Texas Prior Authorization Program
Clinical Criteria

Drug/Drug Class

Hyperlipidemia Agents

This criteria was recommended for review by the Vendor Drug Program to ensure appropriate and safe utilization

Clinical Criteria Information Included in this Document

Juxtapid (Lomitapide)

- **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.

Praluent (Alirocumab)

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
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Repatha (Evolocumab)

- **Drugs requiring prior authorization**: the list of drugs requiring prior authorization for this clinical criteria
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Revision Notes

Annual review by staff

Updated references

Juxtapid (Lomitapide)

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.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
JUXTAPID 10 MG CAPSULE	33912
JUXTAPID 20 MG CAPSULE	33913
JUXTAPID 30 MG CAPSULE	38574
JUXTAPID 5 MG CAPSULE	33909

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Juxtapid (Lomitapide)

Clinical Criteria Logic

1. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes (Go to #2)
   [ ] No (Deny)

2. Does the client have a **diagnosis of homozygous familial hypercholesterolemia (HoFH)** in the last 730 days?
   [ ] Yes (Go to #3)
   [ ] No (Deny)

3. Is the client currently **pregnant**?
   [ ] Yes (Deny)
   [ ] No (Go to #4)

4. Does the client have a claim for a **strong or moderate CYP3A4 inhibitor** in the last 90 days?
   [ ] Yes (Deny)
   [ ] No (Go to #5)

5. Does the client have a **diagnosis of moderate or severe hepatic impairment** in the last 365 days?
   [ ] Yes (Deny)
   [ ] No (Go to #6)

6. Does the client have at least one claim for Juxtapid (lomitapide) in the last 90 days?
   [ ] Yes (Go to #7)
   [ ] No (Go to #8)

7. Has the client shown clinical response (significant lowering of LDL-C*) since initiation of Juxtapid (lomitapide) therapy? [MANUAL]
   [ ] Yes (Go to #10)
   [ ] No (Deny)

8. Has the client had at least **90 consecutive days of high dose atorvastatin therapy, 90 consecutive days of high dose rosuvastatin therapy and 90 consecutive days of ezetimibe therapy** in the last 730 days?
   [ ] Yes (Go to #9)
   [ ] No (Deny)

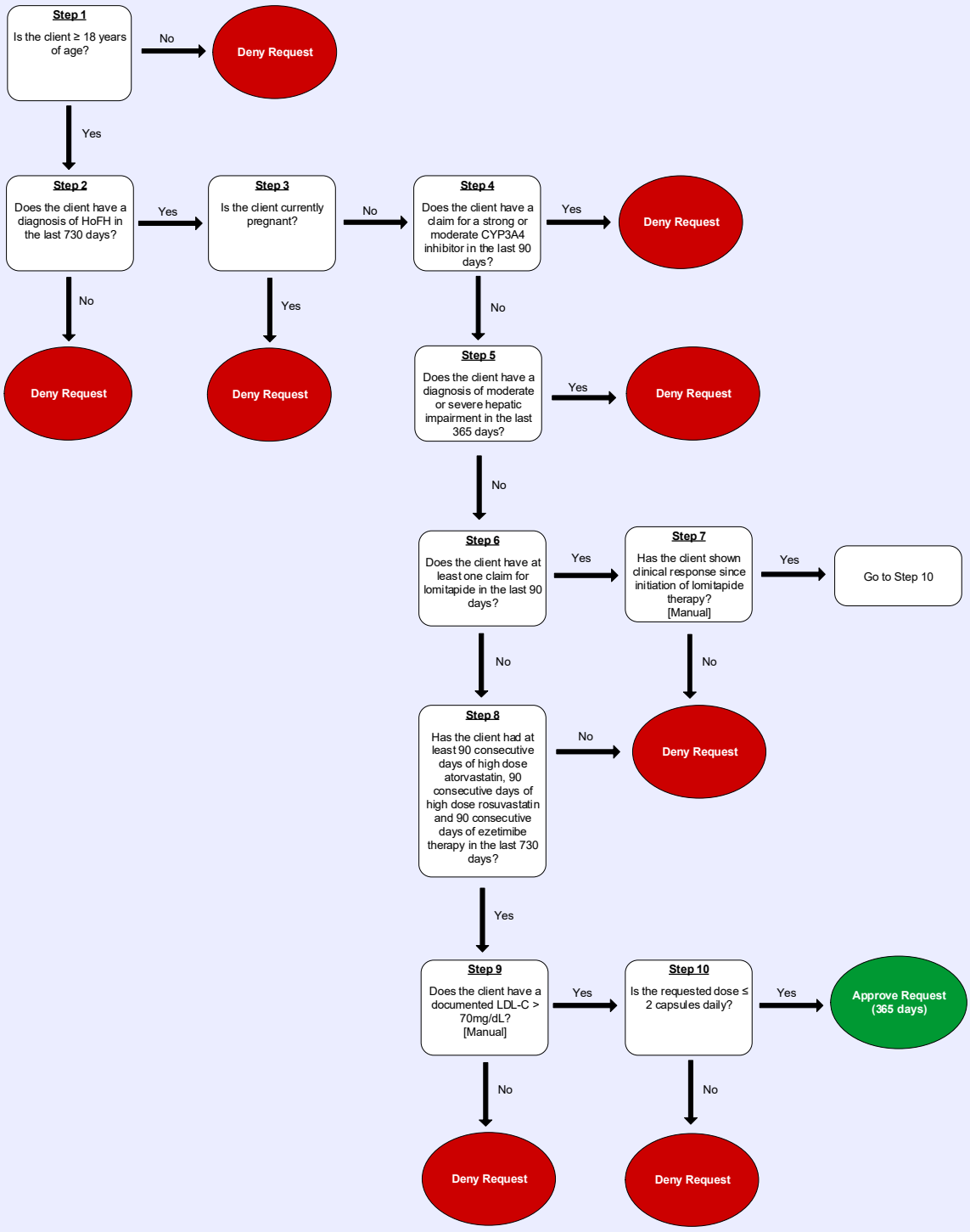
9. Does the client have a documented LDL-C of greater than (>) 70mg/dL? [MANUAL]
   [ ] Yes (Go to #10)
   [ ] No (Deny)

