MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** methylphenidate transdermal patch (Daytrana®)
PAGE: 1 of 6	**REFERENCE NUMBER:** NH.PMN.10
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:**12/16, 10/17
PRODUCT TYPE: Medicaid	**REVISED:** 04/07, 11/09, 02/11, 02/12, 02/13, 02/14, 05/14, 08/15, 06/16

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Daytrana® is a once daily transdermal patch containing methylphenidate. It is applied to the hip (using alternating sites) 2 hours before an effect is needed and is usually worn for 9 hours then removed until the next morning.

Brand: methylphenidate transdermal (Daytrana®): 10mg, 15mg, 20mg, 30mg patches

FDA Labeled Indications: Treatment of Attention Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD) in children and adolescents 6 to 17 years of age, or other mental health conditions.

Criteria for Approval:

Children and adolescents 6-17 years of age:

A. Diagnosed with ADHD/ADD

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** methylphenidate transdermal patch (Daytrana®)
PAGE: 2 of 6	**REFERENCE NUMBER:** NH.PMN.10
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
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B. Failure of a PDL extended release amphetamine AND a PDL oral extended release methylphenidate, at maximized doses, each trialed ≥2 weeks, unless contraindicated; Documented intolerance to oral methylphenidate formulations and Adderall XR therapy

Approval: Initial Approval: 12 months (QL 30 patches per month). Continued Approval: 12 months. If documentation supports improvement in measures such as psychological, educational and social indicators, compliance and no adverse events.

Special Instructions

☐ The safety and efficacy of Daytrana® was established in controlled studies in children (ages 6-12) and adolescents (ages 13-17). The use of Daytrana® in the adult population has not been studied.

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** methylphenidate transdermal patch (Daytrana®)
PAGE: 3 of 6	**REFERENCE NUMBER:** NH.PMN.10
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
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- Stimulant medications generally should not be used in children with known structural cardiac abnormalities due to concern that stimulants may further increase the risk of sudden death above the risk that is already present with such abnormalities.
- Daytrana® should be used with extreme caution in patients with documented hypertension.
- Watch closely for evidence of dependency, personality changes, and severe depression.
- When a request for Daytrana patches is made due to a difficulty in swallowing pills, a trial of Metadate CD is warranted. If swallowing is difficult, the capsule may be opened and the contents gently sprinkled on one tablespoon of cold applesauce (warm applesauce could change the characteristics of the medication) and swallowed. The capsule contents should not be crushed or chewed. Prepare the sprinkle dose just prior to administration (do not store for future use). Drinking fluids (e.g., water, milk or juice) should follow the intake of the sprinkles with applesauce.

References: 1. Daytrana® prescribing information, revised 6/2013. Accessed January, 2014. http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=2c 312c31-3198-4775-91ab-294e0b4b9e7f

2. American Academy of Pediatrics, ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents, Accessed, January 2014. http://pediatrics.aappublications.org/content/early/2011/10/14/peds.2011-2654.

Revision Log	
Revision	**Date**
Revise "Criteria for Approval" from "c. Documented failure to 3	04/07

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MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** methylphenidate transdermal patch (Daytrana®)
PAGE: 4 of 6	**REFERENCE NUMBER:** NH.PMN.10
EFFECTIVE DATE: 01/07	**REPLACES DOCUMENT:**
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month course of Ritalin or Adderall" to "c. Documented failure to 2 month course of Ritalin or Adderall".	
Break out "Criteria for Approval" into two sections, "Children ≥ 6 years of age" and "Adults".	11/09
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	11/09
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	11/09

MEDICAL NECESSITY GUIDELINE

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• 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	
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.	02/11
References updated to reflect current literature search.	02/11
References updated to reflect current literature search.	02/12
Updated FDA Labeling Indication to reflect Daytrana® Prescribing Information for children and adolescents.	02/13
Updated Criteria for Approval section with FDA labeled age indication.	02/13
Updated Criteria for Approval section to include trial of long-acting methylphenidate and Adderall XR at maximum doses.	02/13
Removed Adult Criteria for Approval section.	02/13
Adjusted initial approval to 6 months.	02/13
Exclude the use of Daytrana® in adults by adding clinical studies in children and adolescents statement in Special Instructions section.	02/13
Removed outdated AAP reference and updated with current AAP Clinical Practice Guideline for ADHD in children and adolescents.	02/13
References updated to reflect current literature search.	02/13
References updated to reflect current literature search.	02/14
Modification to contraindications within approval criteria.	02/14
Wording modification to approval criteria item D.	05/14
Removed the drug trial length requirement of one month from “Criteria for Approval” section in item B.	08/15

Removed the following statement from the section "Special Instructions": Give methylphenidate cautiously to emotionally unstable patients (i.e., those with addiction issues) as such patients may increase dosage on their own initiative.	08/15
Removed DSM Criteria. Added or other mental health conditions to FDA Labeled indications section. Removed "No contraindications to ADHD/ADD stimulant medications, which may 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" Changed criteria to "Failure of a PDL extended release amphetamine AND a PDL oral extended release methylphenidate, at maximized doses, each trialed ≥2 weeks, unless contraindicated; Documented intolerance to oral methylphenidate formulations and Adderall XR therapy" Removed "No recent (2 weeks) history of taking a monoamine oxidase inhibitor, **and** No hypersensitivity to methylphenidate or other components of patch and Daytrana® will be used as mono-therapy, **and** 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. Changed initial approval from 6 months to 12 months.	6/16
Annual Review, No Changes	12/16
Annual Review, No Changes	10/17
Centene Medical Policy Statements represent technical documents developed by the Medical Management Staff. Questions regarding interpretation of these policies for the purposes of benefit coverage should be directed to a Medical Management Staff person.	

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POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file