



## PRIOR AUTHORIZATION REQUEST

### Global Cystic Fibrosis

#### Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

#### Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

#### Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

**SECTION A:** Please note that supporting clinical documentation is required for **ALL PA** requests. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

1	Is the request an INITIAL or CONTINUATION of therapy? <input type="checkbox"/> Initial (If checked, go to 7) <input type="checkbox"/> Continuation (If checked, go to 2)		
2	Is the patient currently receiving the requested medication? [If no, skip to question 7.]	Yes	No
3	Has the patient been receiving medication samples of the requested medication? [If yes, skip to question 7.]	Yes	No

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4	<p>Does the patient have a previously approved prior authorization (PA) on file with the current plan?</p> <p>[Note: If the patient does NOT have a previously approved PA on file for the requested medication with the current plan, the renewal request will be considered under initial therapy.]</p> <p>[If no, skip to question 7.]</p>	Yes	No
5	<p>Has the patient been established on therapy for at least 3 months?</p> <p>[If no, skip to question 7.]</p>	Yes	No
6	<p>Has documentation been submitted to confirm that the patient has had a significant response to therapy, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.</p> <p>[Note: Examples of clinical presentation of cystic fibrosis include but are not limited to meconium ileus, sino-pulmonary symptoms include persistent cough, wheezing, pulmonary function tests consistent with obstructive airway disease, excess sputum production, bronchiectasis, sinusitis, failure to thrive, pancreatic insufficiency.]</p> <p>[No further questions.]</p>	Yes	No
7	<p>What is the indication or diagnosis? ACTION REQUIRED: Submit supporting documentation.</p> <p><input type="checkbox"/> Cystic Fibrosis (If checked, go to 8)</p> <p><input type="checkbox"/> Other (If checked, no further questions)</p>		
8	<p>Is the medication requested being prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis?</p> <p>[If no, no further questions.]</p>	Yes	No
9	<p>Will the patient be taking the requested medication in combination with another medication used to treat Cystic Fibrosis?</p> <p>[If no, no further questions.]</p>	Yes	No
10	<p>What medication is required?</p> <p><input type="checkbox"/> Lumacaftor / Ivacaftor (Orkambi) (If checked, go to 11)</p> <p><input type="checkbox"/> Tezacaftor / Ivacaftor (Symdeko) (If checked, go to 13)</p> <p><input type="checkbox"/> Ivacaftor (Kalydeco) (If checked, go to 16)</p> <p><input type="checkbox"/> Elexacaftor / Tezacaftor / Ivacaftor (Trikafta) (If checked, go to 19)</p> <p><input type="checkbox"/> Vanzacaftor / Tezacaftor / Deutivacaftor (Alyftrek) (If checked, go to 21)</p>		

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	<input type="checkbox"/> Other (If checked, no further questions)		
11	Is the patient greater than or equal to 1 years of age? [If no, no further questions.]	Yes	No
12	Does the patient have cystic fibrosis that is homozygous for the F508del (Phe508del) mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene (this means the patient has two copies of the F508del (Phe508del) mutation)? ACTION REQUIRED: Submit supporting documentation. [Note: Documentation required is FDA-approved CF mutation test result.] [No further questions.]	Yes	No
13	Is the patient greater than or equal to 6 years of age? [If no, no further questions.]	Yes	No
14	Does the patient have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (See Appendix A)? Please specify mutation: _____. <b>[Internal CRU note: Please confirm the mutation is in the list provided in Appendix A.]</b>  <input type="checkbox"/> Yes (No further questions)  <input type="checkbox"/> No (If checked, go to 15)  <input type="checkbox"/> Unknown (If checked, no further questions)		
15	Does the patient have two copies of the F508del mutation? ACTION REQUIRED: Submit supporting documentation. [Note: Documentation required is FDA-approved CF mutation test result.] [No further questions.]	Yes	No
16	Is the patient homozygous for the phe508del (F508del) mutation in the cystic fibrosis transmembrane regulator (CFTR) gene? [If yes, no further questions.]	Yes	No
17	Does the patient have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G-->A, 3272-26A-->G, 3849+10kbC-->T, 711+3A-->G, E831X, OR R117H? ACTION REQUIRED: Submit supporting documentation. [Note: Documentation required is FDA-approved CF mutation test result.]  <input type="checkbox"/> Yes (If checked, go to 18)  <input type="checkbox"/> No (If checked, no further questions)		

