

# FY 2022 Final Rule Summary

## Inpatient Prospective Payment System (IPPS)

### August 3, 2021

On August 2, 2021, the Centers for Medicare and Medicaid Services (CMS) issued the final rule for fiscal year (FY) 2022 Inpatient Prospective Payment System (IPPS). The full document is located here: <https://www.federalregister.gov/public-inspection/2021-16519/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the>. The format of the following information is intended to serve as a summary to the finalized changes and readers are encouraged to view the document in its entirety for further details.

### Highlights of Finalized Items

- CMS finalized a 2.5 percent increase to the inpatient payment rates for FY 2022.
- CMS finalized to use the FY 2019 claims data for ratesetting where the FY 2020 data is significantly impacted by the COVID-19 PHE.
- CMS finalized the continued use of the low wage index hospital policy.
- CMS finalized changes to the Hospital Readmissions Reduction Program, some of the finalized changes are adjustments to what was originally proposed.
- CMS sought stakeholder input through an RFI (request for information) on ideas to revise several programs to make reporting of health disparities based on social risk factors and race more comprehensive such as the possible collection of data related to demographic elements by hospital at time of admission.
- CMS finalized, as proposed, the non-O.R. and O.R. status for several procedures which may be of interest to interventional radiologists.
- CMS did not make any changes, as proposed, to the list of devices offered with cost or with credit.
- CMS finalized the extension of the one-year extension for add-on payments for new services and technologies, this includes the Eluvia™ Drug-Eluting Vascular Stent System.
- The application for additional add-on payments for the Briefcase for PE was ultimately not passed as CMS believes it only met 2 of the 3 criteria.
- After consideration of the comments from stakeholders and the applicant, CMS does not believe the newness criteria was met as the “newness” expired during FY 2021 and was not valid for inclusion in FY 2022. Due to this, the Ellipsys® Vascular Access System was not approved for new technology add-on payments for FY 2022.
- After consideration of comments by the applicant and stakeholder CMS does believe INDIGO Aspiration System with Lightning Aspiration Tubing (INDIGO® with Lightning) has a unique mechanism of action in the treatment of patients for pulmonary embolism, deep vein thrombosis and peripheral arterial thromboembolism and meets the newness criteria. CMS could not determine the INDIGO® with

Lightning represented a substantial clinical improvement over existing technologies, due to this it was not approved for new technology add-on payment for FY 2022.

## Payment Rates

Under the Inpatient Prospective Payment System (IPPS) CMS sets rates for most, excluding those defined by law, acute care hospital inpatient stays. The base payment rates are established based on the patient's diagnosis and severity of illness. The hospital will receive one payment for the case per the assigned classification of the patient at discharge. IPPS uses Medicare Severity Diagnosis-Related Groups (MS-DRGs) classification system for determining the corresponding payment rate. Rates assigned to the MS-DRGs are required to be updated annually based on several factors related to the price for goods and services used by the hospitals to treat Medicare beneficiaries as well as other factors, all known as the "market basket." CMS did finalize to repeal the use of market basket MS-DRG relative weight methodology for calculating the MS-DRG relative weights effective in FY 2024. Instead, CMS will use the existing cost-based methodology for calculating the MS-DRG relative weights for FY 2024 and subsequent fiscal years.

Beginning with a base rate, CMS applies other factors which when calculated determine the overall payment for the patient's care per their diagnosis and severity of illness relative to the geographic location of the hospital. For FY 2022, which begins October 1, 2021, CMS finalized to increase payment rates for hospitals that have successfully participated in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users by approximately 2.7 percent. This increase reflects the projected hospital market basket update of 2.7 percent, a 0.7 percent reduction of the productivity adjustment, and the 0.5 percent increase required by previous MACRA (Medicare Access and CHIP Reauthorization Act of 2015) legislation. This results in an increase of approximately 2.5 percent to payment rates.

When calculating the payment rates for FY 2022, CMS would typically utilize the most recently completed claims data which is two years prior. For FY 2022, this would mean utilizing data from FY 2020 (October 1, 2019 – September 30, 2020), which includes a significant portion of time under the public health emergency (PHE) in response to COVID-19. Due the impact COVID-19 has had on hospitals and inpatient services; CMS proposed and finalized the use of FY 2019 data for ratesetting where the FY 2020 data is significantly impacted by the COVID-19 PHE.

CMS is finalizing to continue the low wage index hospital policy implemented in FY 2020, and effective for at least 4 years, to account for disparities between high wage and low wage hospitals. This adjustment to standardized amounts for all hospitals over the 4-year time period allows for employee compensation increases implemented by the hospitals to be appropriately reflected in the calculation for payment.

CMS is proposed to make changes to the Hospital Readmissions Reduction Program which requires a reduction to a hospital's base operating DRG payment to account for excess readmissions for select conditions. Beginning in FY 2017 and in place for subsequent years, the reduction is based on a hospital's risk adjusted readmission rates for a 3-year period for the following: acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. CMS finalized the following changes:

- (1) to adopt a cross-program measure suppression policy for the duration of the public health emergency for COVID-19;
- (2) to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2023 program year;
- (3) to modify the remaining five condition-specific readmission measures to exclude COVID-19 diagnosed patients from the measure denominators, beginning with the FY 2023 program year;
- (4) to use the MedPAR data that aligns with the applicable period for FY 2022;
- (5) to automatically adopt the use of MedPAR data corresponding to the applicable period beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary; and
- (6) to update the regulatory text to reflect that our Hospital Compare website has been renamed and is now referred to as Care Compare.

In response to requirements outlined in the Consolidated Appropriations Act of 2021, to assist in closing the gap in health equity and ensure underserved communities have access to healthcare, CMS outlined how for FY 2023, and each subsequent fiscal year until the aggregate number of full-time equivalent residency positions distributed is equal to 1,000, the Health and Human Services Secretary will initiate separate rounds of applications for the additional residency positions. The Secretary is required to increase the applicable resident limit for each qualifying hospital that submits a timely application by the number of positions that may be approved for the hospital. The Secretary is required to notify hospitals of the number of resident positions distributed to them by January 31<sup>st</sup> of the fiscal year, with the effective date of July 1<sup>st</sup> of that fiscal year. Additionally, there is a limit to the aggregate number of resident positions made available in a single fiscal year to a hospital of no more than 200.

CMS received a significant amount of stakeholder feedback to this request. CMS intends to address the public comments in a separate document.

### **Proposed Changes to Non-O.R. Procedures to O.R. Procedures**

Different from ICD-10-CM, which is used to identify the diagnosis of the patient, ICD-10-PCS (procedural classification system) are the codes reported by the hospital on the claim to represent the services provided for inpatient procedures. ICD-10-PCS codes are alphanumeric and identify the general procedure by type, body system, procedure objective, specific body part, procedure approach and device use. Unlike the CPT® codes used by physicians to report the services performed, the individual ICD-10-PCS codes are not separately tied to reimbursement. Instead, they map to a DRG and reimbursement is tied to the MS-DRG.

ICD-10-PCS codes are either designated as a non-O.R. procedure or not designated as an O.R. procedure. For each procedure that is classified as an O.R. procedure, it is further classified as either extensive or non-extensive. For each procedure that is classified as non-O.R. procedure, it is further classified as either affecting the MS-DRG assignment or not affecting the MS-DRG assignment.

Since the implementation of the designations (O.R. and non-O.R.) there have been smaller changes over time, but CMS indicated in the FY 2020 proposed rule the intention to do a comprehensive, systematic review of the ICD-10-PCS to be conducted over multiple years. In light of the PHE, CMS is considering allowing for more time to begin a review to allow for additional claims data to be available for consideration. However, for this proposed rule, CMS did receive requests for consideration. The following criteria was considered by the advisors for the submitted requests:

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a nonextensive procedure; and
- To which MS-DRGs the procedure should be assigned.

