



Horizon BCBSNJ
Medical Necessity Guideline

Section	Drugs
Policy Number	
Effective Date	6/25/04
Review Date	7/22/05, 10/27/06, 7/27/07, 11/19/07, 7/25/08, 01/23/09, 9/8/09

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.*

BLACK BOX WARNINGS

Adderall, Dexedrine, Dextrostat, LiQuadd

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.

Adderall XR

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.

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	Lisdexmfetamine 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?
[MAOI drugs include: phenelzine (Nardil), tranylcypromine (Parnate), isocarboxazid (Marplan), and selegiline (Eldepryl, Emsam)] | Yes | No |
| 3. In light of the boxed warning, 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 amphetamine products? | | Yes |
| 4. Does the patient have one or more 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 |

5. 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
6. Is the medication being prescribed Vyvanse (lisdexamfetamine) or Desoxyn (methamphetamine)? [If the answer to this question is yes, no further questions are required.]	Yes	No
7. Does the patient have the diagnosis of narcolepsy that was confirmed by sleep studies? [Skip to question 9.]	Yes	No
8. Is the medication being prescribed Desoxyn (methamphetamine)? [If the answer to this question is yes, then no further questions required.]	Yes	No
9. 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
10. Is the request for LiQuadd? [If the answer to this question is no, no further questions are required.]	Yes	No
11. Is the patient unable to swallow tablets/capsules?	Yes	No

Guidelines for Approval					
Duration of Approval			12 Months		
Set 1 – ADHD		Set 2 – Narcolepsy		Set 3- ADHD (LiQuadd)	
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
3	4	3	4	3	4
5	8	7	5	5	8
	9		6	10	9
	10		9	11	
			10		
Set 4 – Narcolepsy (LiQuadd)			Set 5 – ADHD (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)	
1	2	1	2		
3	4	3	4		
7	5	5			
10	6	8			
11	8				
	9				

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.

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. The amphetamine drug class is indicated for, or has compendial support for, the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) and for the treatment of narcolepsy (except for Vyvanse and Desoxyn, which are not indicated for narcolepsy).¹⁻⁶ For patients with a diagnosis of narcolepsy, confirmation should be made by multiple sleep studies.¹⁰ Vyvanse and Desoxyn are not covered for narcolepsy because there is no evidence of efficacy and safety for this indication.

Amphetamines are not recommended for pediatric patients under 3 years of age. Amphetamines are contraindicated during or within 14 days following administration of a monoamine oxidase inhibitor (MAOI) – hypertensive crisis may result. Amphetamines are also contraindicated in patients with advanced arteriosclerosis, symptomatic cardiovascular disease, or moderate to severe hypertension.¹⁻⁸

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 and recommendations for the treatment of obesity set by the National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI), the American Association of Clinical Endocrinologists (AACE), and the American Gastroenterological Association do not recommend the use of amphetamines for the treatment of obesity.¹¹⁻¹³ Therefore, Desoxyn will not be considered for this diagnosis.

If the criteria for approval are met, Horizon BCBSNJ has chosen to allow approval for LiQuadd for patients who are unable to tolerate oral therapy. If the criteria for approval are met, Horizon BCBSNJ has set the approval dispensing limit for Vyvanse at one capsule daily, therefore 30 capsule per 30 days or 90 capsules per 90 days. Horizon BCBSNJ has chosen to limit the patient to a dose of 60 mg per day for Adderall and Dexedrine. Horizon BCBSNJ has also chosen to add a question into the criteria for approval regarding additional contraindications.

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. 2000.
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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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