

## Envolve Pharmacy Solutions Drug Restriction / Benefit Design

### Appropriate Use & Safety Edits

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Envolve Pharmacy Solutions provides a variety of safety edits to promote the use of the right medication, in the right patient, at the right time. These edits are routinely updated as new medication entries come to market and in cases of new medication safety alerts in an effort to maintain best-in-class safety protocols. The items listed below represent the most recent strategies implemented to improve quality of care and cost containment. It is important to note that this is not a comprehensive list of Envolve utilization management strategies. For specific medication restriction information, please see the specific MHS Preferred Drug List (PDL).

### Dose Consolidation Edits

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Restrictions on claims implemented to prevent members from receiving multiple strengths of the same medication. Current medication classes with dose consolidation edits include, but are not limited to:

- Atypical Antipsychotics
- Long-Acting ADHD Medications (stimulants & non-stimulants)
- Selective Serotonin Receptor Inhibitors (SSRI) & Serotonin Norepinephrine Receptor Inhibitors (SNRI)
- Short-Acting ADHD Medications (stimulants only)

### Duplicate Therapy Edits

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Restrictions on claims implemented to prevent members from receiving excessive medication regimens within the same, or similar, medication class. *Please note that members may utilize up to two medications in any classes listed below with an asterisk (\*).* Current medication classes with duplicate therapy edits include, but are not limited to:

- ACE Inhibitor/Angiotensin Receptor Blockers (ARB)
- Alpha Agonists (pediatrics only)
- Antidepressants\* (all classes)
- Atypical Antipsychotics
- Benzodiazepines\*
- Diabetic Medications (sulfonylurea/meglitinides)
- Long-Acting ADHD Medications (stimulants & non-stimulants)
- Muscle Relaxants
- Sedative-Hypnotics
- Selective Serotonin Receptor Inhibitors (SSRI) & Serotonin Norepinephrine Receptor Inhibitors (SNRI)
- Short-Acting ADHD Medications (stimulants only)\*
- Tricyclic Antidepressants (TCA)

### Fraud and Abuse Edits

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Restrictions on claims implemented to assist in limiting opioids to prevent potentially inappropriate utilization. Current medication classes with fraud and abuse edits include, but are not limited to:

- Opioid Claim Restrictions (restricts members to two opioid claims per month)
- Opioid Cumulative Quantity Limits (regimens restricted to a total of 180 units of opioids per month)
- Detox Agents & Opioid (prevents members from receiving detox agents when opioid use is ongoing)

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### Gender Edits

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Restrictions on claims implemented to prevent patients from receiving certain medications which are only approved for a specific gender. Current medication classes with gender edits include, but are not limited to:

- Hormone Replacement Therapy (HRT)
- Contraceptives
- Prenatal vitamins

### Lower Age Limits

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Restrictions on age implemented to prevent children from utilizing medications below FDA recommended age limits. Current medication classes with lower age limits include, but are not limited to:

- Atypical Antipsychotics
- Benzodiazepines
- Long-Acting ADHD Medications (stimulants & non-stimulants)
- Migraine Rescue Medications (triptans & non-triptans)
- Sedative-Hypnotics
- Short-Acting ADHD Medications (stimulants only)
- Smoking Deterrents

### Upper Age Limits

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Restrictions on age implemented to prevent adults from receiving medications commonly indicated for pediatric use only (without proper documentation of diagnosis) or for pregnancy (generally under age 45). Current medication classes with upper age limits include, but are not limited to):

- Long-Acting ADHD Medications (stimulants & non-stimulants)
- Most chewable, liquid, and suspension formulations
- Prenatal vitamins
- Short-Acting ADHD Medications (stimulants only)

### Quantity Limits

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Restrictions on claim quantity per day implemented to prevent daily doses above FDA recommendations. Multiple medications within different medication classes have quantity limit requirements. Current medication classes with quantity limits include, but are not limited:

- Antibiotics
- Anti-Cholesterolemia Therapy
- Antiemetics
- Antifungals
- Anti-Hypertensives
- Asthma Medications
- Cough & Cold Therapy
- Diabetic Medications
- Gastrointestinal Treatment & Prophylaxis
- HIV Therapy
- Hormone Replace Therapy (HRT)
- Migraine Therapy
- Non-Steroidal Anti-Inflammatory Drugs (NSAID)
- Opioid Analgesics
- Osteoporosis Therapy
- Sedative/Hypnotics
- Skeletal Muscle Relaxants
- Topical Steroids



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### **Step Therapy Edits**

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Restrictions on claims implemented to steer members toward the preferred medication in a particular medication class. Current medication classes with step therapy restrictions include, but are not limited to:

- Aromatase Inhibitors (exemestane/letrozole)
- Canagliflozin
- Exenatide
- Isotretinoin
- Lodoxamide/Nedocramil Ophthalmic Solution
- Olanzapine-Fluoxetine
- Valsartan (with or without HCTZ)

### **Buprenorphine/Opioid Edits**

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Identifies opioid use after the patient has begun opioid use disorder treatment with a buprenorphine product. The patient should not receive any new opioid Rx after they start buprenorphine. After reviewing the patient's medication history, the pharmacist will need to contact the prescriber to determine a further course of action. Current medication classes with step therapy restrictions include, but are not limited to:

- Opioid partial agonist
- Opioids

### **Teratogenic Edits**

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Restrictions on claims implemented to prevent female members from receiving potentially harmful medications prior to confirmation of pregnancy status. It is important to note that this list is not all inclusive of medications in FDA pregnancy categories<sup>1</sup> X and/or D. Furthermore, not all medications within the therapeutic categories listed below are categorized as pregnancy X and/or D.

