

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class

Cystic Fibrosis Agents

Clinical Criteria Information included in this Document

Alyftrek (Vanzacaftor, Tezacaftor, and Deutivacaftor)

- [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); provided when applicable
- [References:](#) clinical publications and sources relevant to this clinical criteria

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
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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); provided when applicable
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Symdeko (Tezacaftor/Ivacaftor)

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Trikafta (Elexacaftor/Tezacaftor/Ivacaftor)

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- [References](#): clinical publications and sources relevant to this clinical criteria

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

Revision Notes

Added criteria for Alyftrek as approved by the DUR Board

**Alyftrek (Vanzacaftor,
Tezacaftor, and Deutivacaftor)****Drugs Requiring Prior Authorization**

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
ALYFTREK 4-20-50 MG TABLET	56768
ALYFTREK 10-50-125 MG TABLET	56769

**Alyftrek (Vanzacaftor,
Tezacaftor, and Deutivacaftor)****Clinical Criteria Logic**

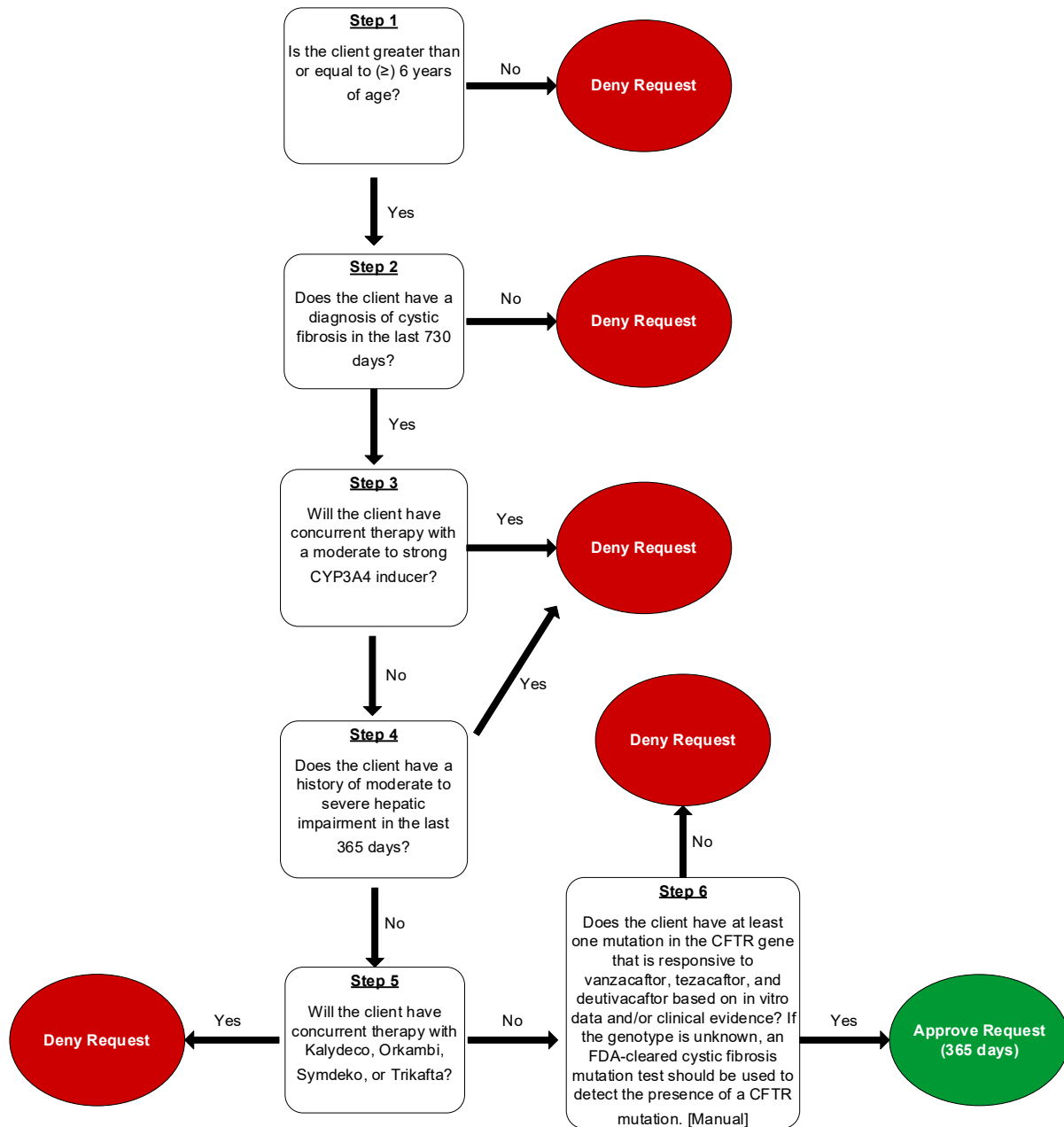
1. Is the client greater than or equal to ($\geq$) 6 years of age?
☐ Yes – Go to #2
☐ No – Deny
2. Does the client have a diagnosis of cystic fibrosis in the last 730 days?
☐ Yes – Go to #3
☐ No – Deny
3. Will the client have concurrent therapy with a moderate to strong CYP3A4 inducer?
☐ Yes – Deny
☐ No – Go to #4
4. Does the client have a history of moderate to severe hepatic impairment in the last 365 days?
☐ Yes – Deny
☐ No – Go to #5
5. Will the client have concurrent therapy with Kalydeco, Orkambi, Symdeko, or Trikafta?
☐ Yes – Deny
☐ No – Go to #6
6. Does the client have at least one mutation in the CFTR gene that is responsive to vanzacaftor, tezacaftor, and deutivacaftor based on in vitro data and/or clinical evidence? If the genotype is unknown, an FDA-cleared cystic fibrosis mutation test should be used to detect the presence of a CFTR mutation.* [Manual]
☐ Yes – Approve (365 days)
☐ No – Deny

*You may use the following link to determine eligibility based on the client's mutations: [Check Your Eligibility | ALYFTREK™ \(vanzacaftor/tezacaftor/deutivacaftor\)](#)



Alyftrek (Vanzacaftor, Tezacaftor, and Deutivacaftor)

Clinical Criteria Logic Diagram





Alyftrek (Vanzacaftor, Tezacaftor, and Deutivacaftor)

Clinical Criteria Supporting Tables

Table 2 (diagnosis of cystic fibrosis (CF)) 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

Table 3 (moderate to strong CYP3A4 inducer) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
92373	BEXAROTENE 75 MG CAPSULE
17460	CARBAMAZEPINE 100 MG TAB CHEW
47500	CARBAMAZEPINE 100 MG/5 ML SUSP
17450	CARBAMAZEPINE 200 MG TABLET
23934	CARBAMAZEPINE ER 100 MG CAP
27820	CARBAMAZEPINE ER 100 MG TAB
23932	CARBAMAZEPINE ER 200 MG CAP
27821	CARBAMAZEPINE ER 200 MG TABLET
23933	CARBAMAZEPINE ER 300 MG CAP

Table 3 (moderate to strong CYP3A4 inducer) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
27822	CARBAMAZEPINE ER 400 MG TABLET
27601	CARBAMAZEPINE 100 MG/5 ML CUP
27602	CARBAMAZEPINE 200 MG/10 ML CUP
23934	CARBATROL ER 100 MG CAPSULE
23932	CARBATROL ER 200 MG CAPSULE
23933	CARBATROL ER 300 MG CAPSULE
17700	DILANTIN 100 MG CAPSULE
17241	DILANTIN 125 MG/5 ML SUSP
17701	DILANTIN 30 MG CAPSULE
17250	DILANTIN 50 MG INFATAB
17450	EPITOL 200 MG TABLET
13781	EQUETRO 100 MG CAPSULE
13805	EQUETRO 200 MG CAPSULE
13818	EQUETRO 300 MG CAPSULE
37810	LYSODREN 500 MG TABLET
17321	MYSOLINE 250 MG TABLET
17322	MYSOLINE 50 MG TABLET
36937	ORKAMBI 100-125 MG GRANULE PKT
42366	ORKAMBI 100-125 MG TABLET
42848	ORKAMBI 150-188 MG GRANULE PKT
39008	ORKAMBI 200-125 MG TABLET
12975	PHENOBARBITAL 100 MG TABLET
12971	PHENOBARBITAL 15 MG TABLET

