



MASSACHUSETTS

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Pharmacy Medical Policy Phosphodiesterase Type-5 Inhibitors for Pulmonary Arterial Hypertension

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Policy Number: 036

BCBSA Reference Number: None

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary status of the medications affected by this policy.

Drug	Formulary Information	
	Standard	
	Formulary Status	
STEP 1		
<ul style="list-style-type: none"> • Alyq (tadalafil) • Sildenafil • Tadalafil 	PA Required	
STEP 2		
<ul style="list-style-type: none"> • Adcirca® (tadalafil) • Revatio®*** (sildenafil) 	Prior Use of Step 1 Required	

*** Non-covered drugs need a formulary exception which requires the use of two covered alternative medications prior to approving a formulary exception.

We cover the Pulmonary Arterial Hypertension medications listed in the chart above for new starts* in the following stepped approach¹

*New start is defined as no previous paid claim for the requested medication within the past 130 days.

Step 1: Formulary step 1 medication(s) need a PAH diagnosis to obtain a prior authorization for coverage.

Step 2: Formulary step 2 medications will be covered when one of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a step 1 or step 2 drug within the previous 130 days.

**Exception requests based exclusively on the use of samples will not meet coverage criteria for non-formulary medications. Additional clinical information demonstrating medical necessity of the non-formulary medication must be submitted by the requesting prescriber for review.

We do not cover drugs listed in the above chart unless the above step therapy criteria are met.

Revatio™ (Sildenafil 20mg) & **Sildenafil** 20mg are not FDA-approved for erectile dysfunction. Please see [Policy 078](#) for coverage options for erectile dysfunction.

Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for the above medications at one of the providers in our retail specialty pharmacy network, see link below:

[Link to Specialty Pharmacy List](#)

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed Care Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale.
Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

PPO and Indemnity Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale.
Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

Policy History

Date	Action
4/2019	Updated to add Alyq (tadalafil) to Step 1 with PA required.
11/2018	Updated to add Tadalafil to the policy and make a two step policy.
10/2017	Updated to clarify exclusion for ED plus to update Walgreens Specialty name.
7/2017	Updated to add AllCare to Pharmacy Specialty list.
6/2017	Updated address for Pharmacy Operations.
7/2015	Updated to add Walgreens Specialty.
2/2014	Updated Onco360 name and removed Curascript in Specialty Pharmacy section.
1/2014	Updated ExpressPAtH language and remove Blue Value.
10/2013	Added Step to this policy.
4/2012	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
3/2011	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
4/2010	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
3/2010	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology. No changes to policy statements.
2/2010	Updated to include prior authorization criteria for Adcirca™.
4/2009	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
4/2008	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
4/2007	Reviewed - Medical Policy Group - Cardiology and Pulmonology. No changes to policy statements.
11/2006	New policy, effective 11/2006, describing covered and non-covered indications.

References

1. Revatio® tablets [package insert]. New York, NY: Pfizer Pharmaceuticals; June 2005.
2. Adcirca™ [package insert]. Indianapolis, IN: Eli Lilly and Company; May 2009.
3. Badesch D, Burgess G, Parpia T, et al. Sildenafil citrate in patients with pulmonary arterial hypertension
4. (PAH):Results of a multicenter, multinational, randomized, double-blind, placebo-controlled trial by WHO functional class (FC) [poster]. Presented at: The American Thoracic Society Annual International Conference, San Diego, CA, May 20-25, 2005
5. Rubin L, Burgess G, Parpia T, Badesch D. Efficacy and safety of sildenafil citrated in pulmonary arterial hypertension (PAH): results of a multinational, randomized, double-blind, placebo-controlled trial [poster]. Presented at: The American Society of Hypertension 20th Annual Scientific Meeting and Exposition, San Francisco, CA, May 14-18, 2005.

6. Rubin L, Burgess G, Parpia T, Barst RJ. Hemodynamic effects of sildenafil citrate in patients with pulmonary arterial hypertension (PAH) [poster]. Presented at: The American Society of Hypertension 20th Annual Scientific Meeting and Exposition, San Francisco, CA, May 14-18, 2005.
7. Galie N, Burgess G, Parpia T, et al. Effects of sildenafil on 1-year survival on patients with idiopathic pulmonary arterial hypertension (PAH) [abstract]. Submitted to: The American Thoracic Society Annual International Conference, San Diego, May 14-18, 2005.
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9. Hoeper MM, Faulentback C, Golpon H, et al. Combination therapy with bosentan and sildenafil in idiopathic pulmonary arterial hypertension. *Eur Respir J*. 2004;24(6):1007-1010.
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11. Humbert M, Sitbon O, Simonneau G. Treatment of pulmonary arterial hypertension. *N Engl J Med*. 2004;351(14):1425-1436.
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14. Jackson G, Chambers J. Sildenafil for primary pulmonary hypertension: short and long-term symptomatic benefit. *Int J Clin Pract*. 2002;56:397-398.
15. Prasad S, Wilkinson J, Gatzoulis MA. Sildenafil in primary pulmonary hypertension. *N Engl J Med*. 2000;343:1342.
16. Sayin T, Ozenci M. Sildenafil in primary pulmonary hypertension – is there a subset of patients who respond favourably. *Can J Cardiol*. 2002;18:676-678.
17. Michelakis ED, Tymchak W, Noga M, et al. Long-term treatment with oral sildenafil is safe and improves functional capacity and hemodynamics in patients with pulmonary arterial hypertension. *Circulation*. 2003;108:2066-2069.
18. Sastry BKS, Narasimhan C, Reddy NK, et al. Clinical efficacy of sildenafil in primary pulmonary hypertension. *J Am Coll Cardiol*. 2004;43:1149-1153.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf