# Clinical Policy: Early and Periodic Screening, Diagnostic, and Treatment Benefit for Pediatric Members

Reference Number: CP.PMN.234
Effective Date: 06.01.20
Last Review Date: 05.25
Line of Business: Medicaid

Revision Log

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

## Description

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) is the Medicaid program's benefit for low-income infants, children, and adolescents, which provides a comprehensive array of prevention, diagnostic, and treatment services as specified in Section 1905(r) of the Social Security Act. The EPSDT benefit is more robust than the Medicaid benefit for adults and is designed to assure that children receive early detection and care, so that health problems are averted or diagnosed and treated as early as possible.

This prior authorization policy provides coverage guidelines for medication requests through the EPSDT benefit and should be used in conjunction with the drug-specific or general medical necessity policy.*

**When available, drug-specific policies supersede general medical necessity policies. If no drug-specific policies exist for the requested agent, refer to CP.PMN.53 for formulary agents and CP.PMN.16 for non-formulary agents.*

## FDA Approved Indication(s)

Refer to the prescribing information for the requested agent.

## 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 the requested agent is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Medication Request Through EPSDT Benefit** (must meet all)**:**

1. Age < 21 years or the state-specific maximum age for coverage under the EPSDT benefit, whichever is lower;
2. Member meets one of the following (a or b):
   a. The initial approval criteria in the drug-specific or general medical necessity policy are met;
   *When available, drug-specific policies supersede general medical necessity policies. If no drug-specific policies exist for the requested agent, refer to CP.PMN.53 for formulary agents and CP.PMN.16 for non-formulary agents*

b. All of the following (i, ii, and iii):
   i. The requested agent fits within any of the following categories of Medicaid-covered services listed in Section 1905(a) and/or 1905(r) of the Social Security Act:
      1) Immunization in accordance with the schedule for pediatric vaccines established by the Advisory Committee on Immunization Practices;
      2) Dental care needed for relief of pain, infection, restoration of teeth, or maintenance of dental health;
      3) Emergency, preventive, or therapeutic treatment for dental disease that, if left untreated, may become acute dental problems or cause irreversible damage to the teeth or supporting structures;
      4) Treatment for defects in vision;
      5) Treatment for defects in hearing;
      6) Treatment for tobacco cessation for a pregnant woman;
         *Requested agent must be recommended for pregnant women by the Public Health Service guidelines on treating tobacco use or recognized as effective by the Secretary of Health and Human Services*
      7) Preventive treatment assigned a grade of A or B by the United States Preventive Services Task Force: https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P&grades%5B%5D=A&grades%5B%5D=B;
      8) Treatment of a mental health or substance use condition, including medication-assisted treatment for opioid-use disorders;
      9) Primary or secondary treatment for sickle cell disease in members who have had a stroke or are at high risk of stroke, including deferoxamine chelation in members receiving chronic blood transfusions;
      10) Medically necessary treatment* to correct or ameliorate the member's physical or mental condition (provider must submit supporting documentation – *see Appendix E*);
         **Benefit exclusions do not apply; evaluation for EPSDT should be based solely on medical necessity, unless the requested drug is not part of the Medicaid Drug Rebate Program (MDRP) (see Appendix D)*
   ii. Failure of formulary alternatives if required in the drug-specific or general medical necessity policy, unless clinically significant adverse effects are experienced, all are contraindicated, or none are available;
      *When available, drug-specific policies supersede general medical necessity policies. If no drug-specific policies exist for the requested agent, refer to CP.PMN.53 for formulary agents and CP.PMN.16 for non-formulary agents*
   iii. The requested agent and prescribed dose are not considered experimental or investigational for the member's diagnosis and age.

**Approval duration: Duration allowed in the drug-specific or general medical necessity policy or 6 months**

## II. Continued Therapy

### A. Medication Request Through EPSDT Benefit (must meet all):

1. Member meets one of the following (a, b, or c):
   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);*
c. The continued therapy criteria in the drug-specific or general medical necessity policy are met;
*When available, drug-specific policies supersede general medical necessity policies. If no drug-specific policies exist for the requested agent, refer to CP.PMN.53 for formulary agents and CP.PMN.16 for non-formulary agents*

2. Member is responding positively to therapy;
3. If request is for a dose increase, the prescribed dose is not considered experimental or investigational for the member's diagnosis and age.

**Approval duration: Duration allowed in the drug-specific or general medical necessity policy or 12 months**

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

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
EPSDT: early and periodic screening, diagnostic and treatment
FDA: Food and Drug Administration
MDRP: Medicaid Drug Rebate Program

*Appendix B: Therapeutic Alternatives*
Refer to the drug-specific or general medical necessity policy.*

**When available, drug-specific policies supersede general medical necessity policies. If no drug-specific policies exist for the requested agent, refer to CP.PMN.53 for formulary agents and CP.PMN.16 for non-formulary agents.*

*Appendix C: Contraindications/Boxed Warnings*
Refer to the prescribing information for the requested agent.

