Clinical Policy: CNS Stimulants

Reference Number: DE.PMN.92
Effective Date: 01.23
Last Review Date: 01.23
Line of Business: Medicaid

Revision Log

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

Description

The following are central nervous system (CNS) stimulants requiring prior authorization: methylphenidate transdermal system (Daytrana®), methylphenidate extended-release chewable tablets (Quillichew ER®), methylphenidate extended-release oral suspension (Quillivant XR®), and amphetamine extended-release oral suspension (Dyanavel XR®).

FDA Approved Indication(s)

Extended-release methylphenidate and amphetamine products are indicated for attention-deficit/hyperactivity disorder (ADHD).

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 Daytrana, Dyanavel XR, Quillichew ER, and Quillivant XR are medically **necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**

1. Diagnosis of ADHD;
2. Member is > 21 years of age;
3. Member has tried and failed behavioral modification techniques;
4. If member is taking a benzodiazepine, prescriber attests to understanding the risks associated with concomitant use with stimulants;
5. Dose does not exceed the following:
   a. Daytrana: 30 mg per day (1 patch per day);
   b. Dyanavel XR: 20 mg per day;
   c. Quillichew ER, Quillivant XR: 60 mg per day (1 tablet or capsule per day).

Approval duration:
Medicaid: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53

II. Continued Therapy

A. Attention Deficit Hyperactivity Disorder (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the following:
   a. Daytrana: 30 mg per day (1 patch per day);
   b. Dyanavel XR: 20 mg per day;
   c. Quillichew ER, Quillivant XR: 60 mg per day (1 tablet or capsule per day).

Approval duration:
Medicaid: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53

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

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ADHD: attention-deficit and hyperactivity disorder
CNS: central nervous system
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
methylphenidate extended release (Ritalin LA®, Concerta®, Metadate CD®)	Concerta: 18 - 36 mg PO QD Ritalin LA, Metadate CD: 20 mg PO QD	Concerta: 72 mg/day Ritalin LA, Metadate CD: 60 mg/day
amphetamine (Adderall XR®)	Patients 6-17 years: 10 mg PO QD Adults: 20 mg PO QD	30 mg/day
dextroamphetamine (Dexedrine SR®)	5 mg PO QD/BID	60 mg/day
Vyvanse® Capsules (lisdexamfetamine)	30 mg PO QD	70 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity; use with monoamine oxidase (MAO) inhibitor, or within 14 days of last MAO inhibitor dose
  - Daytrana: marked anxiety, tension, or agitation; glaucoma; tics or family history of Tourette's syndrome
- Boxed warning(s): abuse and dependence

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Methylphenidate Transdermal System (Daytrana)	10 mg applied to the hip area (using alternating sites) 2 hours before an effect is needed and should be removed 9 hours after application	30 mg/9-hour patch per day
Dyanavel XR (amphetamine oral suspension/tablet)	2.5 - 5 mg PO QD	20 mg/day
Quillichew ER (methylphenidate chewable tablet)	20 mg PO QD	60 mg/day
Quillivant XR (methylphenidate oral suspension)	20 mg PO QD	60 mg/day

VI. Product Availability

Drug Name	Availability
Methylphenidate Transdermal System (Daytrana)	Transdermal patch: 10 mg/9 hours, 15 mg/9 hours, 20 mg/9 hours, and 30 mg/9 hours
Dyanavel XR (amphetamine)	Extended-release oral suspension: 2.5 mg/mL Extended-release tablets: 5 mg, 10 mg, 15 mg, 20 mg
Quillichew ER (methylphenidate chewable)	Extended-release chewable tablets, scored: 20 mg, 30 mg Extended-release chewable tablets, not scored: 40 mg
Quillivant XR (methylphenidate oral suspension)	Extended-release oral suspension: 25 mg/5 mL (5 mg/mL)

VII. References

1. Daytrana Prescribing Information. Miami, FL: Noven Therapeutics, LLC; June 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021514s032lbl.pdf. Accessed September 27, 2021.
2. Dyanavel XR Prescribing Information. Monmouth Junction, NJ: Tris Pharma: November 2021. Available at: http://dyanavelxr.com/. Accessed December 6, 2021.

3. Quillichew ER Prescribing Information. Monmouth Junction, NJ: Tris Pharma. June 2021. Available at: https://www.quillivantxr-quillichewer.com/. Accessed September 27, 2021.
4. Quillivant XR Prescribing Information. Monmouth Junction, NJ: Tris Pharma; June 2021. Available at: https://www.quillivantxr-quillichewer.com/. Accessed September 27, 2021.
5. American Academy of Child and Adolescent Psychiatry. Practice parameter for the assessment and treatment of children and adolescents with Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry. 2007; 46(7):894-921.
6. Wolraich ML, Hagan JF, Allan C, et al. Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics 2019; 144(4):e20192528.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.22	11.22

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.

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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.