Methylphenidate Dexamethylphenidate

**Description**
Adhansia XR*, Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Jornay PM**, Metadate CD, Metadate ER, Relexxii [Methylphenidate ER (OSM)], Methylin, Methylin-ER, Quillivant XR, QuilliChew ER, Ritalin, Ritalin LA, Ritalin-SR, Focalin, Focalin XR (Methylphenidate and Dexamethylphenidate)

*This medication is currently pending tier determination and may not be available at this time

** Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication

**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. The exact mechanism by which methylphenidate acts is unknown; however, it presumably increases dopamine and norepinephrine levels in the brain (1-16). Methylphenidate also has an off-label indication for depression, although published trials are limited in size and duration (17).

For patients 22 years of age and older prior authorization and review is required for both diagnosis and quantity requested. For patients 21 years of age and younger, review is required if the total daily dose exceeds the FDA recommended daily limit.

**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 (1-16).

**Off Label Uses:**
Methylphenidates can be used as adjunctive therapy in the treatment of resistant depression (17).

Methylphenidate has a boxed warning regarding the high potential of abuse and addiction and should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic and or abusive use can lead to marked tolerance and psychological dependence. Quantity limits based on the FDA-approved dosage guidelines help to reduce abuse, addiction, and dose dependent adverse effects (1-16).

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 (1-16).

Safety and efficacy has not been established for Adhansia XR, Daytrana, and Jornay PM in children under six years old (2,15-16).

**Related policies**
Amphetamines, Provigil-Nuvigil

**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 dexamethylphenidate may be considered **medically necessary** for the treatment of narcolepsy, attention deficit disorder, attention deficit hyperactivity disorder, or depression.

Methylphenidate and dexamethylphenidate may be considered **investigational** for all other indications.

**Prior-Approval Requirements**

**Age**
22 years of age or older*
*For patients 21 years of age and younger review is required if the total daily dose exceeds the FDA recommended daily limit.

**Diagnoses**

Patient must have **ONE** of the following:

1. Narcolepsy
2. Attention deficit disorder (ADD)
3. Attention deficit hyperactivity disorder (ADHD)
4. Depression

**Adhansia XR, Daytrana, and Jornay PM**

Patient must be 6 years of age or older

**Prior – Approval Renewal Requirements**

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

<table>
<thead>
<tr>
<th>Age</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 years of age or older</td>
<td>NONE</td>
</tr>
<tr>
<td>21 years of age and younger</td>
<td>Adhansia XR and Daytrana Patient must be 6 – 21 years of age</td>
</tr>
</tbody>
</table>

**Pre - PA Quantity**

<table>
<thead>
<tr>
<th>Medication</th>
<th>Daily Dosing Limits</th>
</tr>
</thead>
</table>
| Adhansia XR (85 mg is reserved for Age ≥ 18 only) | Age 6-17: 70 mg per day  
Age 18-21: 85 mg per day |
| Aptensio / Metadate CD/ Methylin/ Methylphenidate / QuilliChew ER / Ritalin LA | 60 mg per day |
| Concerta / Relexxi [Methylphenidate ER (OSM)] | 72 mg per day |
| Daytrana Patch | 60 mg per day |
| Focalin/Focalin XR | 40 mg per day |
| Cotempla XR-ODT (Pediatric use only) | 51.9 mg per day |
Section: Prescription Drugs  Effective Date: January 1, 2020
Subsection: Central Nervous System Drugs  Original Policy Date: January 1, 2011
Subject: Methylphenidates  Page: 4 of 6

<table>
<thead>
<tr>
<th>Medication</th>
<th>Daily Dosing Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylphenidate oral solution</td>
<td>60 mg per day</td>
</tr>
<tr>
<td>Quillivant XR oral suspension</td>
<td>60 mg per day</td>
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</tbody>
</table>

*Any combination of therapy may be subject to additional review

Prior - Approval Limits

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Medication with approved MFE only</th>
<th>Daily Dosing Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adhansia XR</td>
<td></td>
<td>85 mg per day</td>
</tr>
<tr>
<td>Aptensio / Methylphenidate / QuilliChew ER / Ritalin LA</td>
<td></td>
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<td></td>
<td>40 mg per day</td>
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<td>Cotempla XR-ODT</td>
<td>(Pediatric use only)</td>
<td>None</td>
</tr>
<tr>
<td>Methylphenidate oral solution</td>
<td></td>
<td>60 mg per day</td>
</tr>
<tr>
<td>Quillivant XR oral suspension</td>
<td></td>
<td>60 mg per day</td>
</tr>
<tr>
<td>Jornay PM</td>
<td></td>
<td>100 mg per day</td>
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</tbody>
</table>

Duration  12 months

Prior – Approval Renewal Limits
Same as above

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. Dextymethylphenidate is approved for the treatment of ADHD. The exact mechanism by which methylphenidate acts is unknown; however, it is presumed to increase dopamine and norepinephrine levels in the brain. Methylphenidate has a boxed warning for a high potential of abuse and addiction (1-16).
Prior approval is required to ensure the safe, clinically appropriate and cost effective use of methylphenidate and dexmethylphenidate while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</table>
| December 2011 | New Policy  
Addition of Focalin XR 40mg to product line with the package insert updated to include a 40mg maximum dose for adults; therefore the maximum daily dose for Focalin products will change from 30mg per day to 40mg per day (9). |
| October 2010 | Annual editorial review and reference update |
Section: Prescription Drugs  
Subsection: Central Nervous System Drugs  
Subject: Methylphenidate

Effective Date: January 1, 2020  
Original Policy Date: January 1, 2011

June 2013  
Annual editorial review and reference update

September 2014  
Annual editorial review and reference update

May 2015  
Addition of Aptensio XR

June 2015  
Annual review and reference update.

December 2015  
Addition of QuilliChew

March 2016  
Annual review

September 2016  
Annual review and reference update.

December 2016  
Annual review

July 2017  
Addition of Cotempla XR-ODT

September 2017  
Annual review

January 2018  
Addition of Methylphenidate ER (OSM)

March 2018  
Annual review

August 2018  
Addition of Jornay PM

November 2018  
Annual review and reference update

March 2019  
Annual review and reference update. Addition of Adhansia XR

November 2019  
Addition of statement for Pre-PA “Any combination of therapy may be subject to additional review”

December 2019  
Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.