MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	Cholesterol	**P&T DATE:**	5/12/2020
THERAPEUTIC CLASS:	Cardiovascular	**REVIEW HISTORY:** (MONTH/YEAR)	5/19, 5/18, 5/17, 5/16, 5/15, 2/14, 5/12, 2/11
LOB AFFECTED:	Medi-Cal		

PART 1 – STATINS (HMG-COA REDUCTASE INHIBITORS)

The 2018 American College of Cardiology, American Heart Association, and Multi-society Guideline on the Management of Blood Cholesterol recommend treating to target LDL-C and Non-HDL-C goals and identifies risk categories based on the number of ASCVD risk factors and other underlying risk indicators. The following document outlines current recommendations for appropriate statin therapy for risk reduction of atherosclerotic cardiovascular disease (ASCVD).

Available Statin Agents based on ACC/AHA Clinical Guideline Recommendations

Drug	LDL-C Reduction/Therapy Intensity			Restrictions	Monthly Quantity Limit	Notes	Cost per 30 days
	Low (<30%)	Moderate (30-50%)	High (≥50%)				
Atorvastatin *(Lipitor)*	--	10-20mg	40-80mg	--	30		$6.39
Rosuvastatin *(Crestor)*	--	5-10mg	20-40mg	--	30		$5.16
Simvastatin *(Zocor)*	10mg	20-40mg	--	--	30		$2.57
Pravastatin *(Pravachol)*	10-20mg	40-80mg	--	--	30		$11.86
Lovastatin *(Mevacor)*	20mg	40mg	--	QL*	30*	*40mg Tablet is restricted to 2 tablets per day (60 per month).	$2.68
Fluvastatin *(Lescol)*	20-40mg	40mg (BID)	--	NF	--	--	$$
Fluvastatin XL *(Lescol XL)*	--	80mg	--	NF	--	--	$$
Pitavastatin *(Livalo)*	1mg	2-4mg	--	NF	--	--	$283.47

NF = Non-formulary, TS = Mandatory Tablet Splitting, PA = Prior Authorization Required.

Clinical Justification:

Choosing a Statin Agent:

Members in the following categories are at high risk of ASCVD, and generally have the greatest net benefit from statin therapy. Generally, these members should be on the highest statin dose tolerated (High-intensity). Refer to the table below for additional guidance on intensity of therapy.

- **Individuals with clinical ASCVD**
- **Individuals with primary elevations of LDL-C ≥ 190 mg/dL**
- **Individuals 40 to 75 years of age with diabetes and LDL-C 70-189 mg/dL**
- **Individuals without clinical ASCVD or diabetes who are 40 to 75 years of age with LDL-C ≥70 and an estimated 10-year ASCVD risk of 7.5%-19.9% after discussion of treatment options that favor initiation of statin therapy (i.e. coronary artery calcium levels).**

Definition of ASCVD[2,4]
Clinical ASCVD is defined as the history of 1 or more of the following morbidities: • **Myocardial Infarction/ Acute Coronary Syndrome** • **Stable or unstable Angina** • **Coronary or other Arterial Revascularization** • **Stroke** • **Transient Ischemic Attack** • **Peripheral Artery Disease presumed to be of atherosclerotic origin**

Therapy Intensity	**Patient Benefit Group and Characteristics**
Primary Risk Reduction of ASCVD	
High-intensity	• Patients with Clinical ASCVD • ≥21 years of age and LDL-C ≥190 mg/dL
Moderate-intensity	• Adults 40-75 years of age with diabetes mellitus and LDL-C of ≥70 mg/dL • Adults 40-75 years of age without clinical ASCVD or diabetes with LDL ≥ 70mg/dL and ≥7.5% 10 year ASCVD risk (if discussion of treatment options favors statin therapy or if unsure, consider measuring coronary artery calcium levels for a decision to be made).
Low-intensity	• Reserved for patients unable to tolerate moderate-intensity therapy
Secondary Risk Reduction of ASCVD	
High-intensity	• Patients ≤75 years old with ASCVD
Moderate-intensity	• Patients >75 years old with ASCVD

Contraindication vs. Intolerance:

