JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP056
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Remodulin, generic treprostinil injection**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Remodulin

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I. POLICY

A. Remodulin (treprostinil injection) and its generic formulation will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Generic treprostinil may be approved for patients who meet the following:
   1. Documentation has been submitted showing the following:
      a. Patient has pulmonary arterial hypertension (PAH) that is defined as WHO Group 1, evidenced by a diagnosis of one of the following:
         - Idiopathic PAH
         - Heritable PAH
         - Drug- and toxin-induced PAH
         - PAH associated with one of the following:
            - Connective tissue diseases
            - HIV infection
            - Portal hypertension
            - Congenital heart diseases
            - Schistosomiasis
         - PAH that has responded long-term to calcium channel blockers
         - PAH with overt features of venous/capillaries (PVOD/PCH) involvement
         - Persistent pulmonary hypertension of the newborn syndrome
      b. PAH was confirmed by one of the following:
         - Pretreatment right heart catheterization with all of the following results:
            - mPAP >20 mmHg
            - PCWP ≤ 15 mmHg
            - PVR # 3 Wood units

- Doppler echocardiogram (if the patient is less than one year of age, and right heart catheterization cannot be performed)

B. Brand Remodulin may be approved for the following
   1. Patient meets the initial coverage criteria listed above for the generic product
   2. Documentation has been submitted showing the patient has hypersensitivity to the generic, or provider has a clinical justification as to why the patient cannot use the generic product

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Approval will be granted for the term of enrollment

IV. EXCLUSIONS

A. Remodulin will not be covered for the following:
   1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, treprotinil, 1 mg	J3285

VII. REFERENCES

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VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

Review Dates: 04/20/2022

Revision Dates: