

Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Skyclarys (Omaveloxolone)

Clinical Criteria Information included in this Document

- [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

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

Revision Notes

Annual review by staff

Updated references



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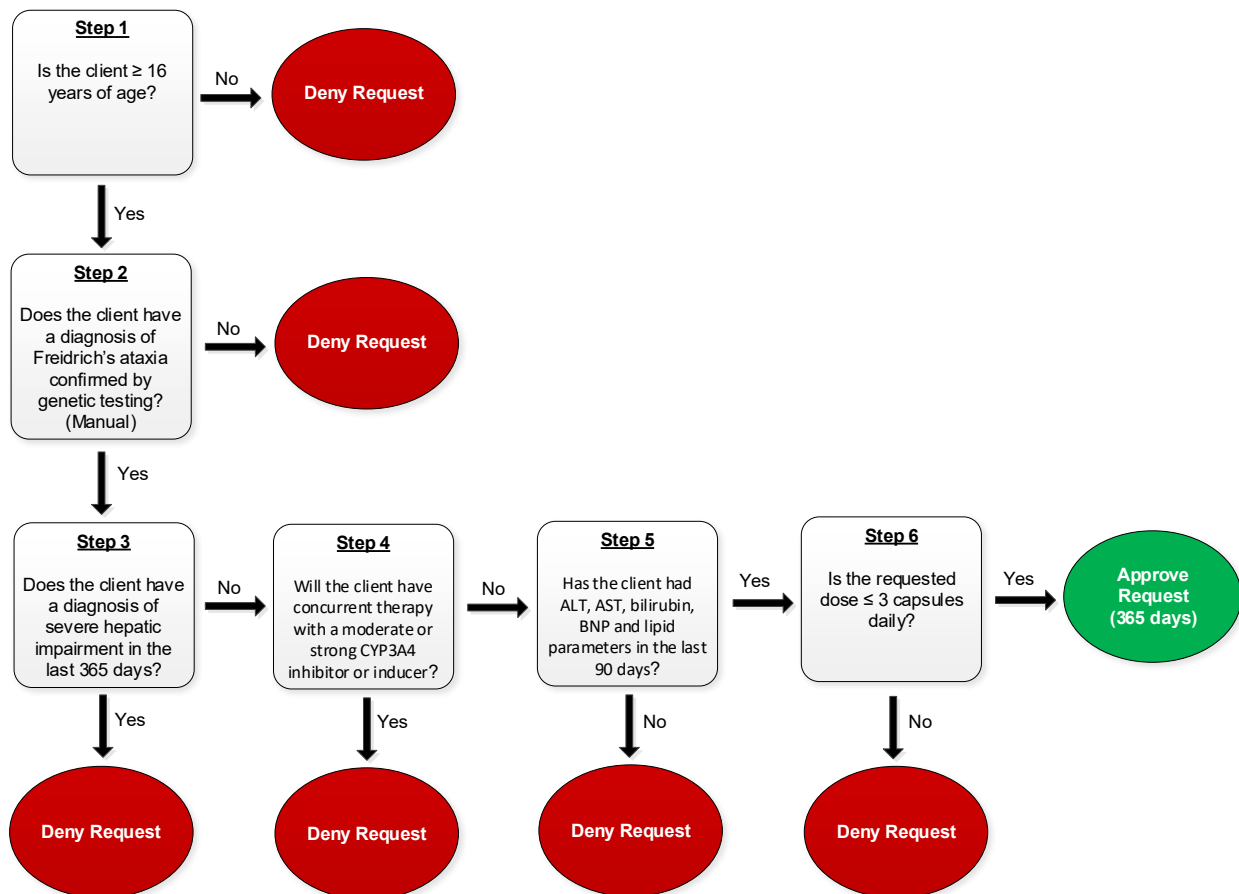
Drugs Requiring Prior Authorization

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
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 Friedrich'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**



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Clinical Criteria Supporting Tables

Table 3 (diagnosis of 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
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

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

Table 3 (diagnosis of severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
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	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS

Table 3 (diagnosis of severe hepatic impairment) Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
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 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
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
36098	APTOM 200 MG TABLET
36099	APTOM 400 MG TABLET
36106	APTOM 600 MG TABLET
27409	APTOM 800 MG TABLET
27346	ATRIPLA TABLET

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
92373	BEXAROTENE 75 MG CAPSULE
14978	BOSENTAN 125 MG TABLET
14979	BOSENTAN 62.5MG TABLET
02341	CALAN 120 MG TABLET
32472	CALAN SR 120 MG CAPLET
32471	CALAN SR 180 MG CAPLET
32470	CALAN SR 240 MG CAPLET
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
27822	CARBAMAZEPINE ER 400 MG TABLET
23934	CARBATROL ER 100 MG CAPSULE
23932	CARBATROL ER 200 MG CAPSULE
23933	CARBATROL ER 300 MG CAPSULE
02363	CARDIZEM 120 MG TABLET
02360	CARDIZEM 30 MG TABLET
02361	CARDIZEM 60 MG TABLET
02326	CARDIZEM CD 120 MG CAPSULE

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
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
11670	CLARITHROMYCIN 125 MG/5 ML SUS
48852	CLARITHROMYCIN 250 MG TABLET
11671	CLARITHROMYCIN 250 MG/5 ML SUS
48851	CLARITHROMYCIN 500 MG TABLET
48850	CLARITHROMYCIN ER 500 MG TAB
45424	COPIKTRA 15 MG CAPSULE
45425	COPIKTRA 25 MG CAPSULE
38095	CRESEMBA 186 MG CAPSULE
38094	CRESEMBA 372 MG VIAL
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

