

**Texas Prior Authorization Program  
Clinical Criteria**

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## **Cystic Fibrosis Agents**

### **Clinical Information Included in this Document**

#### **Kalydeco (Ivacaftor)**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

**Note:** Click the hyperlink to navigate directly to that section.

#### **Orkambi (Lumacaftor/Ivacaftor)**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

**Note:** Click the hyperlink to navigate directly to that section.

**Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

**Note:** Click the hyperlink to navigate directly to that section.

**Trikafta (Elexacaftor/Tezacaftor/ivacaftor)**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

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**Revision Notes**

Added concurrent therapy check to Kalydeco (question 8, pages 4-6), Orkambi (question 8, pages 17 and 18) and Symdeko (question 4, pages 25 and 26)

Added criteria for Trikafta, pages 28 -35

Updated question 11 in criteria logic and logic diagram, page 36, as recommended by DUR Board

Updated references, page 36



## Kalydeco (Ivacaftor)

### Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](http://TxVendorDrug.com/formulary/formulary-search).

Drugs Requiring Prior Authorization	
Label Name	GCN
KALYDECO 150MG TABLET	31312
KALYDECO 25MG GRANULES PACKET	46238
KALYDECO 50MG GRANULES PACKET	38138
KALYDECO 75MG GRANULES PACKET	38139



## Kalydeco (Ivacaftor)

### Clinical Criteria Logic

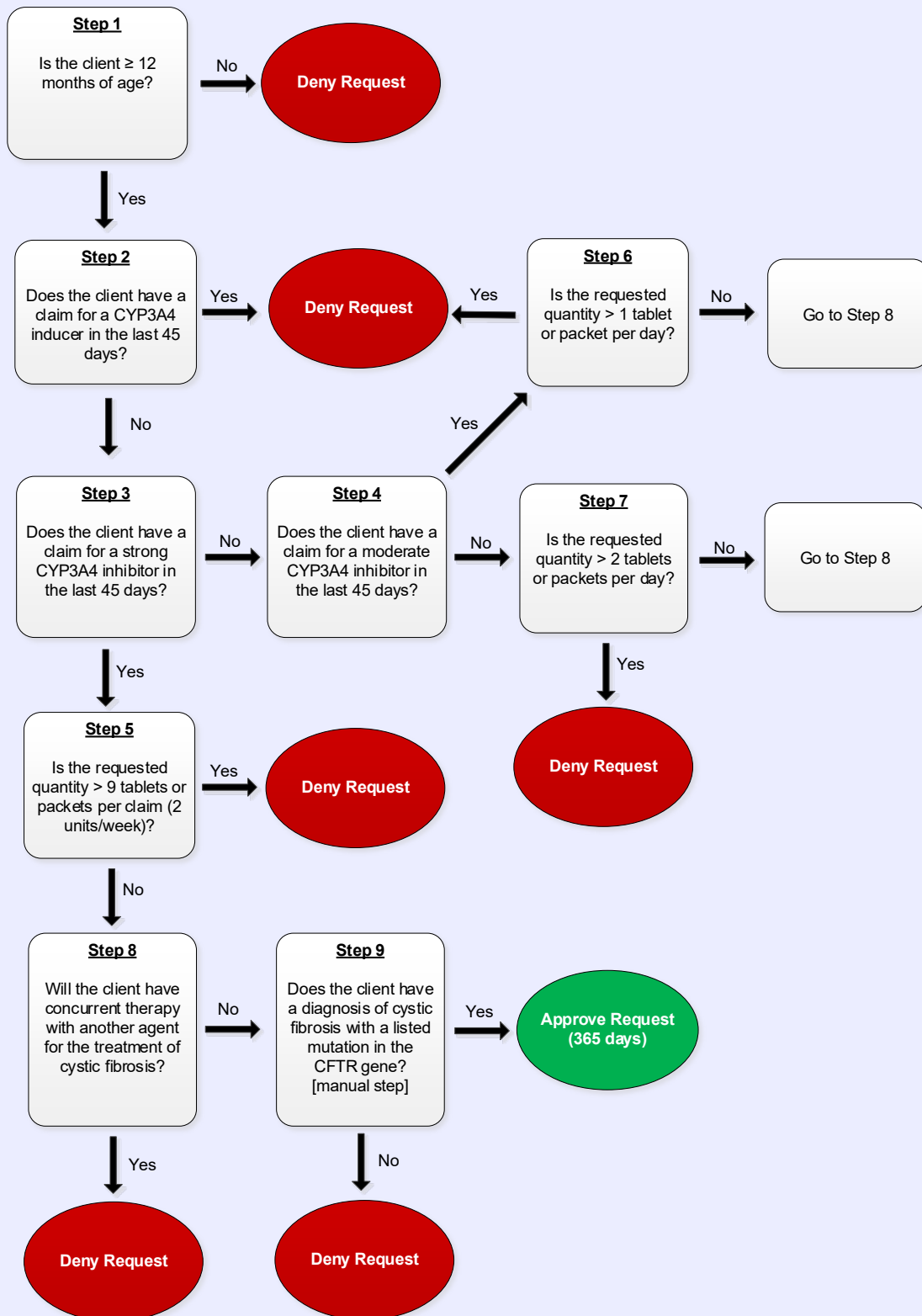
1. Is the client greater than or equal to ( $\geq$ ) 6 months of age?  
 Yes (Go to #2)  
 No (Deny)
2. Does the client have a claim for a **CYP3A4 inducer** in the last 45 days?  
 Yes (Deny)  
 No (Go to #3)
3. Does the client have a claim for a **strong CYP3A4 inhibitor** in the last 45 days?  
 Yes (Go to #5)  
 No (Go to #4)
4. Does the client have a claim for a **moderate CYP3A4 inhibitor** in the last 45 days?  
 Yes (Go to #6)  
 No (Go to #7)
5. Is the requested quantity greater than ( $>$ ) nine tablets or packets per claim (2 units per week)?  
 Yes (Deny)  
 No (Go to #8)
6. Is the requested quantity greater than ( $>$ ) one tablet or packet per day?  
 Yes (Deny)  
 No (Go to #8)
7. Is the requested quantity greater than ( $>$ ) two tablets or packets per day?  
 Yes (Deny)  
 No (Go to #8)
8. Will the client have concurrent therapy with **Orkambi, Symdeko and/or Trikafta**?  
 Yes (Deny)  
 No (Go to #9)

9. Manual step – Does the client have a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193K, E56K, E831X, F1052V, F1074L, G1069R, G1244E, G1349D, G178R, G551D, G551S, K1060T, L206W, P67L, R1070Q, R1070W, R117C, R117H, R347H, R352Q, R74W, S1251N, S1255P, S549N, S549R, S945L, S977F, 2789+5G, 3272-26A, 3849+10kbC or 711+3A?
- Yes (Approve – 365 days)
- No (Deny)



# Kalydeco (Ivacaftor)

## Clinical Criteria Logic Diagram





## Kalydeco (Ivacaftor)

### Clinical Criteria Supporting Tables

<b>Step 2 (history of a CYP3A4 inducer)</b> <b>Number of claims: 1</b> <b>Look back timeframe: 45 days</b>	
Label Name	GCN
APTIOM 200 MG TABLET	36098
APTIOM 400 MG TABLET	36099
APTIOM 600 MG TABLET	36106
APTIOM 800 MG TABLET	27409
ARMODAFINIL 150 MG TABLET	98590
ARMODAFINIL 200 MG TABLET	36082
ARMODAFINIL 250 MG TABLET	98592
ARMODAFINIL 50 MG TABLET	98591
ATRIPLA TABLET	27346
BANZEL 200 MG TABLET	98836
BANZEL 40 MG/ML SUSPENSION	29462
BANZEL 400 MG TABLET	98837
BEXAROTENE 75 MG CAPSULE	92373
BOSENTAN 125 MG TABLET	14978
BOSENTAN 62.5MG TABLET	14979
CARBAMAZEPINE 100 MG TAB CHEW	17460
CARBAMAZEPINE 100 MG/5 ML SUSP	47500
CARBAMAZEPINE 200 MG TABLET	17450
CARBAMAZEPINE ER 100 MG CAP	23934
CARBAMAZEPINE ER 100 MG TAB	27820
CARBAMAZEPINE ER 200 MG CAP	23932
CARBAMAZEPINE ER 200 MG TABLET	27821
CARBAMAZEPINE ER 300 MG CAP	23933
CARBAMAZEPINE ER 400 MG TABLET	27822
CARBATROL ER 100 MG CAPSULE	23934
CARBATROL ER 200 MG CAPSULE	23932
CARBATROL ER 300 MG CAPSULE	23933
CLOBAZAM 10 MG TABLET	09071
CLOBAZAM 2.5 MG/ML SUSPENSION	35026
CLOBAZAM 20 MG TABLET	09070
DEXAMETHASONE 0.5 MG TABLET	27422
DEXAMETHASONE 0.5 MG/5 ML ELX	27400

<b>Step 2 (history of a CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Label Name</b>	<b>GCN</b>
DEXAMETHASONE 0.5 MG/5 ML LIQ	27411
DEXAMETHASONE 0.75 MG TABLET	27425
DEXAMETHASONE 1 MG TABLET	27424
DEXAMETHASONE 1.5 MG TABLET	27427
DEXAMETHASONE 2 MG TABLET	27426
DEXAMETHASONE 4 MG TABLET	27428
DEXAMETHASONE 4 MG/ML VIAL	27354
DEXAMETHASONE 6 MG TABLET	27429
DEXAMETHASONE INTENSOL 1 MG/ML	27412
DICLOXACILLIN 250 MG CAPSULE	39541
DICLOXACILLIN 500 MG CAPSULE	39542
DILANTIN 100 MG CAPSULE	17700
DILANTIN 125 MG/5 ML SUSP	17241
DILANTIN 30 MG CAPSULE	17701
DILANTIN 50 MG INFATAB	17250
EFAVIRENZ 600 MG TABLET	15555
EPITOL 200 MG TABLET	17450
EQUETRO 100 MG CAPSULE	13781
EQUETRO 200 MG CAPSULE	13805
EQUETRO 300 MG CAPSULE	13818
INTELENCE 100 MG TABLET	99318
INTELENCE 200 MG TABLET	29424
INTELENCE 25 MG TABLET	32035
LYSODREN 500 MG TABLET	37810
MODAFINIL 100 MG TABLET	26101
MODAFINIL 200 MG TABLET	26102
MYCOBUTIN 150 MG CAPSULE	29810
MYSOLINE 250 MG TABLET	17321
MYSOLINE 50 MG TABLET	17322
NEVIRAPINE 200MG TABLET	31420
NEVIRAPINE ER 400MG TABLET	29767
NUVIGIL 150 MG TABLET	98590
NUVIGIL 200 MG TABLET	36082
NUVIGIL 250 MG TABLET	98592
NUVIGIL 50 MG TABLET	98591
ONFI 10 MG TABLET	09071
ONFI 2.5 MG/ML SUSPENSION	35026
ONFI 20 MG TABLET	09070



<b>Step 2 (history of a CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Label Name</b>	<b>GCN</b>
ORILISSA 150 MG TABLET	45026
ORILISSA 200 MG TABLET	45028
ORKAMBI 100-125 MG GRANULE PKT	36937
ORKAMBI 100-125 MG TABLET	42366
ORKAMBI 150-188 MG GRANULE PKT	42848
ORKAMBI 200-125 MG TABLET	39008
OXCARBAZEPINE 150MG TABLET	21724
OXCARBAZEPINE 300MG TABLET	21721
OXCARBAZEPINE 300MG/5ML SUSP	21723
OXCARBAZEPINE 600MG TABLET	21722
OXTELLAR XR 150MG TABLET	33556
OXTELLAR XR 300 MG TABLET	33557
OXTELLAR XR 600MG TABLET	33558
PHENOBARBITAL 130 MG/ML VIAL	12892
PHENOBARBITAL 15 MG TABLET	12971
PHENOBARBITAL 16.2 MG TABLET	97706
PHENOBARBITAL 20 MG/5 ML ELIX	12956
PHENOBARBITAL 30 MG TABLET	12973
PHENOBARBITAL 32.4 MG TABLET	97965
PHENOBARBITAL 60 MG TABLET	12972
PHENOBARBITAL 64.8 MG TABLET	97966
PHENOBARBITAL 65 MG/ML VIAL	12894
PHENOBARBITAL 97.2 MG TABLET	97967
PHENYTEK 200 MG CAPSULE	15038
PHENYTEK 300 MG CAPSULE	15037
PHENYTOIN 125 MG/5 ML SUSP	17241
PHENYTOIN 50 MG TABLET CHEW	17250
PHENYTOIN 50 MG/ML VIAL	17200
PHENYTOIN SOD EXT 100 MG CAP	17700
PHENYTOIN SOD EXT 200 MG CAP	15038
PHENYTOIN SOD EXT 300 MG CAP	15037
PRIFTIN 150 MG TABLET	45911
PRIMIDONE 250 MG TABLET	17321
PRIMIDONE 50 MG TABLET	17322
PROVIGIL 100 MG TABLET	26101
PROVIGIL 200 MG TABLET	26102
RIFABUTIN 150 MG CAPSULE	29810
RIFADIN 150 MG CAPSULE	41260

<b>Step 2 (history of a CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Label Name</b>	<b>GCN</b>
RIFADIN 300 MG CAPSULE	41261
RIFADIN IV 600 MG VIAL	41470
RIFAMATE CAPSULE	89800
RIFAMPIN 150 MG CAPSULE	41260
RIFAMPIN 300 MG CAPSULE	41261
RIFAMPIN IV 600 MG VIAL	41470
RIFATER TABLET	14142
SUSTIVA 200 MG CAPSULE	43303
SUSTIVA 50 MG CAPSULE	43301
SUSTIVA 600 MG TABLET	15555
SYMFI 600-300-300 MG TABLET	44548
SYMFI LO 400-300-300 MG TABLET	44425
SYMPAZAN 10 MG FILM	45265
SYMPAZAN 20 MG FILM	45266
SYMPAZAN 5 MG FILM	45264
TAFINLAR 50 MG CAPSULE	34723
TAFINLAR 75 MG CAPSULE	34724
TARGRETIN 75 MG CAPSULE	92373
TEGRETOL 100 MG/5 ML SUSP	47500
TEGRETOL 200 MG TABLET	17450
TEGRETOL XR 100 MG TABLET	27820
TEGRETOL XR 200 MG TABLET	27821
TEGRETOL XR 400 MG TABLET	27822
TRACLEER 125 MG TABLET	14978
TRACLEER 32 MG TABLET FOR SUSP	43819
TRACLEER 62.5 MG TABLET	14979
TRILEPTAL 150 MG TABLET	21724
TRILEPTAL 300 MG TABLET	21721
TRILEPTAL 300 MG/ 5ML SUSP	21723
TRILEPTAL 600 MG TABLET	21722
VIRAMUNE 200 MG TABLET	31420
VIRAMUNE 50 MG/5 ML SUSPENSION	31421
VIRAMUNE XR 400 MG TABLET	29767
XERMELO 250 MG TABLET	43109
XTANDI 40 MG CAPSULE	33183
ZELBORAF 240 MG TABLET	30332

<b>Step 3 (history of a strong CYP3A4 inhibitor)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Label Name</b>	<b>GCN</b>
ATAZANAVIR SULFATE 150MG CAP	19952
ATAZANAVIR SULFATE 200MG CAP	19953
ATAZANAVIR SULFATE 300MG CAP	97430
CLARITHROMYCIN 125 MG/5 ML SUS	11670
CLARITHROMYCIN 250 MG TABLET	48852
CLARITHROMYCIN 250 MG/5 ML SUS	11671
CLARITHROMYCIN 500 MG TABLET	48851
CLARITHROMYCIN ER 500 MG TAB	48850
CRIXIVAN 200 MG CAPSULE	26820
CRIXIVAN 400 MG CAPSULE	26822
EVOTAZ 300-150MG TABLET	37797
GENVOYA TABLET	40092
INVIRASE 500 MG TABLET	23952
ITRACONAZOLE 10 MG/ML SOLUTION	49100
ITRACONAZOLE 100 MG CAPSULE	49101
KALETRA 100-25 MG TABLET	99101
KALETRA 200-50 MG TABLET	25919
KALETRA 400-100/5 ML ORAL SOLU	31782
KETOCONAZOLE 200 MG TABLET	42590
KORLYM 300 MG TABLET	31485
LANSOPRAZOL-AMOXICIL-CLARITHRO	64269
NEFAZODONE 100MG TABLET	16406
NEFAZODONE 150MG TABLET	16407
NEFAZODONE 200MG TABLET	16408
NEFAZODONE 250MG TABLET	16409
NEFAZODONE 50MG TABLET	16404
NORVIR 100 MG POWDER PACKET	40309
NORVIR 100 MG TABLET	28224
NORVIR 80 MG/ML SOLUTION	26810
NOXAFIL 40 MG/ML SUSPENSION	26502
NOXAFIL DR 100 MG TABLET	35649
OMECLAMOX-PAK COMBO PACK	32137
PREZCOBIX 150MG TABLET	37367
PREZISTA 100MG/ML SUSPENSION	31201
PREZISTA 150MG TABLET	23489
PREZISTA 600MG TABLET	99434

<b>Step 3 (history of a strong CYP3A4 inhibitor)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Label Name</b>	<b>GCN</b>
PREZISTA 75MG TABLET	16759
PREZISTA 800MG TABLET	33723
REYATAZ 150MG CAPSULE	19952
REYATAZ 200MG CAPSULE	19953
REYATAZ 300MG CAPSULE	37430
REYATAZ 50MG POWDER PACK	36647
RITONAVIR 100 MG TABLET	28224
SPORANOX 10 MG/ML SOLUTION	49100
SPORANOX 100 MG CAPSULE	49101
STRIBILD TABLET	33130
SYMTUZA 800-150-200-10 MG TAB	43968
TOLSURA 65 MG CAPSULE	45848
TYBOST 150MG TABLET	36468
VFEND 200 MG TABLET	17498
VFEND 40 MG/ML SUSPENSION	21513
VFEND 50 MG TABLET	17497
VFEND IV 200 MG VIAL	17499
VIEKIRA PAK	37614
VIEKIRA XR TABLET	41932
VIRACEPT 250 MG TABLET	40312
VIRACEPT 625 MG TABLET	19717
VORICONAZOLE 200 MG TABLET	17498
VORICONAZOLE 200 MG VIAL	17499
VORICONAZOLE 40 MG/ML SUSP	21513
VORICONAZOLE 50 MG TABLET	17497
ZYDELIG 100MG TABLET	36884
ZYDELIG 150MG TABLET	36885

<b>Step 4 (history of a moderate CYP3A4 inhibitor)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Description</b>	<b>GCN</b>
AKYNZEO 300-0.5 MG CAPSULE	37239
APREPITANT 125 MG CAPSULE	19366
APREPITANT 125-80-80 MG PACK	19367

<b>Step 4 (history of a moderate CYP3A4 inhibitor)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Description</b>	<b>GCN</b>
APREPITANT 40 MG CAPSULE	27278
APREPITANT 80 MG CAPSULE	19365
CALAN 120 MG TABLET	02341
CALAN SR 120 MG CAPLET	32472
CALAN SR 180 MG CAPLET	32471
CALAN SR 240 MG CAPLET	32470
CARDIZEM 120 MG TABLET	02363
CARDIZEM 30 MG TABLET	02360
CARDIZEM 60 MG TABLET	02361
CARDIZEM CD 120 MG CAPSULE	02326
CARDIZEM CD 180 MG CAPSULE	02323
CARDIZEM CD 240 MG CAPSULE	02324
CARDIZEM CD 300 MG CAPSULE	02325
CARDIZEM CD 360 MG CAPSULE	07460
CARDIZEM LA 180 MG TABLET	19183
CARTIA XT 120MG CAPSULE	02326
CARTIA XT 180MG CAPSULE	02323
CARTIA XT 240MG CAPSULE	02324
CARTIA XT 300MG CAPSULE	02325
COPIKTRA 15 MG CAPSULE	45424
COPIKTRA 25 MG CAPSULE	45425
CRESEMBA 186 MG CAPSULE	38095
CRESEMBA 372 MG VIAL	38094
DIFLUCAN 10 MG/ML SUSPENSION	60822
DIFLUCAN 100 MG TABLET	42190
DIFLUCAN 150 MG TABLET	42193
DIFLUCAN 200 MG TABLET	42191
DIFLUCAN 40 MG/ML SUSPENSION	60821
DIFLUCAN 50 MG TABLET	42192
DILT XR 120 MG CAPSULE	07463
DILT XR 180 MG CAPSULE	07461
DILT XR 240 MG CAPSULE	07462
DILTIAZEM 120 MG TABLET	02363
DILTIAZEM 12HR ER 120 MG CAP	02321
DILTIAZEM 12HR ER 60 MG CAP	02322
DILTIAZEM 12HR ER 90 MG CAP	02320

<b>Step 4 (history of a moderate CYP3A4 inhibitor)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Description</b>	<b>GCN</b>
DILTIAZEM 24HR ER 120 MG CAP	02326
DILTIAZEM 24HR ER 180 MG CAP	02323
DILTIAZEM 24HR ER 240 MG CAP	02324
DILTIAZEM 24HR ER 300 MG CAP	02325
DILTIAZEM 24HR ER 360 MG CAP	07460
DILTIAZEM 30 MG TABLET	02360
DILTIAZEM 60 MG TABLET	02361
DILTIAZEM 90 MG TABLET	02362
DILTIAZEM ER 120 MG CAPSULE	02330
DILTIAZEM ER 180 MG CAPSULE	02329
DILTIAZEM HCL ER 240 MG CAP	02332
DILTIAZEM HCL ER 300 MG CAP	02333
DILTIAZEM HCL ER 360 MG CAP	02328
DILTIAZEM HCL ER 420 MG CAP	94691
E.E.S. 200 MG/5 ML GRANULES	40523
E.E.S. 400 FILMTAB	40560
EMEND 125 MG POWDER PACKET	40344
EMEND 125MG CAPSULE	19366
EMEND 40MG CAPSULE	27278
EMEND 80MG CAPSULE	19365
EMEND TRIPACK	19367
ERYPED 200 MG/5 ML SUSPENSION	40523
ERYPED 400 MG/5 ML SUSPENSION	40524
ERY-TAB EC 250 MG TABLET	40730
ERY-TAB EC 333 MG TABLET	40731
ERY-TAB EC 500 MG TABLET	40732
ERYTHROCIN 250 MG FILMTAB	40642
ERYTHROCIN 500 MG ADDVNT VL	25529
ERYTHROMYCIN 200 MG/5 ML SUSP	40523
ERYTHROMYCIN 250 MG FILMTAB	40720
ERYTHROMYCIN 500 MG FILMTAB	40721
ERYTHROMYCIN EC 250 MG CAP	40660
ERYTHROMYCIN ES 400 MG TAB	40560
FLUCONAZOLE 10 MG/ML SUSP	60822
FLUCONAZOLE 100 MG TABLET	42190
FLUCONAZOLE 150 MG TABLET	42193