Table 3 (moderate to strong CYP3A4 inducer) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
97706	PHENOBARBITAL 16.2 MG TABLET
12956	PHENOBARBITAL 20 MG/5 ML ELIX
12973	PHENOBARBITAL 30 MG TABLET
97965	PHENOBARBITAL 32.4 MG TABLET
12972	PHENOBARBITAL 60 MG TABLET
97966	PHENOBARBITAL 64.8 MG TABLET
97967	PHENOBARBITAL 97.2 MG TABLET
12894	PHENOBARBITAL 65 MG/ML VIAL
12892	PHENOBARBITAL 130 MG/ML VIAL
15038	PHENYTEK 200 MG CAPSULE
15037	PHENYTEK 300 MG CAPSULE
17241	PHENYTOIN 125 MG/5 ML SUSP
17250	PHENYTOIN 50 MG TABLET CHEW
17700	PHENYTOIN SOD EXT 100 MG CAP
15038	PHENYTOIN SOD EXT 200 MG CAP
15037	PHENYTOIN SOD EXT 300 MG CAP
17200	PHENYTOIN 50 MG/ML VIAL
17321	PRIMIDONE 250 MG TABLET
17322	PRIMIDONE 50 MG TABLET
41260	RIFADIN 150 MG CAPSULE
41261	RIFADIN 300 MG CAPSULE
41470	RIFADIN IV 600 MG VIAL
89800	RIFAMATE CAPSULE

Table 3 (moderate to strong CYP3A4 inducer) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
41260	RIFAMPIN 150 MG CAPSULE
41261	RIFAMPIN 300 MG CAPSULE
41470	RIFAMPIN IV 600 MG VIAL
14142	RIFATER TABLET
47500	TEGRETOL 100 MG/5 ML SUSP
17460	TEGRETOL 100 MG TABLET CHEW
17450	TEGRETOL 200 MG TABLET
27820	TEGRETOL XR 100 MG TABLET
27821	TEGRETOL XR 200 MG TABLET
27822	TEGRETOL XR 400 MG TABLET
33183	XTANDI 40 MG CAPSULE
46626	XTANDI 40 MG TABLET
48452	XTANDI 80 MG TABLET

Table 4 (moderate to severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER

Table 4 (moderate to severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
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

Table 4 (moderate to severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
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
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

Table 4 (moderate to severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
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
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE

Table 5 (Kalydeco, Orkambi, Symdeko, or Trikafta) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
31312	KALYDECO 150MG TABLET
46238	KALYDECO 25MG GRANULES PACKET
38138	KALYDECO 50MG GRANULES PACKET
38139	KALYDECO 75MG GRANULES PACKET
36937	ORKAMBI 100-125MG GRANULE PKT
42366	ORKAMBI 100MG-125MG TABLET
42848	ORKAMBI 150-188MG GRANULE PKT
39008	ORKAMBI 200MG-125MG TABLET
52865	ORKAMBI 75-94MG GRANULE PKT
46553	SYMDEKO 50/75-75 MG TABS
44444	SYMDEKO 100/150-150 MG TABS
47136	TRIKAFTA 100/50/75MG-150MG
49779	TRIKAFTA 50/25/37.5MG-75MG
54048	TRIKAFTA 80/40/60-59.5MG PACKET
54047	TRIKAFTA 100/50/75-75MG PACKET

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

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
KALYDECO 13.4 MG GRANULES PACKET	45746
KALYDECO 150MG TABLET	31312
KALYDECO 25MG GRANULES PACKET	46238
KALYDECO 50MG GRANULES PACKET	38138
KALYDECO 75MG GRANULES PACKET	38139

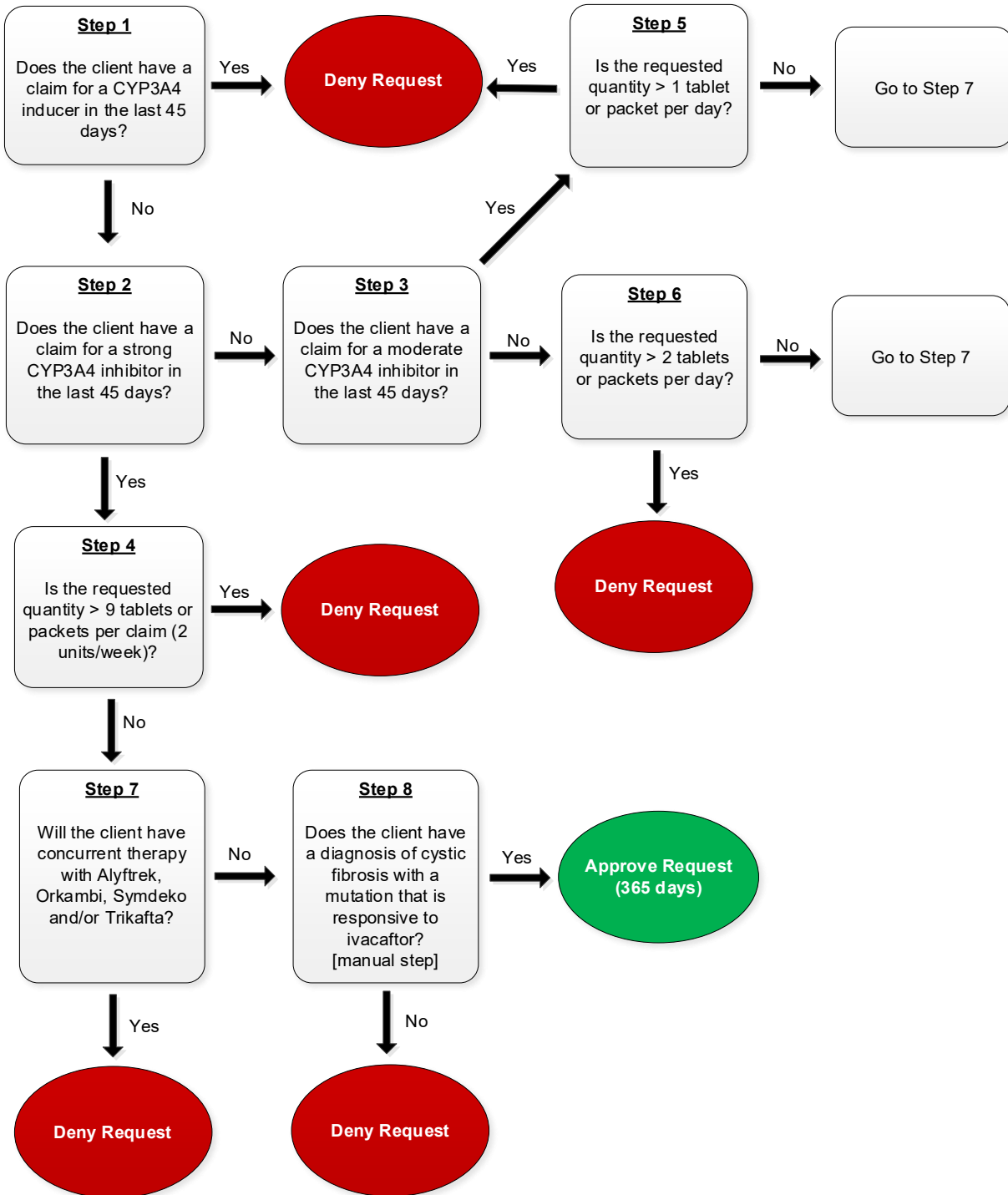
**Kalydeco (Ivacaftor)****Clinical Criteria Logic**

1. Does the client have a claim for a [CYP3A4 inducer](#) in the last 45 days?
☐ Yes – Deny
☐ No – Go to #2
2. Does the client have a claim for a [strong CYP3A4 inhibitor](#) in the last 45 days?
☐ Yes – Go to #4
☐ No – Go to #3
3. Does the client have a claim for a [moderate CYP3A4 inhibitor](#) in the last 45 days?
☐ Yes – Go to #5
☐ No – Go to #6
4. Is the requested quantity greater than (>) nine tablets or packets per claim (2 units per week)?
☐ Yes – Deny
☐ No – Go to #7
5. Is the requested quantity greater than (>) one tablet or packet per day?
☐ Yes – Deny
☐ No – Go to #7
6. Is the requested quantity greater than (>) two tablets or packets per day?
☐ Yes – Deny
☐ No – Go to #7
7. Will the client have concurrent therapy with [Alyftrek, Orkambi, Symdeko and/or Trikafta](#)?
☐ Yes – Deny
☐ No – Go to #8
8. Does the client have a diagnosis of cystic fibrosis with one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or *in vitro* assay data? If the genotype is unknown, an FDA-cleared cystic fibrosis mutation test should be used to detect the presence of a CFTR mutation. [Manual]
☐ Yes – Approve (365 days)
☐ No – Deny



Kalydeco (Ivacaftor)

Clinical Criteria Logic Diagram





Kalydeco (Ivacaftor)

