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 Experimental/ Investigational 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®, Plixda™), tazarotene (Avage®, Tazorac®) and Tretinoin, topical (e.g. Atralin®, Avita®, Retin-A®, Retin A micro®, Altreno™, etc)

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 BOTH of the following:

1. FDA or compendia approved indication; and

2. Not used for an indication that is otherwise excluded (ie cosmetic)

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

Black Box Warning:

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 (Halcion®, Doral®, Restoril®, Ativan®, 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.

Xatmep™ (methotrexate oral solution): severe toxic reactions, including embryo-fetal toxicity. 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™.

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)	Over age 25
Adapalene (Differin®, Plixda™)	Over age 25
Adapalene/ Benzoyl Peroxide (Epiduo®)	Over age 25
Tretinoin/ clindamycin (Ziana®)	Over age 25
Dapsone (Aczone®)	Under age 12
Tazarotene (Fabior®)	Over age 25
Alzheimers Drugs	
Donepezil (Aricept® [ODT])	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
Antimigraine Agents	
Eletriptan (Relpax®)	Under age 18
Sumatriptan (eg Imitrex®, Sumavel®, Onzetra®)	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 (Axert®)	Under age 12

Frovatriptan (Frova®)	Under age 18
Sumatriptan/ naproxen (Treximet®)	Under age 12
Antihypertensives	
Enalapril (Epaned®)	Over age 12
Lisinopril (Qbrelis®)	Over age 12
Antiinfectives	
Zanamivir (Relenza®)	Under age 5
Vancomycin oral solution (Firvanq™)	over age 12
Benign Prostate Hypertrophy	
Dutasteride (Avodart®)	Under age 50
Finasteride (Proscar®)	Under age 50
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
Leuoktriene 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
Codeine containing products	Under age 12
Cough and Cold products	
Codeine and hydrocodone containing cough & cold products	Under age 18
Miscellaneous	
Xatmep® (methotrexate oral solution)	Over age 12
Auvi-Q™ 0.1mg (epinephrine)	Over age 4

Cross References:

Cross reference:
Cosmetic Policy Rx.01.17
Migraine agents Rx.01.56
Opioid Policy Rx.01.197
Prior authorization requirements for select drugs Rx.01.202

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