<b>Step 4 (history of a moderate CYP3A4 inhibitor)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Description</b>	<b>GCN</b>
FLUCONAZOLE 200 MG TABLET	42191
FLUCONAZOLE 40 MG/ML SUSP	60821
FLUCONAZOLE 50 MG TABLET	42192
FLUCONAZOLE-NACL 200 MG/100 ML	69790
FLUCONAZOLE-NACL 400 MG/200 ML	69791
FOSAMPRENAVIR 700 MG TABLET	20553
KISQALI 200 MG DAILY DOSE	43162
KISQALI 400 MG DAILY DOSE	43166
KISQALI 600 MG DAILY DOSE	43167
KISQALI FEMARA 200 MG CO-PACK	43366
KISQALI FEMARA 400 MG CO-PACK	43368
KISQALI FEMARA 600 MG CO-PACK	43369
LEXIVA 50MG/ML SUSPENSION	23783
LEXIVA 700MG TABLET	20553
MATZIM LA 180MG TABLET	19183
MATZIM LA 240MG TABLET	19184
MATZIM LA 300MG TABLET	19185
MATZIM LA 360MG TABLET	19186
MATZIM LA 420MG TABLET	19187
MULTAQ 400 MG TABLET	26586
PREVYMIS 240 MG TABLET	44049
PREVYMIS 480 MG TABLET	44061
TASIGNA 150 MG CAPSULE	28737
TASIGNA 200 MG CAPSULE	99070
TAZTIA XT 120MG CAPSULE	02330
TAZTIA XT 180MG CAPSULE	02329
TAZTIA XT 240MG CAPSULE	02332
TAZTIA XT 300MG CAPSULE	02333
TAZTIA XT 360MG CAPSULE	02328
TRANDOLAPR-VERAPAM ER 1-240 MG	32112
TRANDOLAPR-VERAPAM ER 2-180 MG	32111
TRANDOLAPR-VERAPAM ER 2-240 MG	32113
TRANDOLAPR-VERAPAM ER 4-240 MG	32114
VERAPAMIL 120 MG TABLET	02341
VERAPAMIL 360 MG CAP PELLETT	03004
VERAPAMIL 40 MG TABLET	47110

<b>Step 4 (history of a moderate CYP3A4 inhibitor)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Description</b>	<b>GCN</b>
VERAPAMIL 80 MG TABLET	02342
VERAPAMIL ER 120 MG CAPSULE	03003
VERAPAMIL ER 120 MG TABLET	32472
VERAPAMIL ER 180 MG CAPSULE	03001
VERAPAMIL ER 180 MG TABLET	32471
VERAPAMIL ER 240 MG CAPSULE	03002
VERAPAMIL ER 240 MG TABLET	32470
VERAPAMIL ER PM 100 MG CAPSULE	94122
VERAPAMIL ER PM 200 MG CAPSULE	94123
VERAPAMIL ER PM 300 MG CAPSULE	94124
VERELAN 120 MG CAP PELLETT	03003
VERELAN 180 MG CAP PELLETT	03001
VERELAN 240 MG CAP PELLETT	03002
VERELAN 360 MG CAP PELLETT	03004
VERELAN PM 100 MG CAP PELLETT	94122
VERELAN PM 200 MG CAP PELLETT	94123
VERELAN PM 300 MG CAP PELLETT	94124
XALKORI 200 MG CAPSULE	30458
XALKORI 250 MG CAPSULE	30457
ZYKADIA 150MG CAPSULE	36447

<b>Step 8 (agents for the treatment of Cystic Fibrosis)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: concurrent therapy</b>	
<b>Label Name</b>	<b>GCN</b>
ORKAMBI 100-125MG GRANULE PKT	36937
ORKAMBI 100MG-125MG TABLET	42366
ORKAMBI 150-188MG GRANULE PKT	42848
ORKAMBI 200MG-125MG TABLET	39008
SYMDEKO 100/150-150 MG TABS	44444
SYMDEKO 50/75-75 MG TABS	46553
TRIKAFTA 100/50/75MG-150MG	47136





## Orkambi (Lumacaftor/Ivacaftor)

### Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](http://TxVendorDrug.com/formulary/formulary-search).

Drugs Requiring Prior Authorization	
Label Name	GCN
ORKAMBI 100MG-125MG TABLET	42366
ORKAMBI 100-125MG GRANULE PKT	36937
ORKAMBI 150-188MG GRANULE PKT	42848
ORKAMBI 200MG-125MG TABLET	39008



