

Economic Analysis of DCB: Updated budget impact analysis for the German and U.S. healthcare systems

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Disclosure

Speaker name: Thomas Zeller

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I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

Background and Objectives

- Understanding of the health-economic profiles of endovascular therapies is critical to decision making about therapy adoption and reimbursement.
- Rapidly evolving clinical field requires up-to-date analyses.
- Objectives:
 - Update previously performed budget impact analysis for Germany and the United States (Pietzsch et al, 2014) to reflect
 - Latest clinical evidence
 - 2016 reimbursement and costs

Methods

- Systematic Pubmed and Embase search (June 2015) to identify studies reporting TLR rates of PTA, BMS, DCB, and DES use in femoropopliteal lesions
- Decision-analytic modeling to compute 24-month cost impact to payers
 - Costs based on index procedure and up to one reintervention
 - Therapy-specific TLR rates based on weighted pooling
 - 2016 G-DRG payment for Germany
 - 2016 U.S. Medicare reimbursement, assuming 46% inpatient, 54% outpatient, and new technology payments for DCB
 - Index procedure-specific repeat revascularization strategies

Pooled 24-month TLR rates

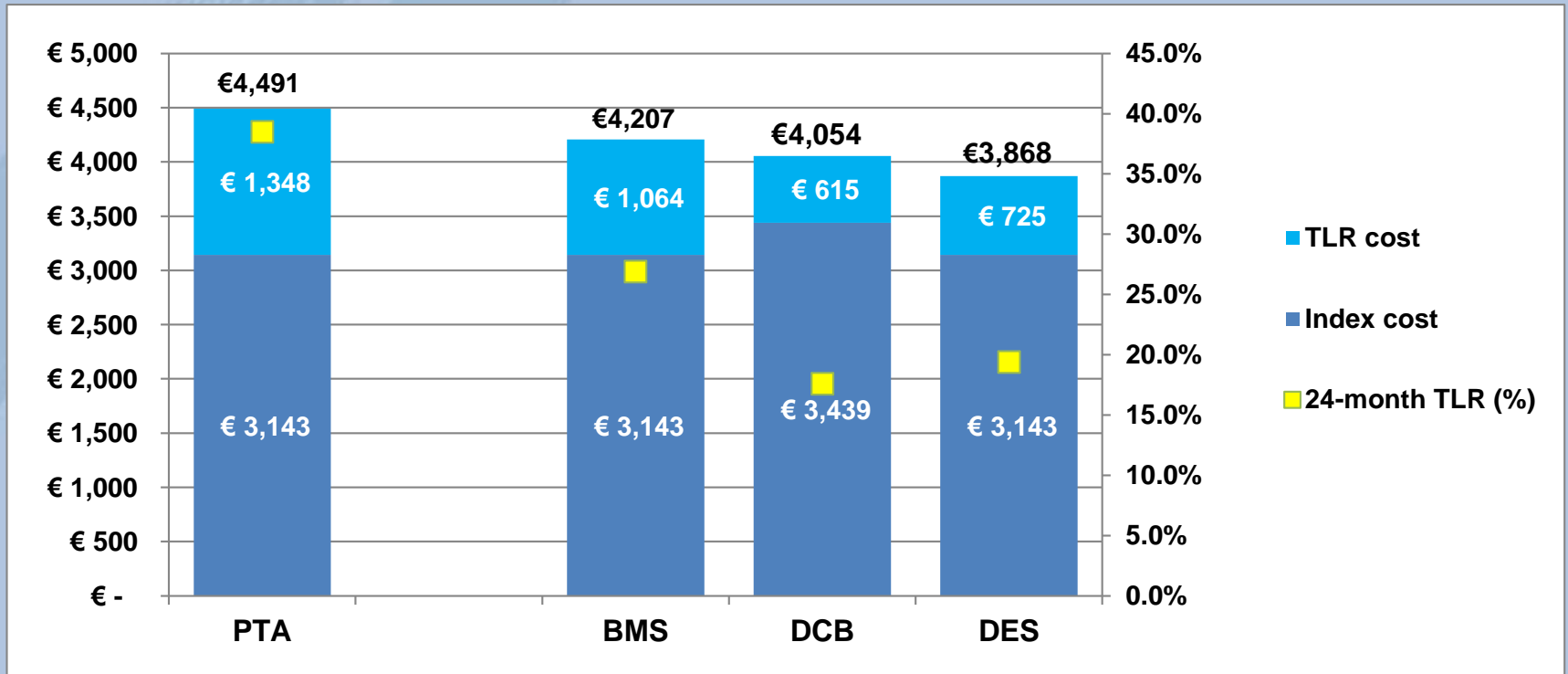
Therapy	Identified Studies	Pooled 24-month TLR
PTA	FAST (Krankenber g et al., 2007)	38.5%
	ZILVER-PTX (Dake et al., 2011)	
	PACIFIER (Werk et al., 2012)	
	BIOLUX-PI (Scheinert et al., 2015)	
	LEVANT 2 (Rosenfield et al., 2015)	
	COMPLIANCE 360 (Dattilo et al., 2014)	
	THUNDER (Tepe et al., 2008)	
	FEM-PAC (Werk et al., 2008)	
	RESILIENT (Laird et al., 2010/2012)	
	LEVANT 1 (Scheinert et al., 2014)	
	IN.PACT SFA (Tepe et al., 2015/Laird et al., 2015)	
BMS	FAST (Krankenber g et al., 2007)	26.9%
	DURABILITY I (Bosiers et al., 2009)	
	Diehl et al., 2012	
	COBRA (Banerjee et al., 2012)	
	ETAP (Rastan et al, 2013)	
	DURABILITY II (Tadros et al, 2014)	
	EPIC (Werner et al., 2013)	
	Gabriella et al., 2015	
	SUPERB (Garcia et al., 2015)	
	MARIS (Krankenber g, 2014)	
	COMPLETE SE (Laird et al., 2014)	
	SIROCCO (Duda et al., 2006)	
	RESILIENT (Laird et al., 2010/2012)	
	MISAGO-2 subc. (Kralj et al., 2013)	
Leipzig SUPERA 500 (Werner et al., 2014)		

Therapy	Identified Studies	Pooled 24-month TLR
DCB	PACIFIER (Werk et al., 2012)	17.6%
	BIOLUX-PI (Scheinert et al, 2015)	
	LEVANT 2 (Rosenfield et al, 2015)	
	THUNDER (Tepe et al., 2008)	
	FEM-PAC (Werk et al., 2008)	
	IT-Registry (Micari et al., 2013)	
	LEVANT 1 (Scheinert et al, 2014)	
	ILLUMENATE FIH (Schroeder et al., 2015)	
	IN.PACT SFA (Tepe et al., 2015/Laird, 2015)	
DES	STRIDES (Lammer et al., 2011)	19.4%
	ZILVER-PTX (Dake et al., 2011)	
	ZILVER-PTX SAS (Dake et al., 2011a)	
	SIROCCO (Duda et al., 2006)	

DCB Subanalyses		
DCB, Urea excipient	PACIFIER (Werk et al., 2012)	11.2%
	IT Registry (Micari et al., 2013)	
	IN.PACT SFA (Tepe et al., 2015/Laird et al., 2015)	
DCB, Other	BIOLUX-PI (Scheinert et al, 2015)	21.9%
	LEVANT 2 (Rosenfield et al, 2015)	
	THUNDER (Tepe et al., 2008)	
	FEM-PAC (Werk et al., 2008)	
	LEVANT 1 (Scheinert et al., 2014)	
ILLUMENATE FIH (Schroeder et al., 2015)		

Blue-shaded studies denote newly added clinical evidence.

24-month Cost to Payers - Germany

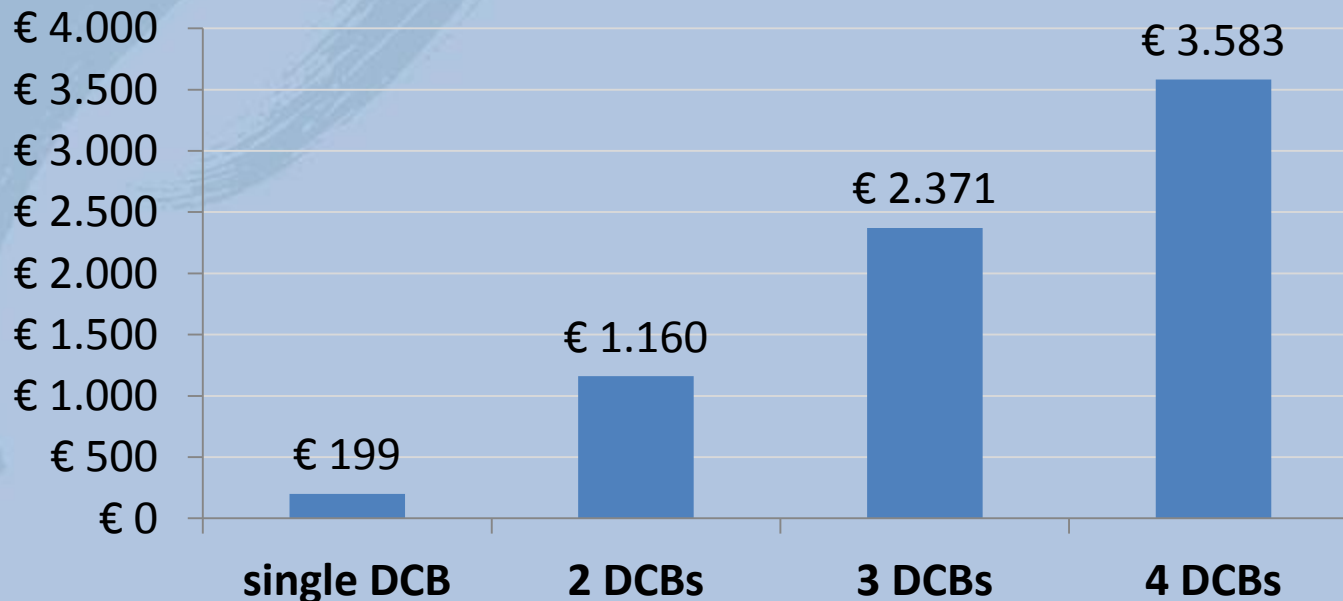


- Drug-eluting therapies associated with improved clinical outcomes, at 24-month cost-savings between 10-14% compared to PTA

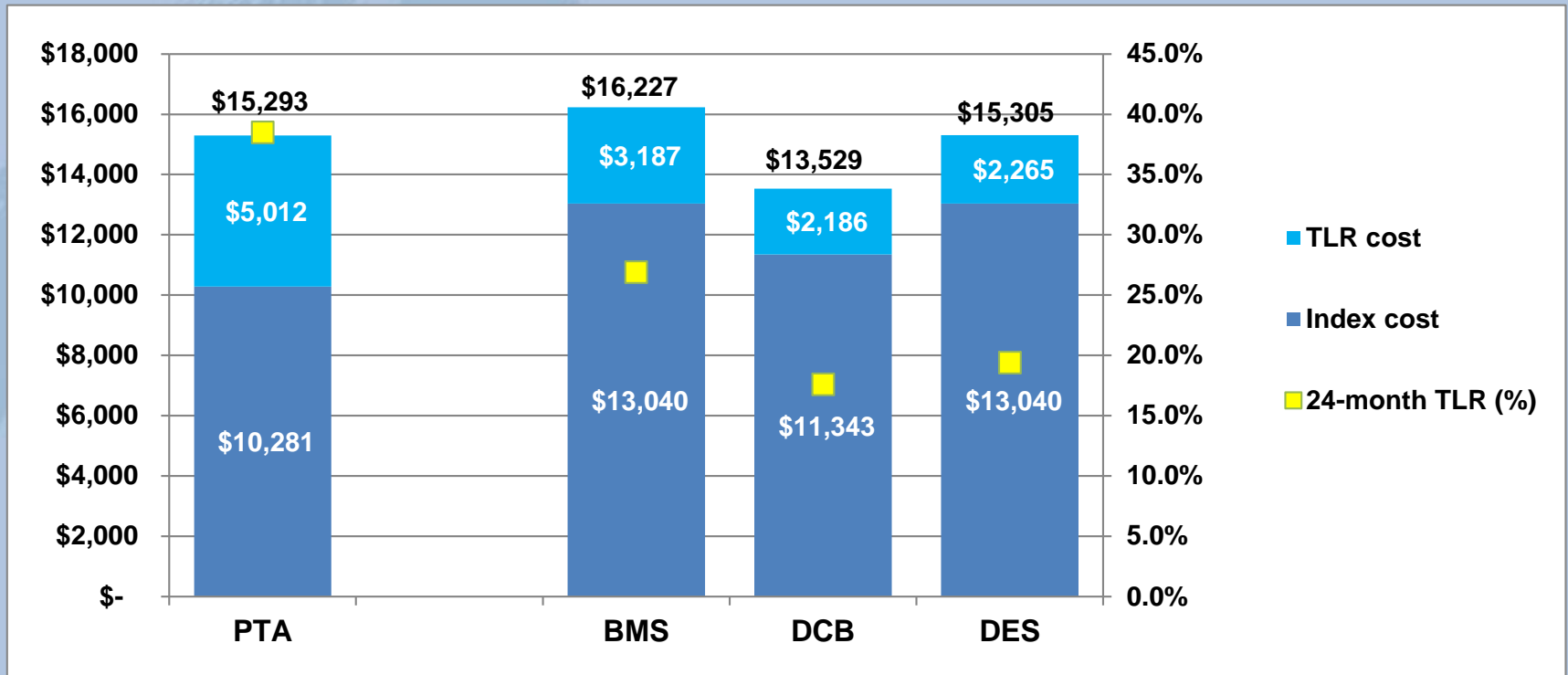
German DRG Reimbursement Tariffs in 2014

