

# ACCESS TO INNOVATIVE MEDICINES

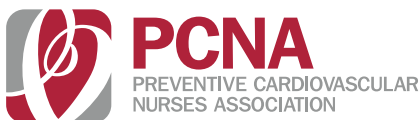
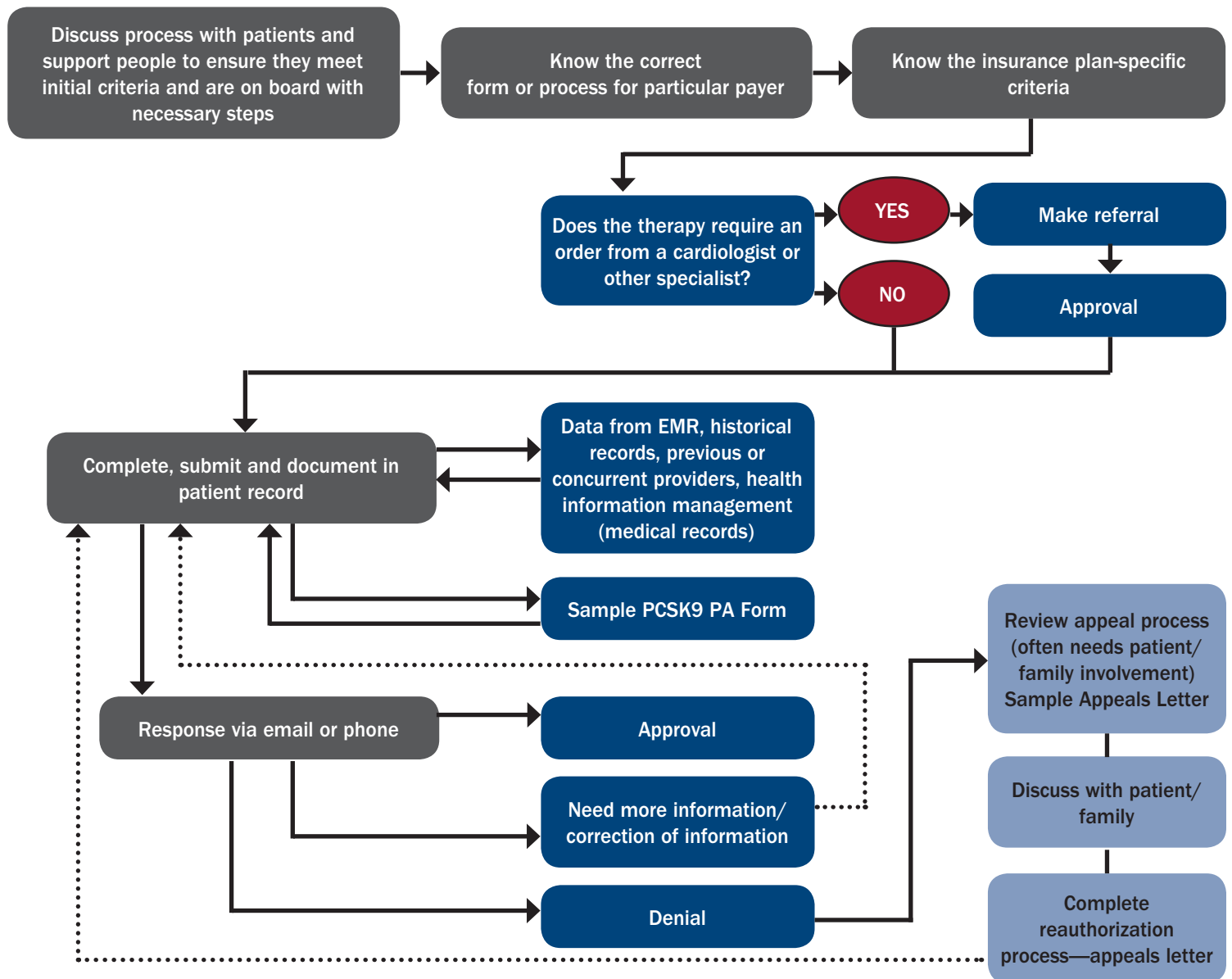
## Implementing Effective Treatments: Beyond the Prescription Pad

While national guidelines may indicate which medications should be prescribed in particular situations, how do you make sure that these medications get into the hands of your patients?

### Preauthorizations (PA):

Many new cardiovascular medications require a preauthorization—a process that can be complex and time-consuming for health care providers (HCPs).