10. Is the requested dose less than or equal to (≤) 2 capsules daily?
    [ ] Yes (Approve – 365 days)
    [ ] No (Deny)

    *Significant lowering of LDL-C is defined as a 30% decrease in LDL for patients with a diagnosis of homozygous familial hypercholesterolemia.

Juxtapid (Lomitapide) Agents

Clinical Criteria Logic Diagram



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Juxtapid (Lomitapide) Agents

Clinical Criteria Supporting Tables

Step 2 (diagnosis of HoFH) Required quantity: *1* Look back timeframe: *730 days*	
ICD-10 Code	**Description**
E7801	FAMILIAL HYPERCHOLESTEROLEMIA

Step 3 (diagnosis of pregnancy) Required quantity: *1* Look back timeframe: *current*	
ICD-10 Code	**Description**
O3670X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, NOT APPLICABLE OR UNSPECIFIED
O3670X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 1
O3670X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 2
O3670X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 3
O3670X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 4
O3670X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, FETUS 5
O3670X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, UNSPECIFIED TRIMESTER, OTHER FETUS
O3671X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, NOT APPLICABLE OR UNSPECIFIED
O3671X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 1
O3671X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 2
O3671X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 3
O3671X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 4
O3671X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, FETUS 5
O3671X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, FIRST TRIMESTER, OTHER FETUS

Step 3 (diagnosis of pregnancy) **Required quantity:** *1* **Look back timeframe:** *current*	
ICD-10 Code	**Description**
O3672X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, NOT APPLICABLE OR UNSPECIFIED
O3672X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 1
O3672X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 2
O3672X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 3
O3672X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 4
O3672X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, FETUS 5
O3672X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, SECOND TRIMESTER, OTHER FETUS
O3673X0	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, NOT APPLICABLE OR UNSPECIFIED
O3673X1	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 1
O3673X2	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 2
O3673X3	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 3
O3673X4	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 4
O3673X5	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, FETUS 5
O3673X9	MATERNAL CARE FOR VIABLE FETUS IN ABDOMINAL PREGNANCY, THIRD TRIMESTER, OTHER FETUS

Step 4 (claim for strong or moderate CYP3A4 inhibitor) **Required claims:** *1* **Look back timeframe:** *90 days*	
Label Name	**GCN**
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
ATAZANAVIR SULFATE 150MG CAP	19952
ATAZANAVIR SULFATE 200MG CAP	19953

Step 4 (claim for strong or moderate CYP3A4 inhibitor) **Required claims:** *1* **Look back timeframe:** *90 days*	
Label Name	**GCN**
ATAZANAVIR SULFATE 300MG CAP	97430
CALAN 120 MG TABLET	02341
CALAN SR 120 MG CAPLET	32472
CALAN SR 180 MG CAPLET	32471
CALAN SR 240 MG CAPLET	32470
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
CRIXIVAN 200 MG CAPSULE	26820
CRIXIVAN 400 MG CAPSULE	26822
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
DILT XR 120 MG CAPSULE	07463

Step 4 (claim for strong or moderate CYP3A4 inhibitor) **Required claims:** *1* **Look back timeframe:** *90 days*	
Label Name	**GCN**
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
EMEND 125 MG POWDER PACKET	40344
EMEND 125MG CAPSULE	19366
EMEND 40MG CAPSULE	27278
EMEND 80MG CAPSULE	19365
EMEND TRIPACK	19367
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
ERYTHROCIN 500 MG ADDVNT VL	25529
ERYTHROCIN 500 MG VIAL	40601
ERYTHROMYCIN 200 MG/5 ML SUSP	40523

Step 4 (claim for strong or moderate CYP3A4 inhibitor) **Required claims:** *1* **Look back timeframe:** *90 days*	
Label Name	**GCN**
ERYTHROMYCIN 250 MG FILMTAB	40720
ERYTHROMYCIN 500 MG FILMTAB	40721
ERYTHROMYCIN EC 250 MG CAP	40660
ERYTHROMYCIN ES 400 MG TAB	40560
EVOTAZ 300-150MG TABLET	37797
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
GENVOYA TABLET	40092
INVIRASE 500 MG TABLET	23952
ITRACONAZOLE 10 MG/ML SOLUTION	49100
ITRACONAZOLE 100 MG CAPSULE	49101
KALETRA 100-25 MG TABLET	99101
KALETRA 200-50 MG TABLET	25919
KALETRA 400-100/5 ML ORAL SOLU	31782
KETOCONAZOLE 200 MG TABLET	42590
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
KORLYM 300 MG TABLET	31485
LANSOPRAZOL-AMOXICIL-CLARITHRO	64269
LEXIVA 50MG/ML SUSPENSION	23783
LEXIVA 700MG TABLET	20553
MATZIM LA 180MG TABLET	19183
MATZIM LA 240MG TABLET	19184
MATZIM LA 300MG TABLET	19185
MATZIM LA 360MG TABLET	19186

Step 4 (claim for strong or moderate CYP3A4 inhibitor) **Required claims:** *1* **Look back timeframe:** *90 days*	
Label Name	**GCN**
MATZIM LA 420MG TABLET	19187
MULTAQ 400 MG TABLET	26586
NEFAZODONE 100MG TABLET	16406
NEFAZODONE 150MG TABLET	16407
NEFAZODONE 200MG TABLET	16408
NEFAZODONE 250MG TABLET	16409
NEFAZODONE 50MG TABLET	16404
NORVIR 100 MG POWDER PACKET	40309
NORVIR 100 MG TABLET	28224
NORVIR 80 MG/ML SOLUTION	26810
NOXAFIL 40 MG/ML SUSPENSION	26502
NOXAFIL DR 100 MG TABLET	35649
OMECLAMOX-PAK COMBO PACK	32137
PREVYMIS 240 MG TABLET	44049
PREVYMIS 480 MG TABLET	44061
PREZCOBIX 800-150MG TABLET	37367
PREZISTA 100MG/ML SUSPENSION	31201
PREZISTA 150MG TABLET	23489
PREZISTA 600MG TABLET	99434
PREZISTA 75MG TABLET	16759
PREZISTA 800MG TABLET	33723
REYATAZ 150MG CAPSULE	19952
REYATAZ 200MG CAPSULE	19953
REYATAZ 300MG CAPSULE	37430
REYATAZ 50MG POWDER PACK	36647
RITONAVIR 100 MG TABLET	28224
SPORANOX 10 MG/ML SOLUTION	49100
SPORANOX 100 MG CAPSULE	49101
STRIBILD TABLET	33130
SYMTUZA 800-150-200-10 MG TAB	43968
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

Step 4 (claim for strong or moderate CYP3A4 inhibitor) **Required claims:** *1* **Look back timeframe:** *90 days*	
Label Name	**GCN**
TAZTIA XT 360MG CAPSULE	02328
TOLSURA 65 MG CAPSULE	45848
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
TYBOST 150MG TABLET	36468
VERAPAMIL 120 MG TABLET	02341
VERAPAMIL 360 MG CAP PELLET	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
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 PELLET	03003
VERELAN 180 MG CAP PELLET	03001
VERELAN 240 MG CAP PELLET	03002
VERELAN 360 MG CAP PELLET	03004
VERELAN PM 100 MG CAP PELLET	94122
VERELAN PM 200 MG CAP PELLET	94123
VERELAN PM 300 MG CAP PELLET	94124
VFEND 200 MG TABLET	17498
VFEND 40 MG/ML SUSPENSION	21513
VFEND 50 MG TABLET	17497
VFEND IV 200 MG VIAL	17499
VIEKIRA PAK	37614
VIRACEPT 250 MG TABLET	40312
VIRACEPT 625 MG TABLET	19717
VORICONAZOLE 200 MG TABLET	17498
VORICONAZOLE 200 MG VIAL	17499

Step 4 (claim for strong or moderate CYP3A4 inhibitor) **Required claims:** *1* **Look back timeframe:** *90 days*	
Label Name	**GCN**
VORICONAZOLE 40 MG/ML SUSP	21513
VORICONAZOLE 50 MG TABLET	17497
XALKORI 200 MG CAPSULE	30458
XALKORI 250 MG CAPSULE	30457
ZYDELIG 100MG TABLET	36884
ZYDELIG 150MG TABLET	36885
ZYKADIA 150MG CAPSULE	36447

Step 5 (diagnosis of moderate to severe hepatic impairment) **Required quantity:** *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	UNSPECIFIFED 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

Step 5 (diagnosis of moderate to severe hepatic impairment) **Required quantity:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
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
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

Step 5 (diagnosis of moderate to severe hepatic impairment) **Required quantity:** *1* **Look back timeframe:** *365 days*	
ICD-10 Code	**Description**
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

Step 8 (high dose statin therapy and ezetimibe therapy) **Required quantity:** *90 days* **Look back timeframe:** *730 days*	
Description	**GCN**
ATORVASTATIN 40MG TABLET	43722
ATORVASTATIN 80MG TABLET	43723
CRESTOR 20MG TABLET	19154
CRESTOR 40MG TABLET	19155
EZALLOR SPRINKLE 20MG CAPSULE	40734
EZALLOR SPRINKLE 40MG CAPSULE	41027
EZETIMIBE 10MG TABLET	18387
LIPITOR 40MG TABLET	43722
LIPITOR 80MG TABLET	43723
ROSUVASTATIN 20MG TABLET	19154
ZETIA 10MG TABLET	18387

Praluent (Alirocumab)

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.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
PRALUENT 150MG/ML PEN	39184
PRALUENT 75MG/ML PEN	39182

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Praluent (Alirocumab)

Clinical Criteria Logic

1. Has the provider submitted a PA form for the request?
   [ ] Yes – Go to #2
   [ ] No – Deny

2. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes – Go to #3
   [ ] No – Deny

3. Does the client have a diagnosis of **primary hyperlipidemia or homozygous familial hypercholesterolemia (HoFH)** in the last 730 days?
   [ ] Yes – Go to #5
   [ ] No – Go to #4

4. Does the client have a diagnosis of clinical **atherosclerotic cardiovascular disease (ASCVD)** in the last 730 days?
   [ ] Yes – Go to #5
   [ ] No – Deny