Intolerance does NOT justify treatment discontinuation, but may suggest the need for an alternative statin or dose reduction. Contraindications should prompt discontinuation. Refer to the following (incomplete) list for examples. Muscle-related side effects may occur while on statin therapy, true statin intolerance is uncommon. Per the 2017 ACC/AHA 2017 guidelines, the approach to statin intolerance should include discontinuation of statin therapy until resolution of symptoms and subsequent rechallenge to verify recurrence of muscle-related symptoms. Whereas there is not a universally accepted definition of statin intolerance, most experts recommend that patients are documented to have unacceptable muscle-related symptoms that resolve with discontinuation of therapy and occur with rechallenge on at least 2 to 3 statins, preferably ones that use different metabolic pathways and have different lipophilicity. If the lowest dose of multiple statins cannot be tolerated on a daily basis, use alternative dosing strategies with long half-life statins (atorvastatin, rosuvastatin) administered 3 times per week or once a week.[7]

Contraindications	Intolerances
ALT > 3 times ULN	Myopathy and or Rhabdomyolysis
Active liver disease (defined as unexplained persistent elevations in transaminase levels.)	The inability to tolerate at least 2 different statins; 1 statin at the lowest starting average daily dose AND another statin at any daily dose
Pregnancy or woman who may become pregnant	Elevation of aminotransferases < 3 times ULN
Breast-feeding	Drug interactions

Caveats:

The American College of Cardiology/ American Heart Association Guidelines are limited to ASCVD risk reduction, therefore, do not apply to all patients presenting with lipid disorders. Patients with severely elevated triglycerides, >1000-2000 mg/dL, are at risk for acute pancreatitis and can be initiated on gemfibrozil or fenofibrate. Alternative therapy options for severe hypertriglyceridemia are niacin or omega-3 fatty acid (indicated for triglycerides >500 mg/dL). Please see the "Non-Statin Lipid-Lowering-Agent Policy" for guidance with these agents.

Triage Information:

- ***Appropriate Diagnosis***
- ***Most recent lipid panel***
- ***Cholesterol medication trial history***
- ***Reasons for respective treatment failure***

APPROVAL CRITERIA / EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

HMG-CoA Reductase Inhibitors ("Statins")

Rosuvastatin (Crestor), Atorvastatin (Lipitor), Simvastatin (Zocor), Pravastatin (Pravachol), Lovastatin (Mevacor)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None* (*Lovastatin is restricted to 2 tablets per day)
- ❒ **Required Information for Approval:** N/A
- ❒ **Other Notes:** The statin medications in this category are listed in order of potency (highest to lowest) at maximum doses. Rosuvastatin and Atorvastatin are considered "high potency statins" and should be used in most cases listed in the "choosing a statin" category above.
- ❒ For statin intolerance with lipophilic statins (Atorvastatin, Simvastatin, etc), May consider re-challenging with hydrophilic statins (Rosuvastatin, Pravastatin).

PART 2 – NON-STATIN LIPID LOWERING AGENTS

The National Lipid Association (NLA) and the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) supports the use of Non-Statin medications to treat to target LDL-C and non-HDL-C goals. Below is a table outlining use of these agents.

Non-Statin Lipid Lowering Agents:

Class	Drug	Therapy Benefits	Form. Status	Restriction	Cost Per Rx
Bile Acid Sequestrants	Cholestyramine	LDL-C levels (↓18%)	F	---	$102.27
	Colesevelam (Welchol)	LDL-C levels (↓18%)	PA, ST	Step therapy to intolerance of two formulary statins.	$340.37
Fibrates	Fenofibrate (54mg tablet, 67mg capsule, 134mg capsule, 160mg tablet, 200mg capsule)	LDL-C (↓20.6%), TC (↓18.7%), TG (↓28.9-46%)* HDL-C (↑11%) *likely higher with more severe elevations.	F	---	$40.19 (Lofibra)
	Gemfibrozil (Lopid)	TG (↓ 31-43%) * *likely higher with more severe elevations.	F	---	$6.34
Niacin	Niacin (Niacor) Niacin ER (Niaspan)	LDL-C (↓12%), Apo B (↓12%), TG levels (↓24-38%), HDL-C (↑20%)	PA	Intolerance to two formulary 1st line statins.	$155.69
Omega 3 Fatty Acids	Omega-3 Fatty Acids (Lovaza)	TG (↓20-30%), HDL (↑3%)	PA, ST	TG>500mg/dL despite statin + fibrate therapy	$97.79
	Omega-3 Fatty Acids (Vascepa)		NF	Non-Formulary	$289.27
Absorption Inhibitors	Ezetimibe (Zetia)	LDL-C (↓18%), Apo B (↓16%), Non-HDL-C (↓16%)	F	---	$17.72
	Ezetimibe/Simvastatin (Vytorin)	Additive effect to simvastatin monotherapy.	PA, ST	Uncontrolled hyperlipidemia despite compliant use of dose-optimized atorvastatin or rosuvastatin.	$86.90
PCSK9 Inhibitors	Alirocumab (Praluent)	LDL (↓50%)	PA	See "Approval Criteria/Exception Consideration" below	$1,142.40
	Evolocumab (Repatha)		PA	See "Approval Criteria/Exception Consideration" below	$1,139.50
Apolipoprotein B Antisense Oligonucleotide	Mipomersen (Kynamro)	LDL (↓25%)	NF	Non-Formulary	--
MTP inhibitor	Lomitapide (Juxtapid)	LDL (↓50%)	NF	Non-Formulary	--

*All therapy benefits refer to monotherapy. NOTE: Non-statin therapies have not shown reduction in ASCVD risk. ǂ Brand Specific formulary restrictions. NF = Non-Formulary, F = Formulary, ST = Step therapy, PA = Prior Authorization required.

Clinical Justification:

Clinical Pearls:

- ACC/AHA guidelines do not provide guidance on the treatment of hypertriglyceridemia. Providers should refer to ATP III for guidance.
- Generally pancreatitis is seen at triglyceride levels >1000 mg/dL, but is treated at >500 mg/dL.
- Combination of statins with fibrates (especially gemfibrozil) can increase risks of rhabdomyolysis. Patient should be monitored for generalized body weakness or fatigue that is not attributable to a known cause.
- Niacin flushing, a common reason for niacin intolerance, can be pretreated by administering aspirin 81mg (or any NSAID) 30 minutes prior to niacin administration.
- Lifestyle modification can play a big part in triglyceride reduction, especially ↓ fatty food intake.

Triage:

- ***Appropriate diagnosis***
- ***Current lipid panel***
- ***Previous lipid lowering drugs used***
- ***History of lipid lowering drug intolerances.***

APPROVAL CRITERIA/ EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Bile Acid Sequestrants

Cholestyramine

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A

Colesevelam (Welchol)

- ❒ **Coverage Criteria:** Welchol is reserved for patients who are intolerant to 2 formulary statins.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Chart notes documenting treatment failure and reaction severity/nature. Pharmacy fill history indicating prescription fills for 2 formulary statins.

Fibrates

Gemfibrozil (Lopid)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A
- ❒ **Other Notes:** Gemfibrozil should not be used in conjunction with a statin, due to increased risk of rhabdomyolysis.

Fenofibrate (Lofibra)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A
- ❒ **Other Notes:** Fenofibrate 54mg, 67mg, 134mg, 160mg and 200mg are on our covered formulary with no restrictions. All other formulations are non-formulary.

Niacin

Niacin (Niacor), Niacin ER (Niaspan, Slo-Niacin)

- ❒ **Coverage Criteria:** Restricted to patients intolerant to two formulary 1st line statins.
- ❒ **Limits:** Prior authorization required.
- ❒ **Required Information for Approval:** Fill history showing use of at least two formulary statins with clinic notes documenting reactions to the statins.
- ❒ **Notes:** Pretreat with aspirin to reduce flushing side effects.

Omega-3 Fatty Acids

Omega-3 Fatty Acids (Lovaza)

- ❒ **Coverage Criteria:** Lovaza is reserved for patients with elevated triglycerides >500 mg/dL despite dose-optimized treatment with both a statin AND fenofibrate.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Laboratory results indicating uncontrolled triglycerides, greater than 500 mg/dL after 6-8 weeks of dose optimized statin and fibrate therapy, as evidenced by pharmacy fill history.

