

Request for APC reassignment for C9755 Procedure (WavelinQ EndoAVF System)

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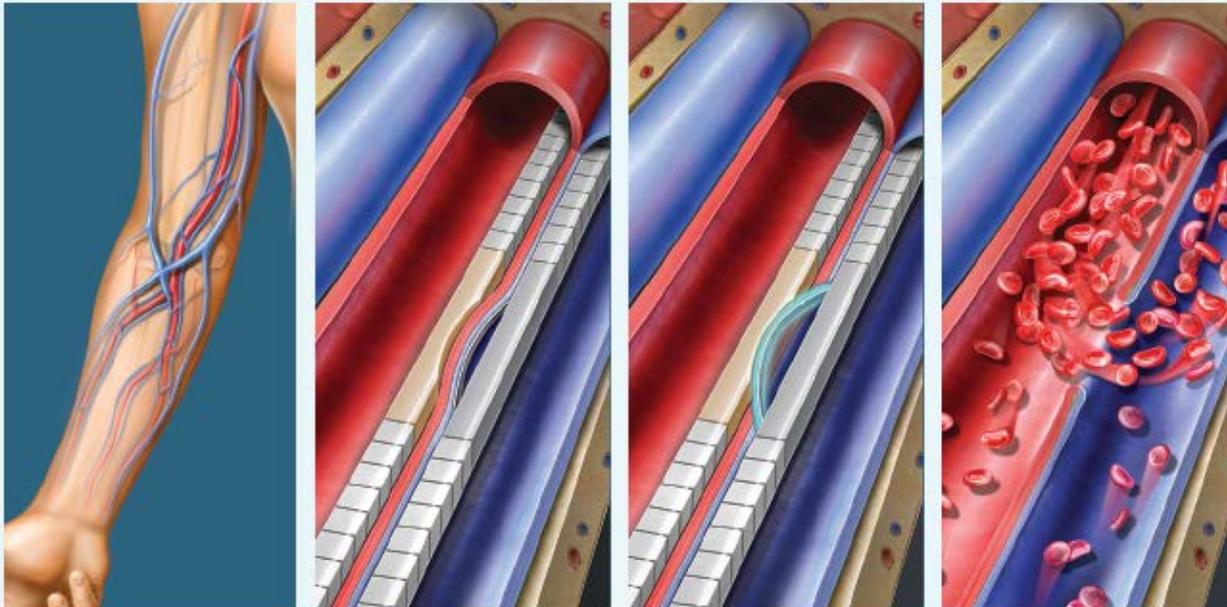
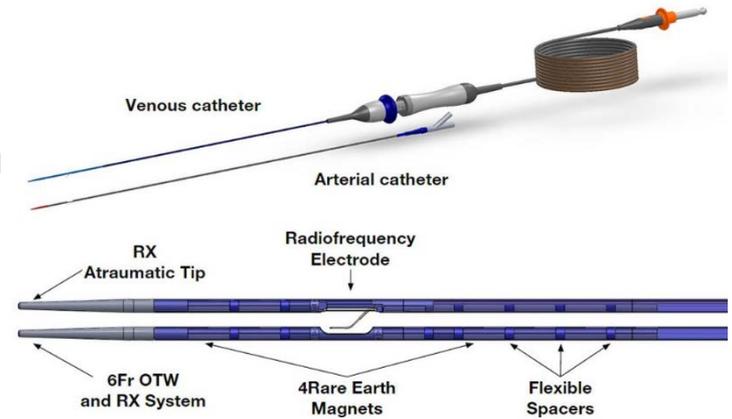


SSM Health Introduction

- **Mission:** Through our exceptional health care services, we reveal the healing presence of God
- **SSM Health is one of the largest employers in every community it serves.**
 - Catholic Not-for-profit comprehensive health system
 - Serving customers in the Midwest
 - Robust and fully integrated health care delivery system
 - Nearly 40,000 employees and 11,000 providers
 - Care delivery sites in Illinois, Missouri, Oklahoma and Wisconsin
 - 23 hospitals and more than 290 physician offices
 - 10 post-acute facilities
 - Comprehensive home care and hospice services
 - Includes a Pharmacy benefit company and Health insurance company
 - Accountable care organization

WavelinQ EndoAVF System

- Endovascular arteriovenous fistula creation
- Utilizes magnets to align catheters
- Deploys RF energy to create a fistula

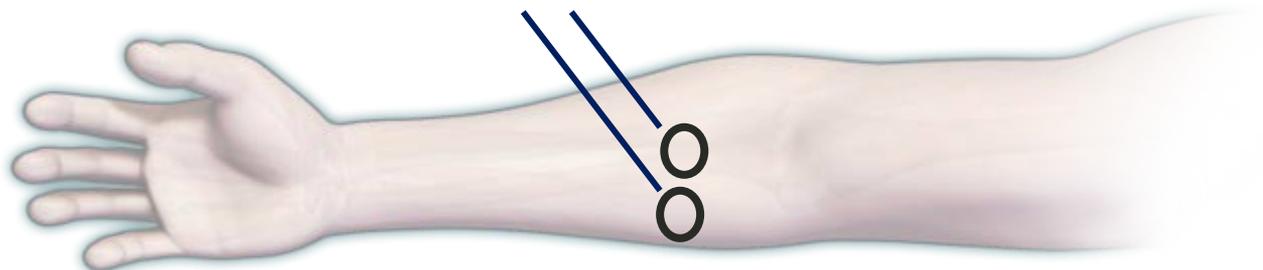


Patient Quality of Care

- Enables the procedure to be done on patients who cannot tolerate general anesthesia
- Avoids surgical scarring and minimizes arm disfigurement associated with open surgery
- Expands anatomic options for AVF creation without eliminating future surgical sites
- Enables multiple cannulation options for patients

WavelinQ 4F EndoAVF System

Ulnar-Ulnar /
Radial-Radial



Multiple Clinical Studies Support the WavelinQ EndoAVF System

Flex Study

N=33

Prospective
Single Center
6F Device

NEAT Study

N=60

Prospective
Multi-Center
6F Device

EASE Study

N=32

Prospective
Single Center
4F Device

Endo AVF Study / EU Post Market Study

N=120

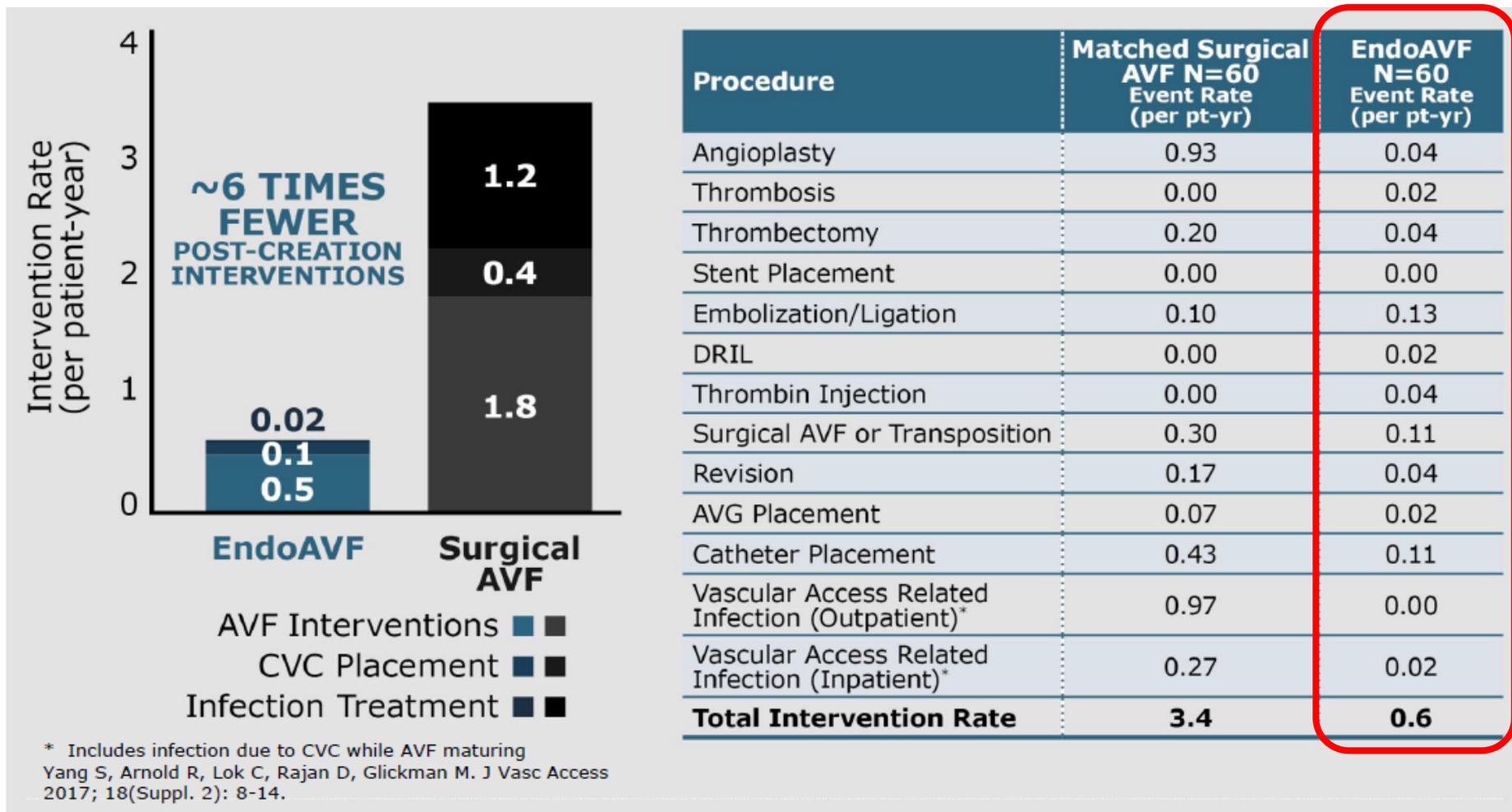
Prospective Multi-
Center
4F Device

Global analysis of 3 prospective, non-randomized, single-arm studies in both dialysis and pre-dialysis patients (4F device)

