Clinical Policy: Methylphenidate Transdermal System(Daytrana)
Reference Number: CP.PMN.10
Effective Date: 01/07
Last Review Date: 02/17
Line of Business: Medicaid

Coding Implications
Revision Log

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

Description
Methylphenidate (Daytrana®) is a central nervous system (CNS) stimulant.

FDA approved indication
Daytrana is indicated for treatment of attention-deficit/hyperactivity disorder (ADHD)

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of health plans affiliated with Centene Corporation® that Daytrana is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of ADHD or attention-deficit disorder (ADD);
2. Ages ≥ 6 years;
3. Failure of one PDL extended release amphetamine and one PDL oral extended release methylphenidate at maximum indicated doses, each trialed for ≥ 2 weeks, unless member experiences clinically significant adverse effects or has contraindication(s) to all relevant PDL extended release amphetamine and methylphenidate products;
4. Request does not exceed 30 mg per day (1 patch/day).

Approval duration: 6 months

B. Other diagnoses/indications – Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Attention-Deficit/Hyperactivity Disorder (ADHD) (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 30 mg per day (1 patch/day).

Approval duration: 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; or

2. Refer to CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

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 policy - CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
ADD: attention-deficit disorder
ADHD: attention-deficit/hyperactivity disorder
CNS: central nervous system
FDA: Food and Drug Administration
PDL: preferred drug list

V. Dosage and Administration

- The recommended starting dose for patients new to or converting from another formulation of methylphenidate is 10 mg.
- Daytrana should be applied to the hip area (using alternating sites) 2 hours before an effect is needed and should be removed 9 hours after application. Daytrana may be removed earlier than 9 hours if a shorter duration of effect is desired or late day side effects appear.
- Dosage should be titrated to effect. Dose titration, final dosage, and wear time should be individualized according to the needs and response of the patient.

VI. Product Availability

Transdermal patch: 10 mg/9 hours, 15 mg/9 hours, 20 mg/9 hours, and 30 mg/9 hours

VII. Workflow Document


CP.PMN.10.methylphenidate transderm

VIII. References

1. Daytrana Prescribing Information. Miami, FL: Noven Therapeutics, LLC; August 2016. Available at: http://www.daytrana.com/. Accessed November 11, 2016.
2. 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.
3. American Academy of Pediatrics subcommittee on attention-deficit/hyperactivity disorder, steering committee on quality improvement and management. ADHD: clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics 2011;128(5):1007-1022.

Reviews, Revisions, and Approvals	Date	Approval Date
Revise "Criteria for Approval" from "c. Documented failure to 3 month course of Ritalin or Adderall" to "c. Documented failure to 2 month course of Ritalin or Adderall".	04/07	04/07
Break out "Criteria for Approval" into two sections, "Children ≥ 6 years of age" and "Adults". Add the following items to the "Criteria for Approval" "Children ≥ 6 years of age" section: ▪ No contraindications to ADHD stimulant medications, to include hyperthyroidism, petit mal and/or partial complex seizures, history of traumatic head injury (disease states that may mimic ADHD), cardiac or vascular disease as demonstrated through EKG, or glaucoma. Daytrana® will be used as mono-therapy Added the following to the "Criteria for Approval" "Adults" section: ▪ Diagnosed with ADHD by a psychiatrist ▪ History of ADHD in childhood ▪ Demonstrates at least 6 ADHD symptoms (DSM-IV) during the last 6 months which significantly impact, impair, or compromise the members ability to function normally ▪ Documented (adequate) trial and failure of at least two short-acting ADHD stimulants. Treatment failure can not be caused by lack of compliance with therapy. ▪ No contraindications to ADHD stimulant medications, to include hyperthyroidism, petit mal and/or partial complex seizures, history of traumatic head injury (disease states that may mimic ADHD), cardiac or vascular disease as demonstrated through EKG, or glaucoma. ▪ No history of tics ▪ No recent history of taking a monoamine oxidase inhibitor ▪ No hypersensitivity to methylphenidate or other components of patch ▪ Patient must be seen every six months by provider to rule out cardiac problems and other potential adverse events ▪ Daytrana® will be used as mono-therapy	11/09	11/09
Criteria simplified to remove h/o of tics and requirement for 6 month provider visits for check of cardiac problems and adverse effects. Added ADD as a separate DSM-IV condition. Removal of specialist prescribing requirements. References updated to reflect current literature search.	02/11	02/11
References updated to reflect current literature search.	02/12	02/12
Updated FDA Labeling Indication to reflect Daytrana® Prescribing Information for children and adolescents.	02/13	02/13

Reviews, Revisions, and Approvals	Date	Approval Date
Updated Criteria for Approval section with FDA labeled age indication. Updated Criteria for Approval section to include trial of long-acting methylphenidate and Adderall XR at maximum doses. Removed Adult Criteria for Approval section. Adjusted initial approval to 6 months. Exclude the use of Daytrana® in adults by adding clinical studies in children and adolescents statement in Special Instructions section. Removed outdated AAP reference and updated with current AAP Clinical Practice Guideline for ADHD in children and adolescents. References updated to reflect current literature search.		
References updated to reflect current literature search. Modification to contraindications within approval criteria Update language to make coverage review easier. Updated references.	02/14	02/14
Converted into new policy template. Modified criteria B – to accept provider's diagnosis without requiring DSM-V criteria; Modified criteria C – to allow the trial of any PDL long acting amphetamine instead of just Adderall XR and to require at least a 2 week trial of each class of stimulant at maximized doses; Deleted requirement for documentation of integrated care plan involving parents, school, psychologist and physician. Deleted requirement for documentation supporting improvement in psychological, educational and social indicators for continued approval; Removed criteria D – "No contraindications to ADHD/ADD stimulant medications, to include hyperthyroidism, petit mal and/or partial complex seizures, history of traumatic head injury (disease states that may mimic ADHD/ADD), cardiac or vascular disease as demonstrated through EKG, glaucoma, or marked anxiety, tension, or agitation" as this cannot be objectively verified and applies to even the PDL stimulants. Removed criteria E "No recent (2 weeks) history of taking a monoamine oxidase inhibitor," as this cannot be objectively verified and applies to even the PDL stimulants. Removed criteria F "No hypersensitivity to methylphenidate or other components of patch" Removed criteria G "Daytrana® will be used as mono-therapy" Removed Criteria H "Documentation that Daytrana® is being given as part of an integrated care plan which includes involvement with parents, school, psychologist if indicated and pediatrician or prescribing physician" Added age appropriate age of use to the continued approval criteria; Added that documentation of diagnosis and of current use would allow for continued approval Added that request must not exceed 30 patches/30 days to initial and renewal approval criteria References updated	11/15	02/16

Reviews, Revisions, and Approvals	Date	Approval Date
Converted to new integrated template; Initial: modified age requirement from ages 6-17 years to ≥ 6 years per new template; Modified QL requirement from 30 patches per month to include specific max dosing and 1 patch/day. Re-auth: removed 1) provider's documentation or claims history shows that member has ADHD/ADD and is currently receiving Daytrana patch and 2) age requirement of 6-17 years; updated to include "Currently receiving medication via Centene benefit…" per template; added positive response to therapy requirement; modified QL to include specific max dose and 1 patch/day; Updated references.	11/16	02/17

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.