Pharmacy Management Drug Policy

SUBJECT: **Step Therapy Policy for Commercial Open, Select Self-Funded Commercial Closed, Child Health Plus, Essential Plan, Small Employer Group and Direct Pay Metal Plans**
POLICY NUMBER: PHARMACY-72
ANNUAL REVIEW DATE: 12/11/2020
EFFECTIVE DATE: 10/11
LAST REVIEW DATE: 3/25/2020

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. Medical or drug policies apply to commercial and Health Care Reform products only when a contract benefit for the specific service exists.

DESCRIPTION:

Step Therapy encourages use of safe, cost-effective medications within different therapeutic drug categories. The entry of new generics and cost-effective therapeutic alternatives has provided an opportunity to promote these therapies as first-line.

POLICY:

Step Therapy requires members try certain first-line options before other medications will be considered medically necessary for treatment of a specific condition. Step therapy requirements may apply to both brands and generics. Typically, first-line medications are classified as generics, but there are instances where brand name medications may be preferred.

Based upon our review and assessment of the peer-reviewed literature, these medications have been medically proven to be effective and therefore **medically necessary** for medical treatment if the request meets the following criteria:

ANALGESICS	
Drug	**Requirement**
Cambia	Coverage requires documentation of serious side effects or drug failure with 2 generic NSAIDs **and** ONE generic triptan **Exception:** requirement is bypassed when requested by a neurologist

ANTIBACTERIALS	
Drug	**Requirement**
Doryx Oracea Doxycycline IR-DR 40 mg	Coverage requires documentation of serious side effects or drug failure with immediate-release doxycycline **and** immediate-release minocycline
Clindagel 75 mL Clindamycin 1% Gel 75 mL (Oceanside) Cleocin T Evoclin	Coverage requires documentation of serious side effects or drug failure with generic clindamycin **and** tretinoin
Amzeeq	Coverage requires serious side effects or drug failure with TWO topical treatments for acne (erythromycin, clindamycin, tretinoin, adapalene, dapsone, tazarotene)
Aktipak	Coverage requires documentation of serious side effects or drug failure with a generic erythromycin/benzoyl peroxide product **and** tretinoin

Dificid	Coverage requires documentation of serious side effects or drug failure with oral vancomycin **Exception:** Prescriptions written by infectious disease specialists

ANTICOAGULANTS

Drug	Requirement
Pradaxa Savaysa	Coverage requires documentation of serious side effects or drug failure with Xarelto or Eliquis

ANTICONVULSANTS

Drug	Requirement
Sympazan	Coverage requires documentation of serious side effects or drug failure with generic clobazam tablets or suspension

ANTIDEPRESSANTS

Drug	Requirement
Aplenzin Bupropion HCL XL 450 mg Emsam Forfivo XL 450 mg Khedezla Pexeva	Coverage requires documentation of serious side effects or drug failure with at least **ONE** of the following first line agents ***when prescribed by a psychiatrist*** OR at least **TWO** of the following first line agents ***when prescribed by a practitioner <u>other than</u> a psychiatrist***: escitalopram, fluoxetine, citalopram, sertraline, paroxetine, mirtazapine, bupropion or venlafaxine **immediate-release** tablets or venlafaxine extended-release **capsules**
Venlafaxine ER **Tablets**	Coverage requires documentation of serious side effects or drug failure with venlafaxine ER capsules, **<u>however:</u>** • Equal doses of venlafaxine HCL extended-release tablets are bioequivalent to venlafaxine ER capsules, but are not substitutable at the pharmacy level • A daily dose of 225 mg venlafaxine ER may be obtained by ordering venlafaxine ER 75 mg capsules, taken as 3 capsules once daily • The claims processing system will not read history for this edit therefore claims will not automatically pay, therefore a manual step therapy request must be made for coverage determination
Drizalma Sprinkle	Coverage requires serious side effects or drug failure with duloxetine

ANTIEMETICS

Drug	Requirement
Anzemet Zuplenz	Coverage requires documentation of serious side effects or drug failure with ondansetron
Sancuso	Coverage requires documentation of serious side effects or drug failure with ondansetron **and** granisetron

ANTIFUNGAL AGENTS	
Drug	**Requirement**
Ecoza	Coverage requires documentation of serious side effects or drug failure with TWO of the following generic topical antifungals: ciclopirox, econazole, ketoconazole, nystatin
Ertaczo	
Extina	
Luzu	
Luliconazole	
Mentax	
Naftin Gel	
Oxiconazole	
Xolegel	

