Clinical Policy: Step Therapy

Reference Number: CP.CPA.83
Effective Date: 09.01.18
Last Review Date: 05.20
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:

Drugs listed in the table below may be approved for the length of benefit 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 (Tekturna®), Aliskiren/HCTZ (Tekturna HCT®)	ARB or ARB combination product (e.g., olmesartan, olmesartan/hctz, irbesartan, losartan, candesartan, telmisartan, valsartan)	Tekturna: 300 mg/day 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
Bepreve® (bepotastine)	Generic ophthalmic olopatadine, and either azelastine or epinastine	2 drops/eye/day (0.34 mL/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
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 clobetasol and fluocinolone	100 g/week (2 g/day)
Delstrigo™ (doravirine, lamivudine, tenofovir disoproxil fumarate)	If treatment naïve: Symfi or Symfi Lo (efavirenz/ lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	100/300/300 mg daily (1 tablet/day)
desvenlafaxine succinate ER (Khedezla®, Pristiq®)	Two generic antidepressants	400 mg/day (or 100 mg/day in moderate to severe hepatic impairment) (1 tablet/day)
Efavirenz/emtricitabine/ tenofovir disoproxil fumarate (Atripla®)	If treatment naïve: Symfi™ or Symfi Lo™ (efavirenz/ lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	600/200/300 mg daily (1 tablet/day)
Emtricitabine/rilpivirine/ tenofovir alafenamide (Odefsey®)	If treatment naïve: Symfi or Symfi Lo (efavirenz/ lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	200/25/25 mg daily (1 tablet/day)
Emtricitabine/rilpivirine/ tenofovir disoproxil fumarate (Complera®)	If treatment naïve: Symfi or Symfi Lo (efavirenz/ lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	200/25/300 mg daily (1 tablet/day)
Envarsus® XR (tacrolimus SR)	Generic tacrolimus	Not applicable
ethacrynic acid (Edecrin®)	Generic bumetanide, furosemide, or torsemide	400 mg/day

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Fetzima® (levomilnacipran)	Two generic antidepressants	120 mg/day (20 mg: 2 tablets/day; Other strengths:1 tablet/day)
Forfivo XL® (bupropion hydrochloride ER)	Two generic antidepressants	450 mg/day (1 tablet/day)
Cimduo™ (lamivudine/tenofovir disoproxil fumarate)	If treatment naïve: Truvada® (emtricitabine/tenofovir)	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
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
risedronate (Actonel®)	One of the following generic bisphosphonates: ibandronate, alendronate, or risedronate (Atelvia®)	150 mg/month (5 mg, 30 mg: 1 tablet/day; 35 mg: 0.15 tablet/day; 150 mg: 0.04 tablet/day)
Seebri™ Neohaler® (glycopyrrolate)	Use preferred Spiriva® or Incruse® Ellipta®	2 capsules/day
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)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Trintellix® (vortioxetine)	Two generic antidepressants	20 mg/day (1 tablet/day)
Tudorza® Pressair® (aclidinium bromide)	Use preferred Spiriva® or Incruse® Ellipta®	800 mcg/day (2 inhalations/day)
Viibryd™ (vilazodone)	Two generic antidepressants	40 mg/day
zileuton ER (Zyflo® CR)	Generic montelukast	2400 mg/day
Zyflo® (zileuton)	Generic montelukast	2400 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: Length of Benefit

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 Atripla, Cimduo, Complera, Delstrigo, Odefsey, or 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: Length of Benefit

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
HIV: human immunodeficiency virus
IR: immediate-release
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
Aliskiren (Tekturna)	Tablets: 150, 300 mg
Aliskiren/HCTZ (Tekturna HCT)	Tablets: 150/12.5, 150/25, 300/12.5, 300/25 mg
Bepotastine (Bepreve)	Ophthalmic solution, 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 ointment, 0.005%/0.064%: 60 g, 100 g Topical suspension, 0.005%/0.064%: 60 g, 100 g
Cimduo (lamivudine/tenofovir disoproxil fumarate)	Tablets: 300 mg lamivudine/ 300 mg tenofovir disoproxil fumarate
Delstrigo (doravirine, lamivudine, tenofovir disoproxil fumarate)	Tablets: 100/300/300 mg
Desvenlafaxine succinate (Pristiq®, Khedezla®)	Tablets, extended release: 25 mg (Pristiq only), 50 mg, 100 mg
(Efavirenz/emtricitabine/ tenofovir disoproxil fumarate) Atripla	Tablets: 600/200/300 mg
(Emtricitabine/rilpivirine/ tenofovir alafenamide) Odefsey	Tablets: 200/25/25 mg
(Emtricitabine/rilpivirine/ tenofovir disoproxil fumarate) Complera	Tablets: 200/25/300 mg
Ethacrynic acid (Edecrin)	Tablets: 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
Risedronate (Actonel)	Tablets: 5 mg, 30 mg, 35 mg, 150 mg
Seebri Neohaler (glycopyrrolate)	Inhalation powder capsules: 15.6 mcg
Symtuza (darunavir, cobicistat, emtricitabine, tenofovir alafenamide)	Tablets: 800/150/200/10 mg
Tacrolimus SR (Astagraf XL)	Capsules, extended release: 0.5 mg, 1 mg, 5 mg
Tacrolimus SR (Envarsus XR)	Tablets, extended release: 0.75 mg, 1 mg, 4 mg

Drug Name	Availability
Tudorza Pressair (aclidinium bromide)	Inhalation powder: 400 mcg
Vilazodone (Viibryd)	Tablets: 10 mg, 20 mg, 40 mg Tablets, starter pack: 10 mg/20 mg
Vortioxetine (Trintellix)	Tablets: 5 mg, 10 mg, 20 mg
Zileuton (Zyflo)	Tablets: 600 mg
Zileuton SR (Zyflo CR)	Tablets, extended release: 600 mg

VI. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created from step therapy policy CP.CPA.219 Antidepressant Step Therapy and CP.CPA.185 General Step Through Criteria.	05.15.18	08.18
Changes align with previously approved clinical guidance: Added Atripla, Odefsey, and Complera to policy requiring step through Symfi if member is treatment naïve per SDC; added continuation of care language for HIV per SDC.	12.07.18	
Changes align with previously approved clinical guidance: added Symtuza to policy requiring step through Symfi if member is treatment naïve 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: added Provigil to policy requiring step through Nuvigil; references reviewed and updated.	03.05.19	05.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Azor and Tribenzor added to policy requiring step through generic or formulary preferred ARB or ARB combination product; retire CP.CPA.61; added Tekturna and Takturna HCT to policy requiring step through ARB or ARB combination product; retire CP.CPA.07.	05.06.19	08.19
Seebri Neohaler and Tudorza Pressair added to policy requiring use of preferred Spiriva or Incruse Ellipta per SDC and prior clinical guidance; retire CP.CPA.150. Added disclaimer statement that policy does not apply to NF drugs.	10.07.19	
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	

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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