Multiple DCB use per-patient incentivized

Add-on Payment on Number of DCB used



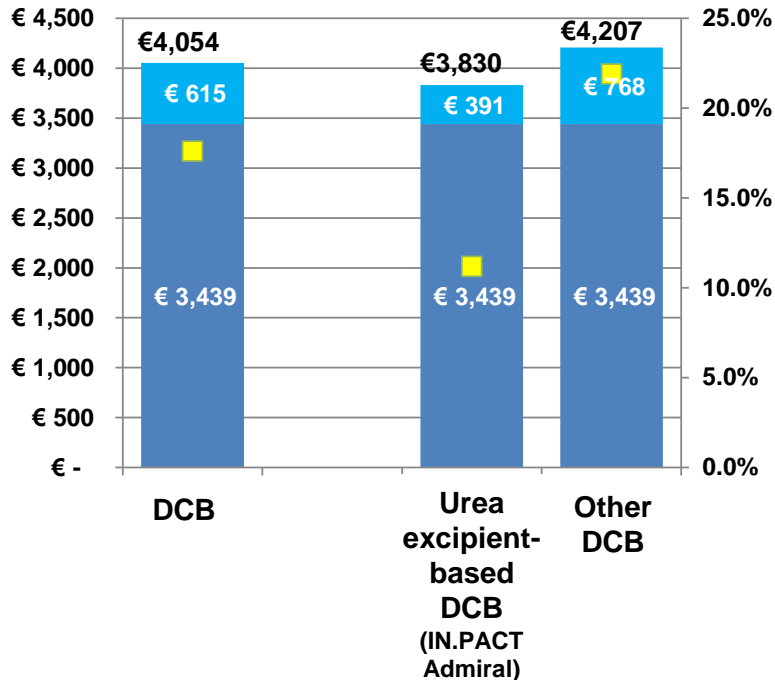
24-month Cost to Payers – U.S.



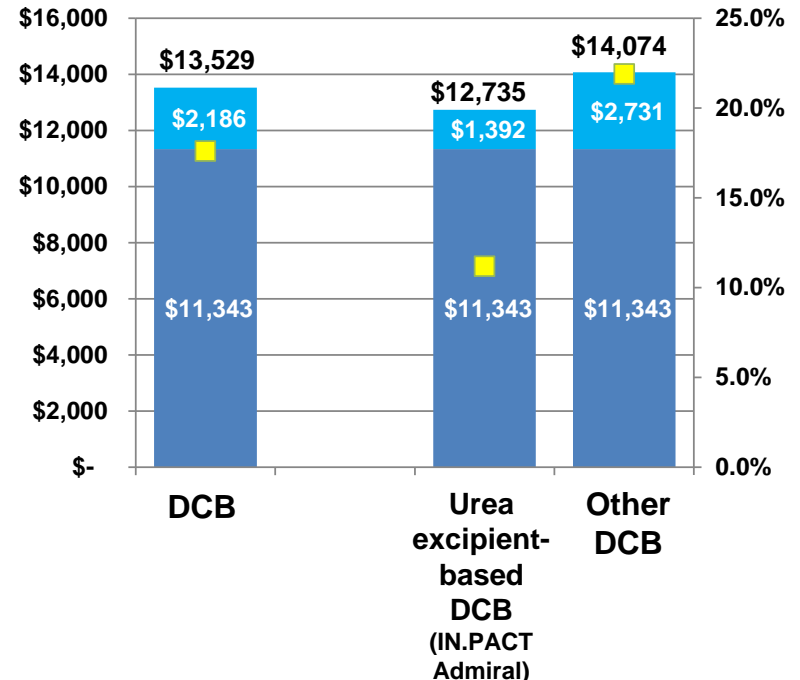
- DCB associated with lowest total cost (\$1.8k savings over 24 months), despite new technology add-on payment
- Stent therapies more expensive because of higher reimbursement for stent procedure

