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ICD-10-PCS Code Request for Insertion of Sustained Release Drug-Eluting Stent(s)

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September 11, 2018

Agenda

1. Coding issue
2. Critical Limb Ischemia
   a. Disease overview
   b. Current therapies
   c. SAVAL™ Drug-Eluting Vascular Stent System
3. Clinical evidence development
4. Rationale for new ICD-10-PCS

Requested Updates to ICD-10 Coding

The existing coding system does not support accurate reporting and tracking of BTK sustained release drug eluting stent procedures for patient outcomes, cost and any device-related complications for data analysis

Current 047 ICD-10 Coding Table

The coding table provides for drug-eluting peripheral vessel stent(s) insertion for below the knee arteries for anterior tibial, posterior tibial and peroneal.

The coding table provides a designation for drug-eluting in the device column.

Gaps

Tibio-peroneal trunk is an additional possible location for insertion and is not provided as a body party in the 047 coding table.

The SAVAL DES Vascular Stent System goes beyond drug eluting designation and is the only technology expected to provide controlled sustained drug release.

Proposed Modification

A body part addition for tibio-peroneal trunk is requested for accurate coding and tracking for the stent insertion in this specific vessel.

A new device value is requested to allow for distinct coding for a sustained drug release stent for accurate coding and tracking for the new technology

Critical Limb Ischemia (CLI) Disease Overview

Disease Description

Terminal stage of obstructive, atherosclerotic PAD

- Patients affected by critical limb ischemia are the most complex subset of those with peripheral arterial disease and typically bear the long-term pathological consequences of hypertension, hyperlipidemia, diabetes mellitus, and renal failure.[1]

Limb loss and pain

- When left untreated, CLI caused major amputation in 73% of the patients with rest pain and in 95% of the patients with tissue loss at 1 year.[2]

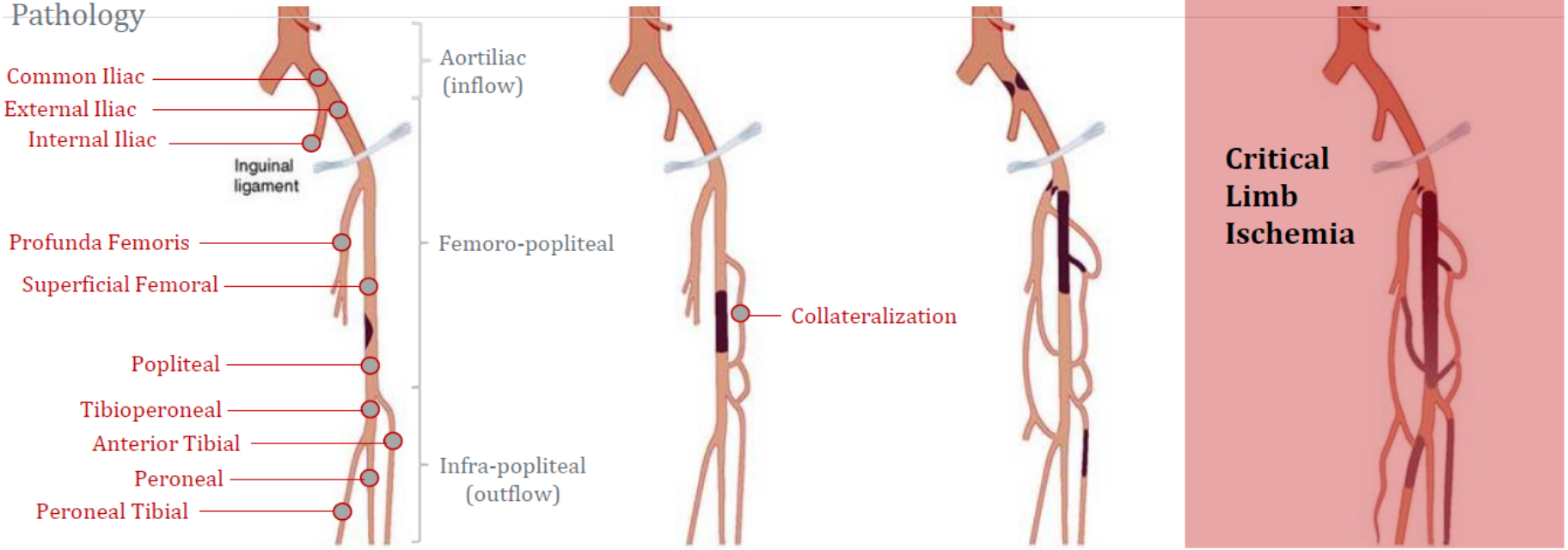
Diabetics

- Diabetics with CLI are at particularly high risk for advanced complications; studies indicate that within one year of CLI diagnosis, 40% to 50% of diabetics will experience an amputation.[3]

Sources:
1. Mustapha, JA, Et. Al. Percutaneous Transluminal Angioplasty in Patients With Infrapopliteal Arterial Disease: Systematic Review and Meta-Analysis. Circ Cardiovasc Interv. 2016 May;9(5)]
2. Karnabatidis D, Katsanos K, Siablis D. Infrapopliteal stents: overview and unresolved issues. J Endovasc Ther. 2009;16(suppl 1): 1153- 162.
3. Elsayed et. al. (2015). Critical limb ischemia. *Cardiol Clin.,* 33(1), 37-47.

