

## Clinical Policy: Step Therapy

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Last Review Date: 05.18

Line of Business: Health Insurance Marketplace

[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.*

It is the policy of health plans affiliated with Centene Corporation® that the drugs identified within this policy are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Electronic Step Therapy:

Drugs listed in the table below may be approved for the 12 months 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.

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
Edarbi® (azilsartan medoxomil)	Two of the following: candesartan, irbesartan, or losartan	80 mg daily (1 tablet/day)	N/A
lovastatin SR (Altoprev®)	Two of the following: atorvastatin, lovastatin IR, pravastatin, or simvastatin	60 mg daily (1 tablet/day)	N/A
Livalo® (pitavastatin calcium)	Two of the following: atorvastatin, lovastatin IR, pravastatin, or simvastatin	4 mg daily (1 tablet/day)	N/A
ezetimibe-simvastatin (Vytorin®)	Two of the following: atorvastatin, lovastatin IR, pravastatin, or simvastatin	10 mg Ezetimibe and 40 mg Simvastatin daily.	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
		10 mg Ezetimibe and 80 mg Simvastatin daily for patients already taking 80 mg daily chronically without evidence of myopathy. (1 tablet/day)	
Dexilant <sup>™</sup> (dexlansoprazole DR)	Two of the following: lansoprazole, omeprazole, pantoprazole, or rabeprazole	60 mg daily (1 tablet/day)	N/A
venlafaxine SR 24HR 225 mg base equivalent (Effexor ER <sup>®</sup> )	Venlafaxine IR	225 mg daily (1 tablet/day)	N/A
eszopiclone (Lunesta <sup>®</sup> )	Two of the following: zaleplon and zolpidem tartrate	3 mg daily for adult. 2 mg daily for geriatric. (1 tablet/day)	≥ 18 years old
Rozerem <sup>®</sup> (ramelteon)	Two of the following: zaleplon and zolpidem	8 mg daily (1 tablet/day)	≥ 18 years old
Vyvanse <sup>®</sup> (lisdexamfetamine dimesylate)	Adderall XR <sup>®</sup>	70 mg daily (1 tablet/day)	N/A
almotriptan malate (Axert <sup>®</sup> )	Two of the following: naratriptan, rizatriptan, or sumatriptan	25 mg daily (0.3 tablet/day for 6.25mg, 0.4 tablet/day for 12.5 mg)	≥ 12 years old
eletriptan (Relpax <sup>®</sup> )	Two of the following: naratriptan, rizatriptan, or sumatriptan	80 mg daily (0.2 tablet/day)	≥ 18 years old
frovatriptan Succinate (Frova <sup>®</sup> )	Two of the following: naratriptan, rizatriptan, or sumatriptan	7.5 mg daily (0.4 tablet/day)	≥ 18 years old
zolmitriptan (Zomig <sup>®</sup> )	Two of the following: naratriptan, rizatriptan, or sumatriptan	5 mg per dose or 10 mg daily (0.3 tablet/day or .2 solution/day)	≥ 12 years old

