



September 27, 2019

Submitted electronically via: <http://www.regulations.gov>

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1717-P
7500 Security Boulevard
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (CMS- 1717-P)

Dear Administrator Verma:

The Dialysis Vascular Access Coalition (DVAC) appreciates the opportunity to offer comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rule with comment for the CY 2020 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (CMS- 1717-P).¹ DVAC is a coalition of entities that provide vascular access services to individuals with advanced kidney disease and End-Stage Renal Disease (ESRD). DVAC represents specialty societies, including the American Society of Diagnostic and Interventional Nephrology (ASDIN) and the Renal Physicians Association (RPA), as well as industry providers, including American Vascular Associates, Arizona Kidney Disease and Hypertension Centers, Azura Vascular Care, Balboa Nephrology Medical Group, Dallas Nephrology Associates, Dialysis Access Specialists, Lifeline Vascular Care, Northwest Renal Clinic, San Antonio Kidney Disease Center, and Vascular Access Centers. **DVAC represents the majority of the non-hospital vascular access sector.**

This letter offers comments and recommendations on the following issues:

- CMS Exception for Vascular Access from Office-Based Designation
- Creation and PD Catheter Placement Services in Non-Hospital VACs
- CMS Should Calculate ASC Device-Intensive Outside of C-APC Method

¹ Federal Register, 84 FR 39398 (August 9, 2019)

CMS EXCEPTION FOR VASCULAR ACCESS FROM OFFICE-BASED DESIGNATION

Background

As noted in our comment to the CY 2020 Physician Fee Schedule Proposed Rule (attached as an addendum), the reduction to the key vascular access code (36902) in 2017 was 39% and resulted in significant center closures in the non-hospital setting. Since the release of the 2017 ASC Final Rule, reimbursement for vascular access preservation codes (36901 – 36909) in the ASC setting also has undergone several important changes to status indicators which are largely responsible for the significant payment volatility between 2018 and 2019 proposed and final ASC reimbursement rates. These changes – relating to office-based designations and device-intensive classifications – have resulted in variability to vascular access preservation codes of roughly 62% (office-based designations) and 20% (device-intensive classifications).

In particular, in the CY 2019 ASC Proposed Rule, CMS noted it was reducing the reimbursement rate for 36902 and 36905 due to the office-based designation.² This proposal would have resulted in significant cuts to 36902 and 36905 as well as huge differentials between the hospital and non-hospital reimbursement rates, as shown in the table below.

Codes	2017 ASC Final Rule	2019 Proposed Rule	Percent Change 2017 to 2019
36901	\$370 (P2)	\$532.59 (P3)	44%
36902	\$2,983 (J8)	\$1,125 (P3)	-62%
36903	\$5,653 (J8)	\$6,082 (J8)	8%
36904	\$2,983 (J8)	\$2,719 (J8)	-9%
36905	\$5,653 (J8)	\$2,080 (P3)	-63%
36906	\$8,850 (J8)	\$9,835 (J8)	11%
36907	N1	N1	NA
36908	N1	N1	NA
36909	N1	N1	NA

J8 = Device-intensive procedure; paid at adjusted rate.

G2 = Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.

P2 = Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight.

P3 = Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs..

N1 = Packaged service/item; no separate payment made.

DVAC noted for the 2019 ASC Proposed Rule that non-hospital vascular access centers already were closing and that CMS' proposed office-based designation would (1) incentivize inappropriate migration of services from the non-hospital setting to the hospital setting, (2) increase the site-of-service reimbursement differential to the detriment of ESRD patient outcomes, and (3) mean significant increases in spending for vascular access services under the Medicare program as well as higher copayments for ESRD patients. We also noted that in the case of vascular access preservation add-on codes (36907 – 36909) that the interaction of the office-based policy with

² 83 FR 37155

packaging policies in the ASC fee schedule would have resulted in reimbursement rates for many complex procedures actually being paid less in the ASC than the office. DVAC noted as well that there was precedent for CMS not implementing the office-based policy for vascular access services given 2011/2012 CMS rulemaking that exempted nuclear medicine and radiology services from the office-based designation due to equivalent concerns with the interaction of the office-based policy with ASC packaging policies.

