



# **THE ECONOMIC COST OF PAD, CLI & VENOUS DISEASE: HOW BIG IS THE MARKET?**

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# DISCLOSURES

**THE SAGE GROUP LLC** is a for-profit research and consulting company specializing in vascular disease in the lower limbs including Peripheral Artery Disease (PAD), Intermittent Claudication (IC), Critical Limb Ischemia (CLI) Acute Limb Ischemia (ALI) and Diabetic Foot Ulcer (DFU) & Amputation.

# CLIENTS



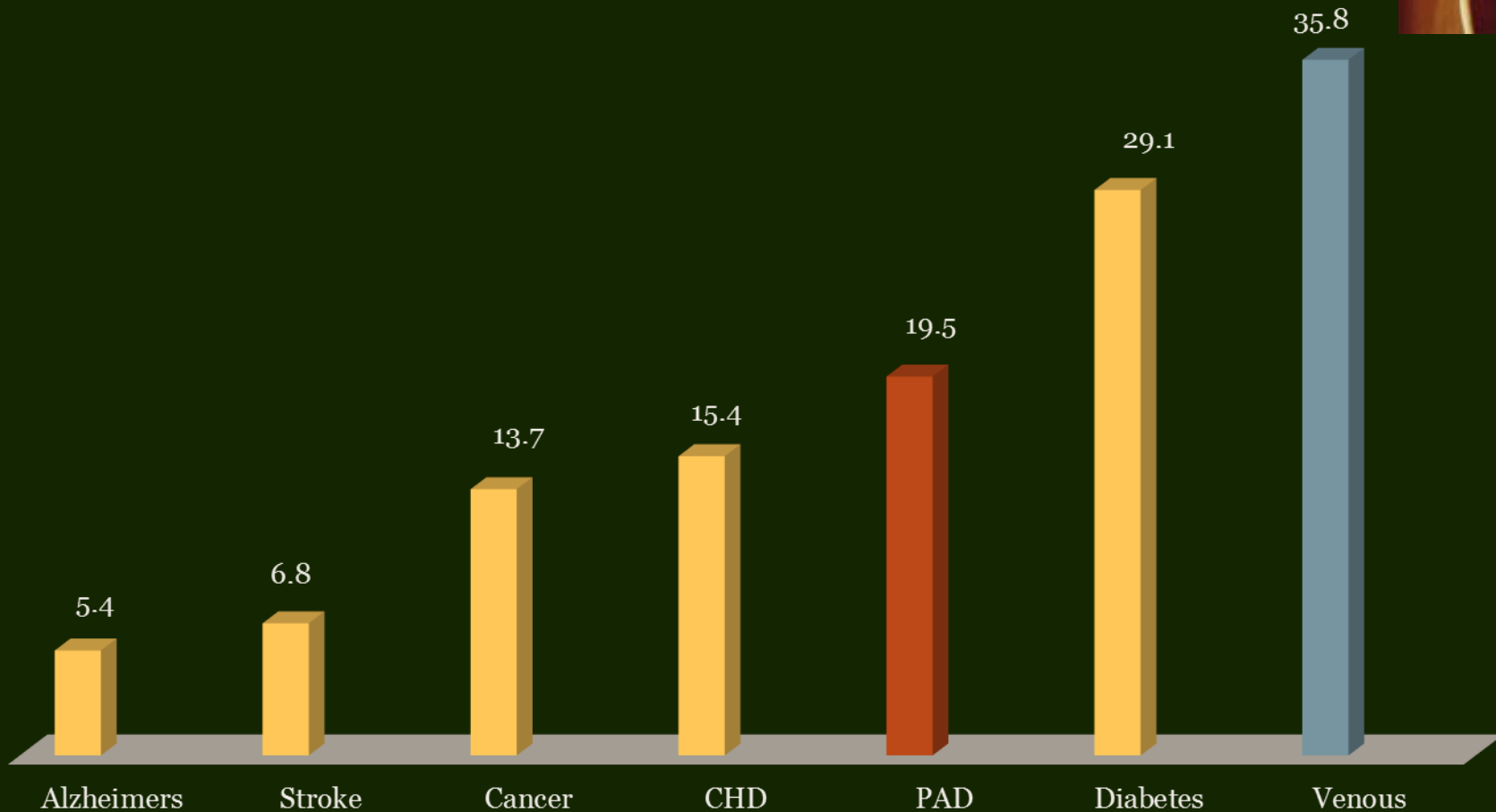
Aastrom Biosciences  
Abbott Vascular  
ActivBiotics  
Advanced Biohealing  
AngioScore  
ANS (St. Jude Medical)  
AtheroMed Inc.  
Bain & Company  
**Bard**  
Baxter  
Bayer (Medrad)  
BioMarin Pharmaceutical  
Boston Scientific  
**Boston Scientific India**  
Chemo France  
**Cardiovascular Systems, Inc.**  
CoDa Therapeutics  
Cordis (Johnson & Johnson)  
Cook Medical  
Diffusion Pharmaceuticals LLC

Diomed Inc.  
Edwards Lifesciences  
Ev3  
FoxHollow Technologies  
GlaxoSmithKline  
**Grifols SA**  
**Harvest Technologies**  
IDev Technologies  
Indigo Pharmaceuticals  
Infocus Research  
**Intact Vascular**  
**Jihad Mustapha MD**  
Joan Piesinger & Associates  
Kerberos Proximal Solution  
King Pharmaceuticals  
Maxis  
Medtronic  
**Merck Serono AG Mexico**  
**Novadaq Technologies**

Nuvelo Inc.  
OmniSonics Medical  
Pathway Medical Technologies  
Pluristem Therapeutics  
Possis Medical  
Rapid Medical  
Sanofi-Aventis  
Schering-Plough Corp.  
Shire Pharmaceuticals  
Solvay Pharmaceuticals  
**Spectranetics Corporation**  
**Stempeutics**  
Stereotaxis  
Straub Medical AG  
Terumo  
The Medicines Company  
ThermoGenesis Corp.  
ThromboGenics NV  
**W. L. Gore**

# U.S. PREVALENCE OF MAJOR DISEASES—2015

(Millions)



Source: Alzheimer's Assoc, ACS, AHA, ADA, Pappas and THE SAGE GROUP.

# COMPARISON OF US PAD ESTIMATES—2015



<b>YEAR</b>	<b>CRIQUI/ PARTNERS (Mill)</b>	<b>DIABETES METHOD (Mill)</b>	<b>NEHLER (Mill)</b>
<b>2015</b>	<b>11-18</b>	<b>20</b>	<b>17</b>

Source: THE SAGE GROUP population-based estimates, Criqui 1985 and Nehler 2014.

# PAD ANNUAL ECONOMIC BURDEN\*



**\$212<sup>†</sup>-\$389<sup>‡</sup> BILLION**

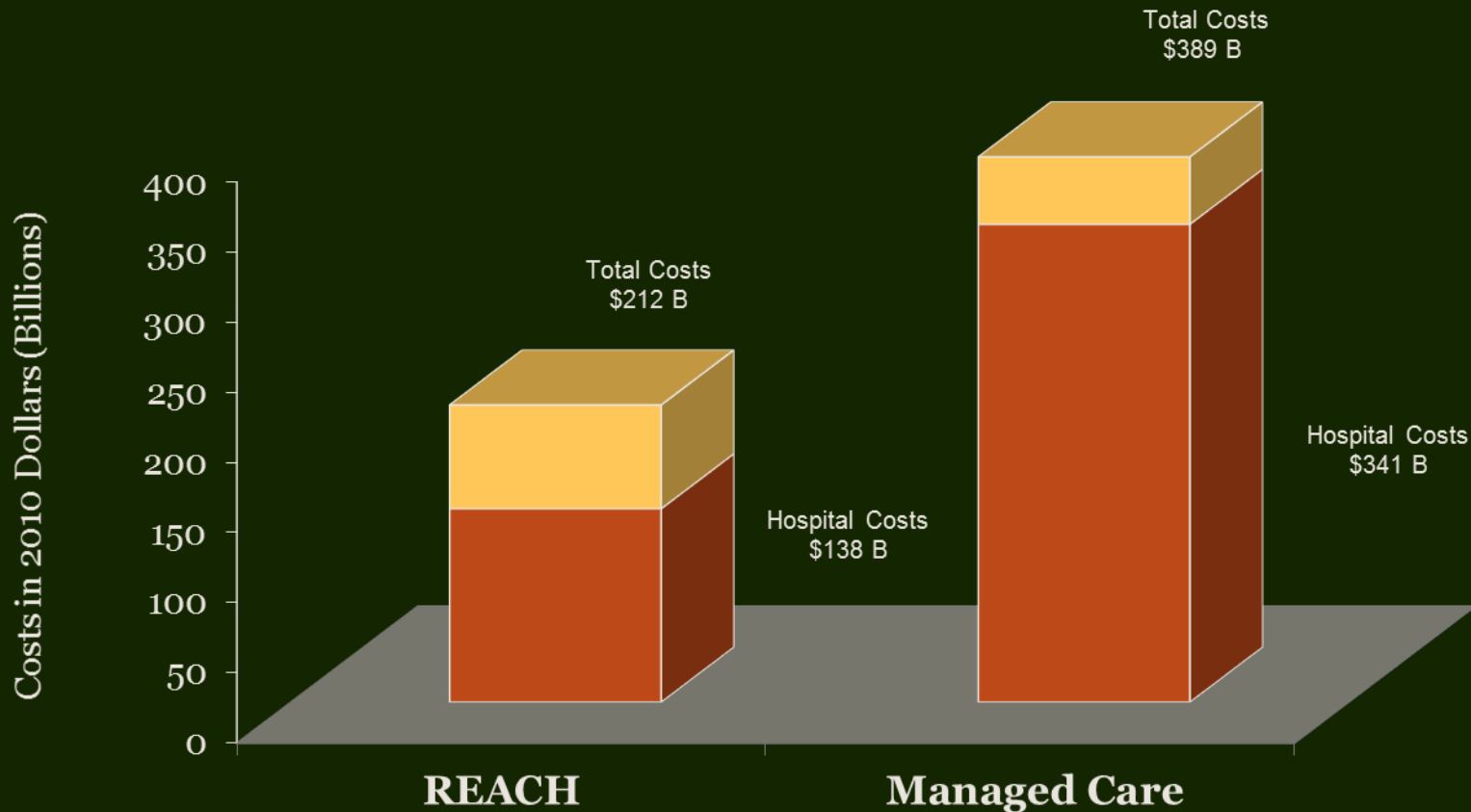
**\*Total Costs Inpatient and Outpatient in 2015**

<sup>†</sup>U.S. REACH population inpatient costs + outpatient medication = \$10,881 X 19.5 Mil PAD in 2015

<sup>‡</sup>Margolis managed care population all-cause hospitalizations + medications + other = \$19,963 x 19.5 Mil PAD. Per pt costs in 2014 \$.

Source Mahoney 2008, Margolis J 2005 and Yost real cost.

# HOSPITAL COSTS REPRESENT MAJORITY OF PAD COSTS

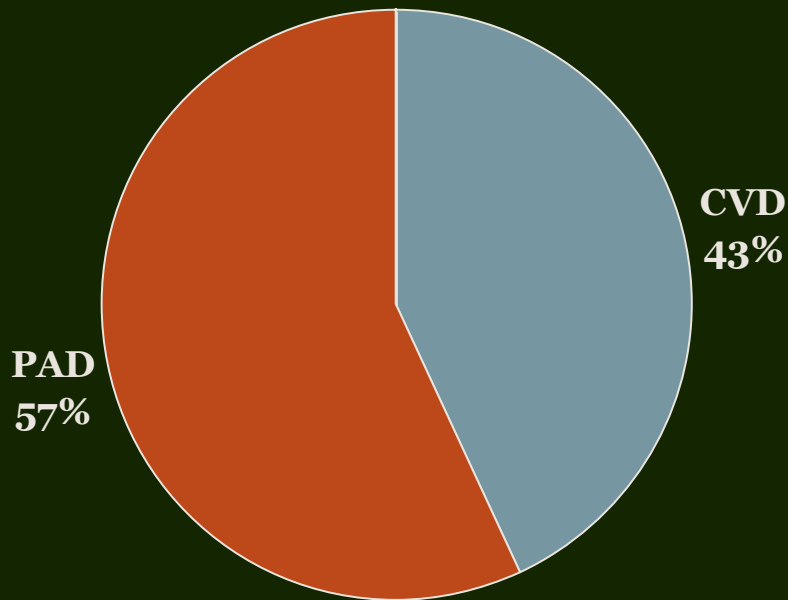


Source Mahoney 2008, Margolis J 2005 and Yost Real cost.

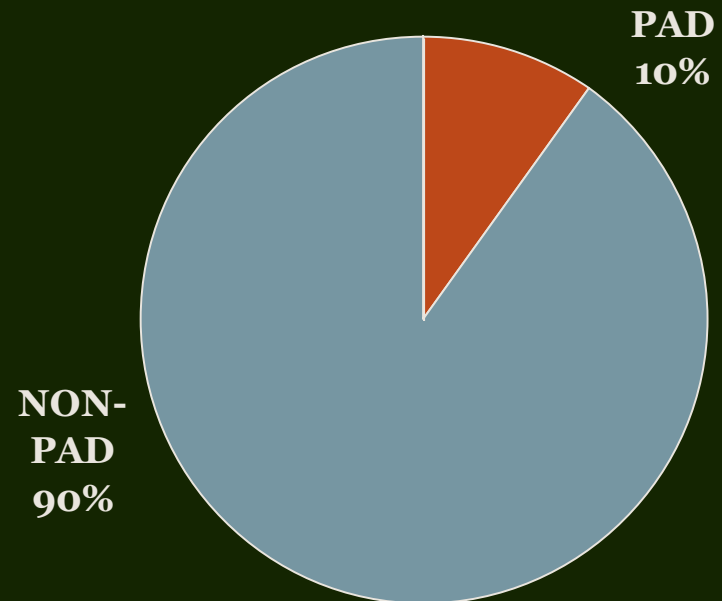
# NON-PAD COSTS ARE SIGNIFICANT



## Cardiovascular Hospitalizations



## All-Cause Hospitalizations

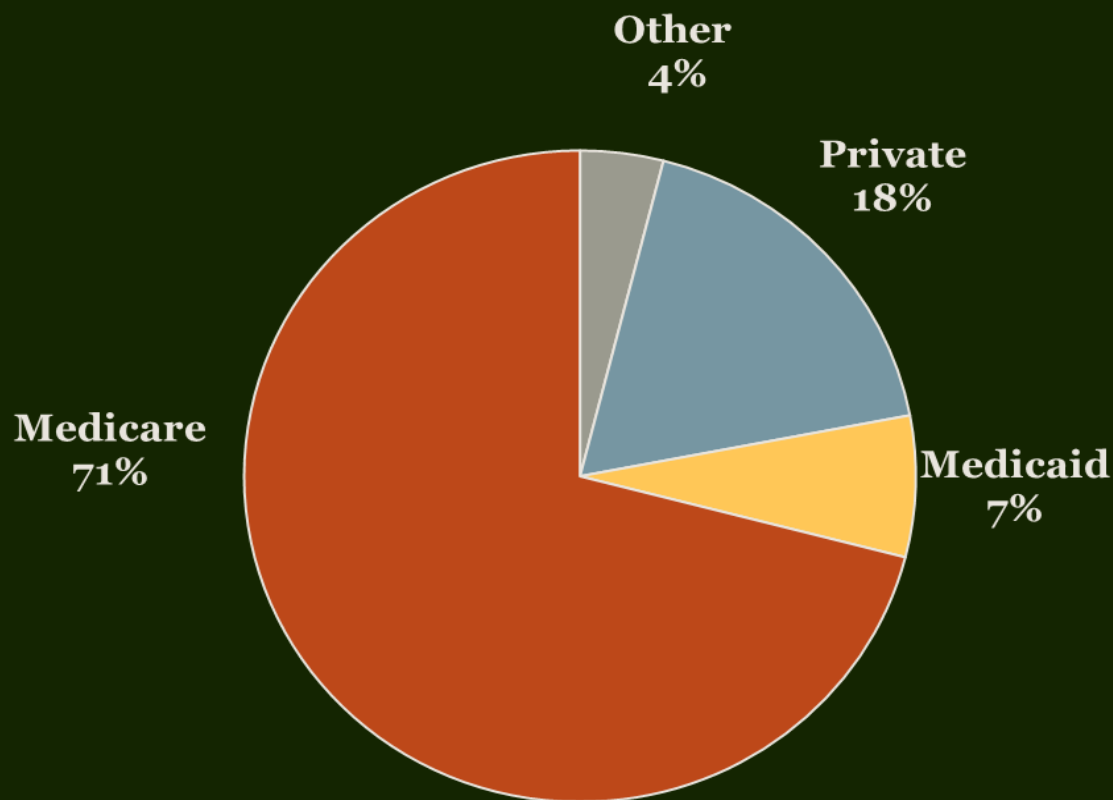




# WHO PAYS THE PAD BILL?



## 2012 PAD Patient Discharges by Payer



Source: HCUP Query. Diagnosis codes for PAD.

# PAD PATIENTS IN MEDICARE



**7%-10% Medicare Patients Treated for PAD**

(2001-2005)

**\$23,609-\$74,864\* Expenditure per Patient**

(Range reflects definition of PAD and types of treatments included, i.e. LT Care)

**AK Amputation**

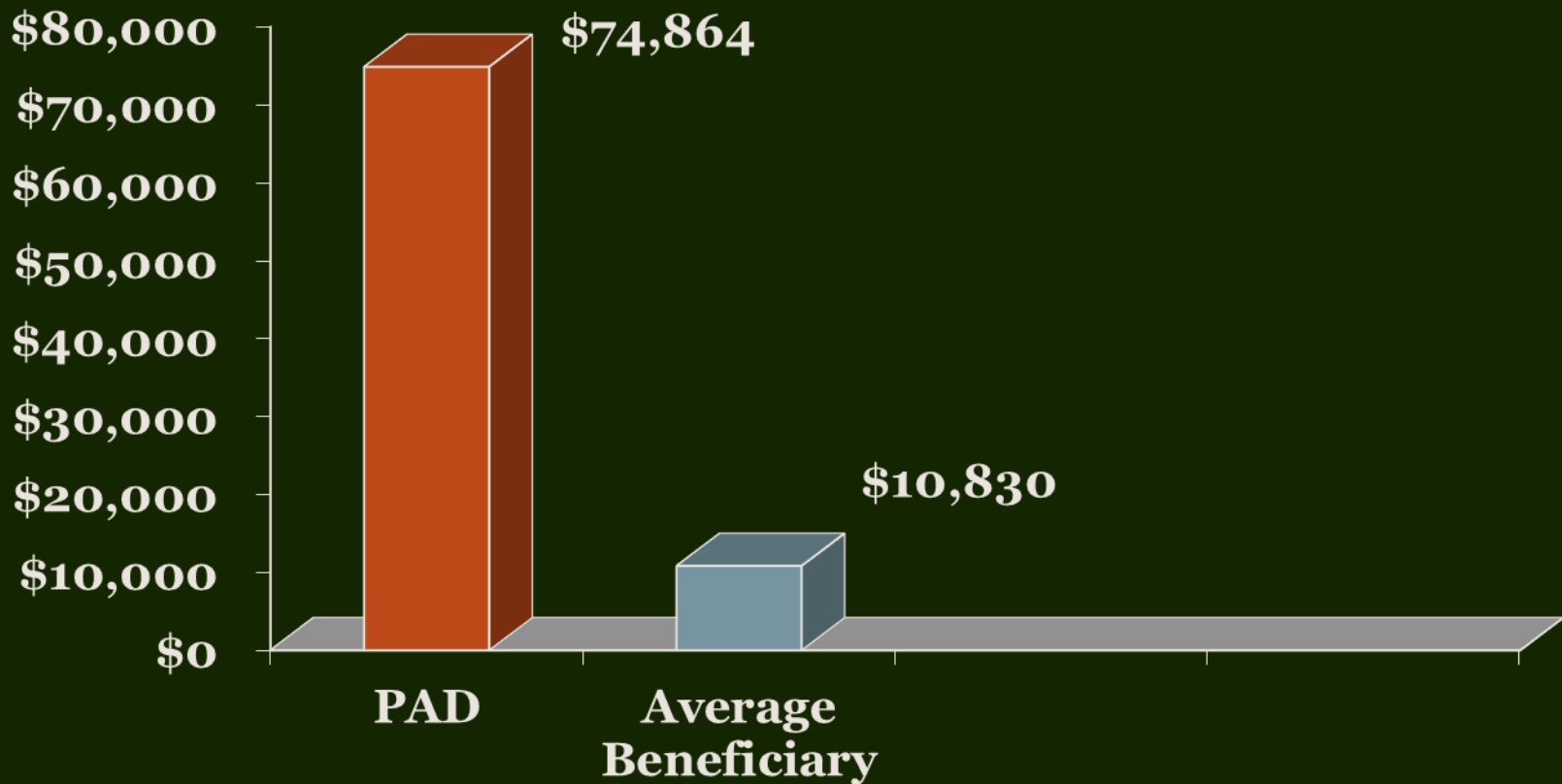
**Third Most Commonly Performed Procedure**

**Total Medicare PAD Bill \$84-\$381B\***

\*2014 \$ X 2012 Medicare beneficiaries w/ PAD

Source: Hirsch 2008, Jaff 2010 and Yost real cost.

# 2015 ANNUAL MEDICARE EXPENDITURES\*



\*Costs in 2014 \$

Source: Jaff 2010 & Yost The real of PAD.

# **PAD—WHY IS EARLY DIAGNOSIS & TREATMENT IMPORTANT?**



- ❖ **Costs ↑ w/ Disease Severity— IC Lowest, Amp Highest**
- ❖ **Hospital Costs: 62%-87% of PAD Costs**
- ❖ **Hospitalizations ↑ w/ Disease Severity (IC 25% Amp 36%)**
- ❖ **70% Have Polyvascular Disease—50% PAD + CAD**
- ❖ **CVD Costs Add Significantly—43% of Total Costs**
- ❖ **CVD Events ↑ w/ Disease Severity—AS 21% Amp 34%**

# PAD A RISK FACTOR EQUIVALENT TO CAD



## RISK FACTOR MODIFICATION THERAPY UNDERUTILIZED

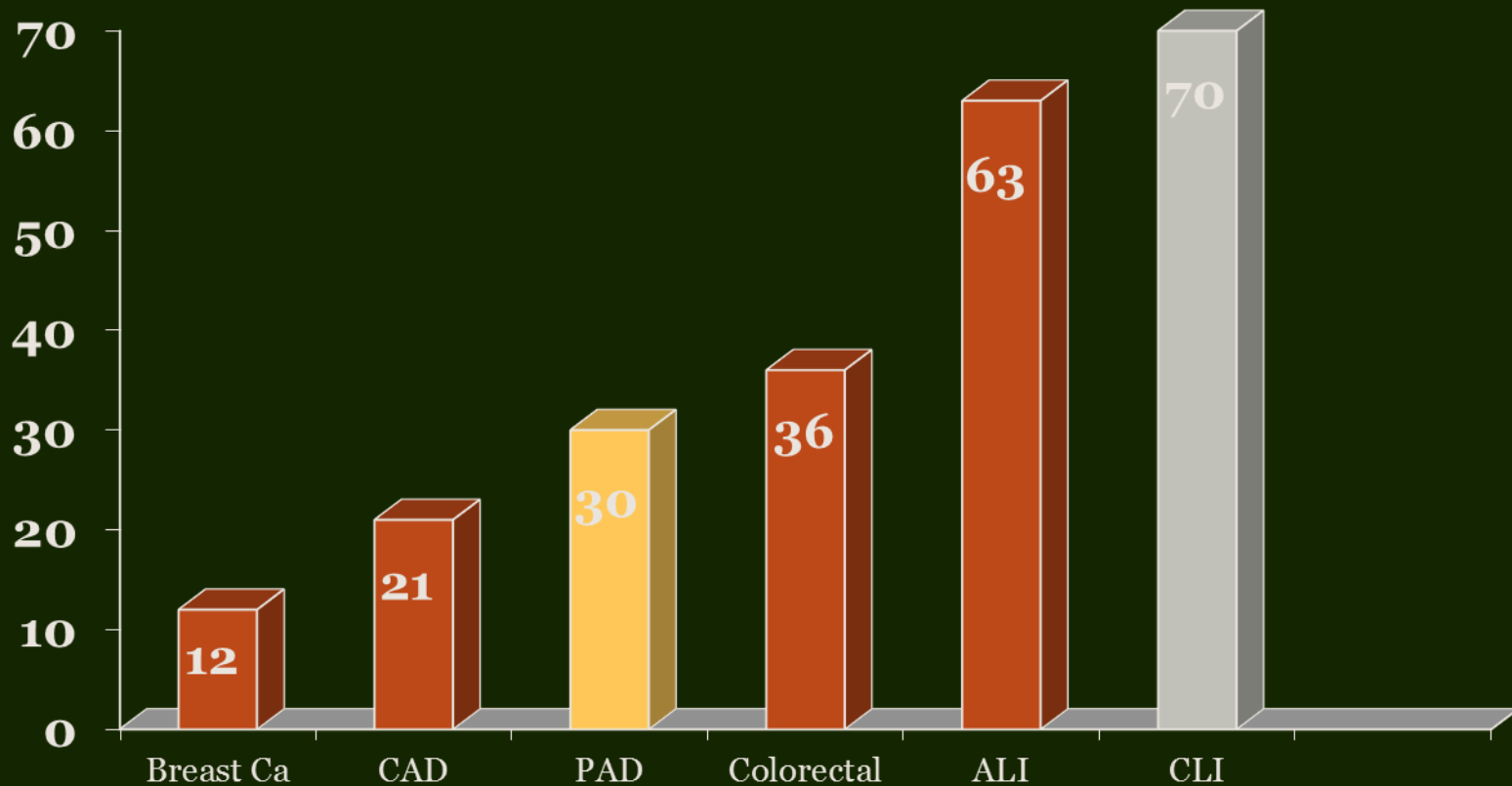
<b>Antihypertensive</b>	<b>No Rx</b>	<b>12%-50%</b>
<b>Antiplatelet</b>	<b>No Rx</b>	<b>33%-70%</b>
<b>Antilipid</b>	<b>No Rx</b>	<b>44%-60%</b>

 **PAD Cost, Morbidity & Mortality**

Source: Margolis J 2005, Hirsch 2001, Conte 2005 and Armstrong 2014.

# FIVE-YEAR ALL-CAUSE MORTALITY

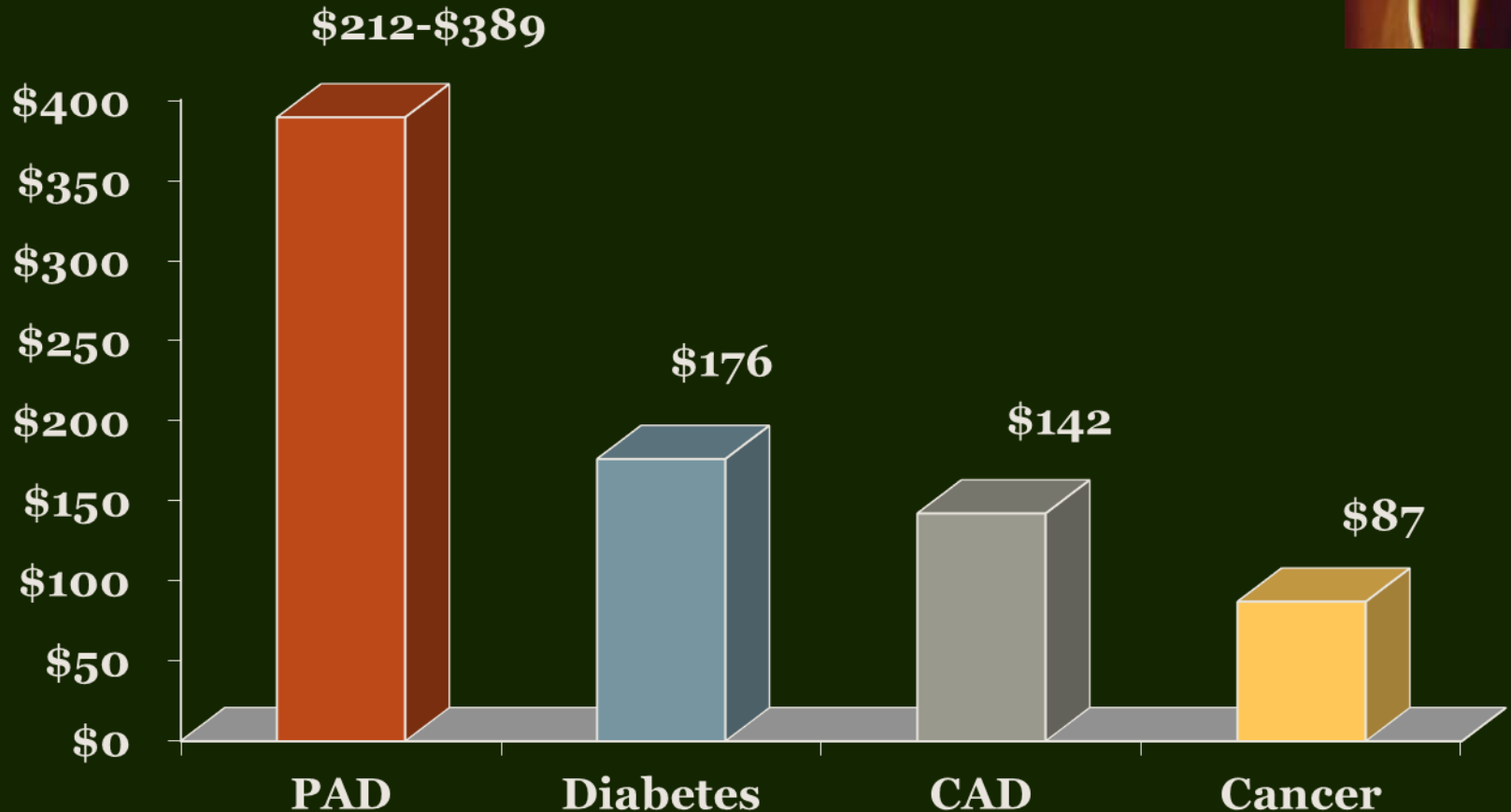
%



Source: Yost ML. CLI V I 2010. ACS, Weitz, Hunt and Ljungman.

# 2015 ANNUAL ECONOMIC BURDEN\*

(Billions \$)



\*Direct costs in the United States: PAD & CAD costs inflated to 2014 \$.

Source: Yost 2011, Mahoney 2008, Margolis 2005, ACS, ADA 2013 and THE SAGE GROUP.

# CLI PREVALENCE & COST 2015



**2-3 Million**

**400,000-700,000 Treated w/  
Revascularization or Amputation-Major & Minor**

**Cost \$40-\$66 Billion**

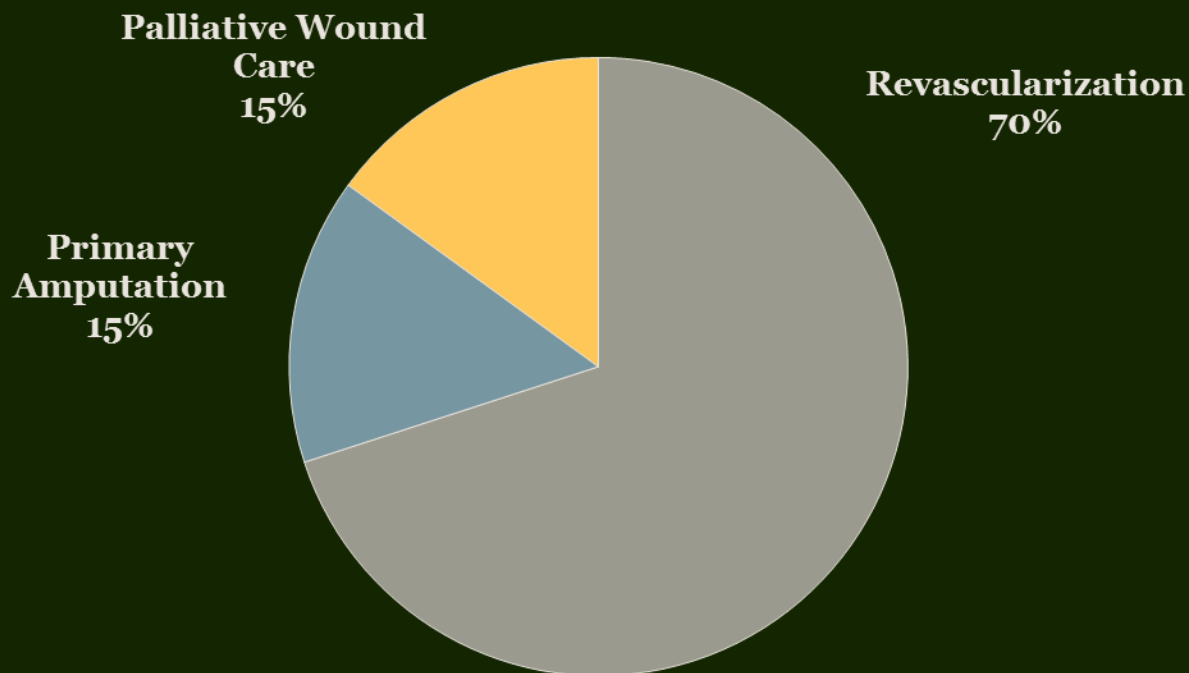
Source: Yost. CLI Vol I, Nehler 2014, Baser, HCUP Queries, Barshes 2012, Mahoney 2010, Dillingham 2005 and THE SAGE GROUP estimates.



# CLI “IDEAL” TREATMENT PATHWAY



## SVS & ESVS Recommendation



Source: Allie 2005 and Hallett.

# MAJOR AMPUTATION



❖ **25%-33% CLI patients undergo primary amputation (PA)**

❖ **65,000-75,000 major amputations performed annually**

# CLI PATHWAY TO AMPUTATION



- ❖ **Frequently the first and only therapy for CLI**
- ❖ **51%-73% No Angiogram—Despite fact that angio ↓ the odds by 90%**
- ❖ **60%-71% No Revascularization**

Source: Henry 2011, Allie 2005, Goodney 2012.

# AMPUTATION LOTTERY



- ❖ **Probability of major amputation depends on who you are and where you live**
- ❖ **Amputation varies by: race, sex, age, socioeconomic status, hospital volume, geographic location**
- ❖ **Medicare & Medicaid-More likely than private, Medicaid most likely!**

Source: Henry 2011, Baser, Goodney 2012, Jones, Margolis DJ 2011 & Eslami 2007.

# MAJOR AMPUTATION ANNUAL ECONOMIC COST\*



**\$11 BILLION**

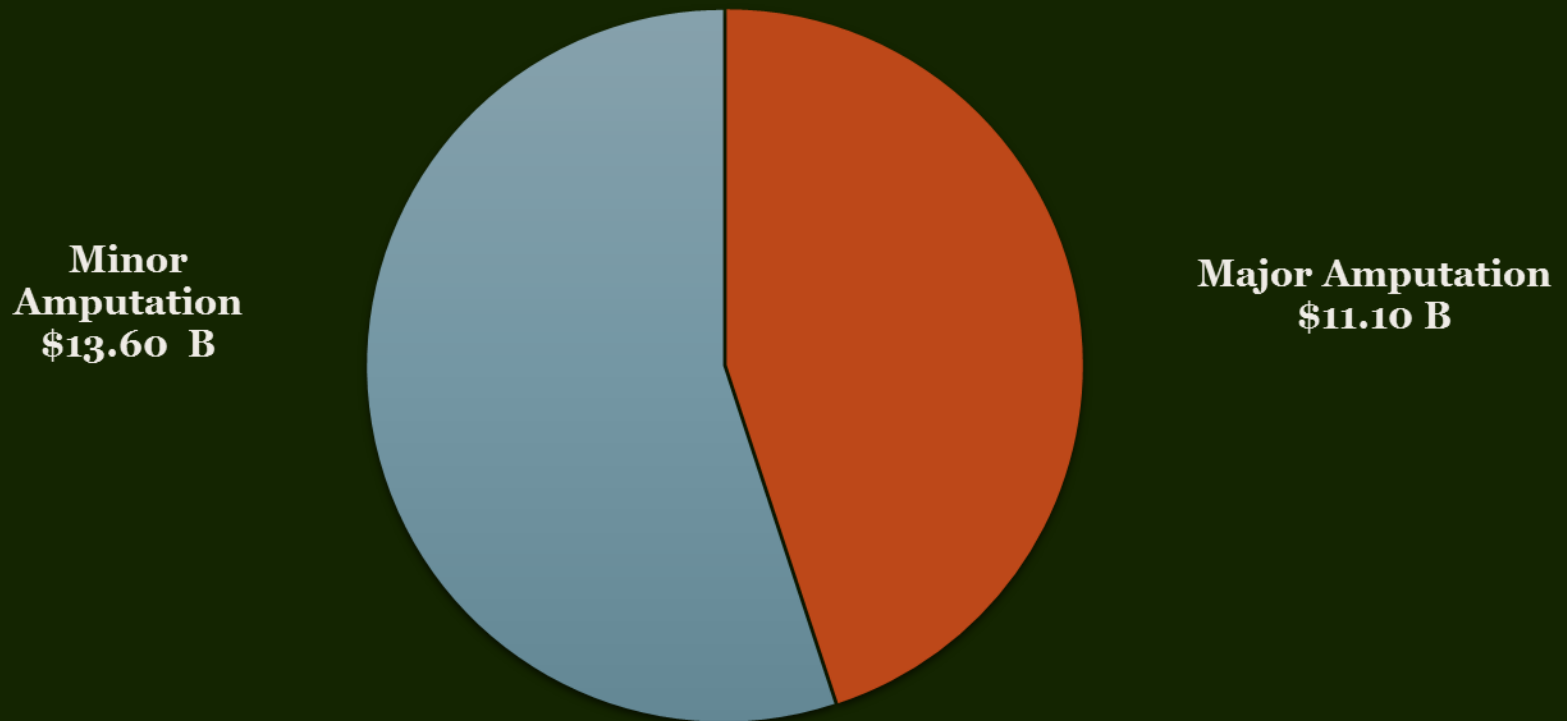
**\*Total Direct Inpatient and Outpatient Costs in 2014 \$**

# TOTAL AMPUTATIONS 208,000

## COST \$24.7 Bil



### 2012 Amputation Cost by Type



Source: Dillingham 2005, HCUP Query and Yost.

# CONCLUSIONS PAD



- ❖ **PAD IS HIGHLY PREVALENT AND COMMONLY UNDERESTIMATED**
- ❖ **PAD MACROECONOMIC COST IS HIGH \$212-\$389B**
- ❖ **HOSPITAL COSTS ACCOUNT FOR THE MAJORITY OF TOTAL PAD COSTS**
- ❖ **HOSPITAL COSTS ARE SIGNIFICANTLY INCREASED BY CARDIOVASCULAR AND NON-PAD EVENTS**
- ❖ **2015 ECONOMIC BURDEN OF PAD EXCEEDS THAT OF DIABETES, CAD AND ALL CANCERS**

# VENOUS DISEASE



## CHRONIC VENOUS INSUFFICIENCY (CVI)

### VENOUS THROMBOLISM (VTE):

DEEP VEIN THROMBOSIS (DVT)

PULMONARY EMBOLISM (PE)



# CVI



## PREVALENCE

<b>VARICOSE VEINS</b>	<b>25+ Mill</b>
<b>MORE SEVERE DISEASE*</b>	<b>6 Mill</b>
<b>VENOUS ULCERS</b>	<b>1.8-2.4 Mill</b>

\*Persistent ambulatory venous hypertension, pain, edema, skin changes & ulcers

Source: Eberhardt RT, 2014, Pappas PJ, Bongiovanni CM, 2006 and THE SAGE GROUP.

# VENOUS ULCERS



**INCIDENCE 500,000-700,000**

**ANNUAL TREATMENT COST \$3 BILL**

**+**

**SOCIOECONOMIC COSTS**

2 to 4.6 Million Workdays Lost Annually  
Patient & Family \$ Costs & Social Burden

# VTE

**INCIDENCE 300,000-900,000**



**CLINICAL PRESENTATION:**

**2/3 DVT**

**1/3 PE:**

**HOSPITAL & NURSING HOME PTS = 60% CASES  
(ONLY 1/3 OF HOSPITAL PTS ADEQUATE PROPHYLAXIS)**

**MORTALITY:**

**30 DAY—10%-30%**

**20%-25% OF PE CASES PRESENT AS SUDDEN DEATH**

# VTE



## ECONOMIC COST

**\$13 BILL\***  
(VTE COSTS ONLY)

**\$28 BILL\***  
(ALL-CAUSE COSTS)

\*Assumes 600,000 VTE and includes primary & recurrent (11% rate) VTE.

Source: Lin J 2014, Casciano JP 2015 and THE SAGE GROUP.

# VTE



## RECURRENCE RATES:

<b>1 YEAR</b>	<b>4%-15%</b>
<b>10 YEAR</b>	<b>33%</b>

**RECURRENT VTE COSTS 2.2X-3.0X MORE**

## DUE TO INCREASED:

**Hospitalizations**  
**LOS**  
**ER Visits**  
**Total Costs**

# VTE COMPLICATIONS



## ❖ **POST-THROMBOTIC SYNDROME (PTS)**

**33%-50% DVT PTS**

## ❖ **HEPARIN INDUCED THROMBOCYTOPENIA (HIT)**

**0.5%-5%**

## ❖ **COSTS**

**PTS COSTS \$11,700 (32% HIGHER)**

**HIT COSTS \$3,118-\$41,133**

# CONCLUSIONS VENOUS



- ❖ **AT 36 MILL VENOUS DISEASE IS LIKELY THE MOST COMMON CHRONIC DISEASE**
- ❖ **VENOUS ULCERS COST \$3 BILL ANNUALLY**
- ❖ **VTE HIGHLY PREVALENT & COSTLY—\$13-\$28 BILL**
- ❖ **MAJORITY OF VTE OCCURS IN HOSPITAL & NH— BUT NOT ADEQUATELY PREVENTED**
- ❖ **RECURRENT VTE AND COMPLICATIONS ADD SIGNIFICANTLY TO MORBIDITY, MORTALITY & COSTS**

# THANK YOU—THE STAFF





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