



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOBRAMYCIN INHALED

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOBRAMYCIN	BETHKIS, TOBRAMYCIN		16122	GPI-14 (07000070002530)	
TOBRAMYCIN IN 0.225% SOD CHLOR	TOBI, TOBRAMYCIN		61551	GPI-14 (07000070002520)	
TOBRAMYCIN	TOBI PODHALER		30025 34461	GPI-14 (07000070000120)	
TOBRAMYCIN/NEBULIZER	KITABIS PAK, TOBRAMYCIN		37569	GPI-14 (07000070002520)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis and meet **ALL** of the following criteria?

- The patient is 6 years of age or older
- The patient has a lung infection with a gram-negative species (such as *Pseudomonas aeruginosa*; *Staphylococcus aureus* is not a gram-negative species)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Is the request for Bethkis (tobramycin), Tobi (tobramycin) inhalation solution, or Kitabis Pak (tobramycin)?

If yes, **approve the requested agent for 12 months by GPID or GPI-14 as follows:**

- **Tobi inhalation solution: #280mL (#56 of 5mL ampules) per 28 days (fill count = 6).**
- **Bethkis: #224mL (#56 of 4mL ampules) per 28 days (fill count = 6).**
- **Kitabis Pak: #280mL per 28 days (fill count = 6).**

If no, continue to #3.

3. Is the request for Tobi Podhaler and the patient meets **ONE** of the following criteria?

- The patient had a trial and failure of or contraindication to ONE generic inhaled tobramycin product
- The patient is not able to tolerate the prolonged administration of nebulizers

If yes, **Tobi Podhaler for 12 months by GPID or GPI-14 with a quantity limit of #224 capsules per 28 days (fill count = 6).**

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TOBRAMYCIN INHALED (Bethkis, Tobi, Tobi Podhaler, Kitabis Pak)** requires the following rule(s) be met for approval:

- A. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
- B. You are 6 years of age or older
- C. You have a lung infection with a gram-negative species (type of bacteria that does not stain a purple color)
- D. **If the request is for Tobi Podhaler, approval also requires ONE of the following:**
 - 1. You had a trial and failure of or contraindication (harmful for) to ONE generic inhaled tobramycin product
 - 2. You are not able to tolerate the prolonged administration of nebulizers

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tobi, Tobi Podhaler, Bethkis or Kitabis.

REFERENCES

- Tobi [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2018.
- Tobi Podhaler [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
- Bethkis [Prescribing Information]. Woodstock, IL: Chiesi USA, Inc.; December 2019.
- Kitabis Pak [Prescribing Information]. Midlothian, VA: PARI Respiratory Equipment, Inc.; September 2019.

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Yes	Yes	No

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