### Common Steps in PA Process (may repeat annually or when insurance changes)



## Data Frequently Requested by Payers for PAs

	PCSK9	NOACs	New HF therapies
<b>Diagnosis/ ICD-10 code</b> <a href="http://www.icd10data.com/">http://www.icd10data.com/</a>	<ul style="list-style-type: none"> <li>FH</li> <li>HoFH, HeFH</li> <li>ASCVD</li> <li>Statin intolerance</li> </ul>	<ul style="list-style-type: none"> <li>NVAF</li> <li>VTE</li> <li>DVT</li> <li>PE</li> </ul>	<ul style="list-style-type: none"> <li>NYHA Class II-IV</li> <li>AHA Classification: HF-PEF or HF-REF</li> </ul>
<b>Medication history</b> (List brand and generic names; dose; duration for each)	<ul style="list-style-type: none"> <li>Statin intolerance</li> <li>Maximally-tolerated statin</li> <li>Ezetimibe</li> <li>Bile Acid Sequestrant</li> <li>Other lipid-lowering therapies</li> <li>Apheresis</li> </ul>	<ul style="list-style-type: none"> <li>Warfarin</li> <li>Heparin</li> <li>NOACs</li> <li>Complications (e.g., adverse reactions to other medications)</li> </ul>	<ul style="list-style-type: none"> <li>History of ACE or ARB use including any adverse effects, e.g., angioedema</li> <li>Aliskiren</li> </ul>
<b>Lab data</b>	<ul style="list-style-type: none"> <li>Lipid panels, especially LDL-C               <ul style="list-style-type: none"> <li>– baseline</li> <li>– current (&lt;30 days)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>INR</li> <li>CrCl</li> <li>eGFR</li> </ul>	<ul style="list-style-type: none"> <li>LVEF</li> <li>eGFR</li> <li>LFT</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>ASCVD</li> <li>ACS/MI/Angina</li> <li>Coronary/Other arterial revascularization</li> <li>Stroke/TIA</li> <li>PAD</li> <li>Subclinical atherosclerosis</li> <li>Pregnancy or plans for pregnancy</li> <li>Renal disease</li> </ul>	<ul style="list-style-type: none"> <li>Pregnancy or plans for pregnancy</li> <li>Renal disease</li> <li>Other extenuating circumstances (e.g., need for reversal agent, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Pregnancy or plans for pregnancy</li> <li>Renal disease</li> </ul>

## Glossary

**ACE:** Angiotensin converting enzyme inhibitor

**ACS:** Acute coronary syndrome

**AHA:** American Heart Association

**ARB:** Angiotensin-receptor blockers

**ASCVD:** Atherosclerotic cardiovascular disease

**CrCl:** Creatinine clearance

**DVT:** Deep vein thrombosis

**eGFR:** Estimated glomerular filtration rate

**FH:** Familial hypercholesterolemia

**HeFH:** Heterozygous familial hypercholesterolemia

**HF:** Heart failure

**HF-PEF:** Heart failure with preserved ejection fraction

**HF-REF:** Heart failure with reduced ejection fraction

**HoFH:** Homozygous familial hypercholesterolemia

**ICD-10:** International Classification of Diseases 10th edition

**INR:** International normalized ratio

**LDL-C:** Low-density lipoprotein cholesterol

**LFT:** Liver function test

**LVEF:** Left ventricular ejection fraction

**MI:** Myocardial infarction

**NOAC:** Novel oral anticoagulant

**NVAF:** Nonvalvular atrial fibrillation

**NYHA:** New York Heart Association

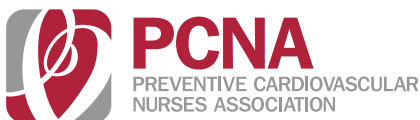
**PA:** Prior authorization

**PAD:** Peripheral artery disease

**PE:** Pulmonary embolism

**TIA:** Transient ischemic attack

**VTE:** Venous thromboembolism



[pcna.net/access](http://pcna.net/access)

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# Best Practice Tips for Clinicians to Help Patients Access Medications

## Initial Conversation with Patients

- ❑ **Make sure patients are committed to the medication and processes before prescribing or putting time into PA process**
  - Are they okay with an injectable? Do they have a physical mailing address? A refrigerator? Comfortable with co-pay cost? Will travel limit their ability to receive medicine deliveries (snowbirds/RV or lengthy trips)? Aware of risks/benefits/adverse effects?