Absorption Inhibitors

Ezetimibe (Zetia)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A

Ezetimibe/Simvastatin (Vytorin)

- ❒ **Coverage Criteria:** It is reserved for uncontrolled hyperlipidemia despite compliant use of (or intolerance to) dose optimized Atorvastatin (Lipitor) AND Rosuvastatin (Crestor).
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Pharmacy fill history of both Atorvastatin and Rosuvastatin.

Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors

***Alirocumab* (*Praluent*)**:

- ❒ **Coverage Criteria:** Praluent is reserved for patients who meet all of the following criteria:
    a. Clinical ASCVD with LDL ≥70 mg/dL or non-HDL-C ≥ 100 mg/dL OR [2] Heterozygous Familial Hypercholesterolemia (HeFH) with LDL > 100 mg/dL or non-HDL-C > 130 mg/dL.
    b. Treatment failure to 12 weeks of ALL of the following:
        i. A high intensity statin or maximally tolerated statin
        ii. Ezetimibe
        iii. Cholestyramine
    c. Triglycerides are ≤ 200 mg/dL
    d. Prescribed by a cardiologist, endocrinologist, or lipid specialist.
    e. For HeFH- genetic testing is required and must meet criteria for definite Familial Hypercholesterolemia according to
        i. Simon-Broome
        ii. Dutch Lipid Network or
        iii. US (MEDPED) diagnostic criteria

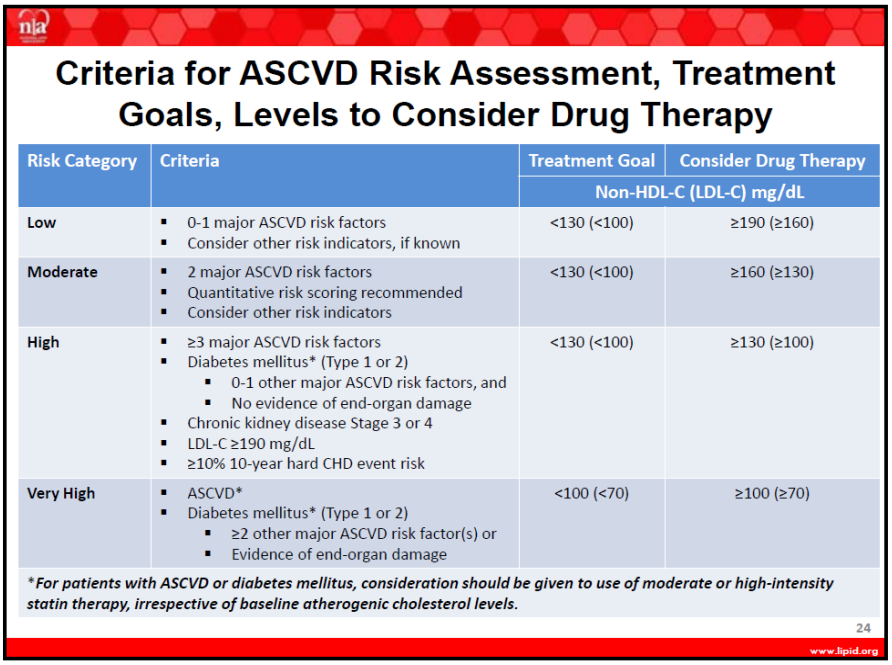
- ❒ **Limits:** 2 injections per 28 days per strength, restricted to specialty pharmacy
- ❒ **Required Information for Approval:**
    - Lipid panel**,** evidence of compliance to 12 weeks of a high intensity or maximally tolerated statin, ezetimibe, and cholestyramine.
    - Statin intolerance: Chart notes documenting the type/severity and nature of intolerance or contraindication to maximally tolerated hydrophilic statin (e.g., pravastatin or rosuvastatin) despite dose de-escalation.