Pathology and Staging of PAD-CLI

Fontaine	Stage IIA	Stage IIB		Stage III-IV
Rutherford	Stage 1	Stage 2	Stage 3	Stage 4-6
Symptom Complex	Start of **Mild Claudication**	Start of **Moderate Claudication**	Start of **Severe Claudication**	Start of **Rest Pain, Ulcer, Gangrene**
Pathology				



[1] Vascular and endovascular surgery, A.W. Bradbury, Clnicalgate 2015

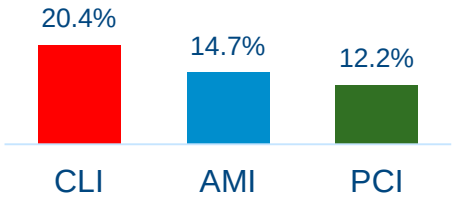
Claudication = cramping pain while walking

Burden of CLI

Economic Challenges

U.S. national estimate of aggregate costs of all index CLI admissions[1]

30 Day Hospital Readmissions[1]



Medicare Challenges

Incidence Among Medicare Beneficiaries[2]

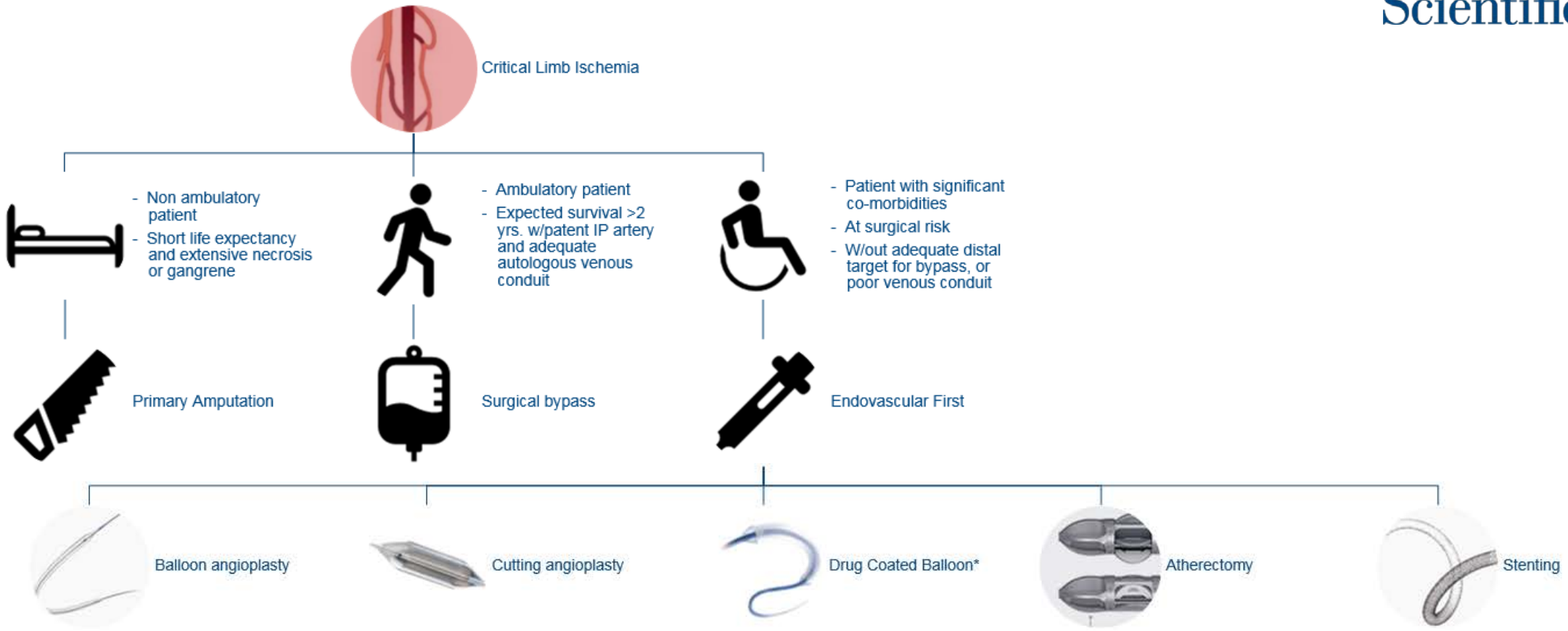
- Ages 65 – 69, 0.13%
- Ages 85+, 0.31%

Primary Amputation within One Year of Diagnosis[2]

33% (among Medicare beneficiaries)

Sources:
1. Kolte D, et. Al., Thirty-Day Readmissions After Endovascular or Surgical Therapy for Critical Limb Ischemia: Analysis of the 2013-2014 Nationwide Readmissions Databases. Circulation. 2017 May 2.
2. Prevalence, incidence, and outcomes of critical limb ischemia in the US Medicare population, Baser, Vasc Dis Manag 2013.

