



NEWS RELEASE

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National Lipid Association Statement Paper Provides Clinicians with Updated Guidance for Enhanced Value of PCSK9 Use in Select Patient Populations

MIAMI, Fla. – (May 16, 2019) – The NLA today released a statement paper providing updated guidance to clinicians with identifying patient groups in which use of PCSK9 monoclonal antibodies (mAbs) provides a reasonable value.

While initial pricing of PCSK9 mAbs limited the cost-benefit ratio of the LDL-lowering drugs, costs of these agents -- along with recent analysis of subgroups from FOURIER and ODYSSEY OUTCOMES trials, based on atherosclerotic cardiovascular disease (ASCVD) burden, control of cardiometabolic risk factors and baseline LDL-C levels -- have provided data suggesting that these drugs could now provide better value in selected patient subgroups.

The three groups of patients on maximally tolerated statin therapy where reasonable cost-effectiveness might be expected are:

- **Extremely high risk ASCVD patients** (extensive burden of or active ASCVD, or ASCVD with extremely high risk cardiometabolic risk factors, including heterozygous familial hypercholesterolemia [HeFH]) with LDL-C greater than or equal to 70 mg/dl
- **Very high risk ASCVD patients** (less extensive ASCVD and poorly controlled cardiometabolic risk factors) with LDL-C greater than or equal to 100 mg/dl, and
- **High risk patients** with less extensive ASCVD and well-controlled risk factors, or primary prevention HeFH or severe genetic hypercholesterolemia with LDL-C greater than or equal to 130 mg/dl

The statement was developed by an NLA team headed by Jennifer G. Robinson, MD, MPH, Professor in the Departments of Epidemiology and Internal Medicine (Division of Cardiology) and Director, Prevention Intervention Center at the University of Iowa College of Public Health.

“Cost effectiveness analyses are intended to provide information to patients, clinicians, healthcare systems and policy makers to support decisions that ensure available resources are used as effectively as possible to improve patient’s health,” said Alan S. Brown, MD, FNLA, FACC, FAHA, President of the NLA. “It is hoped that this assessment of the value following the recent price reduction for PCSK9

inhibitors will improve access for patient groups with the greatest likelihood of improved clinical outcomes and cost-effectiveness.”

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ABOUT THE NATIONAL LIPID ASSOCIATION

The NLA is a multidisciplinary specialty society focused on prevention of cardiovascular disease and other lipid-related disorders. The NLA’s mission is to enhance the practice of lipid management in clinical medicine, and one of its goals is to enhance efforts to reduce death and disability related to disorders of lipid metabolism in patients. Members include physicians (MDs and DOs) and other health care professionals from an array of disciplines including PhDs researchers, nurses, nurse practitioners, physician assistants, pharmacists, exercise physiologists, and dietitians.

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