Clinical Policy: Step Therapy Criteria
Reference Number: HIM.PA.109
Effective Date: 08/17
Last Review Date:
Line of Business: Health Insurance Marketplace Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
This is a general criteria for approval of drugs that require step therapy. The Centene system is programmed to allow for claim processing of step therapy drugs if there are claims in the claim history for drugs that satisfy the step therapy criteria. This policy is applicable in cases where there is a request for step therapy medication that does not satisfy requirements of automated step therapy process.

FDA approved indication
N/A

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Request for Step Therapy Medication (must meet all)**:**

1. Failure of at least two* formulary agents within the same therapeutic class or formulary drugs that are recognized as standards of care for the treatment of the same diagnosis, each trialed for at least 30 days, unless all are contraindicated or clinically significant adverse effects are experienced;
2. Dose does not exceed the FDA approved maximum recommended dose.

Approval duration: 12 months or the requested length of therapy, whichever is less

* *Provided two agents exist in the therapeutic category with comparable labeled indications. Note that many formulary positioned drugs are considered first-line standards of care by governing specialty organizations and recognized under their treatment guidelines for certain conditions, even in the absence of FDA approved labeling.*

II. Continued Therapy

A. Request for Step Therapy Medication (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose.

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. N/A

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
N/A: not applicable

V. References

1. N/A

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created. Converted to new template; added max dose.	06/17	08/17

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.