

**Texas Prior Authorization Program
Clinical Criteria**

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)

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Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

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Revision Notes

Added criteria for Symdeko, pages 23-26. Criteria approved by the DUR Board on April 27, 2018.

Updated references, page 27.

**Kalydeco (Ivacaftor)****Drugs Requiring Prior Authorization**

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



Kalydeco (Ivacaftor)

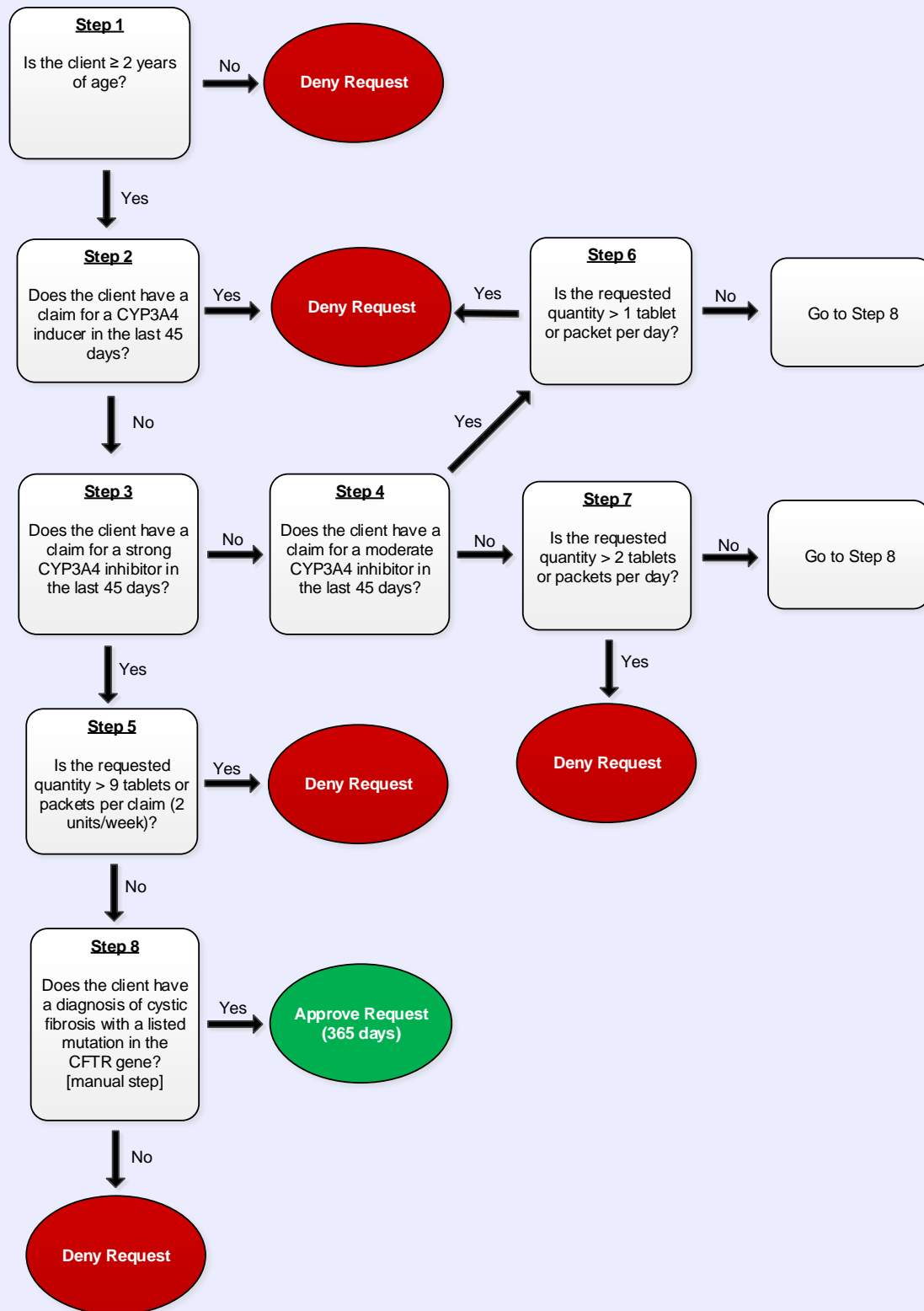
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 2 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 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. 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, E821X, 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

