Facilitating Patient Access To PCSK9 Inhibitors
10 Actions That Optimize the Approval Process
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1 Satisfy Indications for Use
Document all clinically relevant information for payer requirements. Use the “PCSK9 Inhibitor Prior Authorization Form” (Baum SJ, et al. Clin Cardiol 2017;40:243-254), which is freely available online, to organize clinical data for prescribing. Fill the prescription at a specialty pharmacy.

2 Start the Patient on Samples
Remember that “time is plaque” (Baum SJ, et al. J Clin Lipidol 2014;8:542-549). By immediately starting PCSK9i therapy, follow-up LDL numbers will likely demonstrate dramatic improvements, which must be documented for the payer. Experience with a PCSK9i showing efficacy and tolerability will be valuable to support approval. In addition, the patient will be impressed with results and motivated to self-advocate for therapy. Submit new information to the payer if denied.

3 If Denied, Appeal. Use the Single-Page Appeal Form
Medicare initial decisions must be made in 72 hours, but commercial approvals can take weeks. If the decision is again negative, resubmit whatever the payer has requested, which will often mean simply resending the earlier authorization form and sending the single-page appeal form (Baum SJ, et al. Clin Cardiol 2017;40:243-254), which is also freely available online. Good idea: Highlight those areas of the form that pertain to the payer’s specific questions.

4 Engage the Patient
Patients have the loudest voice in this process. They should be instructed to contact their insurance company. Their argument is that their doctor has told them they need the drug, their medical history meets the indications for use of the drug, and a PCSK9i is on their payer’s formulary. Stress: They are at high risk and need the medication to potentially reduce their risk for stroke or heart attack.
5 Meanwhile, Keep the Patient on Samples
Providing the samples is medically appropriate, and maintaining therapy engages the patient and continues to build a bond with the clinician.

6 If Appeal Is Denied, Request a Peer-to-Peer
At the outset of the conversation, get the physician’s name and make a note of it. One’s stance during a peer-to-peer consultation should be courteous but forceful. Have all pertinent records ready and available.

7 Act on the Decision of the Peer-to-Peer Consult
If the peer approves the prescription, write down the confirmation number and give it to your front desk administration staff. If the peer denies the prescription, point out that you have written his or her name in the patient’s chart and as such he or she is now on the record.

8 Keep Fighting for Your Patient
Contact the insurance commissioner and any appropriate advocacy groups in your state. Reach out to organizations like the American Society for Preventive Cardiology (ASPC) or the FH (Familial Hypercholesterolemia) Foundation, which have additional valuable resources. The drug companies also maintain support services, such as RepathaReady and MyPRALUENT.

9 Deploy Social Media
Ask the patient to post comments on Twitter or Facebook about the denial of the prescription, and tag the payer, appropriate legislators and other organizations, such as the ASPC and FH Foundation, so that the problem is noticed by decision makers.

10 Don’t Give Up!
Always encourage behaviors and therapeutic lifestyle changes that will help lower LDL while continuing to appeal.

LDL, low-density lipoprotein; PCSK9i, proprotein convertase subtilisin/kexin type 9 inhibitor.

Resources for Accessing PCSK9 Inhibitors

- Association of Black Cardiologists
  www.abc.org
- ABC Access Initiative
  www.abcardio.org/advocacy/abc-access-initiative
- Partnership to Advance Cardiovascular Health
  www.advancecardiohealth.org
- Alliance for Patient Access
  www.allianceforpatientaccess.org
- American Society for Preventive Cardiology
  www.aspconline.org
- Know Your Health Insurance Rights
  www.coveragerights.org
- National Health Forum
  www.nhfus.org
- The FH Foundation
  www.thefhfoundation.org