Reference number(s)
4229-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☑

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☑
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☑
Value Formulary Chart (VFC)	☑
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Pulmonary Arterial Hypertension (PAH) Orals

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Value Formulary (VF), Standard Formulary Chart (SFC), Advanced Control Specialty Formulary Chart (ACSFC), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the oral pulmonary arterial hypertension (PAH) products specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Oral Pulmonary Arterial Hypertension Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• ambrisentan (generic) • bosentan (generic) • Opsumit (macitentan)
Target	• Letairis (ambrisentan) • Tracleer (bosentan)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Letairis

Coverage for Letairis is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to the preferred product generic ambrisentan, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member has a documented inadequate response or intolerable adverse event with both of the preferred products, generic bosentan and Opsumit.

Tracleer

Coverage for Tracleer is provided when either of the following criteria is met:

- Member meets both of the following:
  - Member has had a documented intolerable adverse event to the preferred product generic bosentan, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member has a documented inadequate response or intolerable adverse event with both of the preferred products, generic ambrisentan and Opsumit.
- Member is a pediatric patient and meets either of the following:
  - Member has had a documented intolerable adverse event to the preferred product generic bosentan, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
  - Member requires Tracleer 32 mg tablets for oral suspension.

References

1. Ambrisentan [package insert]. Weston, FL: Apotex Corp.; November 2020.
2. Bosentan [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2024.

3. Letairis [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2019.
4. Opsumit [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; March 2024.
5. Tracleer [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; February 2024.