

Request for APC reassignment for
C9780 (Insertion of central venous catheter through central
venous occlusion via inferior and superior approaches (e.g.,
inside-out technique), including imaging guidance) using
the Surfacer® Inside-Out® Access Catheter System

Christopher Durham, M.D.
Chief Medical Officer
Vascular and Endovascular Surgeon
Surgery Specialty Hospitals of America
Pasadena, TX



Surgery Specialty Hospitals of America (SSHA)

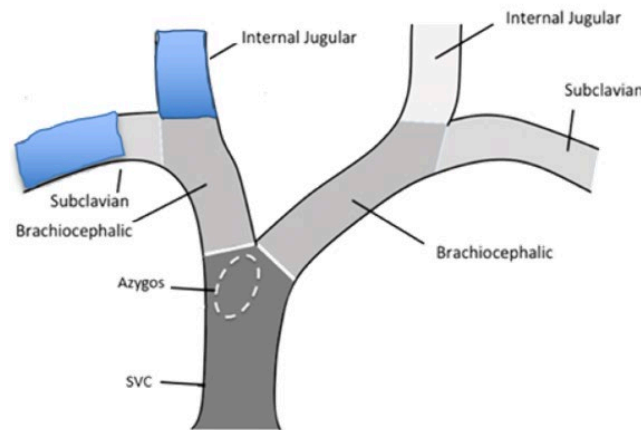
- Well-equipped operating rooms utilized by qualified surgeons and experienced medical professionals focusing on specialized surgical procedures
- Significant focus on performing procedures for both hemodialysis and peritoneal dialysis access (2,500 dialyses access related procedures per year)
- Located in Houston are where the incidence of end-stage renal disease (ESRD) exceeds the national rate and a state which has the second highest prevalence of chronic kidney disease (CKD) in the nation
- Regularly perform the Surfacor System inside-out procedure; however, payment rate from Medicare does not fully cover our costs

Central Venous Obstruction is a Significant Problem for Hemodialysis patients

Hemodialysis vascular access

- 80% of hemodialysis patients initiate dialysis via a catheter, typically inserted in right internal jugular (RIJ)
- Catheters serve as an important bridge while waiting for placement or maturation of permanent arteriovenous (AV) access (AV fistula or graft)
- Guidelines and CMS programs emphasize the clinical and economic benefits of dialyzing via an AV fistula vs. other access options

Fully Occluded RIJ



Central venous obstruction

- 25% to 40% of patients develop central venous obstructions
- Placement of central lines causes irritation and blockage, which can lead to the vein becoming blocked
- Placement of catheters on left side are associated with increased rate of obstructions due to vessel tortuosity, which risks creation and/or maturation of an AV fistula in the left arm (preferred arm for right handed patients)
- Previously, physicians routinely placed catheters in an open vein, progressively occluding veins
- For hemodialysis patients, progressive use of alternative veins can lead to obstruction of all central veins

