Clinical Policy: Step Therapy

Reference Number: CP.CPA.83
Effective Date: 09.01.18
Last Review Date: 05.24
Line of Business: Commercial*

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.

**This step therapy policy does not apply to drugs that are not on the Commercial formulary. For non-formulary drugs, refer to the formulary exception policy, CP.CPA.190 Formulary Exceptions.*

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 following drugs are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Step Therapy:

1. Drugs listed in the table below may be approved for 12 months or duration of request, whichever is less, 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)
aliskiren/HCTZ (Tekturna HCT®)	Generic or preferred ARB (e.g., olmesartan, olmesartan/hctz, irbesartan, losartan, candesartan, telmisartan, valsartan)	Tekturna HCT: 300/25 mg/day
Aplenzin® (bupropion hydrobromide SR)	Two generic antidepressants	348 mg/day (1 tablet/day)
Astagraf XL® (tacrolimus SR)	Generic tacrolimus	0.2 mg/kg/day
Aptiom® (eslicarbazepine)	Carbamazepine or oxcarbazepine	1,600 mg daily (2 tablets/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Bepreve® (bepotastine)	Generic ophthalmic olopatadine, and either azelastine or epinastine	2 drops/eye/day (0.34 mL/day)
calcipotriene-betamethasone ointment (Taclonex®)	Generic topical steroid and either topical calcitriol or calcipotriene cream	100 g/week (2 g/day)
calcipotriene-betamethasone suspension (Taclonex®)	Generic topical clobetasol and topical fluocinolone	100 g/week (2 g/day)
Celecoxib (Celebrex®)* **Applies to Oregon Commercial ONLY; for California Commercial refer to CP.PMN.122*	One of the following (a, b, c, or d), unless member is > 65 years old, has prior gastrointestinal bleed, or active peptic ulcer disease (not gastroesophageal reflux disease [GERD]): a) Meloxicam; b) Generic NSAID; c) Current use of a corticosteroid; d) Current use of an anticoagulant or antiplatelet (e.g., aspirin, warfarin, low molecular weight heparin, direct thrombin inhibitors, factor Xa inhibitors, clopidogrel).	800 mg /day (2 capsules)
Cordran® (flurandrenolide lotion 0.05%, ointment 0.05%)	Generic topical corticosteroid alternatives	3 applications topically per day
desoximetasone spray 0.25% (Topicort®)	Generic desoximetasone 0.25% ointment or cream	Not applicable
doxycycline monohydrate	Doxycycline Hyclate	Not applicable
ethacrynic acid (Edecrin®)	Generic bumetanide, furosemide, or torsemide	400 mg/day
Fetzima® (levomilnacipran)	Two generic antidepressants	120 mg/day (20 mg: 2 tablets/day; Other strengths:1 tablet/day)
bupropion hydrochloride ER (Forfivo XL®)	Two generic antidepressants	450 mg/day (1 tablet/day)
Lastacaft® (alcaftadine ophthalmic solution 0.25%)	Both of the following (a and b): a) Patanol or Pataday	(1 drop/eye/day) 1 bottle/month

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
	b) Azelastine or Epinastine	
modafinil (Provigil®)	armodafinil (Nuvigil®)	200 mg/day for shift work disorder; 400 mg for all other indications
olmesartan/amlodipine (Azor™), olmesartan/amlodipine/HCTZ (Tribenzor™)	Generic or formulary preferred ARB or ARB combination product (e.g., olmesartan, olmesartan/hctz, irbesartan, losartan, candesartan, telmisartan, valsartan)	Azor: 10/40 mg/day Tribenzor: 40/10/25 mg/day
Pataday® Extra Strength (olopatadine HCl ophthalmic solution 0.7%)	Generic ophthalmic olopatadine, and either azelastine or epinastine	1 bottle/month
Oxtellar XR® (oxcarbazepine SR 150 mg, 300 mg, 600 mg)	Generic Trileptal	2,400 mg/day
Retin-A Micro® (tretinoin microsphere gel)	Generic tretinoin product	Once daily application
Trintellix® (vortioxetine)	Two generic antidepressants	20 mg/day (1 tablet/day)
Ubrelvy™ (ubrogepant)* **Ubrelvy should not be prescribed concurrently with other CGRP inhibitors (e.g., Aimovig™, Ajovy™, Emgality™, Nurtec® ODT, Qulipta™, Vyepti™)*	<u>For California Exchange Plans only:</u> **One** $5HT_{1B/1D}$-agonist migraine medication (e.g., sumatriptan, rizatriptan, zolmitriptan) <u>For California & Oregon Commercial formularies:</u> **Two** $5HT_{1B/1D}$-agonist migraine medications (e.g., sumatriptan, rizatriptan, zolmitriptan)	Varies
Xhance® (fluticasone propionate)*	One formulary intranasal steroid (e.g., fluticasone propionate, mometasone, budesonide)	Varies
zileuton ER (Zyflo® CR)	Generic montelukast	2,400 mg/day
Zyflo® (zileuton)	Generic montelukast	2,400 mg/day

