STANDARD COMMERCIAL AND NSA DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

SELEXIPAG

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SELEXIPAG	UPTRAVI	42922		GPI-10	
				(4012007000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- 1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (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, do not approve. **DENIAL TEXT:** See the initial denial text at the end of the guideline.

- 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) of greater than 20 mmHg
 - Pulmonary capillary wedge pressure (PCWP) of less than or equal to 15 mmHg
 - Pulmonary vascular resistance (PVR) of greater than 2 Wood units

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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SELEXIPAG

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 GPID or GPI-14 as follows (enter both approvals):

- FIRST APPROVAL: approve Uptravi 200-800 Titration pack with a quantity limit of #200 per 28 days for 1 fill.
- SECOND APPROVAL: approve the requested strength as follows:
 - 200mcg tablet: #8 per day.
 - 400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.
 - 1,800mcg vial: #2 per day.

(NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

If no, do not approve.

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 **SELEXIPAG (Uptravi)** requires the following rule(s) be met for approval:

- A. You have 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)
- B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
- C. 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:
 - 1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
 - 2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
 - 3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

(Initial denial text continued on next page)

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SELEXIPAG

INITIAL CRITERIA (CONTINUED)

- D. You had a trial of or contraindication (harmful for) to TWO of the following agents from different drug classes:
 - 1. Oral endothelin receptor antagonist (such as Letairis [ambrisentan], Tracleer [bosentan], Opsumit [macitentan])
 - 2. Oral phosphodiesterase-5 inhibitor for PAH (such as Revatio [sildenafil], Adcirca [tadalafil])
 - 3. Oral cGMP stimulator (such as Adempas [riociguat])
 - 4. Intravenous or subcutaneous prostacyclin (such as Flolan [epoprostenol], Remodulin [treprostinil)

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) (WHO Group 1) and meet **ONE** of the following criteria?
 - The patient 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 patients WHO functional class remained stable or has improved

If yes, approve for 12 months by GPID or GPI-14 for the requested strength with the following quantity limits:

- 200mcg tablet: #8 per day.
- 400mcg, 600mcg, 800mcg, 1,000mcg, 1,200mcg, 1,400mcg, 1,600mcg tablet: #2 per day.
- 1,800mcg vial: #2 per day.

(NOTE: Uptravi vial is a non-self-administered [NSA] agent and may not be covered by some plans.)

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

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SELEXIPAG

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 SELEXIPAG (Uptravi) requires the following rule(s) be met for renewal:

- A. You have 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)
- B. You meet 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 a stable or improved World Health Organization (WHO) functional class (classification system for heart failure)

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 Uptravi.

REFERENCES

• Uptravi [Prescribing Information]; San Francisco, CA: Actelion Pharmaceuticals US, Inc.; July 2021.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A Commercial Effective: 07/01/23 Created: 01/16 Client Approval: 05/23

P&T Approval: 04/23