

# Minneapolis

Minnesota | October 13, 2018



## THE BURDEN AND ECONOMIC COST OF PERIPHERAL ARTERY DISEASE

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THE SAGE GROUP



# Disclosures

## Research Clients:

Bard

Cardiovascular Systems Inc.

Otivio AS

Pluristem

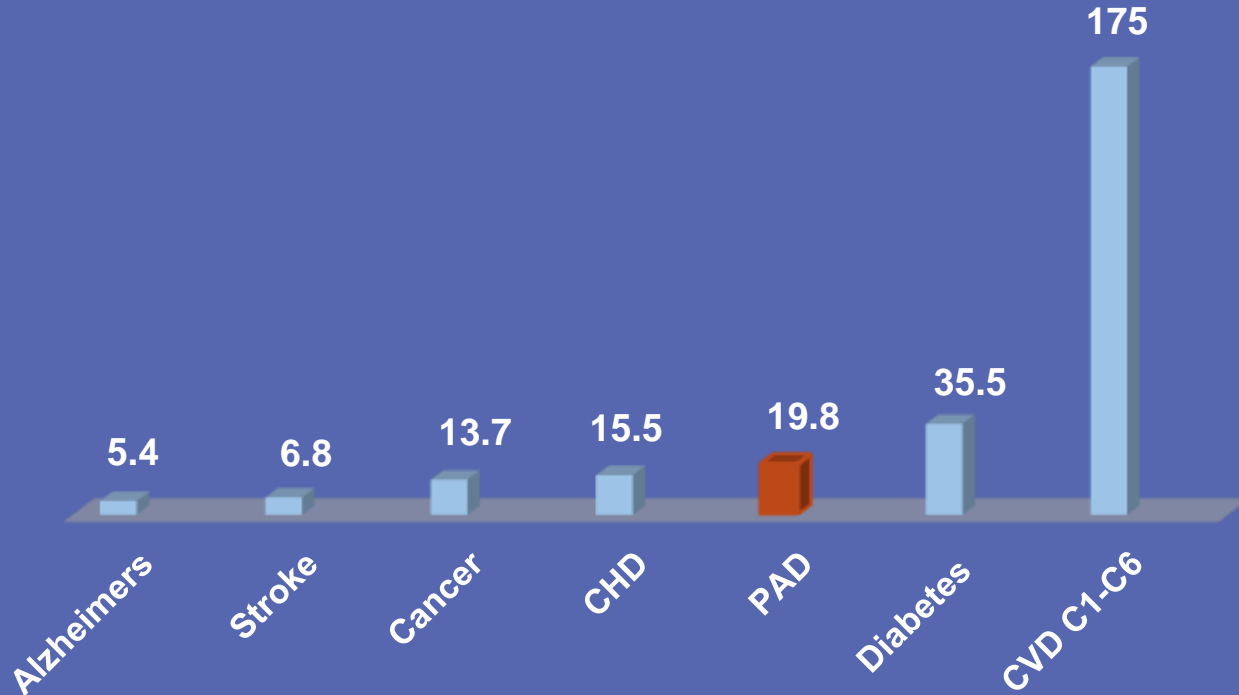
Rexgenero Ltd London

Shockwave Medical

Terumo

# 2015 U.S. PREVALENCE OF SELECTED CHRONIC DISEASES

(Millions)



Source: Alzheimer's Assoc, ACS, AHA, Heidenreich PA. Circulation 2011;123:933-44, Menke A. JAMA 2015; 314:1021-9, Yost CLI Suppl 2016 THE SAGE GROUP and Yost Chronic Venous Disease 2016 THE SAGE GROUP.

# COMPARISON OF US PAD ESTIMATES—2015

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

Source: Criqui Circulation 1985; 71:510-15, Nehler MA. J Vasc Surg 2014;60: 686-95 and Yost CLI US epidemiology supplement 2016 THE SAGE GROUP.

# PAD ANNUAL ECONOMIC BURDEN\*

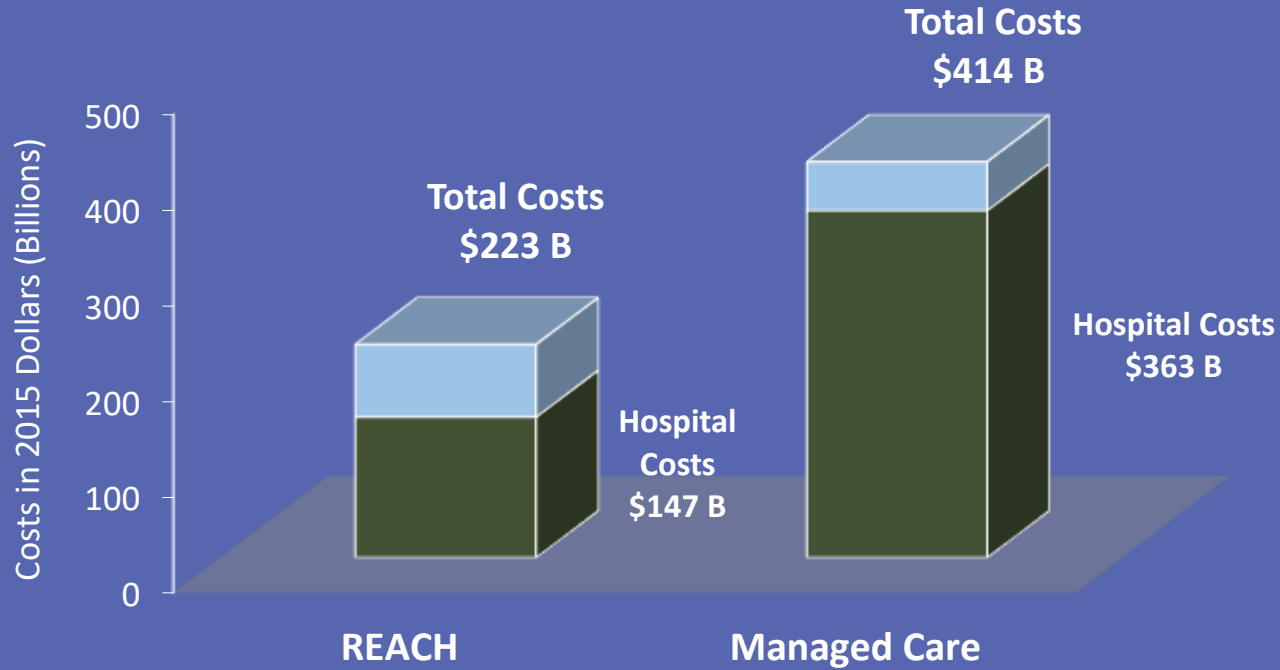
\*Total Costs Inpatient and Outpatient in 2015

**\$223<sup>†</sup>-\$414<sup>‡</sup> BILLION**

<sup>†</sup>U.S. REACH population inpatient costs + outpatient medication = \$11,280 X 19.8 Mil PAD in 2015

<sup>‡</sup>Margolis managed care population all-cause hospitalizations + medications + other =  
\$20,895 x 19.8 Mil PAD. Per pt. costs in 2015 \$.

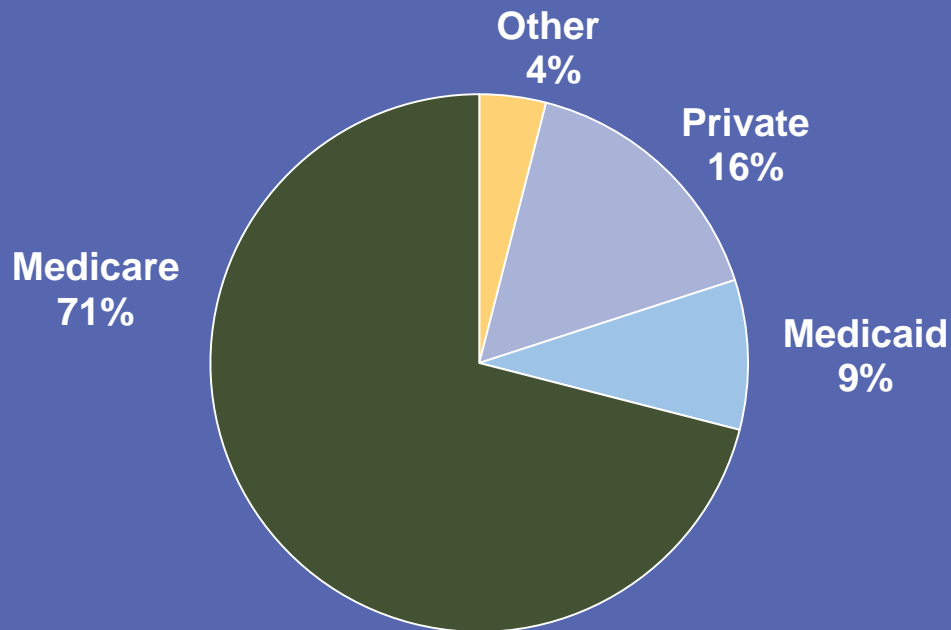
# HOSPITAL COSTS REPRESENT MAJORITY OF PAD COSTS



Source Mahoney EM. Circ Cardiovasc Qual Outcomes 2008;1:38-45, Margolis J. J Manag Care Pharm 2005; 11(9):727-24 and Yost ML. Real cost of PAD 2011 THE SAGE GROUP.

# WHO PAYS THE PAD BILL?

## 2014 PAD Patient Discharges by Payer



Source: HCUP Query. ICD-9 diagnosis codes PAD 440.20-29, 443.9 & 443.81.

# **PAD PATIENTS IN MEDICARE**

**10%-21% Medicare Patients Treated for PAD**

**(2003-2012)**

**\$22,756-\$72,159\* Expenditure per Patient**

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

**AK Amputation**

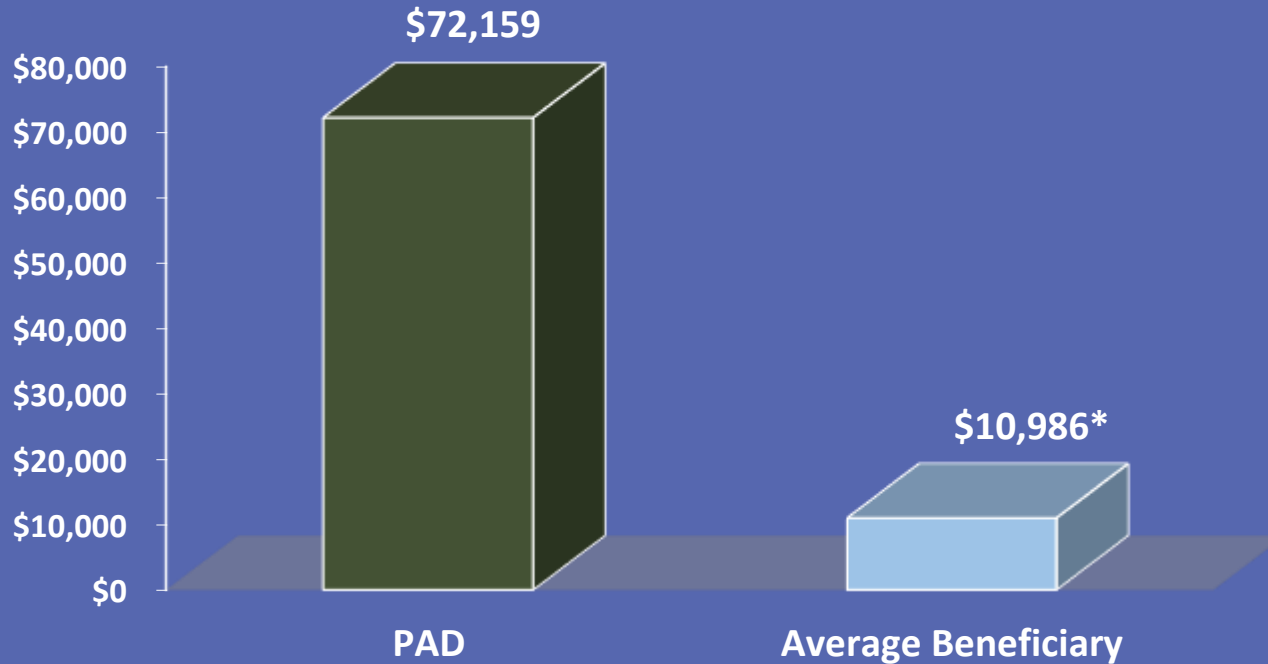
**Third Most Commonly Performed Procedure**

\*2015\$ X 2015 Medicare beneficiaries w/ PAD

Source: Kalbaugh CA. J Am Heart Assoc 2017;6:e003796, Nehler MR. J Vasc Surg 2014;60(3):686-95, Hirsch AJ. Vasc Med 2008;13:209-15 and Jaff MR. Ann Vasc Surg 2010;24:577-87 and Yost Real cost of PAD 2011 THE SAGE GROUP.



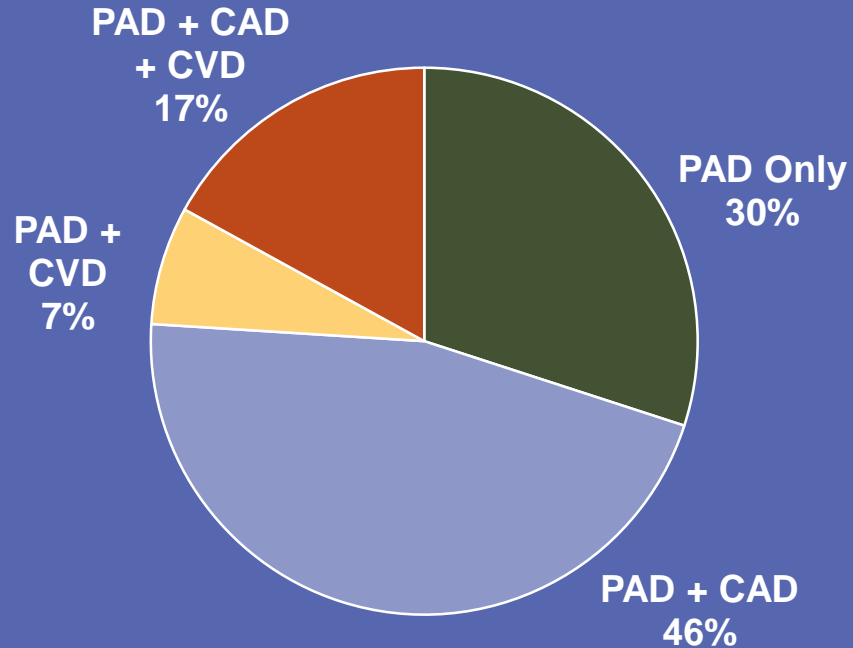
# 2015 ANNUAL MEDICARE EXPENDITURES



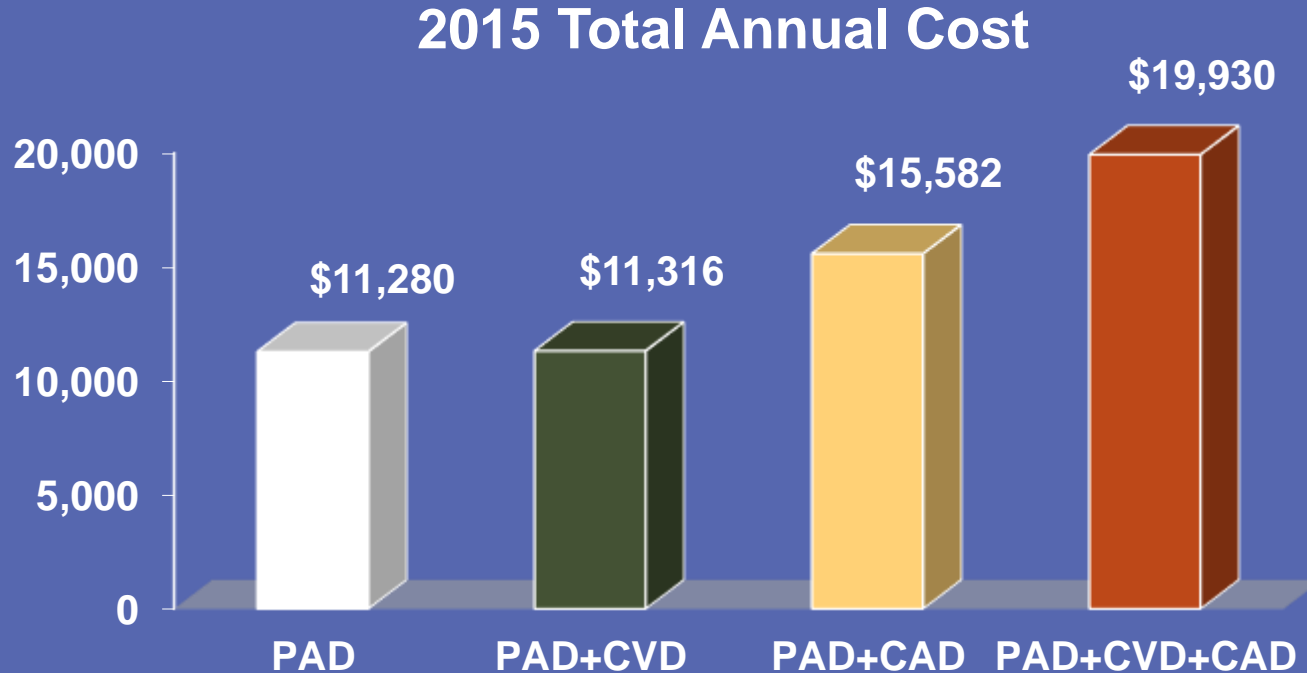
\*2014 Expenditures

Source: Jaff MR. Ann Vasc Surg 2010;24:577-87, CMS NHE Table 21 and Yost ML Real cost of PAD 2011 THE SAGE GROUP.

# POLYVASCULAR DISEASE IN PAD PATIENTS

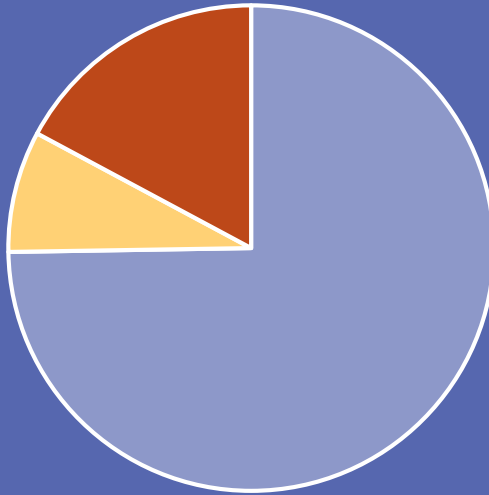


# POLYVASCULAR DISEASE COSTS MORE



Source: Mahoney EM. Circ Cardiovasc Qual Outcomes 2010;3:642-51 and THE SAGE GROUP.

# PAD 2015 SYMPTOMATIC & ASYMPTOMATIC DISEASE



□ Asymptomatic    □ IC    □ CLI

**Asymptomatic = 14.8 Million    CLI = 3.4    IC = 1.6 Million**

# ASYMPTOMATIC PATIENTS COST MORE THAN IC PATIENTS

**IC**

**Cost 2-year \$13,242**

**Costs Due to:**

**PAD** Hospitalizations, Revascularizations & Amputations

**Asymptomatic**

**Cost 2-year \$14,084**

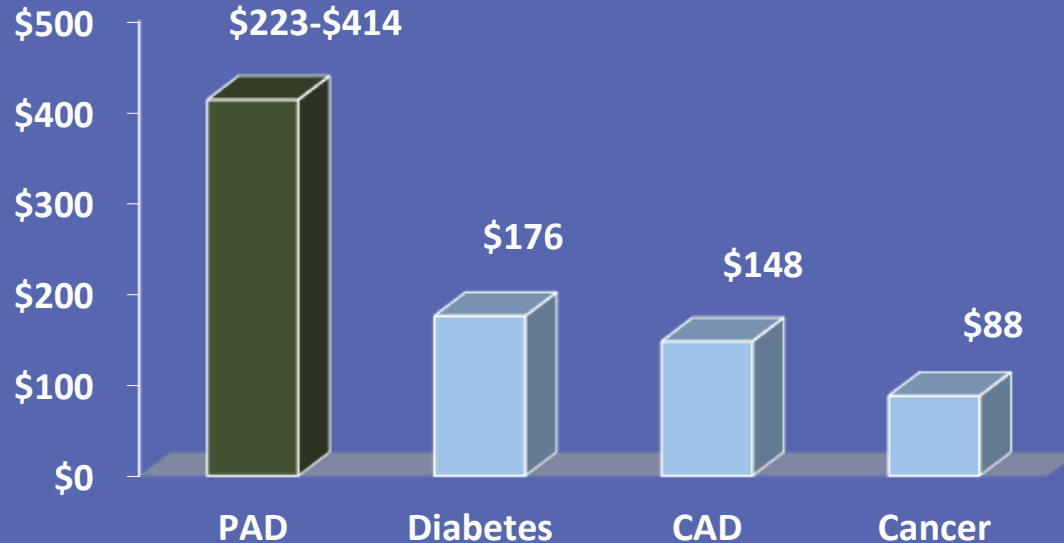
**Costs Due to:**

**CVD** Events, Hospitalizations & Revascularizations

Source: Mahoney EM. Circ Cardiovasc Qual Outcomes 2010;3:642-51 and Yost ML The real cost of PAD. THE SAGE GROUP 2011.

# 2015 ANNUAL ECONOMIC BURDEN\*

(Billions \$)

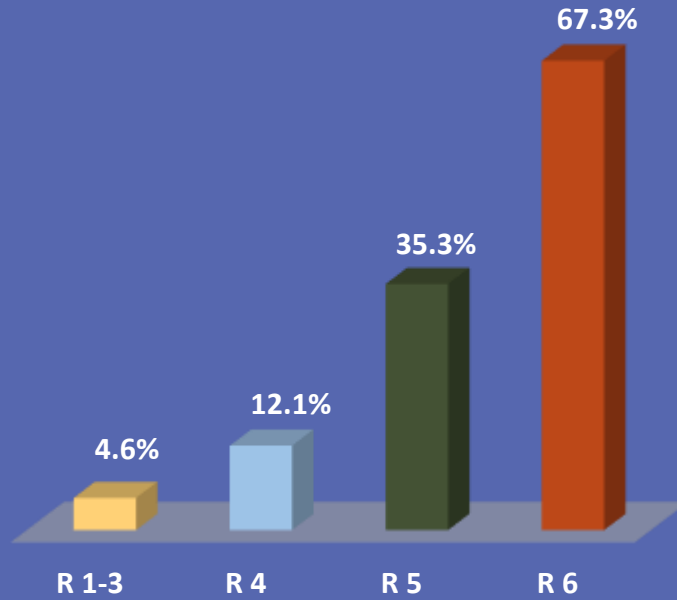


\*Direct costs in the United States: PAD & CAD costs inflated to 2015 \$. Direct cost of diabetes is 2012 and cancer 2014.

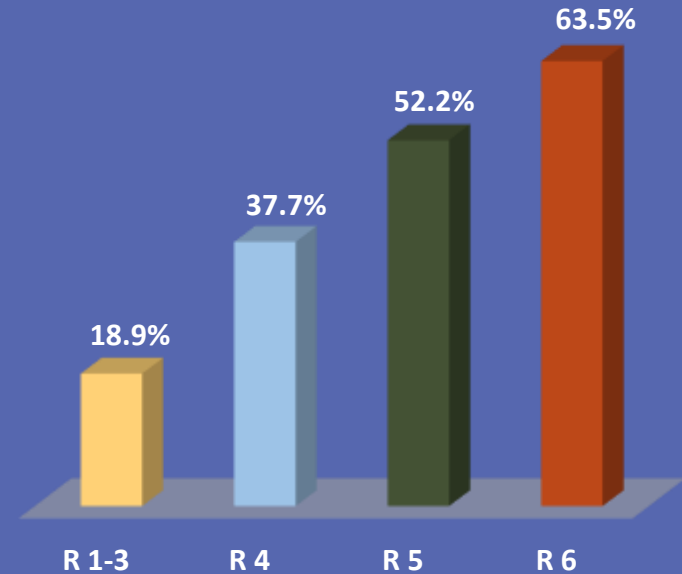
Source: Yost ML. Real cost of PAD 2011 THE SAGE GROUP, Mahoney EM. Circ Cardiovasc Qual Outcomes 2008;1:38-45, American Cancer Society website and ADA Diabetes Care 2013;36(4):1033-46.

# PAD/CLI AMPUTATION & MORTALITY INCREASE WITH DISEASE SEVERITY

## 4-Year Amputation Rates



## 4-Year Mortality Rates



Source: Reinecke H. Eur J 2015; Eur Heart J. 2015 Apr 14;36(15):932-8.

# CLI PREVALENCE 2015

**2.0-3.4 Million**

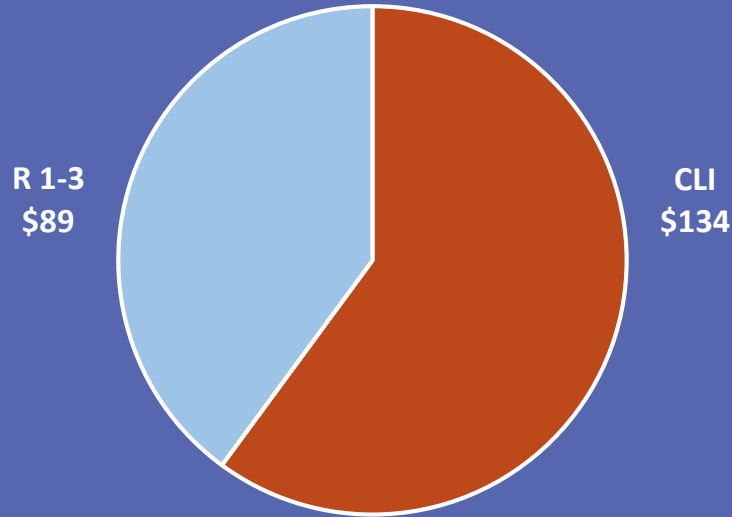
**400,000-700,000 Treated w/  
Revascularization or Amputation-Major & Minor**

Source: Yost. CLI US supplement 2016 THE SAGE GROUP, Nehler MA. J Vasc Surg 2014;60:686-95 and Yost ML. PAD. Interventional market analysis based on treatment with angioplasty or atherectomy. THE SAGE GROUP 2012 and Kolte D. Circulation 2017;136:167-76.

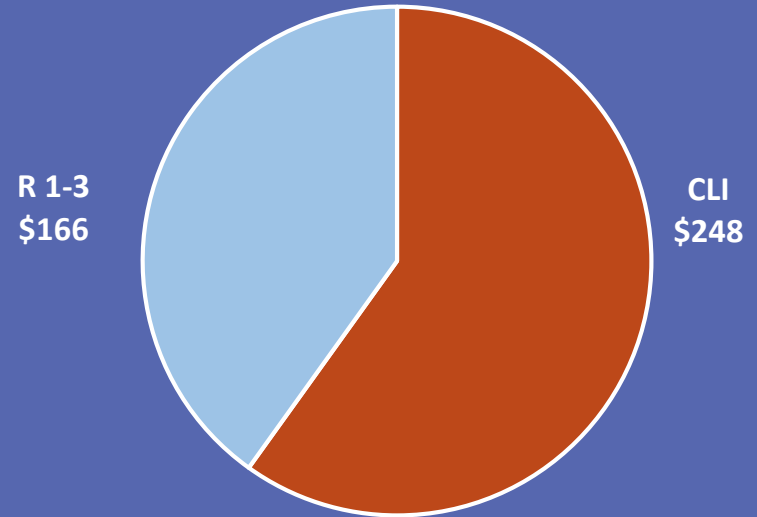


# CLI COSTS ARE THE MAJORITY OF PAD COSTS

**U.S. REACH \$134 Billion**



**U.S. Managed Care \$248 Billion**



Source: Mahoney EM. Circ Cardiovasc Qual Outcomes 2008;1:38-45, Margolis J. J Manag Care Pharm 2005;11(9):727-24, Reinecke H. Eur J 2015; Eur Heart J. 2015 Apr 14;36(15):932-8 and THE SAGE GROUP estimates.

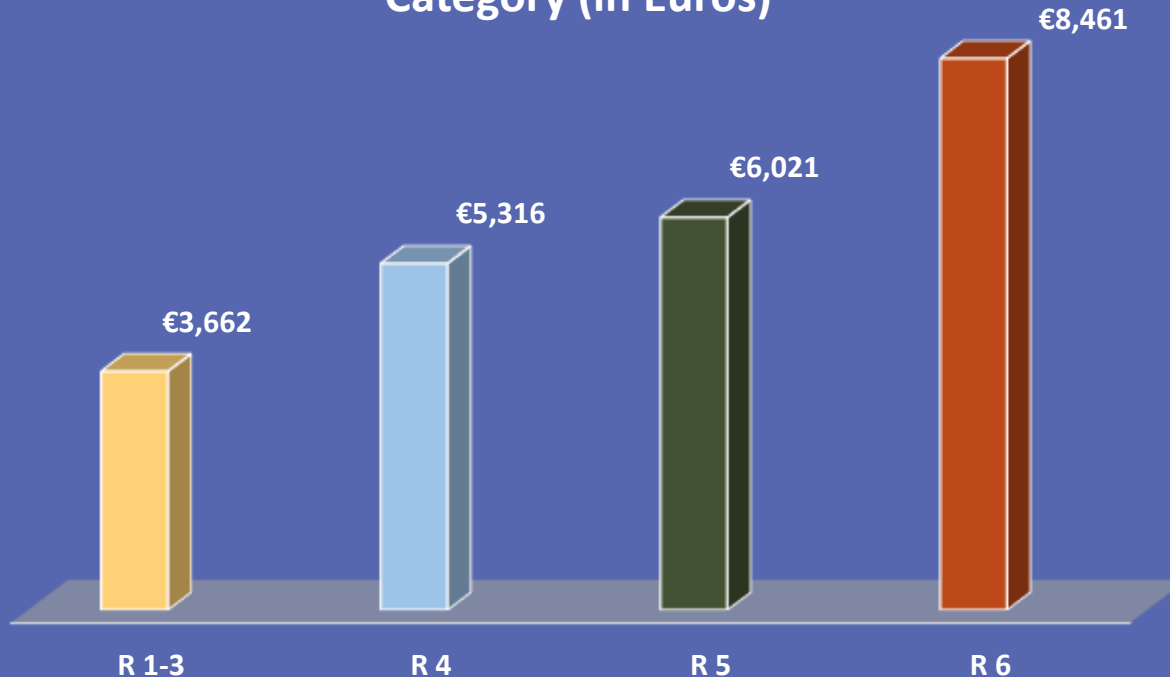
# WHY IS CLI SO COSTLY?

- ❖ **COSTS INCREASE WITH SEVERITY OF RUTHERFORD CATEGORY TREATED**
- ❖ **RISK FACTORS UNDERTREATED→INCREASED MORBIDITY & MORTALITY**
- ❖ **HIGH RATE OF UNPLANNED READMISSIONS**
- ❖ **TREATMENT W/ AMPUTATION VERSUS REVASCULARIZATION—  
REVASCULARIZATION UNDERUTILIZED EVEN VS IC PTS!**

Source: Reinecke H. Eur Heart J. 2015 Apr 14;36(15):932-8, Malyar N. Eur Heart J 2013;34:2706-14, Armstrong EJ. J Am Heart Assoc 2014;3:e000697, Howard DPJ. Circulation 2015;132:1805-15, Chung J. J Vasc Surg 2013;58:972-80, Yost PAD real cost 2011, Mahoney EM. Circ Cardiovasc Qual Outcomes 2008;1:38-45, Mahoney EM. Circ Cardiovasc Qual Outcomes 2010;3:642-51, Agarwal S. J Am Coll Cardiol 2017;69:1897-908, Kolte D. Circulation 2017;136:167-76, and Reed GW. J Am Heart Assoc 2016, May 20;5(5):pii.e003168,

# TREATMENT COSTS INCREASE WITH DISEASE SEVERITY

Mean Inpatient Treatment Costs by Rutherford Category (in Euros)



Source: : Reinecke H. Eur J 2015; Eur Heart J. 2015 Apr 14;36(15):932-8 .

# **CLI PATIENTS UNDERTREATED FOR RISK FACTORS**

## **RISK FACTOR MODIFICATION THERAPIES UNDERUTILIZED**

**Statins prescribed in 50%-62%,**

**Antiplatelets in 60%-90%**

**Anti-hypertensives in only 53%-71%**

**GLUCOSE INADEQUATELY CONTROLLED IN 40%**

**SMOKING PERSISTS IN 27%-52% OF CLI PATIENTS**

**RISK FACTORS UNDERTREATED EVEN COMPARED WITH IC PATIENTS!**

# INADEQUATE MEDICAL MANAGEMENT INCREASES MAJOR ADVERSE EVENTS & DEATH

❖ **SUBOPTIMAL MEDICAL MANAGEMENT INCREASES  
RISK OF AMPUTATION AND/OR DEATH 8X**

❖ **LEADS TO MAJOR ADVERSE CARDIAC AND LEG  
EVENTS AND INCREASES COSTS**

Source: Armstrong EJ. J Am Heart Assoc 2014;3:e000697, Howard DPJ. Circulation 2015; 132: 1805-15, Chung J. J Vasc Surg 2013; 58:972-80, Yost PAD real cost 2011 THE SAGE GROUP, Mahoney EM. Circ Cardiovasc Qual Outcomes 2008; 1:38-45 and Mahoney EM. Circ Cardiovasc Qual Outcomes 2010;3:642-51,

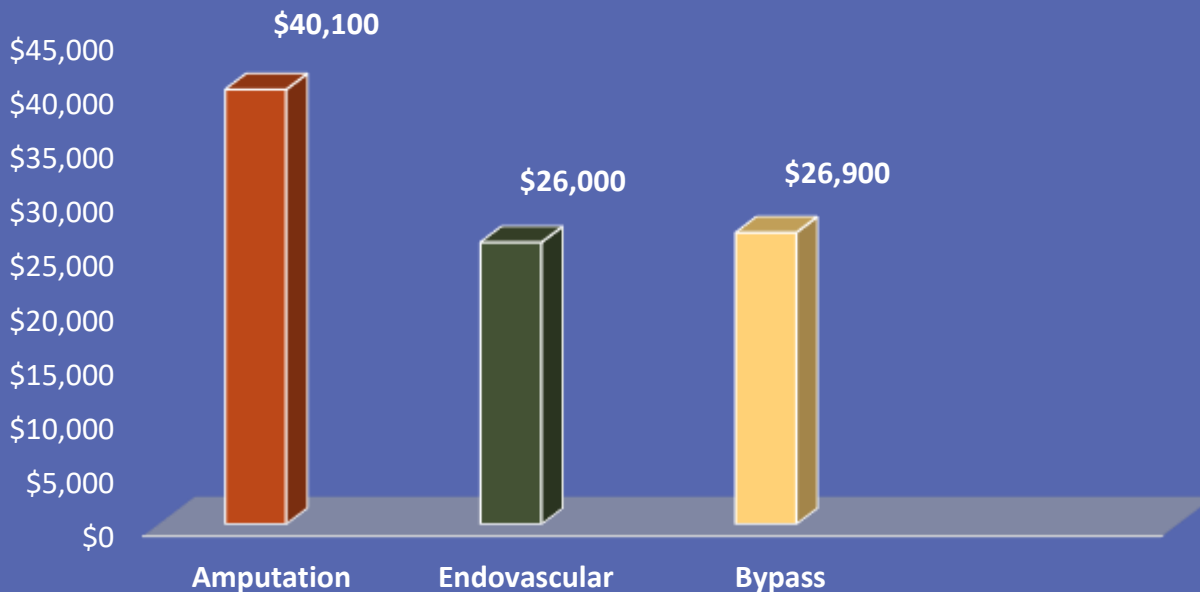
# HIGH RATE OF CLI READMISSIONS INCREASES COSTS

- ❖ READMISSION RATES: 30-DAY 20%-27% & 6-MO 57% VS ISCHEMIC STROKE 12% @ 30 DAY
- ❖ MAJORITY OF READMISSIONS UNPLANNED
- ❖ ONLY 22%-33% DUE TO PRIMARY CLI-RELATED CAUSES, REST DUE TO VARIOUS NON-CLI REASONS: INFECTIONS, PROCEDURE COMPLICATIONS, CVD EVENTS, DIABETES-RELATED NON-VASCULAR PROBLEMS AND OTHER COMORBIDITIES
- ❖ UNPLANNED READMISSIONS INCREASE MORTALITY, MALE & COSTS (\$624 MILLION)

Source: Agarwal S. J Am Coll Cardiol 2017;69:1897-908, Kolte D. Circulation 2017;136:167-76, Vahidy FS. Stroke 2017, April. [Epub ahead of print]. pii. STROKEAHA.116.016085, Reed GW. J Am Heart Assoc 2016, May 20;5(5):pii.e003168, Duwayri Y Ann Vasc Surg 2017; 36:7-12, and Bodewes TC. J Vasc Surg 2017;65(2):484-94.

# AMPUTATION COSTS MORE THAN REVASCULARIZATION

## Per Patient Total Cost\* of Major Amputation, Endovascular & Bypass



\*Total Cost = Procedure Cost + Morbidity, Mortality & Revisions

Source: THE SAGE GROUP estimates.

# CLI - PATHWAY TO AMPUTATION

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



# MAJOR AMPUTATION

**65,000-80,000** Major Amputations Performed Annually

**25%-33% CLI Patients Undergo Primary Amputation (PA)**

Source: Yost ML. Cost-benefit analysis of critical limb ischemia in the era of the Affordable Care Act. Endovasc Today 2014, May, Henry AJ. J Vasc Surg 2011; 53(2): 330-9el and Baser O. Vasc Dis Mgmt 2013;10(20):E26-36.

# **MAJOR AMPUTATION ANNUAL 2015 ECONOMIC COST\***

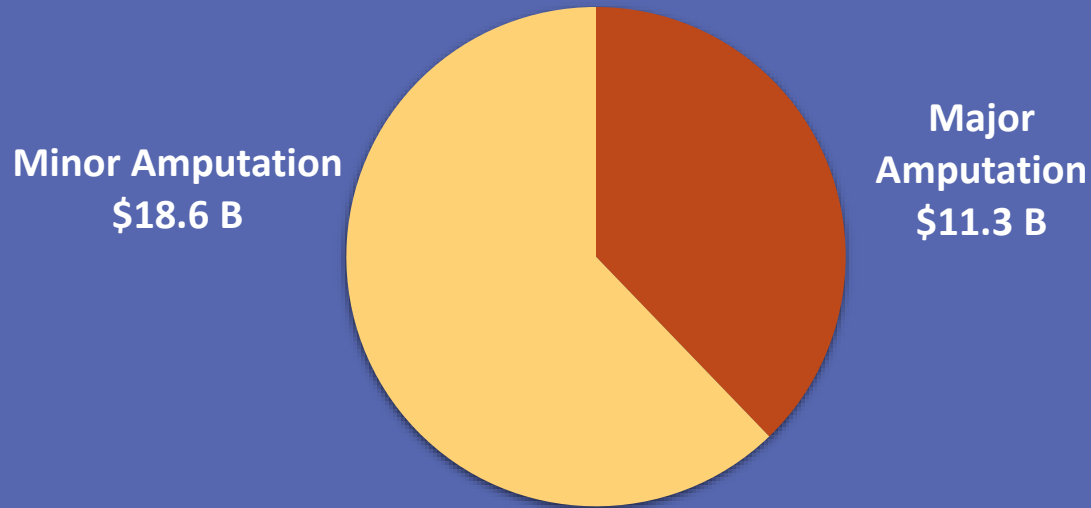
## **\$11.3 BILLION**

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

Source: Dillingham TR. Arch Phys Med Rehabil 2005;86:480-6 and Yost ML. Cost-benefit analysis of critical limb ischemia in the era of the Affordable Care Act. Endovasc Today 2014, May.

# TOTAL AMPUTATIONS 200,000 COST \$29.9 BILLION

2015 Amputation Cost by Type



Source: Dillingham TR. Arch Phys Med Rehabil 2005; 86: 480-6, HCUP Queries Amputation, Medicare 5% sample and THE SAGE GROUP estimates.

# \$11 BILLION UNDERSTATES MAJOR AMPUTATION COSTS

**Total Costs: \$67\* Billion**

- ❖ \$46 billion life-time costs
- ❖ \$9-\$10 billion annual patient costs (eg, medical, home care, handyman, architectural modifications, wheelchair, lift or ramp van, medical equipment, prostheses)

**Economic costs of death to society – How much?**

\*2015 \$

Yost. Endovascular Today, 2014. Alexander Law Group, LLP. Palli S. Value in Health. 2016;19(3):A45 and THE SAGE GROUP estimates.

# AMPUTATION LOTTERY

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

Source: Henry AJ. J Vasc Surg 2011; 53(2): 330-9el, Baser O. Vasc Dis Mgmt 2013: 10(20); E26-36, Goodney PP. Cardiovasc Qual Outcomes 2012; 5:94-102. Jones WS. J Am Coll Cardiol 2012; 59(13s1):E1670, Margolis DJ. Diabetes Care. 2011; 34(11):2363-7 and Eslami MH. J Vasc Surg 2007; 45: 55-9.

# ENDOVASCULAR PATIENT OUTCOMES

- ❖ Discharge status: 65% home; 17% skilled nursing facility or rehabilitation; 16% home healthcare
- ❖ In-hospital mortality: 1.7%
- ❖ Ambulation (2-year)
  - ❖ 81% walking
  - ❖ 88% living independently
- ❖ Revascularization (18-month): 30%-40%
- ❖ Mortality (2-year): 16%-24%

# AMPUTATION PATIENT OUTCOMES

- ❖ Discharge status: Only 11%-24% go home routinely, majority (73%) go to another institution (skilled nursing facility, rehabilitation)
- ❖ In-hospital mortality: 3.4%
- ❖ Ambulation: 60%-80% cannot walk
- ❖ Depression: 35%
- ❖ Mortality (2-year): 30%-50% (frequently MI)
- ❖ Contralateral amputation: 36%-50%

Allie DE. *Eurointervention*. 2005;1(1):60-69. Belmont PJ. *J Am Coll Surg*. 2011;213:370-378. Dillingham TR. *Arch Phys Med Rehabil*. 2005;86:480-486. AHRQ. Healthcare Cost and Utilization Project. HCUP Query Outcomes 84.14-84.17. Dillingham TR. *PMR*. 2011;3(4):336-344. Dormandy JA. *J Vasc Surg*. 2000;31(Suppl):S1-S296. Jackson. Slide presentation at Vascular Annual Meeting. 2011. Jencks SF. *N Engl J Med*. 2009;360:1418-1428. Norgren L. *J Vasc Surg*. 2007;45(suppl):S1-S67. Yeager RA. Rutherford. *Vascular Surgery*. 2005;2474-2481. Subramaniam B. *Anesth Analg*. 2005;100:1241-1247. Gardner SJ. *Endovascular Today* 2011;10(8):38-44 and Yost. *Endovascular Today*, 2014.

# AMPUTATION: MORE PATIENT OUTCOMES

## ❖ Lengthy healing process

- ❖ At 100 days, 45% BKA and 24% AKA not healed

## ❖ Quality of life reduced

- ❖ Severe physical impairment in ambulation, body care, movement, and mobility

## ❖ Chronic pain 95%

- ❖ Phantom limb pain: 79%-80%
- ❖ Residual limb pain: 68%-74%
- ❖ Back pain: 52%-62%

Source: Nehler MR. J Vasc Surg. 2003;38(1):7-14, Peters EJG. Diabetes Care. 2001;24(10):1799-1804, Ephraim PL. Arch Phys Med Rehabil. 2005;86:1910-1919, Ehde DM. Arch Phys Med Rehabil. 2000;81:1039-1044.



# CONCLUSIONS

- ❖ PAD IS HIGHLY PREVALENT AND COMMONLY UNDERESTIMATED
- ❖ PAD MACROECONOMIC COST IS HIGH \$223-\$414 BILLION
- ❖ 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 COMBINED

# CONCLUSIONS

- ❖ ASYMPTOMATIC PATIENTS COST MORE THAN IC PATIENTS—COSTS DUE TO CARDIOVASCULAR EVENTS AND HOSPITALIZATIONS
- ❖ MORTALITY AND AMPUTATION INCREASE WITH DISEASE SEVERITY
- ❖ PAD COSTS INCREASE WITH DISEASE SEVERITY—EARLIER DIAGNOSIS AND TREATMENT LIKELY TO REDUCE COSTS
- ❖ CLI ACCOUNTS FOR MAJORITY OF PAD COSTS—\$134 TO \$248 BILLION

# CONCLUSIONS

- ❖ CLI COSTS INCREASED BY: TREATMENT AT MORE SEVERE DISEASE STAGES, UNDERTREATMENT OF RISK FACTORS, UNPLANNED READMISSIONS AND TREATMENT WITH PRIMARY AMPUTATION
- ❖ OPTIMAL MEDICAL MANAGEMENT UNDERUTILIZED IN CLI— INCREASES RISK OF AMPUTATION AND/OR DEATH 8X
- ❖ 65,000-80,000 MAJOR AMPUTATIONS COST \$11 TO \$67 BILLION
- ❖ PATIENT OUTCOMES AFTER AMPUTATION ARE POOR VERSUS ENDOVASCULAR REVASCULARIZATION
- ❖ MORE RESEARCH IS NEEDED ON PAD & CLI COSTS & CONSEQUENCES

**THANK YOU!**



**CAT ISLAND \* BEAUFORT, SC**