2020 ASC Proposed Rule exempts 36902 and 36905 from office-based designation

In the 2020 ASC Proposed Rule, CMS notes the following regarding 36902 and 36905:

- 36902. *“In reviewing the CY 2018 volume and utilization data for CPT code 36902 we determined that the procedure was performed more than 50 percent of the time in physicians’ offices based on 2018 volume and utilization data. However, the office-based utilization for CPT code 36902 has fallen from 62 percent based on 2017 data to 52 percent based on 2018 data. In addition, there was a sizeable increase in claims for this service in ASCs – from approximately 14,000 in 2017 to 38,000 in 2018. As previously stated in the CY 2019 OPPTS/ASC final rule (83 FR 59036), when we believe that the available data for our review process are inadequate to make a determination that a procedure should be office-based, we either make no change to the procedure’s payment status or make the change on a temporary basis, and reevaluate our decision when more data become available for our next evaluation. In light of these changes in utilization and due to the high utilization of this procedure in all settings (over 125,000 claims in 2018), we believe it may be premature to assign office-based payment status to CPT code 36902 at this time.”*
- 36905. *“The CY 2018 volume and utilization data for CPT code 36905 show the procedure was not performed more than 50 percent of the time in physicians’ offices. Therefore, we are not considering assigning an office-based designation for CPT code 36905 and the procedure will retain its payment indicator of “G2” – non office-based surgical procedure based on OPPTS relative weights.”*

We are grateful for CMS’ determinations on 36902 and 36905 and note that these approaches are consistent with several stakeholder comments made as part of the implementing regulations to the office-based designation policy that a more prudent approach to the office-based designation is for CMS to “follow trends in the sites of service for office-based procedures, and should CMS find significant and unwarranted migration of certain procedures to ASCs, implement the proposed policy at a later date.”³

Recommendation: We strongly support CMS’ proposal to exempt 36902 and 36905 from the office-based designation under 42 CFR 416.171(d).

CREATION AND PD CATHETER PLACEMENT SERVICES IN NON-HOSPITAL VACs

Background

It has been well-established since at least the early 2000s that the AV fistula is the “gold standard” access choice for hemodialysis patients and offers the lowest rate of infection for patients.

³ 72 FR 42511

However, in 2003, fistulas made up only 32% of accesses. In 2005, CMS launched the Fistula First Breakthrough Initiative to promote the use of fistulas. Concurrent with the initiative, vascular access preservation services migrated to the lower cost, superior outcome non-hospital sites-of-service where fistulas are a key focus of these centers of excellence. As a result, fistula use is now well over 60% in the prevalent population.⁴

The success of the Fistula First initiative helps to highlight two important policy matters. First, the initiative underscores the need to secure the gains of Fistula First by maintaining the viability of non-hospital vascular access centers (by, among other things, not implementing the office-based policy for *preservation* services). Second, the initiative helps to highlight other areas where ESRD patients would be well-served by the migration of other important dialysis access services from the hospital to the non-hospital setting. These services include vascular access *creation* services and *PD catheter placement services*.

Vascular Access Creation Services

Like preservation services, creation services in the non-hospital setting are significantly less costly than the HOPD. Since creation services are not payable in the office setting, the ASC is the only non-hospital site-of-service available for comprehensive vascular access services (including both creation and preservation services). It's notable, however, that the vast majority of creation services are still provided in the hospital, rather than the ASC setting. According to a 2019 Braid Forbes Health Research analysis, only 3% of vascular access creation services (36818, 36819, 36820, 36821, 36825, 36830) are done in the non-hospital setting. In this light, we believe that CMS and the vascular access sector can do for *creation* services what we were able to do for *preservation* services. That is to say, the migration of vascular access creation services to the ASC setting will strengthen comprehensive ASC vascular access centers of excellence, improve patient outcomes, and save the Medicare program and ESRD patients money. A 2019 DVAC industry analysis found that Medicare could save up to \$500 million over 10 years if only half of vascular access creation services moved from the hospital outpatient to the ASC setting.

<i>Current Medicare Volume and Spend for Vascular Access Creation Services (2019)</i>					
	HOPD		ASC		Combined HOPD / ASC Spend
CPT	Volume	2019 Spend	Volume	2019 Spend	
36818	5222	\$22,854,187	232	\$521,654	
36819	7779	\$34,044,949	214	\$481,181	
36820	1472	\$6,442,237	182	\$409,229	
36821	28693	\$75,793,133	873	\$1,140,217	
36825	2010	\$8,796,805	75	\$168,638	
36830	18827	\$82,396,742	350	\$786,979	
Total		\$230,328,055		\$3,507,898	\$233,835,952

<i>Scenario: Half of Medicare Volume Moves from Hospital to ASC Setting</i>					
	HOPD		ASC		Combined HOPD / ASC Spend
CPT	Volume	2019 Spend	Volume	2019 Spend	
36818	2611	\$11,427,094	2843	\$6,392,514	
36819	3889.5	\$17,022,475	4103.5	\$9,267,234	

⁴ <http://fistulafirst.esrdncc.org/wp-content/uploads/2015/11/LLFL-Team-Approach-for-Achieving-Catheter-Freedom.pdf>

