Introduction

Cholesterol is a waxy material that is found in all of the body’s cells. The body needs some cholesterol to perform normal functions like making hormones and vitamin D. Cholesterol travels through the blood in bundles called lipoproteins. There are two kinds of lipoproteins: low-density (LDL) and high-density (HDL). A healthy balance of both is needed to help the body work at its best. LDL cholesterol is sometimes called the “bad” cholesterol because too much of it can clog arteries and lead to serious health problems. The usual way to reduce high levels of bad cholesterol is through diet, exercise, and drugs. In unusual cases where the standard treatment doesn’t work and bad cholesterol is very high, there is a treatment that can filter it out of the blood. This filtering is called lipid apheresis. It uses a machine that works a little bit like kidney dialysis. Blood is removed from a vein and the machine separates out the plasma. (Plasma is a yellow colored liquid and is what’s left after red and white cells and platelets are removed from the blood.) The plasma is filtered to remove the bad cholesterol and is then returned to the patient. This policy describes when lipid apheresis may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| **Low-density lipoprotein (LDL) apheresis** | Low-density lipoprotein (LDL) apheresis may be considered medically necessary in patients with homozygous familial hypercholesterolemia as an alternative to plasmapheresis.  

LDL apheresis may be considered medically necessary in patients with heterozygous familial hypercholesterolemia (FH) when the following criteria are met:

- The patient has a positive genetic test for familial hypercholesterolemia  
**AND**
- The patient has tried and failed at least six months of diet therapy, and maximal combination drug therapy that includes the use of a PSK9 inhibitor  
**AND**
- Meet one of the following FDA approved indications (all LDL levels represent best achievable LDL level after diet and drug therapy)  
  - Functional hypercholesterolemic heterozygotes with LDL $\geq 300$ mg/dL  
    **OR**
  - Functional hypercholesterolemic heterozygotes with LDL $\geq 200$ mg/dL and documented coronary artery disease  

*For definitions of maximum tolerated drug therapy and documented coronary artery disease, please see Definition of Terms.*

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| **Low-density lipoprotein (LDL) apheresis** | LDL apheresis is considered investigational for all other uses not listed in this policy, including but not limited to:  
  - Nephrotic syndrome  
  - Non-arteritic acute anterior ischemic optic neuropathy  
  - Nonfamilial hypercholesterolemia  
  - Peripheral artery disease  

Treatment | Investigational
---|---

- Preeclampsia
- Severe diabetic foot ulcerations
- Sudden sensorineural hearing loss

**Therapeutic apheresis (0342T)** | **Therapeutic apheresis with selective high-density lipoprotein (HDL) delipidation and plasma reinfusion is considered investigational for all indications, including but not limited to acute coronary syndrome.**

**Documentation Requirements**
The patient’s medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- History of genetic testing
- Conservative measures attempted
- LDL (low density lipoprotein) level

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td><strong>36516</strong></td>
</tr>
<tr>
<td></td>
<td>Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion</td>
</tr>
</tbody>
</table>

**HCPCS**

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**Related Information**

**Definition of Terms**

**Delipidation:** This term refers to the removal of lipids from the blood.
Documented coronary artery disease: This includes a history of myocardial infarction, coronary artery bypass surgery, percutaneous transluminal coronary angioplasty or alternative revascularization procedure, or progressive angina documented by exercise or non-exercise stress test.

Low density lipoproteins (LDL): Plasma proteins that are the major carriers of cholesterol in the blood; high levels are associated with atherosclerosis.

Maximum tolerated drug therapy: This is defined as a trial of drugs from at least 2 separate classes of hypolipidemic agents such as bile acid sequestrants, HMG-CoA reductase inhibitors, fibric acid derivatives, or niacin/nicotinic acids. In addition the patient needs to have used a PCSK9 inhibitor with a statin.

Plasma: This is the fluid portion of the blood in which the blood cells are suspended; clear to yellowish colored.

Additional Information

A scientific statement from American Heart Association (Gidding et al [2015]) for the treatment of heterozygous familial hypercholesterolemia (FH) has indicated that adults should be treated with available pharmacotherapy with an initial goal of reducing low-density lipoprotein cholesterol (LDL-C) by at least 50%, usually with a statin. This treatment can be followed by achieving an LDL-C of less than 100 mg/dL (absent coronary artery disease [CAD] or other major risk factors) or 70 mg/dL (presence of CAD or other major risk factors). The following approach for pharmacotherapy is suggested:

- High-intensity statin therapy to target >50% LDL-C reduction, such as rosvastatin or atorvastatin.
- If the patient is adherent and LDL-C is above the target goal after 3 months, consider adding ezetimibe.
- If the patient is adherent and LDL-C is above the target goal after 3 months, consider adding a PCSK9 inhibitor or colesevelam (or other bile acid sequestrant or niacin).
- If the patient is adherent and LDL-C is above the target goal after 3 months, proceed to complex therapy combination such as a 4-drug combination plus LDL apheresis.