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<sup>1</sup> *Category D products are those where there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the medication in pregnant women despite potential risks. Category X products are those in which Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the medication in pregnant women clearly outweigh potential benefits.*



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### Pregnancy Category X (absolute fetal risk)

- 5-Alpha Reductase Inhibitors
- Anabolic Steroids
- Androgens
- Anorexiants
- Antineoplastics
- Coumadin Anticoagulants
- Endothelin Receptor Antagonists
- Hepatitis Agents
- HMG CoA Reductase Inhibitors
- Migraine Agents
- Non-Barbiturate Hypnotics
- Non-Steroidal Anti-Inflammatory Drugs (NSAID)
- Progesterone Receptor Antagonists
- Progestins
- Prostaglandins
- Retinoids
- Stimulant Laxatives

### Pregnancy Category D (risk outweighs benefit)

- ACE Inhibitors
- Alkylating Agents
- Aminoglycosides
- Antiandrogens
- Antiestrogens
- Antineoplastics
- Beta Blockers
- Gout Agents
- Mitotic Inhibitors
- Potassium Sparing Diuretics
- Selective Serotonin Reuptake Inhibitors
- Sickle Cell Anemia Agents
- Smoking Deterrents
- Tetracyclines
- Thiazide & Thiazide Like Diuretics
- Tricyclic Antidepressants

### Pregnancy Category D (benefits may outweigh risks)

- Anticonvulsants
- Antiretrovirals
- Antispasmodics
- Antithyroid Agents
- Barbiturate Hypnotics
- Benzodiazepines
- Glucocorticoids
- Hydantoins
- Imidazole Antifungals
- Immunosuppressives
- Lithium
- Non-Barbiturate Hypnotics

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### Safety Edits

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Restrictions on claims implemented to prevent members from receiving combination medication regimens that are contraindicated or may be potentially toxic and life threatening. Current medications with safety edits include, but are not limited to:

### **Human Immunodeficiency Virus (HIV)<sup>2</sup> Medications**

- Atripla (efavirenz, emtricitabine, tenofovir), Combivir (lamivudine, zidovudine)
- Atripla (efavirenz, emtricitabine, tenofovir), Emtriva (emtricitabine), Truvada (emtricitabine, tenofovir)
- Atripla (efavirenz, emtricitabine, tenofovir), Epivir (lamivudine)
- Atripla (efavirenz, emtricitabine, tenofovir), Epzicom (abacavir, lamivudine)
- Atripla (efavirenz, emtricitabine, tenofovir), Trizivir (abacavir, lamivudine, zidovudine)
- Atripla (efavirenz, emtricitabine, tenofovir), Videx (didanosine)
- Combivir (lamivudine, zidovudine), Emtriva (emtricitabine)
- Combivir (lamivudine, zidovudine), Epivir (lamivudine), Trizivir (abacavir, lamivudine, zidovudine)
- Complera (emtricitabine, rilpivirine, tenofovir)
- Emtriva (emtricitabine), Epivir (lamivudine)
- Emtriva (emtricitabine), Trizivir (abacavir, lamivudine, zidovudine)
- Epzicom (abacavir, lamivudine), Emtriva (emtricitabine)
- Epzicom (abacavir, lamivudine), Ziagen (abacavir), Trizivir (abacavir, lamivudine, zidovudine)
- Evotaz (cobicistat and atazanavir) or Crixivan (indinavir)
- Evotaz (cobicistat and atazanavir), Prezcofix (darunavir and cobicistat)
- Prezcofix (darunavir, cobicistat), Prezista (darunavir)
- Rescriptor (delavirdine), Sustiva (efavirenz), INTELENCE (etravirine), Viramune (nevirapine), Atripla (efavirenz, emtricitabine, tenofovir), Edurant (ilpivirine)
- Reyataz (Atazanavir), Crixivan (Indinavir)
- Stribild (cobicistat, emtricitabine, elvitegravir, tenofovir)
- Triumeq (abacavir, dolutegravir, lamivudine), Atripla (efavirenz, emtricitabine, tenofovir)
- Triumeq (abacavir, dolutegravir, lamivudine), Combivir (lamivudine and zidovudine), Epivir (lamivudine), Epzicom (abacavir and lamivudine), Trizivir (abacavir, lamivudine, zidovudine)
- Triumeq (abacavir, dolutegravir, lamivudine), Complera (emtricitabine, rilpivirine, tenofovir)
- Triumeq (abacavir, dolutegravir, lamivudine), Emtriva (emtricitabine)
- Triumeq (abacavir, dolutegravir, lamivudine), Truvada (emtricitabine, tenofovir)
- Truvada (emtricitabine, tenofovir), Combivir (lamivudine, zidovudine)
- Truvada (emtricitabine, tenofovir), Epivir (lamivudine)
- Truvada (emtricitabine, tenofovir), Epzicom (abacavir, lamivudine)

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<sup>2</sup> Based on 2015 HIV guidelines and manufacturer recommendations



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- Truvada (emtricitabine, tenofovir), Trizivir (abacavir, lamivudine, zidovudine)
- Truvada (emtricitabine, tenofovir), Viread (tenofovir)
- Tybost (cobicistat), Norvir (ritonavir), Kaletra (lopinavir and ritonavir)
- Videx (didanosine), Truvada (emtricitabine, tenofovir)
- Videx (didanosine), Viread (tenofovir)
- Videx (didanosine), Zerit (stavudine)
- Zerit (stavudine), Combivir (lamivudine, zidovudine)
- Zerit (stavudine), Retrovir (zidovudine)
- Zerit (stavudine), Trizivir (abacavir, lamivudine, zidovudine)