Clinical Criteria Supporting Tables

Table 1 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
36098	APTIOM 200 MG TABLET
36099	APTIOM 400 MG TABLET
36106	APTIOM 600 MG TABLET
27409	APTIOM 800 MG TABLET
98590	ARMODAFINIL 150 MG TABLET
36082	ARMODAFINIL 200 MG TABLET
98592	ARMODAFINIL 250 MG TABLET
98591	ARMODAFINIL 50 MG TABLET
27346	ATRIPLA TABLET
98836	BANZEL 200 MG TABLET
29462	BANZEL 40 MG/ML SUSPENSION
98837	BANZEL 400 MG TABLET
92373	BEXAROTENE 75 MG CAPSULE
14978	BOSENTAN 125 MG TABLET
14979	BOSENTAN 62.5MG TABLET
17460	CARBAMAZEPINE 100 MG TAB CHEW
47500	CARBAMAZEPINE 100 MG/5 ML SUSP
17450	CARBAMAZEPINE 200 MG TABLET
23934	CARBAMAZEPINE ER 100 MG CAP
27820	CARBAMAZEPINE ER 100 MG TAB

Table 1 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
23932	CARBAMAZEPINE ER 200 MG CAP
27821	CARBAMAZEPINE ER 200 MG TABLET
23933	CARBAMAZEPINE ER 300 MG CAP
27822	CARBAMAZEPINE ER 400 MG TABLET
23934	CARBATROL ER 100 MG CAPSULE
23932	CARBATROL ER 200 MG CAPSULE
23933	CARBATROL ER 300 MG CAPSULE
09071	CLOBAZAM 10 MG TABLET
35026	CLOBAZAM 2.5 MG/ML SUSPENSION
09070	CLOBAZAM 20 MG TABLET
27422	DEXAMETHASONE 0.5 MG TABLET
27400	DEXAMETHASONE 0.5 MG/5 ML ELX
27411	DEXAMETHASONE 0.5 MG/5 ML LIQ
27425	DEXAMETHASONE 0.75 MG TABLET
27424	DEXAMETHASONE 1 MG TABLET
27427	DEXAMETHASONE 1.5 MG TABLET
27426	DEXAMETHASONE 2 MG TABLET
27428	DEXAMETHASONE 4 MG TABLET
27354	DEXAMETHASONE 4 MG/ML VIAL
27429	DEXAMETHASONE 6 MG TABLET
27412	DEXAMETHASONE INTENSOL 1 MG/ML
39541	DICLOXACILLIN 250 MG CAPSULE
39542	DICLOXACILLIN 500 MG CAPSULE

Table 1 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
17700	DILANTIN 100 MG CAPSULE
17241	DILANTIN 125 MG/5 ML SUSP
17701	DILANTIN 30 MG CAPSULE
17250	DILANTIN 50 MG INFATAB
15555	EFAVIRENZ 600 MG TABLET
17450	EPITOL 200 MG TABLET
13781	EQUETRO 100 MG CAPSULE
13805	EQUETRO 200 MG CAPSULE
13818	EQUETRO 300 MG CAPSULE
53749	ERLEADA 240 MG TABLET
44446	ERLEADA 60 MG TABLET
99318	INTELENCE 100 MG TABLET
29424	INTELENCE 200 MG TABLET
32035	INTELENCE 25 MG TABLET
37810	LYSODREN 500 MG TABLET
26101	MODAFINIL 100 MG TABLET
26102	MODAFINIL 200 MG TABLET
29810	MYCOBUTIN 150 MG CAPSULE
17321	MYSOLINE 250 MG TABLET
17322	MYSOLINE 50 MG TABLET
31420	NEVIRAPINE 200MG TABLET
29767	NEVIRAPINE ER 400MG TABLET
98590	NUVIGIL 150 MG TABLET

Table 1 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
36082	NUVIGIL 200 MG TABLET
98592	NUVIGIL 250 MG TABLET
98591	NUVIGIL 50 MG TABLET
09071	ONFI 10 MG TABLET
35026	ONFI 2.5 MG/ML SUSPENSION
09070	ONFI 20 MG TABLET
45026	ORILISSA 150 MG TABLET
45028	ORILISSA 200 MG TABLET
36937	ORKAMBI 100-125 MG GRANULE PKT
42366	ORKAMBI 100-125 MG TABLET
42848	ORKAMBI 150-188 MG GRANULE PKT
39008	ORKAMBI 200-125 MG TABLET
52865	ORKAMBI 75-94 MG GRANULE PKT
21724	OXCARBAZEPINE 150MG TABLET
21721	OXCARBAZEPINE 300MG TABLET
21723	OXCARBAZEPINE 300MG/5ML SUSP
21722	OXCARBAZEPINE 600MG TABLET
33556	OXTELLAR XR 150MG TABLET
33557	OXTELLAR XR 300 MG TABLET
33558	OXTELLAR XR 600MG TABLET
12892	PHENOBARBITAL 130 MG/ML VIAL
12971	PHENOBARBITAL 15 MG TABLET
97706	PHENOBARBITAL 16.2 MG TABLET

Table 1 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
12956	PHENOBARBITAL 20 MG/5 ML ELIX
12973	PHENOBARBITAL 30 MG TABLET
97965	PHENOBARBITAL 32.4 MG TABLET
12972	PHENOBARBITAL 60 MG TABLET
97966	PHENOBARBITAL 64.8 MG TABLET
12894	PHENOBARBITAL 65 MG/ML VIAL
97967	PHENOBARBITAL 97.2 MG TABLET
15038	PHENYTEK 200 MG CAPSULE
15037	PHENYTEK 300 MG CAPSULE
17241	PHENYTOIN 125 MG/5 ML SUSP
17250	PHENYTOIN 50 MG TABLET CHEW
17200	PHENYTOIN 50 MG/ML VIAL
17700	PHENYTOIN SOD EXT 100 MG CAP
15038	PHENYTOIN SOD EXT 200 MG CAP
15037	PHENYTOIN SOD EXT 300 MG CAP
45911	PRIFTIN 150 MG TABLET
17321	PRIMIDONE 250 MG TABLET
17322	PRIMIDONE 50 MG TABLET
26101	PROVIGIL 100 MG TABLET
26102	PROVIGIL 200 MG TABLET
29810	RIFABUTIN 150 MG CAPSULE
41260	RIFADIN 150 MG CAPSULE
41261	RIFADIN 300 MG CAPSULE

Table 1 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
41470	RIFADIN IV 600 MG VIAL
89800	RIFAMATE CAPSULE
41260	RIFAMPIN 150 MG CAPSULE
41261	RIFAMPIN 300 MG CAPSULE
41470	RIFAMPIN IV 600 MG VIAL
14142	RIFATER TABLET
43303	SUSTIVA 200 MG CAPSULE
43301	SUSTIVA 50 MG CAPSULE
15555	SUSTIVA 600 MG TABLET
44548	SYMFI 600-300-300 MG TABLET
44425	SYMFI LO 400-300-300 MG TABLET
45265	SYMPAZAN 10 MG FILM
45266	SYMPAZAN 20 MG FILM
45264	SYMPAZAN 5 MG FILM
34723	TAFINLAR 50 MG CAPSULE
34724	TAFINLAR 75 MG CAPSULE
92373	TARGRETIN 75 MG CAPSULE
47500	TEGRETOL 100 MG/5 ML SUSP
17450	TEGRETOL 200 MG TABLET
27820	TEGRETOL XR 100 MG TABLET
27821	TEGRETOL XR 200 MG TABLET
27822	TEGRETOL XR 400 MG TABLET
45016	TIBSOVO 250 MG TABLET

Table 1 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
14978	TRACLEER 125 MG TABLET
43819	TRACLEER 32 MG TABLET FOR SUSP
14979	TRACLEER 62.5 MG TABLET
21724	TRILEPTAL 150 MG TABLET
21721	TRILEPTAL 300 MG TABLET
21723	TRILEPTAL 300 MG/ 5ML SUSP
21722	TRILEPTAL 600 MG TABLET
31420	VIRAMUNE 200 MG TABLET
31421	VIRAMUNE 50 MG/5 ML SUSPENSION
29767	VIRAMUNE XR 400 MG TABLET
43109	XERMELO 250 MG TABLET
33183	XTANDI 40 MG CAPSULE
30332	ZELBORAF 240 MG TABLET

Table 2 (history of a strong CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
19952	ATAZANAVIR SULFATE 150MG CAP
19953	ATAZANAVIR SULFATE 200MG CAP
97430	ATAZANAVIR SULFATE 300MG CAP
11670	CLARITHROMYCIN 125 MG/5 ML SUS
48852	CLARITHROMYCIN 250 MG TABLET

