Policies Repository

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Policy Title	Methylphenidate Transdermal System (Daytrana®)
Policy Number	FS.CLIN.40

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy

The 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 (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Methylphenidate 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.

Policy Guideline Inclusion

The 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 dexmethylphenidate containing product

Policy Guideline Exclusion

The methylphenidate transdermal patch (Daytrana®) is denied when any of the following exclusion criteria are present:

- No documentation of ADHD
- No documentation of a 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])
  - Antomoxetine hydrochloride (Strattera®)
  - A dextroamphetamine containing product
  - Methamphetamine hydrochloride (Desoxyn®)
  - A dexmethylphenidate containing product

Policy List of Applicable Drugs

Brand Name	Generic Name
Daytrana	methylphenidate transdermal patch

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy References

American Academy of Pediatrics. Subcommittee on Attention-Deficit/Hyperactivity Disorder and Committee on Quality Improvement. Clinical practice guideline: Treatment of the school-aged child with attention- deficit/hyperactivity disorder. Pediatrics. 2001;108(4):1033-1044.

Daytrana® (methylphenidate transdermal patch) [package insert]. Wayne, PA: Shire Pharmaceuticals US Inc.; 2008. Also available online at: http://www.daytrana.com/Consumers/PDFs/DaytranaPrescribingInfo.pdf. [This link is no longer active on the website] Accessed April 15, 2008.

US Food and Drug Administration (FDA). FDA News. FDA approves methylphenidate patch to treat attention deficit hyperactivity disorder in children. [FDA Web site]. Available at: http://www.fda.gov/bbs/topics/news/2006/NEW01352.html. Accessed June 5, 2009.

Policy Link to Related Policies

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