Agents 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 or duration of request, whichever is less

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. 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)*;
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 or duration of request, whichever is less

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ARB angiotensin receptor blocker
CR: controlled-release
ER: extended-release
FDA: Food and Drug Administration
HCTZ: hydrochlorothiazide
IR: immediate-release
NSAID: non-steroidal anti-inflammatory drug
SR: sustained-release
XL: extended-release

Appendix B: Therapeutic Alternatives

Refer to the 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
alcaftadine (Lastacaft)	Ophthalmic solution: 0.25%
aliskiren/HCTZ (Tekturna HCT)	Tablets: 150/12.5, 150/25, 300/12.5, 300/25 mg
bepotastine (Bepreve)	Ophthalmic solutions, 1.5%: 5 mL, 10 mL
bupropion hydrobromide ER (Aplenzin)	Tablets, extended release: 174 mg, 348 mg, 522 mg
bupropion hydrochloride ER (Forfivo XL)	Tablets, extended release: 450 mg
calcipotriene-betamethasone (Taclonex)	Topical ointments, 0.005%/0.064%: 60 g, 100 g Topical suspensions, 0.005%/0.064%: 60 g, 100 g
celecoxib (Celebrex)	Capsules: 50 mg, 100 mg, 200 mg, and 400 mg
Cordran (flurandrenolide lotion, ointment)	Lotion 0.05%: 120 mL Ointment 0.05%: 60 g

Drug Name	Availability
desoximetasone (Topicort)	Topical spray, solution, 0.25%: 100 mL
doxycycline monohydrate	Capsules, tablets: 50 mg, 75 mg, 100 mg, 150 mg
ethacrynic acid (Edecrin)	Tablet: 25 mg
levomilnacipran (Fetzima)	Capsules, extended release: 20 mg, 40 mg, 80 mg, 120 mg Capsules, extended release therapy pack: 20 mg/40 mg
modafinil (Provigil)	Tablets: 100 mg, 200 mg
olmesartan/amlodipine (Azor)	Tablets: 5/20, 10/20, 5/40, 10/40 mg
olmesartan/amlodipine/HCTZ (Tribenzor)	Tablets: 20/5/12.5, 40/5/12.5, 40/5/25, 40/10/12.5, 40/10/25 mg
Retin-A Micro (tretinoin microsphere gel)	Gel (20 g, 45 g tube): 0.1%, 0.04% Gel (50 g pump): 0.06%, 0.08%
tacrolimus SR (Astagraf XL)	Capsules, extended release: 0.5 mg, 1 mg, 5 mg
Ubrelvy (ubrogepant)	Tablets (package size 10, 16, 30): 50 mg, 100 mg
vortioxetine (Trintellix)	Tablets: 5 mg, 10 mg, 20 mg
Xhance (fluticasone propionate)	Nasal spray: 93 mcg of fluticasone propionate in each 106-mg spray with 120 metered sprays per device
zileuton (Zyflo)	Tablet: 600 mg
zileuton SR (Zyflo CR)	Tablet, extended release: 600 mg

