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: 10/11/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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

Non-Preferred Products: Letairis tablets, Tracleer tablets

Pulmonary Arterial Hypertension – Endothelin Receptor Antagonists non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT 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 2022.
2. Letairis® tablets [prescribing information]. Foster City, CA: Gilead; August 2019.
3. Opsumit® tablets [prescribing information]. Titusville, NJ: Actelion/Janssen; June 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/12/2022
Annual Revision	No criteria changes.	10/11/2023