Documented CAD includes a history of myocardial infarction, coronary artery bypass surgery, percutaneous transluminal coronary angioplasty or alternative revascularization procedure, or progressive angina documented by exercise or nonexercise stress test.
Because LDL apheresis represents a chronic, lifelong therapy, Plans may consider requiring precertification or prior approval to ensure that the patient meets patient selection criteria.

The frequency of LDL apheresis varies, but typically averages once every 2 weeks to obtain an interapheresis level of LDL-C at less than 120 mg/dL. Patients with homozygous FH may be treated more frequently. Patients are simultaneously treated with diet and drug therapy.

**Evidence Review**

**Description**

This use of low-density lipoprotein (LDL) apheresis has been proposed to treat various types of familial hypercholesterolemia (FH) and other significant hyperlipidemia and to reduce atherosclerosis in cardiovascular disease. Lipid apheresis discriminately removes LDL particles from plasma while leaving other factors intact, allowing the filtrated plasma to be returned to the patient.

**Background**

**Hyperlipidemia**

A dominantly inherited disorder, familial hypercholesterolemia results from a variant in the gene that encodes for the specific cell surface receptor responsible for low-density lipoprotein (LDL) uptake by the cells. The heterozygous form affects about 1 in 500 people. The number of LDL receptors is halved in this condition, resulting in serum low-density lipoprotein cholesterol levels that are approximately 2 to 3 times levels considered acceptable (ie, >300 mg/dL). Affected male patients typically develop coronary heart disease in their thirties and forties, while women develop the disease in their fifties. Depending on the patient, heterozygous familial hypercholesterolemia may or may not respond adequately to lipid-lowering drugs.

Homozygous hypercholesterolemia is rare, occurring in only in 1 in 1 million subjects. Due to the total lack of functioning LDL receptors, serum levels of low-density lipoprotein cholesterol may be elevated 6-fold (>500 mg/dL). Homozygotes may develop severe aortic stenosis and coronary heart disease by 20 years of age. These patients typically do not adequately respond to drug or diet modification therapies. In the past, patients with homozygous familial hypercholesterolemia may have been treated with plasma exchange, but the advent of LDL
apheresis provides a more targeted approach by permitting selective removal of LDL from plasma.

**Treatment**

**Low-Density Lipoprotein-Apheresis**

LDL apheresis (also referred to as lipid apheresis) involves the extracorporeal removal of apolipoprotein B (apo B)–containing lipoproteins, including LDL, lipoprotein(a), and very low-density lipoprotein.

The apheresis procedure is designed to isolate plasma. The LDLs are then selectively removed from the plasma by immunoadsorption, heparin-induced extracorporeal LDL precipitation, dextran sulfate adsorption, or double-filtration plasma pheresis of lipoprotein. In immunoadsorption, polyclonal antihuman apo B antibodies from sheep selectively bind and remove LDL, because apo B is the protein moiety of LDL. In heparin-induced extracorporeal LDL precipitation, LDL and other particles containing apo B are precipitated by heparin at an acidic pH. Dextran sulfate adsorption removes LDL by binding the positively charged apo B to dextran sulfate particles bound to cellulose.

**High-Density Lipoprotein**

Therapeutic apheresis with selective high-density lipoprotein (HDL) delipidation and plasma reinfusion removes plasma from the body, processed through a delipidation device, and then returned to the patient. The delipidation procedure selectively removes cholesterol from HDL, converting the major α-HDL to pre-β-like HDL, a form of HDL that enhances cholesterol transport to the liver and is thought to reduce atherosclerosis development and burden. The plasma with pre-β-like HDL is then reinfused into the patient.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.
Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td>NCT02791802</td>
<td>Effect of Lipoprotein(a) Elimination by Lipoprotein Apheresis on Cardiovascular Outcomes</td>
<td>1000</td>
<td>Feb 2021</td>
</tr>
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</table>

NCT: national clinical trial.

