

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	DOCUMENT NAME: Medication Safety Policy
PAGE: 1 of 5	REFERENCE NUMBER: GA.PMN.22
EFFECTIVE DATE: 7/2017	REPLACES DOCUMENT:
RETIRED:	REVIEWED: 7/2017, 4/2018
PRODUCT TYPE: Medicaid, Ambetter	REVISED: 4/2018

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

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.

Generic: Any applicable drugs. Generic medications preferred

Policy Indication: Based on current Food and Drug Administration (FDA) approved labeling.

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Criteria for Approval :

Initiation of therapy (must meet all)

- A. Member meet initial criteria for existing policy for requested drug, if one is available.
- B. Medical records and lab to support diagnosis and requested drug or submitted
- C. Diagnosis of a current FDA approved indication as described in FDA prescribing information or recommended guidelines for requested drug.
- D. Guidelines or standard of care treatment regimens are being used in conjunction with requested drug if available
- E. Appropriate guideline and/ or standard care treatment options have been tried and failed for appropriate or recommended length of therapy unless intolerant or contraindicated
- F. FDA recommended or guideline/standard of care dosing and duration of therapy is requested
- G. Member's age is FDA appropriate or adequately studied in member's age population as indicated in FDA prescribing information for requested drug.
- H. 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.

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- I. Member does not have any reasons to discontinue therapy as listed in FDA prescribing information for requested drug.
- J. 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 :

Continuation of therapy (must meet all)

- A. Currently receiving medication via Centene benefit or member has previously and continues to meet all initial approval criteria.
- B. Currently meets continuation criteria for existing policy for requested drug, if one is available.
- C. Medical records documenting a positive response and adherence to therapy since last approval.
- D. Prescription claims and/or medical records document adherence to therapy.

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Background 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.

Rerereencea: Guchelaar H. J, Colen H. B, Kahneijer M. D, Hudson P. T, Teepe-Twiss I. M. Medication errors. *Drugs*. 2005;65(13):1735-1746.
 Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines; Graham R, Mancher M, Miller Wolman D, et al., editors. Washington (DC): National Academies Press(US); 2011.
 Shekelle, P., Aronson, M.D., Melin, J.A. Overview of clinical practice guidelines. *UpToDate*. 2017; {9-5-2017. Ref Type:Online Source).

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Reviews, Revisions and Approvals	Date
New policy created	07/2017
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.	10/2017
Added new criteria for need for medical records and labs to support diagnostic testing, FDA guidelines/standard of care treatment regimen necessity, necessity of prior drug trial and failure including length of therapy, and need for standard of care dosing and duration. Updated continuation to require all necessary medical records for approval. Added new references.	04/2018

POLICY & PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee:	Approval on file
Director, Pharmacy Operations:	Approval on file
Medical Director:	Approval on file