

**Texas Prior Authorization Program
Clinical Criteria**

PCSK9 Inhibitors

Clinical Criteria Information Included in this Document

Praluent (Alirocumab)

- **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.

Repatha (Evolocumab)

- **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

Annual review by staff

Updated question 3 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 9 to $\geq 70\text{mg/dL}$ on criteria logic and logic diagram, pages 4-5.

Updated question 6 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 14 to $\geq 70\text{mg/dL}$ on criteria logic and logic diagram, pages 16-18.

Updated table 5, pages 12-13

Updated references, pages 22-23



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 |



Praluent (Alirocumab)

Clinical Criteria Logic

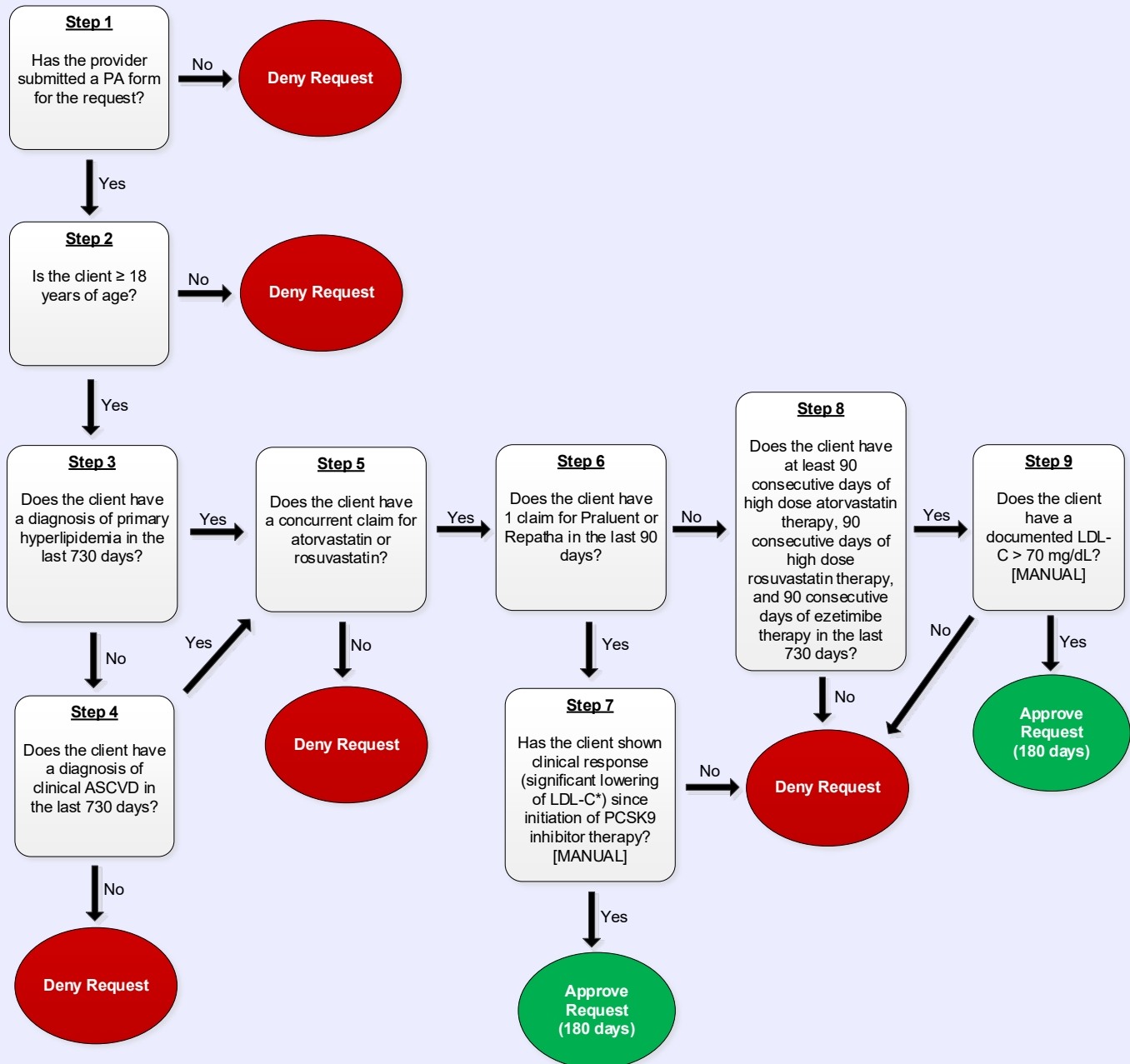
1. Has the provider submitted a PA form for the request?
 Yes – Go to #2
 No – Deny
2. Is the client greater than or equal to (\geq) 18 years of age?
 Yes – Go to #3
 No – Deny
3. Does the client have a diagnosis of primary hyperlipidemia in the last 730 days?
 Yes – Go to #5
 No – Go to #4
4. Does the 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



