

Clinical Policy: Medication Safety Policy

Reference Number: GA.PMN.22

Effective Date: 07/01/17

Last Review Date: 7/2024

Line of Business: HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene[®] medical policy in conjunction with FDA prescribing criteria for all medications.

FDA Approved Indication(s)

Not applicable.

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 medications are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Medication Safety (must meet all):

1. Member meets initial criteria for existing policy for requested drug, if one is available;
2. Diagnosis of a current FDA approved indication as described in FDA prescribing information for requested drug;
3. Member's age is FDA appropriate or adequately studied in member's age population as indicated in FDA prescribing information for requested drug;
4. Member does not currently have any contraindications or concomitant use of any drugs that are recommended to be avoided as listed in FDA prescribing information for requested drug;
5. Member does not have any reasons to discontinue therapy as listed in FDA prescribing information for requested drug;
6. Required or recommended lab monitoring or diagnostic testing as indicated per FDA prescribing information or standard of care guidelines for requested drug or condition has been provided at least within the last 6 months.

Approval duration: follow respective policy for the requested drug

B. Other diagnoses/indications

Not applicable.

II. Continued Therapy

A. Medication Safety (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Currently meets continuation criteria for existing policy for requested drug, if one is available;
3. Member is responding positively to therapy as evidenced by medical records or prior authorization form document;
4. Prescription claims and/or medical records document adherence to therapy.

Approval duration: follow respective policy for the requested drug

B. Other diagnoses/indications:

Not applicable

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

Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: General Information

Medication and prescribing safety should be the utmost of importance to pharmacist and prescribers as appropriate prescribing and dispensing can reduce medication errors. Medication errors have received much attention over the years in efforts of pharmacist and prescribers targeting ways to prevent them. Preventing medication errors can potentially reduce mortality, morbidity, and healthcare cost. Pharmacist that are positioned to oversee the quality of drug prescribing, dispensing, and administration are in optimal positions and can play a vital role in improving medication safety. Pharmacist are commonly now involved in prescribing practices or choice of pharmacotherapy; determining the right drug for the right patient at appropriate doses as determined by evidence base medicine and FDA recommendations with the help of patient specific factors. The FDA also play a key role in promoting medication safety through ensuring drugs are safe and effective in given populations. The FDA accomplished this through evaluation of drug metabolism, drug action, drug interactions, and safety in different ages, genders, and races. With the help of evidence based guidelines and FDA guidance all practitioners can promote medication safety.

V. Dosage and Administration

Refer to the respective policies and package inserts for dosage and administration.

VI. Product Availability

Refer to the respective policies and package inserts for product availability.

VII. References

1. Guchelaar H. J, Colen H. B, Kalmeijer M. D, Hudson P. T, Teepe-Twiss I. M. Medication errors. *Drugs*. 2005;65(13):1735–1746.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.01.17	07.17
4Q 2017 annual review: Updated initial criteria to include language regarding need of standard of care lab or diagnostic testing. Added to initial criteria drugs that member may need to avoid concomitant use with requested drug per prescribing information	10.01.17	10.17
3Q 2018 annual review: no significant changes	07.01.18	07.18
Changed current Georgia policy templates to corporate standard templates for drug coverage criteria to meet corporate compliance. Changes/revisions included; new formatting, font size, use of standard policy language for each section of policy, and rearranged order of certain steps in criteria and sections.	2/19	2/19
Annual review. No changes made.	7/19	7/19
Annual review. No changes made.	7/2020	7/2020
Annual review. No changes made.	7/2021	7/2021
3Q 2022 annual review. No changes made.	7/2022	7/2022
3Q 2023 annual review. No changes made.	7/2023	7/2023
3Q 2024 annual review. No changes made.	7/2024	7/2024

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.

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