

Clinical Policy: Step Therapy

Reference Number: ERX.ST.35

Effective Date: 06.01.18

Last Review Date: 11.20

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)
Acanya® (clindamycin phosphate 1.2% and benzoyl peroxide 2.5% gel)	Generic acne product	1 application/day
Aczone® (dapsonsone 7.5% gel)	Generic acne product	1 application/day
Adasuve® (loxapine inhalation powder)	Generic antipsychotic	10 mg dose/24 hours
Alsuma® (sumatriptan injection)	Generic triptan	12 mg/24 hours (4 syringe autoinjectors/30 days)
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

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Beconase AQ® (beclomethasone dipropionate 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)
Binosto® (alendronate effervescent tablet for oral solution)	Generic alendronate	70 mg/week (1 tablet/week)
Cambia® (diclofenac potassium)	Generic NSAID	50 mg/migraine (9 packets/30 days)
Cardura® XL (doxazosin)	Generic alpha 1 blocker	8 mg day (1 tablet/day)
Cleocin-T®, Clindagel® (clindamycin phosphate topical)	Generic acne product	2 applications/day
Cordran® (flurandrenolide lotion 0.05%, ointment 0.05%)	Generic topical corticosteroid alternatives	50 mg/migraine (9 packets/30 days)
Cuprimine® (penicillamine)	Depen® tablets (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)
Giazo® (balsalazide 1.1 g)	Generic balsalazide	6.75 g/day (6 tablets/day)
Intermezzo® (zolpidem sublingual tablet 1.75 mg, 3.5 mg)	Generic sleep agent	3.5 mg/day (1 tablet/day)
Irenka™ (duloxetine DR)	Generic SNRI	120 mg/day
desvenlafaxine succinate ER (Khedeza™ 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 10 mg, 20 mg, 40 mg, 60 mg (Mevacor®)	Generic statin	60 mg/day

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
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
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)
Oracea® (doxycycline DR 40 mg)	Doxycycline hyclate IR	50 mcg/day (1 capsule/day)
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
Protonix® (pantoprazole) packets 40 mg	Generic PPI	80 mg/day (2 packets/day)
Proventil® HFA (albuterol)	ProAir HFA	12 puffs/day (2 inhalers/30 days)
Qnasl® (beclomethasone) nasal spray	Generic nasal steroid	320 mcg/day
silodosin (Rapaflo®)	Generic alpha 1 blocker	5 mg/day (1 tablet/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)
Solodyn® (minocycline SR 55 mg, 80 mg, 105 mg)	Minocycline HCl IR capsules	1 mg/kg/day or 135 mg/day
Sumavel® (sumatriptan injection)	Generic triptan	12 mg/24 hours (4 cartridges/30 days)
Taclonex® (calcipotriene-betamethasone dipropionate suspension 0.005-0.064%)	Derma-Smoothe and Clobex	100 g/week (1 bottle [60 g]/day)
aliskiren (Tekturna®)	Generic ACE or ARB	300 mg/day (1 tablet/day)
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)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Topicort® (desoximetasone spray 0.25%)	Generic cream or ointment	2 applications/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)
Treximet® (sumatriptan/naproxen tablets)	Generic triptan	2 tablets of 85/500 mg/24 hours (9 tablets/30 days)
Triamex® (triamcinolone acetonide ointment 0.05%)	Alternate steroid ointment	4 applications/day (60 g/day)
Triglide® (fenofibrate)	Generic fibrate	160 mg/day (1 tablet/day)
Trintellix® (vortioxetine)	Generic SSRI	20 mg/day (1 tablet/day)
Ventolin® HFA (albuterol)	ProAir HFA	12 puffs/day (4 inhalers/30 days)
Vesicare® (solifenacin)	Generic antispasmodic	10 mg/day (1 tablet/day)
Viiibryd® (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
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)
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)
Zioptan® (tafluprost ophthalmic solution)	Generic prostaglandin analog	1 drop/eye/day (1 pouch/day)
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 enzyme

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.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed July 16, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: Policy created from step therapy polices: BPH, OAB; decreased number of trials of formulary generic agents to 1 agent only; removed requirement of trial within the past 6 months; removed agents which no longer require step therapy.	02.06.18	05.18
3Q 2018 annual review: added anti-allergy ophthalmic agents (ERX.ST.30), Trintellix (ERX.ST.29), Viiibryd (ERX.ST.12), Desvenlafaxine (Khedezla, Pristiq) (ERX.ST.18), Aplenzin (ERX.ST.02); aligned with electronic programming; references reviewed and updated.	04.11.18	08.18
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added Maryland regulation language.	02.25.21	

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.

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