Table 2 (history of a strong CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
11671	CLARITHROMYCIN 250 MG/5 ML SUS
48851	CLARITHROMYCIN 500 MG TABLET
48850	CLARITHROMYCIN ER 500 MG TAB
26820	CRIXIVAN 200 MG CAPSULE
26822	CRIXIVAN 400 MG CAPSULE
37797	EVOTAZ 300-150MG TABLET
40092	GENVOYA TABLET
23952	INVIRASE 500 MG TABLET
49100	ITRACONAZOLE 10 MG/ML SOLUTION
49101	ITRACONAZOLE 100 MG CAPSULE
99101	KALETRA 100-25 MG TABLET
25919	KALETRA 200-50 MG TABLET
31782	KALETRA 400-100/5 ML ORAL SOLU
15175	KETEK 400 MG TABLET
25905	KETEK 300 MG TABLET
42590	KETOCONAZOLE 200 MG TABLET
31485	KORLYM 300 MG TABLET
64269	LANSOPRAZOL-AMOXICIL-CLARITHRO
99101	LOPINAVIR-RITONAVIR 100-25MG TB
25919	LOPINAVIR-RITONAVIR 200-50MG TB
31782	LOPINAVIR-RITONAVIR 80-20MG/ML
16406	NEFAZODONE 100MG TABLET
16407	NEFAZODONE 150MG TABLET

Table 2 (history of a strong CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
16408	NEFAZODONE 200MG TABLET
16409	NEFAZODONE 250MG TABLET
16404	NEFAZODONE 50MG TABLET
40309	NORVIR 100 MG POWDER PACKET
26812	NORVIR 100 MG CAPSULE
28224	NORVIR 100 MG TABLET
26810	NORVIR 80 MG/ML SOLUTION
26502	NOXAFIL 40 MG/ML SUSPENSION
35649	NOXAFIL DR 100 MG TABLET
36248	NOXAFIL 300 MG/16.7 ML VIAL
49744	NOXAFIL 300 MG POWDERMIX SUSP
32137	OMECLAMOX-PAK COMBO PACK
26502	POSACONAZOLE 200 MG/5 ML SUSP
35649	POSACONAZOLE DR 100 MG TABLET
36248	POSACONAZOLE 300 MG/16.7 ML VL
37367	PREZCOBIX 150MG TABLET
31201	PREZISTA 100MG/ML SUSPENSION
23489	PREZISTA 150MG TABLET
99434	PREZISTA 600MG TABLET
16759	PREZISTA 75MG TABLET
33723	PREZISTA 800MG TABLET
19952	REYATAZ 150MG CAPSULE
19953	REYATAZ 200MG CAPSULE

Table 2 (history of a strong CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
37430	REYATAZ 300MG CAPSULE
36647	REYATAZ 50MG POWDER PACK
28224	RITONAVIR 100 MG TABLET
16406	SERZONE 100 MG TABLET
16407	SERZONE 150 MG TABLET
16408	SERZONE 200 MG TABLET
16409	SERZONE 250 MG TABLET
16404	SERZONE 50 MG TABLET
49100	SPORANOX 10 MG/ML SOLUTION
49101	SPORANOX 100 MG CAPSULE
91170	SPORANOX 250 MG KIT
33130	STRIBILD TABLET
43968	SYMTUZA 800-150-200-10 MG TAB
45848	TOLSURA 65 MG CAPSULE
36468	TYBOST 150MG TABLET
17498	VFEND 200 MG TABLET
21513	VFEND 40 MG/ML SUSPENSION
17497	VFEND 50 MG TABLET
17499	VFEND IV 200 MG VIAL
37614	VIEKIRA PAK
41932	VIEKIRA XR TABLET
40312	VIRACEPT 250 MG TABLET
19717	VIRACEPT 625 MG TABLET

Table 2 (history of a strong CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
17498	VORICONAZOLE 200 MG TABLET
17499	VORICONAZOLE 200 MG VIAL
21513	VORICONAZOLE 40 MG/ML SUSP
17497	VORICONAZOLE 50 MG TABLET
36884	ZYDELIG 100MG TABLET
36885	ZYDELIG 150MG TABLET

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
37239	AKYNZEO 300-0.5 MG CAPSULE
19366	APREPITANT 125 MG CAPSULE
19367	APREPITANT 125-80-80 MG PACK
27278	APREPITANT 40 MG CAPSULE
19365	APREPITANT 80 MG CAPSULE
02341	CALAN 120 MG TABLET
32472	CALAN SR 120 MG CAPLET
32471	CALAN SR 180 MG CAPLET
32470	CALAN SR 240 MG CAPLET
02363	CARDIZEM 120 MG TABLET
02360	CARDIZEM 30 MG TABLET
02361	CARDIZEM 60 MG TABLET

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
02326	CARDIZEM CD 120 MG CAPSULE
02323	CARDIZEM CD 180 MG CAPSULE
02324	CARDIZEM CD 240 MG CAPSULE
02325	CARDIZEM CD 300 MG CAPSULE
07460	CARDIZEM CD 360 MG CAPSULE
19183	CARDIZEM LA 180 MG TABLET
02326	CARTIA XT 120MG CAPSULE
02323	CARTIA XT 180MG CAPSULE
02324	CARTIA XT 240MG CAPSULE
02325	CARTIA XT 300MG CAPSULE
47053	CIPRO 100 MG TABLET
47050	CIPRO 250 MG TABLET
47051	CIPRO 500 MG TABLET
47052	CIPRO 750 MG TABLET
20315	CIPRO XR 1,000 MG TABLET
18898	CIPRO XR 500 MG TABLET
47056	CIPROFLOXACIN 250 MG/5 ML SUSP
20315	CIPROFLOXACIN ER 1,000 MG TAB
18898	CIPROFLOXACIN ER 500 MG TABLET
47053	CIPROFLOXACIN HCL 100 MG TAB
47050	CIPROFLOXACIN HCL 250 MG TAB
47051	CIPROFLOXACIN HCL 500 MG TAB
47052	CIPROFLOXACIN HCL 750 MG TAB

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
45424	COPIKTRA 15 MG CAPSULE
45425	COPIKTRA 25 MG CAPSULE
38095	CRESEMBA 186 MG CAPSULE
38094	CRESEMBA 372 MG VIAL
54696	CRESEMBA 74.5 MG CAPSULE
60822	DIFLUCAN 10 MG/ML SUSPENSION
42190	DIFLUCAN 100 MG TABLET
42193	DIFLUCAN 150 MG TABLET
42191	DIFLUCAN 200 MG TABLET
60821	DIFLUCAN 40 MG/ML SUSPENSION
42192	DIFLUCAN 50 MG TABLET
07463	DILT XR 120 MG CAPSULE
07461	DILT XR 180 MG CAPSULE
07462	DILT XR 240 MG CAPSULE
02363	DILTIAZEM 120 MG TABLET
02321	DILTIAZEM 12HR ER 120 MG CAP
02322	DILTIAZEM 12HR ER 60 MG CAP
02320	DILTIAZEM 12HR ER 90 MG CAP
02326	DILTIAZEM 24HR ER 120 MG CAP
02323	DILTIAZEM 24HR ER 180 MG CAP
02324	DILTIAZEM 24HR ER 240 MG CAP
02325	DILTIAZEM 24HR ER 300 MG CAP
07460	DILTIAZEM 24HR ER 360 MG CAP

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
19180	DILTIAZEM 24H ER(LA) 120 MG TB
19183	DILTIAZEM 24H ER(LA) 180 MG TB
19184	DILTIAZEM 24H ER(LA) 240 MG TB
19185	DILTIAZEM 24H ER(LA) 300 MG TB
19186	DILTIAZEM 24H ER(LA) 360 MG TB
19187	DILTIAZEM 24H ER(LA) 420 MG TB
02360	DILTIAZEM 30 MG TABLET
02361	DILTIAZEM 60 MG TABLET
02362	DILTIAZEM 90 MG TABLET
02330	DILTIAZEM ER 120 MG CAPSULE
02329	DILTIAZEM ER 180 MG CAPSULE
02332	DILTIAZEM HCL ER 240 MG CAP
02333	DILTIAZEM HCL ER 300 MG CAP
02328	DILTIAZEM HCL ER 360 MG CAP
94691	DILTIAZEM HCL ER 420 MG CAP
40523	E.E.S. 200 MG/5 ML GRANULES
40560	E.E.S. 400 FILMTAB
40344	EMEND 125 MG POWDER PACKET
19366	EMEND 125MG CAPSULE
27278	EMEND 40MG CAPSULE
19365	EMEND 80MG CAPSULE
19367	EMEND TRIPACK
99335	EMEND 115 MG VIAL

