Mass General Brigham
Health Plan

Pulmonary Arterial Hypertension Agents
Effective 06/05/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Remodulin® (treprostinil injection) and Veletri® (epoprostenol) are available through pharmacy and medical benefits.		

Overview

No PA	Drugs that require PA †
Flolan® # (epoprostenol)	Adcirca® (tadalafil) * Adempas® (riociguat) Letairis® (ambrisentan) * Opsumit® (macitentan) Orenitram® (treprostinil tablet) Remodulin® (treprostinil injection) * BP Revatio® (sildenafil 20 mg tablet) * Revatio® (sildenafil oral suspension) * BP Tadliq® (tadalafil suspension) Tracleer® (bosentan) * BP Tyvaso® (treprostinil inhalation solution) Tyvaso DPI® (treprostinil inhalation powder) Veletri® (epoprostenol) * BP Ventavis® (iloprost)

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP Brand Preferred over generic equivalents. In general, requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
* A-rated generic available. Both brand and A-rated generic require PA.
† Although not FDA approved, Viagra® (sildenafil) and Cialis® (tadalafil) have been used off-label in the treatment of pulmonary arterial hypertension and are addressed in the Coverage Guidelines.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Adcirca® (tadalafil)
Tadliq® (tadalafil suspension)

1. Diagnosis of pulmonary arterial hypertension (PAH)
2. Prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided
3. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to sildenafil 20 mg tablets*
    b. Member is treatment naïve, and the requested agent will be used in combination with ambrisentan
4. **ONE** of the following:
    a. No recent paid pharmacy claims for Adempas® (defined as any paid claim within the last 30 days or ≥ 15 days of therapy within the last 30 days)
    b. Agent will not be co-administered with Adempas®
5. For Tadliq®, **ONE** of the following:
    a. Member has severe dysphagia AND is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets)
    b. Member utilizes tube feeding
    c. Member is <13 years of age
    d. Medical necessity for the requested formulation instead of tadalafil tablets
6. For BRAND NAME ONLY ("no substitutions") Adcirca®, the above criteria must be met and medical records provided documenting an inadequate response or adverse reaction to generic tadalafil (as per the Brand Name and Non-Preferred Generic Drug guideline)

**In pediatric members <18 years old with PAH, a trial of sildenafil may be bypassed due to increased risk of death in children treated with Revatio® (sildenafil)*

Adempas® (riociguat)
ONE of the following:

1. Diagnosis of PAH
    a. Member is ≥ 18 years of age
    b. Prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided
    c. Paid claims or physician attestation of Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following
        i. Tadalafil
        ii. Sildenafil
    d. Requested quantity is ≤ three tablets/day
    a. **ONE** of the following:
        i. No recent paid pharmacy claims for tadalafil or sildenafil (defined as any paid claim within the last 30 days or ≥ 15 days of therapy within the last 30 days)

ii. Agent will not be co-administered with a phosphodiesterase-5 inhibitor (tadalafil or sildenafil)

2. Diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH)
    a. Member is >18 years of age
    b. Prescriber is a pulmonologist or cardiologist, or consult notes from pulmonologist or cardiologist are provided
    c. **ONE** of the following:
        i. Persistent/recurrent CTEPH after surgical treatment
        ii. Inoperable CTEPH (surgery not an option)
    d. Requested quantity is ≤ three tablets/day
    e. **ONE** of the following:
        i. No recent paid pharmacy claims for tadalafil or sildenafil (defined as any paid claim within the last 30 days or ≥ 15 days of therapy within the last 30 days)
        ii. Agent will not be co-administered with a phosphodiesterase-5 inhibitor (tadalafil or sildenafil)

BRAND NAME **Flolan® (epoprostenol**)
Prescriber provides **medical records** documenting **ONE** of the following:

1. Allergic response or adverse reaction to the generic product or history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain product
2. Inadequate response to the generic product

Letairis® (ambrisentan)
Opsumit® (macitentan)
Tracleer® (bosentan)

1. Diagnosis of PAH
2. If the request is for Tracleer® for suspension, **BOTH** of the following:
    a. Member is < 13 years of age
    b. Member's current weight
3. Prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided
4. ONE of the following:
    a. For ambrisentan or Opsumit®, requested quantity is ≤ one tablet/day
    b. For bosentan tablet, requested quantity is ≤ two tablets/day
    c. For Tracleer® for suspension, requested quantity is ≤ four tablets/day
5. For BRAND NAME ONLY ("no substitutions") Letairis®, the above criteria must be met and medical records provided documenting an inadequate response or adverse reaction to the respective generic equivalent (as per the Brand Name and Non-Preferred Generic Drug guideline)

Orenitram® (treprostinil tablet)
Remodulin® (treprostinil injection)
Tyvaso® (treprostinil inhalation solution)
Tyvaso DPI® (treprostinil inhalation powder)
Ventavis® (iloprost)

1. Diagnosis of PAH
2. Prescriber is a pulmonologist or cardiologist, or consult notes from pulmonologist or cardiologist are provided

3. Paid claims or physician attestation of inadequate response, adverse reaction or contraindication to epoprostenol±
4. For Tyvaso DPI®, medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso® inhalation solution*
5. For Ventavis®, requested quantity is ≤ nine ampules/day

±Trial with epoprostenol may be bypassed if the provider documents one of the following: cognitive or physical issues affecting ability to manage intravenous therapy, need for fluid restriction, low health literacy, risk of infection, or history of IV drug use.

