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

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-Preferred</th>
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</thead>
<tbody>
<tr>
<td>Bronchitol (mannitol)</td>
<td>N/A</td>
</tr>
<tr>
<td>Kalydeco (ivacaftor)</td>
<td></td>
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<tr>
<td>Orkambi (lumacaftor/ivacaftor)</td>
<td></td>
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<tr>
<td>Symdeko (tezacaftor/ivacaftor and ivacaftor)</td>
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<tr>
<td>Trikafta (elexacaftor/tezacaftor/ivacaftor and ivacaftor)</td>
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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 (FEV₁) % 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**


**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.

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.