



**GEORGIA MEDICAID FEE-FOR-SERVICE  
CYSTIC FIBROSIS, ORAL PA SUMMARY**

Preferred	Non-Preferred
Bronchitol (mannitol) Kalydeco (ivacaftor) Orkambi (lumacaftor/ivacaftor) Symdeko (tezacaftor/ivacaftor and ivacaftor) Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor)	N/A

**LENGTH OF AUTHORIZATION:** 1 year

**NOTE:** All agents require prior authorization (PA) and must be prescribed by or in consultation with a pulmonologist or specialist in cystic fibrosis.

**PA CRITERIA:**

Bronchitol

- ❖ Approvable for members 18 years of age or older with a diagnosis of cystic fibrosis (CF) who have a forced expiratory volume in one second (FEV<sub>1</sub>) % of predicted between 40% and 90%, have passed a Bronchitol Tolerance Test, have been prescribed a short-acting bronchodilator and have experienced an inadequate response, allergies, contraindications, drug-drug interactions or intolerable side effects with hypertonic saline and Pulmozyme

AND

- ❖ Must be used as add-on maintenance therapy to improve the member’s pulmonary function.

Kalydeco

- ❖ Approvable for members 1 month of age or older with a diagnosis of cystic fibrosis who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor based on clinical evidence or *in vitro* assay data.

Orkambi

- ❖ Approvable for members 1 year of age or older with a diagnosis of cystic fibrosis who are homozygous for the *F508del* mutation in the CFTR gene.

Symdeko

- ❖ Approvable for members 6 years of age and older with a diagnosis of cystic fibrosis who are homozygous for the *F508del* mutation in the CFTR gene or who have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on clinical evidence or *in vitro* assay data.

Trikafta

- ❖ Approvable for members 2 years of age or older with a diagnosis of cystic fibrosis who have at least one *F508del* mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on *in vitro* data.



**EXCEPTIONS:**

- Exceptions to these conditions of coverage are considered through the prior authorization process.
- The Prior Authorization process may be initiated by calling **OptumRx at 1-866-525-5827**.

**PREFERRED DRUG LIST:**

- For online access to the Preferred Drug List (PDL), please go to <http://dch.georgia.gov/preferred-drug-lists>.

**PA AND APPEAL PROCESS:**

- For online access to the PA process, please go to [www.dch.georgia.gov/prior-authorization-process-and-criteria](http://www.dch.georgia.gov/prior-authorization-process-and-criteria) and click on Prior Authorization (PA) Request Process Guide.

**QUANTITY LEVEL LIMITATIONS:**

- For online access to the current Quantity Level Limits (QLL), please go to [www.mmis.georgia.gov/portal](http://www.mmis.georgia.gov/portal), highlight Pharmacy and click on [Other Documents](#), then select the most recent quarters QLL list.