BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/2017
LAST REVIEW DATE: 11/19/2020
LAST CRITERIA REVISION DATE: 11/19/2020
ARCHIVE DATE:

BETHKIS (tobramycin) inhalation solution
KITABIS™ PAK (tobramycin) inhalation solution
TOBI® (tobramycin) inhalation solution
TOBI® PODHALER™ (tobramycin) inhalation powder, capsule
Tobramycin inhalation solution, generics

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

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Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

- **Criteria for initial therapy:** Bethkis, Kitabis PAK, Tobi, Tobi Podhaler, and tobramycin inhalation solution generics is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Pulmonologist or Infectious Disease Specialist
  2. Individual is 6 years of age or older
  3. A confirmed diagnosis of ***Pseudomonas aeruginosa*** **infection of the lungs of an individual with cystic fibrosis (CF)**
  4. Cultures of airway demonstrating *Pseudomonas aeruginosa* is sensitive to tobramycin
  5. **For Kitabis PAK, Tobi, Tobi Podhaler, and tobramycin inhalation solution generics**: Individual has failure, contraindication, or intolerance to Bethkis (tobramycin) inhalation solution
  6. Individual **IS NOT** colonized with *Burkholderia cepacia*
  7. Individual has adequate renal function (creatinine is < 2 mg/dL)
  8. FEV1 percent predicted is:
     a. For Bethkis and generic: less than 40% or greater than 80%
     b. For TOBI Podhaler: less than 25% or greater than 80%
     c. For Kitabis PAK and generic: less than 25% or greater than 75%
     d. For TOBI and generic: less than 25% or greater than 75%
  9. There are **NO** contraindications.
     a. Contraindications include:
        i. Known hypersensitivity to any aminoglycoside

  Initial approval duration: Approve x 6 months to be used every other month

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- **Criteria for continuation of coverage (renewal request):** Bethkis, Kitabis PAK, Tobi, Tobi Podhaler, and tobramycin inhalation solution generics are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Pulmonologist or Infectious Disease Specialist

2. Individual's condition has responded while on therapy
    a. Response is defined as **ONE** of the following:
        i. Achieved and maintains at least a 10% improvement in FEV_1
        ii. Fewer hospitalization due to infection with *Pseudomonas aeruginosa*
        iii. Decrease in pulmonary exacerbations due to Pseudomonas aeruginosa that required parenteral anti-pseudomonal antibiotics

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    a. Contraindications as listed in the criteria for initial therapy section
    b. Significant adverse effect such as:
        i. Ototoxicity
        ii. Neuromuscular disorders presented as muscle weakness
        iii. Brochospasm
        iv. Nephrotoxicity

5. There are no significant interacting drugs

Renewal duration: 12 months to be used every other month

Description:

Bethkis (tobramycin inhalation solution), Kitabis PAK (tobramycin inhalation solution), Tobi (tobramycin nebulizer solution), Tobi Podhaler (tobramycin inhalation powder), and tobramycin inhalation solution generics all contain tobramycin as the active ingredient intended for delivery by oral inhalation.

Tobramycin by oral inhalation is indicated for the management of cystic fibrosis individuals 6 years of age or older with *Pseudomonas aeruginosa* infection.

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Tobramycin is an aminoglycoside antibiotic produced by *Streptomyces tenebrarius*. It acts by disrupting protein synthesis, leading to altered cell membrane permeability, progressive disruption of the cell envelope, and eventual cell death.

Tobramycin has *in-vitro* activity against a wide range of gram-negative organisms including *Pseudomonas aeruginosa*. It is bactericidal at concentrations equal to or slightly greater than inhibitory concentrations.

Resources:

Bethkis (tobramycin inhalation solution) product information, revised by manufacturer Chiesi Therapeutics Inc 12-2019, at DailyMed http://dailymed.nlm.nih.gov accessed September 21, 2020.

Kitabis PAK (tobramycin inhalation solution) product information, revised by manufacturer Pari Respiratory Equipment, Inc 11-2019, at DailyMed http://dailymed.nlm.nih.gov accessed September 15, 2020.

Tobi (tobramycin inhalation solution) product information, revised by manufacturer Novartis Pharmaceutical Corporation 10-2018, at DailyMed http://dailymed.nlm.nih.gov accessed September 15, 2020.

Tobi Podhaler (tobramycin inhalation powder) product information, revised by manufacturer Novartis Pharmaceutical Corporation 10-2018, at DailyMed http://dailymed.nlm.nih.gov accessed September 15, 2020.

Tobramycin inhalation solution product information, revised by manufacturer Dr. Reddy's Laboratories Inc 02-2019, at DailyMed http://dailymed.nlm.nih.gov accessed September 15, 2020.

Tobramycin inhalation solution PAK product information, revised by manufacturer Genericus, Inc 11-2019, at DailyMed http://dailymed.nlm.nih.gov accessed September 15, 2020.

Simon RH. Cystic fibrosis: Antibiotic therapy for chronic pulmonary infection. In: UpToDate, Mallory GB, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on September 15, 2020.