## Orkambi (Lumacaftor/Ivacaftor)

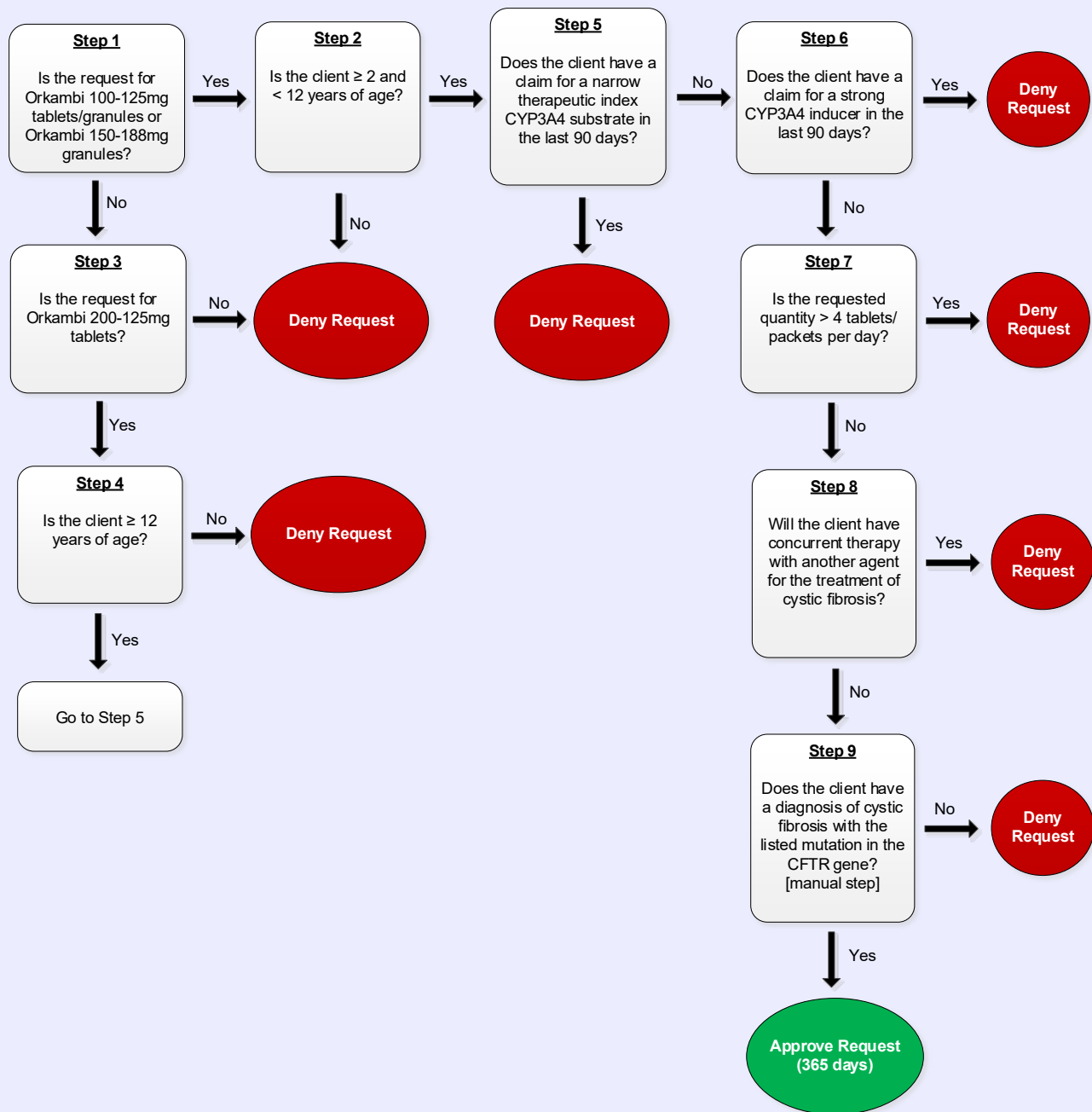
### Clinical Criteria Logic

1. Is the request for Orkambi 100-125mg tablets/granules or Orkambi 150-188mg granules?  
 Yes (Go to #2)  
 No (Go to #3)
2. Is the client greater than or equal to ( $\geq$ ) 2 years of age and less than ( $<$ ) 12 years of age?  
 Yes (Go to #5)  
 No (Deny)
3. Is the request for Orkambi 200-125mg tablets?  
 Yes (Go to #4)  
 No (Deny)
4. Is the client greater than or equal to ( $\geq$ ) 12 years of age?  
 Yes (Go to #5)  
 No (Deny)
5. Does the client have a claim for a **narrow therapeutic index CYP3A4 substrate** in the last 90 days?  
 Yes (Deny)  
 No (Go to #6)
6. Does the client have a claim for a **strong CYP3A4 inducer** in the last 90 days?  
 Yes (Deny)  
 No (Go to #7)
7. Is the requested quantity greater than ( $>$ ) 4 tablets/packets per day?  
 Yes (Deny)  
 No (Go to #8)
8. Will the client have concurrent therapy with **Kalydeco, Symdeko and/or Trikafta**?  
 Yes (Deny)  
 No (Go to #9)
9. Manual step – Is Orkambi being used for the treatment of cystic fibrosis in a client that is homozygous for the F508del mutation in the CFTR gene?  
 Yes (Approve – 365 days)  
 No (Deny)



# Orkambi (Lumacaftor/Ivacaftor)

## Clinical Criteria Logic Diagram





## Orkambi (Lumacaftor/Ivacaftor)

### Clinical Criteria Supporting Tables

<b>Step 5 (history of a narrow therapeutic index CYP3A4 substrate)</b> <b>Number of claims: 1</b> <b>Look back timeframe: 90 days</b>	
<b>Description</b>	<b>GCN</b>
AFINITOR 10MG TABLET	20844
AFINITOR 2.5MG TABLET	28783
AFINITOR 5MG TABLET	20784
AFINITOR 7.5MG TABLET	31396
AFINITOR DISPERZ 2MG TABLET	34589
AFINITOR DISPERZ 3MG TABLET	34590
AFINITOR DISPERZ 5MG TABLET	34592
CYCLOSPORINE 100MG CAPSULE	13910
CYCLOSPORINE 100MG/ML SOLN	13917
CYCLOSPORINE 25MG CAPSULE	13911
CYCLOSPORINE MODIFIED 100MG	13919
CYCLOSPORINE MODIFIED 25MG	13918
CYCLOSPORINE MODIFIED 50MG	13916
ENVARUSUS XR 0.75MG TABLET	39120
ENVARUSUS XR 1MG TABLET	39123
ENVARUSUS XR 4MG TABLET	39124
GENGRAF 100MG CAPSULE	13919
GENGRAF 100MG/ML SOLUTION	13917
GENGRAF 25MG CAPSULE	13918
GENGRAF 50MG CAPSULE	13916
NEORAL 100MG GELATIN CAPSULE	13919
NEORAL 100MG/ML SOLUTION	13917
NEORAL 25MG GELATIN CAPSULE	13918
PROGRAF 0.5MG CAPSULE	28495
PROGRAF 1MG CAPSULE	28491
PROGRAF 5MG CAPSULE	28492
RAPAMUNE 0.5MG TABLET	28502
RAPAMUNE 1MG TABLET	13696

<b>Step 5 (history of a narrow therapeutic index CYP3A4 substrate)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 90 days</b>	
<b>Description</b>	<b>GCN</b>
RAPAMUNE 1MG/ML ORAL SOLN	50356
RAPAMUNE 2MG TABLET	19299
SANDIMMUNE 100MG CAPSULE	13910
SANDIMMUNE 100MG/ML SOLN	08220
SANDIMMUNE 25MG CAPSULE	13911
SIROLIMUS 0.5MG TABLET	28502
SIROLIMUS 1MG TABLET	13696
SIROLIMUS 2MG TABLET	19299
TACROLIMUS 0.5MG CAPSULE	28495
TACROLIMUS 1MG CAPSULE	28491
TACROLIMUS 5MG CAPSULE	28492
TRIAZOLAM 0.125MG TABLET	14282
TRIAZOLAM 0.25MG TABLET	14280
ZORTRESS 0.25MG TABLET	24825
ZORTRESS 0.5MG TABLET	24826
ZORTRESS 0.75MG TABLET	24827

<b>Step 6 (history of a strong CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 90 days</b>	
<b>Description</b>	<b>GCN</b>
ACTOPLUS MED 15-850MG TABLET	25445
ACTOPLUS MET 15-500MG TABLET	25444
ACTOPLUS MET XR 15-1000MG TABLET	28620
ACTOPLUS MET XR 30-1000MG TABLET	28622
ACTOS 15MG TABLET	92991
ACTOS 30MG TABLET	93001
ACTOS 45MG TABLET	93011
ALOGLIPTIN-PIOGLIT 12.5-15MG	34080
ALOGLIPTIN-PIOGLIT 12.5-30MG	34083
ALOGLIPTIN-PIOGLIT 12.5-45MG	34084
ALOGLIPTIN-PIOGLIT 25-15MG TB	34077
ALOGLIPTIN-PIOGLIT 25-30MG TB	34078
ALOGLIPTIN-PIOGLIT 25-45MG TB	34079
ATRIPLA TABLET	27346

<b>Step 6 (history of a strong CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 90 days</b>	
<b>Description</b>	<b>GCN</b>
CARBAMAZEPINE 100 MG TAB CHEW	17460
CARBAMAZEPINE 100 MG/5 ML SUSP	47500
CARBAMAZEPINE 200 MG TABLET	17450
CARBAMAZEPINE ER 100 MG CAP	23934
CARBAMAZEPINE ER 100 MG TABLET	27820
CARBAMAZEPINE ER 200 MG CAP	23932
CARBAMAZEPINE ER 200 MG TABLET	27821
CARBAMAZEPINE ER 300 MG CAP	23933
CARBAMAZEPINE ER 400 MG TABLET	27822
CARBATROL ER 100 MG CAPSULE	23934
CARBATROL ER 200 MG CAPSULE	23932
CARBATROL ER 300 MG CAPSULE	23933
DILANTIN 100 MG CAPSULE	17700
DILANTIN 125 MG/5 ML SUSP	17241
DILANTIN 30 MG CAPSULE	17701
DILANTIN 50 MG INFATAB	17250
DUETACT 30-2MG TABLET	97181
DUETACT 30-4MG TABLET	97180
EPITOL 200 MG TABLET	17450
EQUETRO 100 MG CAPSULE	13781
EQUETRO 200 MG CAPSULE	13805
EQUETRO 300 MG CAPSULE	13818
MYCOBUTIN 150 MG CAPSULE	29810
NEVIRAPINE 200MG TABLET	31420
NEVIRAPINE 50MG/5ML SUSPENSION	31421
NEVIRAPINE ER 400MG TABLET	29767
OSENI 12.5-15MG TABLET	34080
OSENI 12.5-30MG TABLET	34083
OSENI 12.5-45MG TABLET	34084
OSENI 25-15MG TABLET	34077
OSENI 25-30MG TABLET	34078
OSENI 25-45MG TABLET	34079
PHENOBARBITAL 100 MG TABLET	12975
PHENOBARBITAL 130 MG/ML VIAL	12892
PHENOBARBITAL 15 MG TABLET	12971
PHENOBARBITAL 16.2 MG TABLET	97706