*Appendix D: General Information*
- Medicaid EPSDT website: https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html
- Age for EPSDT benefit eligibility: under the age of 21, or, at the option of the state, under the age of 20, 19, or 18 as the state may choose.[1]
- EPSDT benefit coverage under Section 1905(r)(5) of the Social Security Act includes "Such other necessary health care, diagnostic services, treatment, and other measures described in Section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan."[1]
  - A service need not cure a condition in order to be covered under EPSDT.[2]
  - Services that maintain or improve the child's current health condition are also covered in EPSDT because they "ameliorate" a condition. Maintenance services are defined as services that sustain or support rather than those that cure or improve

health problems. Services are covered when they prevent a condition from worsening or prevent development of additional health problems.[2]

- A state may consider the relative cost effectiveness of alternatives as part of the prior authorization process. States may cover services in the most cost effective mode as long as the less expensive service is equally effective and actually available.[2]
- EPSDT does not require coverage of treatments that are experimental or investigational. Neither the Federal Medicaid statute nor the regulations define what constitutes an experimental treatment. The state's determination of whether a service is experimental must be reasonable and should be based on the latest scientific information available. Medicare guidance on whether a service is experimental or investigational is not determinative of the issue and may not be relevant to the pediatric population.[2]
- If the requested service or product is not covered by the member's plan (i.e., excluded use), evaluation for EPSDT should be based solely on medical necessity, rather than benefit eligibility as a non-excluded use, unless the requested drug is not part of the MDRP. A drug and its intended use may be considered medically necessary and approvable under EPSDT while being an excluded use under the member's plan as long as it is part of the MDRP.
    - MDRP is a program authorized by Section 1927 of the Social Security Act that helps offset the Federal and state costs of outpatient prescription drugs dispensed to Medicaid patients. To have their drugs covered under Medicaid, drug manufacturers are required to enter into 3 agreements: 1) a National Drug Rebate Agreement with the Secretary of the Department of Health and Human Services, 2) a pricing agreement for the Section 340B Drug Pricing Program administered by the Health Resources and Services Administration, and 3) a master agreement with the Secretary of Veterans Affairs for the Federal Supply Schedule.
    - Additional information on MDRP can be found on the following website: https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program

*Appendix E: Supporting Documentation Required to Support Medical Necessity*

- Request is considered medical necessary if use is supported by one of the following (a, b, or c):
    a. The National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium level of evidence 1, 2A, or 2B (*see Appendix G*);
    b. 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 (i – iv):
        i. Adequate representation of the member's clinical characteristics, age, and diagnosis;
        ii. Adequate representation of the prescribed drug regimen;
        iii. Clinically meaningful outcomes as a result of the drug therapy in question;
        iv. Appropriate experimental design and method to address research questions (*see Appendix F for additional information*);
    c. Micromedex DrugDex® with strength of recommendation Class I or IIa (*see Appendix G*).

*Appendix F: 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 G: Evidence Categories*

- 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 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, |

| Table 2. Strength of Evidence | |
|---|---|
| | 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. |

## V. Dosage and Administration

Refer to the prescribing information for the requested agent.

## VI. Product Availability

Refer to the prescribing information for the requested agent.

## VII. References

1. Social Security Act, Section 1905. Available at: https://www.ssa.gov/OP_Home/ssact/title19/1905.htm. Accessed January 29, 2025.
2. EPSDT Coverage Guide. Published June 2014. Available at: https://www.medicaid.gov/sites/default/files/2019-12/epsdt_coverage_guide.pdf. Accessed January 28, 2025.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2021 annual review: no significant changes; references reviewed and updated. | 01.15.21 | 05.21 |
| 2Q 2022 annual review: no significant changes; added legacy WellCare line of business (WCG.CP.PMN.234 to be retired) with initial approval duration consolidated to 6 months; references reviewed and updated. | 01.24.22 | 05.22 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Updated link to United States Preventive Services Task Force preventive treatment recommendations. Template changes applied to continued therapy section. | 08.22.22 | |
| 2Q 2023 annual review: no significant changes; references reviewed and updated. | 01.23.23 | 05.23 |
| For determination of medical necessity, added Appendix E to describe supporting documentation required to support medical necessity (adapted from CP.PMN.53 Off-Label Use criteria), added to Appendix D clarification that plan specific benefit excluded uses do not apply. | 09.19.23 | 11.23 |
| 2Q 2024 annual review: no significant changes; references reviewed and updated. | 02.06.24 | 05.24 |
| 2Q 2025 annual review: no significant changes; references reviewed and updated.<br>Per Compliance, revised footnote for medically necessary treatment that "Benefit exclusions do not apply; evaluation for EPSDT should be based solely on medical necessity" to include "unless the requested drug is not part of the MDRP", with additional information included in Appendix D. | 04.10.25 | 05.25 |

**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.

**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.