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Hyperlipidemia Agents

Adenosine triphosphate-citrate lyase (ACL) inhibitors	
PREFERRED	N/A
NON-PREFERRED	Nexletol™ (bempedoic acid) **(refer to specific criteria below)**

Adenosine triphosphate-citrate lyase (ACL) inhibitors & Cholesterol Absorption Inhibitors Combination Products	
PREFERRED	N/A
NON-PREFERRED	Nexlizet™ (bempedoic acid and ezetimibe) **(refer to specific criteria below)**

Angiopoietin-Like Protein 3 (ANGPTL3) Inhibitor	
PREFERRED	N/A
NON-PREFERRED	Evkeeza™ **(refer to specific criteria below)**

Bile Acid Sequestrants	
PREFERRED	Cholestyramine, Cholestyramine light, Colestipol tablets
NON-PREFERRED	Colestid®, Colesevelam, Prevalite®, Questran®, Questran Light®, Welchol®, Colestipol granules

Cholesterol Absorption Inhibitors	
PREFERRED	Ezetimibe
NON-PREFERRED	Zetia®

Fibric Acid Derivatives	
PREFERRED	Fenofibrate, Fenofibrate (micronized), Fenofibrate (nanocrystallized), Gemfibrozil
NON-PREFERRED	Antara® (fenofibrate), Fenofibric acid, Fenoglide® (fenofibrate), Fibricor®, Lipofen®, Lopid®, Tricor®, Trilipix®

Microsomal Triglyceride Transfer Protein (MTP) Inhibitor	
PREFERRED	N/A
NON-PREFERRED	Juxtapid® **(refer to specific criteria below)**

Nicotinic Acid and Derivatives	
PREFERRED	Niacin extended release, Niacor®
NON-PREFERRED	Niaspan®

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Omega-3 Acid Ethyl Esters	
PREFERRED	Omega-3 Acid Ethyl Esters
NON-PREFERRED	Icosapent ethyl, Lovaza®, Triklo®, Vascepa® **(refer to specific criteria below)**

PCSK9 Inhibitors	
PREFERRED	N/A
NON-PREFERRED	Leqvio®, Praluent®, Repatha® **(refer to specific criteria for these drugs below)**

Statins	
PREFERRED	Atorvastatin, Lovastatin, Pravastatin, Rosuvastatin, Simvastatin
NON-PREFERRED	Altoprev®, Crestor®, Ezallor™, FloLipid®, Fluvastatin, Fluvastatin ER, Lescol XL®, Lipitor®, Livalo®, Pravachol®, Zocor®, Zypitamag®

Statin Combination Products	
PREFERRED	N/A
NON-PREFERRED	Amlodipine/Atorvastatin, Caduet®, Ezetimibe/Simvastatin, Rosuvastatin/Ezetimibe, Roszet®, Vytorin®

LENGTH OF AUTHORIZATION: Up to 12 months (please refer to specific drug criteria as noted below)

INITIAL REVIEW CRITERIA:

- The patient has tried and failed medications on the Preferred Drug List or there is a reason (allergy, contraindication) that preferred drugs cannot be used.
- Documentation of previous trials such as progress notes, diagnostic evaluations and lab results are required.
- If the request is for a brand name drug and the generic is preferred, a trial of the generic drug or rationale why the generic cannot be used is required.
- The drug is requested for a medically accepted indication.
- Dosage and administration is appropriate as per labeling or is supported by compendia.

CONTINUATION OF THERAPY:

- The patient met initial review requirements.
- Clinical response to therapy submitted (supporting documentation required).
- Dosage and administration is appropriate as per labeling or is supported by compendia.

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Length of authorization for the following criteria: **Initial therapy: 3 months** **Continuation of therapy: 6 months**	
Drug	**Criteria**
Evkeeza™ (evinacumab)	**Initial Therapy** • Patient must be ≥ 12 years of age. • Patient must have a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by documented functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality or skin fibroblast LDL receptor activity < 20% normal, or a history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300 mg/dL and both parents with a history of total cholesterol > 250 mg/dL; **AND** • Prior treatment history with highest available dose or maximally tolerated dose for lipid lowering therapy (e.g., statins, ezetimibe) with failure to reach target an LDL-C < 70 mg/dL for patients with HoFH; **AND** • Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms. **Continuation of Therapy** • Patient met initial review criteria. • Documentation of improvement of LDL-C compared to baseline labs. • Continued utilization of maximally tolerated combination lipid lowering therapy (e.g., statin, ezetimibe).
Juxtapid® (lomitapide)	**Initial Therapy** • Patient must be ≥18 years old; **AND** • Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) confirmed by documented functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality or skin fibroblast LDL receptor activity <20% normal, or a history of an untreated LDL-C concentration >500 mg/dL and triglycerides <300 mg/dL and both parents with a documented history of total cholesterol >250 mg/dL; **AND** • Prior treatment history with highest available dose or maximally tolerated dose for lipid lowering therapy (e.g., statins, ezetimibe) with failure to reach target an LDL-C <70 mg/dL for patients with HoFH; **AND** • Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms; **AND** • Must be prescribed by a certified REMS provider demonstrated with supporting documentation (signed attestation). ○ http://www.juxtapidremsprogram.com/ **Continuation of Therapy** • Initial criteria met. • Documentation of improvement of LDL-C compared to baseline labs.