ANTIMIGRAINE AGENTS	
Drug	**Requirement**
Onzetra	Coverage requires documentation of serious side effects or drug failure with TWO generic triptans: (Almotriptan, Eletriptan, Frovatriptan, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan)
Zomig Nasal Spray	
Tosymra	Coverage requires documentation of serious side effects or drug failure with generic sumatriptan nasal spray **and** TWO generic oral triptans: (Almotriptan, Eletriptan, Frovatriptan, Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan)
Sumavel	Coverage requires documentation of serious side effects or drug failure with injectable sumatriptan
Zembrace	

ANTINEOPLASTICS	
Drug	**Requirement**
Gleevec	Coverage requires documentation of serious side effects or drug failure with imatinib

ANTIPSYCHOTICS		
Drug	**Diagnosis**	**Requirement**
Caplyta	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
Fanapt	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)

Latuda	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
	Bipolar Depression	Coverage requires documentation of serious side effects or drug failure with TWO alternative therapies for bipolar depression (lamotrigine, lithium, quetiapine, olanzapine, valproate)
Rexulti	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
	Major Depressive Disorder	Coverage requires documentation of serious side effects or drug failure with TWO different antidepressants (with different mechanisms of action) used in combination **or** ONE antidepressant in combination with ONE other augmentation therapy (such as atypical antipsychotic, lithium, buspirone)
Saphris	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
	Bipolar disorder	
Secuado	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
Vraylar	Schizophrenia	Coverage requires documentation of serious side effects or drug failure with TWO generic atypical antipsychotics (risperidone, olanzapine, ziprasidone, quetiapine, aripiprazole, paliperidone ER)
	Bipolar disorder	
	Bipolar Depression	Coverage requires documentation of serious side effects or drug failure with TWO alternative therapies for bipolar depression (lamotrigine, lithium, quetiapine, olanzapine, valproate)

ANTIVIRALS

Drug	**Requirement**
Atripla	The preferred agent(s) is Symfi or Symfi Lo. Atripla will only be authorized if there is medical justification as to why Symfi or Symfi Lo cannot be used

BLOOD GLUCOSE REGULATORS
(SELECT BENEFITS ONLY)

Drug	**Requirement**
Admelog	Coverage requires documentation of serious side effects or drug failure with Humalog or Insulin Lispro (Lilly authorized generic)
Apidra	
Fiasp	
Novolog, Insulin Aspart	

Drug	Requirement
Onglyza Kombiglyze Nesina Alogliptin Kazano Alogliptin/metformin Oseni Alogliptin/pioglitazone	Coverage requires documentation of serious side effects or drug failure with Januvia, Janumet, Tradjenta or Jentadueto
Glumetza Fortamet Metformin ER (generics of Fortamet and Glumetza)	Coverage requires documentation of serious side effects or drug failure with generic immediate-release metformin **and** generic extended-release metformin (generic equivalent of Glucophage XR)
Blood Glucose Meters and Test Strips	Coverage of any non-preferred blood glucose meter or test strip requires either: a previous trial and failure **or** the inability to use any Abbott (Freestyle or Precision Xtra) or One Touch products
Adlyxin Byetta Bydureon	Coverage requires documentation of serious side effects or drug failure with TWO of the following agents: Ozempic, Victoza or Trulicity.

BRONCHODILATORS, SYMPATHOMIMETIC

Drug	Requirement
Xopenex Xopenex Conc Xopenex HFA Levalbuterol Tartrate HFA	Coverage requires documentation of serious side effects or drug failure with an Albuterol inhaler or nebulizer **(Applies to CHP policies only)**

CARDIOVASCULAR AGENTS

Drug	Requirement
Entresto	Coverage requires documentation of serious side effects or drug failure to at least TWO first line medications from 2 of the 3 the following classes: Angiotensin-Converting Enzyme Inhibitors (ACEI), Angiotensin II Receptor Antagonists (ARB) or Beta Blockers. The 2 medication trials documented cannot be form the same drug class, however. For example, approval would not be granted for a patient whom had tried 2 ARBs, but no other agents from the ACEI or Beta Blocker categories
Edarbi	Coverage requires documentation of serious side effects or drug failure with TWO of the following: losartan, irbesartan, valsartan
Edarbyclor	Coverage requires documentation of serious side effects or drug failure with TWO of the following: losartan/hctz, irbesartan/hctz, valsartan/hctz

