Methylphenidate / Dexmethylphenidate
Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Metadate CD, Metadate ER,
Methylin, Methylin-ER, Quillivant XR, QuilliChew ER, Ritalin, Ritalin LA, Ritalin-SR,
Focalin, Focalin XR

RATIONALE FOR INCLUSION IN PA PROGRAM

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 (1-14). Methylphenidate
also has an off-label indication for depression, although published trials are limited in size and
duration (15).

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 (1-14).

Off Label Uses:
Methylphenidates can be used as adjunctive therapy in the treatment of resistant depression (15).

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 (1-14).

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 (1-14).
Methylphenidate / Dexmethylphenidate
Aptensio XR, Concerta, Cotempla XR-ODT, Daytrana, Metadate CD, Metadate ER, Methylin, Methylin-ER, Quillivant XR, QuilliChew ER, Ritalin, Ritalin LA, Ritalin-SR, Focalin, Focalin XR

Safety and efficacy has not been established for Daytrana in children under six years old (2).

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. Dexmethylphenidate 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 (1-14).

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

References