Step 2 (history of a CYP3A4 inducer) Number of claims: 1 Look back timeframe: 45 days	
Label Name	GCN
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
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 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

Step 2 (history of a CYP3A4 inducer)	
Number of claims: 1	
Look back timeframe: 45 days	
Label Name	GCN
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
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

Step 2 (history of a CYP3A4 inducer)	
Number of claims: 1	
Look back timeframe: 45 days	
Label Name	GCN
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
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

Step 3 (history of a strong CYP3A4 inhibitor)	
Number of claims: 1	
Look back timeframe: 45 days	
Label Name	GCN
BIAXIN 250 MG TABLET	48852
BIAXIN 250 MG/5 ML SUSPENSION	11671

Step 3 (history of a strong CYP3A4 inhibitor)	
Number of claims: 1	
Look back timeframe: 45 days	
Label Name	GCN
BIAXIN 500 MG TABLET	48851
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 120 MG TABLET	19180
CARDIZEM LA 180 MG TABLET	19183
CARDIZEM LA 360 MG TABLET	19186
CARDIZEM LA 420 MG TABLET	19187
CARTIA XT 120MG CAPSULE	02326
CARTIA XT 180MG CAPSULE	02323
CARTIA XT 240MG CAPSULE	02324
CARTIA XT 300MG CAPSULE	02325
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
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
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

Step 3 (history of a strong CYP3A4 inhibitor)	
Number of claims: 1	
Look back timeframe: 45 days	
Label Name	GCN
DILTIAZEM ER 120 MG CAPSULE	02330
DILTIAZEM ER 120 MG CAPSULE	07463
DILTIAZEM ER 180 MG CAPSULE	02329
DILTIAZEM ER 180 MG CAPSULE	07461
DILTIAZEM ER 240 MG CAPSULE	07462
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
EVOTAZ 300-150MG TABLET	37797
GENVOYA TABLET	40092
INVIRASE 200 MG CAPSULE	26760
INVIRASE 500 MG TABLET	23952
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
KETEK 300 MG TABLET	25905
KETEK 400 MG TABLET	15175
KETOCONAZOLE 200 MG TABLET	42590
LANSOPRAZOL-AMOXICIL-CLARITHRO	64269
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
NEFAZODONE 100MG TABLET	16406
NEFAZODONE 150MG TABLET	16407
NEFAZODONE 200MG TABLET	16408
NEFAZODONE 250MG TABLET	16409
NEFAZODONE 50MG TABLET	16404
NORVIR 100 MG SOFTGEL CAP	26812
NORVIR 100 MG TABLET	28224
NORVIR 80 MG/ML SOLUTION	26810
NOXAFIL 40 MG/ML SUSPENSION	26502
NOXAFIL DR 100 MG TABLET	35649

Step 3 (history of a strong CYP3A4 inhibitor)	
Number of claims: 1	
Look back timeframe: 45 days	
Label Name	GCN
PREVPAC PATIENT PACK	64269
PREZCOBIX 150MG TABLET	37367
SPORANOX 10 MG/ML SOLUTION	49100
SPORANOX 100 MG CAPSULE	49101
STRIBILD TABLET	33130
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
TECHNIVIE DOSE PACK	37844
TIAZAC ER 120MG CAPSULE	02330
TIAZAC ER 180MG CAPSULE	02329
TIAZAC ER 240MG CAPSULE	02332
TIAZAC ER 300MG CAPSULE	02333
TIAZAC ER 360MG CAPSULE	02328
TIAZAC ER 420MG CAPSULE	94961
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
VICTRELIS 200 MG CAPSULE	29941
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

Step 4 (history of a moderate CYP3A4 inhibitor)	
Number of claims: 1	
Look back timeframe: 45 days	
Description	GCN
BUNAVAIL 2.1-0.3 MG FILM	36677
BUNAVAIL 4.2-0.7 MG FILM	36678
BUNAVAIL 6.3-1 MG FILM	36679
CALAN 120 MG TABLET	02341
CALAN 80 MG TABLET	02342
CALAN SR 120 MG CAPLET	32472
CALAN SR 180 MG CAPLET	32471
CALAN SR 240 MG CAPLET	32470
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
E.E.S. 200 MG/5 ML GRANULES	40523
E.E.S. 400 FILMTAB	40560
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
ERYTHROCIN 500 MG VIAL	40601
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
FLUCONAZOLE 200 MG TABLET	42191

Step 4 (history of a moderate CYP3A4 inhibitor)	
Number of claims: 1	
Look back timeframe: 45 days	
Description	GCN
FLUCONAZOLE 40 MG/ML SUSP	60821
FLUCONAZOLE 50 MG TABLET	42192
FLUCONAZOLE-DEXT 200 MG/100 ML	55590
FLUCONAZOLE-NACL 200 MG/100 ML	69790
FLUCONAZOLE-NACL 400 MG/200 ML	69791
FLUCONAZOLE-NS 200 MG/100 ML	25303
GLEEVEC 100MG TABLET	19908
GLEEVEC 400MG TABLET	19907
LEXIVA 50MG/ML SUSPENSION	23783
LEXIVA 700MG TABLET	20553
PCE 333 MG TABLET	40741
PCE 500 MG TABLET	40742
PREZISTA 100MG/ML SUSPENSION	31201
PREZISTA 150MG TABLET	23489
PREZISTA 600MG TABLET	99434
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
SUBOXONE 12 MG-3 MG SL FILM	33744
SUBOXONE 2 MG-0.5 MG SL FILM	28958
SUBOXONE 4 MG-1 MG SL FILM	33741
SUBOXONE 8 MG-2 MG SL FILM	28959
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
VERAPAMIL 80 MG TABLET	02342
VERAPAMIL ER 120 MG CAPSULE	03003
VERAPAMIL ER 120 MG TABLET	32472
VERAPAMIL ER 180 MG CAPSULE	03001

Step 4 (history of a moderate CYP3A4 inhibitor)	
Number of claims: 1	
Look back timeframe: 45 days	
Description	GCN
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

**Orkambi (Lumacaftor/Ivacaftor)****Drugs Requiring Prior Authorization**

Drugs Requiring Prior Authorization	
Label Name	GCN
ORKAMBI 100MG-125MG TABLET	42366
ORKAMBI 200MG-125MG TABLET	39008



Orkambi (Lumacaftor/Ivacaftor)