***Evolocumab* (*Repatha*)**:

- ❒ **Coverage Criteria:** Repatha is reserved for patients who meet all of the following criteria:
  a. Clinical ASCVD with LDL ≥70 mg/dL or non-HDL-C ≥ 100 mg/dL OR [2] Heterozygous Familial Hypercholesterolemia (HeFH) with LDL > 100 mg/dL or non-HDL-C > 130 mg/dL OR [3] Homozygous Familial Hypercholesterolemia (HoFH) with LDL >300 mg/dL or non-HDL-C > 330 mg/dL
  b. Treatment failure to 12 weeks of ALL of the following:
     i. A high intensity statin or maximally tolerated statin
     ii. Ezetimibe
     iii. Cholestyramine
  c. Triglycerides are ≤ 200 mg/dL
  d. Prescribed by a cardiologist, endocrinologist, or lipid specialist.
  e. For HeFH/HoFH- genetic testing is required and must meet criteria for definite Familial Hypercholesterolemia according to
     i. Simon-Broome
     ii. Dutch Lipid Network or
     iii. US (MEDPED) diagnostic criteria
     iv. Not covered for patients with two LDL receptor negative alleles

- ❒ **Limits:** 2 injections per 28 days per strength, restricted to specialty pharmacy
- ❒ **Required Information for Approval:**
  - Lipid panel**,** evidence of compliance to 12 weeks of a high intensity or maximally tolerated statin, ezetimibe, and cholestyramine.
  - Statin intolerance: Chart notes documenting the type/severity and nature of intolerance or contraindication to maximally tolerated hydrophilic statin (e.g., pravastatin or rosuvastatin) despite dose de-escalation.

2014 NLA Criteria for Treatment Initiation According to Risk



Criteria for ASCVD Risk Assessment, Treatment Goals, Levels to Consider Drug Therapy

Risk Category	Criteria	Treatment Goal	Consider Drug Therapy
		Non-HDL-C (LDL-C) mg/dL	
Low	▪ 0-1 major ASCVD risk factors ▪ Consider other risk indicators, if known	<130 (<100)	≥190 (≥160)
Moderate	▪ 2 major ASCVD risk factors ▪ Quantitative risk scoring recommended ▪ Consider other risk indicators	<130 (<100)	≥160 (≥130)

High	▪ ≥3 major ASCVD risk factors
	▪ Diabetes mellitus* (Type 1 or 2)
	  ▪ 0-1 other major ASCVD risk factors, and
	  ▪ No evidence of end-organ damage
	▪ Chronic kidney disease Stage 3 or 4
	▪ LDL-C ≥190 mg/dL
	▪ ≥10% 10-year hard CHD event risk
		<130 (<100)	≥130 (≥100)

Very High	▪ ASCVD*
	▪ Diabetes mellitus* (Type 1 or 2)
	  ▪ ≥2 other major ASCVD risk factor(s) or
	  ▪ Evidence of end-organ damage
		<100 (<70)	≥100 (≥70)

**For patients with ASCVD or diabetes mellitus, consideration should be given to use of moderate or high-intensity statin therapy, irrespective of baseline atherogenic cholesterol levels.*

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2017 AACE/ACE Criteria For Treatment Initiation According to Risk

Atherosclerotic Cardiovascular Disease Risk Categories and LDL-C Treatment Goals				
		Treatment goals		
Risk category	Risk factors[a]/10-year risk[b]	LDL-C (mg/dL)	Non-HDL-C (mg/dL)	Apo B (mg/dL)
Extreme risk	– Progressive ASCVD including unstable angina in patients after achieving an LDL-C <70 mg/dL – Established clinical cardiovascular disease in patients with DM, CKD 3/4, or HeFH – History of premature ASCVD (<55 male, <65 female)	<55	<80	<70
Very high risk	– Established or recent hospitalization for ACS, coronary, carotid or peripheral vascular disease, 10-year risk >20% – Diabetes or CKD 3/4 with 1 or more risk factor(s) – HeFH	<70	<100	<80
High risk	– ≥2 risk factors and 10-year risk 10-20% – Diabetes or CKD 3/4 with no other risk factors	<100	<130	<90
Moderate risk	≤2 risk factors and 10-year risk <10%	<100	<130	<90
Low risk	0 risk factors	<130	<160	NR

Abbreviations: ACS = acute coronary syndrome; ASCVD = atherosclerotic cardiovascular disease; CKD = chronic kidney disease; DM = diabetes mellitus; HDL-C = high-density lipoprotein cholesterol; HeFH = heterozygous familial hypercholesterolemia; LDL-C = low-density lipoprotein cholesterol; MESA = Multi-Ethnic Study of Atherosclerosis; NR = not recommended; UKPDS = United Kingdom Prospective Diabetes Study.