Treatments for CLI Disease



Sources:
1. Gray BH, Diaz-Sandoval LJ, Dieter RS, Jaff MR, White CJ; Peripheral Vascular Disease Committee for the Society for Cardiovascular Angiography and Interventions. SCAI expert consensus statement for infrapopliteal arterial intervention appropriate use. Catheter Cardiovasc Interv. 2014;84:539–545.

* Boston Scientific has received CE Mark for the Ranger™ Drug-Coated Balloon. In the U.S., the Ranger drug-coated balloon is an investigational device and not available for sale.

Impact of Endovascular Therapies

+	Current standard of care[2]	May be appropriate for lesions resistant to PTA	Anti-proliferative drug	Remove plaque to allow lesion crossing	Prevent vessel recoil, DES anti-proliferative drug
−	High restenosis rates, no impact on vessel recoil	High restenosis rates, no impact on vessel recoil	Equivalent long-term results as PTA, no impact on vessel recoil	High restenosis rates, no impact on vessel recoil	No approved BTK stent for use in the U.S.

Sources:
1. Gray BH, Diaz-Sandoval LJ, Dieter RS, Jaff MR, White CJ; Peripheral Vascular Disease Committee for the Society for Cardiovascular Angiography and Interventions. SCAI expert consensus statement for infrapopliteal arterial intervention appropriate use. Catheter Cardiovasc Interv. 2014;84:539–545.
2. Rand T, Uberoi R. Current status of interventional radiology treatment of infrapopliteal arterial disease. Cardiovasc Intervent Radiol. 013;36:588– 598.

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Need for Novel Intervention

Biological Challenge for Current Endovascular Therapies	Implications	Need for a new solution: Sustained Release Drug Eluting BTK Stent
Long diffuse lesions	PTA: High rate of vessel recoil, dissections	• Mitigate recoil, dissection
High levels of calcification	DCB: Optimal drug uptake may be limited	• Calcification not an impediment
High incidence of re-occlusions	All: frequent re-treatment	• Longer patency, reduced re-interventions

Clinical Benefit

The SAVAL™ Drug-Eluting Vascular Stent System is expected to provide a clinically meaningful advantage over existing on-label treatments to prevent vessel recoil, provide a more durable vessel patency, and reduction in target limb revascularization in CLI patients.

Purpose built stent for below the knee

Specialty polymer release kinetics, providing a sustained release (~1 year)

Timing of restenosis is longer compared to coronary stenting

CAUTION: The Saval Drug-Eluting Vascular Stent System is an investigational device and not available for sale in the US.

The SAVAL™ Pivotal Trial

FDA Expedited Access Pathway Program

"for certain medical devices that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions"[1]

EAP Designation for SAVAL

- First EAP designation in peripheral branch of FDA
- EAP accelerates market approval by ~2 years

SAVAL™ Pivotal Trial

Randomized trial comparing the SAVAL vs PTA in treating infrapopliteal lesions in subjects with critical limb ischemia:

- Randomized 2:1 DES vs PTA
- N=~300
- 6 month primary patency endpoint
- Expect first enrollments in Q3 2018

Sources:
1. Food and Drug Administration, Expedited Access Pathway Program, last accessed at https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/ucm441467.htm on August 6, 2018.

DES BTK RCT Clinical Data
Clinical Outcomes

Study Year (Pts/Lesions)	Control	Patency	TLR (%)	Wound Healing (%)	Minor Amp. (%)	Major Amp. (%)	Death (%)
Falkowski 2009 (50/50)	BMS	84 / 24 6m	12 / 56 6m	NR	NR	NR	NR
YUKON-BTX 2011 (161/161)	BMS	81 / 56 12m	13.8 / 13 12m	**86.4 / 66.6 12m p.**	1.2 / 1.3 12m	1.2 / 1.3 12m	14 / 17 12m
DESTINY 2012 (140/154)	BMS	85 / 24 12m	9 / 34 12m	NR	NR	1.4 / 3.0 12m	17.5 / 15 12m
ACHILLES 2012 (200/228)	PTA	75 / 57 12m	10 / 16.5 12m	72.3 / 56.5 12m c.	10 / 16.5 12m	4 / 4 12m	10 / 12 12m
IDEAS 2014 (50/55)	DCB	72 / 42 6m	**7.7 / 13.6 6m**	50 / 42 6m c.	NR	7.4 / 4.0 6m	12 / 8 6m
PADI 2016 (137/212)	PTA + Bailout	48 / 35 6m	NR	NR	**19 / 27 12m**	**11.4 / 20.5 12m**	23 / 25 12m

Reported as DES vs. control; deeper color indicates that result significantly favored DES; c = wounds completely healed; p = partially healed; bolded text indicates “trend towards” significance

Rationale for new ICD-10-PCS

- Significant unmet meets for CLI patients
- Limited effectiveness of endovascular therapies
- Boston Scientific expects to seek approval for first BTK stent (sustained release DES)
- The existing coding system does not support accurate reporting and tracking of BTK sustained release drug eluting stent procedures for patient outcomes, cost and any device-related complications for data analysis

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Thank you