Clinical Policy: Step Therapy

Reference Number: HIM.PA.109
Effective Date: 08.01.17
Last Review Date: 05.22
Line of Business: HIM

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
amlodipine/ olmesartan (Azor®)	Losartan or irbesartan	10/40 mg daily	N/A
amlodipine/ olmesartan/HCTZ (Tribenzor®)	Losartan or irbesartan	10/40/25 mg daily	N/A
lovastatin SR (Altoprev®)	Two of the following: atorvastatin, lovastatin IR, pravastatin, or simvastatin	60 mg daily (1 tablet/day)	N/A
venlafaxine SR (Effexor ER®)	Venlafaxine IR	225 mg daily (1 tablet/day)	N/A
Equetro® (carbamazepine SR)	Carbamazepine IR	1,600 mg daily (two 100 mg tablets/day,	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
		eight 200 mg tablets/day, or four 300 mg tablets/day)	
eszopiclone (Lunesta®)	Zaleplon and zolpidem tartrate	3 mg daily for adults, 2 mg daily for geriatric (1 tablet/day)	≥ 18 years
Vyvanse® (lisdexamfetamine dimesylate)	Generic Adderall XR®	70 mg daily (1 tablet/day)	N/A
dihydroergotamine mesylate (Migranal®)	Two of the following: naratriptan, rizatriptan, or sumatriptan	2 sprays in each nostril per migraine episode, up to a total of 3 mg/24 hours and 4 mg/week (1 mg or 0.267 mL/day)	N/A
almotriptan malate (Axert®)	Two of the following: naratriptan, rizatriptan, or sumatriptan	25 mg daily (0.3 tablet/day for 6.25 mg, 0.4 tablet/day for 12.5 mg)	≥ 12 years
eletriptan (Relpax®)	Two of the following: naratriptan, rizatriptan, or sumatriptan	80 mg daily (0.2 tablet/day)	≥ 18 years
frovatriptan succinate (Frova®)	Two of the following: naratriptan, rizatriptan, or sumatriptan	7.5 mg daily (0.4 tablet/day)	≥ 18 years
zolmitriptan (Zomig®, Zomig ZMT®)	Two of the following: naratriptan, rizatriptan, or sumatriptan	5 mg per dose, up to 10 mg daily (0.3 tablet/day or 0.2 mL/day)	≥ 12 years
Aptiom® (eslicarbazepine)	Carbamazepine or oxcarbazepine	1,600 mg daily (2 tablets/day)	N/A
ropinirole ER (Requip® XL)	Requip® IR	24 mg daily (1 tablet/day for 2 mg, 4 mg, 6 mg; 2 tablets/day for 8 mg, 12 mg)	N/A
adapalene gel 0.3%, adapalene lotion 0.1% (Differin®)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	1 application to affected area daily	≥ 12 years

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
Azelex® (azelaic acid cream)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	2 applications daily	≥ 12 years
adapalene/benzoyl peroxide (Epiduo®)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	1 application daily	≥ 12 years
clindaymycin phosphate/tretinoin gel (Veltin®, Ziana®)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	1 application to affected area daily	≥ 12 years
sulfacetamide sodium with sulfur wash (Sumadan Wash®)	Two of the following: topical benzoyl peroxide, clindamycin, erythromycin, or tretinoin	2 applications daily	≥ 12 years
clobetasol propionate (Olux®)	betamethasone cream/ solution/ointment	50 mL/week scalp or topical solutions and shampoo; 59 mL/week spray solution; 50 g/week other topicals (foam 3 g/day, gel 2 g/day)	N/A
calcipotriene/ betamethasone diproprionate (Taclonex®)	Calcipotriene and betamethasone diproprionate 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 (Suprax®)	Cefdinir or cefpodoxime	400 mg daily; 8 mg/kg/day if a child weighing ≤ 45 kg	N/A
fenoprofen calcium (Nalfon ®)	Ibuprofen	3,200 mg daily (4 tablets/day)	N/A
mefenamic acid	Ibuprofen	1,250 mg daily (5 capsules/day)	N/A
Nevanac®, Ilevro® (nepafenac ophthalmic suspension)	Diclofenac ophthalmic or ketorolac ophthalmic	0.1%: 3 drops daily each affected eye; 0.3%: 1 drop daily each affected eye (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: preferred single tablet complete regimen (e.g., Biktarvy, Genvoya, Odefsey, Triumeq, Dovato, generic Atripla, Symfi, Symfi Lo) If treatment experienced: any HIV antiretroviral agent	800/150/200/10 mg daily (1 tablet/day)	N/A
lamivudine/tenofovir disoproxil fumarate (Cimduo™, Temixys™)	If treatment naïve: any formulary HIV antiretroviral agent If treatment experienced: any HIV antiretroviral agent	Adults and pediatric patients weighing ≥ 35 kg: 200/300 mg PO QD Pediatric patients weighing between 17 to < 35 kg: 17 kg to < 22 kg: 100/150 mg PO QD 22 kg to < 28 kg: 133/200 mg PO QD 28 kg to < 35 kg: 167/250 mg PO QD	

