA-b gene. HLA-b*1502 is found almost exclusively in patients with ancestry across broad areas of Asia. Patients with ancestry in genetically at-risk populations should be screened for the presence of HLA-b*1502 prior to initiating treatment with Tegretol®, Tegretol XR®. Patients testing positive for the allele should not be treated with Tegretol®, Tegretol XR® unless the benefit clearly outweighs the risk.
b. Aplastic anemia and agranulocytosis have been reported in association with the use of Tegretol®, Tegretol XR®. Data from a population-based case control study demonstrate that the risk of developing these reactions is 5-8 times greater than in the general population. However, the overall risk of these reactions in the untreated general population is low, approximately six patients per one million population per year for agranulocytosis and two patients per one million population per year for aplastic anemia. Although reports of transient or persistent decreased platelet or white blood cell counts are not uncommon in association with the use of Tegretol®, Tegretol XR®, data are not available to estimate accurately their incidence or outcome. However, the vast majority of the cases of leukopenia have not progressed to the more serious conditions of aplastic anemia or agranulocytosis. Because of the very low incidence of agranulocytosis and aplastic anemia, the vast majority of minor hematologic changes observed in monitoring of patients on Tegretol®, Tegretol XR® are unlikely to signal the occurrence of either abnormality. Nonetheless, complete pretreatment hematological testing should be obtained as a baseline. If a patient in the course of treatment exhibits low or decreased white blood cell or platelet counts, the patient should be monitored closely. Discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops.

Felbatol®

a) The use of Felbatol® (felbamate) is associated with a marked increase in the incidence of aplastic anemia. Accordingly, Felbatol® should only be used in patients whose epilepsy is so severe that the risk of aplastic anemia is deemed acceptable in light of the benefits conferred by its use. Ordinarily, a patient should not be placed on and/or continued on Felbatol® without consideration of appropriate expert hematologic consultation. Among Felbatol® treated patients, aplastic anemia (pancytopenia in the presence of a bone marrow largely depleted of hematopoietic precursors) occurs at an incidence that may be more than a 100-fold greater than that seen in the untreated population (i.e., 2 to 5 per million persons per year). The risk of death in patients with aplastic anemia generally varies as a function of its severity and etiology; current estimates of the overall case fatality rate are in the range of 20 to 30%, but rates as high as 70% have been reported in the past. There are too few Felbatol® associated cases, and too little known about them to provide a reliable estimate of the syndrome's incidence or its case fatality rate or to identify the factors, if any, that might conceivably be used to predict who is at greater or lesser risk. In managing patients on Felbatol®, it should be borne in mind that the clinical manifestation of aplastic anemia may not be seen until after a patient has been on Felbatol® for several months (e.g., onset of aplastic anemia among Felbatol® exposed patients for whom data are available has ranged from 5 to 30 weeks). However, the injury to bone marrow stem cells that is held to be ultimately responsible for the anemia may occur weeks to months earlier. Accordingly, patients who are discontinued from Felbatol® remain at risk for developing anemia for a variable, and unknown, period afterwards. It is not known whether or not the risk of developing aplastic anemia changes with duration of exposure. consequently, it is not safe to assume that a patient who has been on Felbatol® without signs of hematologic abnormality for long periods of time is without risk. It is not known whether or not the dose of Felbatol® affects the incidence of aplastic anemia.
b) Evaluation of postmarketing experience suggests that acute liver failure is associated with the use of Felbatol®. the reported rate in the U.S. has been about 6 cases of liver failure leading to death or transplant per 75,000 patient years of use. this rate is an underestimate because of under reporting, and the true rate could be considerably greater than this. For example, if the reporting rate is 10%, the true rate would be one case per 1,250 patient years of use. Of the cases reported, about 67% resulted in death or liver transplantation, usually within 5 weeks of the onset of signs and symptoms of liver failure. The earliest onset of severe hepatic dysfunction followed subsequently by liver failure was 3 weeks after initiation of Felbatol®. Although some reports described dark urine and nonspecific prodromal symptoms (e.g., anorexia, malaise, and gastrointestinal symptoms), in other reports it was not clear if any prodromal symptoms preceded the onset of jaundice. It is not known whether or not the risk of developing hepatic failure changes with duration of exposure. It is not known whether or not the dosage of Felbatol® affects the incidence of hepatic failure. It is not known whether concomitant use of other antiepileptic drugs and/or other drugs affect the incidence of hepatic failure. Felbatol® should not be prescribed for anyone with a history of hepatic dysfunction. Treatment with Felbatol® should be initiated only in individuals without active liver disease and with normal baseline serum transaminases. It has not been proved that periodic serum transaminase testing will prevent serious injury but it is generally believed that early detection of drug induced hepatic injury along with immediate withdrawal of the suspect drug enhances the likelihood for recovery. There is no information available that documents how rapidly patients can progress from normal liver function to liver failure, but other drugs known to be hepatotoxins can cause liver failure rapidly (e.g., from normal enzymes to liver failure in 2-4 weeks). Accordingly, monitoring of serum transaminase levels (AST and ALT) is recommended at baseline and periodically thereafter. While the more frequent the monitoring the greater the chances of early detection, the precise schedule for monitoring is a matter of clinical judgement. Felbatol® should be discontinued if either serum AST or serum ALT levels become increased ≥ 2 times the upper limit of normal, or if clinical signs and symptoms suggest liver failure. Patients who develop evidence of hepatocellular injury while on Felbatol® and are withdrawn from the drug for any reason should be presumed to be at increased risk for liver injury if Felbatol® is reintroduced. Accordingly, such patients should not be considered for re-treatment.

Antidepressants

Wellbutrin XL®, Prozac®, Lexapro®, Zoloft®, Effexor XR®, Fetzima™, Trintellix®, Pristiq®, Viibryd®, Aplenzin®, Cymbalta®, Pamelor™, Forfivo®

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®,Effexor XR, & Pamelor™ are not approved for use in pediatric patients.
e. Trintellix® & Viibryd® is not approved for use in pediatric patients.
f. Aplenzin®: Serious neuropsychiatric reactions have occurred in patients taking bupropion for smoking cessation.

Drizalma®

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior 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

Anti-diabetics

Fortamet®, Kazano®, Jentadueto®, Xigduo® XR, Segluromet™, Invokamet® XR

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®

a. Liraglutide and semaglutide 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® 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 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®, Duetact®

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 increases, 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 of care and discontinuation or dose reduction of pioglitazone in Oseni ® must be 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.

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.

Antipsychotics

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

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.
b. 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.
c. Latuda® is not approved for use in pediatric patients.
d. The safety and efficacy of Rexulti™, Abilify Mycite ®, Vraylar ®,Rexulti ®, & Secuado® have not been established in pediatric patients.
e. Abilify® and Abilify Mycite® increases risk of suicidal thoughts and behavior in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors.

Fanapt®, Invega®, Caplyta™, Lybalvi™

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®, Klonopin®, Loreev XR™

a. Risks from concomitant use with opioids: 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 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.

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.Therefore, continuous long-term use of topical calcineurin inhibitors in any age group should be avoided, and application limited to areas of involvement with atopic dermatitis. These agents are not indicated for use in children less than 2 years of age. Only 0.03% Protopic® ointment is indicated for use in children 2-15 years of age

Estrogen Products

Estrace Cream®, Femring®, Vagifem®

Warning: endometrial cancer, cardiovascular disorders, breast cancer, and probable dementia

Estrogen-Alone Therapy

- There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens
- Estrogen-alone therapy should not be used for the prevention of cardiovascular disease or dementia
- The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT)
- The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

Estrogen Plus Progestin Therapy

- Estrogen plus progestin therapy should not be used for the prevention of cardiovascular disease or dementia
- The WHI estrogen plus progestin substudy reported increased risks of stroke, DVT, pulmonary embolism (PE), and myocardial infarction (MI)
- The WHI estrogen plus progestin substudy reported an increased risk of invasive breast cancer
- The WHIMS estrogen plus progestin ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older

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 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.

Lotronex®

a) Infrequent but serious gastrointestinal adverse reactions have been reported with the use of Lotronex®. These events, including ischemic colitis and serious complications of constipation, have resulted in hospitalization and, rarely, blood transfusion, surgery, and death. Lotronex® is indicated only for women with severe diarrhea predominant irritable bowel syndrome (IBS) who have not responded adequately to conventional therapy. Discontinue Lotronex® immediately in patients who develop constipation or symptoms of ischemic colitis. Do not resume Lotronex® in patients who develop ischemic colitis.

Bowel prep agents

Osmoprep®

A. Rare, serious reports of acute phosphate nephropathy in patients who received oral sodium phosphate products, including OsmoPrep, for colon cleansing prior to colonoscopy. Some cases have resulted in permanent impairment of renal function and some patients required long-term dialysis.
B. Patients at increased risk include those with increased age, hypovolemia, increased bowel transit time (such as bowel obstruction), active colitis, or baseline kidney disease, and those using medicines that affect renal perfusion or function

(such as diuretics, angiotensin-converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs], and possibly nonsteroidal antiinflammatory drugs [NSAIDs]).

C. Advise patients of the importance of following the recommended split dosage regimen and the importance of adequate hydration before, during and after the use of OsmoPrep. Avoid additional sodium phosphate-based products.

MS agents

Mavenclad®

A. Malignancies: Mavenclad® may increase the risk of malignancy. Mavenclad® is contraindicated in patients with current malignancy; evaluate the benefits and risks on an individual basis for patients with prior or increased risk of malignancy. Follow standard cancer screening guidelines in patients treated with Mavenclad ®.
B. Risk of Teratogenicity: Mavenclad® is contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the risk of fetal harm. Malformations and embryolethality occurred in animals. Exclude pregnancy before the start of treatment with Mavenclad ® in females of reproductive potential. Advise females and males of reproductive potential to use effective contraception during Mavenclad ® dosing and for 6 months after the last dose in each treatment course. Stop Mavenclad ® if the patient becomes pregnant.