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
42192	DIFLUCAN 50 MG TABLET
17700	DILANTIN 100 MG CAPSULE
17241	DILANTIN 125 MG/5 ML SUSP
17701	DILANTIN 30 MG CAPSULE
17250	DILANTIN 50 MG INFATAB
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
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

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
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
15555	EFAVIRENZ 600 MG TABLET
40344	EMEND 125 MG POWDER PACKET
19366	EMEND 125MG CAPSULE
27278	EMEND 40MG CAPSULE
19365	EMEND 80MG CAPSULE
19367	EMEND TRIPACK
17450	EPITOL 200 MG TABLET
13781	EQUETRO 100 MG CAPSULE
13805	EQUETRO 200 MG CAPSULE
13818	EQUETRO 300 MG CAPSULE
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
40601	ERYTHROCIN 500 MG VIAL

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
40523	ERYTHROMYCIN 200 MG/5 ML SUSP
40720	ERYTHROMYCIN 250 MG FILMTAB
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
99318	INTELENCE 100 MG TABLET
29424	INTELENCE 200 MG TABLET
32035	INTELENCE 25 MG TABLET
49100	ITRACONAZOLE 10 MG/ML SOLUTION
49101	ITRACONAZOLE 100 MG CAPSULE
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

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
43368	KISQALI FEMARA 400 MG CO-PACK
43369	KISQALI FEMARA 600 MG CO-PACK
23783	LEXIVA 50MG/ML SUSPENSION
20553	LEXIVA 700MG TABLET
37810	LYSODREN 500 MG 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
26101	MODAFINIL 100 MG TABLET
26102	MODAFINIL 200 MG TABLET
26586	MULTAQ 400 MG TABLET
29810	MYCOBUTIN 150 MG CAPSULE
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
12892	PHENOBARBITAL 130 MG/ML VIAL
12971	PHENOBARBITAL 15 MG TABLET

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 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
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
44049	PREVYMIS 240 MG TABLET
44061	PREVYMIS 480 MG TABLET
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

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
29810	RIFABUTIN 150 MG CAPSULE
41470	RIFADIN IV 600 MG VIAL
41260	RIFAMPIN 150 MG CAPSULE
41261	RIFAMPIN 300 MG CAPSULE
41470	RIFAMPIN IV 600 MG VIAL
49100	SPORANOX 10 MG/ML SOLUTION
49101	SPORANOX 100 MG CAPSULE
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
34723	TAFINLAR 50 MG CAPSULE
34724	TAFINLAR 75 MG CAPSULE
92373	TARGRETIN 75 MG CAPSULE
28737	TASIGNA 150 MG CAPSULE
99070	TASIGNA 200 MG CAPSULE
02330	TAZTIA XT 120MG CAPSULE
02329	TAZTIA XT 180MG CAPSULE
02332	TAZTIA XT 240MG CAPSULE
02333	TAZTIA XT 300MG CAPSULE
02328	TAZTIA XT 360MG CAPSULE
47500	TEGRETOL 100 MG/5 ML SUSP

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
17450	TEGRETOL 200 MG TABLET
27820	TEGRETOL XR 100 MG TABLET
27821	TEGRETOL XR 200 MG TABLET
27822	TEGRETOL XR 400 MG TABLET
14978	TRACLEER 125 MG TABLET
43819	TRACLEER 32 MG TABLET FOR SUSP
14979	TRACLEER 62.5 MG TABLET
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
32470	VERAPAMIL ER 240 MG TABLET
94122	VERAPAMIL ER PM 100 MG CAPSULE
94123	VERAPAMIL ER PM 200 MG CAPSULE

Table 4 (concurrent therapy with a moderate or strong CYP3A4 inducer or inhibitor) Required quantity: 1 Look back timeframe: <i>current therapy</i>	
GCN	Label Name
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
17498	VFEND 200 MG TABLET
21513	VFEND 40 MG/ML SUSPENSION
17497	VFEND 50 MG TABLET
17499	VFEND IV 200 MG VIAL
17498	VORICONAZOLE 200 MG TABLET
17499	VORICONAZOLE 200 MG VIAL
21513	VORICONAZOLE 40 MG/ML SUSP
17497	VORICONAZOLE 50 MG TABLET
30458	XALKORI 200 MG CAPSULE
30457	XALKORI 250 MG CAPSULE
33183	XTANDI 40 MG CAPSULE
46626	XTANDI 40 MG TABLET
48452	XTANDI 80 MG TABLET
36447	ZYKADIA 150MG CAPSULE

Table 5 (lab tests) Required Procedure Code: 1 Look back timeframe: 90 days	
CPT Code	Description
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**

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2. 2025 ICD-10-CM Diagnosis Codes, Volume 1. 2025. Available at www.icd10data.com. Accessed on April 16, 2025.
3. Micromedex [online database]. 2025. Available at www.micromedexsolutions.com. Accessed on April 16, 2025.
4. Opal P, Zoghbi HY. Friedreich ataxia. In: UpToDate, Firth HV, Tilton A (Ed), UpToDate, Waltham, MA, 2025.
5. Skyclarys Prescribing Information. Cambridge, MA. Biogen. December 2024.

**Skyclarys (Omaveloxolone)****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
04/30/2025	- Annual review by staff - Updated references