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
29247	EMEND 150 MG VIAL
40523	ERYPED 200 MG/5 ML SUSPENSION
40524	ERYPED 400 MG/5 ML SUSPENSION
40730	ERY-TAB EC 250 MG TABLET
40731	ERY-TAB EC 333 MG TABLET
40732	ERY-TAB EC 500 MG TABLET
40642	ERYTHROCIN 250 MG FILMTAB
25529	ERYTHROCIN 500 MG ADDVNT VL
40523	ERYTHROMYCIN 200 MG/5 ML SUSP
40720	ERYTHROMYCIN 250 MG FILMTAB
40524	ERYTHROMYCIN 400 MG/5 ML SUSP
40721	ERYTHROMYCIN 500 MG FILMTAB
40660	ERYTHROMYCIN EC 250 MG CAP
40560	ERYTHROMYCIN ES 400 MG TAB
60822	FLUCONAZOLE 10 MG/ML SUSP
42190	FLUCONAZOLE 100 MG TABLET
42193	FLUCONAZOLE 150 MG TABLET
42191	FLUCONAZOLE 200 MG TABLET
60821	FLUCONAZOLE 40 MG/ML SUSP
42192	FLUCONAZOLE 50 MG TABLET
69790	FLUCONAZOLE-NACL 200 MG/100 ML
69791	FLUCONAZOLE-NACL 400 MG/200 ML
20553	FOSAMPRENAVIR 700 MG TABLET

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
19908	GLEEVEC 100 MG TABLET
19907	GLEEVEC 400 MG TABLET
19908	IMATINIB MESYLATE 100 MG TAB
19907	IMATINIB MESYLATE 400 MG TAB
43162	KISQALI 200 MG DAILY DOSE
43166	KISQALI 400 MG DAILY DOSE
43167	KISQALI 600 MG DAILY DOSE
43366	KISQALI FEMARA 200 MG CO-PACK
43368	KISQALI FEMARA 400 MG CO-PACK
43369	KISQALI FEMARA 600 MG CO-PACK
23783	LEXIVA 50MG/ML SUSPENSION
20553	LEXIVA 700MG TABLET
19183	MATZIM LA 180MG TABLET
19184	MATZIM LA 240MG TABLET
19185	MATZIM LA 300MG TABLET
19186	MATZIM LA 360MG TABLET
19187	MATZIM LA 420MG TABLET
26586	MULTAQ 400 MG TABLET
44049	PREVYMIS 240 MG TABLET
44061	PREVYMIS 480 MG TABLET
28737	TASIGNA 150 MG CAPSULE
99070	TASIGNA 200 MG CAPSULE
02330	TAZTIA XT 120MG CAPSULE

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
02329	TAZTIA XT 180MG CAPSULE
02332	TAZTIA XT 240MG CAPSULE
02333	TAZTIA XT 300MG CAPSULE
02328	TAZTIA XT 360MG CAPSULE
02330	TIADYLT ER 120 MG CAPSULE
02329	TIADYLT ER 180 MG CAPSULE
02332	TIADYLT ER 240 MG CAPSULE
02333	TIADYLT ER 300 MG CAPSULE
02328	TIADYLT ER 360 MG CAPSULE
94691	TIADYLT ER 420 MG CAPSULE
32112	TRANDOLAPR-VERAPAM ER 1-240 MG
32111	TRANDOLAPR-VERAPAM ER 2-180 MG
32113	TRANDOLAPR-VERAPAM ER 2-240 MG
32114	TRANDOLAPR-VERAPAM ER 4-240 MG
02341	VERAPAMIL 120 MG TABLET
03004	VERAPAMIL 360 MG CAP PELLET
47110	VERAPAMIL 40 MG TABLET
02342	VERAPAMIL 80 MG TABLET
03003	VERAPAMIL ER 120 MG CAPSULE
32472	VERAPAMIL ER 120 MG TABLET
03001	VERAPAMIL ER 180 MG CAPSULE
32471	VERAPAMIL ER 180 MG TABLET
03002	VERAPAMIL ER 240 MG CAPSULE

Table 3 (history of a moderate CYP3A4 inhibitor) Required claims: 1 Look back timeframe: 45 days	
GCN	Label Name
32470	VERAPAMIL ER 240 MG TABLET
94122	VERAPAMIL ER PM 100 MG CAPSULE
94123	VERAPAMIL ER PM 200 MG CAPSULE
94124	VERAPAMIL ER PM 300 MG CAPSULE
03003	VERELAN 120 MG CAP PELLETT
03001	VERELAN 180 MG CAP PELLETT
03002	VERELAN 240 MG CAP PELLETT
03004	VERELAN 360 MG CAP PELLETT
94122	VERELAN PM 100 MG CAP PELLETT
94123	VERELAN PM 200 MG CAP PELLETT
94124	VERELAN PM 300 MG CAP PELLETT
55029	XALKORI 150 MG PELLETT
55027	XALKORI 20 MG PELLETT
55028	XALKORI 50 MG PELLETT
30458	XALKORI 200 MG CAPSULE
30457	XALKORI 250 MG CAPSULE
36447	ZYKADIA 150MG CAPSULE

Table 7 (agents for the treatment of Cystic Fibrosis) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
56768	ALYFTREK 4-20-50 MG TABLET

Table 7 (agents for the treatment of Cystic Fibrosis) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
56769	ALYFTREK 10-50-125 MG TABLET
36937	ORKAMBI 100-125MG GRANULE PKT
42366	ORKAMBI 100MG-125MG TABLET
42848	ORKAMBI 150-188MG GRANULE PKT
39008	ORKAMBI 200MG-125MG TABLET
52865	ORKAMBI 75-94MG GRANULE PKT
44444	SYMDEKO 100/150-150 MG TABS
46553	SYMDEKO 50/75-75 MG TABS
47136	TRIKAFTA 100/50/75MG-150MG
49779	TRIKAFTA 50/25/37.5MG-75MG
54048	TRIKAFTA 80/40/60MG-59.5MG PACKET
54047	TRIKAFTA 100/50/75-75MG PACKET

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

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit 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 75-94MG GRANULE PKT	52865

**Orkambi (Lumacaftor/Ivacaftor)****Clinical Criteria Logic**

1. Is the request for Orkambi 75-94mg granules, 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 ($\geq$) 1 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 [Alyftrek, Kalydeco, Symdeko and/or Trikafta](#)?
☐ Yes – Deny
☐ No – Go to #9

9. Is Orkambi being used for the treatment of cystic fibrosis in a client that is homozygous for the F508del mutation in the CFTR gene? If the genotype is unknown, an FDA-cleared cystic fibrosis mutation test should be used to detect the presence of the F508del mutation of both alleles of the CFTR gene. [Manual]

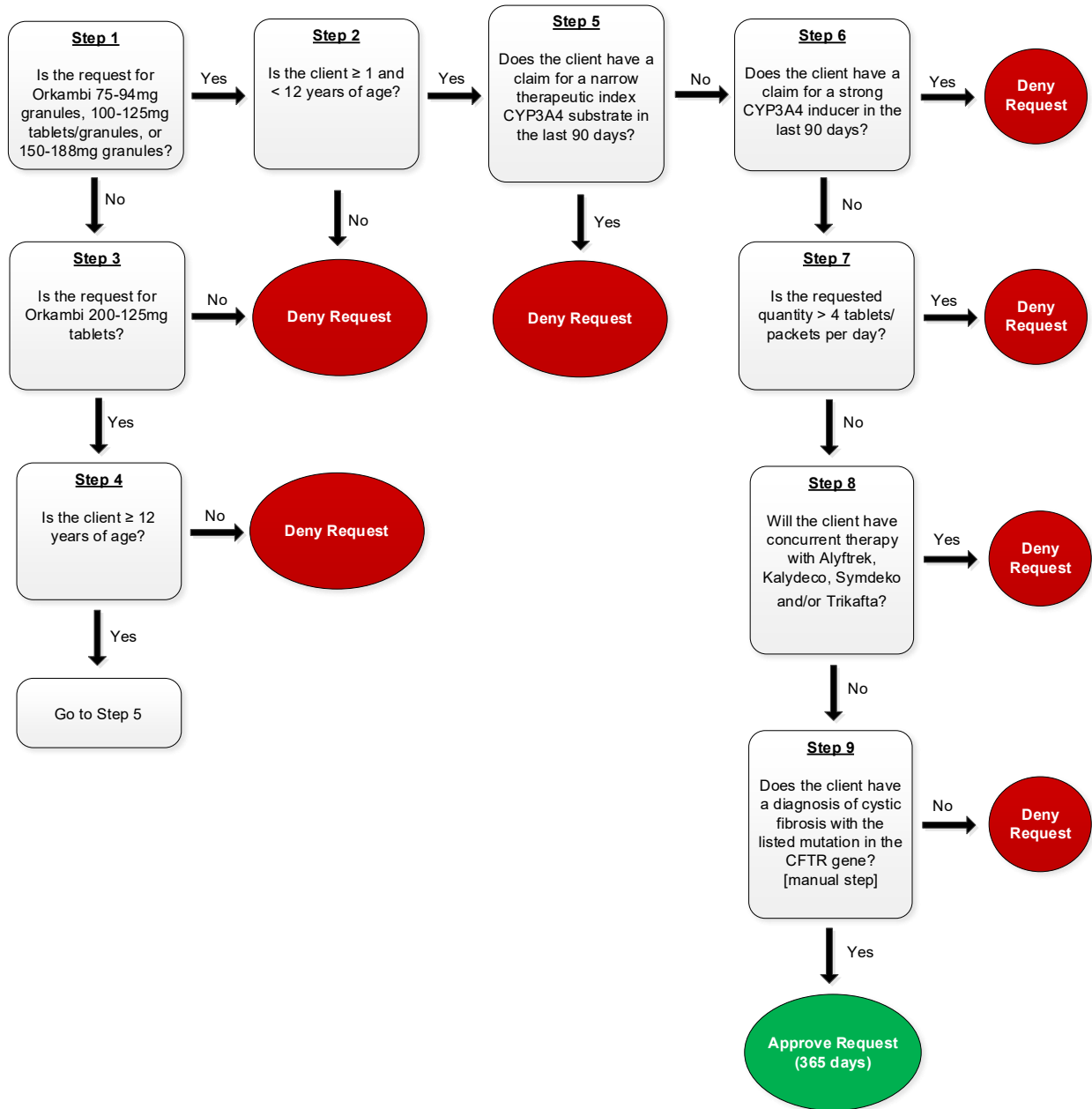
☐ Yes – Approve (365 days)