DCB Subset Analyses

Germany



United States



- Based on 24-month pooled TLR of 11.2%, urea excipient-based DCB (IN.PACT Admiral) are associated with lowest total cost in Germany and the United States.

NNTs and Potential Budget Impact

- Numbers needed to treat:

NNT to avoid 1 TLR over 24 months (compared to PTA)

BMS: 8.6 DES: 5.3 DCB: 4.8 (3.7 IN.PACT Admiral)

- Budget impact estimate:

- If 10,000 PTA index procedures performed as DCB procedures instead:

- ~2,100 TLRs avoided, at overall cost savings of \$17.6 million (U.S. system), or €4.4 million (German system)
- More favorable results for urea-exipient based DCB

Limitations

- Included clinical studies limited to mean lesion length <120mm; primarily claudicants, and only 15-20% CLI
- Limited timeframe of 24 months
- Only up to 1 reintervention allowed
- Assumption of use of 1 device per procedure
- Quality of life/functional health status impact not considered

Conclusions

- Since our prior study in 2013, substantial increase in available evidence (28 vs. 14 studies) and reported follow-up
- Strengthened evidence validated earlier pooled TLR findings
- Improved clinical outcomes of drug-eluting therapies continue to be associated with cost savings to U.S. and German payers
- Higher up-front index procedure costs more than offset by reduction in reintervention cost
- DCBs, and especially urea-exipient based DCBs, seem to provide the most favorable clinical profile