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	<input type="checkbox"/> Unknown (If checked, no further questions)		
18	Is the patient greater than or equal to 1 month of age? [No further questions.]	Yes	No
19	Is the patient greater than or equal to 2 years of age? [If no, no further questions.]	Yes	No
20	<p>Does the patient have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (See Appendix B)? ACTION REQUIRED: Submit supporting documentation. [Note: Documentation required is FDA-approved CF mutation test result.] Please specify mutation: _____.</p> <p><b>[Internal CRU note: Please confirm the mutation is in the list provided in Appendix B.]</b></p> <p><input type="checkbox"/> Yes (If checked, no further questions)</p> <p><input type="checkbox"/> No (If checked, no further questions)</p> <p><input type="checkbox"/> Unknown (If checked, no further questions)</p>		
21	Is the patient greater than or equal to 6 years of age? [If no, no further questions.]	Yes	No
22	<p>Does the patient have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (See Appendix C)? ACTION REQUIRED: Submit supporting documentation. [Note: Documentation required is FDA-approved CF mutation test result.] Please specify mutation: _____.</p> <p><b>[Internal CRU note: Please confirm the mutation is in the list provided in Appendix C.]</b></p> <p><input type="checkbox"/> Yes (If checked, no further questions)</p> <p><input type="checkbox"/> No (If checked, no further questions)</p> <p><input type="checkbox"/> Unknown (If checked, no further questions)</p>		

### APPENDIX A

List of *CFTR* gene (Symdeco):

E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A → G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G → A, 3272-26A → G, 3849 + 10kbC → T, 546insCTA, A120T, A234D, A349V, A554E, A1006E, D192G, D443Y, D443Y;G57A;R668C, D614G, D836Y, D924N, D979V, I618T, I807M, I980K, I1027T, I1139V, I1269N, I1366N, L15P, L320V, R170H, R258G, R334L, R334Q, R347L, R347P, R352W, R553Q, R668C, R751L, V1293G, E60K,

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E92K, E116K, E403D, E558V, E822K, F191V, F311del, F311L, F508C, F508C;S1251N, F575Y, L346P, L967S, L997F, L1324P, L1335P, L1480P, M152V, M265R, M952I, R1066H, R1070Q, R1162L, R1283M, R1283S, S549N, S549R, S589N, S737F, S912L, F1016S, F1099L, G126D, G178E, G178R, G194R, G194V, G314E, G551D, G551S, G576A, G576A;R668C, M952T, P5L, P205S, Q98R, Q237E, Q237H, Q359R, Q1291R, R31L, S1251N, S1255P, T338I, T1036N, T1053I, V201M, V232D, V562I, V754M, V1153E, G622D, G970D, G1069R, G1244E, G1249R, G1349D, H939R, H1054D, H1375P, I148T, I175V, I336K, I601F, R74Q, R74W;D1270N, R74W;V201M, R74W;V201M;D1270N, R75Q, R117G, R117H, R117L, R117P, W1282R, Y109N, Y161S, Y1014C, Y1032C, R792G, R933G, S1159F, S1159P, or V1240G.

## **APPENDIX B**

List of *CFTR* gene (Trikafta):

F508del, 3141del9, E822K, G1069R, L967S, R117L, S912L, 546insCTA, F191V, G1244E, L997F, R117P, S945L, A46D, F311del, G1249R, L1077P, R170H, S977F, A120T, F311L, G1349D, L1324P, R258G, S1159F, A234D, F508C, H139R, L1335P, R334L, S1159P, A349V, F508C;S1251N, H199Y, L1480P, R334Q, S1251N, A455E, H939R, M152V, R347H, S1255P, A554E, F575Y, H1054D, M265R, R347L, T338I, A1006E, F1016S, H1085P, M952I, R347P, T1036N, A1067T, F1052V, H1085R, M952T, R352Q, T1053I, D110E, F1074L, H1375P, M1101K, R352W, V201M, D110H, F1099L, I148T, P5L, R553Q, V232D, D192G, G27R, I175V, P67L, R668C, V456A, D443Y, G85E, I336K, P205S, R751L, V456F, D443Y;G576A;R668C, G126D, I502T, P574H, R792G, V562I, D579G, G178E, I601F, Q98R, R933G, V754M, D614G, G178R, I618T, Q237E, R1066H, V1153E, D836Y, G194R, I807M, Q237H, R1070Q, V1240G, D924N, G194V, I980K, Q359R, R1070W, V1293G, D979V, G314E, I1027T, Q1291R, R1162L, W361R, D1152H, G463V, I1139V, R31L, R1283M, W1098C, D1270N, G480C, I1269N, R74Q, R1283S, W1282R, E56K, G551D, I1366N, R74W, S13F, Y109N, E60K, G551S, K1060T, R74W;D1270N, S341P, Y161D, E92K, G576A, L15P, R74W;V201M, S364P, Y161S, E116K, G576A;R668C, L165S, R74W;V201M;D1270N, S492F, Y563N, E193K, G622D, L206W, R75Q, S549N, Y1014C, E403D, G628R, L320V, R117C, S549R, Y1032C, E474K, G970D, L346P, R117G, S589N, E588V, G1061R, L453S, R117H, S737F, 1507\_151del9, 2183A→G, 2789+5G→A, 3272-26A→G, 3849+10kbC→T, A107G, A309D, A262P, 491R, D1445N, D565G, D993Y, E116Q, E292K, E403D, F1107L, F200I, F587I, G1047R, G1123R, G12474R, G27E, G424S, G480S, G551A, G970S, H620P, H260Q, H939R;H949L, I105N, I125T, I1331N, I148N, 1506L, I556V, K162E, K464E, L1011S, L137P, L333F, L333H, L441P, L619S, 1137V, M150K, N1088D, N1303K, N1303I, N186K, N187K, N418S, P140S, P499A, P705L, Q1313K, Q372H, Q493R, Q552P, R1048G, R117;G576A;R668C, R297Q, R31C, R334L, R516S, F555G, R709Q, R75L, S1045Y, S108F, S1118F, S1235R, T1086I, T1246I, T1299I, V392G, V603F, Y301C, 4005+2T→C, 2789+2insA, 3849+40A→G, 5T;TG13, 1341G→A, 296+28A→G, 3849+4A→G, 621+3A→G, 1898+3A→G, 304115T→G, 3850-3T→G, 711+3A→G, 2752-26A→G, 3600G→A, 5T;TG12, or E831X.