☐ No – Deny



Orkambi (Lumacaftor/Ivacaftor)

Clinical Criteria Logic Diagram





Orkambi (Lumacaftor/Ivacaftor)

Clinical Criteria Supporting Tables

Table 5 (history of a narrow therapeutic index CYP3A4 substrate) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
20844	AFINITOR 10MG TABLET
28783	AFINITOR 2.5MG TABLET
20784	AFINITOR 5MG TABLET
31396	AFINITOR 7.5MG TABLET
34589	AFINITOR DISPERZ 2MG TABLET
34590	AFINITOR DISPERZ 3MG TABLET
34592	AFINITOR DISPERZ 5MG TABLET
13910	CYCLOSPORINE 100MG CAPSULE
13917	CYCLOSPORINE 100MG/ML SOLN
13911	CYCLOSPORINE 25MG CAPSULE
13919	CYCLOSPORINE MODIFIED 100MG
13918	CYCLOSPORINE MODIFIED 25MG
13916	CYCLOSPORINE MODIFIED 50MG
39120	ENVARUSUS XR 0.75MG TABLET
39123	ENVARUSUS XR 1MG TABLET
39124	ENVARUSUS XR 4MG TABLET
13919	GENGRAF 100MG CAPSULE
13917	GENGRAF 100MG/ML SOLUTION
13918	GENGRAF 25MG CAPSULE
13916	GENGRAF 50MG CAPSULE

Table 5 (history of a narrow therapeutic index CYP3A4 substrate) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
13919	NEORAL 100MG GELATIN CAPSULE
13917	NEORAL 100MG/ML SOLUTION
13918	NEORAL 25MG GELATIN CAPSULE
28251	PROGRAF 0.2 MG GRANULE PACKET
28249	PROGRAF 1 MG GRANULE PACKET
28495	PROGRAF 0.5MG CAPSULE
28491	PROGRAF 1MG CAPSULE
28492	PROGRAF 5MG CAPSULE
28502	RAPAMUNE 0.5MG TABLET
13696	RAPAMUNE 1MG TABLET
50356	RAPAMUNE 1MG/ML ORAL SOLN
19299	RAPAMUNE 2MG TABLET
13910	SANDIMMUNE 100MG CAPSULE
08220	SANDIMMUNE 100MG/ML SOLN
13911	SANDIMMUNE 25MG CAPSULE
28502	SIROLIMUS 0.5MG TABLET
13696	SIROLIMUS 1MG TABLET
19299	SIROLIMUS 2MG TABLET
50356	SIROLIMUS 1 MG/ML ORAL SOLN
28495	TACROLIMUS 0.5MG CAPSULE
28491	TACROLIMUS 1MG CAPSULE
28492	TACROLIMUS 5MG CAPSULE
14282	TRIAZOLAM 0.125MG TABLET

Table 5 (history of a narrow therapeutic index CYP3A4 substrate) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
14280	TRIAZOLAM 0.25MG TABLET
24825	ZORTRESS 0.25MG TABLET
24826	ZORTRESS 0.5MG TABLET
24827	ZORTRESS 0.75MG TABLET
28589	ZORTRESS 1 MG TABLET

Table 6 (history of a strong CYP3A4 inducer) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
25445	ACTOPLUS MED 15-850MG TABLET
25444	ACTOPLUS MET 15-500MG TABLET
28620	ACTOPLUS MET XR 15-1000MG TABLET
28622	ACTOPLUS MET XR 30-1000MG TABLET
92991	ACTOS 15MG TABLET
93001	ACTOS 30MG TABLET
93011	ACTOS 45MG TABLET
34080	ALOGLIPTIN-PIOGLIT 12.5-15MG
34083	ALOGLIPTIN-PIOGLIT 12.5-30MG
34084	ALOGLIPTIN-PIOGLIT 12.5-45MG
34077	ALOGLIPTIN-PIOGLIT 25-15MG TB
34078	ALOGLIPTIN-PIOGLIT 25-30MG TB
34079	ALOGLIPTIN-PIOGLIT 25-45MG TB

Table 6 (history of a strong CYP3A4 inducer) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
27346	ATRIPLA TABLET
17460	CARBAMAZEPINE 100 MG TAB CHEW
47500	CARBAMAZEPINE 100 MG/5 ML SUSP
17450	CARBAMAZEPINE 200 MG TABLET
23934	CARBAMAZEPINE ER 100 MG CAP
27820	CARBAMAZEPINE ER 100 MG TABLET
23932	CARBAMAZEPINE ER 200 MG CAP
27821	CARBAMAZEPINE ER 200 MG TABLET
23933	CARBAMAZEPINE ER 300 MG CAP
27822	CARBAMAZEPINE ER 400 MG TABLET
23934	CARBATROL ER 100 MG CAPSULE
23932	CARBATROL ER 200 MG CAPSULE
23933	CARBATROL ER 300 MG CAPSULE
17700	DILANTIN 100 MG CAPSULE
17241	DILANTIN 125 MG/5 ML SUSP
17701	DILANTIN 30 MG CAPSULE
17250	DILANTIN 50 MG INFATAB
97181	DUETACT 30-2MG TABLET
97180	DUETACT 30-4MG TABLET
17450	EPITOL 200 MG TABLET
13781	EQUETRO 100 MG CAPSULE
13805	EQUETRO 200 MG CAPSULE
13818	EQUETRO 300 MG CAPSULE

Table 6 (history of a strong CYP3A4 inducer) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
29810	MYCOBUTIN 150 MG CAPSULE
31420	NEVIRAPINE 200MG TABLET
31421	NEVIRAPINE 50MG/5ML SUSPENSION
29767	NEVIRAPINE ER 400MG TABLET
34080	OSENI 12.5-15MG TABLET
34083	OSENI 12.5-30MG TABLET
34084	OSENI 12.5-45MG TABLET
34077	OSENI 25-15MG TABLET
34078	OSENI 25-30MG TABLET
34079	OSENI 25-45MG TABLET
12975	PHENOBARBITAL 100 MG TABLET
12892	PHENOBARBITAL 130 MG/ML VIAL
12971	PHENOBARBITAL 15 MG TABLET
97706	PHENOBARBITAL 16.2 MG TABLET
12956	PHENOBARBITAL 20 MG/5 ML ELIX
12973	PHENOBARBITAL 30 MG TABLET
97965	PHENOBARBITAL 32.4 MG TABLET
12972	PHENOBARBITAL 60 MG TABLET
97966	PHENOBARBITAL 64.8 MG TABLET
12894	PHENOBARBITAL 65 MG/ML VIAL
97967	PHENOBARBITAL 97.2 MG TABLET
15038	PHENYTEK 200 MG CAPSULE
15037	PHENYTEK 300 MG CAPSULE

