Pharmacy Management Drug Policy

SUBJECT: Step Therapy
POLICY NUMBER: PHARMACY-72
EFFECTIVE DATE: 10/11
LAST REVIEW DATE: 9/07/2023

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. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

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:

ANTIBACTERIALS	
Drug	**Requirement**
Doryx, Doryx MPC	Coverage requires documentation of serious side effects or drug failure with immediate-release doxycycline **AND** immediate-release minocycline
Doxycycline hyclate DR	
Clindagel 75 mL	Coverage requires documentation of serious side effects or drug failure with generic clindamycin **AND** tretinoin
Clindamycin 1% Gel 75 mL (Oceanside & Solaris)	
Amzeeq	Coverage requires serious side effects or drug failure with TWO topical treatments for acne (erythromycin, clindamycin, tretinoin, adapalene, dapsone, tazarotene)
Zilxi 1.5%	Coverage requires serious side effects or drug failure with topical metronidazole and one additional topical antibiotic (such as clindamycin, erythromycin, azelaic acid).

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

ANTIDEPRESSANTS	
Drug	**Requirement**
Emsam	Coverage requires documentation of serious side effects or drug failure with at least **ONE** of the following first line agents: escitalopram, fluoxetine, citalopram, sertraline, paroxetine, mirtazapine, bupropion or venlafaxine **immediate-release** tablets or venlafaxine extended-release **capsules**
Forfivo XL 450 mg	
Venlafaxine ER **Tablets**	Coverage requires documentation of serious side effects or drug failure with venlafaxine ER capsules, **however:** • 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 • A daily dose of 112.5 mg venlafaxine ER may be obtained by ordering venlafaxine ER 37.5 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	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	
Luzu	
Luliconazole	
Naftifine	
Xolegel	
Oxistat Lotion	
Naftin	Coverage requires documentation of serious side effects or drug failure with TWO of the following generic topical antifungals: ciclopirox, econazole, ketoconazole, nystatin, **AND** generic naftifine

ORAL ANTIFUNGAL AGENTS		
Drug	**Diagnosis**	**Requirement**
Brexafemme	Vulvovaginal candidiasis (VVC)	Coverage requires documentation of serious side-effects or drug failure of oral fluconazole
	Recurrent vulvovaginal candidiasis (RVVC)	Coverage requires documentation of serious side-effects or drug failure of a 6-month oral fluconazole treatment course

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

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)
	Bipolar disorder	
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)

	Agitation associated with Dementia due to Alzheimer disease	Requests for this diagnosis will be approved.
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)
	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)

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
Acyclovir 5% cream	Coverage requires documentation of serious side effects or drug failure with acyclovir 5% ointment.
Penciclovir 1% cream	
Xerese 5%-1% cream	
Zovirax 5% cream	Coverage requires documentation of serious side effects or drug failure with acyclovir 5% ointment **AND** generic acyclovir 5% cream
Denavir 1% cream	Coverage requires documentation of serious side effects or drug failure with acyclovir 5% ointment **AND** generic penciclovir 1% cream

BLOOD GLUCOSE REGULATORS
(SELECT BENEFITS ONLY)

Drug	Requirement
Admelog	Coverage requires documentation of serious side effects or drug failure with Humalog, Humalog Mix 75/25, or Insulin Lispro (Lilly authorized generic)
Apidra	
Fiasp	
Novolog, Novolog Mix 70/30, Insulin Aspart	
Onglyza	Coverage requires documentation of serious side effects or drug failure with Januvia, Janumet, Tradjenta or Jentadueto
Kombiglyze	
Nesina	
Alogliptin	
Kazano	
Alogliptin/metformin	

Oseni	
Alogliptin/pioglitazone	
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)
Fortamet	
letformin ER (generics of Fortamet and Glumetza), Metformin HCl 625 mg	
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
Ozempic	Coverage requires documentation of serious side effects or drug failure with metformin
Rybelsus	
Trulicity	
Victoza	
Adlyxin	Coverage requires documentation of serious side effects or drug failure with metformin **AND** TWO of the following agents: Ozempic, Victoza or Trulicity.
Byetta	
Bydureon	
Qtern	Coverage requires documentation of serious side effects **OR** drug failure with Glyxambi and Steglujan.
Rezvoglar	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Lantus, insulin glargine, and insulin glargine-yfgn, the member will be required to use brand name Lantus, insulin glargine, and insulin glargine-yfgn unless there is adequate justification as to why it will not work for you.

