

Date:

Patient Name and Insurance ID #

Address

City, State, Zip

To whom it may concern:

This letter provides necessary information supporting the request to treat (patient) with (drug).

Our mutual patient has:

\_\_\_\_\_ Is taking his/her maximally tolerated statin dose.\* *“Maximally tolerated statin therapy is defined as the highest tolerated intensity and frequency of a statin, even if the dose is zero.”* This is preferably the guideline-recommended intensity of statin, but may of necessity be a lower intensity dose or reduced frequency of statin dosing, or even no statin at all. Statin intolerance can be defined as unacceptable adverse effects that resolve with discontinuation of therapy and recur with re-challenge of 2 to 3 statins, preferably ones that use different metabolic pathways with 1 of which being prescribed at the lowest approved dose.

\_\_\_\_\_ Has HeFH.\* *“HeFH is defined as untreated LDL-C  $\geq$ 160 mg/dL for children and  $\geq$ 190 mg/dL for adults and with 1 first-degree relative similarly affected or with premature coronary artery disease or with positive genetic testing for an LDL-C-raising gene defect (LDL-R, Apo-B, or PCSK9).”*

\_\_\_\_\_ Has HoFH.\* *“HoFH is defined as LDL-C  $\geq$ 400 mg/dL and  $\geq$ 1 parent with clinically diagnosed FH, positive genetic testing for two LDL-C-raising gene defects (LDL-R, apoB, or PCSK9), or autosomal-recessive FH.”*

\_\_\_\_\_ Has Clinical ASCVD.\* *“Clinical ASCVD includes acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin, as well as other forms of atherosclerotic vascular disease including significant atherosclerosis of the coronary, carotid, iliofemoral circulations, and the aorta.”*

\_\_\_\_\_ Requires additional LDL lowering.\* *“Patients with clinical ASCVD, HeFH, or HoFH who may require additional lowering of LDL-C include those with less than expected percent reduction in LDL-C or residual absolute levels of LDL-C, non-HDL-C, or apoB that exceed goals for atherogenic lipoproteins as specifically defined in any of the current guidelines for these very high-risk and ‘extreme risk’ populations.”*

I look forward to your timely approval for our mutual patient. I am available to provide more information if you desire. Time is of the essence; our patient and I appreciate your alacrity.

**In my professional opinion, this patient requires the medication prescribed. The information provided supports this opinion.**

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

N.B. Supply supportive medical records.

\*Baum S, Toth P, Underberg J, Jellinger P, Ross J, Wilemon K. PCSK9 Inhibitor Access Barriers: Issues and Recommendations: Improving the Access Process for Patients, Clinicians and Payers. Clin Cardiol. In Press.