GEORGIA DEPARTMENT OF COMMUNITY HEALTH

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_1) % 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 4 months of age or older with a diagnosis of cystic fibrosis who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a CF mutation test: *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, R117H, A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, F1052V, F1074L, G1069R, K1060T, L206W, P67L, R74W, R117C, R347H, R352Q, R1070Q, R1070W, S945L, S977F, E831X, 711+3A→G, 2789+5G→A, 3272-26A→G or 3849+10kbC→T.*

Orkambi

- Approvable for members 2 years of age or older with a diagnosis of cystic fibrosis who are homozygous for the *F508del* mutation in the CFTR gene as detected by a CF mutation test.

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 as detected by a CF mutation test or who have one of the following mutations in the CFTR gene as detected by a CF mutation

test: *A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, F1052V, F1074L, K1060T, L206W, P67L, R74W, R117C, R347H, R352Q, R1070W, S945L, S977F, E831X, 711+3A→G, 2789+5G→A, 3272-26A→G or 3849+10kbC→T.*

Trikafta

- ❖ Approvable for members 6 years of age or older with a diagnosis of cystic fibrosis who have at least one *F508del* mutation in the CFTR gene as detected by a CF mutation test 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 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, highlight Pharmacy and click on Other Documents, then select the most recent quarters QLL list.