CARDIOVASCULAR AGENTS

Drug	Requirement
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
Thalitone	Coverage requires documentation of serious side effects or drug failure with generic chlorthalidone.

CARDIOVASCULAR AGENTS, DYSLIPIDEMICS

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

NEUROLOGICAL AGENTS

Drug	Requirement
Savella	Coverage requires documentation of serious side effects or drug failure with duloxetine

Adlarity	Coverage requires documentation of serious side effects or drug failure of donepezil, donepezil ODT, galantamine, **OR** rivastigmine
Xadago	Coverage requires documentation of serious side effects or drug failure with generic selegiline

DERMATOLOGICAL AGENTS

Drug	Requirement
Aczone 7.5%, Dapsone 7.5%	Coverage requires documentation of serious side effects or drug failure with a topical retinoid **AND** Dapsone 5%
Adapalene 0.1% Lotion, Soln, Swab	Coverage requires documentation of serious side effects or drug failure with adapalene cream or gel **AND** tretinoin cream or gel
Differin 0.1% Lotion	
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	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 lubiprostone **AND** **either** Linzess **OR** Trulance 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 OR Trulance for a diagnosis of chronic idiopathic constipation (CIC)
Relistor Tablet		Coverage requires documentation of serious side effects or drug failure with Movantik for a diagnosis of opioid-induced constipation
Symproic		
Ibsrela		Coverage requires documentation of serious side effects or drug failure with Linzess, lubiprostone, **AND** Trulance for a diagnosis of irritable bowel syndrome with constipation
Dexilant		Coverage requires documentation of serious side effects or drug failure with lansoprazole or omeprazole
Dexlansoprazole DR		
Omeprazole/Sodium Bicarbonate Packets		Coverage requires documentation of serious side effects or drug failure with THREE of the following: omeprazole, pantoprazole, lansoprazole, rabeprazole
Zegerid Packets		

GENITOURINARY AGENTS; ANTISPASMODICS, URINARY	
Drug	**Requirement**
Oxytrol	Coverage requires documentation of serious side effects or drug failure with TWO of the following: oxybutynin, oxybutynin ER, tolterodine, trospium, trospium XR **Exception:** Gelnique does not require step therapy for individuals 65 years of age or older
Gelnique	
Gemtesa	Coverage requires documentation of serious side effects or drug failure with Myrbetriq and a generic antimuscarinic agent (such as oxybutynin/ER, tolterodine/ER, trospium/ER)

HORMONAL AGENTS, STIMULANT/REPLACEMENT/MODIFYING (ADRENAL)	
Drug	**Requirement**
Bryhali	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
Cloderm, Clocortolone Pivalate	
Cordran (Cream, Lotion, Ointment)	
Desonide 0.05% Gel	
Halog, Halcinonide	
Halobetasol Propionate 0.05% Foam	
Impeklo	
Impoyz Spray	
Lexette	
Pandel	
Sernivo Lotion	
Ultravate Lotion	
Verdeso	

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

MULTIPLE SCLEROSIS AGENTS	
Drug	**Requirement**
Aubagio, generic teriflunomide	Coverage requires documentation of serious side effects or drug failure with ONE of the following: Avonex, Copaxone (or Glatiramer), Plegridy, Rebif
Bafiertam	Coverage requires documentation of serious side effects or drug failure with TWO of the following agents: Gilenya (or fingolimod), dimethyl fumarate, Mayzent, Zeposia.
Ponvory	
Vumerity	

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 Lumigan **AND** either latanoprost or travoprost
Zioptan		
Iyuzeh		
Tafluprost		

Rhopressa, Rocklatan	Coverage requires documentation of serious side effects or drug failure with any covered prostaglandin analogue (such as bimatoprost, travoprost, latanoprost, Lumigan)
Restasis 0.05%	Coverage requires documentation of serious side effects or drug failure of cyclosporine 0.05% eye emulsion **AND** Xiidra 5% eye drops
Restasis Multidose 0.05%	
Atropine Sulfate/PF	Coverage requires documentation of serious side effects or drug failure of generic atropine 1% drops

