

Metadate ER, Methylin/Methylin ER, and Ritalin/Ritalin SR should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative.

Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression as well as the effects of chronic overactivity can be unmasked. Long-term follow-up may be required because of the patient's basic personality disturbances.

Metadate CD should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorders that may require follow up.

FDA-APPROVED INDICATIONS

Concerta

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of Concerta in the treatment of ADHD was established in three controlled trials of children aged 6 to 12 years who met the *Diagnostic and Statistical Manual of Mental Disorders, 4th Edition* (DSM-IV) criteria for ADHD.

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD; DSM-IV) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age seven years. The symptoms must cause clinically significant impairment (e.g., in social, academic, or occupational functioning) and be present in two or more settings (e.g., school [or work] and at home). The symptoms must not be better accounted for by another mental disorder. For the Inattentive Type, at least six of the following symptoms must have persisted for at least six months: lack of attention to details/careless mistakes, lack of sustained attention, poor listening, failure to follow through on tasks, poor organization, avoiding tasks requiring sustained mental effort, losing things, easily distracted, forgetful. For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least six months: fidgeting/squirming, leaving seat, inappropriate running/climbing, difficulty with quiet activities, "on the go," excessive talking, blurting answers, can't wait turn, intrusive. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of the required number of DSM-IV characteristics.

Concerta is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, and/or social) for patients with this syndrome. Drug treatment may not be indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and /or other primary psychiatric disorder, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's syndrome.

The effectiveness of Concerta for long-term use, i.e., for more than 4 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Concerta for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Metadate CD

Metadate CD is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of Metadate CD in the treatment of ADHD was established in one controlled trial of children aged 6 to 15 years who met DSM-IV criteria for ADHD.

A diagnosis of Attention Deficit Hyperactivity Disorder (ADHD, DSM-IV) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age seven years. The symptoms must cause clinically significant impairment (e.g., in social, academic, or occupational functioning) and be present in two or more settings (e.g., school [or work] and at home). The symptoms must not be better accounted for by another mental disorder. For the Inattentive Type, at least six of the following symptoms must have persisted for at least six months: lack of attention to details/careless mistakes, lack of sustained attention, poor listening, failure to follow through on tasks, poor organization, avoiding tasks requiring sustained mental effort, losing things, easily distracted, forgetful. For the Hyperactive-Impulsive type, at least six of the following symptoms must have persisted for at least six months: fidgeting/squirming; leaving seat, inappropriate running/climbing; difficult with quiet activities, "on the go," excessive talking, blurting answers; can't wait turn; intrusive. The Combined Types requires both inattentive and hyperactive-impulsive criteria be met.

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of the required number of DSM-IV characteristics.

Metadate CD is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and /or other primary psychiatric disorder, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's syndrome.

The effectiveness of Metadate CD for long-term use, i.e., for more than 3 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Metadate CD for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Metadate/Metadate ER

Metadate/Metadate ER is indicated for the treatment of Attention Deficit Disorders and Narcolepsy.

Metadate/Metadate ER is indicated as an integral part of a total treatment program that typically includes other remedial measures (e.g., psychological, education, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and /or other primary psychiatric disorder, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's syndrome.

Methylin/Methylin ER

Methylin is indicated for the treatment of Attention Deficit Disorders and Narcolepsy.

Methylin is indicated as an integral part of a total treatment program that typically includes other remedial measures (e.g., psychological, education, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and

abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and /or other primary psychiatric disorder, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's syndrome.

Ritalin/Ritalin SR

Ritalin is indicated for the treatment of Attention Deficit Disorders (ADD) and Narcolepsy.

Ritalin is indicated as an integral part of a total treatment program that typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and /or other primary psychiatric disorder, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

Ritalin LA

Ritalin LA is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of Ritalin LA in the treatment of ADHS was established in two controlled trials of patients aged 6 to 12 years of age who met DSM-IV criteria for ADHD.

A diagnosis of ADHS (DSM-IV) implies the presence of hyperactive-impulsive or inattentive symptoms that cause impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and be present in two or more settings, e.g., school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the inattentive type, at least six of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful. For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; "on the go"; excessive talking; blurting answers; cannot wait turn; intrusive. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources. Learning may or may not be impaired. The

diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of the required number of DSM-IV characteristics.

Ritalin LA is indicated as an integral part of a total treatment program for ADHS that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all children with the syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

The effectiveness of Ritalin LA for long-term use, i.e., for more than 2 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Ritalin LA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Focalin

Focalin is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

The efficacy of Focalin in the treatment of ADHS was established in two controlled trials of patients aged 6 to 17 years of age who met DSM-IV criteria for ADHD.

A diagnosis of ADHD (DSM-IV) implies the presence of hyperactive-impulsive or inattentive symptoms that cause impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and be present in two or more settings, e.g., school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the inattentive type, at least six of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful. For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; "on the go"; excessive talking; blurting answers; cannot wait turn; intrusive. The Combined Type requires both inattentive and hyperactive-impulsive criteria to be met.

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of the required number of DSM-IV characteristics.

Focalin is indicated as an integral part of a total treatment program for ADHS that may include other measures (psychological, educational, and/or social) for patients with this syndrome. Stimulants are not intended for use in the patients who exhibit symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the patient's symptoms.