ILLUMENATE FIH Health Economic Analysis

Stellarex™ DCB arm



ILLUMENATE FIH
Pre-dilatation
cohort **N=47**

POBA arm

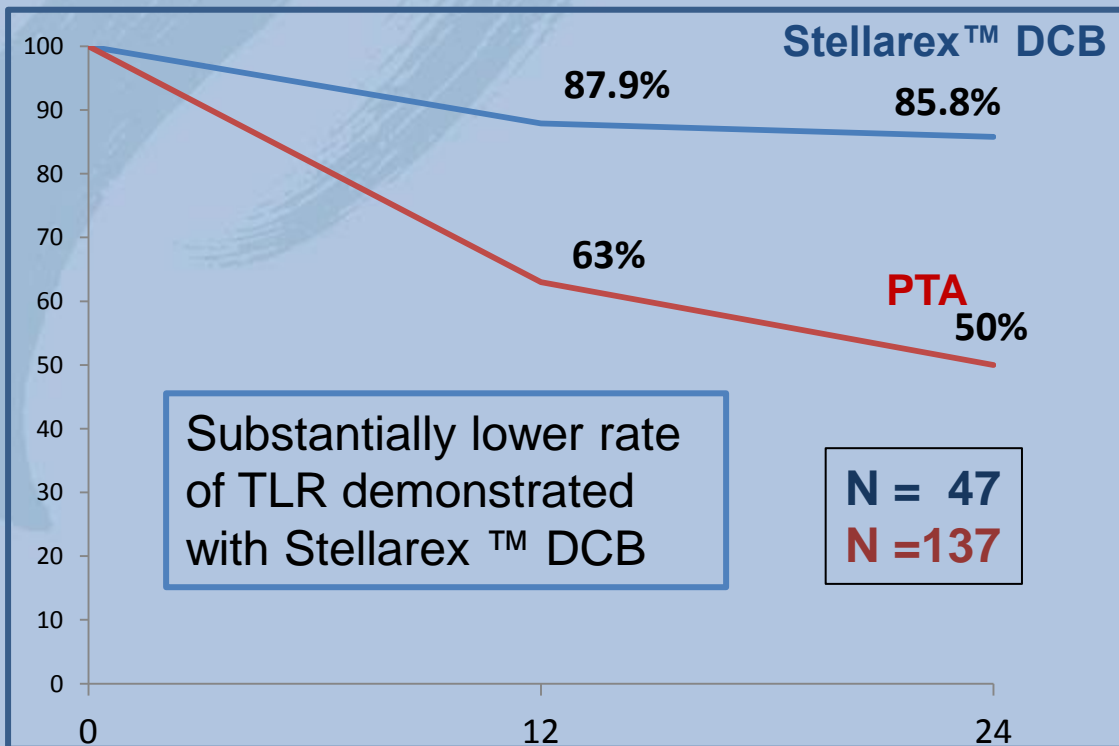


Historical data (trials):
Thunder¹
Levant I²
Fem-Pac³ **N=137**

1. Tepe, G., et al., N Engl J Med, 2008;358: p. 689-699.
2. Scheinert, D., et al., J Am Coll Cardiol Inv, 2014;7: p. 11-19.
3. Micari, A., et al., J Am Coll Cardiol Inv, 2013;6: p. 282-289.

Economic value of Stellarex DCB vs. PTA analyzed from a German HC system Payer's perspective

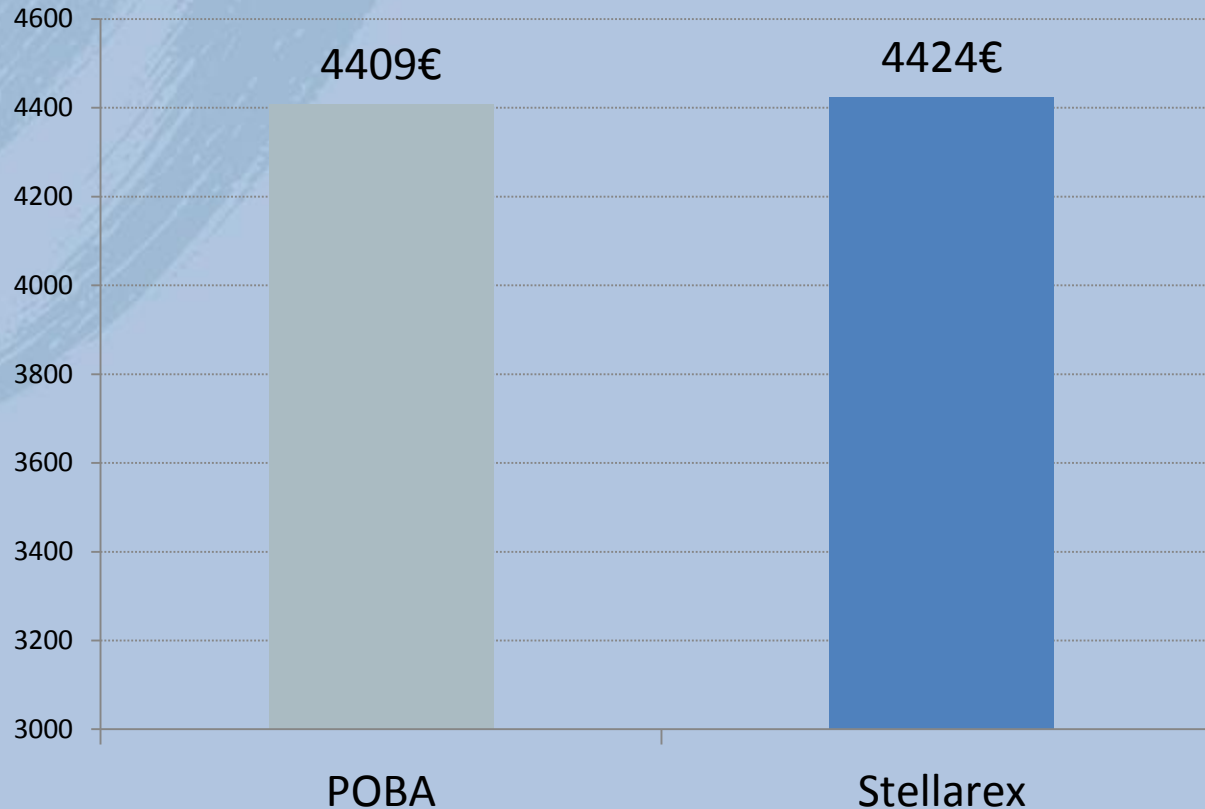
- **Key cost economic driver:** Target Lesion Revascularization rate through 2 years
- **Stellarex DCB source:** ILLUMENATE FIH (pre-dil cohort)
- **PTA Source:** pooled TLR rates derived from published clinical studies¹⁻³, weighted by sample size