5. Does the client have a concurrent claim for **atorvastatin or rosuvastatin**?
   [ ] Yes – Go to #6
   [ ] No – Deny

6. Does the client have 1 claim for **Praluent or Repatha** in the last 90 days?
   [ ] Yes – Go to #7
   [ ] No – Go to #8

7. Has the client shown clinical response (significant lowering of LDL-C*) since initiation of PCSK9 inhibitor therapy? [MANUAL]
   [ ] Yes – Approve (180 days)
   [ ] No – Deny

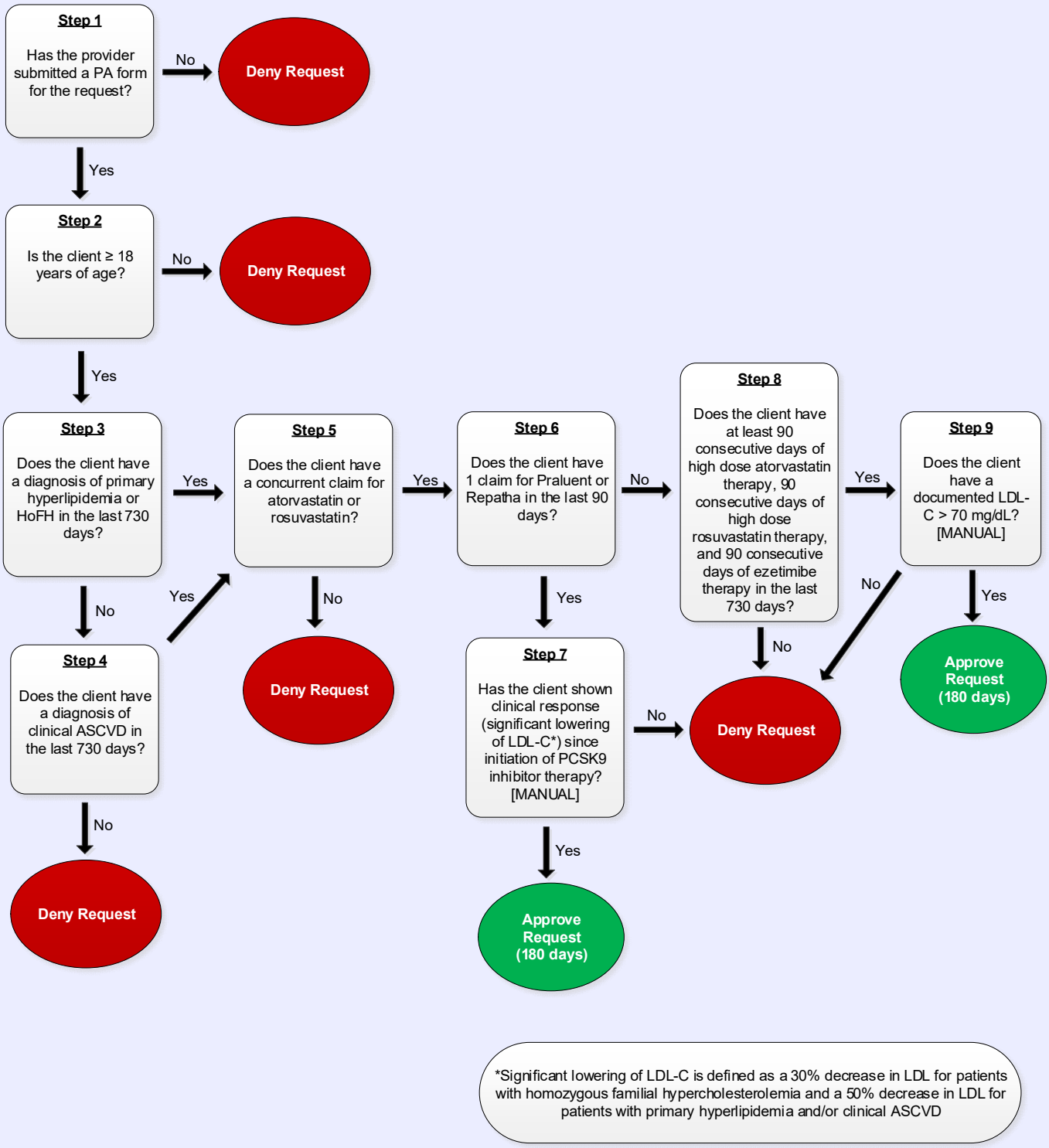
8. Does the client have at least 90 consecutive days of **high dose atorvastatin therapy, 90 consecutive days of high dose rosuvastatin therapy, and 90 consecutive days of ezetimibe therapy** in the last 730 days?
   [ ] Yes – Go to #9
   [ ] No – Deny

9. Does the client have a documented LDL-C of greater than (>) 70mg/dL? [MANUAL]
   [ ] Yes – Approve (180 days)
   [ ] No – Deny

*Significant lowering of LDL-C is defined as a 30% decrease in LDL for patients with a diagnosis of homozygous familial hypercholesterolemia and a 50% decrease in LDL for patients with a diagnosis of primary hyperlipidemia and/or clinical ASCVD.