Praluent (Alirocumab)

Clinical Criteria Supporting Tables

| Step 3 (diagnosis of primary hyperlipidemia) 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 | OCCCLUSION AND STENOSIS OF OTHER PRECEREBRAL ARTERIES |
| I659 | OCCCLUSION AND STENOSIS OF UNSPECIFIED PRECEREBRAL ARTERY |
| I6609 | OCCCLUSION AND STENOSIS OF UNSPECIFIED MIDDLE CEREBRAL ARTERY |
| I6619 | OCCCLUSION AND STENOSIS OF UNSPECIFIED ANTERIOR CEREBRAL ARTERY |
| I6629 | OCCCLUSION AND STENOSIS OF UNSPECIFIED POSTERIOR CEREBRAL ARTERY |
| I669 | OCCCLUSION 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 quantity: 90 days | |
| Look back timeframe: 120 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 |
| ROSUVASTATIN 40MG TABLET | 19155 |
| ZETIA 10MG TABLET | 18387 |



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 |



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 (\geq) 13 years of age?
 Yes – Go to #3
 No – Deny
3. Does the client have a diagnosis of homozygous familial hypercholesterolemia in the last 730 days? [MANUAL]
 Yes – Go to #4
 No – Go to #5
4. Is the prescribed dose equal to 420mg monthly?
 Yes – Go to #10
 No – Deny
5. Is the client greater than or equal to (\geq) 18 years of age?
 Yes – Go to #6
 No – Deny
6. Does the client have a diagnosis of primary hyperlipidemia in the last 730 days?
 Yes – Go to #8
 No – Go to #7
7. Does the client have a diagnosis clinical atherosclerotic cardiovascular disease (ASCVD) in the last 730 days?
 Yes – Go to #8
 No – Deny
8. Is the prescribed dose equal to 140mg every 2 weeks?
 Yes – Go to #10
 No – Go to #9
9. Is the prescribed dose equal to 420mg every 4 weeks?
 Yes – Go to #10
 No – Deny
10. Does the client have a concurrent claim for atorvastatin or rosuvastatin?
 Yes – Go to #11
 No – Deny
11. Does the client have 1 claim for Repatha or Praluent in the last 90 days?
 Yes – Go to #12
 No – Go to #13

