Reference number(s)
7532-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)	☐
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	☐
Combined Benefit Management (CBM)	☐
Combined Benefit Management Pharmacy (CBMP)	☐
Medical Benefit Managed Medicaid (MMMB)	☐

Exceptions Criteria
Pulmonary Arterial Hypertension (PAH)

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: Value Formulary (VF).

Plan Design Summary

This program applies to the oral pulmonary arterial hypertension (PAH) products specified in this document. Coverage for the targeted product is provided based on clinical circumstances that would exclude the use of the preferred product 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 the targeted products.

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) • macitentan (generic)
Target	• Letairis (ambrisentan) • Opsumit (macitentan) • 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 generic macitentan.

Opsumit

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

- Member has had a documented intolerable adverse event to the preferred product generic macitentan, 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 generic bosentan.

Tracleer

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

- Member is 18 years of age or older and 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 generic macitentan.

- Member is less than 18 years of age and 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.

References

1. Ambrisentan [package insert]. Weston, FL: Apotex Corp.; May 2025.
2. Bosentan [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; August 2025.
3. Letairis [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2025.
4. Macitentan [package insert]. Basking Ridge, NJ: Torrent Pharma, Inc.; June 2026.
5. Opsumit [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; April 2025.
6. Tracleer [package insert]. Titusville, NJ: Actelion Pharmaceuticals US, Inc.; July 2025.