## Office Procedures

- ❑ Designated person/team in practice setting to coordinate PA process
- ❑ Workable tracking system (spreadsheets, folders) and resource list including:
  - pharmaceutical company representatives: names and contact info
  - specific insurance PA forms and coverage criteria (review regularly for updates)
  - co-pay cards and assistance programs
    - requirements and availability
- ❑ Templates—examples of PA and Appeals letters that were approved
- ❑ Before completing full PA process, consider a medication trial to ensure patient tolerance
  - 30-day free cards, samples
- ❑ Be prepared in advance of patient visits:
  - Update insurance info, PA needed? Review medical records make sure you have needed information from health history

## Communicating with Other HCPs

- ❑ Communicate with pharmacy representatives who can provide company resources: patient assistance, updates, co-pay cards, etc.
- ❑ Nurture effective communication between hospital, specialists and primary care
  - Dispense enough medication at discharge to bridge patient to first outpatient visit
  - At office visit, reconcile medication list from hospital

## Cost Considerations

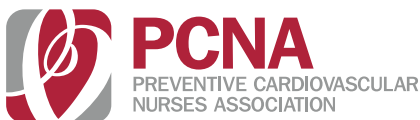
- ❑ Have patient contact pharmacy to get medication processed to determine cost before filling prescription
  - Patients should know that once they leave the pharmacy counter with a prescription, it cannot be returned
  - Have patient contact your office if the medication is too costly

## Patient Follow-up

- ❑ Contact with patient within 1-2 weeks of prescribing a new therapy
  - Helps ensure prescriptions have been filled
  - Provides opportunity to ID and resolve any concerns related to cost or starting the medicine

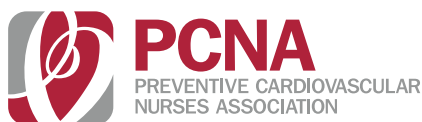
## Patients as Their Own Advocates and Champions

- ❑ Encourage patients to contact their insurance company and/or their benefits manager for employer-sponsored insurance plans
- ❑ Patients may also contact their state insurance commission office regarding commercial insurance concerns and/or federal/state representatives about Medicare/Medicaid/Tri-Care/VA coverage



## Helpful Resources to Access Medicines

<p><b>Alliance for Patient Access (AfPA)</b>  <a href="http://allianceforpatientaccess.org/">http://allianceforpatientaccess.org/</a></p>	<p>Physician working groups (cardiovascular, diabetes and others) that advocate for patient access and develop helpful resources for healthcare providers.</p>
<p><b>The Coupon and Co-Pay Resource</b>  <a href="http://www.cou-co.com/detail/Cardiovascular">http://www.cou-co.com/detail/Cardiovascular</a></p>	<p>Resource for pharmacists and patients with links to patient assistance programs provided by pharmaceutical companies for specific medications. Organized by disease states and medication name.</p>
<p><b>FH Foundation</b>  <a href="https://thefhfoundation.org/">https://thefhfoundation.org/</a>  <b>Affording treatment for FH</b>  <b>Navigating Insurance Guide</b></p>	<p>Patient-centered nonprofit organization dedicated to research, advocacy, and education of Familial Hyperlipidemia (FH); raise awareness and promote early diagnosis and treatment.</p>
<p><b>GoodRx</b>  <a href="https://www.goodrx.com/">https://www.goodrx.com/</a></p>	<p>Consumer resource center. Provides price comparisons, discount coupons and a directory of patient assistance programs for specific medications.</p>
<p><b>Needy Meds</b>  <a href="http://www.needymeds.org/">http://www.needymeds.org/</a></p>	<p>National non-profit organization that maintains a website of free information on programs that help people who can't afford medication and healthcare costs.</p>
<p><b>Partnership to Advance Cardiovascular Health (PACH)</b>  <a href="http://www.advancecardiohealth.org/">http://www.advancecardiohealth.org/</a></p>	<p>Advances public policies and practices that result in accelerated innovation and improved cardiovascular health for patients. Payer report cards, infographics and white papers focus on access to PCSK9 therapy.</p>
<p><b>Partnership for Prescription Assistance</b>  <a href="https://www.pparx.org/">https://www.pparx.org/</a></p>	<p>Free service helping patients who are uninsured or underinsured access medicine they need through the program that is right for them. Patient will need to supply demographic and financial information.</p>
<p><b>Patient Access Network (PAN)</b>  <a href="https://panfoundation.org/index.php/en/">https://panfoundation.org/index.php/en/</a></p>	<p>Helps uninsured or underinsured people cover cost of medications.</p>
<p><b>Patient Advocate Foundation (PAF)</b>  <a href="http://www.patientadvocate.org/">http://www.patientadvocate.org/</a></p>	<p>Tips and other web-based resources to help patients get access to medications and treatments.</p>
<p><b>RxAssist</b>  <a href="http://rxassist.org/">http://rxassist.org/</a></p>	<p>Comprehensive database of Patient Assistance programs (run by pharmaceutical companies to provide free medications to people who cannot afford to buy their medicines); practical tools, news and articles that help HCPs and patients find the information they need.</p>



