Clinical Policy: Step Therapy

Reference Number: CP.PST.01
Effective Date: 12.28.17
Last Review Date: 08.18
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/valsartan (Exforge®)	Losartan or irbesartan	10/320mg daily (1 tablet/day)
Amlodipine/valsartan/ HCTZ (Exforge HCT®)	Losartan or irbesartan	10/320/25 mg daily (1 tablet/day)
Olmesartan (Benicar®)	Losartan or irbesartan	40mg daily (1 tablet/day)
HCTZ/olmesartan (Benicar HCT®)	Losartan or irbesartan	40/25mg daily (1 tablet/day)
Amlodipine/olmesartan (Azor®)	Losartan or irbesartan	10/40mg daily (1 tablet/day)
Olmesartan/amlodipine/ HCTZ (Tribenzor®)	Losartan or irbesartan	40/10/25mg daily (1 tablet/day)
Lamotrigine (Lamictal® XR™)	Lamotrigine IR	Varies

Drug Name	Required Step-Through Agents	Maximum Dose (Quantity Limit)
Levetiracetam (Keppra XR™)	Levetiracetam IR	3000mg daily (4 tablet/day)
Rosuvastatin (Crestor®)	Atorvastatin or simvastatin	40 mg/day (1 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

Approval duration: Length of Benefit

II. Continued Therapy

A. Step Therapy (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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

HCTZ: hydrochlorothiazide
FDA: Food and Drug Administration
IR: immediate release
PDL: preferred drug list

Appendix B: Therapeutic Alternatives

Refer to required step-through drug above.

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

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
Rosuvastatin (Crestor)	Tablets: 5 mg, 10 mg, 20 mg, and 40 mg
Lodoxamide (Alomide)	0.1% ophthalmic solution: 10 mL
Nedocromil (Alocril)	2% ophthalmic solution: 5 mL, 10 mL

VI. Workflow Document

Not applicable

VII. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: 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.

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

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.