<b>Step 6 (history of a strong CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 90 days</b>	
<b>Description</b>	<b>GCN</b>
PHENOBARBITAL 20 MG/5 ML ELIX	12956
PHENOBARBITAL 30 MG TABLET	12973
PHENOBARBITAL 32.4 MG TABLET	97965
PHENOBARBITAL 60 MG TABLET	12972
PHENOBARBITAL 64.8 MG TABLET	97966
PHENOBARBITAL 65 MG/ML VIAL	12894
PHENOBARBITAL 97.2 MG TABLET	97967
PHENYTEK 200 MG CAPSULE	15038
PHENYTEK 300 MG CAPSULE	15037
PHENYTOIN 125 MG/5 ML SUSP	17241
PHENYTOIN 50 MG TABLET CHEW	17250
PHENYTOIN 50 MG/ML VIAL	17200
PHENYTOIN SOD EXT 100 MG CAP	17700
PHENYTOIN SOD EXT 200 MG CAP	15038
PHENYTOIN SOD EXT 300 MG CAP	15037
PIOGLITAZONE HCL 15 MG TABLET	92991
PIOGLITAZONE HCL 30 MG TABLET	93001
PIOGLITAZONE HCL 45 MG TABLET	93011
PIOGLITAZONE-GLIMEPIRIDE 30-2	97181
PIOGLITAZONE-GLIMEPIRIDE 30-4	97180
PIOGLITAZONE-METFORMIN 15-500	25444
PIOGLITAZONE-METFORMIN 15-850	25445
RIFABUTIN 150 MG CAPSULE	29810
RIFADIN 150 MG CAPSULE	41260
RIFADIN 300 MG CAPSULE	41261
RIFADIN IV 600 MG VIAL	41470
RIFAMATE CAPSULE	89800
RIFAMPIN 150 MG CAPSULE	41260
RIFAMPIN 300 MG CAPSULE	41261
RIFAMPIN IV 600 MG VIAL	41470
RIFATER TABLET	14142
SUSTIVA 200MG CAPSULE	43303
SUSTIVA 50MG CAPSULE	43301
SUSTIVA 600MG TABLET	15555
TEGRETOL 100 MG/5 ML SUSP	47500
TEGRETOL 200 MG TABLET	17450

<b>Step 6 (history of a strong CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 90 days</b>	
<b>Description</b>	<b>GCN</b>
TEGRETOL XR 100 MG TABLET	27820
TEGRETOL XR 200 MG TABLET	27821
TEGRETOL XR 400 MG TABLET	27822
VIRAMUNE 200MG TABLET	31420
VIRAMUNE 50MG/5ML SUSPENSION	31421
VIRAMUNE XR 100MG TABLET	30935
VIRAMUNE XR 400MG TABLET	29767
XTANDI 40MG CAPSULE	33183

<b>Step 8 (agents for the treatment of Cystic Fibrosis)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: concurrent therapy</b>	
<b>Label Name</b>	<b>GCN</b>
KALYDECO 150MG TABLET	31312
KALYDECO 25MG GRANULES PACKET	46238
KALYDECO 50MG GRANULES PACKET	38138
KALYDECO 75MG GRANULES PACKET	38139
SYMDEKO 100/150-150 MG TABS	44444
SYMDEKO 50/75-75 MG TABS	46553
TRIKAFTA 100/50/75MG-150MG	47136





## Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

### Drugs Requiring Prior Authorization

The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](http://TxVendorDrug.com/formulary/formulary-search).

Drugs Requiring Prior Authorization	
Label Name	GCN
SYMDEKO 100/150-150 MG TABS	44444
SYMDEKO 50/75-75 MG TABS	46553



## Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

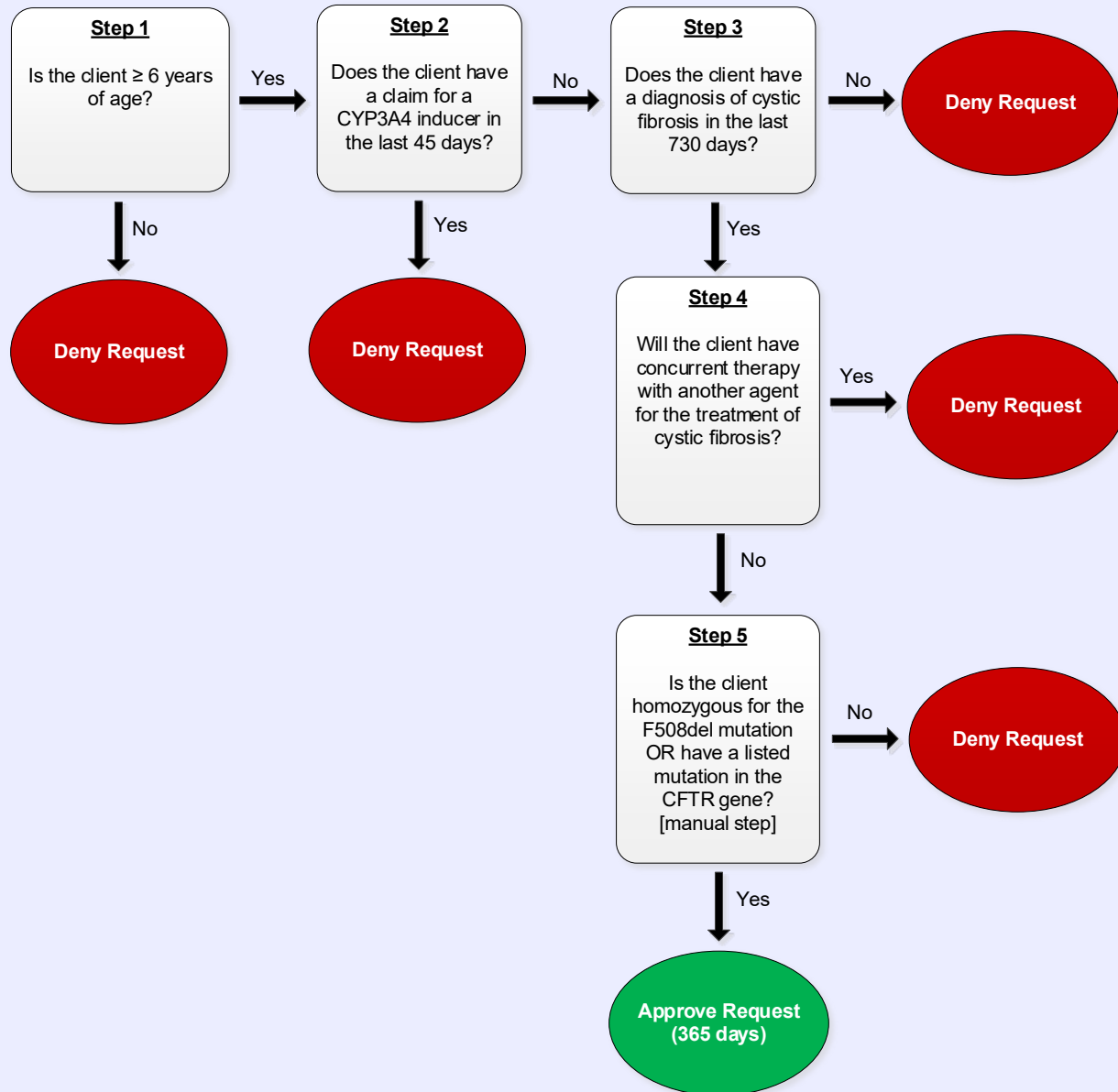
### Clinical Criteria Logic

1. Is the client greater than or equal to ( $\geq$ ) 6 years of age?  
 Yes (Go to #2)  
 No (Deny)
2. Does the client have a claim for a **CYP3A4 inducer** in the last 45 days?  
 Yes (Deny)  
 No (Go to #3)
3. Does the client have a diagnosis of **cystic fibrosis** in the last 730 days?  
 Yes (Go to #4)  
 No (Deny)
4. Will the client have concurrent therapy with **Kalydeco, Orkambi or Trikafta**?  
 Yes (Deny)  
 No (Go to #5)
5. Manual step – Is the client homozygous for the F508del mutation OR does the client have at least one of the following mutations in the CFTR gene: A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193K, E56K, E831X, F1052V, F1074L, K1060T, L206W, P67L, R1070W, R117C, R347H, R352Q, R74W, S945L, S977F, 711+3A->G, 2789+5G->A, 3272-26A->G, 3849+10kbC->T?  
 Yes (Approve – 365 days)  
 No (Deny)



# Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

## Clinical Criteria Logic Diagram





## Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

### Clinical Criteria Supporting Tables

#### Step 2 (claim for a CYP3A4 inducer)

**Number of claims: 1**

**Look back timeframe: 45 days**

For the list of GCNs that pertain to this step, see the **CYP3A4 inducer** table in the previous "Supporting Tables" section.

**Note:** Click the hyperlink to navigate directly to the table.

#### Step 3 (diagnosis of cystic fibrosis)

**Required diagnosis: 1**

**Look back timeframe: 730 days**

ICD-10 Code	Description
E840	CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
E8411	MECONIUM ILEUS IN CYSTIC FIBROSIS
E8419	CYSTIC FIBROSIS WITH OTHER INTESTINAL MANIFESTATIONS
E848	CYSTIC FIBROSIS WITH OTHER MANIFESTATIONS
E849	CYSTIC FIBROSIS, UNSPECIFIED

#### Step 4 (agents for the treatment of Cystic Fibrosis)

**Number of claims: 1**

**Look back timeframe: concurrent therapy**

Label Name	GCN
KALYDECO 150MG TABLET	31312
KALYDECO 25MG GRANULES PACKET	46238
KALYDECO 50MG GRANULES PACKET	38138
KALYDECO 75MG GRANULES PACKET	38139
ORKAMBI 100-125MG GRANULE PKT	36937
ORKAMBI 100MG-125MG TABLET	42366
ORKAMBI 150-188MG GRANULE PKT	42848
ORKAMBI 200MG-125MG TABLET	39008
TRIKAFTA 100/50/75MG-150MG	47136



**Trikafta**  
**(Elexcaftor/Tezacaftor/Ivacaftor)**  
**Drugs Requiring Prior Authorization**

*The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit [TxVendorDrug.com/formulary/formulary-search](http://TxVendorDrug.com/formulary/formulary-search).*

<b>Drugs Requiring Prior Authorization</b>	
<b>Label Name</b>	<b>GCN</b>
TRIKAFTA 100/50/75MG-150MG	47136



**Trikafta**  
**(Elexcaftor/Tezacaftor/Ivacaftor)**  
**Clinical Criteria Logic**

1. Is the client greater than or equal to ( $\geq$ ) 12 years of age?  
 Yes (Go to #2)  
 No (Deny)
2. Manual step – Does the client have a diagnosis of cystic fibrosis and at least one F508del mutation in the CFTR gene?  
 Yes (Go to #3)  
 No (Deny)
3. Does the client have a diagnosis of **severe hepatic impairment** in the last 365 days?  
 Yes (Deny)  
 No (Go to #4)
4. Does the client have a claim for a **CYP3A4 inducer** in the last 45 days?  
 Yes (Deny)  
 No (Go to #5)
5. Does the client have a claim for a **strong CYP3A4 inhibitor** in the last 45 days?  
 Yes (Go to #7)  
 No (Go to #6)
6. Does the client have a claim for a **moderate CYP3A4 inhibitor** in the last 45 days?  
 Yes (Go to #8)  
 No (Go to #9)
7. Is the daily dose adjusted for co-administration with a strong CYP3A4 inhibitor\*?  
 Yes (Go to #10)  
 No (Deny)
8. Is the daily dose adjusted for co-administration with a moderate CYP3A4 inhibitor\*?  
 Yes (Go to #10)  
 No (Deny)
9. Is the requested quantity greater than ( $>$ ) 84 tablets per 28 days?  
 Yes (Deny)  
 No (Go to #10)

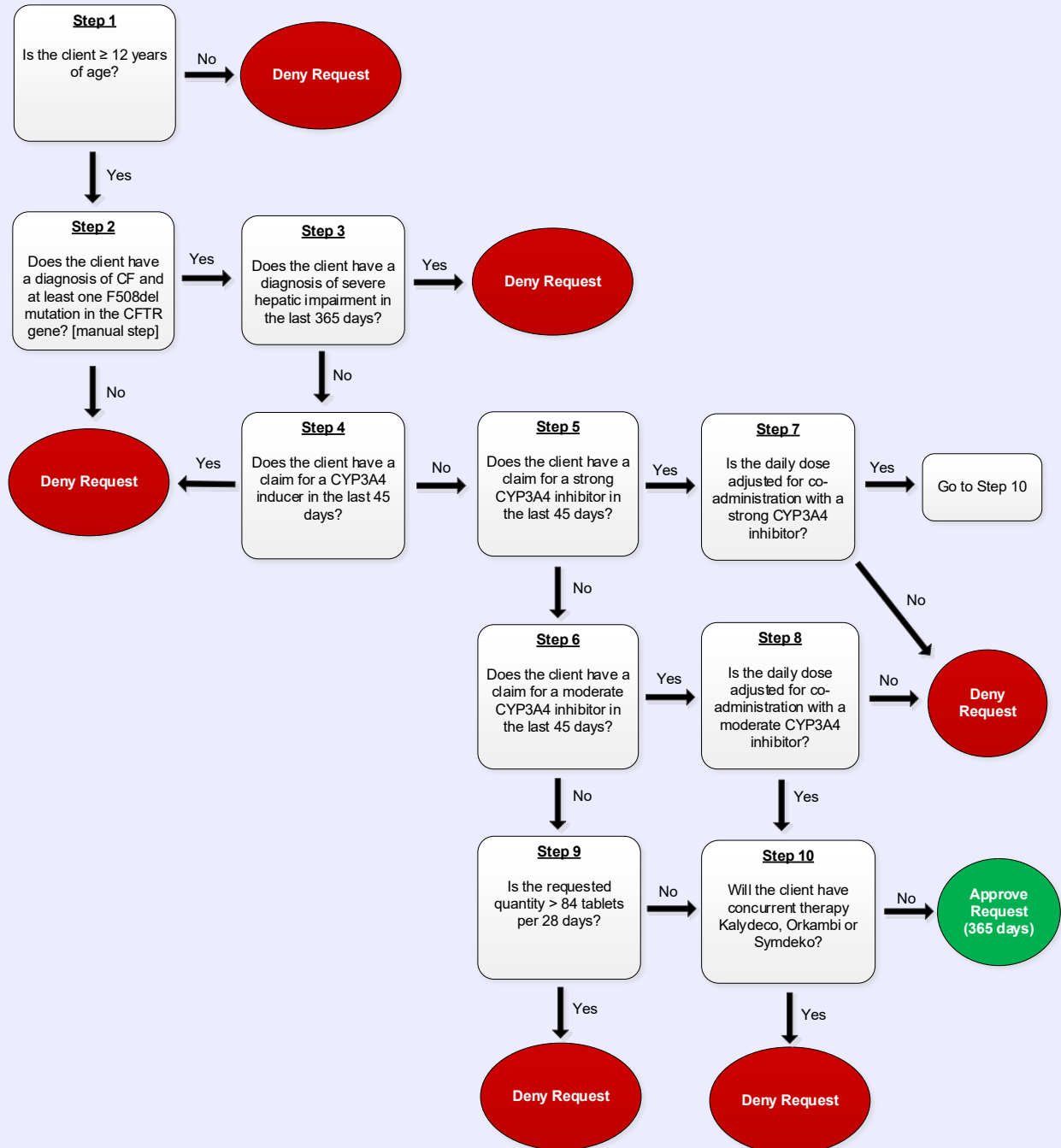
10. Will the client have concurrent therapy **Kalydeco, Orkambi or Symdeko**?
- Yes (Deny)
- No (Approve – 365 days)