The effectiveness of Focalin for long-term use, i.e., for more than 6 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Focalin for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Daytrana

Daytrana is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

A diagnosis of ADHD (DSM-IV-TR) implies the presence of hyperactive-impulsive or inattentive symptoms that caused impairment and were present before age 7 years. The symptoms must cause clinically significant impairment, e.g., in social, academic, or occupational functioning, and be present in two or more settings, e.g., school (or work) and at home. The symptoms must not be better accounted for by another mental disorder. For the Inattentive Type, at least six of the following symptoms must have persisted for at least 6 months: lack of attention to details/careless mistakes; lack of sustained attention; poor listener; failure to follow through on tasks; poor organization; avoids tasks requiring sustained mental effort; loses things; easily distracted; forgetful. For the Hyperactive-Impulsive Type, at least six of the following symptoms must have persisted for at least 6 months: fidgeting/squirming; leaving seat; inappropriate running/climbing; difficulty with quiet activities; "on the go"; excessive talking; blurting answers; can't wait turn; intrusive. The Combined Types requires both inattentive and hyperactive-impulsive criteria to be met.

Special Diagnostic Considerations

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of the required number of DSM-IV-TR characteristics.

Need for Comprehensive Treatment Program

Daytrana is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all children with the syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician’s assessment of the chronicity and severity of the child’s symptoms.

Long-Term Use

The effectiveness of Daytrana for long-term use, i.e., for more than 7 weeks, has not been systematically evaluated in controlled trials. The physician who elects to use Daytrana for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

CRITERIA FOR APPROVAL

1. Is the patient 6 years old or older?	Yes	No
2. Will the patient be on a monoamine oxidase inhibitor (MAOI) drug while taking this therapy or has the patient been on an MAOI drug in the previous 14 days? [MAOI drugs include: phenelzine (Nardil), tranylcypromine (Parnate), isocarboxazid (Marplan), and selegiline (Eldepryl, Emsam)]	Yes	No
3. Does the patient have one or more of the following contraindications to methylphenidates: marked anxiety, tension, or agitation, glaucoma, motor tics, family history or diagnosis of Tourette’s syndrome, cardiac abnormalities?	Yes	No
4. In light of the boxed warning, has the prescriber weighed/considered the benefits of treatment No versus the potential risks that chronic, abusive use of methylphenidates can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior?		Yes
5. Has the prescriber weighed/considered the benefits of treatment versus the potential risks of serious cardiovascular events (including sudden death) associated with the use of methylphenidate products?	Yes	No
6. Does the patient have a diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD)? [If the answer to this question is yes, skip to question 8.]	Yes	No
7. Does the patient have the diagnosis of narcolepsy that was confirmed by sleep studies? [If the answer to this question is no, no further questions are required.]	Yes	No
8. Is the request for Daytrana? [If the answer to this question is no, then skip to question 10.]	Yes	No
9. Has the patient had a trial and failure of oral methylphenidate products?	Yes	No
10. Is the request for MORE THAN the following dispensing limits: Concerta – 72 mg per day Daytrana – 1 patch per day Focalin Products – 20 mg per day Ritalin, Ritalin SR, Ritalin LA, Metadate, Metadate CD, Metadate ER, Methylin, Methylin ER, or generic methylphenidate products – 60 mg per day	Yes	No

Guidelines for Approval

Duration of Approval				12 months			
Set 1 - ADHD		Set 2 - Narcolepsy		Set 3 - ADHD		Set 4 - Narcolepsy	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	2	1	2	1	2	1	2
4	3	4	3	4	3	4	3
5	8	5	6	5	10	5	6
6	10	7	8	6		7	10
			10	8		8	
				9		9	

Horizon BCBSNJ Pharmacy Guideline Development Process: This Horizon BCBSNJ Pharmacy Guideline (the “Pharmacy Guideline”) has been developed by Horizon BCBSNJ’s Pharmacy Drug Policy Subcommittee, Clinical Issues Subcommittee, and Quality Improvement Committee which include practicing physicians and pharmacists. This guideline is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ’s view of the subject health care services, supplies drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Guideline also considers whether and to what degree the subject health care services, supplies or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Guideline considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

RATIONALE

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and practice guidelines in order to decrease potential for inappropriate utilization. Methylphenidate drug products are indicated for, or have compendial support for, the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) and for the treatment of narcolepsy. For patients with a diagnosis of narcolepsy, confirmation should be made by multiple sleep studies. Dexmethylphenidate drug products are indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

The safety and efficacy of methylphenidate/dexmethylphenidate in children under 6 years of age have not been established. Methylphenidate / dexmethylphenidate are contraindicated during or within 14 days following administration of a monoamine oxidase inhibitor (MAOI) – hypertensive crisis may result. Methylphenidate / dexmethylphenidate should not be used in patients with severe hypertension, angina pectoris, cardiac arrhythmias, heart failure, recent myocardial infarction, known serious structural cardiac abnormalities, cardiomyopathy, coronary artery disease, hyperthyroidism or thyrotoxicosis.

Horizon BCBSNJ has chosen to inquire about the trial and failure of an oral methylphenidate product before approval of the Daytrana Patch. Horizon BCBSNJ has chosen to add questions to inquire about the black box warning and additional contraindications. Horizon BCBSNJ has also chosen to add the following dose limitations:

- Daytrana – one patch per day
- Concerta – less than or equal to 72 mg per day
- Focalin XR – less than or equal to 20 mg per day
- Methylphenidate – less than or equal to 60 mg per day

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Pharmacy Guidelines can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

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