Adherence & Insurance Issues

JOYCE L ROSS, MSN, CRNP, CCS, FNLA, FPCNA
PAST PRESIDENT PCNA, PRESIDENT-ELECT NELA
UNIVERSITY OF PENNSYLVANIA RETIRED
INDEPENDENT EDUCATION AND CLINICAL CONSULTANT
CARDIOVASCULAR RISK INTERVENTION
WEST CHESTER, PA 19380
Disclosures

- **Speakers Bureau:**
  - KOWA
  - AstraZeneca
  - Abbott/AbbVie
  - Aegerion
  - Amarin

- **Consultant:**
  - Genzyme
  - Kaneka America
Adherence & Insurance Issues

Objectives

- After attending this presentation the participant will be able to:
  - Discuss adherence issues for both the patient and provider
  - Recall process for enrolling the patient to apheresis treatment
  - Understand pertinent insurance issues with regard to LDL apheresis treatments
Adherence to treatment

- Understanding and patience are the keys to adherence to LDL apheresis

- Key tenants
  - Patient must have reasonable access to treatment
  - Patient must understand the need for the procedure
  - Patient needs to be a believer in the process
  - All family members need to have buy-in to the process
    - Can be educated by use of media films with follow up opportunity to have questions/concerns addressed
Referral or Identification of a potential patient for LDL Apheresis

- Pt. referred to practice for evaluation and treatment recommendations related to her known cardiovascular disease and sub-optimal response to tradition medications in the setting of muscle symptomology with high doses of statin therapy

  - Questions:
    - Have all options for lifestyle and medication been exhausted
      - Response to treatments
        - Lipid goal achievement
        - Toleration
    - Establishing the lipid diagnosis and LDL goal
    - What are the patients/family’s feelings about potential LDL apheresis treatments?
      - Do they have any information about LDL apheresis?
Patient with known CAD and refractory to traditional treatment

- **Social History:**
  - Married homemaker, 6 children
  - Non smoker
  - No ETOH
  - Exercises generally 3 Xs a week walking for 30 minutes – has been difficult with “leg pain” in the past

- **Family History:**
  - Mother died from breast cancer in her 40’s, but there is history of extensive heart disease in her Mother’s siblings
  - Father died from CAD at 76
Medication History

• Medications at presentation
  • Niacin (Niaspan) 2 Gm.
  • Lisinopril 5 mg.
  • Metoprolol 25 mg daily
  • MVI – one daily
  • Omeprazole 20 mg daily
  • Clopidroegrel 75 mg

• Past Experience with antihyperlipidemic medications
  • Lovastatin, Atorvastatin and Gemfibrozil resulted in myositis
  • Able to tolerate Simvastatin for a number of years but did not have adequate LDL lowering with a 40 mg dose, (LDL 190-200)
Laboratory Studies

- TG 269
- TC 461
- HDL 58
- LDL 349
- Non-HDL 403
- Glucose 113
- ALT - WNL
- AST – WNL
- Creatinine: 0.5
- TSH: WNL
Diagnosis & Treatment Plan
Is LDL Apheresis Necessary?

- **Lipid Diagnosis:**
  - Severe Heterozygous Familial Hypercholesterolemia
  - Super-imposed hypertriglyceridemia

- **Treatment Plan:** It’s a process (some short/long)
  - trial of combination lipid lowering medication and TLC
    - Start Simvastatin 40 mg continue prescription Niacin at 2 Gm and then add consider adding Colesevelam to see if adequate LDL level can be obtained
    - Meet with Registered Dietician – focus on weight reduction, recommendations for reduction of TG, glucose
    - Discussed potential for Implementation of LDL Apheresis
    - Continue with aerobic exercise program
    - Blood work in 6 weeks, Full lipid panel, CMP, TSH, Hema1c
First Follow up appointment

- Changes in status: continues with frequent anginal symptoms unchanged with intensity or frequency
- Current Meds: Simvastatin 80 mg (cardiologist increased), Prescription Niacin 2 Gms, Lisinopril 5 mg, Metoprolol 25 mg, Omeprazole 20 mg, Clopidroogrel 75 mg
- PE: Weight 183, BMI 36, BP 140/80, HR 76, otherwise unchanged from previous visit
- Labs: TGs 225, TC 327, HDL 56, LDL 266, down from 461, Non-HDL 271, Glucose 97, LFTs WNLs, Creatinine 0.9
Impression and Plan

• Impression
  ○ Severe Heterozygous Familial Hypercholesterolemia
  ○ Sub-optimal LDL with some lowering with the addition of Simvastatin at 80 mg but clearly well above target of < 70 given her vascular disease

• Plan:
  ○ Paperwork completed for LDL apheresis, insurance coverage verification completed
  ○ Vessels evaluated for access at the unit
  ○ Colesevelam added and other LLMs continued at current doses
  ○ Return appointment 3 months
Return Visit

- **Current Meds**: Simvastatin 80 mg, Prescription Niacin 2 Gms, Lisinopril 5 mg, Metoprolol 25 mg, Omeprazole 20 mg, Clopidogrel 75 mg, Colesevelam 625 (3) tabs 2 Xs daily, complaining of some diffuse muscle ache which are unchanged in character or quantity, feels that they are tolerable.

- **New Problems**: Nocturnal leg cramps, leg pain with walking 1 block in R leg, relieved with stopping of activity. Increased GI complaints of nausea. No change with anginal pain with exertion

- **PE**: Weight 185, BMI 36, BP 140/82, HR 72

- **Labs**: Improved with TG 107, TC 269, HDL 71, LDL 177, LFTs WNLs, glucose WNL
Impression and Plan

• Impression & Plan
  • CAD, angina, FH, HTN, PAD, muscle symptoms, increased GI complaints, patient is somewhat hesitant about the potential for LDL apheresis.
  • Follow up with local cardiologist for recurrent anginal symptoms and intermittent claudication

• Lipids: continue with current medications but add Ezetimibe 10 mg. for optimal control of LDL at least until decision for LDL apheresis is made. Encouraged to contact office if muscle symptoms increase or feels that GI problems continue or escalate

• RTC 4 months
Follow up appointment

- 4 month FUA
- Isosorbide mononitrate added by local cardiologist, medications otherwise unchanged
- Continues to have “muscle ache/pain” and would like to consider stopping some of the lipid lowering medication
  - Ezetimibe, Prescription Niacin, Colesevelam 625 mg., Simvastatin 80 mg
  - Current labs on the 4 medication regimen:
    - TG 162, TC 259, HDL 55, LDL 172
- Impression and Plan:
  - Severe FH with still sub-optimal LDL cholesterol on 4 medication regimen
  - Stop Niacin, Ezetimibe, Colesevelam, and continue with Simvastatin for relief of symptoms
  - Proceed to LDL aphaeresis
# Lipid Values on LDL Apheresis

<table>
<thead>
<tr>
<th></th>
<th>Pre - treatment Value</th>
<th>Post - treatment Value</th>
<th>Impression:</th>
<th>Plan:</th>
</tr>
</thead>
<tbody>
<tr>
<td>TG</td>
<td>144</td>
<td>29</td>
<td>FH, tolerated LDL Apheresis without difficulty, less fatigue reported off of all but Simvastatin at 80 mg. Patient well pleased with process and outcome.</td>
<td>No change with medications, treatment every other week as scheduled</td>
</tr>
<tr>
<td>TC</td>
<td>311</td>
<td>124</td>
<td></td>
<td>Follow up appointment in 3 months</td>
</tr>
<tr>
<td>HDL</td>
<td>57</td>
<td>59</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LDL</td>
<td>225</td>
<td>59</td>
<td></td>
<td></td>
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</tbody>
</table>

**Pre - treatment Value**
- TG: 144
- TC: 311
- HDL: 57
- LDL: 225

**Post - treatment Value**
- TG: 29
- TC: 124
- HDL: 59
- LDL: 59
Insurance Issues

- As the patient is following initial treatment plans will need to:
  - Anticipate the need for LDL apheresis
  - Establish if additional access is necessary
    - Will need to know this prior to contact with insurance for approvals etc
  - Contact the insurance company to establish coverage
  - Many changes have occurred since our initial patient was covered in 1996
    - No CPT code
    - Insurance companies were not familiar with treatment
    - Difficult for them to give approval
Outpatient Apheresis:
Commercial Insurers Often Require Preauthorization

- **Necessary documentation will include:**
  - Detailed patient history
  - Examination findings
  - Treatment records
  - Laboratory records

Any additional procedures necessary such as access
How often treatment will occur
For what period is LDL Apheresis treatment anticipated
Published evidence of clinical benefit
The Coverage Appeals Process:
Get What the Patient Needs; Educate the Insurer

• Insurer coverage policies often lag behind or miss recent published evidence in the clinical literature
• Don’t give up when an insurer denies coverage:
  ✓ Ask for review on an individual consideration basis
  ✓ Provide available published studies to document efficacy
  ✓ As applicable, document failures with other treatment options
• Current examples:
  ✓ LDL apheresis for very high LP(a)
Physician Billing for Apheresis Procedure Supervision (professional fee)

- CMS-1500 Claim Form: Key Coding Elements
  - ICD-9-CM diagnosis codes specifying diagnosis that relates to each physician service or billed item
  - CPT procedure and E/M codes
  - Place of service code

Therapeutic Apheresis: A Guide to Billing and Securing Appropriate...
www.apheresis.org/resource/resmgr/.../asf_therapeutic_apheresis_r.pdf
Medicare Therapeutic Apheresis Coverage Policy
Re: The Physician’s Role

“...Apheresis is covered...when the following conditions are met:*

- A physician...is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
- Each patient is under the care of a physician; and
- All non-physician services are furnished under the direct, personal supervision of a physician.

