Clinical Policy: Step Therapy

Reference Number: ERX.ST.35
Effective Date: 06.01.18
Last Review Date: 11.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
This policy provides a list of drugs that require step therapy.

FDA Approved Indication(s)
Various.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that the following drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Step Therapy:

Drugs listed in the table below may be approved for the length of benefit for members who have had a previous trial of or who have contraindications to required step-through agents, when the request does not exceed the maximum indicated dose and stated quantity limit.

For Maryland beneficiaries only, a step therapy or fail-first protocol will not be required if:

1. The step therapy drug has not been approved by the U.S. FDA for the medical condition being treated; or
2. A prescriber providing supporting medical information to the entity that a prescription drug covered by the entity: (i) was ordered by a prescriber for the insured or enrollee within the past 180 days; and (ii) based on the professional judgment of the prescriber, was effective in treating the insured's or enrollee's disease or medical condition.

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Aczone® (dapsone 7.5% gel)	Generic acne product	1 application/day
Adasuve® (loxapine inhalation powder)	Generic antipsychotic	10 mg dose/24 hours
Amrix® (cyclobenzaprine ER 15 mg, 30 mg)	Generic cyclobenzaprine	30 mg/day (1 tablet/day)
Aplenzin® (bupropion SR 174 mg, 348 mg, 522 mg)	2 generic antidepressants	522 mg/day (1 tablet/day)
Azelex® (azelaic acid cream)	Generic acne product	2 applications/day
Beconase AQ® (beclomethasone diproprionate nasal spray)	Generic nasal steroid	168 mcg/day (2 bottles [50 g] 30 days)
Belsomra® (suvorexant)	Generic sleep agent	20 mg/day (1 tablet/day)
bepotastine 1.5% (Bepreve®)	Olopatadine 0.1% plus either azelastine or epinastine	2 drops/eye/day (1 bottle [10 mL]/30 days)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Binosto® (alendronate effervescent tablet for oral solution)	Generic alendronate	70 mg/week (1 tablet/week)
Cambia® (diclofenac potassium)	Generic NSAID and rizatriptan orally disintegrating tablet	50 mg/migraine (9 packets/30 days)
Cardura® XL (doxazosin)	Generic alpha 1 blocker	8 mg day (1 tablet/day)
Cordran® (flurandrenolide lotion 0.05%, ointment 0.05%)	Generic topical corticosteroid alternatives	50 mg/migraine (9 packets/30 days)
Cuprimine® (penicillamine)	Depen® Titratabs (penicillamine)	4 g/day
Dexilant® (dexlansoprazole)	Generic PPI	60 mg/day (1 capsule/day)
Edarbi® (azilsartan medoxomil)	Generic ACE or ARB	80 mg/day (1 tablet/day)
Edarbyclor® (azilsartan medoxomil/chlorthalidone)	Generic ACE or ARB	40/25 mg/day (1 tablet/day)
Edluar™ (zolpidem sublingual tablets 5 mg, 10 mg)	Generic zolpidem	10 mg/day (1 tablet/day)
Fabior® (tazarotene foam 0.1%)	Generic acne product	1 application/day (1 can [50 g/30 days
Fanapt™ (iloperidone)	Generic antipsychotic	24 mg/day (2 tablets/day)
Fenortho™ (fenoprofen calcium capsule 200 mg)	Generic NSAID	3,200 mg/day (16 capsules/day)
Fetzima® (levomilnacipran)	Generic SNRI	120 mg/day (2 capsules/per for 20 mg; 1 capsule/day for all other strengths)
Forfivo XL® (bupropion SR 450 mg)	2 generic antidepressants	450 mg/day (1 tablet/day)
Fosamax® Plus D (alendronate sodium/ cholecalciferol)	Generic alendronate	70 mg/week (1 tablet/week)
icosapent ethyl (Vascepa®)	Generic Lovaza, unless member has atherosclerotic disease or diabetes with at least 2 cardiovascular risk factors (*refer to ERX.NPA.140 for prior authorization criteria*)	4 g/day (4 capsules/day)
desvenlafaxine succinate ER (Khedezla™ 50 mg, 100 mg)	Generic SNRI	400 mg/day (1 tablet/day)
Latuda® (lurasidone)	Generic antipsychotic	160 mg/day
Livalo® (pitavastatin)	Generic statin	4 mg/day (1 tablet/day)
lovastatin tablet SR 24HR 20 mg, 40 mg, 60 mg (Mevacor®)	Generic statin	60 mg/day
Lumigan® (bimatoprost)	Generic prostaglandin analog	1 drop/eye/day (1 bottle [2.5 mL]/day)
Myrbetriq® (mirabegron)	Generic antispasmodic	50 mg/day (1 tablet/day)
Nalfon® (fenoprofen calcium capsule 400 mg)	Generic NSAID	3,200 mg/day (8 capsules/day)
Noritate® (metronidazole cream 1%)	Generic metronidazole	1 application/day

