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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

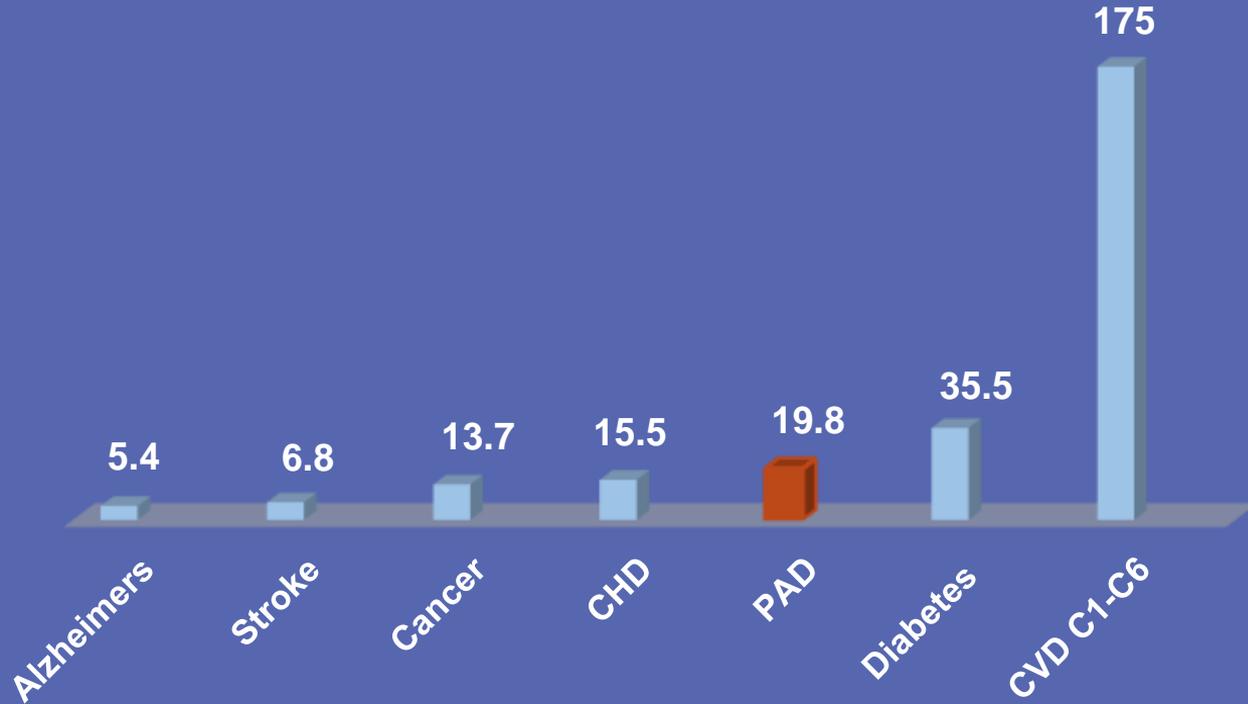
Pluristem

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/ PARTNERS (Mill)	DIABETES METHOD (Mill)	NEHLER (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*

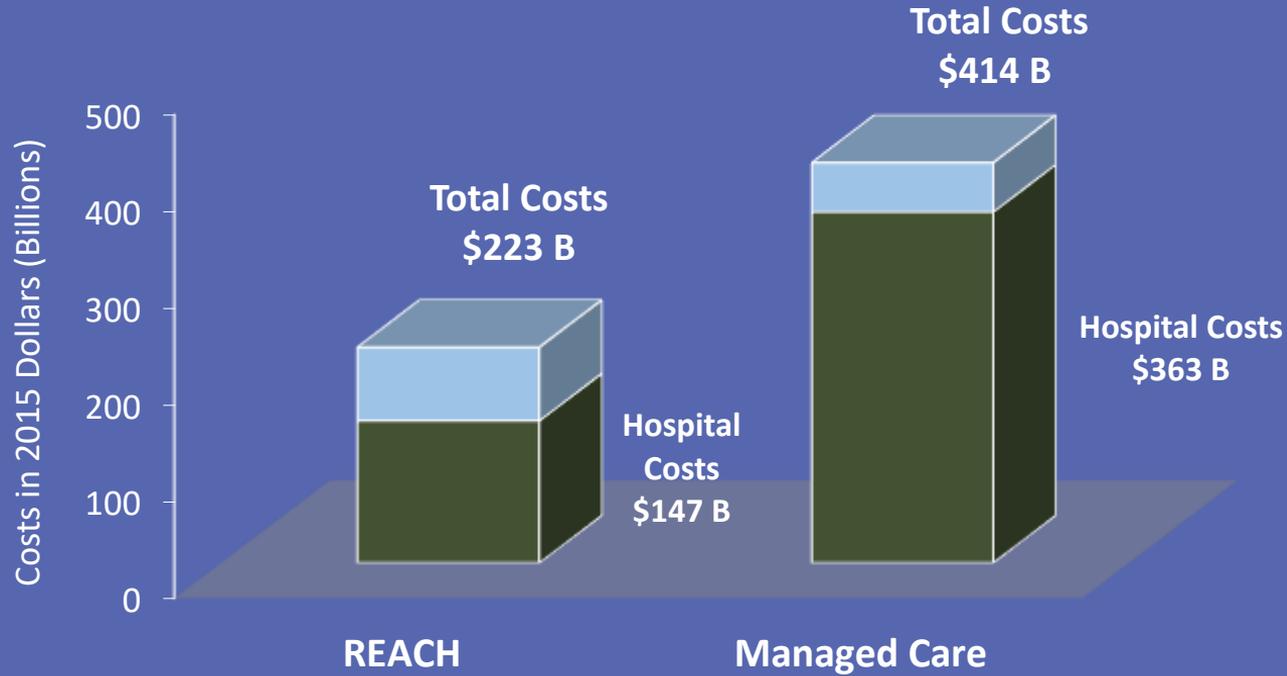
*Total Costs Inpatient and Outpatient in 2015

\$223[†]-\$414[‡] BILLION

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

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

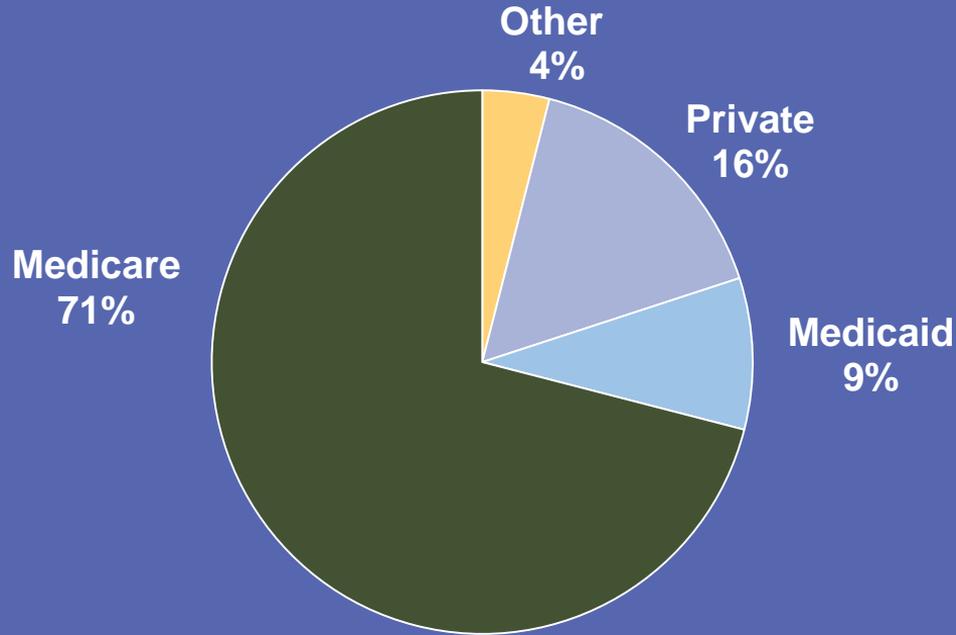
HOSPITAL COSTS REPRESENT MAJORITY OF PAD COSTS



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)

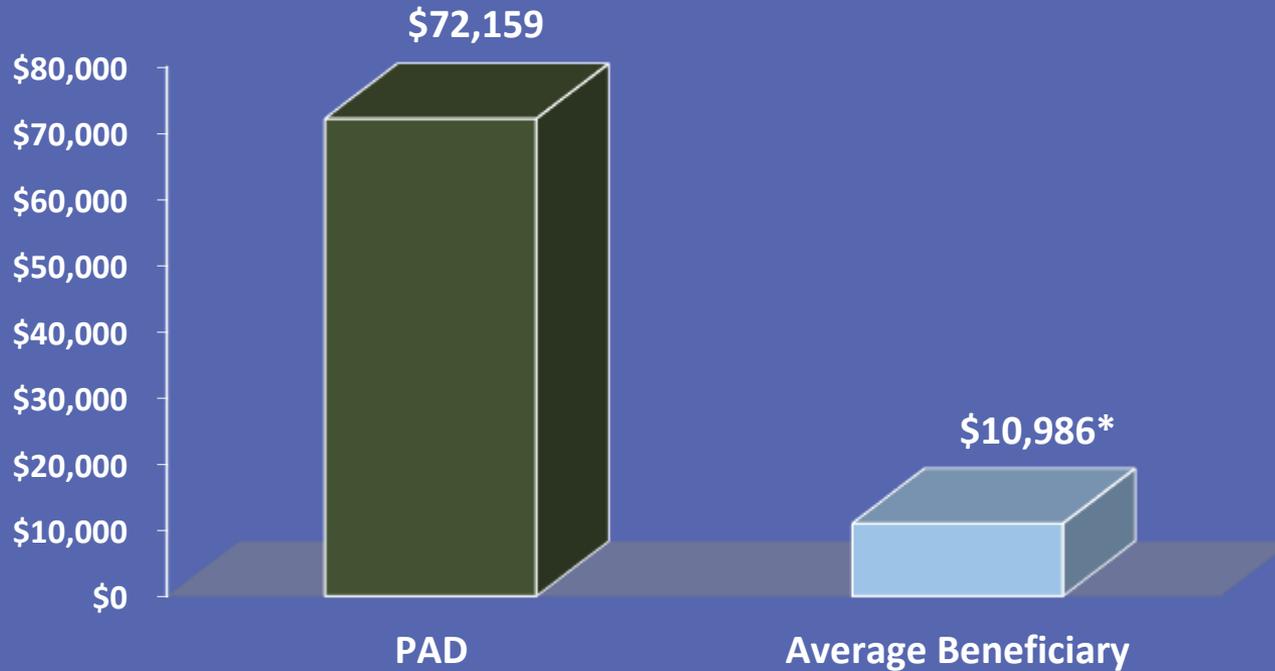
AK Amputation

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.

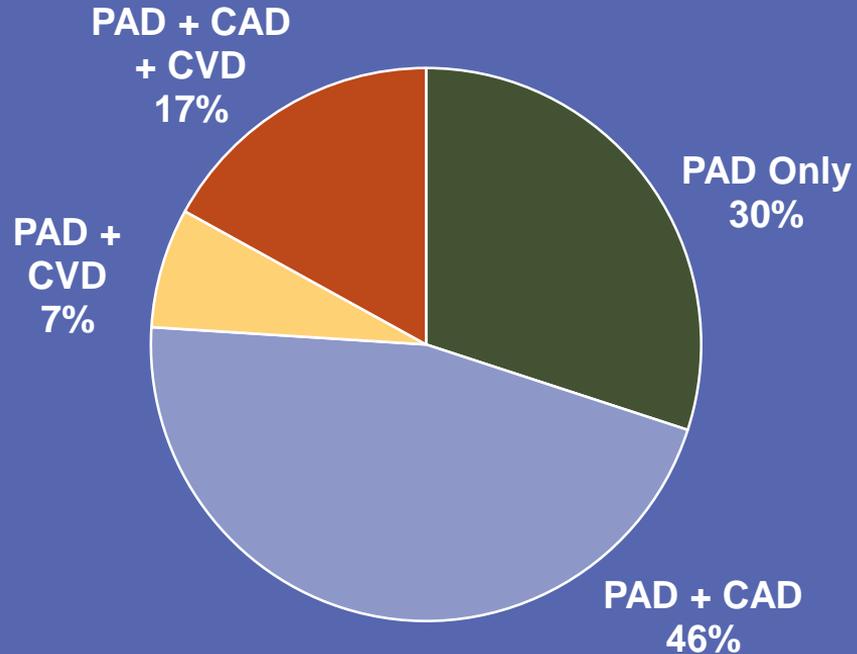
2015 ANNUAL MEDICARE EXPENDITURES



*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.

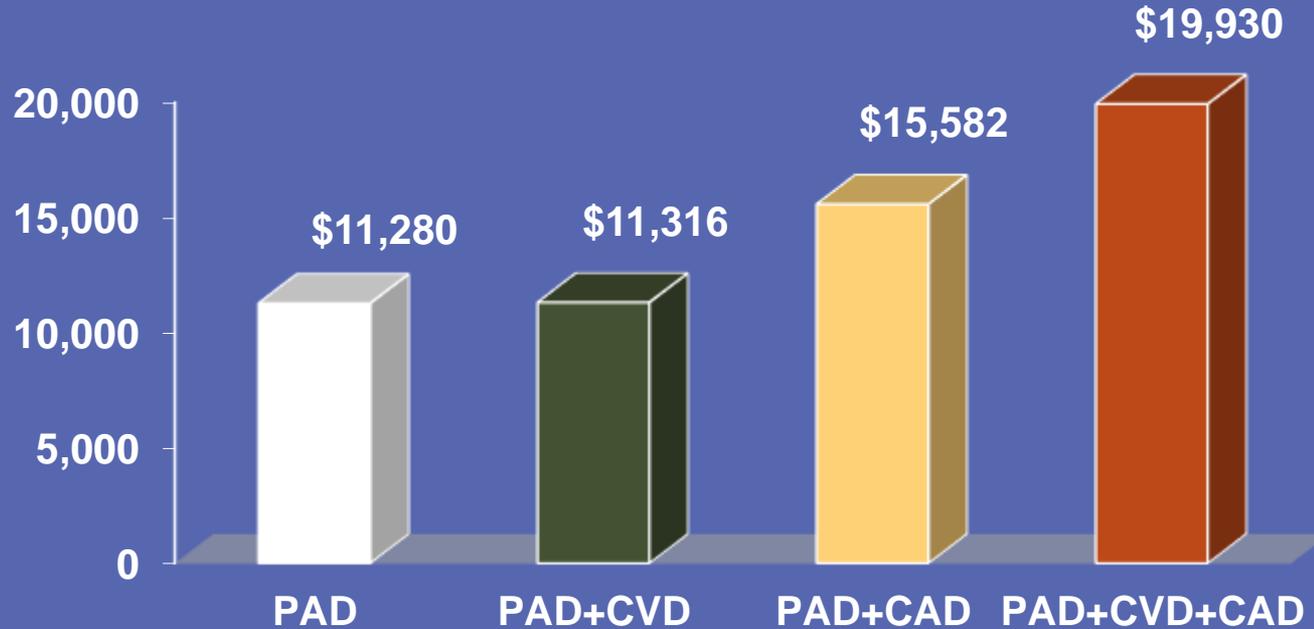
POLYVASCULAR DISEASE IN PAD PATIENTS



Source: Mahoney EM. Circ Cardiovasc Qual Outcomes 2010;3:642-51.

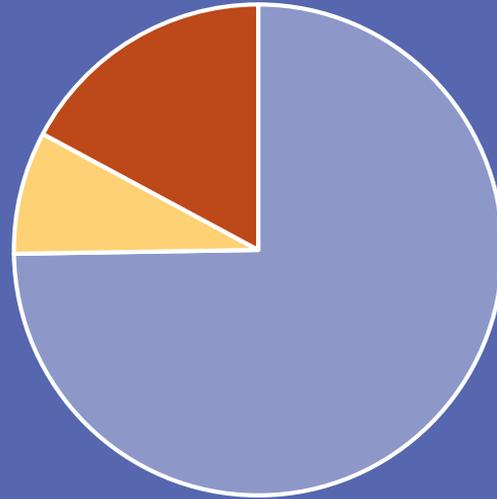
POLYVASCULAR DISEASE COSTS MORE

2015 Total Annual Cost



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

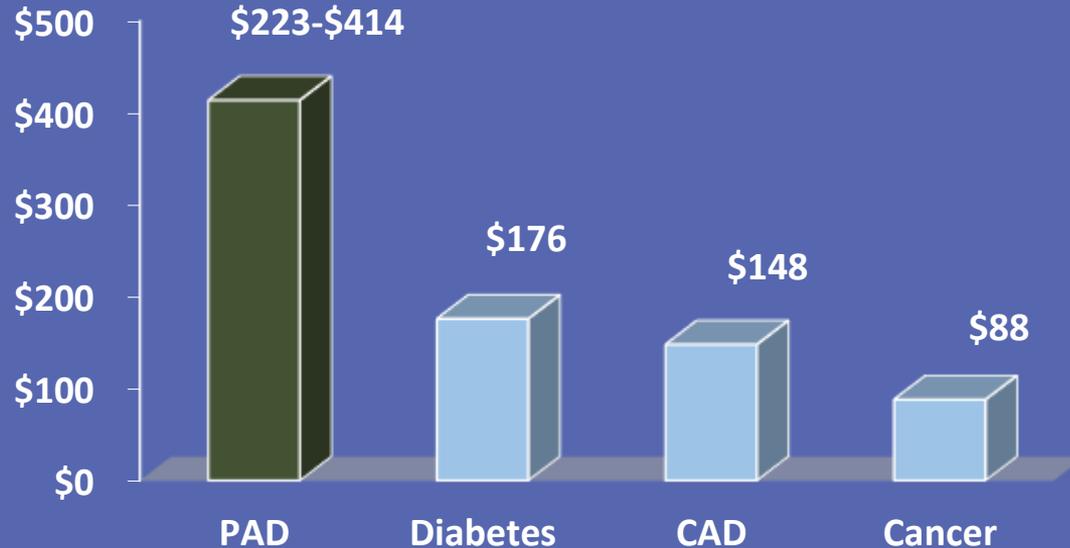
Cost 2-year \$14,084

Costs Due to:

CVD Events, Hospitalizations & Revascularizations

2015 ANNUAL ECONOMIC BURDEN*

(Billions \$)

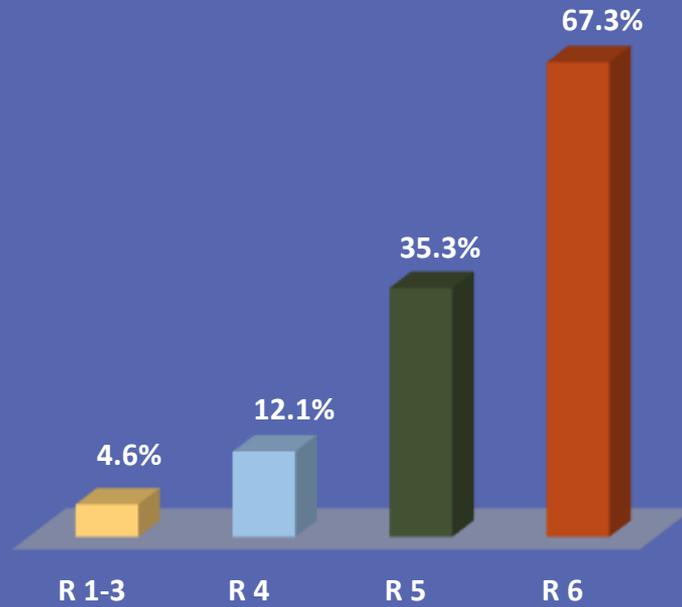


*Direct costs in the United States: PAD & CAD costs inflated to 2015 \$. Direct cost of diabetes is 2012 and cancer 2014.

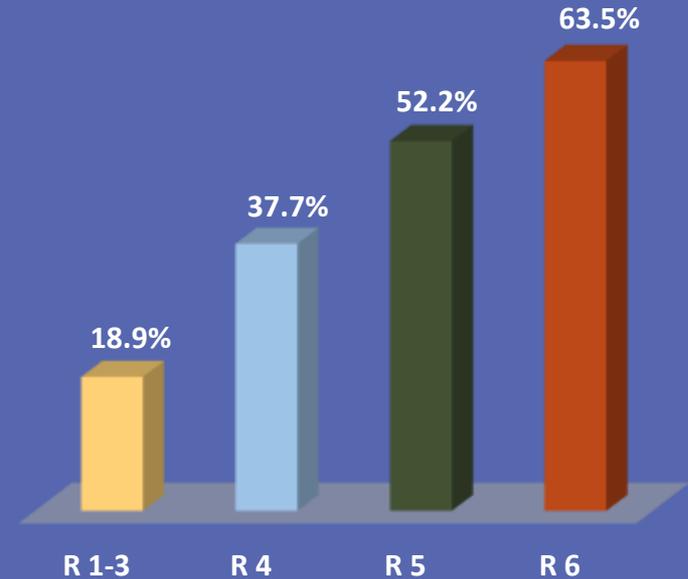
Source: Yost ML. Real cost of PAD 2011 THE SAGE GROUP, Mahoney EM. Circ Cardiovasc Qual Outcomes 2008;1:38-45, American Cancer Society website and ADA Diabetes Care 2013;36(4):1033-46.

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

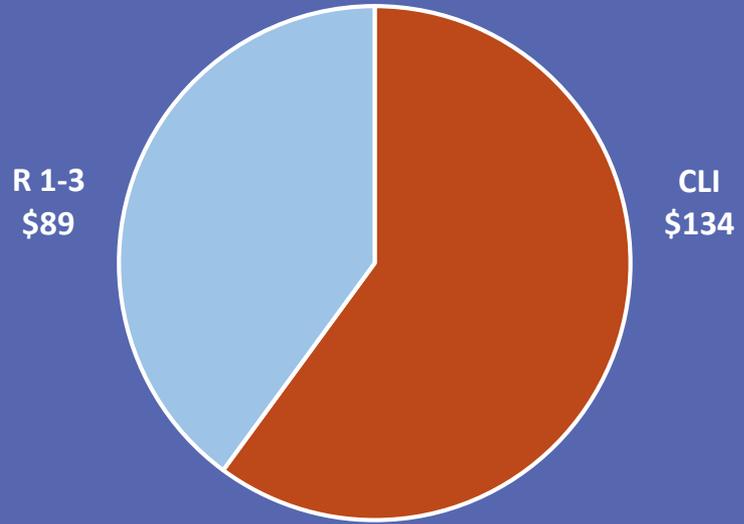
2.0-3.4 Million

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

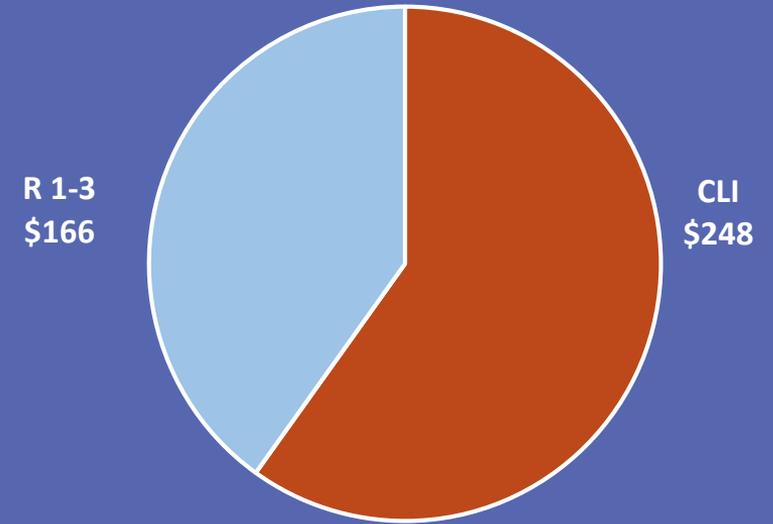
Source: Yost. CLI US supplement 2016 THE SAGE GROUP, Nehler MA. J Vasc Surg 2014;60:686-95 and Yost ML. PAD. Interventional market analysis based on treatment with angioplasty or atherectomy. THE SAGE GROUP 2012 and Kolte D. Circulation 2017;136:167-76.

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,

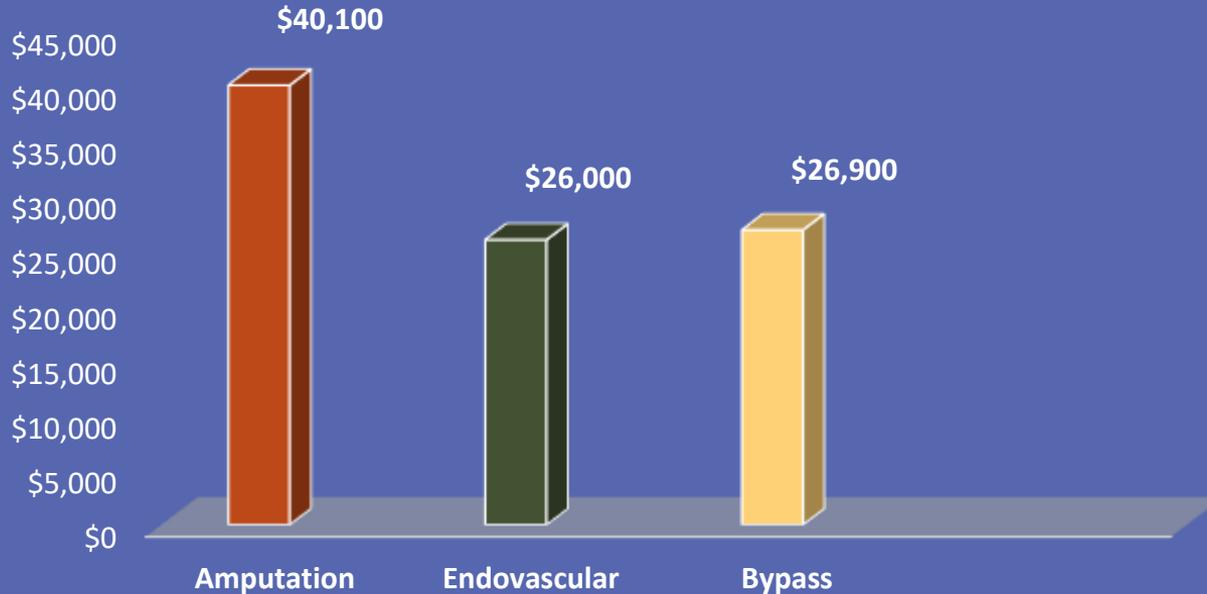
HIGH RATE OF CLI READMISSIONS INCREASES COSTS

- ❖ **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): 330-9e1 and Baser O. Vasc Dis Mgmt 2013;10(20):E26-36.

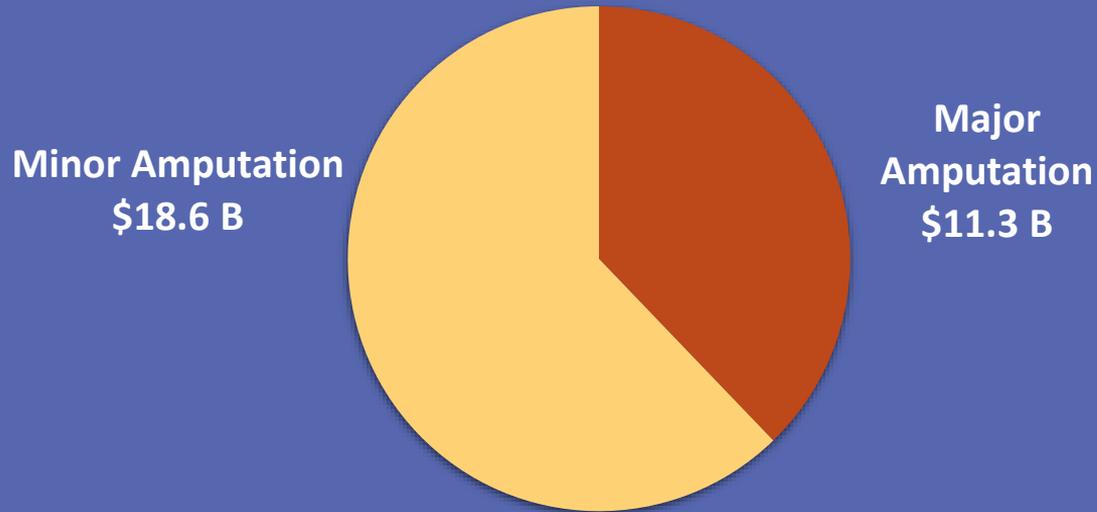
MAJOR AMPUTATION ANNUAL 2015 ECONOMIC COST*

\$11.3 BILLION

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

TOTAL AMPUTATIONS 200,000 COST \$29.9 BILLION

2015 Amputation Cost by Type



\$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%

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%

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