

**Texas Prior Authorization Program
Clinical Criteria**

Cystic Fibrosis Agents

Clinical Information Included in this Document

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.

Revision Notes



Symdeko (Tezacaftor/Ivacaftor and Ivacaftor)

Drugs Requiring Prior Authorization

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



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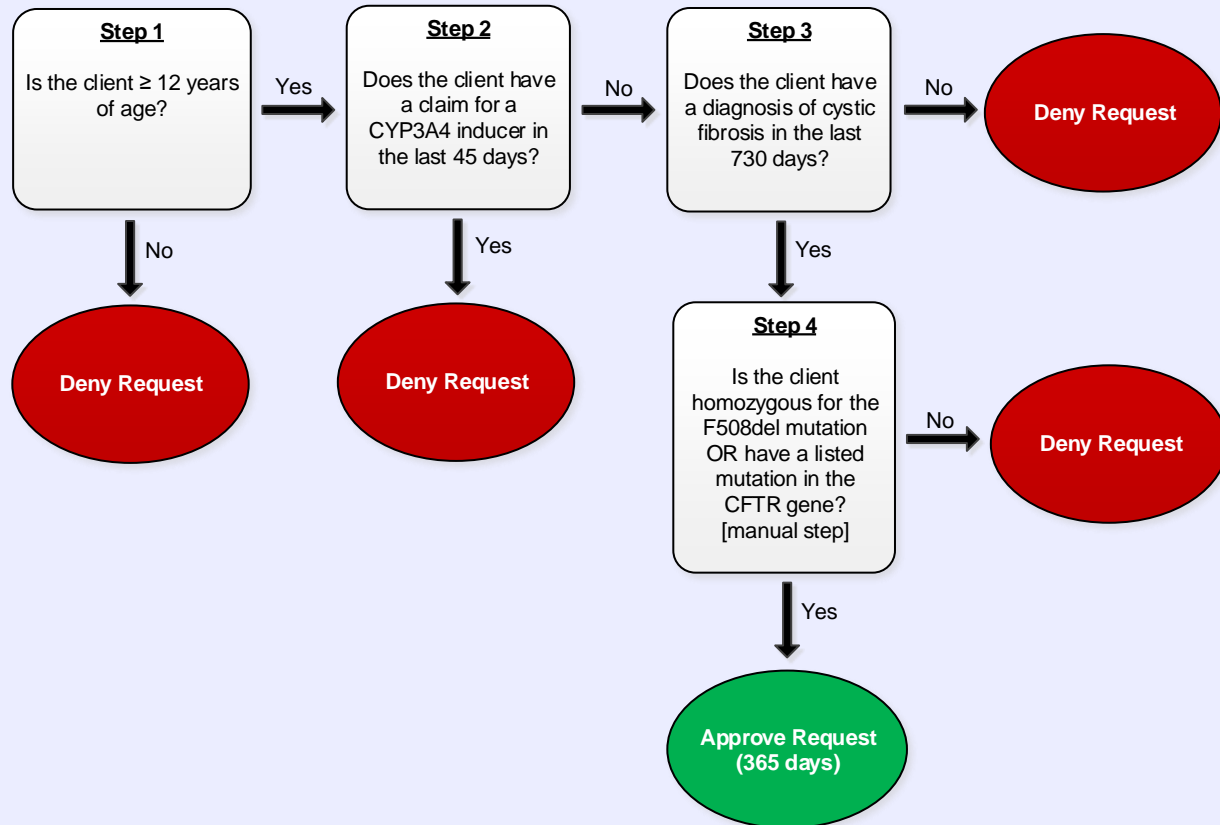
Clinical Criteria Logic

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)



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Clinical Criteria Logic Diagram





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Clinical Criteria Supporting Tables

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



Cystic Fibrosis Agents

Clinical Criteria References

1. Symdeko Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. February 2018.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2018. Available at www.clinicalpharmacology.com. Accessed on April 27, 2018.
3. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on April 27, 2018.
4. Indiana University, Department of Medicine, Clinical Pharmacology Research Institute. P450 Interaction Table. Available at medicine.iupui.edu. Accessed on April 27, 2018.
5. 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 April 27, 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
04/27/2018	Initial publication and posting to website