Praluent (Alirocumab)

Clinical Criteria Logic Diagram



*Significant lowering of LDL-C is defined as a 30% decrease in LDL for patients with homozygous familial hypercholesterolemia and a 50% decrease in LDL for patients with primary hyperlipidemia and/or clinical ASCVD

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Praluent (Alirocumab)

Clinical Criteria Supporting Tables

Step 3 (diagnosis of primary hyperlipidemia or HoFH) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
E7801	FAMILIAL HYPERCHOLESTEROLEMIA
E782	MIXED HYPERLIPIDEMIA
E785	HYPERLIPIDEMIA, UNSPECIFIED

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
G450	VERTEBRO-BASILAR ARTERY SYNDROME
G451	CAROTID ARTERY SYNDROME (HEMISPHERIC)
G452	MULTIPLE AND BILATERAL PRECEREBRAL ARTERY SYNDROMES
G453	AMAUROSIS FUGAX
G454	TRANSIENT GLOBAL AMNESIA
G458	OTHER TRANSIENT CEREBRAL ISCHEMIC ATTACKS AND RELATED SYNDROMES
G459	TRANSIENT CEREBRAL ISCHEMIC ATTACK, UNSPECIFIED
I200	UNSTABLE ANGINA
I2101	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT MAIN CORONARY ARTERY
I2102	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT ANTERIOR DESCENDING CORONARY ARTERY
I2109	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF ANTERIOR WALL
I2111	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING RIGHT CORONARY ARTERY
I2119	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF INFERIOR WALL
I2121	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT CIRCUMFLEX CORONARY ARTERY
I2129	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER SITES

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I213	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF UNSPECIFIED SITE
I214	NON-ST ELEVATION (NSTEMI) MYOCARDIAL INFARCTION
I240	ACUTE CORONARY THROMBOSIS NOT RESULTING IN MYOCARDIAL INFARCTION
I248	OTHER FORMS OF ACUTE ISCHEMIC HEART DISEASE
I63011	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT VERTEBRAL ARTERY
I63012	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT VERTEBRAL ARTERY
I63019	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED VERTEBRAL ARTERY
I6302	CEREBRAL INFARCTION DUE TO THROMBOSIS OF BASILAR ARTERY
I63031	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT CAROTID ARTERY
I63032	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT CAROTID ARTERY
I63039	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED CAROTID ARTERY
I6309	CEREBRAL INFARCTION DUE TO THROMBOSIS OF OTHER PRECEREBRAL ARTERY
I6310	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED PRECEREBRAL ARTERY
I63111	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT VERTEBRAL ARTERY
I63112	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT VERTEBRAL ARTERY
I63119	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED VERTEBRAL ARTERY
I6320	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED PRECEREBRAL ARTERIES
I63211	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT VERTEBRAL ARTERIES
I63212	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT VERTEBRAL ARTERIES
I63219	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED VERTEBRAL ARTERIES
I6322	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF BASILAR ARTERIES
I63231	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT CAROTID ARTERIES
I63232	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT CAROTID ARTERIES

Step 4 (diagnosis of ASCVD) Required quantity: *1* Look back timeframe: *730 days*	
ICD-10 Code	**Description**
I63239	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED CAROTID ARTERIES
I6329	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF OTHER PRECEREBRAL ARTERIES
I6330	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED CEREBRAL ARTERY
I63311	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT MIDDLE CEREBRAL ARTERY
I63312	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT MIDDLE CEREBRAL ARTERY
I63319	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I63321	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT ANTERIOR CEREBRAL ARTERY
I63322	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT ANTERIOR CEREBRAL ARTERY
I63329	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I63331	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT POSTERIOR CEREBRAL ARTERY
I63332	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT POSTERIOR CEREBRAL ARTERY
I63339	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I63341	CEREBRAL INFARCTION DUE TO THROMBOSIS OF RIGHT CEREBELLAR ARTERY
I63342	CEREBRAL INFARCTION DUE TO THROMBOSIS OF LEFT CEREBELLAR ARTERY
I63349	CEREBRAL INFARCTION DUE TO THROMBOSIS OF UNSPECIFIED CEREBELLAR ARTERY
I6339	CEREBRAL INFARCTION DUE TO THROMBOSIS OF OTHER CEREBRAL ARTERY
I6340	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED CEREBRAL ARTERY
I63411	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT MIDDLE CEREBRAL ARTERY
I63412	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT MIDDLE CEREBRAL ARTERY
I63419	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I63421	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT ANTERIOR CEREBRAL ARTERY
I63422	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT ANTERIOR CEREBRAL ARTERY

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I63429	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I63431	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT POSTERIOR CEREBRAL ARTERY
I63432	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT POSTERIOR CEREBRAL ARTERY
I63439	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I63441	CEREBRAL INFARCTION DUE TO EMBOLISM OF RIGHT CEREBELLAR ARTERY
I63442	CEREBRAL INFARCTION DUE TO EMBOLISM OF LEFT CEREBELLAR ARTERY
I63449	CEREBRAL INFARCTION DUE TO EMBOLISM OF UNSPECIFIED CEREBELLAR ARTERY
I6349	CEREBRAL INFARCTION DUE TO EMBOLISM OF OTHER CEREBRAL ARTERY
I6350	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED CEREBRAL ARTERY
I63511	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT MIDDLE CEREBRAL ARTERY
I63512	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT MIDDLE CEREBRAL ARTERY
I63519	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I63521	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT ANTERIOR CEREBRAL ARTERY
I63522	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT ANTERIOR CEREBRAL ARTERY
I63529	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I63531	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT POSTERIOR CEREBRAL ARTERY
I63532	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT POSTERIOR CEREBRAL ARTERY
I63539	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I63541	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF RIGHT CEREBELLAR ARTERY
I63542	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF LEFT CEREBELLAR ARTERY
I63549	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF UNSPECIFIED CEREBELLAR ARTERY
I6359	CEREBRAL INFARCTION DUE TO UNSPECIFIED OCCLUSION OR STENOSIS OF OTHER CEREBRAL ARTERY