Table 6 (history of a strong CYP3A4 inducer) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
17241	PHENYTOIN 125 MG/5 ML SUSP
17250	PHENYTOIN 50 MG TABLET CHEW
17200	PHENYTOIN 50 MG/ML VIAL
17700	PHENYTOIN SOD EXT 100 MG CAP
15038	PHENYTOIN SOD EXT 200 MG CAP
15037	PHENYTOIN SOD EXT 300 MG CAP
92991	PIOGLITAZONE HCL 15 MG TABLET
93001	PIOGLITAZONE HCL 30 MG TABLET
93011	PIOGLITAZONE HCL 45 MG TABLET
97181	PIOGLITAZONE-GLIMEPIRIDE 30-2
97180	PIOGLITAZONE-GLIMEPIRIDE 30-4
25444	PIOGLITAZONE-METFORMIN 15-500
25445	PIOGLITAZONE-METFORMIN 15-850
29810	RIFABUTIN 150 MG CAPSULE
41260	RIFADIN 150 MG CAPSULE
41261	RIFADIN 300 MG CAPSULE
41470	RIFADIN IV 600 MG VIAL
89800	RIFAMATE CAPSULE
41260	RIFAMPIN 150 MG CAPSULE
41261	RIFAMPIN 300 MG CAPSULE
41470	RIFAMPIN IV 600 MG VIAL
14142	RIFATER TABLET
43303	SUSTIVA 200MG CAPSULE

Table 6 (history of a strong CYP3A4 inducer) Required claims: 1 Look back timeframe: 90 days	
GCN	Label Name
43301	SUSTIVA 50MG CAPSULE
15555	SUSTIVA 600MG TABLET
47500	TEGRETOL 100 MG/5 ML SUSP
17450	TEGRETOL 200 MG TABLET
27820	TEGRETOL XR 100 MG TABLET
27821	TEGRETOL XR 200 MG TABLET
27822	TEGRETOL XR 400 MG TABLET
31420	VIRAMUNE 200MG TABLET
31421	VIRAMUNE 50MG/5ML SUSPENSION
30935	VIRAMUNE XR 100MG TABLET
29767	VIRAMUNE XR 400MG TABLET
33183	XTANDI 40MG CAPSULE

Table 8 (agents for the treatment of Cystic Fibrosis) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
56768	ALYFTREK 4-20-50 MG TABLET
56769	ALYFTREK 10-50-125 MG TABLET
31312	KALYDECO 150MG TABLET
46238	KALYDECO 25MG GRANULES PACKET
38138	KALYDECO 50MG GRANULES PACKET
38139	KALYDECO 75MG GRANULES PACKET

Table 8 (agents for the treatment of Cystic Fibrosis)	
Required claims: 1	
Look back timeframe: <i>current therapy</i>	
GCN	Label Name
44444	SYMDEKO 100/150-150 MG TABS
46553	SYMDEKO 50/75-75 MG TABS
47136	TRIKAFTA 100/50/75MG-150MG
49779	TRIKAFTA 50/25/37.5MG-75MG
54048	TRIKAFTA 80/40/60-59.5MG PACKET
54047	TRIKAFTA 100/50/75-75MG PACKET

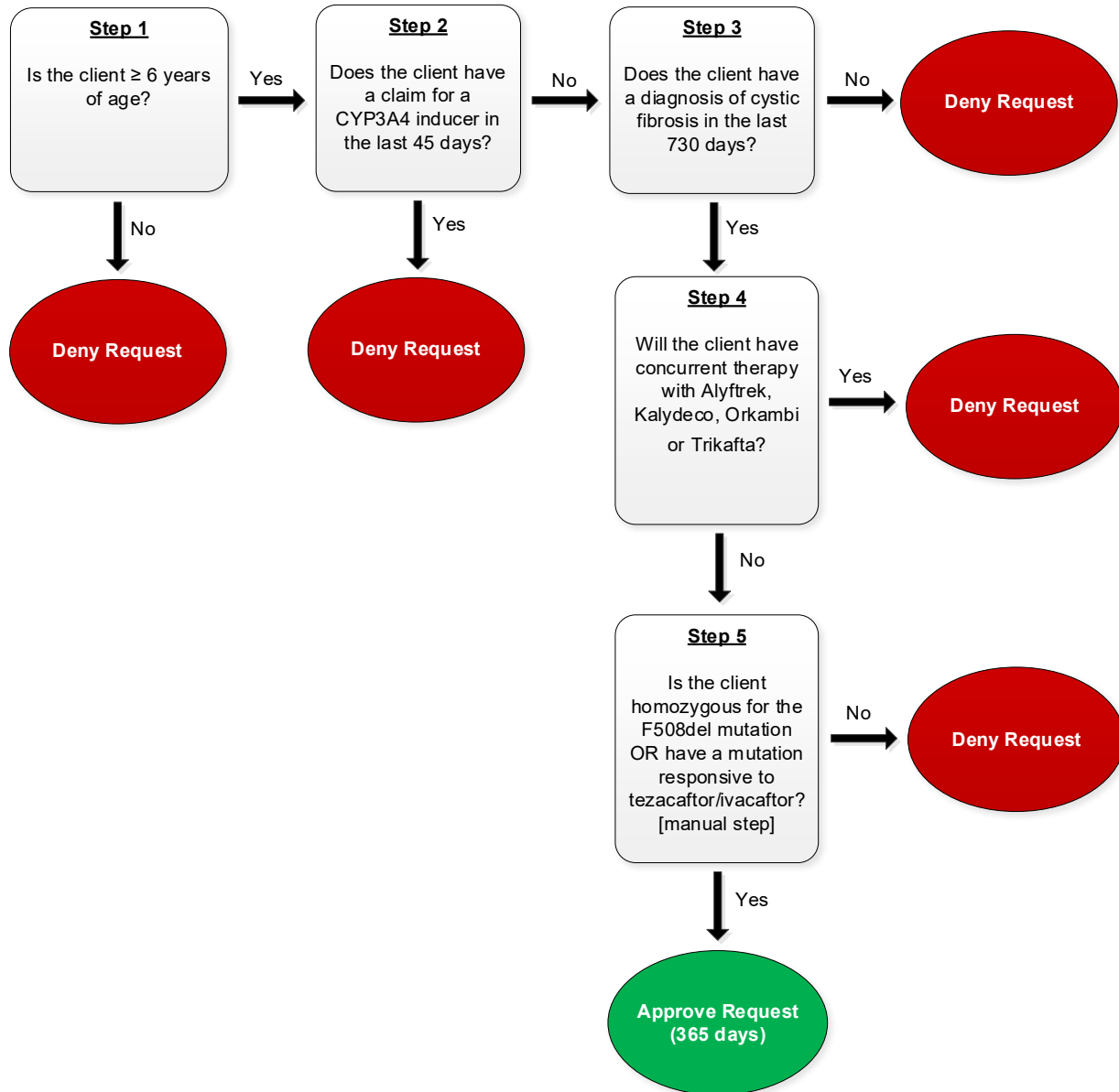
**Symdeko (Tezacaftor/Ivacaftor)****Drugs Requiring Prior Authorization**

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

**Symdeko (Tezacaftor/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 [Alyftrek, Kalydeco, Orkambi or Trikafta](#)?
☐ Yes – Deny
☐ No – Go to #5
5. Is the client homozygous for the F508del mutation OR does the client have at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on *in vitro* data and/or clinical evidence? If the genotype is unknown, an FDA-cleared cystic fibrosis mutation test should be used to detect the presence of a CFTR mutation. [Manual]
☐ Yes – Approve (365 days)
☐ No – Deny

**Symdeko (Tezacaftor/Ivacaftor)****Clinical Criteria Logic Diagram**



Symdeko (Tezacaftor/Ivacaftor)

Clinical Criteria Supporting Tables

Table 2 (claim for a CYP3A4 inducer)

Required 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.

Table 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

Table 4 (agents for the treatment of Cystic Fibrosis)

Required claims: 1

Look back timeframe: *current therapy*

GCN	Label Name
56768	ALYFTREK 4-20-50 MG TABLET
56769	ALYFTREK 10-50-125 MG TABLET
31312	KALYDECO 150MG TABLET
46238	KALYDECO 25MG GRANULES PACKET
38138	KALYDECO 50MG GRANULES PACKET

Table 4 (agents for the treatment of Cystic Fibrosis) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
38139	KALYDECO 75MG GRANULES PACKET
36937	ORKAMBI 100-125MG GRANULE PKT
42366	ORKAMBI 100MG-125MG TABLET
42848	ORKAMBI 150-188MG GRANULE PKT
39008	ORKAMBI 200MG-125MG TABLET
52865	ORKAMBI 75-94MG GRANULE PKT
47136	TRIKAFTA 100/50/75MG-150MG
49779	TRIKAFTA 50/25/37.5MG-75MG
54048	TRIKAFTA 80/40/60-59.5MG PACKET
54047	TRIKAFTA 100/50/75-75MG PACKET



Trikafta (Elexcaftor/ Tezacaftor/Ivacaftor)

Drugs Requiring Prior Authorization

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/formulary/formulary-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
TRIKAFTA 100/50/75-75MG PACKET	54047
TRIKAFTA 100/50/75MG-150MG	47136
TRIKAFTA 50/25/37.5MG-75MG	49779
TRIKAFTA 80/40/60-59.5MG PACKET	54048

