

## Clinical Policy: Step Therapy

Reference Number: CP.PST.01

Effective Date: 12.28.17

Last Review Date: 02.26

Line of Business: Medicaid\*

[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 for drugs on the Preferred Drug List (PDL).

*\*This step therapy policy does not apply to drugs that are not on the Medicaid Health Plan's PDL. For non-formulary drugs, refer to the formulary exception policy, CP.PMN.16 Request for Medically Necessary Drug not on the PDL.*

### 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<sup>®</sup> that the drugs identified within this policy are **medically necessary** when the following criteria are met:

### I. Initial Approval Criteria

#### A. Electronic Step Therapy:

1. 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)
alogliptin-containing products (Kazano <sup>®</sup> , Nesina <sup>®</sup> , Oseni <sup>®</sup> )	Metformin	Varies
amlodipine/olmesartan (Azor <sup>®</sup> )	Losartan or irbesartan	10/40 mg daily (1 tablet/day)
amlodipine/valsartan (Exforge <sup>®</sup> )	Losartan or irbesartan	10/320 mg daily (1 tablet/day)
amlodipine/valsartan/ HCTZ (Exforge HCT <sup>®</sup> )	Losartan or irbesartan	10/320/25 mg daily (1 tablet/day)
ascorbic acid (Vitamin C)	Ferrous sulfate	1,500 mg daily
atazanavir (Reyataz <sup>®</sup> )	One of the following: ritonavir, Cobicistat, Genvoya <sup>®</sup> , or Stribild <sup>®</sup>	400 mg daily (2 capsules/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
atomoxetine (Strattera <sup>®</sup> )	One amphetamine-containing product and one methylphenidate-containing product, unless member or parent/guardian of member has a history of substance abuse	100 mg daily
bimatoprost ophthalmic solution, travoprost ophthalmic solution	Latanoprost	One drop in the affected eye(s) daily
clonidine (Kapvay <sup>®</sup> )	Guanfacine	0.4 mg daily (4 tablets/day)
darunavir (Prezista <sup>®</sup> )	One of the following: ritonavir, Cobicistat, Genvoya <sup>®</sup> , or Stribild <sup>®</sup>	800 mg daily (1 tablet/day) or 12 mL/day
desvenlafaxine (Pristiq <sup>®</sup> )	Trazodone, venlafaxine, or selective serotonin reuptake inhibitor (SSRI)	100 mg daily (1 tablet/day)
dexlansoprazole (Dexilant <sup>®</sup> )	Omeprazole, lansoprazole, or pantoprazole	60 mg daily (1 tablet/day)
exemestane (Aromasin <sup>®</sup> )	One PDL aromatase inhibitor (e.g., anastrozole, letrozole), unless request is for Stage IV or metastatic cancer for a State with regulations against step therapy in advanced oncology settings ( <i>see Appendix D</i> )	25 mg/day (1 tablet/day)
ezetimibe (Zetia <sup>®</sup> )	One of the following (a or b) a) Currently receiving ezetimibe or ezetimibe-simvastatin b) Prior use of at least one of the following generic statins: atorvastatin calcium, fluvastatin sodium, lovastatin, rosuvastatin calcium, pravastatin sodium, simvastatin, amlodipine besylate-atorvastatin calcium	10 mg/day (1 tablet/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
ezetimibe/simvastatin (Vytorin <sup>®</sup> )	One of the following (a or b) a) Currently receiving ezetimibe or ezetimibe-simvastatin b) Prior use of at least one of the following generic statins: atorvastatin calcium, fluvastatin sodium, lovastatin, rosuvastatin calcium, pravastatin sodium, simvastatin, amlodipine besylate-atorvastatin calcium	10/40 mg/day for most patients  10/80 mg/day for patients already taking simvastatin 80 mg/day chronically without evidence of myopathy
galantamine extended release	Galantamine immediate release	24 mg daily (1 capsule/day)
HCTZ/olmesartan (Benicar HCT <sup>®</sup> )	Losartan or irbesartan	40/25 mg daily (1 tablet/day)
lamivudine/tenofovir disoproxil fumarate (Cimduo <sup>™</sup> )	If treatment naïve: Truvada <sup>®</sup> (emtricitabine/tenofovir)	Adults and pediatric patients weighing ≥ 35 kg: 300/300 mg PO QD
lamotrigine (Lamictal <sup>®</sup> XR <sup>™</sup> )	Lamotrigine IR	Varies
levalbuterol nebulized solution	Albuterol inhalation (Proventil <sup>®</sup> HFA, Ventolin <sup>®</sup> HFA) or albuterol nebulized solution	3.75 mg daily
levetiracetam (Keppra XR <sup>™</sup> )	Levetiracetam IR	3000 mg daily (4 tablet/day)
memantine extended release (Namenda XR <sup>®</sup> )	Memantine immediate release	28 mg daily (1 capsule/day)
nebivolol (Bystolic <sup>®</sup> )	One of the following: acebutolol, atenolol, bisoprolol, or metoprolol	40 mg daily (2 tablets/day)
olmesartan (Benicar <sup>®</sup> )	Losartan or irbesartan	40 mg daily (1 tablet/day)
olmesartan/amlodipine/ HCTZ (Tribenzor <sup>®</sup> )	Losartan or irbesartan	40/10/25 mg daily (1 tablet/day)
oxycodone oral solution	Cladribine or any antineoplastic therapy	Varies
paromomycin (Humatin <sup>®</sup> )	Metronidazole or tinidazole	35 mg/kg daily
paroxetine oral suspension	Two PDL alternatives from the following classes:	60 mg daily (30 ml/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
	selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), monoamine oxidase inhibitors (MAOIs), atypical antidepressants (e.g., bupropion, mirtazapine, nefazodone, trazodone)	
rosuvastatin (Crestor <sup>®</sup> )	Atorvastatin or simvastatin	40 mg/day (1 tablet/day)
silodosin (Rapaflo <sup>®</sup> )	Alfuzosin or tamsulosin	8 mg daily (1 capsule/day)
spinosad (Natroba <sup>®</sup> )	Malathion or permethrin	Varies
tinidazole	Metronidazole	2,000 mg daily for up to 5 days
tipranavir (Aptivus <sup>®</sup> )	Ritonavir	1,000 mg daily (4 capsules/day)
trosipium	One of the following: oxybutynin, solifenacin, or tolterodine	60 mg daily (1 capsule/day)
zolpidem extended release (Ambien CR <sup>®</sup> )	Zolpidem immediate release	12.5 mg daily (1 tablet/day)

