Clinical Policy: Age Limit Override

Reference Number: HIM.PA.177
Effective Date: 01.01.26
Last Review Date: 11.26
Line of Business: HIM/ICHRA

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 have been exceeded and do not require prior authorization (PA). Examples of such agents include, but may not be limited to, tretinoin cream and gel (e.g., Retin-A®), benzoyl peroxide, methylphenidate, aripiprazole, quetiapine, sumatriptan, rizatriptan, and 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 AL overrides for formulary drugs 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 AL;
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 E 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 F* for supportive references by State;

5. Request is not for a benefit-excluded use (e.g., cosmetic);
6. Request does not exceed health plan-approved quantity limit, if applicable;*
   ** 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. Request does not exceed health plan-approved quantity limit, if applicable;*
   ** Requests exceeding the health plan-approved quantity limit should also be reviewed against CP.PMN.59 Quantity Limit Override and Dose Optimization*
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
NCCN: National Comprehensive Cancer Network
PA: prior authorization

Appendix B: Therapeutic Alternatives

Varies by drug product

Appendix C: Contraindications/Boxed Warnings

Varies by drug product

Appendix D: General Information

- The U.S. FDA approves drugs for specific indications included in the drug's product information label. The approval by the FDA means that the company can include the information in their package insert. Omission of uses for a specific age group or a specific disorder from the approved label means that the evidence required by law to allow their inclusion in the label has not been submitted to the FDA. Off-label, or "unlabeled," drug use is the utilization of an FDA-approved drug for indications, treatment regimens, or populations other than those listed in the FDA-approved labeling. Many off-label uses are effective and well-documented in the peer-reviewed literature, and they are widely used even though the manufacturer has not pursued the additional indications. Refer to the drug's FDA-approved indication(s) and labeling (varies among drug products).
- NCCN Categories of Evidence and Consensus:
  - Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
  - Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
  - Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
  - Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.
- Micromedex DrugDex Strength of Evidence, Strength of Recommendation, and Efficacy Definitions (Tables 1, 2, and 3):

Table 1. Strength of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminate	Evidence Inconclusive	Not applicable

Table 2. Strength of Evidence	
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard

Table 2. Strength of Evidence	
	to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies)
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports, or case series
No Evidence	Not applicable

Table 3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.

Appendix E: Appropriate Experimental Design Methods

- Randomized, controlled trials are generally considered the gold standard; however:
  - In some clinical studies, it may be unnecessary or not feasible to use randomization, double-blind trials, placebos, or crossover.
  - Non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- Case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Appendix F: Supportive References by State in Pediatrics Where Request is for a Member with Age Beyond the FDA Labeled Indication and Prescribing Information

State	Supportive References
LA	The drug has been recognized for the treatment of the disease or condition in pediatric application by one of the following: • The American Medical Association Drug Evaluations • The American Hospital Formulary Service (AHFS) Drug Information • The United States Pharmacopeia Dispensing Information, Volume 1, "Drug Information for the Health Care Professional" • Recognized in two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe

State	Supportive References
	and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed journal

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.; 2026. Available at: https://www.clinicalkey.com/pharmacology/. Accessed July 29, 2026.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 29, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.17.25	12.25
4Q 2026 annual review: no significant changes; added Appendices D, E, and F in support of existing criteria; added ICHRA line of business; references reviewed and updated.	07.29.26	11.26

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.

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