

**Texas Prior Authorization Program  
Clinical Criteria**

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## **Skyclarys (Omaveloxolone)**

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

#### **Skyclarys (Omaveloxolone)**

- **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**

Initial publication and presentation for the DUR Board



## Skyclarys (Omaveloxolone)

### 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](https://TxVendorDrug.com/formulary/formulary-search).

Drugs Requiring Prior Authorization	
Label Name	GCN
SKYCLARYS 50 MG CAPSULE	53799



## Skyclarys (Omaveloxolone)

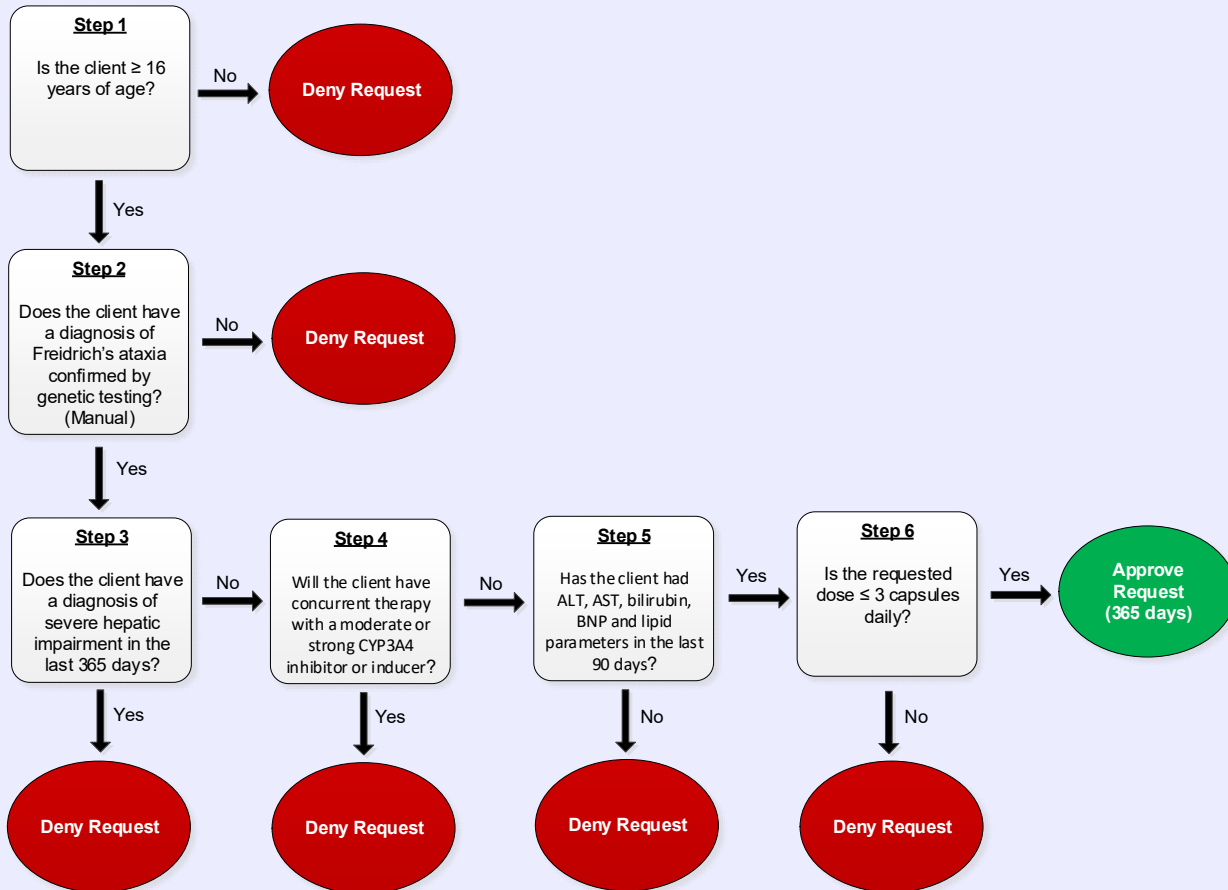
### Clinical Criteria Logic

1. Is the client greater than or equal to ( $\geq$ ) 16 years of age?  
 Yes – Go to #2  
 No – Deny
2. Does the client have a diagnosis of Freidrich’s ataxia confirmed by genetic testing? [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. Will the client have concurrent therapy with a **moderate or strong CYP3A4 inhibitor or inducer**?  
 Yes – Deny  
 No – Go to #5
5. Has the client had **ALT, AST, bilirubin, B-type natriuretic peptide (BNP) and lipid parameters** in the last 90 days?  
 Yes – Go to #6  
 No – Deny
6. Is the requested dose less than or equal to ( $\leq$ ) 3 capsules daily?  
 Yes – Approve (365 days)  
 No – Deny



# Skyclarys (Omaveloxolone)

## Clinical Criteria Logic Diagram





## Skyclarys (Omaveloxolone)

### Clinical Criteria Supporting Tables

<b>Step 3 (diagnosis of severe hepatic impairment)</b>	
<b>Required quantity: 1</b>	
<b>Look back timeframe: 365 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
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
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
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED

<b>Step 3 (diagnosis of severe hepatic impairment)</b>	
<b>Required quantity: 1</b>	
<b>Look back timeframe: 365 days</b>	
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
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	ABSCCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS

<b>Step 3 (diagnosis of severe hepatic impairment)</b>	
<b>Required quantity: 1</b>	
<b>Look back timeframe: 365 days</b>	
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

<b>Step 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor)</b>	
<b>Label Name</b>	<b>GCN</b>
AKYNZEO 300-0.5 MG CAPSULE	37239
APREPITANT 125 MG CAPSULE	19366
APREPITANT 125-80-80 MG PACK	19367
APREPITANT 40 MG CAPSULE	27278
APREPITANT 80 MG CAPSULE	19365
APTIOM 200 MG TABLET	36098
APTIOM 400 MG TABLET	36099
APTIOM 600 MG TABLET	36106
APTIOM 800 MG TABLET	27409
ATRIPLA TABLET	27346
BEXAROTENE 75 MG CAPSULE	92373
BOSENTAN 125 MG TABLET	14978
BOSENTAN 62.5MG TABLET	14979
CALAN 120 MG TABLET	02341
CALAN SR 120 MG CAPLET	32472
CALAN SR 180 MG CAPLET	32471
CALAN SR 240 MG CAPLET	32470
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

<b>Step 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor)</b>	
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
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
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
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
DILANTIN 100 MG CAPSULE	17700
DILANTIN 125 MG/5 ML SUSP	17241
DILANTIN 30 MG CAPSULE	17701
DILANTIN 50 MG INFATAB	17250
DILT XR 120 MG CAPSULE	07463



<b>Step 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor)</b>	
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
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
EFAVIRENZ 600 MG TABLET	15555
EMEND 125 MG POWDER PACKET	40344
EMEND 125MG CAPSULE	19366
EMEND 40MG CAPSULE	27278
EMEND 80MG CAPSULE	19365
EMEND TRIPACK	19367
EPITOL 200 MG TABLET	17450
EQUETRO 100 MG CAPSULE	13781
EQUETRO 200 MG CAPSULE	13805
EQUETRO 300 MG CAPSULE	13818
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

<b>Step 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor)</b>	
ERYTHROCIN 500 MG ADDVNT VL	25529
ERYTHROCIN 500 MG VIAL	40601
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
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
INTELENCE 100 MG TABLET	99318
INTELENCE 200 MG TABLET	29424
INTELENCE 25 MG TABLET	32035
ITRACONAZOLE 10 MG/ML SOLUTION	49100
ITRACONAZOLE 100 MG CAPSULE	49101
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
LYSODREN 500 MG TABLET	37810
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
MODAFINIL 100 MG TABLET	26101
MODAFINIL 200 MG TABLET	26102
MULTAQ 400 MG TABLET	26586

<b>Step 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor)</b>	
MYCOBUTIN 150 MG CAPSULE	29810
MYSOLINE 250 MG TABLET	17321
MYSOLINE 50 MG TABLET	17322
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
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
PREVMIS 240 MG TABLET	44049
PREVMIS 480 MG TABLET	44061
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 IV 600 MG VIAL	41470
RIFAMPIN 150 MG CAPSULE	41260
RIFAMPIN 300 MG CAPSULE	41261
RIFAMPIN IV 600 MG VIAL	41470

<b>Step 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor)</b>	
SPORANOX 10 MG/ML SOLUTION	49100
SPORANOX 100 MG CAPSULE	49101
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
TAFINLAR 50 MG CAPSULE	34723
TAFINLAR 75 MG CAPSULE	34724
TARGRETIN 75 MG CAPSULE	92373
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
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
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
VERAPAMIL ER 180 MG TABLET	32471
VERAPAMIL ER 240 MG CAPSULE	03002

<b>Step 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor)</b>	
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
VFEND 200 MG TABLET	17498
VFEND 40 MG/ML SUSPENSION	21513
VFEND 50 MG TABLET	17497
VFEND IV 200 MG VIAL	17499
VORICONAZOLE 200 MG TABLET	17498
VORICONAZOLE 200 MG VIAL	17499
VORICONAZOLE 40 MG/ML SUSP	21513
VORICONAZOLE 50 MG TABLET	17497
XALKORI 200 MG CAPSULE	30458
XALKORI 250 MG CAPSULE	30457
XTANDI 40 MG CAPSULE	33183
XTANDI 40 MG TABLET	46626
XTANDI 80 MG TABLET	48452
ZYKADIA 150MG CAPSULE	36447

<b>Step 5 (lab tests)</b>	
<b>Look back timeframe: 90 days</b>	
<b>CPT Code</b>	<b>Description</b>
80053	COMPREHENSIVE METABOLIC PANEL
80076	HEPATIC FUNCTION PANEL
82248	BILIRUBIN, DIRECT/INDIRECT
82247	BILIRUBIN, TOTAL
83880	NATRIURETIC PEPTIDE
80061	LIPID PANEL



## Skyclarys (Omaveloxolone)

### Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2023. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on October 13, 2023
2. 2023 ICD-10-CM Diagnosis Codes, Volume 1. 2023. Available at [www.icd10data.com](http://www.icd10data.com). Accessed on October 13, 2023.
3. Skyclarys Prescribing Information. Plano, TX. Reata Pharmaceuticals, Inc. February 2023.



## Skyclarys (Omaveloxolone)

### Publication History

### 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
10/13/2023	Initial publication and presentation to the DUR Board