36820	736	\$3,221,119	918	\$2,176,558	
36821	14346.5	\$37,896,567	15219.5	\$19,259,475	
36825	1005	\$4,398,403	1080	\$2,781,407	
36830	9413.5	\$41,198,371	9763.5	\$21,688,003	
Total		\$115,164,027		\$61,565,190	\$176,729,217
Total Savings Potential Per Year					\$57,106,735

PD Catheter Placements

A key component of the Administration’s “Advancing American Kidney Health” initiative is to increase home dialysis rates across the country. Much as creating and preserving the best vascular accesses are critical to optimal in-center dialysis, the creation and preservation of the best PD catheters are critical to optimal home dialysis. Here again we note, however, that most PD catheter placements services are still done in the hospital outpatient setting. According to a 2019 analysis by the Moran Company, only 6% of PD catheter placements (49418, 49421, 49324) are done in the non-hospital setting. In the case of PD catheter placements, a 2019 DVAC industry analysis found Medicare could save up to \$130 million over 10 years if only half of PD catheter placement services moved from the hospital to the ASC setting.

<i>Current Medicare Volume and Spend for PD Catheter Services (2019)</i>					
	HOPD		ASC		Combined HOPD / ASC Spend
CPT	Volume	2019 Spend	Volume	2019 Spend	
49324	1472	\$7,224,591	182	\$399,459.06	
49418	5222	\$16,439,430	232	\$319,025.52	
49421	7779	\$24,489,148	214	\$294,273.54	
Total		\$48,153,169		\$1,012,758	\$49,165,927

<i>Scenario: Half of Medicare Volume Moves from Hospital to ASC Setting</i>					
	HOPD		ASC		Combined HOPD / ASC Spend
CPT	Volume	2019 Spend	Volume	2019 Spend	
49324	736	\$3,612,295	918	\$2,014,854	
49418	2611	\$8,219,715	2843	\$3,909,438	
49421	3889.5	\$12,244,574	4103.5	\$5,642,764	
Total		\$24,076,584		\$11,567,056	\$35,643,640
Total Savings Potential Per Year					\$13,522,287

Recommendation: We urge CMS to support policies which encourage the appropriate migration of vascular access creation services and PD catheter placement services to the more cost-effective and patient preferred non-hospital (ASC and office) settings.

CMS SHOULD CALCULATE ASC DEVICE-INTENSIVE OUTSIDE OF C-APC METHOD

As CMS is aware, the OPSS/ASC rule calculates the device proportion of a service in two ways. The first way is by using the comprehensive APC payment rates to develop the “device offset” amount reflected in “Addendum P” of the OPSS Proposed Rule. The second way CMS calculates the device proportion relates to the way CMS actually calculates ASC payment rates. While CMS does not provide an addendum to reflect this, the calculation is as follows:

- A. Geometric mean cost (traditional method)
- B. Geometric mean cost (traditional method) – without device costs
- C. Device cost (difference of A and B)
- **Device proportion = (C / A)**

Because the above calculation is part of the larger calculation used to set payment rates for the ASC, we believe it is entirely appropriate that CMS use the above calculation to calculate the device proportion to establish device-intensive status for services in the ASC. Furthermore, we note that this would establish consistency with the way that CMS determines the no cost/full credit and partial credit amounts for ASC procedures (i.e. which uses the traditional approach and utilizes non-comprehensive APC inputs). Under the traditional method, DVAC believes key vascular access codes would be less likely to be subject to payment anomalies, such as the 2019 anomaly by which CMS proposed to pay 36904 (\$2,719) significantly more than 36905 (\$2,080) under the ASC fee schedule even though 36905 is the more complex procedure.⁵

Recommendation: We urge CMS to utilize the traditional (without comprehensive) methodology to calculate the device percentage for purposes of designating device intensive status in the ASC reimbursement system as it is more consistent with the overall payment system of the ASC.

Conclusion

DVAC’s comments on the CY 2020 ASC Proposed Rule seek to ensure ongoing access to vascular access services. We look forward to continuing to work with CMS to (1) maintain and improve access to ESRD patient-focused vascular access services and (2) further the important work of the Administration’s “Advancing American Kidney Health” initiative, particularly as it relates to vital vascular access services for ESRD patients. If you have additional questions regarding these matters and the views of the DVAC, please contact Jason McKitrick at (202) 465-8711.



⁵ The AMA’s “CPT, 2018 Professional” describes 36905 as follows: “Code 36905 includes the services in 36904 plus transluminal balloon angioplasty in the peripheral segment of the dialysis circuit.”

ATTACHMENT –
DVAC COMMENT TO THE
2020 PHYSICIAN FEE SCHEDULE
PROPOSED RULE