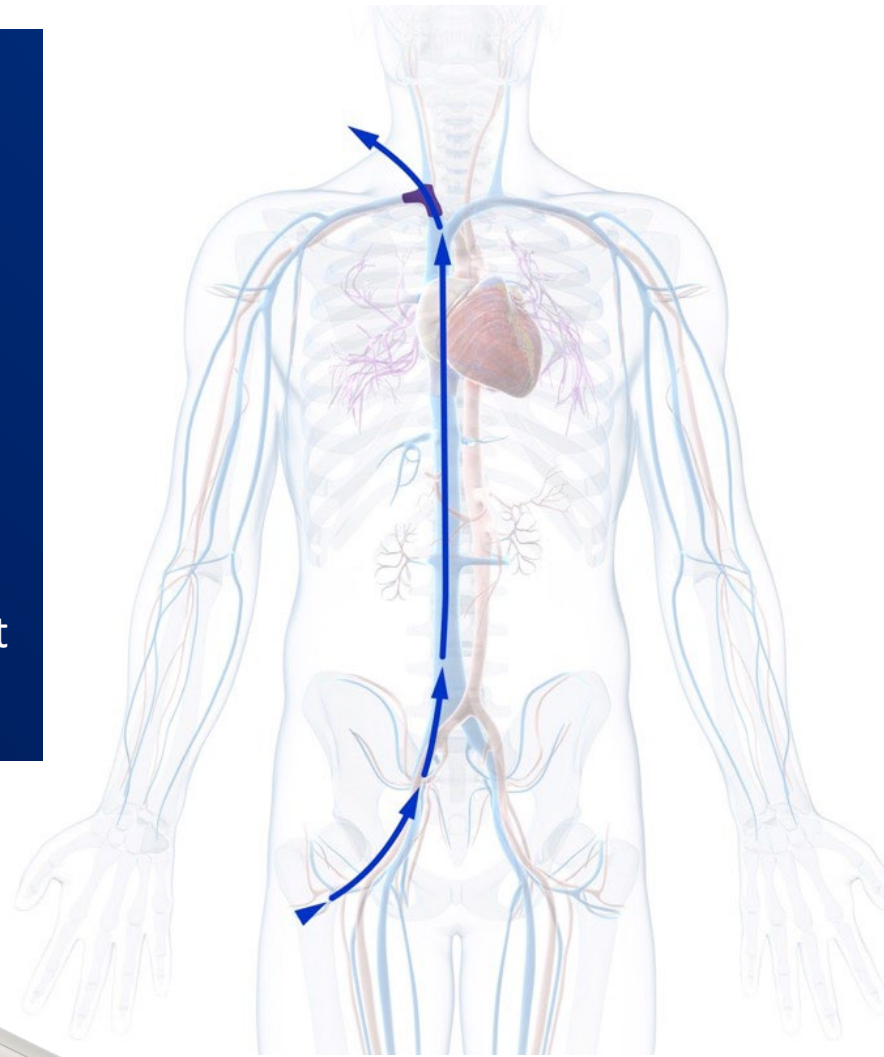
Surfacer System Inside-Out Catheter Access System

Inside-Out® Approach

- Unique, minimally invasive approach
- Delivered under fluoroscopy

Targeted Navigation

- Advanced through the vasculature of the torso
- The device then exits out a desired exit point in the right internal jugular



- Enables the ability to gain repeated central vascular access via the RIJ vein in patients with venous obstructions
- Prevents progression of blocked veins and associated downstream clinical issues and costs
- This preferred right-sided access path is supported by the Surfacer System's novel Don't Go Left™ approach
- Received FDA De Novo clearance in February 2020
- No other FDA cleared or approved devices for this indication

Multicenter Clinical Studies with the Surfacer System

U.S. FDA approved IDE Study¹

- **7 sites**
- Prospective, single-arm, multicenter study
- **30 patients**
- **90% success rate**
- **No device related AEs**

International Registry²

- **5 sites**
- Prospective, single-arm, multicenter study
- **30 patients**
- **97% success rate**
- **No Adverse Events** or post-op complications

Investigator Initiated Independent Study³

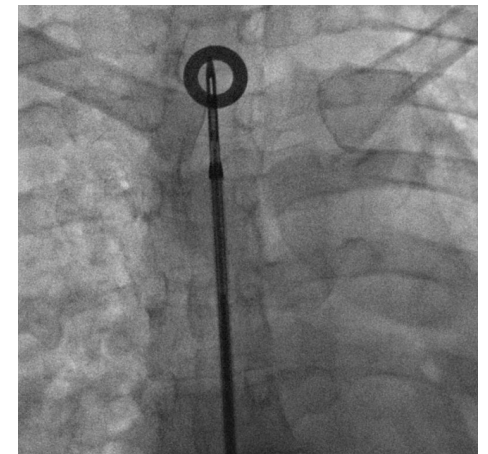
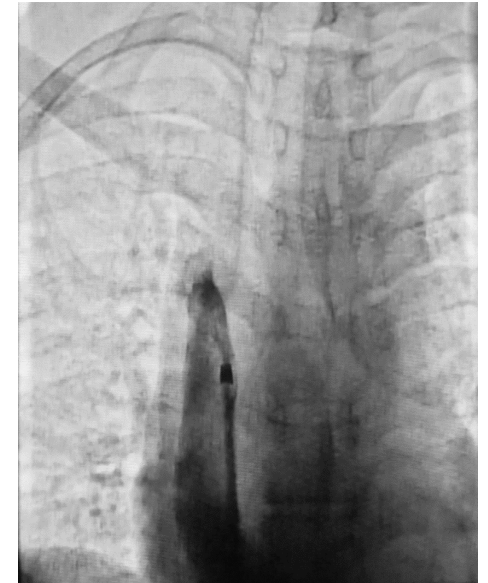
- **3 sites**
- Retrospective, single-arm, multicenter study
- **32 patients (39 proc.)**
- **97% technical success & patency @3 months**
- **No complications or Adverse Events**

