Clinical Policy: Step Therapy

Reference Number: HIM.PA.109
Effective Date: 08.01.17
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
Dexilant™ (dexlansoprazole DR)	Two of the following: lansoprazole, omeprazole,	60 mg daily (1 tablet/day)	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
	pantoprazole, or rabeprazole		
venlafaxine SR 24HR 225 mg base equivalent (Effexor ER®)	Venlafaxine IR	225 mg daily (1 tablet/day)	N/A
eszopiclone (Lunesta®)	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® (ramelteon)	Two of the following: zaleplon and zolpidem	8 mg daily (1 tablet/day)	≥ 18 years old
Vyvanse® (lisdexamfetamine dimesylate)	Adderall XR®	70 mg daily (1 tablet/day)	N/A
almotriptan malate (Axert®)	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®)	Two of the following: naratriptan, rizatriptan, or sumatriptan	80 mg daily (0.2 tablet/day)	≥ 18 years old
frovatriptan Succinate (Frova®)	Two of the following: naratriptan, rizatriptan, or sumatriptan	7.5 mg daily (0.4 tablet/day)	≥ 18 years old
zolmitriptan (Zomig®)	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
Aptiom® (eslicarbazepine)	Carbamazepine or oxcarbazepine	1.600 mg daily (2 tablets/day)	N/A
ropinirole SR (Requip® XL)	Requip® IR	24 mg daily (1 tablet/day) (2 tablet/day for 8 mg, 12 mg)	N/A
ropinirole SR (Ropinirole ER)	Requip® IR	24 mg daily (1 tablet/day) (2 tablet/day for 8 mg, 12 mg)	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
bimatoprost ophth soln 0.01% (Lumigan®)	Latanoprost	No information available	N/A
adapalene gel 0.3%, adapalene lotion 0.1% (Differin®)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	No information available	≥ 12 years old
Azelex® (azelaic acid cream)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	No information available	≥ 12 years old
adapalene-benzoyl peroxide (Epiduo®)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	1application/day topically	≥ 12 years old
clindaymycin phosphate – tretinoin gel (Veltin®, Ziana®)	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®, Sumadan Wash®)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	2 application daily	≥ 12 years old
clobetasol Propionate (Clobetasol Propionate®, Olux®)	Two of the following: clobetasol cream, solution, ointment, or desonide ointment	50 ml/week scalp or topical solutions and shampoo; 59 ml/week spray solution; 50 g/week other topicals (Foam 3g/day, gel 2g/day)	N/A
calcipotriene-betamethasone diproprionate (Calcipotriene/Betamethasone	Calcipotriene and betamethasone diproprionate as a separate agents	100 g per week topically, or 60 g foam every 4 days topically; treatment of more	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
Diproprionate®, Taclonex®)		than 30% body surface area not recommended	
cefixime for suspension (Cefixime®, Suprax®)	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®, Ponstel®)	Ibuprofen	1250 mg daily Age 14 and older 1250 mg daily. Age less than 14: No information available (6 capsules/day)	N/A
Nevanac®, Ilevro® (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
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
Delstrigo™ (doravirine, lamivudine,	If treatment naïve: Symfi or Symfi Lo (efavirenz/	100/300/300 mg daily (1 tablet/day)	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
tenofovir disoproxil fumarate)	lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent		
Steglatro™ (ertugliflozin)	Metformin	15 mg daily (1 tablet/day)	N/A

Drugs are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) 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. Documentation supports that member is currently receiving Symtuza or Delstrigo 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	Tablets: 40, 80 mg

Drug Name	Availability
(azilsartan medoxomil)	
lovastatin SR (Altoprev)	Tablets: 20, 40, 60 mg
Livalo (pitavastatin calcium)	Tablets: 1, 2, 4 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: 03% 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%
clindaymycin phosphate – tretinoin gel (Veltin®, Ziana®)	Topical Gel: 1.2%-0.025%
(Clindaymycin Phosphate – Tretinoin Gel) Clindamycin Phosphate- Tretinoin	Topical Gel: 1.2%-0.025%
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%

Drug Name	Availability
calcipotriene-betamethasone diproprionate (Calcipotriene/Betamethasone Diproprionate, 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
mefanamic acid (Mefenamic Acid, Ponstel)	Capsules: 250 mg
Nevanac, Ilevro (nepafenac ophthalmic suspension)	Nevanac Opthalmic Suspension: 0.1% Ilevro Opthalmic Suspension: 0.3%
Symtuza (darunavir, cobicistat, emtricitabine, tenofovir alafenamide)	Tablets: 800/150/200/10 mg
Delstrigo (doravirine, lamivudine, tenofovir disoproxil fumarate)	Tablets: 100/300/300 mg
Steglatro (ertugliflozin)	Tablets: 5 mg, 15 mg

VII.References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. URL: URL: http://www.clinicalpharmacology.com. Accessed January 24, 2019.
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®, Migranal®) no longer requires EST.	07.06.18	
No significant changes: specified adapalene *gel 0.3%* and adapalene *lotion 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	
Changes align with previously approved clinical guidance: added Delstrigo to policy requiring step through Symfi if member is treatment naïve per SDC.	02.01.19	
Changes align with previously approved clinical guidance and currently existing programming: added Steglatro requiring step through of metformin per HIM formulary changes	03.01.19	
Removed Vytorin from policy per SDC.	03.04.19	

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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