

Clinical Policy: Methylphenidate Transdermal System(Daytrana)

Reference Number: PA.CP.PMN.10

Effective Date: 01/18 Last Review Date: 02/17 Line of Business: Medicaid Coding Implications
Revision Log

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 <u>must</u> submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria *

It is the policy of Pennsylvania Health and Wellness[®] 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 \geq 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 PA.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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy, PA.LTSS,PHAR.01, applies;;
 - 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):

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- 1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care policy, PA.LTSS,PHAR.01, applies;; or
- 2. Refer to PA.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 – PA.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. References

- 1. Daytrana Prescribing Information. Miami, FL: Noven Therapeutics, LLC; August 2016. Available at: http://www.daytrana.com/. Accessed November 11, 2016.
- 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.

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Reviews, Revisions, and Approvals	Date	Approval Date