



Horizon BCBSNJ  
Medical Necessity Guideline

<b>Section</b>	Drugs
<b>Policy Number</b>	
<b>Effective Date</b>	6/25/04
<b>Review Date</b>	7/22/05, 10/27/06, 7/27/07, 11/19/07, 7/25/08, 01/23/09

**Subject:**  
**Drug Class: Amphetamines**

- BRAND NAME: Adderall (all oral)  
(Generic) (amphetamine mixture)
- Adderall XR (all oral)  
(amphetamine extended release mixture)
- Dexedrine (all oral)  
(dextroamphetamine)
- Dextrostat (all oral)  
(dextroamphetamine)
- Desoxyn (all oral)  
(methamphetamine)
- LiQuadd  
(dextroamphetamine)
- Vynanse (all oral)  
(lisdexamfetamine dimesylate)

**IMPORTANT NOTE:**

*The purpose of this policy is to provide general information applicable to the administration of outpatient prescription drug benefits that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") insures or administers. **Outpatient prescription drugs are not covered under all Horizon benefit plans.** If the member's contract benefits differ from the pharmacy guideline, the contract prevails. Although a service, supply drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply drug or procedure is not covered and the member proceeds to obtain the service, supply drug or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.*

<p><b>BLACK BOX WARNINGS</b></p> <p><b>Adderall, Dexedrine, Dextrostat, LiQuadd</b> AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.</p> <p><b>Adderall XR</b> AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR</p>
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PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

**Desoxyn**

METHAMPHETAMINE HAS A HIGH POTENTIAL FOR ABUSE. IT SHOULD THUS BE TRIED ONLY IN WEIGHT REDUCTION PROGRAMS FOR PATIENTS IN WHOM ALTERNATIVE THERAPY HAS BEEN INEFFECTIVE. ADMINISTRATION OF METHAMPHETAMINE FOR PROLONGED PERIODS OF TIME IN OBESITY MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING METHAMPHETAMINE FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUG SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

**Vyvanse**

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY. MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.

**FDA APPROVED INDICATIONS:**

*Adderall:*

Attention Deficit Disorder with Hyperactivity and in Narcolepsy.

Attention Deficit Disorder with Hyperactivity: Adderall is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with 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.

*Adderall XR:*

Attention Deficit Disorder with Hyperactivity.

Attention Deficit Disorder with Hyperactivity: Adderall XR is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with 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.

*Desoxyn:*

Attention Deficit Disorder with Hyperactivity and Obesity:

Desoxyn Gradumet tablets are indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children over 6 years of age 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.

Exogenous Obesity –as a short-term (i.e., a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients in whom obesity is refractory to alternative therapy, e.g., repeated diets, group programs, and

other drugs. The limited usefulness of Desoxyn Gradumet tablets should be weighed against possible risks inherent in use of the drug.

**LiQuadd**  
**Narcolepsy**

**Attention Deficit Disorder with Hyperactivity**

as an integral part of a total treatment program that typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 years to 16 years) 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.

***Dexedrine products:***

Attention Deficit Disorder with Hyperactivity and Narcolepsy.

Attention Deficit Disorder - as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in pediatric patients (ages 3 years to 16 years) 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.

**Medical Necessity guideline:**

1. Prescriptions for all drugs in the Amphetamine drug class will be subject to dispensing limit parameters as defined below.

TRADE NAME	GENERIC NAME	AGE LIMIT	MAXIMUM DOSE	UNITS
Adderall	dextroamphetamine + amphetamine	≥ 3 y/o	60 mg	per day
Dexedrine	dextroamphetamine	≥ 3 y/o	60 mg	per day
Vyvanse	Lisdexamfetamine dimesylate	≥ 6 y/o	70 mg	per day

2. The following questionnaire will be used to establish the medical necessity for all drugs in the Amphetamine drug class.

**REVIEW CRITERIA:**

- |  |     |    |
|--|-----|----|
| 1. Is the patient 3 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?<br>[MAOI drugs include: phenelzine (Nardil), tranylcypromine (Parnate), isocarboxazid (Marplan), and selegiline (Eldepryl, Emsam)]    | Yes | No |
| 3. Will the patient be regularly monitored for adverse events, including weight loss and decreased growth velocity for children, increased heart rate and blood pressure, the appearance or worsening of aggressive behavior or hostility, sleep disturbances, and long-term usefulness of the drug? | Yes | No |
| 4. As per the Black Box Warning, are the physician and patient aware that misuse of amphetamines may cause sudden death and serious cardiovascular adverse reactions?  | Yes | No |
| 5. Does the patient have any of the following contraindications to amphetamines: advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, glaucoma, agitated states, history of drug abuse?  | 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 10.]	Yes	No
7.	Is the medication being prescribed Vyvanse (lisdexamfetamine)? [If the answer to this question is yes, no further questions are required.]	Yes	No
8.	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
9.	Has the patient been evaluated for other causes of excessive daytime sleepiness (e.g., insufficient sleep syndrome, upper airway resistance syndrome, depression)? [Skip to question 13]	Yes	No
10.	Does the patient have ADHD symptoms in more than one setting? (e.g., school/daycare or work, home)	Yes	No
11.	Has the patient had ADHD symptoms for longer than 6 months?	Yes	No
12.	Are the ADHD symptoms causing clinically significant impairment in social, academic, or occupational functioning?	Yes	No
13.	Is the medication being prescribed Desoxyn (methamphetamine)? [If the answer to this question is yes, then no further questions required.]	Yes	No
14.	Is the request for MORE THAN the following dispensing limits: Vyvanse (lisdexamfetamine) – 1 capsule per day Amphetamine products or dextroamphetamines products – 60 mg per day	Yes	No
a.	Is the request for LiQuadd? [If the answer to this question is no, no further questions are required.]	Yes	No
16.	Is the patient unable to swallow tablets/capsules?	Yes	No