- **96.7% Procedural success rate**
- **85% 2-needle cannulation at 6 months** (Kaplan-Meier estimate)
- **Time to cannulation – 1.5 months**
- **72% Primary patency at 6 months**
- **<25% Patients required a reintervention at 6 months**

WavelinQ EndoAVF vs. Surgical AVF

Propensity-score matched comparison of NEAT and Medicare patients using a 5% CMS sample of claims data for surgical AVF cohort



Yang S, Lok C, Arnold R, Rajan D, Glickman M, J. Vasc Access 2017; 18(Suppl 2): 8-14

Cost Savings to Payer in the Literature

Arnold et al, J Vasc Inter Radiology 2018

Propensity Score Matched analysis of NEAT study and surgical AVF patients using USRDS data

Difference in per patient-year costs (\$US) between WavelinQ 6F EndoAVF and surgical AVF (positive values imply a cost savings for WavelinQ 6F EndoAVF).¹⁹

	Angioplasty	Thrombolysis	Thrombectomy	Stent placement	Embolization/ligation	Thrombin injection	DRIL (Steal Syndrome)	Revision	Catheter placement	AVG creation	New surgical AVF	Inpatient infection	Outpatient infection	Total Cost Difference
Prevalent Patients	\$6,916	-\$12	\$1,290	\$1,836	\$139	\$0	\$0	\$338	\$474	\$1,129	\$797	\$332	\$151	\$13,389
Incident Patients	\$2,586	\$0	-\$13	\$387	-\$59	-\$14	-\$120	\$1,612	\$1,616	\$621	\$1,642	\$7,332	\$904	\$16,494

Substantial savings vs. surgical AVFs in the following areas:

- Angioplasties
- Stent Placements
- Revisions
- Catheter placements
- New surgical AVFs
- **Inpatient infections**

SSM St. Mary's Real-World WavelinQ Experience

- **35 endoAVF's created since October 2018**
 - 20 of 35 matured for cannulation
 - 7 patients <4 weeks post op (maturing favorably)
 - 5 of 35 patients pending elevation (2 stage planned)
 - 3 of 35 patients failed to mature
-
- **16 of 18 patients 6+ months post op matured for cannulation (89%)**
 - Compares favorably versus published surgical literature
 - Aligns with published studies of endoAVF
-
- **Patient satisfaction with their vascular access has substantially increased**
 - No appreciable recovery time
 - Cosmetic benefits versus conventional surgery
 - Less apprehension to have vascular access created (“procedure vs surgery”)



Economics of C9755

Medicare OPPS payment for C9755 in APC 5193 is \$9,150.97. Conservative estimate of costs is over \$12,500

APC

Valid From	Wage Index	APC Group	CPT Status Indicator	Group Status Indicator	Min Unadjusted Co Ins	Min Adjusted Co Ins	Relative Weight	Adjusted Payment Rate
01 Jan 2019	0.9107	5193	J1	J1	\$1,933.81	\$1,830.20	121.6384	\$9,150.97
01 Apr 2019	0.9107	5193	J1	J1	\$1,933.81	\$1,830.20	121.6384	\$9,150.97
01 Jul 2019	0.9107	5193	J1	J1	\$1,933.81	\$1,830.20	121.6384	\$9,150.97

35 endo AVF's created since October 2018 to July 31, 2019

Payer	# of Proc.	Average Payment
Medicare	11	\$8,995
Anthem BC	6	\$10,864
Humana Gold HMO	2	\$8,064
Essence Medicare	3	\$3,410
Medicaid Missouri	4	\$7,410
Aetna	3	\$8,400
Medicaid – Illinois	1	Pending payment
UHC Choice Select	2	\$11,247
UHC Care	1	\$7,308
UHC Medicare complete	1	\$8,856
UHC UMR PPO	1	Pending payment

Economics of C9755

SSM's average variable cost (no mark up) per case is \$11,480 which includes: Medical Supplies, the magnetic catheters, embolization coils, wires, support staff etc.

APC Group	Status Indicator	Payment Rate	Adjusted Rate	MU Co Ins	NA Co Ins	Rel Weight
Level 3 Endovascular Procedures (5193)	J1	\$9669.04	\$9150.97	\$1933.81	\$0	121.6384

At the current APC rate of \$9,151.00 - all hospital providers are at a deficit when treating these patients. We respectfully request C9755 be moved to a more homogenous APC group to 5194.

APC

Valid From	Wage Index	APC Group	CPT Status Indicator	Group Status Indicator	Min Unadjusted Co Ins	Min Adjusted Co Ins	Relative Weight	Adjusted Payment Rate
01 Jan 2019	0.9107	5194	J1	J1	\$3,070.90	\$2,906.36	193.1626	\$14,531.81
01 Apr 2019	0.9107	5194	J1	J1	\$3,070.90	\$2,906.36	193.1626	\$14,531.81
01 Jul 2019	0.9107	5194	J1	J1	\$3,070.90	\$2,906.36	193.1626	\$14,531.81