CARDIOVASCULAR AGENTS, DYSLIPIDEMICS

Drug	Requirement
Livalo Zypitamag	Documentation of serious side effects or drug failure with TWO of the following generic statins: atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin

CENTRAL NERVOUS SYSTEM AGENTS	
Drug	**Requirement**
Savella	Coverage requires documentation of serious side effects or drug failure with duloxetine

DERMATOLOGICAL AGENTS	
Drug	**Requirement**
Aczone 5 %, 7.5%, Dapsone 7.5%	Coverage requires documentation of serious side effects or drug failure with a topical retinoid
Adapalene 0.1% Lotion, Soln, Swab Differin 0.1% Lotion Plixda 0.1% Swab	Coverage requires documentation of serious side effects or drug failure with adapalene cream or gel **and** tretinoin cream or gel
Eucrisa Ointment	Coverage requires documentation of serious side effects or drug failure with ONE generic topical steroid (aclometasone, amcinonide, betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide–E, fluticasone, halobetasol, hydrocortisone 2.5%, hydrocortisone valerate, hydrocortisone butyrate, mometasone, prednicarbate, triamcinolone) **or** ONE of the following: tacrolimus ointment or pimecrolimus cream.
Noritate Soolantra, Ivermectin	Coverage requires documentation of serious side effects or drug failure with generic metronidazole cream, gel or lotion

GASTROINTESTINAL AGENTS		
Drug		**Requirement**
Amitiza	Chronic idiopathic constipation or IBS-C	Coverage requires documentation of serious side effects or drug failure with Linzess for a diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation.
	Opioid-induced constipation	Coverage requires documentation of drug failure or serious side effects with Movantik for a diagnosis of opioid induced constipation.
Motegrity		Coverage requires documentation of serious side effects or drug failure with Linzess for a diagnosis of chronic idiopathic constipation (CIC)
Symproic		Coverage requires documentation of serious side effects or drug failure with Movantik for a diagnosis of opioid-induced constipation
Trulance		Coverage requires documentation of serious side effects or drug failure with Linzess for a diagnosis of chronic idiopathic constipation or irritable bowel syndrome with constipation
Dexilant		Coverage requires documentation of serious side effects or drug failure with lansoprazole or omeprazole
Nexium		Coverage requires documentation of serious side effects

Omeprazole/Sodium Bicarbonate Zegerid	or drug failure with THREE of the following: omeprazole, pantoprazole, lansoprazole, rabeprazole

GENITOURINARY AGENTS; ANTISPASMODICS, URINARY	
Drug	**Requirement**
Oxytrol Gelnique	Coverage requires documentation of serious side effects or drug failure with TWO of the following: oxybutynin, oxybutynin ER, tolterodine, trospium, trospium XR **Exception:** Gelinique does not require step therapy for individuals 65 years of age or older

HORMONAL AGENTS, STIMULANT/REPLACEMENT/MODIFYING (ADRENAL)	
Drug	**Requirement**
Bryhali Cloderm Clocortolone pivalate Cordran (Cream, Lotion, Ointment) Desonate Halog, Halcinonide Halobetasol Propionate 0.05% Foam Hydrocortisone Butyrate 0.1% Lotion Impoyz Kenalog Spray Lexette Locoid, Locoid Lipocream Pandel Sernivo Ultravate Lotion Vanos Verdeso	Coverage requires documentation of a serious side effects or drug failure with TWO of the following generic topical steroids: aclometasone, amcinonide, betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide–E, fluticasone, halobetasol (except foam), hydrocortisone 2.5%, hydrocortisone valerate, hydrocortisone butyrate (except lotion), mometasone, prednicarbate, triamcinolone

IMMUNOLOGICAL AGENTS	
Drug	**Requirement**
Azasan	Coverage requires documentation of a serious side effects or drug failure with generic azathioprine
Prograf Granules	Must have documentation of serious side effects or drug failure with generic tacrolimus capsules **Exception:** age less than 9 years old

MONOAMINE OXIDASE (MAO-B) INHIBITORS	
Drug	**Requirement**
Xadago	Coverage requires documentation of serious side effects or drug failure with generic selegiline

MULTIPLE SCLEROSIS AGENTS	
Drug	**Requirement**
Aubagio	Coverage requires documentation of serious side effects or drug failure with ONE of the following: Avonex, Copaxone (or Glatiramer), Plegridy, Rebif
Betaseron	Coverage requires documentation of serious side effects or drug failure with TWO of the following agents: Avonex, Copaxone (or Glatiramer), Gilenya, Plegridy, Rebif, Tecfidera
Vumerity	Coverage requires documentation of serious side effects or drug failure with TWO of the following agents: Gilenya, Tecfidera and Mayzent
Glatopa 20mg/ml	Coverage requires documentation of serious side effects or drug failure with Glatiramer 20 mg/mL

