## Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Potentiators:
Kalydeco (ivacaftor)
Orkambi (lumacaftor/ivacaftor)
Symdeko (tezacaftor/ivacaftor)
Trikafta (elexacaftor/tezacaftor/ivacaftor)
Effective 08/01/2021

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☑ Commercial/Exchange</th>
<th>Program Type</th>
<th>☑ Prior Authorization</th>
<th>☐ Quantity Limit</th>
<th>☐ Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit</td>
<td>☑ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
<td>☑ Commercial/Exchange</td>
<td>☑ Prior Authorization</td>
<td>☐ Quantity Limit</td>
<td>☐ Step Therapy</td>
</tr>
</tbody>
</table>

### Specialty Limitations
This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

<table>
<thead>
<tr>
<th>Specialty Medications</th>
<th>All Plans</th>
<th>Phone: 866-814-5506</th>
<th>Fax: 866-249-6155</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Specialty Medications</td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
</tr>
<tr>
<td></td>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
</tr>
<tr>
<td></td>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
</tr>
</tbody>
</table>

### Contact Information
Medical Specialty Medications (NLX)
All Plans | Phone: 844-345-2803 | Fax: 844-851-0882 |

### 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.

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
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
1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

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

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.
05/19/2021 – Updated and Reviewed May P&T Mtg; Separated out Comm/Exch vs. MH UPPL; Added duration of approval to Limitations. Effective 08/01/2021.

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.