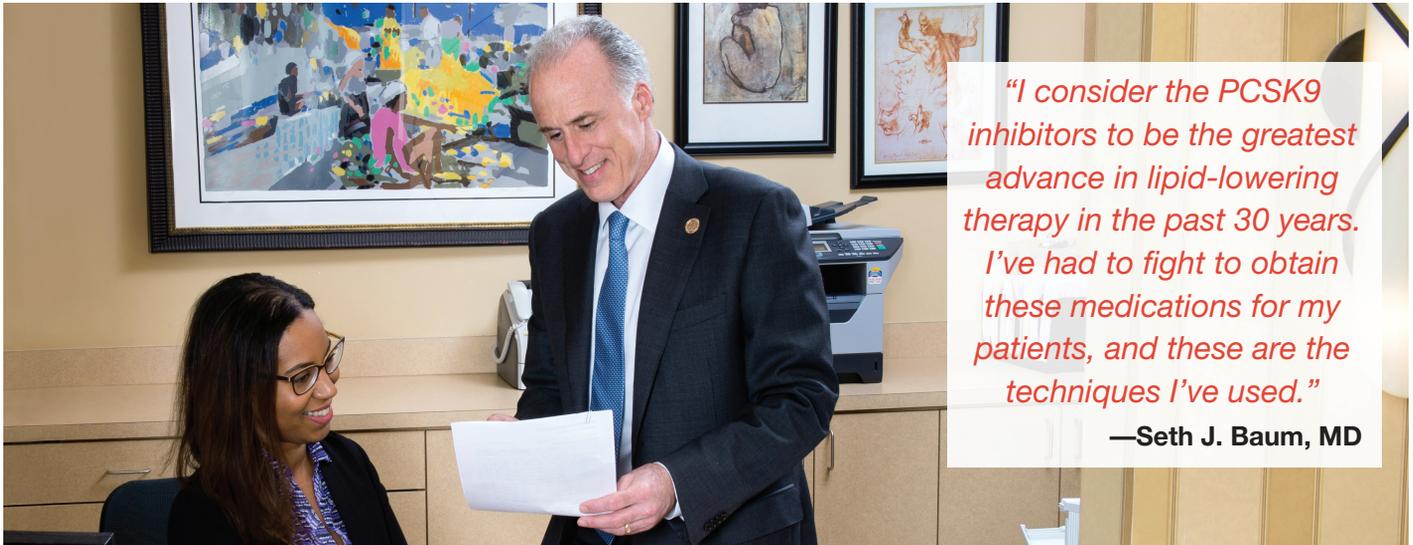


Facilitating Patient Access To PCSK9 Inhibitors

10 Actions That Optimize the Approval Process

Developed by Seth J. Baum, MD, FACC, FACPM, FAHA, FNLA, FASPC



“I consider the PCSK9 inhibitors to be the greatest advance in lipid-lowering therapy in the past 30 years. I’ve had to fight to obtain these medications for my patients, and these are the techniques I’ve used.”

—Seth J. Baum, MD

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.abc.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.theffoundation.org