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	• Continued utilization of maximally tolerated combination lipid lowering therapy (e.g., statin, ezetimibe).
Leqvio® (inclisiran)	**Initial Therapy** • Patient must be ≥ 18 years of age; **AND** • Patient must have a diagnosis of atherosclerotic cardiovascular disease (ASCVD), or heterozygous familial hypercholesterolemia (HeFH) diagnosed either by genotyping or clinical criteria using the Simon Broome or WHO/Dutch Lipid Network criteria; **AND** • Must be used as an adjunct to diet and maximally tolerated statin therapy; **OR** • Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms; **AND** • Baseline lipid panel demonstrating failure to achieve target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH) following at least three months of continuous statin therapy. **Continuation of Therapy** • Patient met initial review criteria. • Documentation of improvement of LDL-C compared to baseline labs. • Patient has not experienced any treatment-restricting adverse effects. • Continued adherence to diet and maximally tolerated statin dose.
Nexletol™ (bempedoic acid) and Nexlizet™ (bempedoic acid and ezetimibe	**Initial Therapy** • Patient is ≥ 18 years of age; **AND** • Diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH); **AND** • Adherence to highest available dose or maximally tolerated dose of high intensity statin (e.g., atorvastatin or rosuvastatin) for at least three continuous months. If request is for Nexlizet, patient must also have concurrent trial with ezetimibe. If patient is using simvastatin, dose should not exceed 20 mg/day; if patient is using pravastatin, dose should not exceed 40 mg/day; **OR** • Patient has demonstrated statin intolerability, as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms; **AND** • Baseline lipid panel demonstrating failure to reach target LDL-C (70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH and no history of clinical ASCVD); **AND** • Patient (if eligible) will continue adjunct therapy with maximally tolerated high intensity statin. If patient is using simvastatin, dose should not exceed 20 mg/day; if patient is using pravastatin, dose should not exceed 40 mg/day. **Continuation of Therapy** • Patient met initial review criteria; **AND** • Lipid panel showing a reduction in LDL-C compared to baseline labs; **AND** • Patient is absent unacceptable toxicity from therapy (e.g., hyperuricemia and tendon rupture); **AND** • Continued adherence to maximally tolerated statin dose (if eligible).

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Praluent® (alirocumab)	**Initial Therapy** • Patient must be ≥ 18 years old; **AND** • Patient must have a diagnosis of Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria); **OR** • Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) confirmed by documented DNA test for functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality; or a history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300 mg/dL and both parents with documented untreated total cholesterol > 250 mg/dL; **AND** • Prior treatment history with highest available dose or maximally tolerated dose for lipid lowering therapy (e.g., statins, ezetimibe) with failure to reach target an LDL-C <70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH or HoFH and no history of clinical ASCVD; **AND** • Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms; **AND** • Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor. **Continuation of Therapy** • Patient met initial review criteria; **AND** • Lipid panel showing a reduction in LDL-C compared to baseline labs; **AND** • Continued utilization of maximally tolerated combination lipid lowering therapy established prior to initiating alirocumab.
Repatha® (evolocumab)	**Initial Therapy** • Patient must be ≥ 18 years old with the diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR** • Patient must be ≥ 10 years old with the diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome, WHO/Dutch Lipid Network criteria, or MEDPED); **OR** • Patient must be ≥ 10 years old with the diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by: documented DNA test for functional mutation(s) in both low-density lipoprotein (LDL) receptor alleles or alleles known to affect LDL receptor functionality; or a history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300 mg/dL and both parents with documented untreated total cholesterol > 250 mg/dL; **AND** • Prior treatment history with highest available dose or maximally tolerated dose for lipid lowering therapy (e.g., statins, ezetimibe) with failure to reach target an LDL-C < 70 mg/dL for patients with clinical ASCVD and 100 mg/dL for patients with HeFH or HoFH and no

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	history of clinical ASCVD. (Baseline lipid panel demonstrating failure to reach target LDL-C must be provided); **AND** • Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms. • Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor; **OR** • Adult patient age ≥ 18 years old, for the prevention of cardiovascular events, (myocardial infarction, stroke, and coronary revascularization) with established cardiovascular disease: o LDL-C ≥ 70 mg/dL and/or non-HDL-C ≥ 100 mg/dL; **AND** o Prior treatment history with highest available dose or maximally tolerated dose of high intensity statin (e.g., atorvastatin or rosuvastatin); **AND** o Other cardiovascular medication(s) currently in the regimen (e.g., anti-platelet, beta blocker, angiotensin converting enzyme inhibitor, or angiotensin receptor blocker). **Continuation of Therapy** • Initial criteria met. • Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating evolocumab. • Continued utilization of maximally tolerated combination lipid lowering therapy established prior to initiating evolocumab.
Vascepa® (icosapent ethyl)	**Initial Therapy** • Patient must be ≥ 18 years of age. • Patient must use as an adjunct to a low-fat diet and exercise. • If seeking approval for cardiovascular risk reduction: – Triglyceride (TG) levels ≥ 150 mg/dL; **AND** – Established cardiovascular disease as defined as being greater than age 45 with one of the following: o history of myocardial infarction o stable or unstable angina o heart valve disease o stroke or transient ischemic attack o congestive heart failure o arrhythmia o peripheral arterial disease **OR** – Diagnosis of Diabetes Mellitus and 2 additional risk factors for cardiovascular disease o Men ≥ 45 years and women ≥ 55 years o Cigarette smoker or recently stopped smoking o Hypertension o Family history of early heart disease

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	○ Obesity ○ Dyslipidemia **AND** ○ Patient is stable on maximally tolerated statin therapy and will continue therapy or documented contraindication/intolerance to statin therapy. • If seeking approval for severe hypertriglyceridemia: TG levels ≥ 500 mg/dL. • Must have supporting documentation of lab values. Lab values should have been measured within 1 month of request. **Continuation of Therapy** • Patient met initial review criteria. • Documentation of improvement of laboratory values compared to baseline values. • For cardiovascular risk reduction, patient continues to receive maximally tolerated statin therapy or documented contraindication/intolerance to statin therapy. • Patient continues to use therapy as an adjunct to a low-fat diet and exercise.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/