

This document applies to the following:

| Formulary | Applies |
|--|-------------------------------------|
| Standard Control (SF) | <input type="checkbox"/> |
| Standard Control – Choice (SCCF) | <input type="checkbox"/> |
| Preferred Drug Plan Design (PDPD) | <input type="checkbox"/> |
| Advanced Control Specialty (ACSF) | <input type="checkbox"/> |
| Advanced Control Specialty – Choice (ACSCF) | <input type="checkbox"/> |
| Managed Medicaid Template (MMT) | <input checked="" type="checkbox"/> |
| Marketplace (MF) | <input checked="" type="checkbox"/> |
| Aetna Small Group Affordable Care Act (SG ACA) | <input checked="" type="checkbox"/> |
| Aetna Health Exchange (AHE) | <input checked="" type="checkbox"/> |
| Aetna Individual Lives (IVL) | <input checked="" type="checkbox"/> |
| Value (VF) | <input type="checkbox"/> |

| Formulary | Applies |
|---|--------------------------|
| New to Market (NTM) | <input type="checkbox"/> |
| Standard Formulary Chart (SFC) | <input type="checkbox"/> |
| Basic Control Chart Preferred Drug Plan Design (BCC PDPD) | <input type="checkbox"/> |
| Advanced Control Specialty Formulary Chart (ACSFC) | <input type="checkbox"/> |
| Value Formulary Chart (VFC) | <input type="checkbox"/> |
| Medical Benefit | <input type="checkbox"/> |
| Medical Benefit: Advanced Biosimilars First | <input type="checkbox"/> |
| Medical Benefit: Managed Medicaid (MMMB) | <input type="checkbox"/> |
| Medicare Part B | <input type="checkbox"/> |
| Medicare Part B: Advanced Biosimilars First | <input type="checkbox"/> |

Exceptions Criteria

Inhaled Tobramycin

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: Managed Medicaid Template (MMT), Marketplace (MF), Aetna Individual Lives (IVL), and Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE).

Plan Design Summary

This program applies to the inhaled tobramycin products specified in this document. Coverage for targeted products 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 a targeted product.

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

Table. Inhaled Tobramycin Products

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

| | Product(s) |
|-----------|---|
| Preferred | <ul style="list-style-type: none"> tobramycin inhalation solution (generic) |
| Target | <ul style="list-style-type: none"> Bethkis (tobramycin inhalation solution) Kitabis Pak (tobramycin inhalation solution) TOBI (tobramycin inhalation solution) TOBI Podhaler (tobramycin inhalation powder) |

Exception Criteria

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

Coverage for a targeted product is provided when the member has experienced a documented intolerable adverse event with the preferred product generic tobramycin inhalation solution, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References

1. Bethkis [package insert]. Woodstock, IL: Chiesi USA, Inc.; February 2023.
2. Kitabis Pak [package insert]. Midlothian, VA: PARI Respiratory Equipment, Inc.; August 2023.
3. TOBI [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
4. TOBI Podhaler [package insert]. Morgantown, WV: Mylan Specialty L.P.; February 2023.
5. Tobramycin inhalation solution [package insert]. Princeton, NJ: Dr. Reddy's Laboratories, Inc.; February 2023.