1. Razavi MK, et al. Efficacy and safety associated with the use of the Surfacer® Inside-Out® Access Catheter System: Results from a prospective, multicenter Food and Drug Administration-approved Investigational Device Exemption study. J Vasc Access. 2021 Jan;22(1):141-146. doi: 10.1177/1129729820937121.
2. Gallieni M, et al. Multicenter Experience with the Surfacer Inside-Out Access Catheter System in Patients with Thoracic Venous Obstruction: Results from the SAVE Registry. J Vasc Interv Radiol. 2020 Oct;31(10):1654-1660.e1. doi: 10.1016/j.jvir.2020.06.020.
3. Reindl-Schwaighofer R, et al. A Novel Inside-out Access Approach for Hemodialysis Catheter Placement in Patients With Thoracic Central Venous Occlusion. Am J Kidney Dis. 2020 Apr;75(4):480-487. doi: 10.1053/j.ajkd.2019.08.024.

See addendum slide for detailed summary of studies

SSHA Experience with the Surfacer System

- 21 hemodialysis patients have been treated with the Surfacer System since August 2020.
- Procedures performed on an outpatient basis.
- Right sided central venous access obtained for all patients (100% technical success).
- No device-related complications or adverse events.



Economics of C9780

- CMS established HCPCS Level II code C9780 for Surfacar procedure effective 10/1/2021
- C9780 assigned to New Technology APC 1534
- 2023 proposed Medicare HOPPS payment for C9780 in APC 1534 is \$8250.50.

Addendum B.-Proposed OPPS Payment by HCPCS Code for CY 2023								
HCPCS Code	Short Descriptor	CI	SI	APC	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
C9780	Insert cv cath inf & sup app		S	1534		\$8,250.50	.	\$1,650.10

- We have performed 18 Surfacar procedures for Medicare patients (85.7% of all of our Surfacar System procedures)
- Average Medicare payment rate for C9780 has been \$8,187.63.

Analysis of Surfacar Procedure Cost for SSHA

- We analyzed hospital cost information associated with performing the inside-out procedure with the Surfacar System to obtain central venous access and placement of a hemodialysis catheter in patients with central venous occlusions
- Assumed 2 hours for OR time (prep+procedure) and 4 hours in recovery room
- Cost components included:
 - Surfacar System (\$5,595)
 - Hemodialysis catheter
 - Other supplies need to perform the procedure
 - Imaging costs (fluoroscopy/contrast/ultrasound)
 - Personnel costs (nurses and techs)
 - Overhead costs
- Average estimated cost per procedure was **\$12,567.04**

Conclusion

- SSHA's average variable costs (no mark up) per case is **\$12,567**.
- At the proposed APC rate of \$8,250.50, **SSHA loses \$4,316.50 per case** when performing this procedure for Medicare beneficiaries
- We are requesting CMS assign C9780 to APC 1575 (New Technology - Level 38) with a payment rate of \$12,500.50

Addendum A.-Proposed OPPS APCs for CY 2023						
APC	Group Title	SI	Relative Weight	Payment Rate	National Unadjusted Copayment	Minimum Unadjusted Copayment
1534	New Technology - Level 34 (\$8001-\$8500)	S		\$8,250.50	.	\$1,650.10
1535	New Technology - Level 35 (\$8501-\$9000)	S		\$8,750.50	.	\$1,750.10
1536	New Technology - Level 36 (\$9001-\$9500)	S		\$9,250.50	.	\$1,850.10
1537	New Technology - Level 37 (\$9501-\$10000)	S		\$9,750.50	.	\$1,950.10
1575	New Technology - Level 38 (\$10,001-\$15,000)	S		\$12,500.50	.	\$2,500.10

Thank you - Questions

Christopher Durham, M.D.
Chief Medical Officer
Vascular and Endovascular Surgeon
Surgery Specialty Hospitals of America
Pasadena, TX



**SURGERY SPECIALTY
HOSPITALS** **OF AMERICA**

Multicenter Clinical Studies Documenting the Safety and Efficacy of the Surfac[®] Inside-Out[®] Access Catheter System

	U.S. IDE Study [1]	International Registry [2]	Independent Multicenter Study [3]
Trial design	Prospective, single-arm, multicenter study	Prospective, single-arm, multicenter study	Retrospective, single-arm, multicenter study
Year(s) performed	2017-2019	2017-2018	2016-2018
Main inclusion criteria	Patients referred for placement of CVC with limited or diminishing upper body venous access or pathology impeding standard access methods	Patients referred for placement of a CVC with limited or diminishing upper body venous access pathology	Patients with bilateral TCVO requiring urgent vascular access and patients with right-sided TCVO requiring a CVC
Number of study sites	7	5	3
Site locations	USA	Austria, Germany, Italy and Uruguay	Austria, Germany United Kingdom
Number of patients	30	30	32 [*]
Mean age, years \pmSD, (range)	55.5 \pm 12.9 (30-79)	60.1 \pm 12.8 (38-80)	59 ^d (20-82)
Gender (males/females)	15/15	18/12	6/26
% requiring venous access for hemodialysis	28 (93.3%)	29 (96.7%)	100%
TVCO type, number of patients (%)			
Type 1	7 (23.3%)	8 (26.7%)	3 (8%)
Type 2	6 (20.0%)	5 (16.7%)	27 (75%)
Type 3	16 (53.3%)	8 (26.7%)	3 (8%)
Type 4	1 (3.3%)	9 (30.0%)	3 (8%)
# patients with successful catheter placement (%)	27/30 (90%)	29 (96.7%)	38 (97.4%)
Mean procedure time, minutes \pmSD (range)	44.1 \pm 30.6 ^a (10-130)	24 \pm 14.9 ^b (6-70)	43 ^{c,d} (25 to 80)
Mean fluoroscopy time, minutes \pmSD (range)	11.2 \pm 9.72 (2.5-49.4)	6.8 \pm 4.5 (2.2-25.5)	6 ^d (2-14)
Mean contrast used, mL \pmSD (range)	95.4 \pm 107.3 (5-360)	29.7 \pm 22.2 (6-100)	15 ^d (0-90)
Device-related complications	None	None	None

CVC = Central venous catheter, SD = Standard deviation, TCVO = Thoracic central venous obstruction

^{*} 7 patients repeated the procedure during the study period but more than 3 months following initial procedure in order to replace a malfunctioning catheter

^a from initial femoral access through skin closure

^b from initial device insertion to removal of the workstation sheath

^c initial femoral access to end of central venous catheter implantation

^d Standard deviation not reported

1. Razavi MK, et al. Efficacy and safety associated with the use of the Surfac[®] Inside-Out[®] Access Catheter System: Results from a prospective, multicenter Food and Drug Administration-approved Investigational Device Exemption study. J Vasc Access. 2021 Jan;22(1):141-146. doi: 10.1177/1129729820937121.
2. Gallieni M, et al. Multicenter Experience with the Surfac Inside-Out Access Catheter System in Patients with Thoracic Venous Obstruction: Results from the SAVE Registry. J Vasc Interv Radiol. 2020 Oct;31(10):1654-1660.e1. doi: 10.1016/j.jvir.2020.06.020.
3. Reindl-Schwaighofer R, et al. A Novel Inside-out Access Approach for Hemodialysis Catheter Placement in Patients With Thoracic Central Venous Occlusion. Am J Kidney Dis. 2020 Apr;75(4):480-487. doi: 10.1053/j.ajkd.2019.08.024.