Clinical Policy: Step Therapy

Reference Number: CP.PST.01
Effective Date: 12.28.17
Last Review Date: 02.19
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)
darunavir, cobicistat, emtricitabine, tenofovir alafenamide (Symtuza™)	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)
doravirine, lamivudine, tenofovir disoproxil fumarate (Delstrigo™)	If treatment naïve: Symfi or Symfi Lo (efavirenz/	100/300/300 mg daily (1 tablet/day)

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
	lamivudine/tenofovir disoproxil fumarate) If treatment experienced: any HIV antiretroviral agent	
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)
ertugliflozin (Steglatro™)	90 days of metformin in the last 365 days or if current (within the last 3 months) HbA1c is ≥ 8.5%	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 ≥ 8.5%	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

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
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)
mesalamine (Apriso™, Asacol® HD, Lialda®, Pentasa®, and Delzicol®)	Generic preferred 5-aminosalicylate (e.g., mesalamine, sulfasalazine, balsalazide)	Varies

Drug names 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, Complera, Delstrigo, Odefsey, or Symtuza 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(s) 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
darunavir, cobicistat, emtricitabine, tenofovir alafenamide (Symtuza)	Tablets: 800/150/200/10 mg
doravirine, lamivudine, tenofovir disoproxil fumarate (Delstrigo)	Tablets: 100/300/300 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
Mesalamine (Apriso)	Extended-release (24 hr) capsules: 0.375 g
Mesalamine (Asacol HD)	Delayed-release tablets: 800 mg
Mesalamine (Delzicol)	Delayed-release capsules: 400 mg
Mesalamine (Lialda)	Delayed-release tablets: 1.2 g
Mesalamine (Pentasa)	Extended-release capsules: 250 mg, 500 mg

VI. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology.com. Accessed October 30, 2018.
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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	
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	
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	

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.

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.