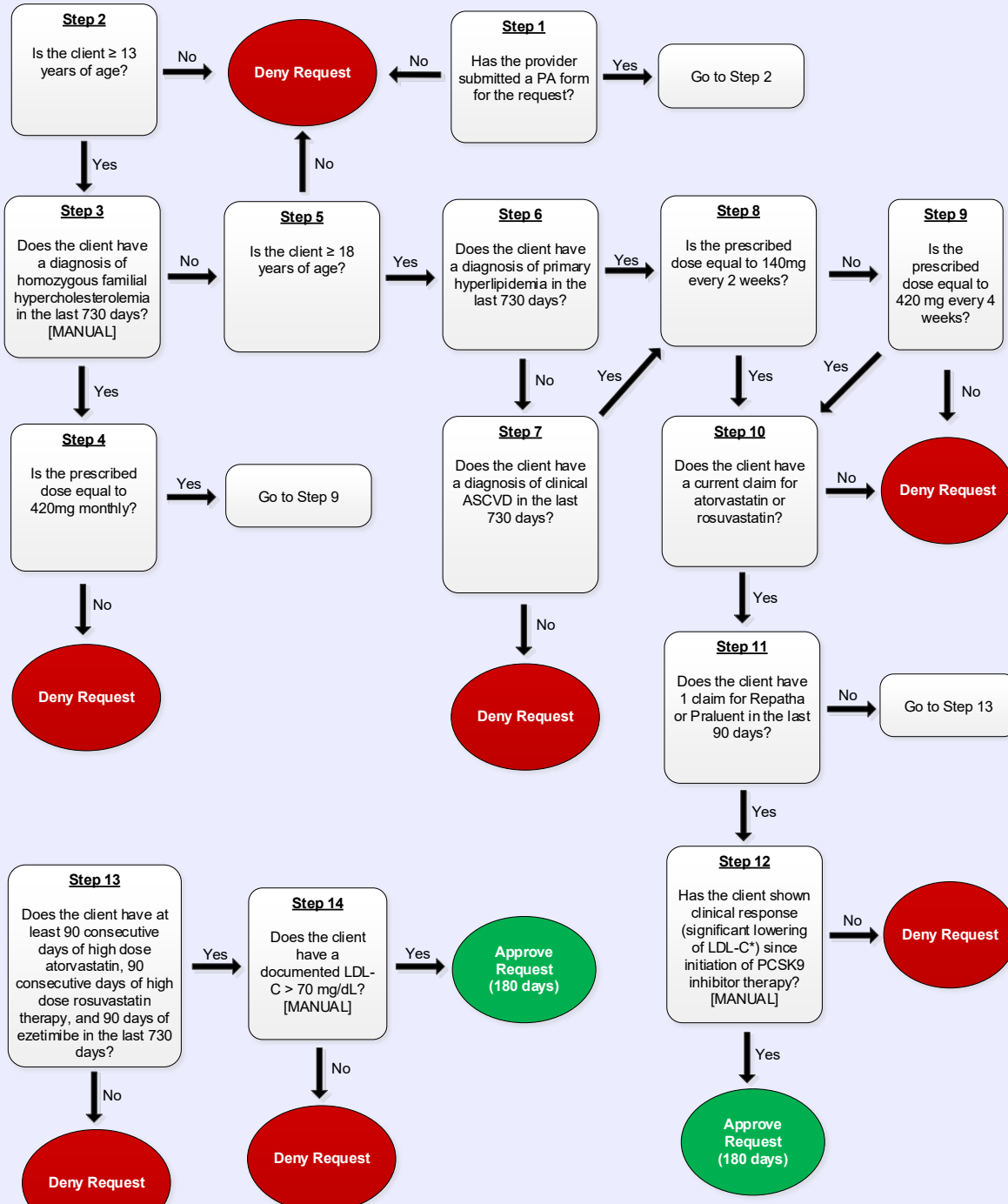
12. Has the client shown clinical response (significant lowering of LDL-C*) since initiation of PCSK9 inhibitor therapy? [MANUAL]
[] Yes – Approve (180 days)
[] No – Deny
13. Does the client have at least 90 consecutive days of high dose atorvastatin therapy, 90 consecutive days of high dose rosuvastatin, and 90 consecutive days of ezetimibe therapy in the last 730 days?
[] Yes – Go to #14
[] No – Deny
14. 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



*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



Repatha (Evolocumab)

Clinical Criteria Supporting Tables

| Step 6 (diagnosis of primary hyperlipidemia) Required quantity: 1 Look back timeframe: 730 days | |
|--|-------------------------------|
| ICD-10 Code | Description |
| E7801 | FAMILIAL HYPERCHOLESTEROLEMIA |
| E782 | MIXED HYPERLIPIDEMIA |
| E785 | HYPERLIPIDEMIA, UNSPECIFIED |

| Step 7 (diagnosis of ASCVD) Required quantity: 1 Look back timeframe: 180 days |
|---|
|---|