VI. References

1. Clinical Pharmacology [database online]. Elsevier, Inc.; 2023. Available at: https://www.clinicalkey.com/pharmacology/. Accessed February 5, 2024.
2. American Psychiatric Association: Practice guideline for the treatment of patients with major depressive disorder 3rd edition. Am J Psychiatry 2010;167(suppl):1-152.
3. Qaseem A, Owens DK, Etxeandia-Ikobaltzeta I, et al. Nonpharmacologic and Pharmacologic Treatments of Adults in the Acute Phase of Major Depressive Disorder: A Living Clinical Guideline From the American College of Physicians. Ann Intern Med. 2023 Feb; 176(2): 239-252.
4. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Neurology. July 10, 2018; 91(2):74-81.
5. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment resistant epilepsy. Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology and the American Epilepsy Society. Epilepsy Curr. Jul-Aug 2018;18(4):269-78.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2020 annual review: no significant changes.	03.05.20	05.20
Added Cimduo requiring use of Truvada for treatment naïve members per April SDC and prior clinical guidance.	04.27.20	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Removed Tudorza Pressair and Seebri Neohaler per October SDC and prior clinical guidance.	10.07.20	
Removed Atripla per November SDC and prior clinical guidance	11.16.20	
2Q 2021 annual review: added the following: Lastacraft requiring step through Patanol or Pataday and either azelastine or epinastine; olopatadine ophthalmic solution 0.7% requiring step through generic ophthalmic olopatadine, and either azelastine or epinastine; Oxtellar requiring step through Trileptal; added desoximetasone spray requiring step through generic desoximetasone ointment and cream; references reviewed and updated.	02.24.21	05.21
Per June SDC and prior clinical guidance, removed Symtuza, Complera, Delstrigo, and Odefsey from policy.	06.02.21	08.21
Revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less	09.27.21	02.22
2Q 2022 annual review: added the following to align with formulary and clinical pharmacy messaging: Androderm, Cordran, doxycycline monohydrate, fluoxetine, Retin-A Micro; references reviewed and updated.	02.23.22	05.22
Per August SDC and prior clinical guidance, added Ubrelvy requiring step through two $5HT_{1B/1D}$-agonist migraine medications (e.g., sumatriptan, rizatriptan, zolmitriptan); removed Viibryd from policy. Per September SDC removed Androderm from policy.	09.26.22	11.22
2Q 2023 annual review: removed fluoxetine, Envarsus XR, desvenlafaxine, Tekturna, and Cimduo as EST is not required; for risedronate referenced brand name Atelvia as Actonel does not require step therapy, deleted dosing other than 35 mg strength; template changes applied to continued therapy; references reviewed and updated.	02.02.23	05.23
Per SDC, added Xhance to policy requiring one intranasal steroid; added clarification that this applies to California Commercial formularies only, for Oregon formularies, refer to CP.PMN.95.	05.04.23	
Per May SDC, added celecoxib to policy requiring step through meloxicam or generic NSAID or current use of corticosteroid or anticoagulant. For Cordran, corrected max dosing per label.	05.24.23	08.23
For Ubrelvy, added clarification that Ubrelvy should not be prescribed concurrently with other CGRP inhibitors.	08.28.23	
For Celebrex added clarification that step therapy criteria applies to Oregon Commercial only, for California Commercial refer to CP.PMN.122.	09.18.23	
Per September SDC and prior clinical guidance, added Aptiom to policy requiring step through carbamazepine or oxcarbazepine.	09.21.23	12.23

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2024 annual review: removed Atelvia as it is non-formulary; for Taclonex clarified step through drugs are topical formulations; references reviewed and updated. Per March SDC, revised Ubrelvy step-through agent requirements for California Commercial Exchange Plans from two to one $5HT_{1B/1D}$-agonist medication (all other commercial formularies retain requirements for two $5HT_{1B/1D}$-agonist medications).	03.12.24	05.24
Added reference to the American Psychiatric Association, American College of Physicians, and American Academy of Neurology clinical practice guidelines per compliance request. For Ubrelvy, clarified that "California Commercial Exchange Plans" refers to "California Exchange Plans."	07.16.24	
For Xhance, removed the following clarification: "Applies to California Commercial formularies only. For Oregon formularies, refer to CP.PMN.95."	08.05.24	

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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