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Poster# **EE88**

Budget Impact Analysis of Inclisiran for the Management of Patients with Atherosclerotic Cardiovascular Disease in India: A Multi Payer Analysis

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KEY FINDINGS & CONCLUSIONS

- Introducing Inclisiran for ASCVD patients uncontrolled on statins led to projected avoidance of 48,405 MACE+ events over five years, including 14,493 CV deaths. The model estimated cumulative budget savings of €58.7M (public) and €133.36M (private), driven by reduced CV event costs despite higher drug acquisition costs.
- Inclisiran offers sustained LDL-C reduction and meaningful clinical and economic value for ASCVD management in India, supporting its inclusion in lipid-lowering strategies. The model's use of local epidemiological and cost data enhances its relevance for Indian healthcare decision-makers, though real-world adherence and indirect costs remain limitations.

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BACKGROUND

The prevalence of hypercholesterolemia in India is rising, currently impacting an estimated 15–30% of the population[1,2,3]. Hypercholesterolemia, characterised by increased serum low-density lipoprotein cholesterol (LDL-C) concentrations, is an emerging public health issue and constitutes a major risk factor for atherosclerotic cardiovascular disease (ASCVD). Notably, ASCVD accounts for one in five deaths among the Indian population[4,5,6]. Clinical and genetic studies have further highlighted that reducing LDL-C lowers the risk of cardiovascular (CV) events. Hence to address this the Lipid Association of India recommends lowering LDL-C to below specific targets according to risk categories[7]. Statins are effective in lowering serum LDL-C; however, even with maximally tolerated statin therapy, most patients do not achieve recommended target levels. Monoclonal antibodies against proportion convertase subtilisin/kexin type 9 (PCSK9i) inhibits the PCSK9i induced degradation of LDL-C receptors, thereby increasing the hepatocellular uptake and decreasing the serum LDL-C concentrations. Inclisiran a novel small interfering RNA (siRNA) therapy inhibits the PCSK9i, leading to sustained LDL-C reductions of approximately 50%[8,9,10]. Hence it becomes essential to evaluate the potential financial implication of introducing Inclisiran into the Indian healthcare system, assessing its impact on healthcare expenditure and long-term savings from a multi-payer perspective.

OBJECTIVE:

To evaluate budget impact of introducing Inclisiran for adults with ASCVD in India who remain uncontrolled despite usage of on maximally tolerated dose (MTD) statins.

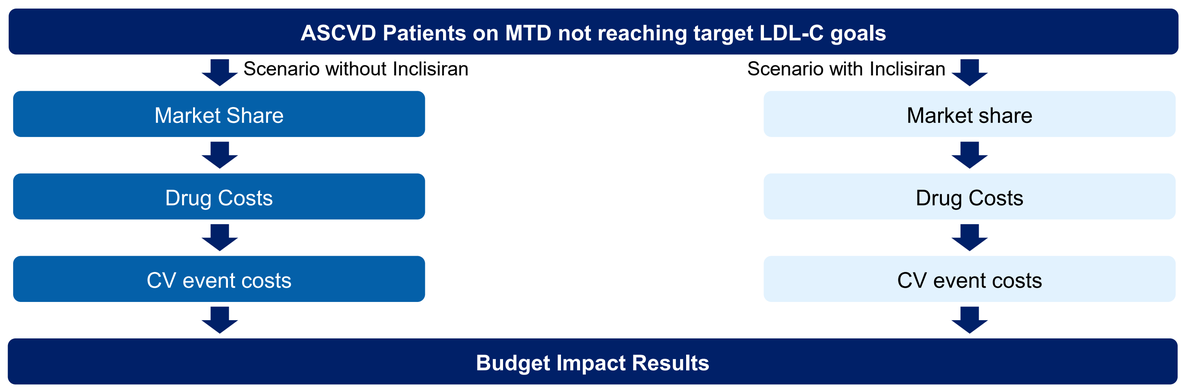
METHOD:

- **Study Design**: An Excel based Markov model performing Budget impact analysis (BIA), as reported in line with the ISPOR task force report [11], was developed.
- **Population:** The modelled population comprised ASCVD patients with history of one or more CV events who did not achieve the recommended LDL-C level despite MTD statins in line with lipid management guidelines [4,12]. For the base case analysis population were defined by baseline serum LDL-C ≥ 2.6 mmol/L in accordance with conservative LDL-C levels used for add-on therapy.
- **Intervention & Comparator:** The BIA assessed the impact of introducing Inclisiran 300 mg as add on to standard of care (SoC) i.e., high-dose intensity statins (Atorvastatin & Rosuvastatin). Comparators included lipid lowering therapies used in real world practices as confirmed by local clinical experts: a) SoC alone; b) Evolocumab+SoC, c) Bempedoic acid (BPA)+ SoC, d) Ezetimibe (Eze)+SoC and e) BPA+Eze+SoC.
- **Perspective & Time Horizon**: The analysis was conducted from the perspective of both the public and private healthcare systems. A five-year time horizon was considered for this assessment.
- **Model Flow:** Prevalent population was considered for the model (calculated based on ASCVD prevalence). Patients eligible for inclisiran entered the model from Year 0 (base year). The model then uses the market share data from year 1 to distribute the eligible population cohort into respective therapy. In each year, the patients are at risk of experiencing a CV event: myocardial infarction (MI), unstable angina (UA), stroke and revascularisation and CV death hereby referred to as major adverse cardiovascular events (*MACE+)*. Additionally, the patients also have a risk of all-cause mortality in each year. The treatment efficacy of each therapy is based on the key relationship between LDL-C reduction and CV event risk reduction as established by the Cholesterol Trial Treatment (CTT) meta-analysis. Total costs were calculated for the population with or without Inclisiran and the net budget impact was calculated (Figure 1). Key model inputs adapted are presented in Table 1.
- **Market Share:** Market share represents the percentage of patients on each treatment (see comparators) in the inclisiran eligible population (ASCVD patients on MTD not able to achieve target LDL-C goals). The market share for Inclisiran for Year 1 was taken at 3% and assumed projection annual growth rate at 3.16%.

Table 1: Input Parameters for Budget Impact Model

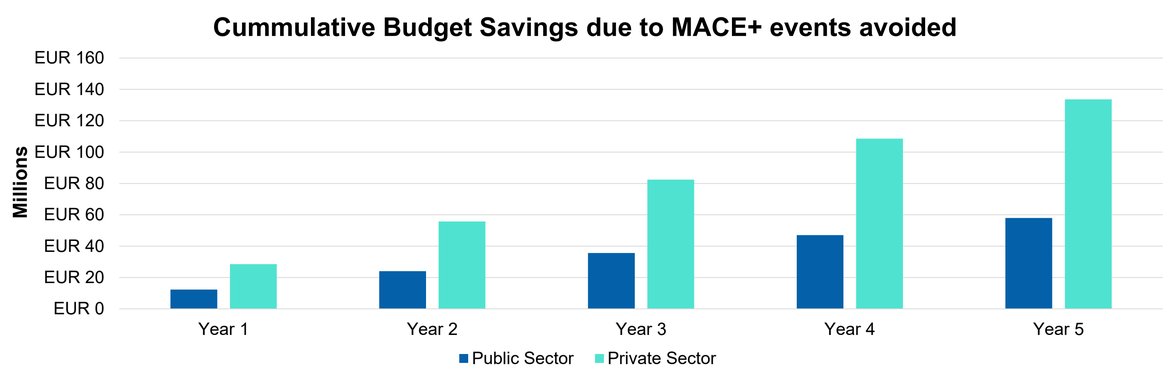
Epidemiological Parameters	
Total Indian Adult population	87,01,13,313[13]
ASCVD Prevalence	4%[14]
% Prevalence of Dyslipidaemia	70%[13]
% of patients not being able to reach target LDL-C goal	67.40%[15]
Prevalent population eligible to receive Inclisiran	1,68,37,486 (calculated)
Baseline Population Characteristics	
Age	52[16]
% Female	52%[17]
% Diabetes	45.80[17]
Baseline LDL-C	122.64 mg/dl[16]
Baseline CV event risk	CPRD (UK) and Mohrschladt et al. 2004 (the Netherlands); validated with local experts[19,20]
Distribution of patients across ASCVD sub-populations	Clinical expert opinion
Relative reduction in LDL-C levels against statins and PCSK9i	Network meta-analysis[21]
Rate ratios adjusting risk of CV event per mmol/L reduction in LDL-C	Cholesterol Treatment Trialists meta-analysis; validated with local experts[22]
Non-CV mortality	Indian Life Tables[13]
AEs	AEs were excluded based on Clinical expert opinion
Utilities	NICE TA393[22]
Cost inputs	
Drug acquisition costs	Novartis and Market Rates
Cost of managing CV events	AB-PMJAY package rates and Private insurance data
Market Share Data for base year (IQVIA Market share data)	
SoC	81.17%
Ezetimibe+SoC	16.07%
Bempedoic Acid+SoC	2.01%
Evolocumab + SoC	0.75%
Bempedoic acid+Ezetimibe+SoC	0.01%

