

**Texas Prior Authorization Program  
Clinical Edit Criteria**

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**Drug/Drug Class**

## **Kalydeco (Ivacaftor) Tablets**

**Clinical Edit Information Included in this Document**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical edit
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical edit criteria rules
- **Logic diagram:** a visual depiction of the clinical edit 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 edit

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

**Revision Notes**

Added additional mutations to the CFTR gene to the clinical edit criteria.



## Kalydeco (Ivacaftor) Tablets

### Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
KALYDECO 150MG TABLET	31312



## Kalydeco (Ivacaftor) Tablets

### Clinical Edit 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 any of the following medications (CYP3A inducers) in the last 45 days: rifampin, rifabutin, phenobarbital, carbamazepine, or phenytoin?  
 Yes (Deny)  
 No (Go to #3)
3. Does the client have a claim for any of the following medications (strong CYP3A4 inhibitors) in the last 45 days: ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, clarithromycin, boceprevir, isoniazid, dalfopristin-quinupristin, nefazodone, ritonavir, lopinavir-ritonavir, atazanavir, saquinavir, amprenavir, indinavir, nelfinavir, or delavirdine?  
 Yes (Go to #5)  
 No (Go to #4)
4. Does the client have a claim for any of the following medications (moderate CYP3A4 inhibitors) in the last 45 days: fluconazole, erythromycin, erythromycin-sulfisoxazole, dronedarone, verapamil, or diltiazem?  
 Yes (Go to #6)  
 No (Go to #7)
5. Is the claim greater than ( $>$ ) nine tablets of 150mg each (total 1350mg) (two per week)?  
 Yes (Deny)  
 No (Go to #8)
6. Is the claim greater than ( $>$ ) one tablet (150mg) per day?  
 Yes (Deny)  
 No (Go to #8)
7. Is the claim greater than ( $>$ ) two tablets (300mg) per day?  
 Yes (Deny)  
 No (Go to #8)