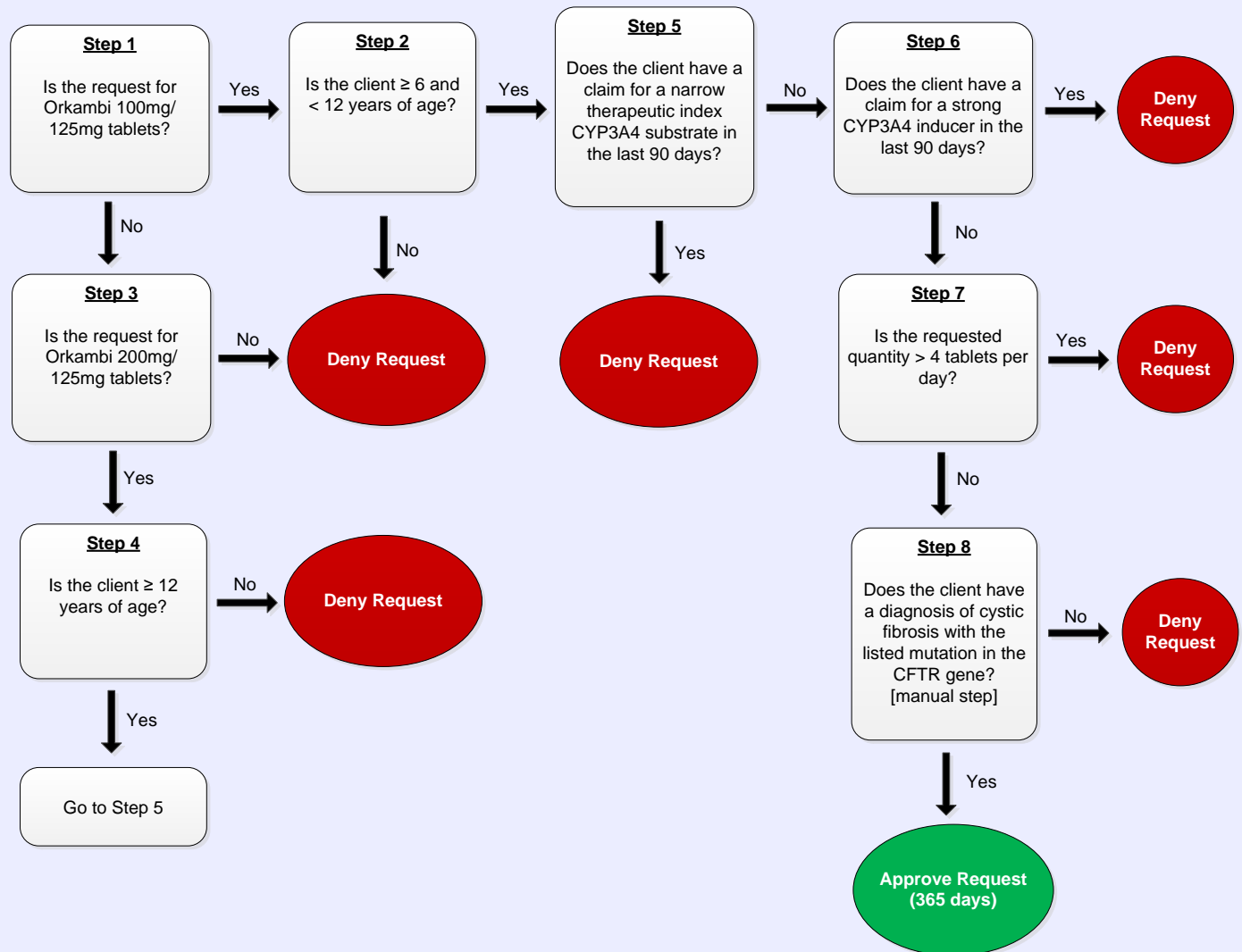
Clinical Criteria Logic

1. Is the request for Orkambi 100mg/125mg tablets?
 Yes (Go to #2)
 No (Go to #3)
2. Is the client greater than or equal to (\geq) 6 years of age and less than ($<$) 12 years of age?
 Yes (Go to #5)
 No (Deny)
3. Is the request for Orkambi 200mg/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 per day?
 Yes (Deny)
 No (Go to #8)
8. 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

Step 5 (history of a narrow therapeutic index CYP3A4 substrate) Number of claims: 1 Look back timeframe: 90 days	
Description	GCN
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
RAPAMUNE 1MG/ML ORAL SOLN	50356

Step 5 (history of a narrow therapeutic index CYP3A4 substrate)	
Number of claims: 1	
Look back timeframe: 90 days	
Description	GCN
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

Step 6 (history of a strong CYP3A4 inducer)	
Number of claims: 1	
Look back timeframe: 90 days	
Description	GCN
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
CARBAMAZEPINE 100 MG TAB CHEW	17460

Step 6 (history of a strong CYP3A4 inducer)	
Number of claims: 1	
Look back timeframe: 90 days	
Description	GCN
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
PHENOBARBITAL 20 MG/5 ML ELIX	12956

Step 6 (history of a strong CYP3A4 inducer)	
Number of claims: 1	
Look back timeframe: 90 days	
Description	GCN
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
TEGRETOL XR 100 MG TABLET	27820

Step 6 (history of a strong CYP3A4 inducer)	
Number of claims: 1	
Look back timeframe: 90 days	
Description	GCN
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



Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

Drugs Requiring Prior Authorization

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



Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

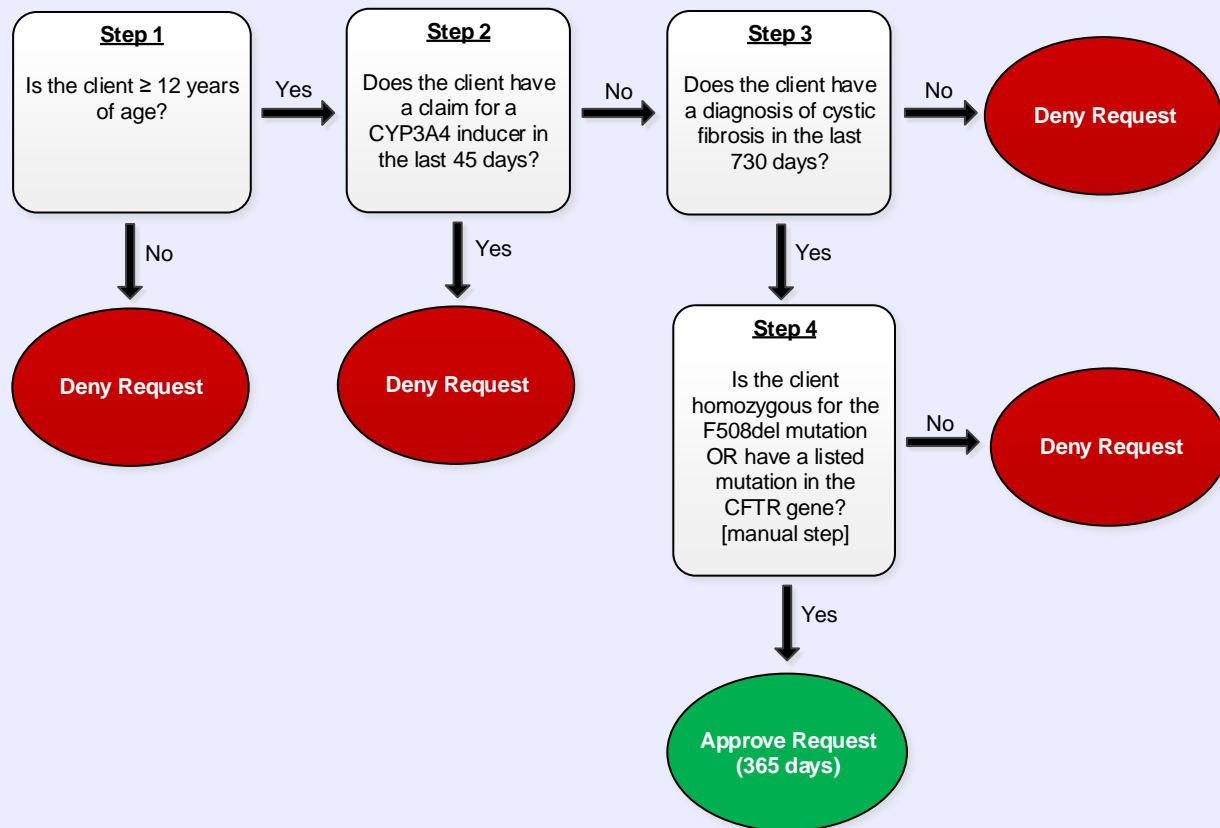
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 12 years of age?
 Yes (Go to #2)
 No (Deny)
2. 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. 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.



Cystic Fibrosis Agents

Clinical Criteria References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. July 2017.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2018. Available at www.clinicalpharmacology.com. Accessed on April 27, 2018.
3. Indiana University, Department of Medicine, Clinical Pharmacology Research Institute. P450 Interaction Table. Available at medicine.iupui.edu. Accessed on August 31, 2015.
4. Orkambi Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. September 2016.
5. Indiana University, Department of Medicine, Clinical Pharmacology Research Institute. P450 Interaction Table. Available at 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. Accessed on February 19, 2016.
7. Symdeko Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. February 2018.

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 E821X 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