Clinical Policy: Step Therapy

Reference Number: CP.PST.01
Effective Date: 12.28.17
Last Review Date: 02.22
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® 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 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)
amlodipine/olmesartan (Azor®)	Losartan or irbesartan	10/40 mg daily (1 tablet/day)
amlodipine/valsartan (Exforge®)	Losartan or irbesartan	10/320 mg daily (1 tablet/day)
amlodipine/valsartan/ HCTZ (Exforge HCT®)	Losartan or irbesartan	10/320/25 mg daily (1 tablet/day)
exemestane (Aromasin®)	One PDL aromatase inhibitor (e.g., anastrozole), unless request is for Stage IV or metastatic cancer for a State with regulations against step therapy in	25 mg/day (1 tablet/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
	advanced oncology settings *(see Appendix D)*	
ezetimibe (Zetia®)	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)
ezetimibe/simvastatin (Vytorin®)	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
HCTZ/olmesartan (Benicar HCT®)	Losartan or irbesartan	40/25 mg daily (1 tablet/day)
lamivudine/tenofovir disoproxil fumarate (Cimduo™)	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

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
		28 kg to < 35 kg: 167/250 mg PO QD
lamotrigine (Lamictal® XR™)	Lamotrigine IR	Varies
levetiracetam (Keppra XR™)	Levetiracetam IR	3000 mg daily (4 tablet/day)
olmesartan (Benicar®)	Losartan or irbesartan	40 mg daily (1 tablet/day)
olmesartan/amlodipine/ HCTZ (Tribenzor®)	Losartan or irbesartan	40/10/25 mg daily (1 tablet/day)
rosuvastatin (Crestor®)	Atorvastatin or simvastatin	40 mg/day (1 tablet/day)
atomoxetine (Strattera®)	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
Soliqua (lixisenatide/ insulin glargine)	Basal insulin or a preferred GLP-1 receptor agonist	60 units insulin/20 mcg lixisenatide/ 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 for HIV infection and has received this medication for at least 30 days;
2. Dose does not exceeded 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	For stage 4 advanced, metastatic cancer or associated conditions. 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
OH	Yes	**Applies to Commercial and HIM requests only** For stage 4 metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes	For advanced metastatic cancer and associated conditions
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
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
Atomoxetine (Strattera)	Capsules: 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg, 100 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
lamivudine/tenofovir disoproxil fumarate (Cimduo)	Tablets: 300 mg lamivudine/ 300 mg tenofovir disoproxil fumarate

Drug Name	Availability
lamotrigine (Lamictal XR)	Extended-release tablets: 25 mg, 50 mg, 100 mg, 200 mg, 250 mg, 300 mg
levetiracetam (Keppra XR)	Film-coated extended-release tablets: 500 mg, 750 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
rosuvastatin (Crestor)	Tablets: 5 mg, 10 mg, 20 mg, 40 mg
Soliqua (lixisenatide/ insulin glargine)	Single-patient use pen: 33 mcg/100 units per mL in 3 mL

VI. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology.com. Accessed October 20, 2021.
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 20, 2021.
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
Policy created	12.28.17	05.18
3Q 2018 annual review: CP.PST.03 added; references reviewed and updated.	04.11.18	08.18
4Q 2018 annual review: CP.PST.05 added; references reviewed and updated.	07.26.18	11.18
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.	10.17.18	
Changes align with previously approved clinical guidance: added Steglatro and Segluromet per SDC decision.	10.17.18	
1Q 2019 annual review: CP.PST.08 added; modified minimum A1c related to concurrent use of metformin from 9% to 8.5% based on 2019 ADA guidelines; references reviewed and updated.	10.30.18	02.19
Changes align with previously approved clinical guidance: added Symtuza to policy requiring step through Symfi if member is treatment naïve per SDC.	12.18.18	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	
Changes align with previously approved clinical guidance: added Zetia and Vytorin to policy requiring step through generic statin or previous treatment with ezetimibe; archived CP.PMN.77 Vytorin and CP.PMN.78 Zetia policies.	03.04.19	
Added disclaimer statement that policy does not apply to NF drugs.	05.21.19	
1Q 2020 annual review: Changes align with previously approved clinical guidance and SDC decision: added Dulera, Symbicort, and Breo Ellipta to policy requiring step through fluticasone/salmeterol (generic Advair).	01.03.20	02.20
Per February SDC and prior clinical guidance for Dulera and Breo Ellipta: added additional step through option of budesonide/formoterol (generic Symbicort); removed Symbicort stepping through generic Advair; and retire CP.PMN.228.	03.26.20	
Added Cimduo requiring use of Truvada for treatment naïve members per April SDC and prior clinical guidance.	04.27.20	
Removed Atripla per November SDC and prior clinical guidance	11.16.20	
Removed Steglatro and Segluromet per December SDC and prior clinical guidance.	12.15.20	
1Q 2020 annual review: Added Strattera requiring step through of one amphetamine-containing product and one methylphenidate-containing product (retire CP.PST.17); removed step through requirements for Breo Ellipta and Dulera (both added to the new asthma/COPD class policy).	10.26.20	02.21
Per June SDC and prior clinical guidance, removed Symtuza, Complera, Delstrigo, and Odefsey from policy.	06.02.21	08.21
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	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.