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Omnaris® (ciclesonide nasal spray 50 mcg)	Generic nasal steroid	200 mcg/day (1 bottle [12.5 g]/day)
Onzetra® (sumatriptan nasal powder)	Generic triptan	44 mg/day (1 box [8 pouches]/30 days)
Oxtellar XR® (oxcarbazepine SR 150 mg, 300 mg, 600 mg)	Generic Trileptal	2,400 mg/day
oxybutynin (Oxytrol®)	Generic antispasmodic	1 patch twice weekly (every 3-4 days)
Gelnique® (oxybutynin)	Generic antispasmodic	1 sachet or actuation/day
Pexeva® (paroxetine)	Generic SSRI	60 mg/day
Prestalia® (perindopril/ amlodipine 3.5/2.5 mg, 7/5 mg, 14/10 mg)	Amlodipine and perindopril	14/10 mg/day (1 tablet/day)
Prilosec® (omeprazole) packets 2.5 mg, 10 mg, 40 mg	Generic PPI	40 mg/day
ProAir® HFA (albuterol sulfate)	Albuterol sulfate HFA	12 puffs/day (2 inhalers/30 days)
Proventil® HFA (albuterol)	Albuterol sulfate HFA	12 puffs/day (2 inhalers/30 days)
Qnasl® (beclomethasone) nasal spray	Generic nasal steroid	320 mcg/day
Rexulti® (brexpiprazole)	Generic antipsychotic	4 mg/day
Riax® foam (benzoyl peroxide 5.5% and 9.5%)	Generic acne product	1 application/day
Rozerem® 8 mg (ramelteon)	Generic sleep agent	8 mg/day (1 tablet/day)
Saphris® (asenapine)	Generic antipsychotic	20 mg/day
Silenor® (doxepin HCl)	Generic sleep agent	6 mg/day (1 tablet/day)
Taclonex® (calcipotriene-betamethasone dipropionate suspension 0.005-0.064%)	Derma-Smoothe and Clobex	2 g/day (1 bottle [60 g]/month)
Tekturna HCT® (aliskiren/HCTZ)	Generic ACE or ARB	300/25 mg/day (1 tablet/day)
Tivorbex® (indomethacin 20 mg , 40 mg)	Generic NSAID	120 mg/day (3 capsules/day)
fesoterodine (Toviaz®)	Generic antispasmodic	8 mg/day (1 tablet/day)
Travatan Z® (travoprost ophthalmic solution 0.004%)	Generic prostaglandin analog	1 drop/eye/day (1 bottle [2.5 mL]/day)
Tretin-X® (tretinoin cream)	Generic acne product	1 application/day (1 box [35 g]/day)
Trianex® (triamcinolone acetonide ointment 0.05%)	Generic triamcinolone	4 applications/day (60 g/day)
Trintellix® (vortioxetine)	Generic SSRI	20 mg/day (1 tablet/day)
Ventolin® HFA (albuterol)	Albuterol sulfate HFA	12 puffs/day (4 inhalers/30 days)
Vesicare® (solifenacin)	Generic antispasmodic	10 mg/day (1 tablet/day)
Viibryd® (vilazodone)	Generic SSRI	40 mg/day (1 tablet/day)
Vivlodex (meloxicam capsule 5 mg, 10 mg)	Generic NSAID	10 mg/day (1 capsule/day)
Vraylar® (cariprazine)	Generic antipsychotic	6 mg/day