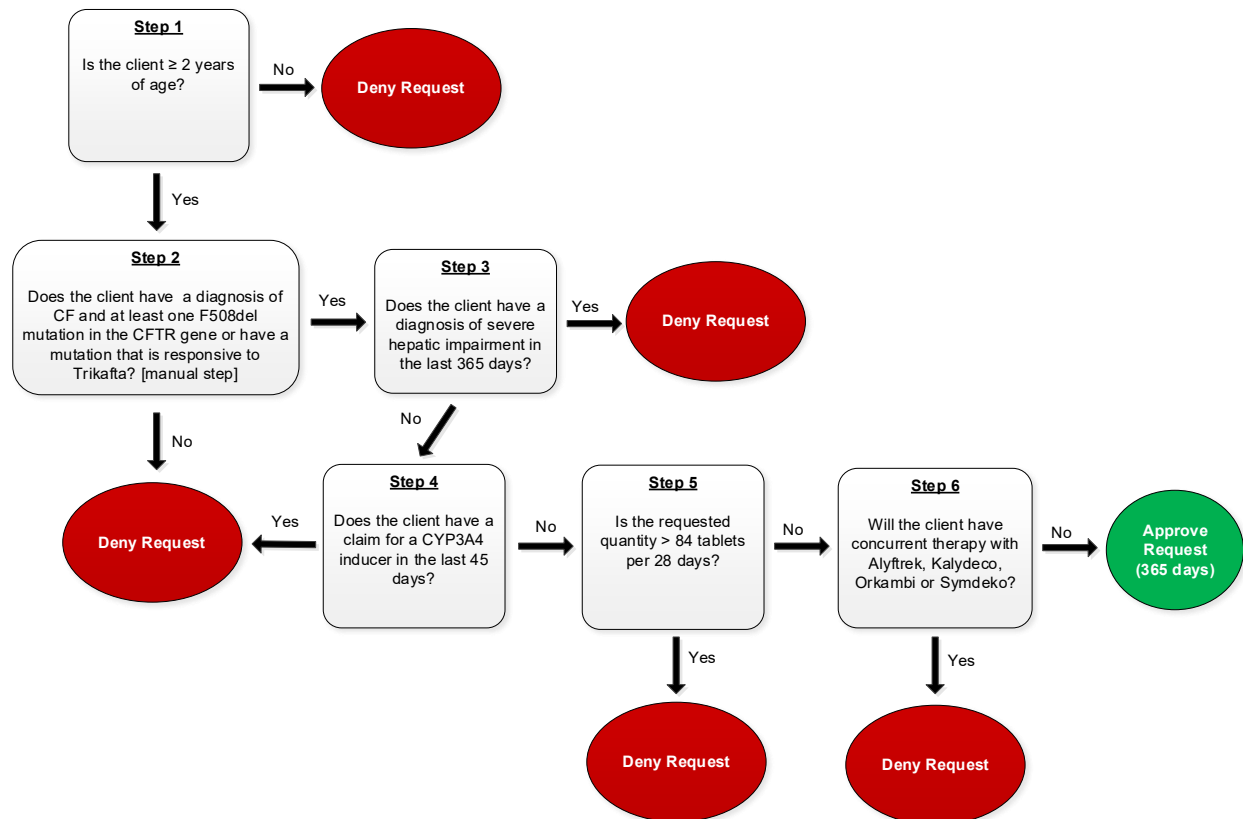
**Trikafta (Elexcaftor/
Tezacaftor/Ivacaftor)****Clinical Criteria Logic**

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 diagnosis of cystic fibrosis and at least one F508del mutation in the CFTR gene OR a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor based on *in vitro* data? If the genotype is unknown, an FDA-cleared cystic fibrosis mutation test should be used to detect the presence of a CFTR mutation. [Manual]
☐ 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. Is the requested quantity greater than ($>$) 84 tablets per 28 days?
☐ Yes – Deny
☐ No – Go to #6
6. Will the client have concurrent therapy with [Alyftrek, Kalydeco, Orkambi or Symdeko](#)?
☐ Yes – Deny
☐ No – Approve (365 days)



Trikafta (Elexcaftor/ Tezacaftor/Ivacaftor)

Clinical Criteria Logic Diagram





Trikafta (Elexcaftor/ Tezacaftor/Ivacaftor)

Clinical Criteria Supporting Tables

Table 3 (diagnosis of severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
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

Table 3 (diagnosis of severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
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
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

Table 3 (diagnosis of severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
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

Table 4 (history of a CYP3A4 inducer) Required claims: 1 Look back timeframe: 45 days
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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.

Table 6 (agents for the treatment of Cystic Fibrosis) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
56768	ALYFTREK 4-20-50 MG TABLET
56769	ALYFTREK 10-50-125 MG TABLET
31312	KALYDECO 150MG TABLET

Table 6 (agents for the treatment of Cystic Fibrosis) Required claims: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
46238	KALYDECO 25MG GRANULES PACKET
38138	KALYDECO 50MG GRANULES PACKET
38139	KALYDECO 75MG GRANULES PACKET
36937	ORKAMBI 100-125MG GRANULE PKT
42366	ORKAMBI 100MG-125MG TABLET
42848	ORKAMBI 150-188MG GRANULE PKT
39008	ORKAMBI 200MG-125MG TABLET
52865	ORKAMBI 75-94MG GRANULE PKT
44444	SYMDEKO 100/150-150MG TABS
46553	SYMDEKO 50/75-75 MGTABS



Cystic Fibrosis Agents

Clinical Criteria References

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Cystic Fibrosis Agents

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, Prezcofix 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 - Updated Table 3 - Updated Table 4 - Added GCN for Orkambi 100mg/125mg tablet to Drugs Requiring PA - Updated Criteria Logic - Updated Logic Diagram - Updated Table 2 - Updated Table 3 - Updated References
05/30/2017	- Updated Kalydeco criteria logic – 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

Publication Date	Notes
08/02/2017	- Updated Kalydeco criteria logic – updated step 8 to include the following mutations on the CFTR gene: 2789+5G, 3272-26A, 3849+10kbC, 711+3A and E831X - Updated References
04/27/2018	- Added criteria for Symdeko. Criteria approved by the DUR Board on April 27, 2018 - Updated references
11/27/2018	- Updated age requirements for Kalydeco (to 12 months of age and older) - Added GCNs for Orkambi granules to 'Drugs Requiring PA' - Updated age requirements for Orkambi (to 2 years of age and older) - Updated references
01/30/2019	Updated change log from 08/02/2017 to read E831X instead of E821X
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 TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table
05/09/2019	- Added GCN for Kalydeco 25mg packet to 'Drugs Requiring PA' - Changed age on question 1 to greater than or equal to 6 months on criteria logic and logic diagram - Updated references
07/10/2019	- Added GCN for Symdeko 50/75-75mg tablet to 'Drugs Requiring PA' - Changed age on question 1 to greater than or equal to 6 years on criteria logic and logic diagram - Updated references
01/30/2020	- Added concurrent therapy check to Kalydeco (question 8), Orkambi (question 8) and Symdeko (question 4) - Added criteria for Trikafta - Updated question 11 in criteria logic and logic diagram, as recommended by DUR Board - Updated references
10/19/2020	- Updated age in Kalydeco criteria logic and logic diagram - Updated references
01/13/2021	- Updated Symdeko question 5 on criteria logic and logic diagram - Updated Trikafta question 2 on criteria logic and logic diagram

Publication Date	Notes
	Updated references
01/20/2021	- Updated Kalydeco question 9 on criteria logic - Updated Orkambi question 9 on criteria logic - Updated Symdeko question 5 on criteria logic - Updated Trikafta question 2 on criteria logic - Updated references
07/01/2021	- Added GCN for Trikafta 50/25/37.5 – 75 mg (49779) - Updated age for Trikafta to 6 years and older - Removed check for adjusted dosing in Trikafta
09/21/2022	Updated age for Orkambi to 1 year and older
05/04/2023	- Removed age check for Kalydeco - Updated age for Trikafta to 2 years and older - Updated references
07/07/2023	Added GCNs for Orkambi (52865) and Trikafta (54048, 54047)
09/13/2023	Added GCN for Kalydeco (45746)
12/08/2023	- Annual review by staff - Updated references
07/31/2024	- Annual review by staff - Updated references
04/30/2025	- Annual review by staff - Updated CYP3A4 Inducer, Strong CYP3A4 Inhibitor, Moderate CYP3A4 Inhibitor, and Narrow Therapeutic Index CYP3A4 Substrate supporting tables - Updated references
07/25/2025	Added criteria for Alyftrek as approved by the DUR Board