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I636	CEREBRAL INFARCTION DUE TO CEREBRAL VENOUS THROMBOSIS, NONPYOGENIC
I638	OTHER CEREBRAL INFARCTION
I639	CEREBRAL INFARCTION, UNSPECIFIED
I658	OCCLUSION AND STENOSIS OF OTHER PRECEREBRAL ARTERIES
I659	OCCLUSION AND STENOSIS OF UNSPECIFIED PRECEREBRAL ARTERY
I6609	OCCLUSION AND STENOSIS OF UNSPECIFIED MIDDLE CEREBRAL ARTERY
I6619	OCCLUSION AND STENOSIS OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY
I6629	OCCLUSION AND STENOSIS OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY
I669	OCCLUSION AND STENOSIS OF UNSPECIFIED CEREBRAL ARTERY
I672	CEREBRAL ATHEROSCLEROSIS
I6781	ACUTE CEREBROVASCULAR INSUFFICIENCY
I6782	CEREBRAL ISCHEMIA
I6789	OTHER CEREBROVASCULAR DISEASE
I67848	OTHER CEREBROVASCULAR VASOSPASM AND VASOCONSTRICTION
I70201	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70202	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70203	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70208	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70209	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY
I70211	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, RIGHT LEG
I70212	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, LEFT LEG
I70213	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, BILATERAL LEGS
I70218	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, OTHER EXTREMITY
I70219	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, UNSPECIFIED EXTREMITY
I70221	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, RIGHT LEG
I70222	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, LEFT LEG

Step 4 (diagnosis of ASCVD) **Required quantity:** *1* **Look back timeframe:** *730 days*	
ICD-10 Code	**Description**
I70223	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, BILATERAL LEGS
I70228	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, OTHER EXTREMITY
I70229	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, UNSPECIFIED EXTREMITY
I70231	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF THIGH
I70232	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF CALF
I70233	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF ANKLE
I70234	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70235	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF FOOT
I70238	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF LOWER RIGHT LEG
I70239	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I70241	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF THIGH
I70242	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF CALF
I70243	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF ANKLE
I70244	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70245	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF FOOT
I70248	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF LOWER LEFT LEG
I70249	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I7025	ATHEROSCLEROSIS OF NATIVE ARTERIES OF OTHER EXTREMITIES WITH ULCERATION
I70261	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, RIGHT LEG
I70262	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, LEFT LEG
I70263	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, BILATERAL LEGS
I70268	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, OTHER EXTREMITY

Step 4 (diagnosis of ASCVD) Required quantity: *1* Look back timeframe: *730 days*	
ICD-10 Code	**Description**
I70269	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, UNSPECIFIED EXTREMITY
I70291	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70292	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70293	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70298	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70299	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY

Step 5 (concurrent claim for atorvastatin or rosuvastatin) Required quantity: *1* Look back timeframe: *90 days*	
Description	**GCN**
AMLODIPINE-ATORVAST 10-10 MG	21395
AMLODIPINE-ATORVAST 10-20 MG	21396
AMLODIPINE-ATORVAST 10-40 MG	21397
AMLODIPINE-ATORVAST 10-80 MG	21398
AMLODIPINE-ATORVAST 2.5-10 MG	23866
AMLODIPINE-ATORVAST 2.5-20 MG	23867
AMLODIPINE-ATORVAST 2.5-40 MG	23868
AMLODIPINE-ATORVAST 5-10 MG	21391
AMLODIPINE-ATORVAST 5-20 MG	21392
AMLODIPINE-ATORVAST 5-40 MG	21393
AMLODIPINE-ATORVAST 5-80 MG	21394
ATORVASTATIN 10MG TABLET	43720
ATORVASTATIN 20MG TABLET	73721
ATORVASTATIN 40MG TABLET	43722
ATORVASTATIN 80MG TABLET	43723
CADUET 10-10MG TABLET	21395
CADUET 10-20MG TABLET	21396
CADUET 10-40MG TABLET	21397
CADUET 10-80MG TABLET	21398
CADUET 5-10MG TABLET	21391

Step 5 (concurrent claim for atorvastatin or rosuvastatin) **Required quantity:** *1* **Look back timeframe:** *90 days*	
Description	**GCN**
CADUET 5-20MG TABLET	21392
CADUET 5-40MG TABLET	21393
CADUET 5-80MG TABLET	21394
CRESTOR 10MG TABLET	19153
CRESTOR 20MG TABLET	19154
CRESTOR 40MG TABLET	19155
CRESTOR 5MG TABLET	20229
EZALLOR SPRINKLE 10MG CAPSULE	39996
EZALLOR SPRINKLE 20MG CAPSULE	40734
EZALLOR SPRINKLE 40MG CAPSULE	41027
EZALLOR SPRINKLE 5MG CAPSULE	38314
LIPITOR 10MG TABLET	43720
LIPITOR 20MG TABLET	43721
LIPITOR 40MG TABLET	43722
LIPITOR 80MG TABLET	43723
ROSUVASTATIN 10MG TABLET	19153
ROSUVASTATIN 20MG TABLET	19154
ROSUVASTATIN 40MG TABLET	19155
ROSUVASTATIN 5MG TABLET	20229

Step 6 (Praluent or Repatha therapy) **Required quantity:** *1* **Look back timeframe:** *90 days*	
Description	**GCN**
PRALUENT 150MG/ML PEN	39184
PRALUENT 75MG/ML PEN	39182
REPATHA 140MG/ML SURECLICK	38178
REPATHA 140MG/ML SYRINGE	39363
REPATHA 420MG/3.5ML PUSHTRONX	41834

Step 8 (high dose statin therapy and ezetimibe therapy)
Required Diagnosis: *90*
Look back timeframe: *730 days*

For the list of high dose statin and ezetimibe GCNs that pertain to this step, see the **High Dose Statin and Ezetimibe GCN** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Repatha (Evolocumab)

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.