<b>*Trikafta Dosing Table For HID Use Only</b>	
<b>Co-administration with:</b>	<b>Recommended Trikafta Dosing:</b>
Strong CYP3A4 Inhibitor	Less than or equal to ( $\leq$ ) 20 tablets per 28 days <u>OR</u> $\leq 0.72$ units/day when calculated, if days supply exceeds 28
Moderate CYP3A4 Inhibitor	Less than or equal to ( $\leq$ ) 42 tablets per 28 days <u>OR</u> $\leq 1.5$ units/day when calculated, if days supply exceeds 28



# Trikafta (Elexcaftor/Tezacaftor/Ivacaftor)

## Clinical Criteria Logic Diagram







**Trikafta**  
**(Elexcaftor/Tezacaftor/Ivacaftor)**  
**Clinical Criteria Supporting Tables**

<b>Step 3 (diagnosis of severe hepatic impairment)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 365 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES

<b>Step 3 (diagnosis of severe hepatic impairment)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 365 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES

<b>Step 4 (history of a CYP3A4 inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	

For the list of GCNs that pertain to this step, see the **CYP3A4 Inducer** table in the previous "Supporting Tables" section.

**Note:** Click the hyperlink to navigate directly to the table.

**Step 5 (history of a strong CYP3A4 inhibitor)****Number of claims:** 1**Look back timeframe:** 45 days

For the list of GCNs that pertain to this step, see the **Strong CYP3A4 Inhibitor** table in the previous "Supporting Tables" section.

**Note:** Click the hyperlink to navigate directly to the table.

**Step 6 (history of a moderate CYP3A4 inhibitor)****Number of claims:** 1**Look back timeframe:** 45 days

For the list of GCNs that pertain to this step, see the **Moderate CYP3A4 Inhibitor** table in the previous "Supporting Tables" section.

**Note:** Click the hyperlink to navigate directly to the table.

**Step 10 (agents for the treatment of Cystic Fibrosis)****Number of claims:** 1**Look back timeframe:** concurrent therapy

<b>Label Name</b>	<b>GCN</b>
KALYDECO 150MG TABLET	31312
KALYDECO 25MG GRANULES PACKET	46238
KALYDECO 50MG GRANULES PACKET	38138
KALYDECO 75MG GRANULES PACKET	38139
ORKAMBI 100-125MG GRANULE PKT	36937
ORKAMBI 100MG-125MG TABLET	42366
ORKAMBI 150-188MG GRANULE PKT	42848
ORKAMBI 200MG-125MG TABLET	39008
SYMDEKO 100/150-150 MG TABS	44444
SYMDEKO 50/75-75 MG TABS	46553



## Cystic Fibrosis Agents

### Clinical Criteria References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. April 2019
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2018. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on November 27, 2018.
3. Indiana University, Department of Medicine, Clinical Pharmacology Research Institute. P450 Interaction Table. Available at [medicine.iupui.edu](http://medicine.iupui.edu). Accessed on August 31, 2015.
4. Orkambi Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. August 2018.
5. Indiana University, Department of Medicine, Clinical Pharmacology Research Institute. P450 Interaction Table. Available at [medicine.iupui.edu](http://medicine.iupui.edu). Accessed on February 19, 2016.
6. U.S. Food and Drug Administration (FDA). Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at [www.fda.gov](http://www.fda.gov). Accessed on February 19, 2016.
7. Symdeko Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. June 2019.
8. Trikafta Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. October 2019.

## Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
04/03/2013	Initial publication and posting to website
10/30/2014	Added additional mutations to the CFTR gene in the clinical edit criteria
02/05/2015	Added R117H mutation in the CFTR gene to the indicated diagnoses Updated prescribing information reference
03/20/2015	Added GCNs for Tybost, Prezcobix and Evotaz to supporting tables, Step 3
05/14/2015	Updated to add Kalydeco granules
09/09/2015	Updated to include Orkambi
02/26/2016	Updated CYP3A4 inhibitor/inducer tables
11/15/2016	Updated Table 2, page 6 Updated Table 3, page 8 Updated Table 4, page 12 Added GCN for Orkambi 100mg/125mg tablet to Drugs Requiring PA, page 15 Updated Criteria Logic, page 16 Updated Logic Diagram, page 17 Updated Table 2, page 18 Updated Table 3, page 19 Updated References, page 23
05/30/2017	Updated Kalydeco criteria logic, page 4 – updated step 8 to include the following mutations on the CFTR gene: A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193K, E56K, F1052V, F1074L, G1069R, K1060T, L206W, P67L, R1070Q, R1070W, R117C, R347H, R352Q, R74W, S945L and S977F Updated References, page 23
08/02/2017	Updated Kalydeco criteria logic, page 4 – updated step 8 to include the following mutations on the CFTR gene: 2789+5G, 3272-26A, 3849+10kbC, 711+3A and E831X Updated References, page 23
04/27/2018	Added criteria for Symdeko, pages 23-26. Criteria approved by the DUR Board on April 27, 2018 Updated references, page 27
11/27/2018	Updated age requirements for Kalydeco (to 12 months of age and older), pages 4-5 Added GCNs for Orkambi granules to 'Drugs Requiring PA', page 15 Updated age requirements for Orkambi (to 2 years of age and older), pages 16-17

<b>Publication Date</b>	<b>Notes</b>
	Updated references, page 27
01/30/2019	Updated change log from 08/02/2017 to read E831X instead of E821X, page 28
03/27/2019	Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit <a href="http://TxVendorDrug.com/formulary/formulary-search">TxVendorDrug.com/formulary/formulary-search</a> .) on each 'Drug Requiring PA' table
05/09/2019	Added GCN for Kalydeco 25mg packet to 'Drugs Requiring PA', page 3 Changed age on question 1 to greater than or equal to 6 months on criteria logic and logic diagram, pages 4-5 Updated references, page 27
07/10/2019	Added GCN for Symdeko 50/75-75mg tablet to 'Drugs Requiring PA', page 23 Changed age on question 1 to greater than or equal to 6 years on criteria logic and logic diagram, pages 24-25 Updated references, page 27
01/30/2020	Added concurrent therapy check to Kalydeco (question 8, pages 4-6), Orkambi (question 8, pages 17 and 18) and Symdeko (question 4, pages 25 and 26) Added criteria for Trikafta, pages 28 -35 Updated question 11 in criteria logic and logic diagram, page 36, as recommended by DUR Board Updated references, page 36