Guidelines for Approval							
Duration of Approval				12 Months			
Set 1 – ADHD (not Desoxyn)		Set 2 – ADHD (Desoxyn)		Set 3-Narcolepsy(not Desoxyn)		Set 4 – Narcolepsy (Desoxyn)	
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
3	5	3	5	3	5	3	5
4	13	4		4	6	4	6
6	14	6		8	7	8	7
10	15	10		9	13	9	
11		11			14	13	
12		12			15		
		13					
Set 5 – ADHD (LiQuadd)				Set 6- Narcolepsy (LiQuadd)			
Yes to question(s)		No to question(s)		Yes to question(s)		No to question(s)	
1		2		1		2	
3		5		3		5	
4		13		4		6	
6		14		8		7	
10				9		13	
11				15		14	
12				16			

15			
16			

Drugs in the Amphetamine class are not considered medically necessary for the treatment of obesity.

**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.

**Informational Notes:**

**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 fraud and abuse. The amphetamine drug class is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, and social) and narcolepsy.

Desoxyn is no longer recommended for the treatment of obesity by the manufacturer, even though the FDA approved indication remains in the labeling. Additionally, the clinical guidelines for the treatment of obesity set by the National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI), and American Association of Clinical Endocrinologists (AACE) do not recommend the use of amphetamines for the treatment of obesity. Therefore, Desoxyn will not be considered for this diagnosis.

For the initiation of therapy, the patient must have the diagnosis of ADHD or narcolepsy. The safety and efficacy of amphetamines in children under 3 years of age has not been established. (All medications in this group will be subject to the same age restrictions since these agents are treated the same in clinical practice.) For the patient with a diagnosis of ADHD, the symptoms must be persistent (present for greater than 6 months), must be more severe than is typically observed in individuals at a comparable level of development, must be clinically significant impairment, e.g. in social, academic, or occupational functioning, and must be present in two or more setting, e.g., school (work) and at home. The symptoms must not be accounted for by another mental disorder, since drug treatment is not intended for use in the patient who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Additionally, the physician who elects to use amphetamines for extended periods should periodically reevaluate the long-term usefulness of the drug and for the presence of adverse events. For those patients with narcolepsy, the diagnosis of narcolepsy should be confirmed by multiple sleep studies.<sup>14</sup> Additionally, patients with the diagnosis of narcolepsy must be evaluated for other disorders that could cause excessive daytime sleepiness.

**ADDITIONAL INFORMATION:**

**Dosage and administration:** Administer at the lowest effective dosage and adjust individually. Avoid late evening doses, particularly with long-acting forms due to resulting insomnia. There is potential for abuse and dependence resulting from prolonged use of these agents and other nonamphetamine medications are available for the treatment of obesity; therefore, the amphetamines are not approved for this indication.

**RISK FACTORS/CONTRAINDICATIONS:**

Advanced arteriosclerosis; symptomatic cardiovascular disease; moderate to severe hypertension; hyperthyroidism; glaucoma; agitated states; history of drug abuse; use during or within 14 days of MAO inhibitors (hypertensive crisis may develop).

**Warnings:**

Clinical experience suggests that in psychotic children, administration of amphetamine may exacerbate symptoms of behavior disturbance and thought disorder. Data are inadequate to determine whether chronic administration of amphetamine may be associated with growth inhibition; therefore, growth should be monitored during treatment.

Long-term effects of amphetamines in children have not been well established. Amphetamines are not recommended for use in children under 3 years of age with Attention Deficit Disorder with Hyperactivity.

**HISTORY**

<b>6/25/04</b>	<b>Reviewed with revision</b>
<b>7/22/05</b>	<b>Reviewed with minor revisions</b>
<b>10/27/06</b>	<b>Reviewed with minor revisions:</b> updated references
<b>7/27/07</b>	<b>Reviewed with no revisions.</b>
<b>11/19/07</b>	<b>Reviewed with revisions:</b> addition of Vyvanse
<b>7/25/08</b>	<b>Reviewed with revision:</b> reformatted the questions
<b>01/23/09</b>	<b>Review with revision:</b> addition of LiQuadd

**REFERENCES:**

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2. Adderall XR product information. Shire US Inc. revised September 2004.
3. Dexedrine product information. GlaxoSmithKline. January 2002.
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21. National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. [www.guideline.gov](http://www.guideline.gov). 2000.
22. American Association of Clinical Endocrinologists (AACE). Clinical guidelines; Prevention, diagnosis, and treatment of obesity. [www.guideline.gov](http://www.guideline.gov). 1998.
23. American Gastroenterological Association Medical Position Statement on Obesity. *Gastroenterology*. 2002;123:879-881.

24. Vyvanse product information. New River Pharmaceuticals. February 2007.

*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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