Apheresis Supervision: General Billing Principles

- The physician:
  - Bills the CPT code applicable for that procedure
    - 36516
    - with extracorporeal selective adsorption or filtration and plasma reinfusion (LDL apheresis)
  - Bills the professional fee for each date he/she supervises an apheresis procedure
  - To bill an apheresis professional fee, the physician must examine the patient and must be [immediately] available during the procedure.*

The physician should prepare a procedure note documenting his/her services (consistent with the institution’s standards).

Evaluation & management (E/M) codes should not be used to bill for supervision of apheresis procedures.
The physician is responsible for documenting supervision of the procedure in the patient record according to the institution’s standards.*

The procedure note should document that the physician:
- Reviewed/evaluated clinical and lab data relevant to the treatment of the patient that day.
- Made the decision to perform the procedure on that day.
- Saw and evaluated the patient for the procedure.
- Remained available throughout the duration of the procedure to respond in person to emergencies and other situations requiring his/her presence.

*ASFA Guidelines for Documentation of Therapeutic Apheresis Procedures in the Medical Record by Apheresis Physicians (www.apheresis.org)
Clarifying Medicare’s “Direct, Personal Supervision” Requirement

- 2010: ASFA asks CMS to clarify the meaning of this term

- CMS responds: “The intent of ‘direct, personal’...means literally the regulatory definition of ‘direct’ supervision” (1)

“Direct supervision” defined by CMS for Medicare coverage:

- “As of 1/1/2011, “direct supervision means that the physician...must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician...must be present in the room when the procedure is performed.”

Clarifying the Definition of “Immediately Available” for Medicare Apheresis Services

- “Immediate availability requires the immediate physical presence of the supervisory physician...practitioner. CMS has not specifically defined the word ‘immediate’ in terms of time or distance...

- Examples of a lack of immediate availability would be situations where the supervisory practitioner is performing another procedure or service that he/she could not interrupt, or where he/she is so physically far away from the location where [apheresis] is being furnished that he/he could not intervene right away...”*

Clarifying the Definition of “Immediately Available” for Medicare Apheresis Services

- “The...supervisory practitioner must judge [his/her] relative location to ensure that he/she is immediately available.

- A supervisory practitioner may supervise from a physician office or other nonhospital space that is not officially part of the hospital campus where services are being furnished as long as he/she remains immediately available.”

Codes: The Shorthand of Insurance Billing

- CPT codes. 5-digit codes used by physicians and hospitals to bill insurers for outpatient procedures and services

- ICD-9-CM procedure codes. Used by hospitals to identify significant procedures during an inpatient stay

- ICD-9-CM diagnosis codes. Used to identify diagnoses that are both related and unrelated to the procedure or admission

- Revenue codes. 3-digit codes that define the hospital department or service category under which procedures or products are billed.

Therapeutic Apheresis: A Guide to Billing and Securing Appropriate...
www.apheresis.org/resource/resmgr/.../asf_therapeutic_apheresis_r.pdf
Claims for Payment

- Hospitals and Physicians Submit Separate Claims for Payment
  - Physicians: CMS-1500
  - Hospitals: UB-04

Medicare (Hospital Outpatients):  
2013 Plasma/Cellular Apheresis Payment

- 36514
- for plasmapheresis
  - APC 0111 (blood product exchange)
  - $951 (U.S. average)
  - Medicare payment rate varies by locality: e.g. about $1,140 in Manhattan; $870 in Pittsburgh
LDL Apheresis: A gap exists between Insurance Coverage Policies and Best Clinical Practice

For heterozygotes with familial hypercholesterolemia (FH) 272.0 and very high risk characteristics (CHD, other CV disease, diabetes)

Device indication and prevalent insurance coverage policies: National Lipid Association Expert Panel on FH

- LDL cholesterol 200 mg/dL
- LDL cholesterol 160 mg/dL
THERAPEUTIC APHERESIS

A Guide to Billing and Securing Appropriate Reimbursement

2013 Edition

ASFA – American Society for Apheresis

Therapeutic Apheresis: A Guide to Billing and Securing Appropriate...
www.apheresis.org/resource/resmgr/.../asf_therapeutic_apheresis_r.pdf