SPECIALTY QUANTITY LIMIT PROGRAM

Cystic Fibrosis Medications

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. The recommended dosing parameters for all FDA-approved indications fall within the standard limits. Coverage of an additional quantity may be reviewed on a case-by-case basis upon request.

II. COVERED QUANTITIES

Medication	Standard Limit	FDA-recommended dosing
Cayston (aztreonam for inhalation solution) 75 mg vials	84 vials per 28 days	One vial (75 mg) reconstituted with 1 mL of sterile diluent administered 3 times a day for a 28-day course (followed by 28 days off Cayston therapy)
Kalydeco (ivacaftor) tablets 150 mg	60 tablets per 30 days	One 150 mg tablet every 12 hours
Kalydeco (ivacaftor) oral granules 25mg packets	56 packets per 28 days	One 25 mg packet every 12 hours
Kalydeco (ivacaftor) oral granules 50 mg packets	56 packets per 28 days	One 50 mg packet every 12 hours
Kalydeco (ivacaftor) oral granules 75 mg packets	56 packets per 28 days	One 75 mg packet every 12 hours
Orkambi (lumacaftor/ivacaftor) 100 mg/125 mg tablets	112 tablets per 28 days	Two lumacaftor 100 mg/ivacaftor 125 mg tablets every 12 hours
Orkambi (lumacaftor/ivacaftor) 200 mg/125 mg tablets	112 tablets per 28 days	Two lumacaftor 200 mg/ivacaftor 125 mg tablets every 12 hours
Orkambi (lumacaftor/ivacaftor) 100mg/125mg packets	56 packets per 28 days	One lumacaftor 100mg/ivacaftor 125mg packet every 12 hours for weight less than 14kg
Orkambi (lumacaftor/ivacaftor) 150mg/188mg packets	56 packets per 28 days	One lumacaftor 150mg/ivacaftor 188mg packet every 12 hours for weight of 14kg or greater
Pulmozyme (dornase alfa inhalation solution) 2.5mg/2.5mL ampules	150 mL per 30 days (60 ampules per 30 days)	One 2.5 mg ampule administered once daily *Some patients may benefit from twice daily administration.

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Medication	Standard Limit	FDA-recommended dosing
tobramycin inhalation solution 300mg/5mL ampules	280 mL per 28 days (56 ampules per 28 days)	One ampule (300 mg/5 mL) administered twice daily for 28 days (28 days on/28 days off cycle)
TOBI (tobramycin inhalation solution) 300mg/5mL ampules	280 mL per 28 days (56 ampules per 28 days)	One ampule (300 mg/ 5mL) administered twice daily for 28 days (28 days on/28 days off cycle)
TOBI Podhaler (tobramycin inhalation powder) 28 mg capsules	224 capsules per 28 days	Four 28 mg capsules twice daily for 28 days (28 days on/28 days off cycle)
Bethkis (tobramycin inhalation solution) 300mg/4mL ampules	224 mL per 28 days (56 ampules per 28 days)	One ampule (300 mg/4 mL) twice daily for 28 days (28 days on/28 days off cycle)
Kitabis Pak (tobramycin inhalation solution) 300mg/5mL ampules	280 mL per 28 days (56 ampules per 28 days)	One ampule (300 mg/5 mL) twice daily for 28 days (28 days on/28 days off cycle)
Symdeko (tezacaftor/ivacaftor) 100mg/150mg tablets	56 tablets per 28 days	One tablet (tezacaftor 100mg/ivacaftor 150mg) in the morning and one 150mg ivacaftor tablet in the evening.

III. REFERENCES

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- 2. Kalydeco [package insert]. Boston, MA: Vertex Pharmaceuticals Inc.; April 2019.
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- 4. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; January 2018.
- 5. Tobramycin inhalation solution [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; December 2015.
- 6. TOBI [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2015.
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- 8. Bethkis [package insert]. Woodstock, IL: Chiesi USA, Inc.; July 2017.
- 9. Kitabis Pak [package insert]. Midlothian, VA; PARI Respiratory Equipment, Inc.; May 2016.
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