STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TREPROSTINIL INHLAED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TREPROSTINIL, TREPROSTINIL DPI	TYVASO, TYVASO DPI	36537 36539 36541		GPI-14 40170080002020, 40170080002960, 40170080002920, 40170080002930, 40170080002950, 40170080002940, 40170080002980, 40170080002970	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1 **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units (WU)

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

3. Has the patient had a trial of or contraindication to **TWO** of the following agents from different drug classes?
   - Oral endothelin receptor antagonist (e.g., Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
   - Oral phosphodiesterase-5 inhibitor (e.g., Revatio [sildenafil], Adcirca [tadalafil])
   - Oral cGMP stimulator (e.g., Adempas [riociguat])
   - IV/SQ prostacyclin (e.g., Flolan [epoprostenol], Remodulin [treprostinil])

   If yes, **approve for 12 months by HICL or GPI-14. (NOTE: Enter approval for all of the available HICLs.)**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units (WU)

   If yes, **approve for 6 months by HICL or GPI-14. (NOTE: Enter approval for all of the available HICLs.)**

   If not, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL INHALED (Tyvaso, Tyvaso DPI)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO: Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) World Health Organization (WHO Group 3: a way to classify the severity of disease)

B. **If you have PAH (WHO Group 1), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on all of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units
   3. You had a trial of or contraindication (harmful for) to TWO of the following medications from different drug classes:
      a. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
      b. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
      c. Oral cGMP stimulator (such as Adempas [riociguat])
      d. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil])

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TREPROSTINIL INHALED

INITIAL CRITERIA (CONTINUED)

C. **If you have PH-ILD (WHO Group 3), approval also requires:**
   1. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
   2. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on all of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart
      a. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
      b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
      c. Pulmonary vascular resistance (PVR) greater than 2 Wood units

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1 and meet **ONE** of the following criteria?
   - The patient has shown improvement from baseline in the 6-minute walk distance test
   - The patient remains stable from baseline in the 6-minute walk distance test AND the patient's World Health Organization (WHO) functional class has improved or remained stable

   If yes, **approve for 12 months by HICL or GPI-14. (NOTE: Enter approval for all of the available HICLs.)**
   If no, continue to #2.

2. Does the patient have a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) (WHO Group 3) and meet **ONE** of the following criteria?
   - The patient has shown improvement from baseline in the 6-minute walk distance test
   - The patient has a stable 6-minute walk distance test

   If yes, **approve for 12 months by HICL or GPI-14. (NOTE: Enter approval for all of the available HICLs.)**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TREPROSTINIL INHALED

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TREPROSTINIL INHALED (Tyvaso, Tyvaso DPI)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO: Group 1: a way to classify the severity of disease)
   2. Pulmonary hypertension associated with interstitial lung disease (PH-ILD: a type of heart and lung condition) World Health Organization (WHO Group 3: a way to classify the severity of disease)

B. **If you have PAH (WHO Group 1), renewal also requires ONE of the following:**
   1. You have shown improvement from baseline in the 6-minute walk distance test
   2. You remain stable from baseline in the 6-minute walk distance test with an improved or stable World Health Organization functional class (WHO-FC: classification system for heart failure)

C. **If you have PH-ILD (WHO Group 3), renewal also requires ONE of the following:**
   1. You have shown improvement from baseline in the 6-minute walk distance test
   2. You remained stable in the 6-minute walk distance test

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tyvaso or Tyvaso DPI.

REFERENCES

- Tyvaso [Prescribing Information]. Research Triangle Park, NC United Therapeutics Corp., May 2022.
- Tyvaso DPI [Prescribing Information]. Research Triangle Park, NC: United Therapeutics Corp., May 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 03/23
Client Approval: 05/23
P&T Approval: 04/23