Summary of Evidence

Familial Hypercholesterolemia

For individuals with homozygous FH and unable to achieve target LDL-C with maximally tolerated pharmacotherapy who receive LDL apheresis, the evidence includes multiple nonrandomized prospective and retrospective small cohort studies and a systematic review. The relevant outcomes are overall survival, disease-specific survival, change in disease status, morbid events, and treatment-related morbidity. Studies have reported reductions in LDL-C levels after apheresis, with means ranging from 57% to 75%. Currently, the direct evidence does not demonstrate that reductions in LDL-C levels seen with LDL apheresis will reduce adverse cardiovascular events. RCTs comparing drug therapy alone, apheresis alone, no intervention, usual care, or apheresis plus drug therapy are not feasible, and unlikely to resolve any clinical uncertainty because lipid apheresis is generally used as a treatment of last resort when maximally tolerated pharmacotherapy has failed to achieve target LDL-C levels. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with heterozygous FH and unable to achieve target LDL-C with maximally tolerated pharmacotherapy who receive LDL apheresis, the evidence includes multiple nonrandomized prospective and retrospective small cohort studies as well as a systematic review. The relevant outcomes are overall survival, disease-specific survival, change in disease status, morbid events, and treatment-related morbidity. Studies have reported reductions in LDL-C levels after apheresis with means ranging from 58% to 63%. Currently, there is no direct evidence that reductions in LDL-C levels seen with LDL apheresis will reduce adverse cardiovascular events. RCTs comparing drug therapy alone, apheresis alone, no intervention, usual care, or apheresis plus drug therapy are not feasible, and unlikely to resolve any clinical uncertainty because lipid apheresis is generally used as a treatment of last resort when maximally tolerated pharmacotherapy has failed to achieve target LDL-C levels. The evidence is
sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Nonfamilial Hypercholesterolemia**

For individuals with non-FH who receive LDL apheresis, the evidence includes multiple retrospective and prospective nonrandomized cohort studies. The relevant outcomes are overall survival, disease-specific survival, change in disease status, morbid events, and treatment-related morbidity. These studies have reported improvements in lipid levels pre- and posttreatment. Randomized trials in patient populations that are well-characterized regarding previous treatments, lipid levels, and comorbidities are necessary to demonstrate improvements in health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Nephrotic Syndrome**

For individuals with treatment-resistant nephrotic syndrome who receive LDL apheresis, the evidence includes multiple nonrandomized prospective and retrospective cohort studies. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. Using variable schedules of LDL apheresis with short-term follow-up, these studies have reported that LDL apheresis may improve proteinuria and lipid abnormalities in patients with steroid-resistant nephrotic syndrome. Additional studies with concurrent controls and longer term follow-up are necessary to determine whether outcomes are improved with the use of LDL apheresis in nephrotic syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Other Indications**

For individuals with sudden sensorineural hearing loss who receive LDL and fibrinogen apheresis, the evidence includes two RCTs. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. One RCT compared LDL apheresis with the standard treatment of prednisolone, hydroxyethyl starch, and pentoxifylline; it reported no statistically significant differences in hearing recovery between groups. The second RCT compared the combination of a single lipid apheresis procedure plus standard treatment with standard treatment alone; it reported statistically significant differences in hearing recovery with
the addition of apheresis to standard treatment. An a priori primary end point, power calculations, and the statistical plan to control for type I error for multiple comparisons were not reported in the second trial. Further evaluation and replication of these findings are required given the inconsistent reporting. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with severe diabetic foot ulcerations who receive LDL apheresis, the evidence includes a single prospective case series. The relevant outcomes are symptoms, change in disease status, morbidity events, and treatment-related morbidity. In the case series, patients underwent from 1 to 7 treatment procedures and were followed for 2 to 73 months. Authors reported improved wound healing and reductions in the risk of lower leg amputations but results were insufficient to ascertain the effects on outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with peripheral artery disease who receive LDL apheresis, the evidence includes a single prospective case series. The relevant outcomes are change in disease status and treatment-related morbidity. Improvements in symptomatic parameters such as coldness, numbness, and resting pain were reported, but insufficient to ascertain the effects on outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with preeclampsia who receive LDL apheresis, the evidence includes a prospective case series. The relevant outcomes are overall survival, disease-specific survival, change in change in disease status, morbidity events, and treatment-related morbidity. Improvements in gestation were reported, but insufficient to ascertain the effects on outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with non–arteritic acute anterior ischemic optic neuropathy who receive LDL apheresis, the evidence includes a prospective case series. The relevant outcomes are symptoms, change in change in disease status, and treatment-related morbidity. Improvement in visual outcomes was reported, but insufficient to ascertain the effects on outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Acute Coronary Syndrome**

