BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/16/17**
SECTION: DRUGS	**LAST REVIEW DATE: 11/15/18**
	LAST CRITERIA REVISION DATE: 11/15/18
	ARCHIVE DATE:

KITABIS™ PAK (tobramycin) inhalation solution
Tobramycin (tobramycin) inhalation solution
TOBI® (tobramycin) inhalation solution
TOBI® PODHALER™ (tobramycin) inhalation capsule

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.

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)

KITABIS™ PAK (tobramycin) inhalation solution
Tobramycin (tobramycin) inhalation solution
TOBI® (tobramycin) inhalation solution
TOBI® PODHALER™ (tobramycin) inhalation capsule (cont.)

864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Criteria:

- **Criteria for initial therapy:** Kitabis Pak, Tobi, Tobi Podhaler, or Tobramycin is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a Pulmonologist
  2. Individual is 6 years of age or older
  3. A confirmed diagnosis of cystic fibrosis with *Pseudomonas aeruginosa*
  4. Individual has failure, contraindication, or intolerance to Bethkis
  5. There are **NO** contraindications.
     - Contraindications include:
       - Known hypersensitivity to any aminoglycoside

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

- **Criteria for continuation of coverage (renewal request):** Kitabis Pak, Tobi, Tobi Podhaler, or Tobramycin is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a Pulmonologist
  2. Individual's condition has not worsened while on therapy
     - Worsening is defined as:
       - Hospitalization due to infections
  3. The indication for use is one that requires a longer duration than the usual duration such as use for diagnosis description(s)
  4. Individual has been adherent with the medication
  5. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Ototoxicity
     - Neuromusculur disorders presented as muscle weakness
     - Brochospasm
     - Nephrotoxicity

KITABIS™ PAK (tobramycin) inhalation solution
Tobramycin (tobramycin) inhalation solution
TOBI® (tobramycin) inhalation solution
TOBI® PODHALER™ (tobramycin) inhalation capsule (cont.)

6. 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 all contain tobramycin as the active ingredient intended for delivery by oral inhalation. Tobi is the only product that has a generic formulation available for use.

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

Solutions for inhalation are given over approximately 15 minutes using a handheld reusable nebulizer (PARI-LC PLUS) with a PARI Vios air compressor (for Bethkis) or a DeVilbiss Pulmo-Aide air compressor (for Kitabis Pak and Tobi). The inhalation powder is given with the Podhaler device only, a new Podhaler device is provided with each weekly pack.

Dosing of the solution for inhalation is 300 mg every 12 hours, administered in alternating periods of 28 days on drug and 28 days off drug, while the dosing of the powder for inhalation is 112 mg every 12 hours, administered in alternating periods of 28 days on drug and 28 days off drug.

Bethkis is supplied as a 300 mg/4 mL ampule. Kitabis Pak, Tobi, and tobramycin generic are supplied as 300 mg/5 mL ampules. Tobi Podhaler is supplied as 28 mg capsules with a Podhaler device.

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:

Kitabis. Package Insert. Revised by manufacturer 12/2014. Accessed 10/27/17.

Tobi. Package Insert. Revised by manufacturer 10/2015. Accessed 10/27/17.

Tobi Podhaler. Package Insert. Revised by manufacturer 10/2015. Accessed 10/27/17.

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.