## Kalydeco (Ivacaftor) Tablets

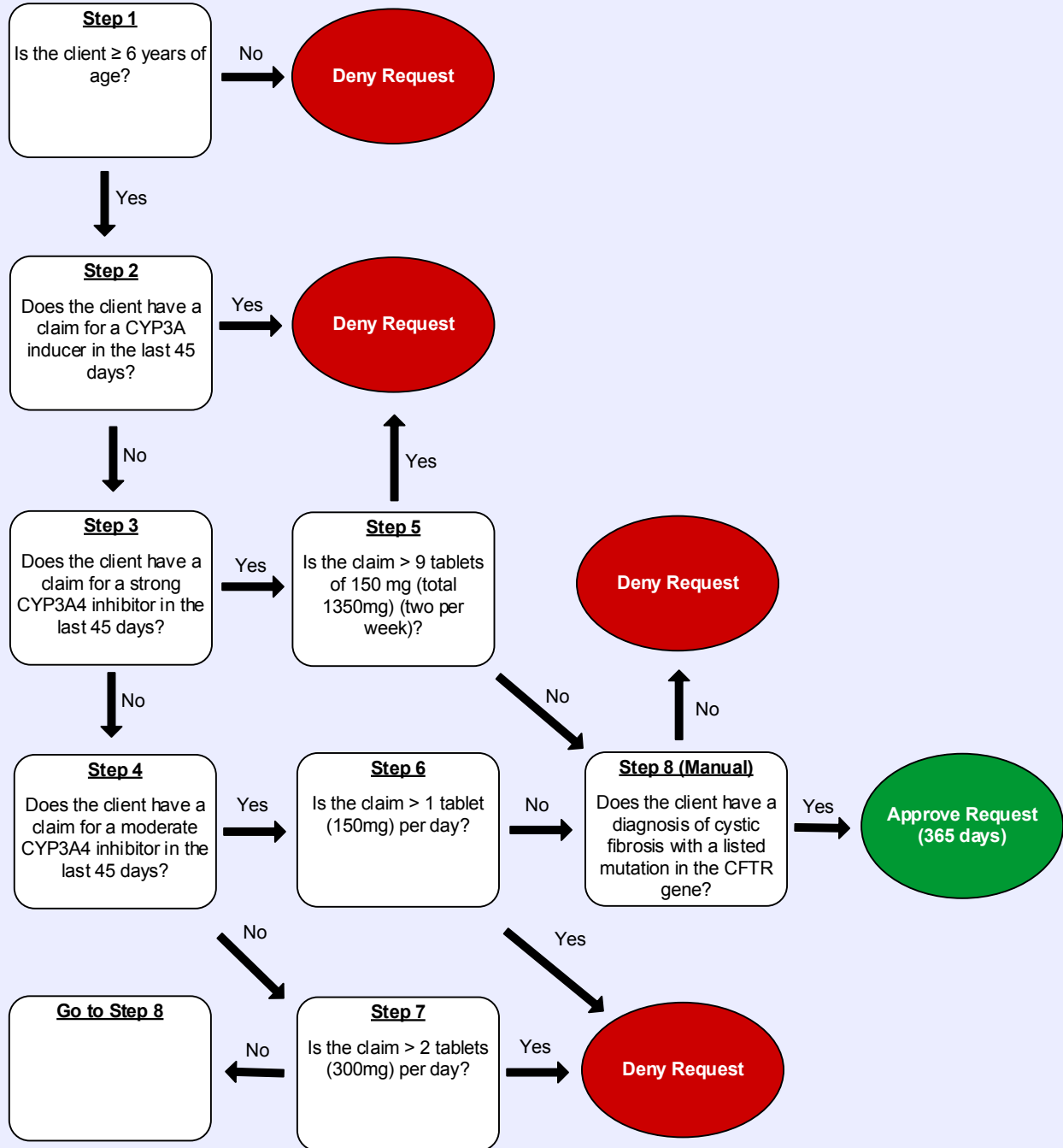
### Clinical Edit Criteria Logic

8. Manual step – Does the client have a diagnosis of cystic fibrosis with a G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S5849R mutation in the CFTR gene?
- Yes (Approve – 365 days)
  - No (Deny)



# Kalydeco (Ivacaftor) Tablets

## Clinical Edit Criteria Logic Diagram





## Kalydeco (Ivacaftor) Tablets

### Clinical Edit Criteria Supporting Tables

<b>Step 2 (history of a CYP3A inducer)</b> <b>Number of claims: 1</b> <b>Look back timeframe: 45 days</b>	
<b>Label Name</b>	<b>GCN</b>
BELLADONA-PHENOBARBITAL TAB	74070
CARBAMAZEPINE 100MG CHEW TAB	17460
CARBAMAZEPINE 100MG/5ML SUSPENSION	47500
CARBAMAZEPINE ER 100MG CAPSULE	23934
CARBAMAZEPINE ER 200MG CAPSULE	23932
CARBAMAZEPINE ER 300MG CAPSULE	23933
CARBAMAZEPINE XR 200MG TABLET	27821
CARBAMAZEPINE XR 400MG TABLET	27822
CARBAMEZEPINE 200MG TABLET	17450
DILANTIN 30MG CAPSULE	17701
DILANTIN 50MG INFATAB	17250
EQUETRO 100MG CAPSULE	13781
EQUETRO 200MG CAPSULE	13805
EQUETRO 300MG CAPSULE	13818
MYCOBUTIN 150MG CAPSULE	29810
PHENOBARBITAL 20MG/5ML SOLUTION	12956
PHENOBARBITAL 15MG TABLET	12971
PHENOBARBITAL 16.2 TABLET	97706
PHENOBARBITAL 30MG TABLET	12973
PHENOBARBITAL 32.4MG TABLET	97965
PHENOBARBITAL 60MG TABLET	12972
PHENOBARBITAL 64.8 TABLET	97966
PHENOBARBITAL 97.2 TABLET	97967
PHENOBARBITAL 100MG TABLET	12975
PHENYTOIN 125MG/5ML SUSPENSION	17241
PHENYTOIN SOD EXT 100MG CAPSULE	17700
PHENYTOIN SOD EXT 200MG CAPSULE	15038
PHENYTOIN SOD EXT 300MG CAPSULE	15037
RIFAMPIN 150MG CAPSULE	41260
RIFAMPIN 300MG CAPSULE	41261

<b>Step 2 (history of a CYP3A inducer)</b>	
<b>Number of claims: 1</b>	
<b>Look back timeframe: 45 days</b>	
<b>Label Name</b>	<b>GCN</b>
TEGRETOL XR 100MG TABLET	27820

<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>
AGENERASE 15MG/ML ORAL SOLUTION	91491
CLARITHROMYCIN 125MG/ML SUSPENSION	11670
CLARITHROMYCIN 250MG/ML SUSPENSION	11671
CLARITHROMYCIN 250MG TABLET	48852
CLARITHROMYCIN 500MG TABLET	48851
CLARITHROMYCIN ER 500MG TABLET	48850
CRIXIVAN 100MG CAPSULE	26823
CRIXIVAN 200MG CAPSULE	26820
CRIXIVAN 333MG CAPSULE	26824
CRIXIVAN 400MG CAPSULE	26822
INVIRASE 200MG CAPSULE	26760
INVIRASE 500MG TABLET	23952
ISONIAZID 50MG/5ML SYRUP	41730
ISONIAZID 100MG TABLET	41741
ISONIAZID 300MG TABLET	41742
ITRACONAZOLE 100MG CAPSULE	49101
KALETRA 100-25MG TABLET	99101
KALETRA 133.3-33.3MG SOFTGEL	31781
KALETRA 200-50MG TABLET	25919
KALETRA 400-100MG/5ML SOLUTION	31782
KETEK 300MG TABLET	25905
KETEK 400MG TABLET	15175
KETOCONAZOLE 200MG TABLET	42590
NEFAZODONE HCL 50MG TABLET	16404
NEFAZODONE HCL 100MG TABLET	16406
NEFAZODONE HCL 150MG TABLET	16407
NEFAZODONE HCL 200MG TABLET	16408
NEFAZODONE HCL 250MG TABLET	16409
NORVIR 80MG/ML SOLUTION	26810