For individuals with acute coronary syndrome who receive selective high-density lipoprotein (HDL) delipidation and plasma reinfusion, the evidence includes an RCT. The relevant outcomes are overall mortality, disease-specific survival, change in disease status, morbidity events, and treatment-related morbidity. Results have shown improvements in certain biochemical measures (eg, pre-β-like HDL and α-HDL levels). There were no significant changes in atheroma volume.
Larger randomized trials, with longer follow-up and clinically relevant outcomes, are needed to determine the impact of delipidated HDL plasma on acute coronary syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Practice Guidelines and Position Statements**

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence’s (2017) guidance on familial hypercholesterolemia (FH) states the following:

1.3.3.1 Healthcare professionals should consider offering LDL [low-density lipoprotein] apheresis for the treatment of adults and children/young people with homozygous FH. The timing of initiation of LDL apheresis should depend on factors such as the person's response to lipid-modifying drug therapy and presence of coronary heart disease.

1.3.3.2 In exceptional instances (such as when there is progressive, symptomatic coronary heart disease, despite maximal tolerated lipid-modifying drug therapy and optimal medical and surgical therapy), healthcare professionals should consider offering LDL apheresis for the treatment of people with heterozygous FH. This should take place in a specialist center on a case-by-case basis and data recorded in an appropriate registry.19

**American Society for Apheresis**

The American Society for Apheresis (2016) issued guidelines on the use of apheresis for seven conditions (see Table 2).18

**Table 2. Guidelines on Use of Apheresis**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Category</th>
<th>Gradea</th>
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</thead>
<tbody>
<tr>
<td>Low-density lipoprotein apheresis for homozygous familial hypercholesterolemia</td>
<td>I</td>
<td>1A</td>
</tr>
<tr>
<td>Heterozygous familial hypercholesterolemia</td>
<td>II</td>
<td>1A</td>
</tr>
<tr>
<td>Focal segmental glomerulosclerosis</td>
<td>III</td>
<td>2C</td>
</tr>
<tr>
<td>Lipoprotein (a) hyperlipoproteinemia</td>
<td>II</td>
<td>1B</td>
</tr>
<tr>
<td>Peripheral vascular diseases</td>
<td>II</td>
<td>1B</td>
</tr>
</tbody>
</table>
### American Heart Association

A scientific statement from American Heart Association (2015) on the treatment of heterozygous FH has indicated that high-risk adults should be treated with available pharmacotherapy with an initial goal of reducing low-density lipoprotein cholesterol (LDL-C) by at least 50%, usually with a statin, and treatment should be intensified based on the response.\(^\text{19}\) It also stated that there are no data to inform pediatric treatment goals, whether to target an LDL-C level of less than 100 or 130 mg/dL or to aim to achieve a 50% reduction in LDL-C from baseline.

For homozygous FH, the American Heart Association has recommended that lipid apheresis should be considered by five years of age or earlier in exceptional circumstances and should be used after maximally tolerated pharmacotherapy fails to achieve target LDL-C levels. The LDL-C selection criteria for lipid apheresis include a reduction in LDL-C of less than 50% by other treatments and residual severe LDL-C elevation of more than 300 mg/dL or more than 200 mg/dL with prevalent cardiovascular disease.

No guidelines on therapeutic apheresis with selective high-density lipoprotein delipidation and plasma reinfusion were identified.

### Medicare National Coverage

National Coverage Decision 110.14 on apheresis lists the indications for which apheresis is a covered benefit in cellular and immune-complex mediated disorders. There is no determination for hypercholesterolemia or LDL apheresis.\(^\text{20}\)
Regulatory Status

Two LDL apheresis systems have been approved by the U.S. Food and Drug Administration (FDA) for marketing. In 1996, the Liposorber® LA-15 System” (Kaneka Pharma), dextran sulfate device “was approved by the FDA through the premarket approval process for use to “acutely remove LDL-C from the plasma of high-risk patient populations for whom diet has been ineffective or not tolerated.”

In 1997, the HELP® System (B. Braun), a heparin-induced extracorporeal LDL precipitation, was approved by the FDA through the premarket approval process for the same indication. FDA product code: MMY.