- Budget Model incorporated cost of index procedure and revascularizations
- Fewer revascularizations = less cost over time

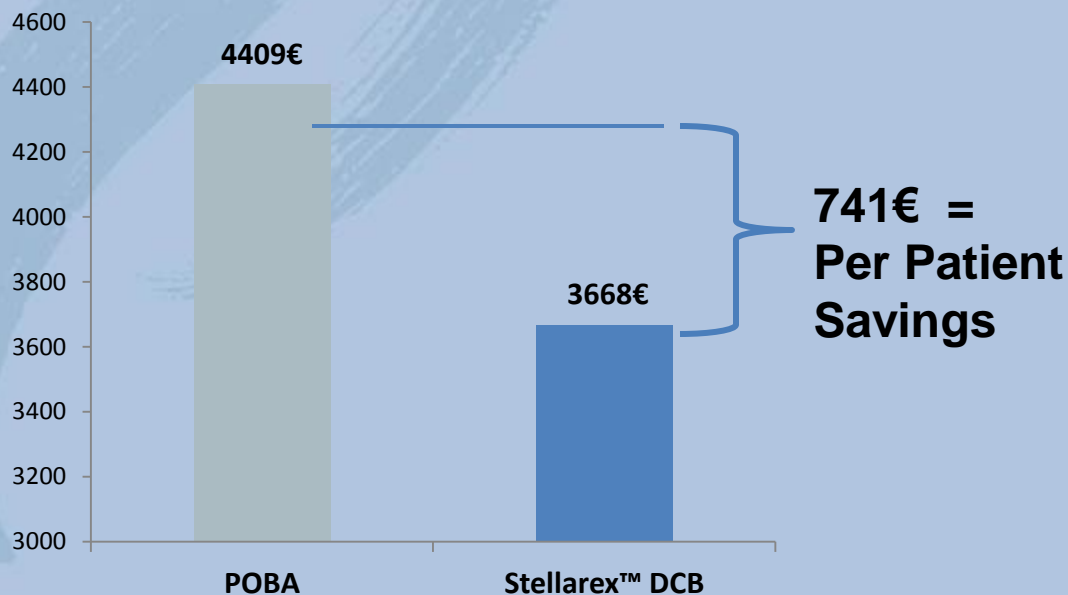
1. Tepe, G., et al., N Engl J Med, 2008;358: p. 689-699.
2. Scheinert, D., et al., J Am Coll Cardiol Inv, 2014;7: p. 11-19.
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24 Month Budget Impact (including the use up to 3 DCB): Cost Neutral



24 Month Budget Impact: Second Model Assuming 1 DCB - 741€ Per Patient Savings

24 Month Budget Impact



Savings to health care system
over 24 months using Stellarex™
DCB vs. POBA:

Per Patient= € 741
Per 25,000 pts = €18,500,000

*POBA baseline= 2939.50€
POBA retreatment = $2939.50 \times 0.50 = 1,469.75€$
POBA baseline + Retreatment = $2939.50 + 1469.75 = 4409.25$

**Stellarex baseline= $2939.50 + 198.97 = 3138.47€$
Stellarex retreatment = $3635.97 \times 0.15 = 472.65$
Stellarex baseline + Retreatment = $3138.47 + 472.65 = 3611.12$

Costs of DCB SFA-Disease Treatment

Conclusions

- DCBs have shown clinical and economic value against PTA in various healthcare systems including Germany and the US
- Within the German healthcare system, IN.PACT DCB and Stellarex demonstrated cost effectiveness up to 2 years
 - Savings per patient when 1 DCB used
 - Cost neutrality demonstrated in patients where more than one DCB was used
- Outside the German and the US healthcare system, adequate reimbursement levels are needed to make DCB convenient for payers and attractive for care providers

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