## Medication Adherence

Now that you've invested the time to get your patients the medication they need, how do you make certain they take it as prescribed?

Factors that place patients at risk for non-adherence:	Assess patients for medication non-adherence; Questions to ask:	Provide education to enhance medication adherence
<ul style="list-style-type: none"> <li>• Cost of medicine</li> <li>• Concern over adverse effects</li> <li>• Complexity of medication regimen</li> <li>• Taking multiple medications</li> <li>• “Silent” conditions (medicines don’t make them feel better)</li> <li>• Forgetfulness</li> <li>• Lack of prioritization of the importance of medication</li> <li>• Low health literacy</li> <li>• Depression</li> <li>• Cognitive impairment</li> <li>• Medication as a reminder of the patient’s condition               <ul style="list-style-type: none"> <li>– Don’t want to be perceived as “sick”</li> <li>– Makes patient feel “old” or “bad” about themselves for having to take a “pill;” perceived “failure”</li> </ul> </li> <li>• Negative previous experience with drug therapies</li> </ul>	<ul style="list-style-type: none"> <li>• Do you ever forget to take your medicine?</li> <li>• How many times a week do you forget to take your medicine?</li> <li>• Are you careless at times about taking your medicine?</li> <li>• What is the main reason you might miss your medicine?</li> <li>• Do you ever cut pills in half or skip medicines to save money?</li> <li>• Sometimes if you feel worse when you take the medicine, do you stop taking it?</li> <li>• When you feel better, do you sometimes stop taking your medicine?</li> </ul>	<ul style="list-style-type: none"> <li>• Assess patient need for verbal and/or written information</li> <li>• Stress the benefits of therapies and reasons for prescribing               <ul style="list-style-type: none"> <li>– Use visuals such as risk communication tools</li> </ul> </li> <li>• Highlight importance of lifestyle change along with medication to treat problem</li> <li>• Use teach back to ensure patient understanding</li> <li>• Create a collaborative environment to encourage questions</li> <li>• Explain how to take medication—frequency, time of day, with or without food, timing with other medications</li> <li>• Include patient support people in the conversation (family member, friend, etc.)               <ul style="list-style-type: none"> <li>– Can assist with information, questions and help with reminders</li> </ul> </li> <li>• Discuss tracking methods and reminder systems               <ul style="list-style-type: none"> <li>– Pill boxes</li> <li>– Smart phone apps</li> <li>– Daily medication schedules</li> <li>– Calendar notifications when to request refills to avoid gaps in therapy</li> </ul> </li> <li>• Discuss potential adverse effects               <ul style="list-style-type: none"> <li>– Tell patient you want to be called if they believe they are experiencing any adverse effect</li> <li>– Emphasize risks of stopping therapy or not taking therapy as directed</li> </ul> </li> <li>• Schedule follow-up calls or visits to assess patient’s response to therapy</li> </ul>

## Specialty Pharmaceuticals and Pharmacies

The fastest growing segment of the prescription drug market, specialty pharmaceuticals and pharmacies, may be new to cardiovascular clinicians. Typically, the products are used to treat chronic and/or rare diseases; they are often high-cost, and may be administered by injection or infusion. Many are biologics—drugs that are derived from living cells—including PCSK9 Inhibitor therapies. They typically require close patient supervision and monitoring, special handling, temperature control, and administrative processes resulting in the delivery of these medications by specialty pharmacies.

Cardiovascular clinicians will need to become familiar with the specialty pharmacies serving their area. Larger health care systems often have them within their institution while other specialty pharmacies are aligned with health plans, managed care organizations, or retail chains. Several independent specialty pharmacies also exist throughout the country.

