Clinical Policy: Step Therapy

Reference Number: HIM.PA.109
Effective Date: 08.01.17
Last Review Date: 05.24
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.

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***For Eucrisa requests**, this policy applies only to Fidelis Health Plan members, for all other Eucrisa requests refer to CP.PMN.110*

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
Equetro® (carbamazepine SR)	Carbamazepine IR	1,600 mg daily (two 100 mg tablets/day, eight 200 mg	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
		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
lisdexamfetamine dimesylate (Vyvanse®)	Generic Adderall XR®	70 mg daily (1 tablet/day)	N/A
almotriptan malate	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®) zolmitriptan ODT	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	ropinirole 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 gel 0.1%, adapalene lotion 0.1%, adapalene cream 0.1% (Differin®)	Two of the following topical products: benzoyl peroxide, clindamycin, erythromycin, or tretinoin* **Prior authorization may be required for tretinoin*	1 application to affected area daily	≥ 12 years
Azelex® (azelaic acid cream)	Two of the following topical products: benzoyl peroxide, clindamycin, erythromycin, or tretinoin* **Prior authorization may be required for tretinoin*	2 applications daily	≥ 12 years

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
adapalene/benzoyl peroxide (Epiduo®)	Two of the following topical products: benzoyl peroxide, clindamycin, erythromycin, or tretinoin* **Prior authorization may be required for tretinoin*	1 application daily	≥ 12 years
clindaymycin phosphate/tretinoin gel (Veltin®, Ziana®)	Two of the following topical products: benzoyl peroxide, clindamycin, erythromycin, or tretinoin* **Prior authorization may be required for tretinoin*	1 application to affected area daily	≥ 12 years
sulfacetamide sodium with sulfur wash (Sumadan Wash®)	Two of the following topical products: benzoyl peroxide, clindamycin, erythromycin, or tretinoin* **Prior authorization may be required for tretinoin*	2 applications daily	≥ 12 years
clobetasol propionate foam (Olux®), clobetasol proprionate gel 0.05%	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® (nepafenac ophthalmic suspension)	Diclofenac ophthalmic or ketorolac ophthalmic	0.1%: 3 drops daily each affected eye	N/A

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)	Age Limit
lamivudine/tenofovir disoproxil fumarate (Cimduo™)	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	N/A
Ubrelvy™ (ubrogepant)* **Ubrelvy should not be prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™, Nurtec® ODT, Qulipta™, Vyepti™)*	One $5HT_{1B/1D}$-agonist migraine medication (e.g., sumatriptan, rizatriptan, zolmitriptan)	Varies	N/A
Eucrisa™ (crisaborole)† *†applies only to Fidelis Health Plan members, for all other Eucrisa requests refer to CP.PMN.110*	One of the following (a or b): a) Generic topical corticosteroid (e.g. betamethasone, clobetasol, halobetasol, fluocinolone); b) For age ≥ 2 years: topical calcineurin inhibitor (e.g. tacrolimus, pimecrolimus).	60 grams/ 30 days	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, b, or c):

a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
c. Documentation supports that member is currently receiving Cimduo 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
eszopiclone (Lunesta)	Tablets: 1, 2, 3 mg
Rozerem (ramelteon)	Tablets: 8 mg
lisdexamfetamine dimesylate (Vyvanse)	Capsules: 10, 20, 30, 40, 50, 60, 70 mg
almotriptan malate	Tablets: 6.25, 12.5 mg
eletriptan (Relpax)	Tablets: 20, 40 mg
frovatriptan succinate (Frova)	Tablets: 2.5 mg
zolmitriptan (Zomig), zolmitriptan ODT	Tablets: 5 mg Nasal solution*: 2.5, 5 mg/spray ODT: 2.5, 5 mg
Aptiom (eslicarbazepine)	Tablets: 200, 400, 600, 800 mg
ropinirole SR	Tablets: 2, 4, 6, 8, 12 mg
adapalene (Differin)	Topical cream, gel, lotion: 0.1% Topical gel: 03% Topical gel pump: 0.3%

Drug Name	Availability
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%
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 (nepafenac ophthalmic suspension)	Nevanac opthalmic suspension: 0.1%
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
lamivudine/tenofovir disoproxil fumarate (Cimduo)	Tablets: 300 mg lamivudine/ 300 mg tenofovir disoproxil fumarate
Ubrelvy (ubrogepant)	Tablets (package size 10, 16, 30): 50 mg, 100 mg
Eucrisa (crisaborole)	Topical ointment: 2%

**Available as branded product only*

VII. References

1. Clinical Pharmacology [database online]. Elsevier, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed February 5, 2024.
2. Dailymed. Bethesda, MD: U.S. National Library of Medicine, National Institutes of Health, Health & Human Services, 2023. Available at: https://dailymed.nlm.nih.gov/dailymed/index.cfm. Accessed February 5, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	
Per August SDC and prior clinical guidance, added Ubrelvy requiring step through two $5HT_{1B/1D}$-agonist migraine medications (e.g., sumatriptan, rizatriptan, zolmitriptan).	08.23.22	11.22
2Q 2023 annual review: removed Symtuza, dihydroergotamine, lovastatin SR as EST is no longer required; added clobetasol gel with similar requirements as Olux; clarified age limit is not required for Cimduo/Temixys; template changes applied to continued therapy; references reviewed and updated.	02.02.23	05.23
Per May SDC, added celecoxib to policy requiring step through meloxicam or generic NSAID or current use of corticosteroid or anticoagulant.	05.24.23	
For Ubrelvy, added clarification that Ubrelvy should not be prescribed concurrently with other CGRP inhibitors.	08.28.23	
Per April SDC, removed Ilevro from policy. Per August SDC, added Eucrisa to policy for Fidelis health plan requiring step through one generic topical corticostetoid or topical calcineurin inhibitor.	08.22.23	12.23
Added clarification stating prior authorization may be required for tretinoin.	02.14.24	
2Q 2024 annual review: removed venlafaxine SR as EST is no longer required; removed references to Temixys, Axert, Zomig-ZMT, Requip XL, and Requip IR as products are discontinued; references reviewed and updated. Per March SDC, revised Ubrelvy step-through agent requirement from two to one $5HT_{1B/1D}$-agonist medication; removed celecoxib as EST is no longer required.	03.12.24	05.24
Ad hoc: Added adapalene cream 0.1% and gel 0.1% to criteria with existing adapalene step requirements	05.03.24	

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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