

ENHANCING THE VALUE OF PCSK9 Monoclonal Antibodies (mAb) by Identifying Patients Most Likely to Benefit



PCSK9 mAb may provide value if LDL-C remains ≥ 100 mg/dl despite maximally tolerated statin and ezetimibe therapy in patients at very high or extremely high atherosclerotic cardiovascular disease (ASCVD) risk.

SYSTEMATIC REVIEW

Clinical Trial Data

VALUE

5-year Number Needed to Treat (NNT):

Discount	Price	Value
21-28 (NNT)		
(\approx) 60%	\approx \$5,400/Year	\$100,000/QALY <i>(Reasonable Value)</i>

Cost per Quality Adjusted Life Year (QALY)

Approximate Reduced Cost*
 \approx \$5,400/YEAR

Patients with heterozygous familial hypercholesterolemia (HeFH) or severe hypercholesterolemia (SH)

On Maximally Tolerated Statin & Ezetimibe Therapy		
	High Value <\$50,000/QALY	Reasonable Value <\$100,000/QALY
5-year NNT	≤ 14	≤ 28
Secondary Prevention		
HeFH or SH >220 mg/dl with clinical ASCVD <i>(ASCVD risk likely similar when coronary artery calcium >100 Agatston units)</i>	LDL-C ≥ 100 mg/dl	LDL-C ≥ 70 mg/dl
Primary Prevention		
HeFH or SH >220 mg/dl with risk factor(s)*	LDL-C ≥ 190 mg/dl	LDL-C ≥ 100 mg/dl

Patients with ASCVD on Maximally Tolerated Statin +/- Ezetimibe Therapy

	High Value <\$50,000/QALY	Reasonable Value <\$100,000/QALY
5-year NNT	≤ 10	≤ 21
10-year ASCVD risk		
$\geq 40\%$	LDL-C >130 mg/dl	LDL-C ≥ 70 mg/dl
30-39%	LDL-C ≥ 190 mg/dl	LDL-C >100 mg/dl
20-29%	N/A	LDL-C ≥ 130 mg/dl

High, Very High and Extremely High-Risk Patients

On Maximally Tolerated Statin +/- Ezetimibe

Extreme High Risk $>40\%$ 10y ASCVD risk	Very High Risk 30-39% 10y ASCVD risk	High Risk 20-29% 10y ASCVD risk
LDL-C ≥ 70 mg/dl	LDL-C ≥ 100 mg/dl	LDL-C ≥ 130 mg/dl
<ul style="list-style-type: none"> Extensive or active burden of ASCVD, usually with extremely high risk and poorly controlled cardiometabolic risk factors. Less extensive ASCVD and extremely high risk cardiometabolic risk factors 	<ul style="list-style-type: none"> Less extensive ASCVD and poorly controlled cardiometabolic risk factors 	<ul style="list-style-type: none"> Less extensive ASCVD and well controlled cardiometabolic risk factors Primary prevention HeFH or SH LDL-C >220 mg/dl and poorly controlled cardiometabolic risk factors