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 Cimduo, Symtuza or Temixys 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

CR: controlled release
DR: delayed release
ER: extended release
FDA: Food and Drug Administration
IR: immediate release
SR: sustained release
XL: extended 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
venlafaxine SR (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 (Axert)	Tablets: 6.25, 12.5 mg
eletriptan (Relpax)	Tablets: 20, 40 mg
frovatriptan succinate (Frova)	Tablets: 2.5 mg
zolmitriptan (Zomig, Zomig ZMT)	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
adapalene gel (Differin)	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%
clindaymycin phosphate/tretinoin gel (Veltin, Ziana)	Topical gel: 1.2%-0.025%
sulfacetamide sodium with sulfur wash (Sumadan Wash)	Topical wash: 9%-4.5%
clobetasol propionate (Olux)	Topical foam: 0.05% Topical gel: 0.05%

Drug Name	Availability
calcipotriene/betamethasone diproprionate (Taclonex)	Topical ointment: 0.005%-0.064% Topical suspension: 0.005%-0.064% Topical foam: 0.005%-0.064%
cefixime for suspension (Suprax)	Oral suspension: 100/5, 200/5, 500/5 mg/mL
fenoprofen calcium (Profeno)	Tablets: 600 mg
mefanamic 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
amlodipine/olmesartan (Azor)	Tablets: 5/20, 5/40, 10/20, 10/40 mg
olmesartan/amlodipine/HCTZ (Tribenzor)	Tablets: 20/5/12.5, 40/10/12.5, 4/10/25, 40/5/12.5, 40/5/25 mg
Equetro (carbamazepine SR)	Capsules: 100, 200, 300 mg
zolpidem tartrate ER (Ambien CR)	Tablets: 6.25, 12.5 mg
dihydroergotamine mesylate (Migranal)	Nasal spray: 4 mg/mL
lamivudine/tenofovir disoproxil fumarate (Cimduo, Temixys)	Tablets: 300 mg lamivudine/ 300 mg tenofovir disoproxil fumarate

**Available as branded product only*

VII.References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. URL: URL: https://www.clinicalkey.com/pharmacology/. Accessed February 23, 2022.
2. Dailymed. Bethesda, MD: U.S. National Library of Medicine, National Institutes of Health, Health & Human Services, 2019. Available at: https://dailymed.nlm.nih.gov/dailymed/index.cfm. Accessed February 23, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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 Delzicol are NF, and Oleptro is no longer available on the market; corrected max dose of Altoprev.	10.03.18	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	
2Q 2019 annual review: no significant changes; added Azor, Equetro, Migranal, Tribenzor and modified requirement for clobetasol to align with currently programmed step therapy edits; references reviewed and updated.	02.01.19	05.19
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	
Per SDC apply the following which align with previously approved clinical guidance: added Atripla, Odefsey, and Complera to policy requiring step through Symfi/Symfi Lo if member is treatment naïve; added continuation of care language for HIV; remove Steglatro and Dexilant.	12.04.19	
Per pharmacy director, revised redirection of clobetasol propionate (Olux®, Temovate®) from generic clobetasol formulations to generic betamethasone formulations.	01.23.20	02.20
2Q 2020 annual review: no significant changes.	02.19.20	05.20
Removed Atripla per November SDC and prior clinical guidance; added Cinduo requiring any other formulary HIV agent for treatment naïve members per Ambetter formulary director.	12.08.20	
2Q 2021 annual review: no significant changes. Per March SDC, removed Odefsey from policy.	03.26.21	05.21
Per June SDC and prior clinical guidance, modified Complera, Delstrigo, and Symtuza to require preferred single-tablet complete regimen if member is treatment naïve.	06.02.21	08.21
For CY2022 per March SDC, remove Livalo and Lumigan from policy as these products will be non-formulary.	08.10.21	11.21
2Q 2022 annual review: removed Delstrigo and Complera as EST is no longer required; added new branded Temixys product to align with current step requirements for Cimduo; removed the following obsolete products: Ponstel, Profeno, Temovate; references reviewed and updated.	02.23.22	05.22
Per May SDC and prior clinical guidance, removed zolpidem tartrate ER and ramelteon from criteria.	05.20.22	

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.
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