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
Aptiom <sup>®</sup> (eslicarbazepine)	Carbamazepine or oxcarbazepine	1.600 mg daily (2 tablets/day)	N/A
ropinirole SR (Requip <sup>®</sup> XL)	Requip <sup>®</sup> IR	24 mg daily (1 tablet/day) (2 tablet/day for 8 mg, 12 mg)	N/A
ropinirole SR (Ropinirole ER)	Requip <sup>®</sup> IR	24 mg daily (1 tablet/day) (2 tablet/day for 8 mg, 12 mg)	N/A
bimatoprost ophth soln 0.01% (Lumigan <sup>®</sup> )	Latanoprost	No information available	N/A
adapalene gel 0.3%, adapalene lotion 0.1% (Differin <sup>®</sup> )	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	No information available	≥ 12 years old
Azelex <sup>®</sup> (azelaic acid cream)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	No information available	≥ 12 years old
adapalene-benzoyl peroxide (Epiduo <sup>®</sup> )	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	1 application/day topically	≥ 12 years old
clindamycin phosphate – tretinoin gel (Veltin <sup>®</sup> , Ziana <sup>®</sup> )	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	No Information Available	≥ 12 years old
sulfacetamide sodium w/ sulfur wash (Sodium Sulfacetamide/Sulfur Wash <sup>®</sup> , Sumadan Wash <sup>®</sup> )	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	2 application daily	≥ 12 years old
clobetasol Propionate (Clobetasol Propionate <sup>®</sup> , Olux <sup>®</sup> )	Two of the following: clobetasol cream, solution, ointment, or desonide ointment	50 ml/week scalp or topical solutions and shampoo; 59 ml/week spray	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
		solution; 50 g/week other topicals (Foam 3g/day, gel 2g/day)	
calcipotriene-betamethasone dipropionate (Calcipotriene/Beta methasone Dipropionate <sup>®</sup> , Taclonex <sup>®</sup> )	Calcipotriene and betamethasone dipropionate as a separate agents	100 g per week topically, or 60 g foam every 4 days topically; treatment of more than 30% body surface area not recommended	N/A
cefixime for suspension (Cefixime <sup>®</sup> , Suprax <sup>®</sup> )	Cefdinir or cefpodoxime	400 mg daily Children weight more than 45 kg max is 400 mg daily. Children weight 45 kg or less max is 8 mg/kg daily.	N/A
(Fenoprofen calcium) Fenoprofen Calcium, Profeno	Ibuprofen	3200 mg daily (4 tablets/day)	N/A
mefenamic acid (Mefenamic Acid <sup>®</sup> , Ponstel <sup>®</sup> )	Ibuprofen	1250 mg daily Age 14 and older 1250 mg daily. Age less than 14: No information available (6 capsules/day)	N/A
Nevanac <sup>®</sup> , Ilevro <sup>®</sup> (nepafenac ophthalmic suspension)	Diclofenac ophthalmic or ketorolac ophthalmic	3 drops daily each affected eye for the 0.1%. 1 drop daily each affected eye for the 0.3%. Age less than 10: No available information (0.2 ml/day)	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
Symtuza™ (darunavir, cobicistat, emtricitabine, tenofovir alafenamide)	If treatment naïve: Symfi or Symfi Lo (efavirenz/ lamivudine/tenofovir disoproxil fumarate)  If treatment experienced: any HIV antiretroviral agent	800/150/200/10 mg daily (1 tablet/day)	N/A

*Drugs are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

**Approval duration: 12 months**

## II. Continued Therapy

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

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. If request is for Symtuza, documentation supports that member is currently receiving Symtuza for HIV infection and has received this medication for at least 30 days;
2. If request is for a dose increase, new 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: 12 months**

## III. Appendices/General Information

### *Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

IR: immediate release

ER: extended release

DR: delayed release

SR: sustained release

XL: extended release

CR: controlled release

### *Appendix B: Therapeutic Alternatives*

Refer to required step-through drugs above in Section I.

### *Appendix C: Contraindications/Boxed Warnings*

Refer to the package inserts for each of the drugs requiring step therapy.

## IV. Dosage and Administration

Refer to the step therapy table in Section I.

