Clinical Policy: Methylphenidate XR and transdermal (Jornay PM and Daytrana)

Reference Number: IL.PMN.92
Effective Date: 1.1.23
Last Review Date: 11.20.23
Line of Business: Medicaid

Revision Log

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

Description
Methylphenidate extended-release (Jornay PM™) and methylphenidate transdermal system (Daytrana®), are central nervous system stimulants.

FDA Approved Indication(s)
Extended-release methylphenidate products are indicated for attention-deficit/hyperactivity disorder (ADHD).

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Jornay PM and Daytrana 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. Age ≥ 6 years;
3. Member meets one of the following (a or b):
   a. Request is Jornay and failure of an adequate trial of at least two preferred* ADHD agents at maximum indicated doses, unless clinically significant adverse effect are experienced or all are contraindicated in the past 18 months.
   b. Request is for Daytrana and documentation supports inability to use dosage forms available on the formulary (e.g., inability to swallow tablets or capsules), or clinically significant adverse effect are experienced with preferred agents;
4. Dose does not exceed the following:
   a. Jornay PM: 100 mg per day
   b. Daytrana (both i and ii):
      i. 30 mg per day;
      ii. 1 patch per day;

Approval duration: 12 months

B. Other diagnoses/indications

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL, refer to the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, refer to the non-formulary policy: CP.PMN.16; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Attention Deficit Hyperactivity Disorder (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. If request is for a dose increase, new dose does not exceed the following:
   a. Jornay PM:100 mg per day
   b. Dyanavel XR (both i and ii):
      i. 20 mg per day;
      ii. 1 tablet per day;

Approval duration:12 months

B. Other diagnoses/indications (must meet 1 and 2)**:**

1.
If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

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

1.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 Policy CP.PMN.53 for Medicaid, or evidence of coverage documents.

III. 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® (lisdexamfetamine)	30 mg PO QAM	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.

AppendixCB. Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to methylphenidate or any component of formulary; use with monoamine oxidase (MAO) inhibitor, or within 14 days of last MAO inhibitor dose
- Boxed warning(s): abuse and dependence

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Methylphenidate ER	Starting dose 20 mg PO QHS, dose may be	100 mg/day
Methylphenidate	10 mg applied to the hip area (using	30 mg/9-hour patch

VI. Product Availability

Drug Name	Availability
Methylphenidate ER (Jornay PM)	Extended-release capsules: 20 mg, 40 mg, 60 mg, 80 mg, 100 mg
Methylphenidate Transdermal System (Daytrana)	Transdermal patch: 10 mg/9 hours, 15 mg/9 hours, 20 mg/9 hours, and 30 mg/9 hours

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 November 2, 2022.
2. Jornay PM Prescribing Information. Cherry Hill, NJ: Ironshore Pharmaceuticals, Inc.; June 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/209311s008lbl.pdf. Accessed September 27, 2021.
3. 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.

4. 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
Criteria created for migration to HFS PDL	12.1.22	
Included criteria for Daytrana, updated section II, added Appendix B therapeutic alternatives, updated sections V and VI, and references reviewed and updated.	11.20.23	

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.

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.