**Trial with Tyvaso® inhalation solution may be bypassed if the provider documents that the member is unable to manage the use of the inhalation solution due to arthritis or cognitive issues.*

Revatio® (sildenafil 20 mg tablet, suspension)

1. Diagnosis of PAH
2. Prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided
3. **ONE** of the following:
    a. No recent paid pharmacy claims for Adempas® (defined as any paid claim within the last 30 days or ≥ 15 days of therapy within the last 30 days)
    b. Agent will not be co-administered with Adempas®
4. For sildenafil oral suspension, **ONE** of the following:
    a. Member has severe dysphagia AND is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets)
    b. Member utilizes tube feeding
    c. Member is <13 years of age
    d. Medical necessity for the requested formulation instead of sildenafil tablets
5. For BRAND NAME Revatio® tablet, the above criteria must be met, and medical records provided documenting an inadequate response or adverse reaction to generic sildenafil (as per the Brand Name and Non-Preferred Generic Drug guideline)

Tyvaso® (treprostinil inhalation solution)
Tyvaso DPI® (treprostinil inhalation powder)

1. Diagnosis of pulmonary hypertension interstitial lung disease (PH-ILD)
2. Prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided
3. For Tyvaso DPI®, medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso® inhalation solution*

**Trial with Tyvaso® inhalation solution may be bypassed if the provider documents that the member is unable to manage the use of the inhalation solution due to arthritis or cognitive issues*

Veletri® (epoprostenol)

1. Diagnosis of PAH
2. Prescriber is a pulmonologist or cardiologist, or consult notes from a pulmonologist or cardiologist are provided
3. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to an epoprostenol product available without prior authorization

Off-Label Indications
Adcirca® (tadalafil)
Cialis (tadalafil)

Revatio® (sildenafil 20 mg tablet)
Revatio® (sildenafil oral suspension)
sildenafil (generic for Viagra®)

1. Diagnosis of Raynaud phenomenon
2. **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to **ONE** of the following
        i. amlodipine
        ii. nifedipine
        iii. topical nitroglycerin
    b. PDE5 inhibitor is being used for the healing of digital ulcers
3. For Adcirca®, Cialis®, or tadalafil (generic for Adcirca®), **ONE** of the following:
    a. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to sildenafil (generic Revatio®).
    b. Medical necessity for use of the requested agent instead of sildenafil (generic Revatio®) (e.g., member requires doses that cannot be achieved with generic Revatio®).
4. For sildenafil oral suspension, the prescribed dose cannot be obtained from the tablet formulation
5. For BRAND NAME Adcirca®, Cialis®, or Revatio® tablet the above criteria must be met, and medical records provided documenting an inadequate response or adverse reaction to generic sildenafil (as per the Brand Name and Non-Preferred Generic Drug guideline)

Continuation of Therapy

Reauthorization approvals must meet the following diagnostic-specific criteria:

- **PAH, PH-ILD, or CTEPH (***except sildenafil oral suspension and tablets)*: Resubmission by prescriber will infer a positive response to therapy

- **PAH** (*Tadliq® and sildenafil oral suspension):* member continues to meet the criteria for use of the suspension instead of the tablet formulation as noted by **ONE** of the following:
    1. Member has severe dysphagia AND is currently utilizing only formulations that can easily be swallowed (e.g., solutions, suspensions, films, or dispersible tablets)
    2. Member utilizes tube feeding
    3. Member is <13 years of age
    4. Medical necessity for the requested formulation instead of tablets

- **PAH** (*sildenafil tablet):* Resubmission by prescriber will infer a positive response to therapy

- **Other Indications:** Prescriber provides documentation of positive response or presence of consistent claims

Limitations

1. Initial approvals will be granted for the following durations:
    a. **Raynaud Phenomenon**: 6 months
    b. **All other indications**: 12 months
2. Reauthorization approvals will be granted for 12 months
3. The following quantity limits apply:

Adempas® (riociguat)	90 tablets per 30 days
Letairis® (ambrisentan)	30 tablets per 30 days

Opsumit® (macitentan)	30 tablets per 30 days
Tracleer® (bosentan)	60 tablets per 30 days
Tracleer® for suspension	120 tablets per 30 days
Ventavis® (iloprost)	270 ampules per 30 days

Appendix

Requests for Veletri® (epoprostenol)

Veletri®(epoprostenol) is not A-rated to Flolan®(epoprostenol); however, the main difference between the products is how long the reconstituted product can remain in the refrigerator (up to 8 days for Veletri® [epoprostenol] versus up to 48 hours for Flolan®[epoprostenol]). Alternatively, reconstituted Veletri® (epoprostenol) solution can be administered immediately at room temperature for 48 to 72 hours depending on concentration. In contrast, total storage, and infusion time for Flolan®(epoprostenol) must not exceed 48 hours for reconstituted solutions and may require the use of cold packs during infusion depending on the duration of refrigeration.

Requests noting that the member does not have access to cold packs for infusion pump can be **approved**.

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Review History

Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Added Tadliq as requiring PA. Reauthorization criteria and approval durations were updated. Revatio susp criteria was updated regarding swallowing disorders. Added sildenafil

(generic for Viagra) to off-label indication Raynaud phenomenon. Added appendix for Veletri requests. References were updated. Effective 6/5/23