Narcotic analgesics

ConZip®, Ultram®, Ultracet®, Qdolo™

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. Instruct patients to swallow ER tablets intact, and not to cut, break, chew, crush or dissolve the tablets to avoid exposure to potentially fatal dose.
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 neonatalogy experts. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that the appropriate treatment will be available.
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®, Tivorbex™, Vivlodex®, Zorvolex®, Cataflam®

a. Cardiovascular risk: NSAIDs cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. These agents are 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 and patients with a prior history of peptic ulcer and/or GI bleeding are at greater risk for serious gastrointestinal events.
c. For diclofenac and misorostol (Arthrotec®), the administration to women who are pregnant can cause abortion, premature birth, or birth defects. Uterine rupture has been reported when misoprostol was administered to pregnant women to induce labor or to induce abortion beyond the eighth week of pregnancy. Diclofenac/misoprostol should not be taken by pregnant women.

Opioid Analgesics

1. Life-Threatening Respiratory depression: TIRFs (Actiq® , Abstral®, Fentora®, Subsys®), Lazanda®, Duragesic®, Fiorinal®, Hydromorphone (Dilaudid, Exalgo®), Hysingla™ ER, Morphine Sulfate: Arymo™ ER, Kadian®, and MS Contin®, Morphabond ER®, Opana ER®, Oxycodone (Oxycontin®, Oxaydo®), Zohydro ER™ (hydrocodone ER),**Primlev®, Prolate™, Nalocet®**

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, 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: 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®), Fiorinal®, Hysingla™ ER, Morphine Sulfate: Arymo™ ER, *Kadian*®, and MS Contin®, Morphabond ER®, Opana ER®, Oxycodone (Oxycontin®, Oxaydo®), Zohydro ER™ (hydrocodone ER),Primlev®, Prolate™, Nalocet®

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®), Fiorinal®, Lazanda®, Duragesic®, Oxycodone (Oxycontin®, Oxaydo®), Zohydro ER™ (hydrocodone ER),Primlev®, Prolate™, Hysingla™, Nalocet®

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, Kadian®, MS Contin®, Morphabond ER® , Opana ER®, Oxycodone (Oxycontin®, Oxaydo®), Zohydro ER™,**Primlev®**, **Nalocet®**
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®), Fiorinal®, Hysingla™ ER, Morphine Sulfate: Arymo™ ER, Kadian®, and MS Contin®, Morphabond ER® , Opana ER® (**tapentadol ER, and oxymorphone ER), **Zohydro ER™**, **Oxycodone (Oxycontin®, Oxaydo®), Primev®, Prolate™, Nalocet®** 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. Warn patients to avoid exposing the application site and surrounding area to direct external heat sources.

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

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: Kadian®, and MS Contin®, Oxycodone (Oxycontin®, Oxaydo®)

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, Hysingla™ ER, Morphabond ER®,Primlev®, Prolate™, Nalocet®**

Concomitant use of opioid with benzodiazepines or other CNS depressants may result in profound sedation, respiratory depressions, coma, and death. Addiction, abuse and misuse: life-threatening respiratory depression, accidental ingestion; neonatal opioid withdrawal; and risks from concomitant use with benzodiazepines or other CNS depressants.

1. Morphabond ER: Risk evaluation and mitigation strategy (REMS).
2. Primlev ®: Hepatoxicity, cytochrome P450 3A4 interaction
3. Prolate™: Hepatoxicity, cytochrome P450 3A4 interaction

<u>Sleep agents</u>

Restoril™, Halcion®, Doral®,

Risk from concomitant use with opioids: 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.

Zolpidem tartrate (Ambien® and Ambien CR®), zolpidem (Intermezzo®, Zolpimist®), zolpidem tartrate sublingual tablets (Edluar®), eszopiclone 3mg (Lunesta®)

Complex sleep behaviors including sleepwalking, sleep driving, and engaging in other activities while not fully awake have been reported following use of zolpidem tartrate and eszopiclone. Some of these events have resulted in serious injuries, including death. Discontinue immediately if a patient experiences a complex sleep behavior.

Thyroid replacement agents

Thyquidity™: Thyroid hormones, including THYQUIDITY, should not be used for the treatment of obesity or for weight loss. Doses beyond the range of daily hormonal requirements may produce serious or even life-threatening manifestations of toxicity.

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:

Rx.01.33 Off-Label Use

Rx.01.76 Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit

Policy Version Number:	20.00
P&T Approval Date:	December 09, 2021
Policy Effective Date:	April 01, 2022
Next Required Review Date:	September 23, 2022