Drugs Requiring Prior Authorization	
Label Name	**GCN**
REPATHA 140MG/ML SURECLICK	38178
REPATHA 140MG/ML SYRINGE	39363
REPATHA 420MG/3.5ML PUSHTRONX	41834

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Repatha (Evolocumab)

Clinical Criteria Logic

1. Has the provider submitted a PA form for the request?
   [ ] Yes – Go to #2
   [ ] No – Deny

2. Is the client greater than or equal to (≥) 10 years of age?
   [ ] Yes – Go to #3
   [ ] No – Deny

3. Does the client have a **diagnosis of homozygous familial hypercholesterolemia (HoFH)** in the last 730 days?
   [ ] Yes – Go to #4
   [ ] No – Go to #5

4. Is the prescribed dose less than or equal (≤) to 420mg every 2 weeks?
   [ ] Yes – Go to #11
   [ ] No – Deny

5. Does the client have a diagnosis of **heterozygous familial hypercholesterolemia (HeFH)** in the last 730 days?
   [ ] Yes – Go to #9
   [ ] No – Go to #6

6. Is the client greater than or equal to (≥) 18 years of age?
   [ ] Yes – Go to #7
   [ ] No – Deny

7. Does the client have a diagnosis of **primary hyperlipidemia** in the last 730 days?
   [ ] Yes – Go to #9
   [ ] No – Go to #8

8. Does the client have a diagnosis clinical **atherosclerotic cardiovascular disease (ASCVD)** in the last 730 days?
   [ ] Yes – Go to #9
   [ ] No – Deny

9. Is the prescribed dose equal to 140mg every 2 weeks?
   [ ] Yes – Go to #11
   [ ] No – Go to #10

10. Is the prescribed dose equal to 420mg every 4 weeks?
    [ ] Yes – Go to #11
    [ ] No – Deny

11. Does the client have a concurrent claim for **atorvastatin or rosuvastatin**?
    [ ] Yes – Go to #12
    [ ] No – Deny

12. Does the client have 1 claim for **Repatha or Praluent** in the last 90 days?
    [ ] Yes – Go to #13
    [ ] No – Go to #14

13. Has the client shown clinical response (significant lowering of LDL-C*) since initiation of PCSK9 inhibitor therapy? [MANUAL]
    [ ] Yes – Approve (180 days)
    [ ] No – Deny

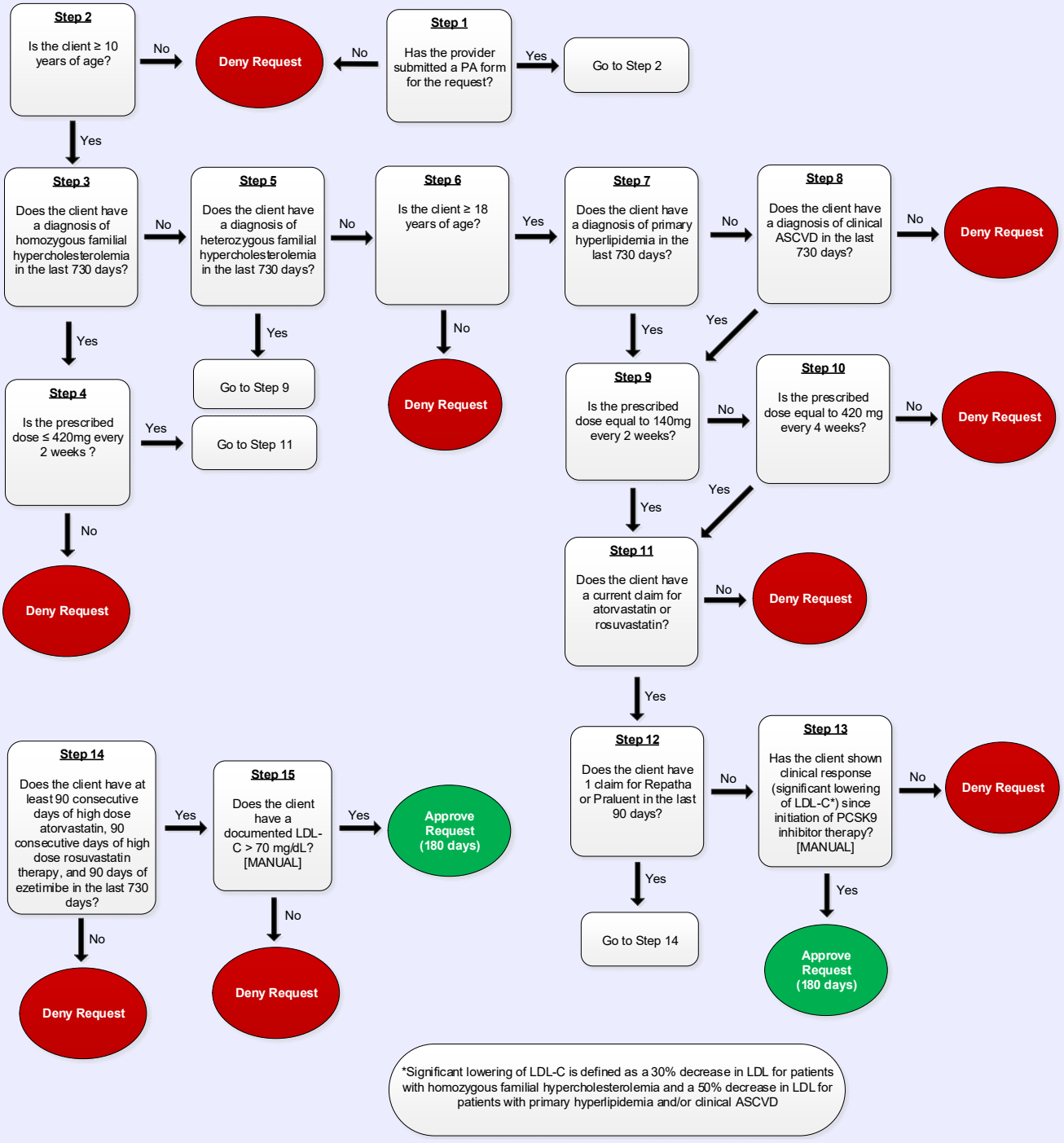
14. Does the client have at least 90 consecutive days of **high dose atorvastatin therapy, 90 consecutive days of high dose rosuvastatin, and 90 consecutive days of ezetimibe therapy** in the last 730 days?
    [ ] Yes – Go to #15
    [ ] No – Deny

