STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BOSENTAN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BOSENTAN	TRACLEER, BOSENTAN	22990		GPI-10 (4016001500)	

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?
   - The patient is 3 years of age or older
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient does not have idiopathic pulmonary fibrosis (IPF)
   - Tracleer (bosentan) will NOT be used concurrently with cyclosporine A or glyburide

   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 that 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 GPID or GPI-14 for all strengths with the following quantity limits:**
   - **62.5mg tablet: #2 per day.**
   - **125mg tablet: #2 per day.**
   - **32mg tablet for suspension: #4 per day.**

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

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BOSENTAN

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 **BOSENTAN (Tracleer)** 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 Group 1: a way to classify the severity of disease)
B. You are 3 years of age and older
C. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung doctor)
D. You do not have idiopathic pulmonary fibrosis (scarring of the lungs for an unknown reason)
E. Tracleer (bosentan) will NOT be used concurrently (at the same time) with cyclosporine A or glyburide
F. 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

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 (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. Is the patient using Tracleer (bosentan) concurrently with cyclosporine A or glyburide?

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

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RENEWAL CRITERIA (CONTINUED)

3. Is the patient between the ages of 3 and 17 years old and meets **ONE** of the following criteria?
   - The patient has demonstrated an improvement in pulmonary vascular resistance (PVR)
   - The patient has remained stable or shown improvement in exercise ability (e.g., 6-minute walk test, World Health Organization [WHO] functional class symptoms)

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **62.5mg tablet: #2 per day.**
   - **125mg tablet: #2 per day.**
   - **32mg tablet for suspension: #4 per day.**

   If no, continue to #4.

4. Is the patient 18 years of age or older and meets **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 World Health Organization (WHO) functional class has remained stable or improved

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths with the following quantity limits:**
   - **62.5mg tablet: #2 per day.**
   - **125mg tablet: #2 per day.**
   - **32mg tablet for suspension: #4 per day.**

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

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BOSENTAN

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 **BOSENTAN (Tracleer)** 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 Group 1: a way to classify the severity of disease)
B. Tracleer (bosentan) will NOT be used concurrently (at the same time) with cyclosporine A or glyburide
C. **If you are 3 to 17 years of age, renewal also requires ONE of the following:**
   1. You have demonstrated an improvement in pulmonary vascular resistance (a type of measurement for pulmonary arterial hypertension)
   2. You have remained stable or shown improvement in exercise ability (such as the 6-minute walk test, World Health Organization [WHO] functional class symptoms) [way to classify how limited you are during physical activity])
D. **If you are 18 years of age or older, renewal 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 AND World Health Organization (WHO) functional class has remained stable or improved

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 Tracleer.

REFERENCES

- Tracleer [Prescribing Information]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; January 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