



Horizon BCBSNJ
 Medical Necessity Guideline

Section Drugs
 Policy Number
 Effective Date 9/8/09
 Review Date

BRAND NAME (Generic) **Adcirca (tadalafil)**

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.

Horizon BCBSNJ pharmacy guidelines do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

FDA-APPROVED INDICATION

Adcirca is indicated for the treatment of pulmonary arterial hypertension (WHO Group I) to improve exercise ability.¹

CRITERIA FOR APPROVAL

1.	Does the patient have a diagnosis of pulmonary arterial hypertension (PAH), (WHO Group 1)? [If no, then no further questions.]	Yes	No
2.	Does the patient require nitrate therapy on a regular OR an intermittent basis?	Yes	No
3.	Is the request for MORE THAN the recommended dose of two 20 mg tablets per day?	Yes	No

Guidelines for Approval	
Duration of Approval	12 Months
Set 1:	
Yes to question	No to question(s)
1	2
	3

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 patients follow selection elements in the labeling established by Horizon BCBS of New Jersey.

If the prescribing physician confirms a diagnosis of PAH and the patient is not receiving concomitant nitrate therapy, coverage will be approved at a limit of two 20 mg tablets per day. Confirmation of PAH by right heart catheterization is not required.

Adcirca is indicated for the treatment of pulmonary arterial hypertension (WHO Group I) to improve exercise ability. PAH is defined and classified in nomenclature developed at the third World Conference on Pulmonary Hypertension held in Venice in 2003. PAH is further classified by the NYHA according to functional status.

The Revised Clinical Classification of Pulmonary Hypertension (Venice 2003):²

WHO Group I	Pulmonary arterial hypertension (PAH)
WHO Group II	Pulmonary hypertension with left heart disease
WHO Group III	Pulmonary Hypertension associated with lung diseases and/or hypoxemia
WHO Group IV	Pulmonary hypertension due to chronic thrombotic and/or embolic disease
WHO Group V	Miscellaneous (Sarcoidosis, Histiocytosis X, Lymphangiomatosis, Compression of pulmonary vessels)

Adcirca should not be used in patients who are using any form of organic nitrate, either regularly or intermittently. Adcirca potentiates the hypotensive effect of nitrates. Adcirca has mild systemic vasodilatory properties that may result in transient decreases in blood pressure. Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD). The primary efficacy endpoint for a randomized, double-blind, 16 week placebo-controlled study for Adcirca was the change from baseline at week 16 in 6-minute walk distance (MWD). The improvement in 6-MWD was apparent at 8 weeks of treatment and then maintained at week 12 and week 16.¹

REFERENCES

1. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2009.

2. Simonneau G, Galiè N, Rubin LJ et. al., Clinical classification of pulmonary hypertension. *J Am Coll Cardiol.* 2004;43: 5S-12S.

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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