Clinical Policy: Age Limit Override

Reference Number: HIM.PA.177
Effective Date: 01.01.26
Last Review Date: 12.25
Line of Business: HIM

Revision Log

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

Description

This policy applies to formulary* drugs with health plan-approved age limits (AL) that was exceeded and the drug does not require prior authorization (PA). Examples of such agents include: tretinoin cream and gel (e.g., Retin-A®), benzoyl peroxide, methylphenidate, aripiprazole, quetiapine, sumatriptan, rizatriptan, zolmitriptan.

** All requests for non-formulary drugs should be reviewed against HIM.PA.103 Brand Name Override and Non-Formulary Medications*

FDA Approved Indication(s)

Varies by drug product.

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 formulary drugs with age limits are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Age Limit Override (must meet all)**:**

1. Request is for a formulary drug;*
   ** All requests for non-formulary drugs should be reviewed against HIM.PA.103 Brand Name Override and Non-Formulary Medications*
2. Request is for a drug other than aspirin;*
   ** Aspirin is approvable only for members 45 to 79 years of age*
3. Member's age exceeds the health plan-approved age limit;
4. One of the following (a or b):
   a. Prescribed indication is FDA-approved;
   b. Prescribed indication is off-label and use is supported by one of the following (i, ii, iii, or iv):
      i. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B (*see Appendix D*);
      ii. Evidence from at least two high-quality, published studies in reputable peer-reviewed journals or evidence-based clinical practice guidelines that provide all of the following (1 – 4):
         1) Adequate representation of the member's clinical characteristics, age, and diagnosis;

2) Adequate representation of the prescribed drug regimen;
3) Clinically meaningful outcomes as a result of the drug therapy in question;
4) Appropriate experimental design and method to address research questions (*see Appendix F for additional information*);

iii. Micromedex DrugDex® with strength of recommendation Class I or IIa (*see Appendix D*);
iv. For state(s) with state-specific regulations for supportive evidence for requests in pediatrics where member's age is beyond the FDA labeled indication and prescribing information, refer to *Appendix G* for supportive references by State;

5. Request is not for a benefit-excluded use (e.g., cosmetic);
6. Requested dose does not exceed health plan-approved quantity limit;*
   ** Requests exceeding the health plan-approved quantity limit should also be reviewed against CP.PMN.59 Quantity Limit Override and Dose Optimization*
7. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication

Approval duration: 12 months

II. Continued Therapy

A. Age Limit Override (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. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Requested dose does not exceed health plan-approved quantity limit;
4. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

Approval duration: 12 months

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

Not applicable.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
AL: age limit
FDA: Food and Drug Administration
PA: prior authorization

Appendix B: Therapeutic Alternatives
Varies by drug product

Appendix C: Contraindications/Boxed Warnings
Varies by drug product

V. Dosage and Administration
Varies by drug product

VI. Product Availability
Varies by drug product

VII. References
1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed March 11, 2025.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed March 11, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.17.25	12.25

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.