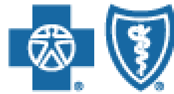

MASSACHUSETTS

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

Table of Contents

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Policy Number: 036

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #**621B**
- Sexual Dysfunction Diagnosis and Therapy Medical Policy #**078**
- Benign Prostatic Hyperplasia Medical Policy #**040**

Prior Authorization Information

<table>
<tr><td>Policy</td><td>☒ Prior Authorization
☒ Step Therapy
☐ Quantity Limit
☐ Administrative</td><td>Reviewing Department

Policy Effective Date</td><td>Pharmacy Operations:
Tel: 1-800-366-7778
Fax: 1-800-583-6289

10/1/2023</td></tr>
<tr><td>Pharmacy (Rx) or Medical (MED) benefit coverage</td><td>☒ Rx
☐ MED</td><td colspan="2" rowspan="2">To request for coverage: Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.

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

Individual Consideration for the atypical patient: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration</td></tr>
<tr><td colspan="2">Policy applies to Commercial Members:
• Managed Care (HMO and POS),
• PPO and Indemnity
• MEDEX with Rx plan
• Managed Major Medical with Custom BCBSMA Formulary
• Comprehensive Managed Major Medical with Custom BCBSMA Formulary
• Managed Blue for Seniors with Custom BCBSMA Formulary
Policy does <u>NOT</u> apply to:
• Medicare Advantage</td></tr>
</table>

Summary

This is a comprehensive policy covering step therapy requirements for phosphodiesterase type-5 (PDE-5) inhibitors for pulmonary arterial hypertension (PAH).

Policy

Step Therapy Requirements

Length of Approval	24 months
Formulary Status	All requests must meet the Step Therapy requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

The step therapy criteria for covered formulary medications is as follows:

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Alyq ™ (tadalafil)	PA	Covered if PA criteria is met (see below)
Sildenafil 20 mg, 10mg/12mL, 10mg/mL	PA	
Tadalafil 20mg	PA	
Step 2		
Adcirca ® (tadalafil)	ST	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication within the previous 130 days. See below for prior use criteria.
Liqrev ® (sildenafil)	ST	
Revatio ® (sildenafil)	NFNC	
Tadliq ® (tadalafil)	ST	

ST – Step Therapy; NF – Non-formulary

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Prior Authorization Requirements

Length of Approval	12 months
Formulary Status	All requests must meet the PA requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.

Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

The prior authorization criteria for medications used to treat PAH is as follows:

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Alyq ™ (tadalafil)	PA	Covered if PA criteria below are met.
Sildenafil 20 mg, 10mg/12mL, 10mg/mL	PA	
Tadalafil 20mg	PA	

Alyq (tadalafil), **Tadalafil 20 mg tablets, 10mg/12mL vial, 10mg/mL oral suspension**, or **Tadalafil 20mg** may be covered when there is a documented diagnosis of pulmonary arterial hypertension (PAH).

NOTE: Alyq, Sildenafil 20mg, and tadalafil 20mg are not FDA-approved for erectile dysfunction. Please see Policy 078 for coverage options for erectile dysfunction.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

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

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
9/2023	Reformatted Policy and updated IC to align with 118E MGL § 51A.
8/2023	Updated to add Liqrev ® to Step 2 in the policy
7/2023	Reformatted Policy.
1/2023	Updated to add Tadliq ® to step 2 in the policy.
9/2019	Updated to revise Step Criteria.
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.

Forms

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

Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. Revatio® tablets [package insert]. New York, NY: Pfizer Pharmaceuticals; June 2005.
2. Adcirca™ [package insert]. Indianapolic, 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.
8. Data on file. SUPER-1SM and SUPER-2 SM studies. Pfizer Pharmaceuticals; June 1, 2005.
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.
10. Ghofrani HA, Rose F, Schermuly RT, et al. Oral sildenafil as long-term adjunct therapy to inhaled iloprost in severe pulmonary arterial hypertension. *J Am Coll Cardiol.* 2003;42(1):158-164.
11. Humbert M, Sitbon O, Simonneau G. Treatment of pulmonary arterial hypertension. *N Engl J Med.*2004;351(14):1425-1436.
12. Badesch DB, Abman SH, Ahearn GS, et al. Medical therapy for pulmonary arterial hypertension: ACCP evidence-based clinical practice guidelines. *Chest.* 2004;126(Suppl 1):35S-62S.
13. Watanabe H, Ohashi K, Takeuchi K, et al. Sildenafil for primary and secondary pulmonary hypertension. *Clin Pharmacol Ther.* 2002;71:398-402.
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.