**Approval duration: Length of Benefit**

## 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 or Temixys for HIV infection and has received this medication for at least 30 days;
2. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug.

**Approval duration: Length of Benefit**

## III. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

GLP-1: glucagon-like peptide-1

HbA1c: glycated hemoglobin  
HCTZ: hydrochlorothiazide  
HIV: human immunodeficiency virus

IR: immediate release  
PDL: preferred drug list

*Appendix B: Therapeutic Alternatives*

Refer to required step-through drug(s) above.

*Appendix C: Contraindications/Boxed Warnings*

Refer to the package inserts for each of the drugs requiring step therapy.

*Appendix D: States with Regulations against Redirections in Stage IV or Metastatic Cancer*

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions.
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness.
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA.
LA	Yes <sup>‡</sup>	For stage 4 advanced, metastatic cancer or associated conditions. <sup>‡</sup> Exception if “clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy.
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes <sup>^</sup>	For stage 4 advanced metastatic cancer, metastatic blood cancer, and associated conditions <sup>^</sup> Exception if step therapy is for AB-rated generic equivalent, interchangeable biological product, or biosimilar product to the equivalent brand drug
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

**IV. Dosage and Administration**

Refer to the step therapy table in Section I.

**V. Product Availability**

Drug Name	Availability
alogliptin-containing products (Kazano <sup>®</sup> , Nesina <sup>®</sup> , Oseni <sup>®</sup> )	Alogliptin tablets: 6.25 mg, 12.5 mg, 25 mg Alogliptin/metformin tablets: 12.5/500 mg, 12.5/1000 mg Alogliptin/pioglitazone tablets: 12.5/30 mg, 25/15 mg, 25/30 mg, 25/45 mg
amlodipine/olmesartan (Azor)	Tablets 5/20 mg, 10/20 mg, 5/40 mg, 10/40 mg
amlodipine/valsartan (Exforge)	Tablets: 5/160 mg, 10/160 mg, 5/320 mg, 10/320 mg
amlodipine/valsartan/ HCTZ (Exforge HCT)	Tablets: 5/160/12.5 mg, 10/160/12.5 mg, 5/160/25 mg, 10/160/25 mg, 10/320/25 mg
ascorbic acid (Vitamin C)	Tablet, chewable tablet: 100 mg, 250 mg, 500 mg

Drug Name	Availability
atazanavir (Reyataz <sup>®</sup> )	Capsules: 150 mg, 200 mg, 300 mg Oral suspension: 50 mg
atomoxetine (Strattera)	Capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 mg
bimatoprost ophthalmic solution	ophthalmic solution: 0.03%
clonidine (Kapvay <sup>®</sup> )	Tablet, sustained release: 0.1 mg
darunavir (Prezista <sup>®</sup> )	Tablet: 75 mg, 150 mg, 600 mg, 800 mg Oral suspension: 100 mg/mL
desvenlafaxine (Pristiq <sup>®</sup> )	Tablet, sustained release: 25 mg, 50 mg, 100 mg
dexlansoprazole (Dexilant <sup>®</sup> )	Capsule, delayed release: 30 mg, 60 mg
exemestane (Aromasin)	Tablets: 25 mg
ezetimibe (Zetia)	Tablets: 10 mg
ezetimibe/simvastatin (Vytorin)	Tablets (ezetimibe mg/simvastatin mg): 10/10, 10/20, 10/40, 10/80
galantamine extended release	Capsule, extended release: 8 mg, 16 mg, 24 mg
lamivudine/tenofovir disoproxil fumarate (Cimduo)	Tablets: 300 mg lamivudine/ 300 mg tenofovir disoproxil fumarate
lamotrigine (Lamictal XR)	Extended-release tablets: 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, 300 mg
levalbuterol nebulized solution	Nebulized solution: 0.31 mg/3mL, 0.63 mg/3mL, 1.25 mg/3mL, 1.25 mg/0.5mL
levetiracetam (Keppra XR)	Film-coated extended-release tablets: 500 mg, 750 mg
memantine extended release (Namenda XR <sup>®</sup> )	Capsule, extended release: 7 mg, 14 mg, 21 mg, 28 mg
nebivolol (Bystolic <sup>®</sup> )	Tablet: 2.5 mg, 5 mg, 10 mg, 20 mg
olmesartan (Benicar)	Tablets: 5 mg, 20 mg, 40 mg
olmesartan/amlodipine/ HCTZ (Tribenzor)	Tablets: 20/5/12.5 mg, 40/5/12.5 mg, 40/5/25 mg, 40/10/12.5 mg, 40/10/25 mg
olmesartan/HCTZ (Benicar HCT)	Tablets: 20/12.5 mg; 40/12.5 mg, 40/25 mg
oxycodone oral solution	Oral solution: 5 mg/5 mL
paromomycin (Humatin <sup>®</sup> )	Capsule: 250 mg
paroxetine oral suspension	Oral suspension: 10 mg/4 mL
rosuvastatin (Crestor)	Tablets: 5 mg, 10 mg, 20 mg, 40 mg
silodosin (Rapaflo <sup>®</sup> )	Capsule: 4 mg, 8 mg
spinosad (Natroba <sup>®</sup> )	Topical suspension: 0.9%
tinidazole	Tablet: 250 mg, 500 mg
tipranavir (Aptivus <sup>®</sup> )	Capsule: 250 mg
travoprost ophthalmic solution	ophthalmic solution: 0.004%
tropium	Capsule, extended release: 60 mg
zolpidem extended release (Ambien CR <sup>®</sup> )	Tablet, extended release: 6.25 mg, 12.5 mg

**VI. References**

1. Clinical Pharmacology [database online]. Elsevier, Inc. Updated periodically. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed October 21, 2025.
2. Dailymed. Bethesda, MD: U.S. National Library of Medicine, National Institutes of Health, Health & Human Services, 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>. Accessed October 21, 2025.
3. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. *J Am Coll Cardiol* 2016;68:92–125.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: removed the following as EST is no longer required: lodoxamide, mesalamine, nedocomil; for Zetia and Vytorin clarified required step through agent should be a generic statin and removed pitavastatin and niacin-simvastatin as these are not available generically; for Aromasin requests, added allowance for bypassing redirection if state regulations do not allow step therapy in Stage IV or metastatic cancer settings with additional details in appendix D; per November SDC added Soliqua to policy requiring step through a basal insulin or a preferred GLP-1 receptor agonist; references reviewed and updated.	10.20.21	02.22
Template changes applied to other diagnoses/indications and continued therapy section.	10.10.22	
1Q 2023 annual review: no significant changes; added Temixys to policy with similar step requirements as Cimduo; references reviewed and updated.	10.27.22	02.23
Per February SDC, removed Soliqua as EST is no longer required.	02.21.23	05.23
1Q 2024 annual review: no significant changes; removed Temixys as product is discontinued; for exemestane added letrozole as an example of a PDL aromatase inhibitor; references reviewed and updated.	10.24.23	02.24
Removed Ohio from Appendix D as this only applies to Commercial and HIM requests.	06.06.24	
1Q 2025 annual review: no significant changes; references reviewed and updated.	10.22.24	02.25
1Q 2026 annual review: added levalbuterol nebulized solution, alogliptin-containing products, ascorbic acid, atazanavir, bimatoprost ophthalmic solution, travoprost ophthalmic solution, clonidine, darunavir, desvenlafaxine, dextlansoprazole, galantamine extended release, memantine extended release, nebivolol, oxycodone oral solution, paroxetine oral suspension,	10.21.25	02.26

Reviews, Revisions, and Approvals	Date	P&T Approval Date
silodosin, Spinosad, tinidazole, tipranavir, trospium, and zolpidem extended release to criteria; references reviewed and updated.		

**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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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