**V. Product Availability**

Drug Name	Availability
Edarbi (azilsartan medoxomil)	Tablets: 40, 80 mg
lovastatin SR (Altoprev)	Tablets: 20, 40, 60 mg
Livalo (pitavastatin calcium)	Tablets: 1, 2, 4 mg
ezetimibe-simvastatin (Vytorin)	Tablets: 10/10, 10/20, 10/40, 10/80 mg
Dexilant (dexlansoprazole DR)	Capsules: 30, 60 mg
venlafaxine SR 24HR 225 mg base equivalent (Effexor ER)	Tablets: 37.5, 75, 150, 225 mg
eszopiclone (Lunesta)	Tablets: 1, 2, 3 mg
Rozerem (ramelteon)	Tablets: 8 mg
Vyvanse (lisdexamfetamine dimesylate)	Capsules: 10, 20, 30, 40, 50, 60, 70 mg
(Almotriptan malate) Almotriptan malate	Tablets: 6.25, 12.5 mg
almotriptan malate (Axert)	Tablets: 6.25, 12.5 mg
eletriptan (Relpax)	Tablets: 20, 40 mg
(Eletriptan) Eletriptan	Tablets: 20, 40 mg
(Frovatriptan) Frovatriptan Succinate	Tablets: 2.5 mg
frovatriptan Succinate (Frova)	Tablets: 2.5 mg
(Zolmitriptan) Zolmitriptan	Tablets: 2.5, 5 mg ODT: 2.5, 5 mg
zolmitriptan (Zomig)	Tablets: 5 mg Nasal Solution: 2.5, 5 mg/spray ODT (ZMT): 2.5, 5 mg
Aptiom® (eslicarbazepine)	Tablets: 200, 400, 600, 800 mg
ropinirole SR (Requip XL®)	Tablets: 2, 4, 6, 8, 12 mg
(Ropinirole SR) Ropinirole ER	Tablets: 2, 4, 6, 8, 12 mg
bimatoprost ophth soln 0.01% (Lumigan)	Bottle: 0.01% solution
adapalene gel (Differin, Adapalene pump)	Topical Cream, Gel, Lotion: 0.1% Topical Gel: 0.3% Topical Gel Pump: 0.3%
Azelex (azelaic acid cream)	Topical Cream: 20%
adapalene-benzoyl peroxide (Epiduo)	Topical gel: 0.1%-2.5% Topical gel forte pump: 0.3%-2.5% Topical gel pump: 0.1%-2.5%
(adapalene-Benzoyl Peroxide) Adapalene-Benzoyl Peroxide	Topical gel: 0.1% - 2.5% Topical gel: 0.3% - 2.5%
clindamycin phosphate – tretinoin gel (Veltin®, Ziana®)	Topical Gel: 1.2%-0.025%
(Clindamycin Phosphate – Tretinoin Gel) Clindamycin Phosphate- Tretinoin	Topical Gel: 1.2%-0.025%

Drug Name	Availability
sulfacetamide sodium w/ sulfur wash (Sodium Sulfacetamide/Sulfur Wash®, Sumadan Wash)	Topical Wash: 9%-4.5%
clobetasol Propionate (Clobetasol Propionate, Olux)	Topical Foam: 0.05% Topical Gel: 0.05%
calcipotriene-betamethasone dipropionate (Calcipotriene/Betamethasone Dipropionate, Taclonex)	Topical Ointment: 0.005%-0.064% Topical Suspension: 0.005%-0.064% Topical Foam: 0.005%-0.064%
esomeprazole magnesium DR (Nexium)	Capsules: 20, 40 mg
omeprazole-sodium bicarbonate (Zegerid, Omeppi)	Capsules: 20/1100, 40/1100 mg Powder Oral Suspension: 20/1680, 40/1680
cefixime for suspension (Cefixime, Suprax)	Oral Suspension: 100/5, 200/5, 500/5 mg/ml
(Fenoprofen calcium) Fenoprofen Calcium, Profeno	Tablets: 600 mg
mefenamic acid (Mefenamic Acid, Ponstel)	Capsules: 250 mg
Nevanac, Ilevro (nepafenac ophthalmic suspension)	Nevanac Ophthalmic Suspension: 0.1% Ilevro Ophthalmic Suspension: 0.3%
Symtuza (darunavir, cobicistat, emtricitabine, tenofovir alafenamide)	Tablets: 800/150/200/10 mg

## VII. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: <http://www.clinicalpharmacology.com>. Accessed January 30, 2018.
2. Dailymed. Bethesda, MD: U.S. National Library of Medicine, National Institutes of Health, Health & Human Services, 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>. Accessed January 29, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created. Converted to new template; added max dose.	06.17	08.17
Q2 2018 annual review: generic step therapy criteria is replaced with actual step through requirement for specific drugs requiring step therapy	03.12.18	05.18
No significant changes: changes in this document is covered by P&T approved clinical guidance/formulary: The following drugs are removed from the list due to the stated reasons: Lantus is NF; Vascepa is PA, Not EST; Zegerid is blocked, not EST; prescription Nexium is blocked not EST; Ndihydroergotamine mesylate nasal spray (Dihydroergotamine Mesylate <sup>®</sup> , Migranal <sup>®</sup> ) no longer requires EST.	07.06.18	
No significant changes: specified adapalene <i>gel</i> 0.3% and adapalene <i>lotion</i> 0.1% for clarity; added age limits per formulary; The following drugs are removed from the list due to the stated reasons: Pentasa and	10.03.18	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Delzicol are NF, and Oleptro is no longer available on the market; corrected max dose of Altoprev.		
Changes align with previously approved clinical guidance: added Symtuza to policy requiring step through Symfi if member is treatment naïve per SDC; added continuation of care language for HIV per SDC.	12.19.18	

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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