15. Does the client have a documented LDL-C of greater than (>) 70mg/dL? [MANUAL]
    [ ] Yes – Approve (180 days)
    [ ] No – Deny

*Significant lowering of LDL-C is defined as a 30% decrease in LDL for patients with a diagnosis of homozygous familial hypercholesterolemia and a 50% decrease in LDL for patients with a diagnosis of primary hyperlipidemia and/or clinical ASCVD.

Repatha (Evolocumab)

Clinical Criteria Logic Diagram



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Repatha (Evolocumab)

Clinical Criteria Supporting Tables

Step 3 (diagnosis of HoFH) Required quantity: *1* Look back timeframe: *730 days*

For the list of diagnosis codes that pertain to this step, see the **HoFH** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 5 (diagnosis of HeFH) Required quantity: *1* Look back timeframe: *730 days*	
ICD-10 Code	**Description**
E7801	FAMILIAL HYPERCHOLESTEROLEMIA

Step 7 (diagnosis of primary hyperlipidemia) Required quantity: *1* Look back timeframe: *730 days*

For the list of diagnosis codes that pertain to this step, see the **Primary Hyperlipidemia** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 8 (diagnosis of ASCVD) Required quantity: *1* Look back timeframe: *180 days*

For the list of diagnosis codes that pertain to this step, see the **ASCVD** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 11 (concurrent claim for atorvastatin or rosuvastatin)
Required quantity: *1*
Look back timeframe: *90 days*

For the list of GCNs that pertain to this step, see the **Atorvastatin / Rosuvastatin** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 12 (claim for Praluent or Repatha)
Required quantity: *1*
Look back timeframe: *90 days*

For the list of GCNs that pertain to this step, see the **Praluent / Repatha** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 14 (high dose statin therapy)
Required quantity: *90 days*
Look back timeframe: *730 days*

For the list of GCNs that pertain to this step, see the **High Dose Statin Therapy** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

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Hyperlipidemia Agents

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at **www.clinicalpharmacology.com**. Accessed on January 9, 2024.

2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on January 9, 2024.

3. 2015 ICD-10-CM Diagnosis Codes, Volume 1. 2015. Available at **www.icd10data.com**. Accessed on September 2, 2015.

4. Repatha Prescribing Information. Amgen Inc. Thousand Oaks, CA. September 2021.

5. Praluent Prescribing Information. Tarrytown, NY. Regeneron Pharmaceuticals Inc; April 2021.

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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
10/22/2015	Presented to the DUR Board
11/17/2016	• Updated Criteria Logic • Updated Logic Diagram • Updated Table 4 • Updated Table 5 • Added Table 6 • Added GCN for Repatha 420mg/3.5mL Pushtronx to "Drugs Requiring PA" • Updated Criteria Logic • Updated Logic Diagram • Updated Table 10 • Added Table 11
03/29/2019	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
04/06/2020	• Annual review by staff • Updated question 3 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 9 to ≥ 70mg/dL on criteria logic and logic diagram • Updated question 6 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 14 to ≥ 70mg/dL on criteria logic and logic diagram • Updated Table 5
04/23/2021	• Initial publication and presentation of Juxtapid (lomitapide) clinical criteria to the DUR Board
05/10/2021	• Added diagnosis of homozygous familial hypercholesterolemia (HoFH) for Praluent • Updated maximum dose of Repatha to 420mg every 2 weeks for clients with a diagnosis of HoFH
10/07/2021	• Updated age to ≥ 10 years for Repatha for HoFH and HeFH
12/02/2022	• Annual review by staff • Remove GCNs for Juxtapid 40 mg (38571) and Juxtapid 60 mg (38573) – products have been discontinued • Updated references
01/09/2024	• Annual review by staff

Publication Date	Notes
	• Updated references

