PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Pulmonary Arterial Hypertension – Endothelin Receptor Antagonists 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: 10/12/2022

OVERVIEW

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

- Letairis is indicated to improve exercise ability and delay clinical worsening as well as for use in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.[2]
- Opsumit is noted to reduce the risks of disease progression and hospitalization for PAH.[3]
- Tracleer is indicated in adults to improve exercise ability and decrease the rate of clinical worsening and in pediatric patients ≥ 3 years of age with idiopathic or congenital PAH to improve pulmonary vascular resistance, which is expected to result in an improvement in exercise ability.[1]

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

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RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Letairis	**1.** Approve for 1 year if the patient meets both of the following (A and B): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy* criteria; AND **B)** Patient meets both of the following (i and ii): **i.** Patient has tried generic ambrisentan tablets; AND **ii.** Patient cannot continue to use generic ambrisentan tablets 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 *Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy* criteria but have not tried generic ambrisentan, approve generic ambrisentan.
Tracleer tablets	**1.** Approve for 1 year if the patient meets both of the following (A and B): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy* criteria; AND **B)** Patient meets both of the following (i and ii): **i.** Patient has tried generic bosentan tablets; AND **ii.** Patient cannot continue to use generic bosentan tablets 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 *Pulmonary Arterial Hypertension – Endothelin Receptor Antagonist Prior Authorization Policy* 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/Janssen; July 2021.
2. Letairis® tablets [prescribing information]. Foster City, CA: Gilead; August 2019.
3. Opsumit® tablets [prescribing information]. Titusville, NJ: Actelion/Janssen; July 2022.

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