<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>
NORVIR 100MG SOFTGEL CAP	26812
NORVIR 100MG TABLET	28224
NOXAFIL 40MG/ML SUSPENSION	26502
RESCRIPTOR 100MG TABLET	43560
RESCRIPTOR 200MG TABLET	51631
REYATAZ 100MG CAPSULE	19949
REYATAZ 150MG CAPSULE	19952
REYATAZ 200MG CAPSULE	19953
REYATAZ 300MG CAPSULE	97430
SPORANOX 10MG/ML SOLUTION	49100
SPORANOX 250MG KIT	91170
SYNERCID 500MG VIAL	50355
VFEND 40MG/ML SUSPENSION	21513
VICTRELIS 200MG CAPSULE	29941
VIRACEPT 250MG TABLET	40312
VIRACEPT 625MG TABLET	19717
VORICONAZOLE 50MG TABLET	17497
VORICONAZOLE 200MG TABLET	17498

<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 120MG TABLET	2363
DILTIAZEM 24HR ER 120MG CAPSULE	2326
DILTIAZEM 24HR ER 180MG CAPSULE	2323
DILTIAZEM 24HR ER 240MG CAPSULE	2324
DILTIAZEM 24HR ER 300MG CAPSULE	2325
DILTIAZEM 24HR ER 360MG TABLET	7460
DILTIAZEM 24HR ER 420MG TABLET	19187
DILTIAZEM 30MG TABLET	2360
DILTIAZEM 60MG TABLET	2361
DILTIAZEM 90MG TABLET	2362
DILTIAZEM ER 60MG 12-HR CAPSULE	2322
DILTIAZEM ER 90MG 12-HR CAPSULE	2320



<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 ER 120MG CAPSULE	2330
DILTIAZEM ER 180MG CAPSULE	7461
DILTIAZEM ER 240MG CAPSULE	7462
DILTIAZEM ER 360MG CAPSULE	2328
DILTIAZEM ER 420MG CAPSULE	94691
ERY-TAB EC 250MG TABLET	40730
ERY-TAB EC 500MG TABLET	40732
ERYTHROMYCIN 200MG/5ML GRANULES	40523
ERYTHROMYCIN 250MG FILMTAB	40720
ERYTHROMYCIN 333MG TABLET EC	40731
ERYTHROMYCIN 400MG/5ML SUSPENSION	40526
ERYTHROMYCIN 500MG FILMTAB	40721
ERYTHROMYCIN EC 250MG CAPSULE	40660
ERYTHROMYCIN ES 400MG TABLET	40560
ERYTHROMYCIN ST 250MG TABLET	40642
ERYTHROMYCIN ST 500MG TABLET	40644
ERYTHROMYCIN/SULFISOXAZOLE SUSPENSION	89560
FLUCONAZOLE 10MG/ML SUSPENSION	60822
FLUCONAZOLE 40MG/ML SUSPENSION	60821
FLUCONAZOLE 50MG TABLET	42192
FLUCONAZOLE 100MG TABLET	42190
FLUCONAZOLE 150MG TABLET	42193
FLUCONAZOLE 200MG TABLET	42191
MULTAQ 400MG TABLET	26586
PCE 333MG TABLET	40741
PCE 500MG TABLET	40742
VERAPAMIL 40MG TABLET	47110
VERAPAMIL 80MG TABLET	2342
VERAPAMIL 120MG TABLET	2341
VERAPAMIL 360MG CAPSULE PELLETT	3004
VERAPAMIL ER 120MG CAPSULE	3003
VERAPAMIL ER 120MG TABLET	32472
VERAPAMIL ER 180MG CAPSULE	3001
VERAPAMIL ER 180MG TABLET	32471
VERAPAMIL ER 240MG CAPSULE	3002

<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 ER 240MG TABLET	32470
VERAPAMIL ER PM 100MG CAPSULE	94122
VERAPAMIL ER PM 200MG CAPSULE	94123
VERAPAMIL ER PM 300MG CAPSULE	94124



## Kalydeco (Ivacaftor) Tablets

### Clinical Edit Criteria References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. June 2014.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2014. Available at <http://www.clinicalpharmacology.com>. Accessed on October 30, 2014.
3. 2014 ICD-9-CM Diagnosis Codes, Volume 1. 2013. Available at <http://www.icd9data.com/>. Accessed on October 30, 2014.

## 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.

<b>Publication Date</b>	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