In 2013, the Liposorber® LA-15 System was approved for additional indications through the humanitarian device exemption1 process for the treatment of pediatric patients with primary focal segmental glomerulosclerosis, when the following conditions apply:

- Standard treatment options, including corticosteroid and/or calcineurin inhibitor treatments, are unsuccessful or not well-tolerated, and the patient has a GFR [glomerular filtration rate] ≥60 mL/min/1.73 m²

**OR**

- The patient is post-renal transplantation

No devices have been approved by FDA specifically for HDL delipidation. The Lipid Sciences Plasma Delipidation System-2 (Lipid Sciences, Pleasanton, CA) was tested in clinical studies, but the company ceased business operations in 2012.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tr>
<td>09/07/99</td>
<td>Add to Therapy Section - New Policy</td>
</tr>
<tr>
<td>11/12/02</td>
<td>Replace Policy - Policy reviewed without literature review; new review date only</td>
</tr>
<tr>
<td>05/13/03</td>
<td>Replace Policy - Update CPT code only.</td>
</tr>
<tr>
<td>02/10/04</td>
<td>Replace Policy - Policy reviewed without literature review; codes added.</td>
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<td>05/10/05</td>
<td>Replace Policy - Policy reviewed with a literature search; no change to policy statement.</td>
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<td>05/09/06</td>
<td>Replace Policy - Policy reviewed with a literature search; reference added; no change to policy statement.</td>
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<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
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<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search. Policy statement expanded to include LDL apheresis for all other uses, including use in preeclampsia as investigational. References and code added.</td>
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<td>Replace Policy - Policy updated with literature review. References have been added; no change in policy statement.</td>
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<td>10/11/11</td>
<td>Replace Policy – Policy updated with literature search; reference number 3 added; references renumbered; no change in policy statements. ICD-10 codes added.</td>
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<td>10/26/12</td>
<td>Replace Policy. Policy reviewed, literature search through July 2012 resulted in no additions to the reference section. Policy statement is unchanged.</td>
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<td>02/12/13</td>
<td>Update Related Policies, change title to policy 8.02.02.</td>
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<td>10/14/13</td>
<td>Replace policy. Policy guideline deleted as not applicable stated “Since LDL apheresis represents a chronic, lifelong therapy, Plans may consider requiring precertification or prior approval to ensure that the patient meets the patient selection criteria”. Policy guidelines codes and descriptions reformatted for ease of use. Rationale updated with literature search through June 2013. Reference 8 added, previous reference 8 deleted; others renumbered/removed. Policy statements unchanged.</td>
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<tr>
<td>12/23/13</td>
<td>Coding Update. Add CPT 0342T effective 01/01/14.</td>
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<tr>
<td>05/28/14</td>
<td>Correct policy effective date from 10/14/14 to 10/14/13.</td>
</tr>
<tr>
<td>10/13/14</td>
<td>Annual Review. Policy updated with literature review through July 24, 2014; references 7-8 and 10-11 added; added policy statement indicating therapeutic apheresis with selective high-density lipoprotein (HDL) delipidation and plasma reinfusion is investigational; title changed to Lipid Apheresis.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>------------</td>
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<tr>
<td>11/01/16</td>
<td>Interim Update, approved October 11, 2016: Policy now requires genetic testing for FH, and requires the use of PSK9 inhibitor trial and failure prior to considering lipid apheresis. This varies slightly from BCBSA.</td>
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<tr>
<td>03/24/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
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<tr>
<td>08/01/17</td>
<td>Annual Review, approved July 11, 2017. Policy updated with literature review through March 23, 2017; references added. The investigational statement on LDL apheresis for all other uses expanded with, “…including but not limited to: non-FH, sudden sensorineural hearing loss, severe diabetic foot ulcerations, peripheral artery disease, and non–arteritic acute anterior ischemic optic neuropathy.” Revised Definition of Terms updated for “Maximum tolerated drug therapy...” now defined as “…a trial of drugs from at least 2 separate classes of hypolipidemic agents such as bile acid sequestrants, HMG-CoA reductase inhibitors, fibric acid derivatives, or niacin/nicotinic acids.”</td>
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<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 25, 2018. Policy updated with literature review through March 2018; references 20-21 updated. Policy statement on high density lipoprotein apheresis was clarified.</td>
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<tr>
<td>11/01/18</td>
<td>Minor update, removed 8.02.02 from related policies as it was archived.</td>
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<td>04/01/19</td>
<td>Minor update, added Documentation Requirements section.</td>
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<tr>
<td>07/02/2020</td>
<td>Coding update. Removed 0342T and S2120.</td>
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</tbody>
</table>

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Language Assistance


Language Assistance