BlueCross BlueShield
Federal Employee Program

TRACLEER **(bosentan**)
Preferred product: generic bosentan

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Pulmonary Arterial Hypertension (PAH) – **WHO Group I**
   a. Prescribed by or recommended by a cardiologist or pulmonologist
   b. Patient and prescriber enrolled in and meet all the conditions of the bosentan REMS Program
   c. **Brand Tracleer 62.5mg and 125mg ONLY**: Patient **MUST** have tried the preferred product (generic Tracleer: bosentan) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for <u>patients 18 years of age or older:</u>

1. NYHA functional classification of physical activity - Class II, III, or IV
2. **NOT** receiving treatment with cyclosporine A or glyburide (Diabeta, Micronase, Glynase or Glucovance)
3. Female patients of reproductive potential **ONLY**: pregnancy will be excluded before and during treatment with Tracleer, and patient will be advised to use two reliable forms of contraception during treatment and for one month after stopping Tracleer
4. Prescriber agrees to monitor for pulmonary edema and discontinue if confirmed

Prior - Approval Limits

Duration 2 years

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

1. Pulmonary Arterial Hypertension (PAH) – **WHO Group I**

TRACLEER **(bosentan**)
Preferred product: generic bosentan

a. Prescribed by or recommended by a cardiologist or pulmonologist
b. Patient and prescriber enrolled in and meet all the conditions of the bosentan REMS Program
c. **Brand Tracleer 62.5mg and 125mg ONLY**: Patient **MUST** have tried the preferred product (generic Tracleer: bosentan) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

AND ALL of the following for patients 18 years of age or older:

1. Symptoms have improved or stabilized
2. **NOT** receiving treatment with cyclosporine A or glyburide (Diabeta, Micronase, Glynase or Glucovance)
3. Female patients of reproductive potential **ONLY**: pregnancy will be excluded during treatment with Tracleer, and patient will be advised to use two reliable forms of contraception during treatment and for one month after stopping Tracleer
4. Prescriber agrees to monitor for pulmonary edema and discontinue if confirmed

Prior – Approval *Renewal* Limits

Same as above