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 **AND** generic roflumilast
Roflumilast	Coverage requires documentation of serious side effects or drug failure with an inhaled corticosteroid or long-acting beta agonist

PANCREATIC ENZYMES

Drug	Requirement
Pancreaze	Coverage requires documentation of serious side effects or drug failure with Creon and Zenpep
Pertzye	

RESPIRATORY TRACT/PULMONARY AGENTS

Drug	Requirement
Fluticasone Propionate HFA	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Flovent HFA, the member will be required to use brand name Flovent HFA unless there is adequate justification as to why it will not work for you.
Fluticasone-Salmeterol HFA	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Advair HFA, the member will be required to use brand name Advair HFA unless there is adequate justification as to why it will not work for you.
Fluticasone-Vilanterol	Based on comparable indications, efficacy, safety profile, and equivalent strength of brand name Breo, the member will be required to use brand name Breo unless there is adequate justification as to why it will not work for you.
Tudorza Pressair	Coverage requires documentation of serious side effects or drug failure with ONE of the following: Spiriva or Incruse.
Alvesco	Coverage requires documentation of serious side effects or drug failure with ONE of the following: Arnuity Ellipta, Asmanex, Flovent or Qvar Redihaler.
Pulmicort Flexhaler	
Armonair Digihaler	
AirDuo Respiclick	

AirDuo Digihaler	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 antagonists (LAMA) containing inhalers: Anoro Ellipta, Bevespi Aerosphere, Incruse Ellipta, Neohaler, Spiriva Handihaler, Spiriva Respimat, Stiolto Respimat, 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.
Breztri	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, Spiriva, Stiolto, Symbicort, Utibron

SELECTIVE ESTROGEN RECEPTOR MODIFYING AGENTS

Drug	Requirement
Estring	Coverage requires documentation of serious side effects or drug failure with a topical vaginal estrogen product such as conjugated estrogen vaginal cream (Premarin) or estradiol vaginal cream (Estrace).
Osphena	

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	
Orphenadrine/ Aspirin/Caffeine	

SLEEP DISORDER AGENTS

Drug	Requirement
Edluar	Coverage requires documentation of serious side effects or drug failure with zolpidem
Zolpimist	
Belsomra, Dayvigo, Quviviq	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.
7. In addition to the full prescribing information for each individual drug, the corresponding clinical guidelines (i.e., NCCN, DSM, etc.) are reviewed on an annual basis to determine the appropriateness of the medical necessity criteria that is applied.

UPDATES:

Date	Revision
9/7/2023	Revised
8/10/2023	Revised
7/7/2023	Revised
6/8/2023	Revised
4/24/2023	Revised
4/5/2023	Revised
3/31/2023	Revised
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11/3/22	Revised

10/3/22	Revised
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8/25/22	Revised
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5/9/2022	Revised
05/05/2022	P&T Committee Approval
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1/22	Revised
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10/21	Revised
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5/21	Revised
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1/21	Revised
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8/2020	Revised
7/2020	Revised
6/2020	Revised
5/2020	Revised
3/20	Revised
2/20	Revised
1/20	Revised
12/19	Revised
11/19	Revised
10/19	Revised
8/19	Revised
7/19	Revised
5/19	P&T Committee Approval
4/19	Revised
3/19	Revised
2/19	Revised
1/19	Revised
11/18	Revised
10/18	Revised
9/18	Revised
5/18	Revised

4/18	Revised
3/18	Revised
2/18	Revised
1/18	Revised- Both STEP Policies combined to one policy The Commercial Open step therapy and Exchange Closed/CHP policies have been merged. The policy has also been changed into a table format with headers that match the web formularies (derived from RxFlex).
12/17	Revised
11/2017	P&T Committee Approval
9/17	Revised
7/17	Revised
5/17	Revised
4/17	Revised
1/17	Revised
10/16	Revised
9/16	Revised
8/16	Revised
7/16	Revised
6/16	Revised
5/16	Revised
4/16	Revised
3/16	Revised
1/16	Revised
12/15	Revised
11/15	Revised
8/15	Revised
7/15	Revised
6/15	Revised
5/15	Revised
4/15	Revised
3/15	Revised
1/15	Revised
11/14	Revised
10/14	Revised
8/14	Revised
7/14	Revised
5/14	Revised
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