BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/16/17**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE:
	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)

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

Kitabis (tobramycin)
Tobramycin
Tobi (tobramycin)

Medication class:
Aminoglycoside

FDA-approved indication(s):
- For the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with *Pseudomonas aeruginosa*

Recommended Dose:
Kitabis, Tobramycin, Tobi:
- Administer tobramycin inhalation solution as one single–use ampule (300 mg/5 mL) twice a day by oral inhalation in alternating periods of 28 days on drug, followed by 28 days off drug.
- Take doses as close to 12 hours apart as possible; but not less than 6 hours apart.

Tobi Podhaler:
- The recommended dosage is the inhalation of four 28 mg capsules twice-daily for 28 days

Available Dosage Forms:
Kitabis, Tobramycin, Tobi:
- Inhalation solution: 300 mg in a single-use 5 mL ampule

Tobi Podhaler:
- Inhalation powder: 28 mg in a capsule

Limitations of use:
Tobi Podhaler:
- Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV_1) <25% or >80%, or patients colonized with *Burkholderia cepacia.*

Warnings and Precautions:
Kitabis, Tobramycin, Tobi:
- *Bronchospasm:* Can occur with inhalation of tobramycin inhalation solution. Treat as medically appropriate, if it occurs.

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TOBI® PODHALER™ (tobramycin) inhalation capsule (cont.)

- *Ototoxicity:* Tinnitus and hearing loss have been reported in patients receiving tobramycin inhalation solution. If noted, manage as medically appropriate, including potentially discontinuing tobramycin inhalation solution.
- *Nephrotoxicity:* Has been associated with aminoglycosides as a class. If nephrotoxicity develops, manage the patient as medically appropriate, including potentially discontinuing tobramycin inhalation solution.
- *Neuromuscular Disorders:* Aminoglycosides may aggravate muscle weakness because of a potential curare-like effect on neuromuscular function. If neuromuscular blockade occurs, it may be reversed by the administration of calcium salts but mechanical assistance may be necessary.

Tobi Podhaler:
- Caution should be exercised when prescribing Tobi Podhaler to patients with known or suspected auditory, vestibular, renal, or neuromuscular dysfunction.
- Ototoxicity, as measured by complaints of hearing loss or tinnitus, was reported in clinical trials.
- Aminoglycosides may aggravate muscle weakness because of a potential curare-like effect on neuromuscular function.
- Bronchospasm can occur with inhalation of Tobi Podhaler.
- Audiograms, serum concentrations, and renal function should be monitored as appropriate.
- Fetal harm can occur when aminoglycosides are administered to a pregnant woman. Apprise women of the potential hazard to the fetus.

Criteria:

- **Criteria for initial therapy:** Kitabis, Tobramycin, Tobi, or Tobi Podhaler 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

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- **Criteria for continuation of coverage (renewal request):** Kitabis, Tobramycin, Tobi, or Tobi Podhaler 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

  6. There are no significant interacting drugs

  Renewal duration: 12 months to be used every other month

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.

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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

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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.

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