

Clinical Policy: Step Therapy

Reference Number: CP.PST.01

Effective Date: 12.28.17

Last Review Date: 11.18

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.

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)
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)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
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)
Ertugliflozin (Steglatro [™])	90 days of metformin in the last 365 days or if current (within the last 3 months) HbA1c is $\geq 9\%$	15 mg/day (1 tablet/day)
Ertugliflozin/metformin (Segluromet [™])	90 days of metformin in the last 365 days or if current (within the last 3 months) HbA1c is $\geq 9\%$	15/2000 mg daily (2 tablets/day)
Exemestane (Aromasin)	One PDL aromatase inhibitor (e.g., anastrozole)	25 mg/day (1 tablet/day)
HCTZ/olmesartan (Benicar HCT [®])	Losartan or irbesartan	40/25 mg daily (1 tablet/day)
Lamotrigine (Lamictal [®] XR [™])	Lamotrigine IR	Varies
Levetiracetam (Keppra XR [™])	Levetiracetam IR	3000 mg daily (4 tablet/day)
Lodoxamide (Alomide)	Two PDL anti-allergy ophthalmic agents	8 drops/eye/day
Nedocromil (Alocril)	Two PDL anti-allergy ophthalmic agents	8 drops/eye/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)

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, Odefsey, or Complera 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

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 above.

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
(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
(Olmesartan) Benicar	Tablets: 5 mg, 20 mg, 40 mg
(Olmesartan/HCTZ) Benicar HCT	Tablets: 20/12.5 mg; 40/12.5 mg, 40/25 mg
(Amlodipine/olmesartan) Azor	Tablets 5/20 mg, 10/20 mg, 5/40 mg, 10/40 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
(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
Rosuvastatin (Crestor)	Tablets: 5 mg, 10 mg, 20 mg, 40 mg
Lodoxamide (Alomide)	0.1% ophthalmic solution: 10 mL
Nedocromil (Alocril)	2% ophthalmic solution: 5 mL, 10 mL
Exemestane (Aromasin)	Tablets: 25 mg
(Ertugliflozin/metformin) Segluromet	Tablets: 2.5/500 mg, 2.5/1000 mg, 7.5/500 mg, 7.5/1000 mg
(Ertugliflozin) Steglatro	Tablets: 5 mg, 15 mg

Drug Name	Availability
(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

VI. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: <http://www.clinicalpharmacology.com>. Accessed April 11, 2018.
2. Dailymed. Bethesda, MD: U.S. National Library of Medicine, National Institutes of Health, Health & Human Services, 2018. Available at: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>. Accessed April 11, 2018.
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.
4. Exemestane. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed July 26, 2018.
5. Segluromet Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; December 2017. Available at www.segluromet.com. Accessed August 27, 2018.
6. Steglatro Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; December 2017. Available at www.steglatro.com. Accessed August 27, 2018.

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	

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.

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