

PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Preferred Specialty Management Policy

- Letairis® (ambrisentan tablets – Gilead, generic)
- Opsumit® (macitentan tablets – Actelion)
- Tracleer® (bosentan tablets [generic] and tablets for oral suspension – Actelion)

REVIEW DATE: 10/07/2020

OVERVIEW

Letairis, Opsumit, and Tracleer are endothelin receptor antagonists (ERAs) indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1).¹⁻³ Letairis and Tracleer tablets (traditional, not tablets for oral suspension) are available as generics.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Prior Authorization Policy* criteria. The patient is also required to try the equivalent generic Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals for Preferred and Non-Preferred products are provided for 1 year. If the patient meets the standard *Pulmonary Arterial Hypertension – Endothelin Receptor Antagonists Prior Authorization Policy* criteria but has not tried the respective generic Preferred Product, approval for the generic Preferred Product will be authorized.

Documentation: Documentation is required for use of Letairis and Tracleer tablets as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

Preferred Products: generic ambrisentan, Opsumit tablets, generic bosentan tablets, and Tracleer tablets for oral suspension

Non-Preferred Products: Letairis tablets, Tracleer tablets

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Letairis	<ol style="list-style-type: none"> 1. Patient must meet both of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy</i> criteria; AND B) Patient meets both of the following (i <u>and</u> ii): <ol style="list-style-type: none"> i. Patient has tried generic ambrisentan tablets; AND ii. Medication is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent product which, per the prescriber, would result in a significant allergy or serious adverse reaction [documentation required]. 2. For patients who meet the standard <i>Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy</i> criteria but have not tried generic ambrisentan, approve generic ambrisentan.
Tracleer tablets	<ol style="list-style-type: none"> 1. Patient must meet both of the following (A <u>and</u> B): <ol style="list-style-type: none"> A) Patient meets the standard <i>Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy</i> criteria; AND B) Patient meets both of the following (i <u>and</u> ii): <ol style="list-style-type: none"> i. Patient has tried generic bosentan tablets; AND ii. Medication is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent product which, per the prescriber, would result in a significant allergy or serious adverse reaction [documentation required]. 2. For patients who meet the standard <i>Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy</i> criteria but have not tried generic bosentan tablets, approve bosentan tablets.

REFERENCES

1. Tracleer® tablets and tablets for oral suspension [prescribing information]. South San Francisco, CA: Actelion; May 2019.
2. Letairis® tablets [prescribing information]. Foster City, CA: Gilead Sciences; August 2019.
3. Opsumit® tablets [prescribing information]. South San Francisco, CA: Actelion; April 2019.