OPHTHALMIC AGENTS		
Drug		**Requirement**
Zerviate		Coverage requires documentation of serious side effects or drug failure with TWO of the following antihistamine eye drops: azelastine, olopatadine, epinastine
Xelpros	Vyzulta	Coverage requires documentation of serious side effects or drug failure with latanoprost AND either Lumigan or Travatan Z
Zioptan		
Rhopressa	Rocklatan	Coverage requires documentation of serious side effects or drug failure with latanoprost

PHOSPHATE BINDERS	
Drug	**Requirement**
Veltassa	Coverage requires documentation of serious side effects or drug failure with Lokelma

PHOSPHODIESTERASE INHIBITORS, AIRWAYS DISEASE	
Drug	**Requirement**
Daliresp	Coverage requires documentation of serious side effects or drug failure with an inhaled corticosteroid or long-acting beta agonist

RESPIRATORY TRACT/PULMONARY AGENTS	
Drug	**Requirement**
Aerospan	Coverage requires documentation of serious side effects or drug failure with ONE of the following: Arnuity Ellipta, Asmanex, Flovent or Qvar
Alvesco	
Pulmicort Flexhaler	
AirDuo Respiclick	Coverage requires documentation of severe intolerance or

	therapeutic failure with generic fluticasone/salmeterol inhaler
Lonhala Magnair 25 mcg Starter	Coverage requires documentation of serious side effects or drug failure with any TWO of the following long-acting muscarinic receptor antagonist (LAMA) containing inhalers: Anoro Ellipta, Bevespi Aerosphere, Incruse Ellipta, Seebri Neohaler, Spiriva Handihaler, Spiriva Respimat, Stiolto Respimat, Trelegy Ellipta, Tudorza Pressair, or Utibron
Lonhala Magnair 25 mcg Refill	
Yupelri	
Duaklir Pressair	Coverage requires serious side effects or drug failure with at least TWO long-acting muscarinic receptor antagonist/long-acting beta agonist (LAMA/LABA) agents. Agents include: Anoro, Bevespi, Stiolto and Utibron.
Trelegy Ellipta	Coverage requires documentation of serious side effects or drug failure with at least ONE long-acting muscarinic receptor antagonist (LAMA) OR long-acting muscarinic receptor antagonist/long-acting beta agonist (LAMA/LABA) OR long-acting beta agonist/inhaled corticosteroid (LABA/ICS). Agents Include: Advair, Anoro, Bevespi, Breo, Fluticasone/Salmeterol, Incruse, Seebri, Spiriva, Stiolto, Symbicort, Tudorza, Utibron

SELECTIVE ESTROGEN RECEPTOR MODIFYING AGENTS

Drug	Requirement
Osphena	Coverage requires documentation of serious side effects or drug failure with ONE of the following vaginal estrogen products: Estrace cream, Premarin cream, Femring, Vagifem

SKELETAL MUSCLE RELAXANTS

Drug	Requirement
Norgesic Forte	Coverage requires documentation of serious side effects or drug failure with THREE of the following (generic) agents: baclofen, carisoprodol, chlorzoxazone, cyclobenzaprine, methocarbamol, metaxalone, orphenadrine, tizanidine
Orphengesic Forte	

SLEEP DISORDER AGENTS

Drug	Requirement
Edluar	Coverage requires documentation of serious side effects or drug failure with zolpidem
Intermezzo	
Rozerem	
Silenor, Doxepin HCL	
Zolpimist	
Belsomra	Coverage requires documentation of serious side effects or drug failure with TWO of the following: zolpidem, eszopiclone, zaleplon

POLICY GUIDELINES:

1. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Coverage Exception Evaluation Policy for All Lines of Business Formularies policy for review guidelines.
2. Supportive documentation of previous drug use must be submitted for any criteria requiring trial of a preferred agent, if the preferred drug is not found in claims history.
3. Approval for step therapy requirements may not bypass MAC penalty. Please see MAC penalty policy for detail of this benefit.
4. Prior-authorization is contract dependent.
5. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    d. The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
6. Initial approval will be granted for a period of 1 year.

UPDATES:

Date	Revision
3/20	Revised
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1/20	Revised
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