

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI#:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

STEP
2

Diagnosis	<input type="checkbox"/> Pulmonary Arterial Hypertension, primary or secondary etiology <input type="checkbox"/> WHO Group I <input type="checkbox"/> NYHA Functional Class II to IV symptoms	<input type="checkbox"/> Other (please state): _____ _____ _____
Physician Specialty	<input type="checkbox"/> Pulmonology <input type="checkbox"/> Cardiology	<input type="checkbox"/> Other (please state): _____ _____
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Tracleer [®] (bosentan) Strength _____ Sig _____ Qty _____ Refills _____	
	<i>*Please attach all relevant medical records and test results*</i> We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.	

STEP 3
 I certify that the above is correct and accurate to the best of my knowledge and that the form is complete.
 (please sign and date)

 Prescriber Signature

 Date

STEP 4 Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
970-248-5034

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/10/12

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Tracleer® (bosentan)

CLASSIFICATION

- Pulmonary Antihypertensive
- Dual endothelin receptor antagonist

DESCRIPTION

- Tracleer® is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening. Efficacy trials included predominately patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital systemic-to-pulmonary shunts (18%).
- Patients with WHO Class II symptoms: treatment with bosentan showed a reduction in the rate of clinical deterioration and a trend for improvement in walk distance. Physicians should consider whether these benefits are sufficient to offset the risk of liver injury in WHO Class II patients, which may preclude future use as their disease progresses.
- Tracleer® is only available through a special restricted distribution program called the Tracleer Access Program (T.A.P.) due to the *black box warning* for risk of liver injury and birth defects. Prescribers and pharmacies must be registered in order to prescribe and distribute Tracleer®.
- Required monitoring of liver aminotransferase levels must be completed prior to start of therapy and monthly thereafter. Results may lead to dose reductions, interruption, or discontinuation of Tracleer®.
- Females of child-bearing potential are required to have a negative pregnancy test and must use two reliable methods of contraception. Urine or serum pregnancy tests should be obtained monthly. Contraception must be continued during and for one month following discontinuation of Tracleer®.
- Improvement in signs and symptoms of pulmonary arterial hypertension (dyspnea or fatigue, chest pain, or near syncope), exercise capacity, WHO functional classification, and a decrease in the rate of clinical worsening are indicative of efficacy.
- Due to the complicated nature and severity of PAH as a disease state as well as the high cost of the agents used for PAH, patients should be managed by a pulmonary specialist. Consideration will be given to cardiology specialists.
- Bosentan decreases both pulmonary and systemic vascular resistance leading to increased cardiac output without increasing heart rate.
- Bosentan is a specific and competitive antagonist at endothelin receptor types ET_A and ET_B with a higher affinity for ET_A. Endothelin-1 (ET-1) is a neurohormone and a potent vasoconstrictor that can promote fibrosis, cell proliferation and tissue remodeling. This effect is mediated by the binding to ET_A and ET_B in the endothelium and vascular smooth muscle. ET-1 is a suggested target in PAH because concentrations are elevated in plasma and lung tissue of patients with PAH. The speculated result is peripheral vasodilation.
- Administration of combination treatment of sildenafil, iloprost, and bosentan significantly increased exercise capacity, dyspnea, and Borg scale scores in patients with advanced pulmonary arterial hypertension compared to monotherapy in a prospective observational 6-month study.

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 4
Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Tracleer (bosentan) meets the definition of **medical necessity** for the following:

- Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening.
 - NYHA Functional Class II-IV symptoms
- Safety and efficacy not established in children.

Tracleer (bosentan) is considered **experimental** for the following:

- Bosentan will not be covered for any indication that is not FDA approved or Compendia supported.
- Consideration will be given to Compendia supported uses including Eisenmenger's syndrome (WHO group III).
- Patients with WHO Class II symptoms: treatment with bosentan showed a reduction in the rate of clinical deterioration and a trend for improvement in walk distance. Physicians should consider whether these benefits are sufficient to offset the risk of liver injury in WHO Class II patients, which may preclude future use as their disease progresses.

Required Provider Specialty:

- Approval is limited to Pulmonary and Cardiology specialists.

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy has not been determined for children):

- Pulmonary Arterial Hypertension:
 - Initiate with 62.5mg twice daily for 4 weeks
 - May be increased to maintenance dose of 125mg twice daily
 - Consider dose reduction to 62.5mg twice daily for 3 to 7 days for treatment discontinuation

Dose adjustments:

- Liver disease:
 - Treatment should be stopped if elevated ALT or AST with clinical symptoms or increases in bilirubin of 2 or more times the ULN.
 - ALT/AST levels >3 and ≤ 5 times ULN, reduce daily dose to 62.5 mg twice daily or interrupt treatment and monitor aminotransferase levels at least every 2 weeks; if levels return to pretreatment values, continue or reintroduce the treatment as appropriate; if reintroduced, the dose should be the starting dose; check aminotransferase levels within 3 days and thereafter at least every 2 weeks.
 - Stop treatment and monitor aminotransferase levels at least every 2 weeks if ALT/AST levels >5 and ≤ 8 times ULN; if aminotransferase levels return to pretreatment values, consider reintroduction of the treatment; if reintroduced, the dose should be the starting dose; check aminotransferase levels within 3 days and thereafter at least every 2 weeks

- Stop treatment if ALT/AST levels >8 times ULN. Reintroduction should not be considered due to no experience with reintroduction in these circumstances.
- Low body weight (over 12 years old and less than 40 kg): initial and maintenance dose is 62.5 mg ORALLY twice daily
- Concomitant ritonavir:
 - Start bosentan at 62.5 mg once daily or every other day in patients already receiving ritonavir for at least 10 days.
 - If initiating ritonavir, discontinue bosentan at least 36 hours prior to administration of ritonavir; resume bosentan at 62.5 mg daily or every other day at least 10 days after initiation of ritonavir.

PRECAUTIONS:

- **Black Box Warning**
 - Risk of liver injury and teratogenicity
- Contraindications
 - Use with cyclosporine A or glyburide
 - Pregnant or may become pregnant
 - Hypersensitivity to bosentan or any of its components
- Precautions
 - Liver injury (liver failure and cirrhosis): monitor liver enzymes and bilirubin elevations; may require dosage adjustment, therapy interruption, or discontinuation
 - Moderate to severe hepatic impairment or elevated aminotransferase (> 3 times the ULN) at baseline; avoid use.
 - Do not rely on hormonal contraception alone; oral, injectable, transdermal, and implantable contraception may be ineffective during bosentan therapy; use of 2 effective contraception methods is required.
 - Do not discontinue treatment abruptly; taper to avoid potential for clinical deterioration.
 - Concomitant use of a CYP2C9 inhibitor (e.g. fluconazole, amiodarone) plus a strong or moderate CYP3A inhibitor (e.g. ketoconazole, itraconazole, amprenavir, erythromycin, fluconazole, diltiazem) is not recommended.
 - Fluid retention and peripheral edema may occur; sometimes occurring within weeks of initiation; may require discontinuation of therapy and medical management.
 - Hemoglobin and hematocrit dose-related decreases have been observed and monitoring is recommended
 - Signs of pulmonary edema may occur; if associated with pulmonary veno-occlusive disease then discontinue use.

Billing/Coding information

CPT Coding:

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified
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HCPCS Coding:

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ICD-9 Diagnoses Codes That Support Medical Necessity:

416.0	Primary pulmonary hypertension

COST

- AWP (November 2011):
 - Tracleer 62.5mg tablets (60): \$6,876.00
 - Tracleer 125mg tablets (60): \$6,876.00

COMMITTEE APPROVAL:

- March 2002

GUIDELINE UPDATE INFORMATION:

March 2002	Prior Authorization Form created
November 2011	Coverage Policy created

REFERENCES:

- DRUGDEX®, accessed 11/17/2011
- Product Information: Tracleer ® (bosentan) oral. Actelion Pharmaceuticals US, Inc., South San Francisco, CA, 2009.