[a] Major independent risk factors are high LDL-C, polycystic ovary syndrome, cigarette smoking, hypertension (blood pressure ≥140/90 mm Hg or on hypertensive medication), low HDL-C (<40 mg/dL), family history of coronary artery disease (in male, first-degree relative younger than 55 years; in female, first-degree relative younger than 65 years), chronic renal disease (CKD) stage 3/4, evidence of coronary artery calcification and age (men ≥45; women ≥55 years). Subtract 1 risk factor if the person has high HDL-C.

[b] Framingham risk scoring is applied to determine 10-year risk.

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Diagnostic Criteria for Familial Hypercholesterolemia

There are currently three accepted resources for FH diagnosis: the Simon Broom criteria, the Med Ped Criteria, and the FH Dutch Lipid Clinic Criteria

Simon Broome criteria

Total-cholesterol (LDL-C) in mg/dl >260 (155) in patients with age <18 years and >290 (190) in patients >18 years	AND	Family history of elevated total-cholesterol >290 mg/dl in first or second degree relative or Family history of coronary disease at age <60 years in first degree relative or <50 years in second degree relative	Possible FH
		Tendon xanthomas in the patient or in first or second degree relative	Probable FH
		DNA mutation consistent with FH	Definite FH

MEDPED criteria (87% sensitivity and 98% specificity)

Age in years	Total-cholesterol (LDL-C) in mg/dl			
	General population	First degree relative	Second degree relative	Third degree relative
<18	270 (200)	220 (155)	230 (165)	240 (170)
18-29	290 (220)	240 (170)	250 (185)	260 (185)
30-39	340 (240)	270 (190)	280 (200)	290 (210)
≥40	360 (260)	290 (205)	300 (215)	310 (225)

Dutch Lipid Clinic criteria

LDLR gene functional mutation or LDL-cholesterol >330 mg/dl	8 points	Possible FH 3-5 points
Presence of tendon xanthoma	6 points	
LDL-C between 250 and 329 mg/dl	5 points	Probable FH 6-7 points
Presence of arcus corneae at age <45 years	4 points	
LDL-C between 190 and 249 mg/dl	3 points	Definite FH ≥8 points
Personal history of CAD or First degree relative age <18 years with LDL-C >95th percentile or First degree relative with tendon xanthoma or arcus corneae	2 points	
LDL-C between 190 and 249 mg/dl or Personal history of premature cerebral or peripheral artery disease or First degree adult relative with premature CAD or LDL-C >95th percentile	1 points	

LDL-C: Low-density lipoprotein-cholesterol, FH: Familial hypercholesterolemia, DNA: Deoxyribonucleic acid, CAD: Coronary artery disease, LDLR: LDL receptor

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Lipid- Lowering Class Review- Statins 3-07.doc	3/2007	Allen Shek PharmD BCPS
Update to Policy	Potential Generics 2007 and 2008.doc	5/2007	Allen Shek PharmD BCPS
Update to Policy	Statins class review 5-07.doc	5/2007	Allen Shek PharmD BCPS
Update to Policy	Formulary realignment 2-2010.xlsx	2/2010	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment 5-11.xlsx	5/2011	Allen Shek PharmD BCPS
Update to Policy	Statin Realignment 9-20-11.docx	9/2011	Allen Shek PharmD BCPS
Update to Policy	Cholesterol Therapy Review 2014-05-29.docx	5/2014	Jonathan Szkotak, PharmD BCACP
Update to Policy	PCSK9 Inhibitors 5-2015.docx	5/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Cholesterol 2015-05.docx	5/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Cholesterol 2016-05.docx	5/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Cholesterol 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Cholesterol 2018-05.docx	5/2018	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Cholesterol 2019-05.docx	5/2019	Matthew Garrett, Pharm D
Update to Policy	HPSJ Coverage Policy – Cardiovascular – Cholesterol 2020-05.docx	5/2020	Matthew Garrett, Pharm D

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy