STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MACITENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MACITENTAN	OPSUMIT	40677		GPI-10 (4016005000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (WHO Group 1) and meet **ALL** of the following criteria?
   - 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, **approve for 12 months by HICL or GPI-10 for #1 per day.**
   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 **MACITENTAN (Opsumit)** 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/breathing 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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MACITENTAN

INITIAL CRITERIA (CONTINUED)

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)?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has shown improvement from baseline in the 6-minute walk distance test
   - The patient has 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-10 for #1 per day.**
   If no, do not approve.
   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 **MACITENTAN (Opsumit)** 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 an improved or stable World Health Organization functional class (WHO-FC: 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.

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MACITENTAN

RATIONALE

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

REFERENCES

- Opsumit [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; October 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 10/22
Client Approval: 05/23
P&T Approval: 04/23