Pharmacy Policy Bulletin

Title: Methylphenidate Transdermal System (Daytrana®)
Policy #: Rx.01.55

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Modifier:

Intent:
Methylphenidate transdermal patch (Daytrana®) is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children 6 to 12 years of age.

The use of the methylphenidate transdermal patch (Daytrana®) requires prior authorization (i.e. clinical pharmacist and/or Medical Director review).

Description:
Methylphenidate transdermal patch (Daytrana®) is a central nervous system (CNS) stimulant. Its mode of therapeutic action in attention deficit hyperactivity disorder (ADHD) is unknown, but methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neurons and to increase the release of these monoamines into the extraneuronal space. At this time there are no clinical trials showing methylphenidate transdermal patch (Daytrana) to have superior efficacy to other agents used to treat ADHD.

Black Box Warning:
Drug dependence:
Give methylphenidate cautiously to patients with a history of drug dependence or alcoholism.

Chronic abusive use can lead to marked tolerance and psychological dependence, with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use because severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Policy:
Methylphenidate transdermal patch (Daytrana®) is approved when all of the following inclusion criteria are met:

- Documented diagnosis of attention deficit hyperactivity disorder (ADHD)
- Documented trial and failure of or contraindication/intolerance/allergy to two of the following agents:
  - A methylphenidate containing product
  - A mixed amphetamine salts containing product (eg, amphetamine-dextroamphetamine [Adderall® or Adderall XR®])
  - Atomoxetine (Strattera®)
  - A dextroamphetamine-containing product
  - Methamphetamine hydrochloride (Desoxyn®)
  - A dexamethylphenidate containing product

Guidelines:
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.
BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:


Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Daytrana</td>
<td>methylphenidate transdermal patch</td>
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Cross References:

Policy Version Number: 3.00
P&T Approval Date: April 11, 2013
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