Methylphenidate and Dexmethylphenidate

**Description**
Concerta / Daytrana / Metadate CD / Metadate ER / Methylin / Methylin-ER / Quillivant XR / Ritalin / Ritalin LA / Ritalin-SR and Focalin/ Focalin XR (Methylphenidate and Dexmethylphenidate)

**Background**
Methylphenidate is a DEA schedule II drug and a CNS stimulant which is FDA approved for attention deficit disorder (ADD), attention deficit hyperactivity disorder (ADHD) and narcolepsy (1,2,3). The exact mechanism by which methylphenidate acts is unknown; however, it presumably increases dopamine and norepinephrine levels in the brain. Although not all formulations are FDA-approved for narcolepsy, they are considered interchangeable in clinical practice. The criteria reflect not only FDA approved indications but also current standards of practice.

Methylphenidate has many unapproved uses, including weight loss, autism, bipolar disorder, bulimia, cancer, cerebral palsy spasticity, dementia, epilepsy, fatigue, schizophrenia, syncope and traumatic brain injury (4). It is also used for depression, although published trials are limited in size, and duration (5-8). However, two consultants to FEP, both practicing psychiatrists, report that methylphenidate can be a useful adjunct to conventional therapy in selected patients with depression and that this use can be considered accepted medical practice.

**Regulatory Status**
The products addressed by this policy are FDA-approved for use in one or more of the following conditions: attention deficit disorder (ADD), attention deficit hyperactivity disorder (ADHD) and narcolepsy (1, 9-15).

Methylphenidate has a boxed warning regarding the high potential of abuse and addiction (1, 9-15). Quantity limits based on the FDA-approved dosage guidelines help to reduce abuse, addiction, and dose dependent adverse effects.
Other safety issues associated with methylphenidate include sudden death in patients who have heart defects. Stroke, myocardial infarction, seizures, visual disturbances and hypertension have been reported. Growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted. Periodic CBC, differential, and platelet counts are advised during prolonged therapy. Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. (1,2,3,9-15).

Contraindications with the use of methylphenidate include marked anxiety, tension, agitation, glaucoma, tics, or a family history or diagnosis of Tourette’s syndrome. Methylphenidate is contraindicated in patients currently using or within 2 weeks of using an MAO inhibitor (1, 9-15).

Safety and efficacy has not been established in children less than six years old (1, 9-15).

Related Policies

Policy
*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Methylphenidate and dexamphetamine may be considered medically necessary in patients under 22 years of age or younger. Methylphenidate and dexamphetamine may be considered medically necessary in patients 22 years of age and older for the treatment of narcolepsy, attention deficit disorder, attention deficit hyperactivity disorder, or depression. Methylphenidate and dexamphetamine may be considered investigational in patients who do not meet the criteria for medical necessity.

Prior-Approval Requirements

Age
22 years of age or greater
Under age 22 – prior approval not required

Diagnoses
Patient must have ONE of the following:
- Narcolepsy
- Attention deficit disorder
- Attention deficit hyperactivity disorder
- Depression
**Section:** Prescription Drugs  
**Effective Date:** July 1, 2013  
**Subsection:** CNS  
**Original Policy Date:** December 1, 2011  
**Subject:** Methylphenidate, Dexmethylphenidate  
**Page:** 3 of 5

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**Prior – Approval Renewal Requirements**
Same as above

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**Policy Guidelines**

**Pre - PA Allowance**

None

This is a covered benefit for members less than 22 years of age

**Prior - Approval Limits**

**Quantity**
- Methylphenidate – Maximum adult dose for all indications 60mg/day
- Concerta – Maximum adult dose for all indications 72mg/day
- Focalin/Focalin XR – Maximum adult dose for all indications 40mg/day

**Duration**

12 months

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**Prior – Approval Renewal Limits**

Same as above

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**Rationale**

**Summary**
Methylphenidate is a DEA schedule II drug and a CNS stimulant which is FDA approved for attention deficit disorder (ADD), attention deficit hyperactivity disorder (ADHD) and narcolepsy.
Dexamethylphenidate is approved for the treatment of ADHD. The exact mechanism by which methylphenidate acts is unknown; however, it presumably increases dopamine and norepinephrine levels in the brain. Methylphenidate has many unapproved uses, including weight loss, autism, bipolar disorder, bulimia, cancer, cerebral palsy spasticity, dementia, epilepsy, fatigue, schizophrenia, syncope and traumatic brain injury. Methylphenidate has a boxed warning for a high potential of abuse and addiction.

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of methylphenidate and dexamethylphenidate while maintaining optimal therapeutic outcomes.
Reference

Keywords

This policy was approved by the FEP Pharmacy and Medical Policy Committee on June 6, 2013 and is effective July 1, 2013.

Signature on File

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