## **APPENDIX C**

List of *CFTR* gene (Alyftrek):

F508del, A455E, G551D, L1077P, R352Q, S549N, V754M, D1152H, G85E, L206W, R75Q, S549R, W1098C, H1054D, M1101K, S1159F, S945L, W1282R, G1244E, I336K, R1066H, S1251N, V562I, Y563N, 1507\_1515del9, E116Q, G424S, I556V, P140S, R334L, T1053I, 2183A→G, E193K, G463V, I601F, P205S, R334Q, T1086I, 3141del9, E292K, G480C, I618T, P499A, R347H, T1246I, 3195del6, E403D, G480S, I807M, P5L, R347L, T1299I, 3199del6, E474K, G551A, I980K, P574H, R347P, T338I, 546insCTA, E56K, G551S, K1060T, P67L, R352W, T351I, A1006E, E588V, G576A, K162E, P750L, R516G, T604I, A1067P, E60K, G576A;R668C, K464E, P99L, R516S, V1153E, A1067T, E822K, G622D, L1011S, Q1100P, R553Q, V1240G, A107G, E92K, G628R, L102R, Q1291R, R555G, V1293G, A120T, F1016S, G91R, L1065P, Q1313K, R560S, V201M, A234D, F1052V, G970D, L1324P, Q237E, R560T, V232D, A309D, F1074L, G970S, L1335P, Q237H, R668C, V392G, A349V, F1099L, H1085P, L137P, Q359R, R709Q, V456A, A46D, F1107L, H1085R, L1480P, Q372H, R74Q, V456F, A554E, F191V, H1375P, L15P, Q452P, R74W, V520F, A559T, F200I, H139R, L165S, Q493R, R74W;D1270N, V603F, A559V, F311del, H199R, L320V, Q552P, R74W;V201M, W361R, A561E, F311L, H199Y, L333F, Q98R, R74W;V201M;D,

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1270N, Y1014C, A613T, F508C, H609R, L333H, R1048G, R75L, Y1032C, A62P, F508C;S1251N, H620P, L346P, R1066C, R751L, Y109N, A72D, F575Y, H620Q, L441P, R1066L, R792G, Y161D, C491R, F587I, H939R, L453S, R1066M, R933G, Y161S, D110E, G1047R, H939R;H949L, L619S, R1070Q, S1045Y, Y301C, D110H, G1061R, I1027T, L967S, R1070W, S108F, Y569C, D1270N, G1069R, I105N, L997F, R1162L, S1118F, Y913C, D1445N, G1123R, I1139V, M1101R, R117C, S1159P, D192G, G1247R, I1234Vdel6aa, M1137V, R117C;G576A;R668C, S1235R, D443Y, G1249R, I125T, M150K, R117G, S1255P, D443Y;G576A;R668C, G126D, I1269N, M152V, R117H, S13F, D513G, G1349D, I331N, M265R, R117L, S341P, D565G, G149R, I1366N, M952I, R117P, S364P, D579G, G178E, I1398S, M952T, R1283M, S492F, D614G, G178R, I148N, N1088D, R1283S, S549I, D836Y, G194R, I148T, N1303I, R170H, S589N, D924N, G194V, I175V, N1303K, R258G, S737F, D979V, G27E, I502T, N186K, R297Q, S912L, D993Y, G27R, I506L, N187K, R31C, S977F, E116K, G314E, I506T, N418S, R31L, T1036N, 1341G→A, 2789+2insA, 3041-15T→G, 3849+10kbC→T, 3850-3T→G, 5T;TG13, 711+3A→G, 1898+3A→G, 2789+5G→A, 3272-26A→G, 3849+4A→G, 4005+2T→C, 621+3A→G, E831X 2752-26A→G, 296+28A→G, 3600G→A, 3849+40A→G, 5T;TG12.

**Please document the diagnoses, symptoms, and/or any other information important to this review:**

### SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

**FAX COMPLETED FORM TO: 1-833-896-0656**

**Disclaimer:** An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

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