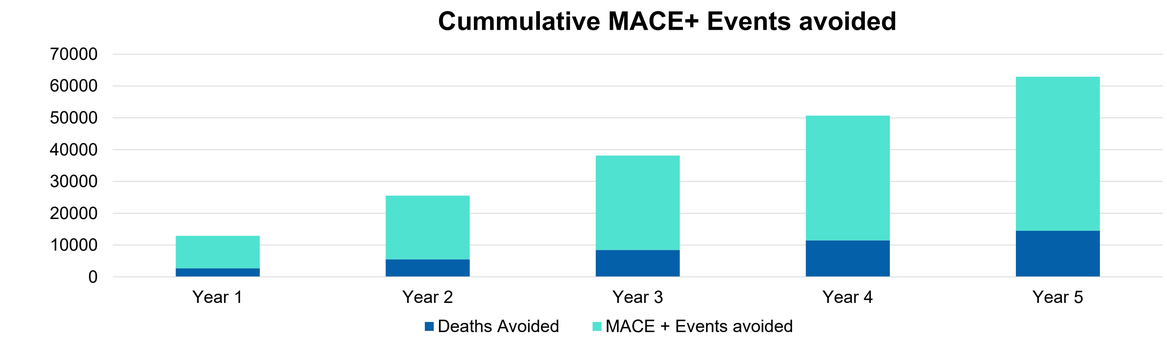
Figure 1 Budget Impact Model Structure



RESULTS

The total budget expenditure per person with the introduction of inclisiran over a 5-year time horizon was estimated at €60.17 (€1= 101.35 INR) in public setup and €70.67 in the private setup. Assuming full uptake among the eligible population, the cumulative budget savings from the prevention of any MACE+ events were calculated to be €58.7 million in public sector and €133.36 million for private sector. Over five years, a total of 48,405 MACE+ were avoided, including 14,493 cardiovascular deaths. One-way sensitivity analysis revealed budget impact is primarily affected by adjustment for age of non-fatal and fatal events, ASCVD prevalence and the event rate adjustment for CV death.





DISCUSSION

This BIA demonstrates that incorporating inclisiran into lipid-lowering therapy for ASCVD patients in India can deliver meaningful clinical and economic benefits. Inclisiran's sustained LDL-C reduction (~50%) is associated with avoidance of approximately **10,193 MACE+** each year. Despite higher upfront drug costs, projected long-term savings—estimated at **€57.96–€133.67 million** are driven by reduced cardiovascular event management costs. An important strength of this analysis is its utilisation of locally relevant epidemiological and cost data, which significantly improves its applicability to the Indian healthcare landscape also upholds the methodological robustness and credibility of the findings. By evaluating the budget impact from both public and private payer perspectives, the study offers comprehensive and actionable insights for policymakers.

However, certain limitations must be acknowledged. The model relies on clinical trial efficacy data, which may not fully capture real-world adherence and outcomes. Indirect costs, such as productivity losses, were not included due to recommendation from Indian Reference case[23], potentially underestimating societal benefits. Additionally, limited availability of Indian-specific event rates and discontinuation data necessitated reliance on assumptions validated by expert opinion, which may introduce uncertainty.

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