Improving Access to PCSK9-Modulating Therapy

Kim Birtcher, MS, PharmD, AACC, FNLA, BCPS-AQ Cardiology, CDCES
Adjunct Clinical Professor
University of Houston College of Pharmacy
kbirtcher@uh.edu
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Dr. Birtcher has no financial interests to disclose.
Objectives

• Provide steps for facilitating the prior authorization process
• Share the National Lipid Association, the American College of Cardiology, and the 2018 ACC/AHA Multisociety Cholesterol Guideline’s position on team-based care
• Provide examples of how team-based care can improve patient outcomes
• Discuss innovative models of care, which include pharmacists, to provide patients with easy access to clinician administration of long-acting PCSK9-modulating therapy.
Progress Note - Include All Pertinent Information

1. Patient’s FDA-approved indication
2. Recent lipid values, including LDL-C
3. Adherence with lifestyle modifications
4. Adherence with maximally tolerated statin therapy
5. Adherence with other LDL-C–lowering therapy
6. History of statin use and other agents
   • Include intolerances
7. Desired % LDL-C reduction goal and LDL-C threshold

Complete Documentation

- Medical history
- Diagnosis
- Family history of premature ASCVD
- Physical exam
- Other specific required criteria

Increased Likelihood of Approval

Leverage the Electronic Medical Record

*Add Details to Problem List and Allergy/Intolerance Section*

Add patient-specific information to the default problem list entries

- Premature CAD (ex. MI at 43 years; CABGx3 at 46 years)
- Familial hypercholesterolemia (ex. AHA criteria: Baseline LDL-C ≥190 mg/dL + family history of premature CAD)
- Family history of premature CAD (ex. father, grandfather, paternal aunt)
- Statin intolerances (ex. daily atorvastatin, pravastatin, rosuvastatin - intolerable myalgia; interfered with normal daily activities; resolved when discontinued; recurred with rechallenge)
  - Also add to the allergy section
Leverage the Electronic Medical Record
Create smart phrases and snapshots to ease charting

• Create template/smart phrase for progress note
  • Will ease the documentation process
  • Ensures a complete note
• Create useful snapshots or summary pages
  • Name
  • Allergies
  • Problem list
  • Medication list
  • Lab history
• Send the snapshot or summary pages with the progress note + prior authorization form
NLA and ACC Support Team-Based Care (TBC)

- NLA and ACC Core Values
  - Promotes multidisciplinary approach to enhance outcomes
- ACC Health Policy Statement on Cardiovascular Team-Based Care and Role of Advanced Practice Providers
  - Advanced Practice Providers includes nurse practitioners, physician assistants, and pharmacists
  - TBC can transform care, improve heart health, and help meet the demands of the future
  - TBC improves care coordination and population health; lowers costs
2018 ACC/AHA Multisociety Cholesterol Guideline Recommends Team-Based Activities to Improve Adherence

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendation for Implementation</th>
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<tbody>
<tr>
<td>I</td>
<td>A</td>
<td>Interventions focused on improving adherence to prescribed therapy are recommended for management of adults with elevated cholesterol levels, including telephone reminders, calendar reminders, integrated multidisciplinary educational activities, and pharmacist-led interventions, such as simplification of the drug regimen to once-daily dosing.</td>
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ACC, American College of Cardiology; AHA, American Heart Association
Multidisciplinary Lipid Clinic in Health-System

- **Purpose:** increase guideline-directed care for lipid conditions
- **Background**
  - Established in January 2019 within health-system (45 counties in central and northeast Pennsylvania)
  - Located centrally
  - Staff: cardiologist with board certification in lipidology; pharmacist; genetic counselor
  - Patient referrals from PCPs and cardiologists
  - Clinic met bimonthly

PCPs, Primary Care Providers
Multidisciplinary Lipid Clinic in Health-System

- Used pre/post-study design to evaluate outcomes at 1 year
- Results
  - Improved diagnosis of specific lipid condition
  - Increased prescribing of guideline-directed treatment
  - Significant improvement in lipid values
    - Familial hypercholesterolemia (n=12); LDL-C ↓ 79 mg/dL (p<0.001)
    - Uncharacterized dyslipidemia (n=21): LDL-C ↓ 48 mg/dL (p<0.001)
  - High rates of medication prior authorization approvals
- Transitioned from face-to-face visits to telehealth appointments to increase accessibility and usage of clinic

Engaging the Team - Designate a Prior Authorization Expert Within the Practice Site

- Designate specific team members to complete prior authorization forms
  - Become familiar with insurance plans, requirements
  - Allows expertise to develop
  - May save time
  - May increase approval rate
- Specialty pharmacy staff can sometimes help!

Central Pharmacist-Led PA Process:

<table>
<thead>
<tr>
<th></th>
<th>Pharmacist-Led (n = 47)</th>
<th>Usual Care (n = 77)</th>
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<tbody>
<tr>
<td>Mean processing time</td>
<td>0.53 days</td>
<td>7.02 days</td>
</tr>
<tr>
<td>Mean preparation time</td>
<td>15 min</td>
<td>64 min</td>
</tr>
<tr>
<td>Approval rate</td>
<td>93%</td>
<td>68%</td>
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<tr>
<td>Mean time to fill (days)</td>
<td>2.49 days</td>
<td>5.52 days</td>
</tr>
<tr>
<td>Pick-up rate</td>
<td>75%</td>
<td>52%</td>
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<tr>
<td>Labor cost per PA</td>
<td>$11.50</td>
<td>$37.50</td>
</tr>
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All P <0.05.

Pharmacist-Administered PCSK9 Service
Possible Solution to Improve Patient Access and Adherence

• Long-acting PCSK9-modulating therapy may improve adherence with lipid lowering therapy.

• Health-systems will need innovative models to provide patients with easy access to clinician administration of long-acting PCSK9-modulating therapy.

• Pharmacists associated with the health system or community pharmacists could:
  • Help navigate the prior authorization process;
  • Administer the long-acting PCSK9-modulating therapy to improve access to care and patient adherence; and
  • Provide point-of-care lipid testing to ensure efficacy over time.

• Adequate reimbursement will be needed to implement innovative models for clinician administered long-acting PCSK9-modulating therapy.

Conclusions

• In order to facilitate the prior authorization process for nonstatin therapy, the clinician should use appropriate patient selection, write a complete progress note, and leverage the electronic medical record.

• The National Lipid Association, the American College of Cardiology, and the 2018 ACC/AHA Multisociety Cholesterol Guideline support team-based care.

• Team-based care improves patient outcomes.

• Health-systems will need innovative models to provide patients with easy access to clinician administration of long-acting PCSK9-modulating therapy.

• Pharmacists associated with the health system or community pharmacists could improve access and adherence to PCSK9-modulating therapy, requiring clinician administration.