Pharmacy Policy Bulletin

Title:	Applicable Age Edits
Policy #:	Rx.01.2

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

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

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

Intent:

The intent of this policy is to communicate the medical necessity criteria for medications that have age edits as provided under the member's prescription drug benefit.

Description:

Age edits are used to ensure appropriate utilization in certain age groups. An age edit may be placed on a medication when there are concerns for safe use or inappropriate utilization based on indication in a particular age group. Age edits may be based on the FDA approved label, available literature or accepted compendia as listed in the Off-Label Use Policy. When a medication listed below is prescribed to a member outside of the defined age range, the age edit will be applied and prior authorization will be required.

Retinoids: adapelene (Differin®), tazarotene (Avage®, Tazorac®) and Tretinoin, topical (e.g., Atralin®, Avita®, Retin-A®, Retin A micro®, Altreno™, etc), triafarotene (Aklief®).

Topical retinoids may be used for cosmetic indications, including fine lines and wrinkles, in addition to treating acne. Coverage of medications intended for cosmetic indications is an excluded benefit. Studies of topical retinoids for fine lines and wrinkles included patients beginning in their 20s. An age edit for members over the age of 25 years will be applied to ensure indication is not cosmetic.

Alzheimer medications: Donepezil (Aricept® [ODT]), Rivastigmine (Exelon®), Memantine (Namenda® [XR]), Galantamine (Razadyne® [ER]), Memantine/ donepezil (Namzaric®))

Studies for Alzheimer's disease were primarily conducted in patients over the age of 50 years. An age edit will be applied to evaluate indication in members under the age of 50 years.

Oral liquids: Age edits may be applied to liquid dosage forms that have a tablet or capsule with the same indication to limit use to those under age 12 years. Studies show that children as young as 6-11 years of age can be taught how to swallow solid dosage forms.

Benign Prostate Hypertrophy (BPH); Dutasteride (Avodart®), Finasteride (Proscar®): Studies for BPH indicate this condition is most prevalent in men over the age of 50 years. An age edit will be applied to evaluate indication in members under the age of 50 years.

Policy:

The drugs in the following table are approved in the age ranges listed when there is documentation of all of the following:

1. FDA or compendia approved indication; and
2. Not used for an indication that is otherwise excluded (i.e., cosmetic); and
3. Oral liquid dosage forms that have a tablet or capsule formulation available, one of the following:

    a. Drug will be administered via nasogastric or gastronomy tube; or

b. Member is unable to swallow an intact capsule or tablet

***Note: Age edits apply to brand and generic products. Some brand name products have prior authorization in addition to age edit.

Authorization Duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

Opioids (Butorphanol tartrate NS, Ultram®, Ultram ER®, Ultracet®, Conzip®, codeine containing products, hydrocodone containing cough and cold products)

- 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.
- 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.
- Accidental exposure, especially by children, can result in fatal overdose.
- 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.
- Interactions with drugs affecting cytochrome P450 isoenzymes: the concomitant use of butorphanol tartrate NS with all cytochrome P450 3A4 inhibitors may result in an increase in butorphanol plasma concentrations, which could increase or prolong adverse reactions and potentially fatal respiratory depression. Discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in butorphanol concentration. The effects of concomitant use or discontinuation of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol or codeine are complex and requires careful consideration of the effects on the parent drug and the active metabolite.
- Concomitant use of opioids with benzodiazepines or other CNS depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Treximet® (sumatriptan/naproxen):

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

ACE inhibitors (Epaned®, Qbrelis®):

- Fetal toxicity. When pregnancy is detected discontinue Epaned®/Qbrelis® as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

Benzodiazepines (Clobazem, Halcion®, Doral®, Restoril®, Ativan®, Onfi®, Oxazepam®, Tranxene®, Chlordiazepoxide, Estazolam, Flurazepam and Xanax®):

- 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.
- The use of benzodiazepines exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing benzodiazepine and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
- Abrupt discontinuation or rapid dosage reduction of benzodiazepines after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue the benzodiazepine or reduce the dosage.

Non-Steroidal Anti-Inflammatory Drugs (Naprosyn®, Indocin®)

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

Nortriptyline

- Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of nortriptyline hydrochloride or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Nortriptyline hydrochloride is not approved for use in pediatric patients.