For the list of active infection 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 10 (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 |

| Step 10 (concurrent claim for atorvastatin or rosuvastatin) | |
|--|------------|
| Required quantity: 1 | |
| Look back timeframe: 90 days | |
| Description | GCN |
| 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 |
| 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 |
| LIPITOR 10MG TABLET | 43720 |
| LIPITOR 20MG TABLET | 43721 |
| LIPITOR 40MG TABLET | 43722 |
| LIPITOR 80MG TABLET | 43723 |
| LIPTRUZET 10-10MG TABLET | 34469 |
| LIPTRUZET 10-20MG TABLET | 34606 |
| LIPTRUZET 10-40MG TABLET | 34607 |
| LIPTRUZET 10-80MG TABLET | 34608 |
| ROSUVASTATIN 10MG TABLET | 19153 |
| ROSUVASTATIN 20MG TABLET | 19154 |
| ROSUVASTATIN 40MG TABLET | 19155 |
| ROSUVASTATIN 5MG TABLET | 20229 |

| Step 11 (claim for Repatha or Praluent) | |
|--|------------|
| 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 13 (high dose statin therapy)**Required quantity:** 90 days**Look back timeframe:** 730 days

For the list of active infection diagnosis codes 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.



PCSK9 Inhibitors

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2015. Available at www.clinicalpharmacology.com. Accessed on March 6, 2020.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on March 6, 2020.
3. 2015 ICD-9-CM Diagnosis Codes, Volume 1. 2015. Available at www.icd9data.com. Accessed on September 2, 2015.
4. 2015 ICD-10-CM Diagnosis Codes, Volume 1. 2015. Available at www.icd10data.com. Accessed on September 2, 2015.
5. Repatha Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2019.
6. Praluent Prescribing Information. sanofi-aventis U.S. LLC. Bridgewater, NJ. April 2019.
7. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;129:S1-S45.
8. James PA, Oparil S, Carter BL, et al. 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults. Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC8). *JAMA*. 2014;311(5):507-520.
9. Robinson JG, Nedergaard BS, Rogers WJ, Fialkow J, Neutel JM, et al. Effect of evolocumab or ezetimibe added to moderate- or high-intensity statin therapy on LDL-C lowering in patients with hypercholesterolemia: the LAPLACE-2 randomized clinical trial. *JAMA* 2014; 311(18): 1870-82.
10. Colhoun HM, Robinson JG, Farnier M, Cariou B, Blom D, et al. Efficacy and safety of alirocumab, a fully human PCSK9 monoclonal antibody, in high cardiovascular risk patients with poorly controlled hypercholesterolemia on maximally tolerated doses of statins: rationale and design of the ODYSSEY COMBO I and II trials. *BMC Cardiovascular Disorders* 2014; 14: 121-31.
11. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline

on the Management of Blood Cholesterol. A Report of the American College of Cardiology / American Heart Association Task Force on Clinical Practice Guidelines. J Amer Coll Card. June 2019;73(24);3168-3209.

12. Robinson JG, Farnier M, Krempf M, Bergeron J, Luc G, et al. Efficacy and safety of alirocumab in reducing lipids and cardiovascular events. NEJM 2015; 372: 1489-99.



PCSK9 Inhibitors

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 |
|------------------|--|
| 10/22/2015 | Presented to the DUR Board |
| 11/17/2016 | <ul style="list-style-type: none"> Updated Criteria Logic, page 4 Updated Logic Diagram, page 5 Updated Table 4, page 6 Updated Table 5, page 14 Added Table 6, page 15 Added GCN for Repatha 420mg/3.5mL Pushtonx to "Drugs Requiring PA", page 17 Updated Criteria Logic, page 18 Updated Logic Diagram, page 20 Updated Table 10, page 21 Added Table 11, page 22 Updated References |
| 03/29/2019 | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Annual review by staff Updated question 3 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 9 to $\geq 70\text{mg/dL}$ on criteria logic and logic diagram, pages 4-5 Updated question 6 to 'diagnosis of primary hyperlipidemia' and the LDL requirement on question 14 to $\geq 70\text{mg/dL}$ on criteria logic and logic diagram, pages 4-5 Updated Table 5, pages 12-13 Updated references, pages 22-23 |