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Vyzulta® (latanoprostene bunod ophthalmic solution)	Generic prostaglandin analog	1 drop/eye/day
Xerese® (acyclovir-hydrocortisone cream 5-1%)	Generic acyclovir ointment and oral antiviral agents	5 applications/day (1 tube [5 g]/day)
Xhance™ (fluticasone propionate nasal exhaler susp 93 mcg/actuation)	Generic intranasal steroids including fluticasone	744 mcg per day (2 devices per 30 days)
Zembrace® (sumatriptan injection)	Generic triptan	12 mg/day (4 syringe autoinjectors/30 days)
Zetonna™ (ciclesonide nasal aerosol)	Generic nasal steroid	74 mcg/day (3 canisters [18 g]/60 days)
Zipsor® (diclofenac capsules)	Generic NSAID	100 mg/day (4 capsules/day)
Zolpimist® 5 mg/actuation (zolpidem oral spray)	Generic sleep agent	10 mg/day (1 bottle [4.5 mL/30 days)
Zorvolex® (diclofenac capsules)	Generic NSAID	105 mg/day (3 capsules/day)
Zovirax® (acyclovir cream 5%)	Generic acyclovir ointment and oral antiviral agents	5 applications/day (1 tube [5 g]/30 days)
Zyclara® (imiquimod cream 3.75%)	Generic Aldara cream (imiquimod 5%)	1 application/day (1 packet/day)
Zyclara® Pump (imiquimod cream 2.5%)	Generic Aldara cream (imiquimod 5%)	1 application/day (2 bottles [16 g]/25 days)
Zyflo®, Zyclo CR® (zileuton tablet 600 mg, zileuton tablet SR 12HR 600 mg)	Montelukast sodium or zafirlukast	2,400 mg/day (4 tablets/day)

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

II. Continued Therapy

A. Step Therapy (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Dose does not exceed the FDA approved maximum recommended dose and quantity limit as stated in the initial approval criteria for the relevant drug.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACE: angiotensin-converting enzume
ARB: angiotensin II receptor blocker
ER: extended-release
FDA: Food and Drug Administration
IR: immediate-release
NSAID: non-steroidal anti-inflammatory drug
PPI: proton pump inhibitor
SNRI: serotonin norepinephrine reuptake inhibitor
SSRI: selective serotonin reuptake inhibitor

Appendix B: Therapeutic Alternatives

Refer to the required step-through drug in the table in Section I.

Appendix C: Contraindications/Boxed Warnings
Refer to the individual prescribing information.

IV. Dosage and Administration
Refer to the step therapy table in Section I.

V. Product Availability
Refer to the individual prescribing information.

VI. References
1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 27, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2018 annual review: added Cuprimine (pencillamine) in alignment with electronic programming; references reviewed and updated.	08.03.18	11.18
4Q 2019 annual review: removed agents no longer requiring step therapy per BEF; added additional agents in alignment with current electronic step therapy programming; added Medicaid line of business with 12 month approval durations; references reviewed and updated.	08.30.19	11.19
Removed Vascepa from the list of drugs requiring step therapy since it now requires PA.	01.22.20	02.20
4Q 2020 annual review: updated in alignment with current electronic programming; references reviewed and updated.	07.16.20	11.20
Added Maryland regulation language.	02.25.21	
4Q 2021 annual review: added icosapent ethyl; revised Taclonex suspension quantity limit to 2 g/day (1 bottle [60 g]/month); for Trianex modified step from alternate steroid ointment to generic triamcinolone; added Xhance; added ProAir HFA and modified Proventil HFA step through option to albuterol sulfate HFA; for Cambia modified step to additionally require rizatriptan orally disintegrating tablets; removed the following that are no longer included on the step therapy list: Acanya, Alsuma, Cleocin-T, Giazo, Intermezzo, Irenka, Oracea, Protonix, Rapaflo, Solodyn, Sumavel, Tekturna, Topicort, Treximet, Triglide, Zioptan; references reviewed and updated.	07.27.21	11.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.