Xatmep™ (methotrexate oral solution):

- Methotrexate can cause severe or fatal toxicities. Monitor closely and modify dose or discontinue for the following toxicities: bone marrow suppression, infection, renal, gastrointestinal, hepatic, pulmonary, hypersensitivity, and dermatologic. Methotrexate can cause embryo-fetal toxicity and fetal death. Use in polyarticular juvenile idiopathic arthritic arthritis is contraindicated in pregnancy. Consider the benefits and risks of Xatmep™ and risks to the fetus when prescribing Xatmep™ to a pregnant patient with a neoplastic disease. Advise patients to use effective contraception during and after treatment with Xatmep™.

Tegretol® (carbamazepine):

- Serious and sometimes fatal dermatologic reactions, including Toxic Epidermal Necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), have been reported during treatment with Tegretol®. Studies in patients of Chinese ancestry have found a strong association between the risk of developing TEN/SJS 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®. Patients testing positive for the allele should not be treated with Tegretol® unless the benefit clearly outweighs the risk.
- Aplastic anemia and agranulocytosis have been reported in association with the use of Tegretol®. 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®, 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® 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.

Riomet® [ER] (metformin):

- Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally > 5 mcg/mL.

- Risk factors include renal impairment, concomitant use of certain drugs, age ≥ 65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, 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 lactic acidosis is suspected, discontinue Riomet institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.

Proazac® (fluoxetine)

- Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.
- Monitor for worsening and emergence of suicidal thoughts and behaviors.

Qdolo™ (tramadol)

- Ensure accuracy when prescribing, dispensing, and administering QDOLO. Dosing errors due to confusion between mg and mL can result in accidental overdose and death
- QDOLO exposes users to the risks of addiction, abuse and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing QDOLO, and monitor regularly for these behaviors or conditions.
- To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for these products.
- Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially during initiation or following a dose increase.
- Accidental ingestion of QDOLO, especially by children, can result in a fatal overdose of tramadol.
- Life-threatening respiratory depression and death have occurred in children who received tramadol. Some of the reported cases followed tonsillectomy and/or adenoidectomy; in at least one case, the child had evidence of being an ultra-rapid metabolizer of tramadol due to a CYP2D6 polymorphism
- QDOLO is contraindicated in children younger than 12 years of age and in children younger than 18 years of age following tonsillectomy and/or adenoidectomy (4). Avoid the use of QDOLO in adolescents 12 to 18 years of age who have other risk factors that may increase their sensitivity to the respiratory depressant effects of tramadol.
- Prolonged use of QDOLO, during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.
- The effects of concomitant use or discontinuation of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with tramadol are complex. Use of cytochrome P450 3A4 inducers, 3A4 inhibitors, or 2D6 inhibitors with QDOLO requires careful consideration of the effects on the parent drug, tramadol, and the active metabolite, M1.
- Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

Thyquidity™ (levothyroxine sodium)

- Thyroid hormones, including THYQUIDITY, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

Valcyte® (valganciclovir)

- Hematologic Toxicity: Severe leukopenia, neutropenia, anemia, thrombocytopenia, pancytopenia, and bone marrow failure including aplastic anemia have been reported in patients treated with VALCYTE.
- Impairment of Fertility: Based on animal data and limited human data, VALCYTE may cause temporary or permanent inhibition of spermatogenesis in males and suppression of fertility in females.
- Fetal Toxicity: Based on animal data, VALCYTE has the potential to cause birth defects in humans.
- Mutagenesis and Carcinogenesis: Based on animal data, VALCYTE has the potential to cause cancers in humans.

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.

Drug Name	Age Edit: Prior Authorization Required (years)
Acne Medications	
Tretinoin, topical (e.g. Atralin®, Avita®, Retin-A®, Retin A micro®, Altreno™ etc)	Age 26 and over
Adapalene (Differin®)	Age 26 and over
Adapalene/ Benzoyl Peroxide (Epiduo®)	Age 26 and over

Tretinoin/ clindamycin (Ziana®)	Age 26 and over
Dapsone (Aczone®)	Under age 12
Tazarotene (Fabior®, Arazlo®, Tazorac®)	Age 26 and over
Triafarotene (Aklief®)	Age 26 and over
Tretinoin-benzoyl peroxide (Twyneo®)	Age 26 and over
Alzheimers Drugs	
Donepezil (Aricept® [ODT], Adlarity®)	Under age 50
Rivastigmine (Exelon®)	Under age 50
Memantine (Namenda® [XR])	Under age 50
Galantamine (Razadyne® [ER])	Under age 50
Memantine/ donepezil (Namzaric®)	Under age 50
Anticonvulsant Agents	
Carbamazepine (Tegretol®) suspension	Age 13 and over
Gabapentin (Neurontin®) solution	Age 13 and over
Brivaracetam solution (Briviact®)	Age 13 and over
Clobazem suspension (Onfi®)	Age 13 and over
Pregabalin solution (Lyrica®)	Age 13 and over
Oxcarbazepine suspension (Trileptal®)	Age 13 and over
Antidepressants	
Nortriptyline solution	Age 13 and over
Fluoxetine solution (Prozac®)	Age 13 and over
Antidiabetic Agents	
Metformin (Riomet® [ER]) solution/suspension	Age 13 and over
Acute Migraine Agents	
Eletriptan (Relpax®)	Under age 18
Sumatriptan (eg Imitrex®, Onzetra® Xsail, Zembrace® Symtouch, Tosymra®)	Under age 18
Butorphanol tartrate NS	Under age 18
Naratriptan (Amerge®)	Under age 18
Rizatriptan (Maxalt®/ Maxalt MLT®)	Under age 6
Zolmitriptan (Zomig®/Zomig ZMT®)	Under age 12
Almotriptan	Under age 12
Frovatriptan (Frova®)	Under age 18
Sumatriptan/ naproxen (Treximet®)	Under age 12
Lasmiditan (Reyvow®)	Under age 18
Ubrogepant (Ubrelvy®)	Under age 18
Rimegepant (Nurtec™ ODT)	Under age 18
Antihypertensives	
Amlodipine (Katerzia®, Norliqva®)	Age 13 and over
Enalapril (Epaned®)	Age 13 and over
Lisinopril (Qbrelis®)	Age 13 and over
Valsartan oral solution	Age 13 and over
Antiinfectives	
Zanamivir (Relenza®)	Under age 5
Vancomycin oral solution (Firvanq™)	Age 13 and over
Valganciclovir oral solution (Valcyte®)	Age 13 and over
Nitrofurantoin suspension (Furadantin®)	Age 13 and over
Doxycycline hyclate DR 75mg, 150mg (Doryx® 75mg, 150mg), Doxycycline hyclate 75mg, 150mg (Acticlate® 75mg, 150mg), Doxycycline monohydrate /Mondoxyn NL® 75mg capsule (Monodox® 75mg), Doxycycline monohydrate 150mg capsule and tablet (Adoxa® 150mg)	Age 18 and over

Benign Prostate Hypertrophy	
Dutasteride (Avodart®)	Under age 50
Finasteride (Proscar®)	Under age 50
Erectile Dysfunction agents	
Alprostadil® (Muse®, Edex®, Caverject®, IFE-PG20)	Under age 55
Benzodiazepines	
Flurazepam	Under age 15
Triazolam (Halcion®)	Under age 18
Quazepam (Doral®)	Under age 18
Estazolam	Under age 18
Temazepam (Restoril®)	Under age 18
Lorazepam (Ativan®)	Under age 12
Chlordiazepoxide	Under age 6
Oxazepam	Under age 12
Clorazepate (Tranxene®)	Under age 9
Alprazolam (Xanax®)	Under age 18
Leukotriene Inhibitors	
Zafirlukast (Accolate®)	Under age 5
Zileuton (Zyflo® [CR])	Under age 12
Pain	
Tramadol/Tramadol ER containing products (e.g., Ultram®, Ultram® ER, Ultracet®, Conzip®)	Under age 12
Tramadol solution (Qdolo®)	Under age 18
Codeine containing products	Under age 12
Indomethacin (Indocin®) suspension	Age 13 and over
Naproxen suspension (Naprosyn®)	Age 13 and over
Cough and Cold products	
Codeine and hydrocodone containing cough & cold products	Under age 18
Miscellaneous	
Xatmep® (methotrexate oral solution)	Age 13 and over
Auvi-Q™ 0.1mg (epinephrine)	Age 4 and over
Pyridostigmine Bromide solution (Mestinon®)	Age 13 and over
Simvastatin suspension (Flolipid®)	Age 13 and over
Thyquidity™ solution	Age 13 and over

Cross References:

Cross reference:
Cosmetic Policy Rx.01.17
Acute Migraine agents Rx.01.56
Opioid Policy Rx.01.197
Prior authorization requirements for select drugs Rx.01.202
New Jersey Prior Authorization Requirement for Select Drugs Rx.01.239
Off-Label Use Rx.01.33
Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit. Rx.01.76

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The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.