Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Potentiators:
Kalydeco (ivacaftor)
Orkambi (lumacaftor/ivacaftor)
Symdeko (tezacaftor/ivacaftor)
Trikafta (elexacaftor/tezacaftor/ivacaftor)
Effective 07/07/2020

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
<th>Benefit</th>
<th>Pharmacy Benefit</th>
<th>Medical Benefit (NLX)</th>
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<tbody>
<tr>
<td>MassHealth</td>
<td>☑ Prior Authorization</td>
<td>☑ MassHealth</td>
<td>☑ Commercial/Exchange</td>
<td>☑ Medical Benefit (NLX)</td>
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<td>Commercial/Exchange</td>
<td>☑ Quantity Limit</td>
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<tr>
<td>☑ Step Therapy</td>
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**Specialty Limitations**: This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

**Contact Information**

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Plans</td>
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**Non-Specialty Medications**

<table>
<thead>
<tr>
<th>MassHealth</th>
<th>Phone: 877-433-7643</th>
<th>Fax: 866-255-7569</th>
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<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
</tr>
<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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**Medical Specialty Medications (NLX)**

<table>
<thead>
<tr>
<th>All Plans</th>
<th>Phone: 844-345-2803</th>
<th>Fax: 844-851-0882</th>
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</table>

**Exceptions**

**Overview**

CF is caused by genetic mutations in the CFTR protein. The CFTR protein is present in the respiratory epithelium and plays an important role in the regulation of airway surface liquid. Genetic mutations in the protein result in abnormal airway secretions, chronic endobronchial infection, and progressive airway obstruction. The CFTR potentiators treat the underlying cause of CF by targeting the defective CFTR protein to help facilitate increased chloride transport.

**Coverage Guidelines:**

**Kalydeco (ivacaftor)**

Authorization may be granted for members who are currently receiving treatment with Kalydeco for an FDA approved indication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted for treatment of cystic fibrosis when all of the following criteria are met:

1. Documentation of genetic testing to detect a mutation in the CFTR gene.
3. The member is ≥ 6 months of age
4. Kalydeco will not be used in combination with Symdeko, Orkambi, or Trikafta

**Orkambi (lumacaftor/ivacaftor)**
Authorization may be granted for members who are currently receiving treatment with Orkambi for an FDA approved indication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**
Authorization may be granted for treatment of cystic fibrosis when all of the following criteria are met:
1. Documentation of genetic testing to detect a mutation in the CFTR gene.
2. The member is positive for the F508del mutation on both alleles of the CFTR gene.
3. The member is 2 years of age or older.
4. Orkambi will not be used in combination with Kalydeco, Symdeko, or Trikafta.

**Symdeko (tezacaftor/ivacaftor)**
Authorization may be granted for members who are currently receiving treatment with Symdeko for an FDA approved indication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**
Authorization may be granted for treatment of cystic fibrosis when all of the following criteria are met:
1. Documentation of genetic testing to detect a mutation in the CFTR gene.
3. The member ≥ 6 years of age or older
4. Symdeko will not be used in combination with Kalydeco, Orkambi, or Trikafta

**Trikafta (eluxacaftor/tezacaftor/ivacaftor)**
Authorization may be granted for members who are currently receiving treatment with Trikafta for an FDA approved indication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**
Authorization may be granted for treatment of cystic fibrosis when all of the following criteria are met:
1. Documentation of genetic testing to detect a mutation in the CFTR gene.
2. The member is positive for the F508del mutation on one or more alleles of the CFTR gene.
3. The member is 12 years of age or older.
4. The member has previously trialed and experienced an inadequate response to Kalydeco, Symdeko, and Orkambi.
5. Trikafta will not be used in combination with Kalydeco, Symdeko, or Orkambi.

**Continuation of Therapy**
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**Limitations**
The following quantity limits apply:

<table>
<thead>
<tr>
<th>Product</th>
<th>Limit</th>
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<tbody>
<tr>
<td>Kalydeco 150mg tablets</td>
<td>56 tablets per 28 days</td>
</tr>
<tr>
<td>Kalydeco 25mg, 50mg, or 75mg packets</td>
<td>56 packets per 28 days</td>
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<tr>
<td>------------------------------------</td>
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</tr>
<tr>
<td>Orkambi 200-125mg tablets</td>
<td>112 tablets per 28 days</td>
</tr>
<tr>
<td>Orkambi 150-188mg granules</td>
<td>56 packets per 28 days</td>
</tr>
<tr>
<td>Symdeko 50-75mg tablets</td>
<td>56 tablets per 28 days</td>
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<tr>
<td>Symdeko 100-150mg tablets</td>
<td>56 tablets per 28 days</td>
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<tr>
<td>Trikafta 100-50-75mg tablets</td>
<td>84 tablets per 28 days</td>
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**References**


**Review History**

05/20/2020 – Created and Reviewed P&T Mtg; Merged Orkambi, Symdeko, Trikafta and Kalydeco into one program. Effective 7/1/20.

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