BlueCross BlueShield
Federal Employee Program

METHYLPHENIDATE / DEXMETHYLPHENIDATE

Adhansia XR, Aptensio XR, Concerta, Cotempla XR-ODT*, Daytrana, Jornay PM, Metadate CD, Metadate ER, Relexxii, Methylin, Methylin-ER, Quillivant XR, QuilliChew ER, Ritalin, Ritalin LA, Ritalin-SR (methylphenidate)

Focalin, Focalin XR (dexmethylphenidate)

Azstarys (serdexmethylphenidate and dexmethylphenidate)

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

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Methylphenidate is a DEA schedule II drug and a CNS stimulant used in the treatment of 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 (1-18). Methylphenidate also has an off-label indication for depression, although published trials are limited in size and duration. Dexmethylphenidate is the more pharmacologically active form of methylphenidate (19).

Attention deficit disorder (ADD) is no longer a medical diagnosis, however, it is often used to refer to predominantly inattentive type ADHD and associated symptoms. The terms ADD and ADHD will be used throughout this policy (20).

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

FDA-approved indications: The products addressed by this policy are FDA-approved for use in one or both of the following conditions: attention deficit hyperactivity disorder (ADHD) and narcolepsy (1-18).

<u>Off-Label Uses:</u>

Methylphenidates can be used as adjunctive therapy in the treatment of resistant depression (19).

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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 (1-18).

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 (1-18).

The safety and efficacy have not been established for Adhansia XR, Azstarys, Daytrana, and Jornay PM in pediatric patients less than 6 years of age (2,15-17).

Summary

Methylphenidate is a DEA schedule II drug and a CNS stimulant which is FDA approved for 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 (1-18).

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

References

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