#### Percutaneous Revision of Intraluminal Devices

A request was received to change the following currently designated non-O.R. procedure to O.R. procedure, percutaneous revision of intraluminal devices. One requestor identified five ICD-10-PCS codes that described the percutaneous revision of intraluminal vascular devices. The five procedure codes are:

ICD-10-PCS Code	Code Description
02WY3DZ	Revision of intraluminal device in the great vessel, percutaneous approach
03WY3DZ	Revision of intraluminal device in upper artery, percutaneous approach
04WY3DZ	Revision of intraluminal device in lower artery, percutaneous approach
05WY3DZ	Revision of intraluminal device in upper vein, percutaneous approach
06WY3DZ	Revision of intraluminal device in lower vein, percutaneous approach

The request states the codes should be designated as O.R. procedures to compensate for the resources needed to perform the procedure and they require anesthesia, specialized equipment for intravascular visualization, significant skill, and time. CMS did agree the five procedure codes require the resources typically provided in an operating room.

- Add code 02WY3DZ as an O.R. procedure assigned to MS-DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures, with MCC, with CC, and without CC/MCC, respectively)
- Add codes 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ as O.R. procedures assigned to MS-DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively)

After consideration of comments CMS has finalized the change of the ICD-10-PCS codes from non-O.R. procedure to an O.R. procedure effective October 1, 2021.

#### Open Revision and Removal of Devices from Subcutaneous Tissue and Fascia

A request was received to change 6 identified ICD-10-PCS procedures describing open revision and removal of neurostimulator generators, monitoring devices, and totally implantable vascular access devices (TIVADs) to O.R. procedure status.

ICD-10-PCS Code	Code Description
OJPT0MZ	Removal of stimulator generator from trunk subcutaneous tissue and fascia, open
OJPT0ZZ	Removal of monitoring device from trunk subcutaneous tissue and fascia, open
OJPT0WZ	Removal of totally implantable vascular access device from trunk subcutaneous
OJWT0MZ	Revision of stimulator generator from trunk subcutaneous tissue and fascia, open
OJWT0WZ	Revision of totally implantable vascular access device from trunk subcutaneous
OJWT03Z	Revision of infusion device in trunk subcutaneous tissue and fascia, open approach

The request did mention the removal of the devices is often performed in outpatient surgery, complications can require removal or revision during inpatient hospitalizations. The CMS clinical advisors did not agree these procedures should be changed to O.R. procedure status since they are typically performed in an outpatient setting and when performed during hospitalization, it is usually due to some other O.R. procedure.

After consideration of comments CMS is finalizing their proposal to maintain the non-O.R. designation for the codes describing open revision and removal of neurostimulator generators, monitoring devices, and totally implantable vascular access devices (TIVADs).

#### Percutaneous Tunneled Vascular Access Devices

The request to add Percutaneous Tunneled Vascular Access Devices to the list of O.R. procedures is due to the fact the devices are placed in an interventional radiology suite or operating room under anesthesia. The following 10 codes are requested for change in status.

ICD-10-PCS Code	Code Description
OJH63XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, percutaneous approach
OJH83XZ	Insertion of tunneled vascular access device into abdomen subcutaneous tissue and fascia, percutaneous approach
OJHD3XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, percutaneous approach
OJHF3XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, percutaneous approach
OJHG3XZ	Insertion of tunneled vascular access device into right lower arm subcutaneous tissue and fascia, percutaneous approach
OJHH3XZ	Insertion of tunneled vascular access device into left lower arm subcutaneous tissue and fascia, percutaneous approach
OJHL3XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, percutaneous approach

OJHM3XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, percutaneous approach
OJHN3XZ	Insertion of tunneled vascular access device into right lower leg subcutaneous tissue and fascia, percutaneous approach
OJHP3XZ	Insertion of tunneled vascular access device into left lower leg subcutaneous tissue and fascia, percutaneous approach

CMS acknowledged they have addressed requests in the past for these particular codes to be changed in status. The current review by advisors did not agree the procedures performed to insert a tunneled vascular access device should group to MS-DRGs across all MDCs (major diagnostic category). These are typically performed in outpatient setting and when performed during a hospitalization it is with another O.R. procedure.

After consideration of comments CMS is finalizing their proposal to maintain the non-O.R. designation for the codes for Percutaneous Tunneled Vascular Access Devices effective October 1, 2021.

### Replaced Devices Offered without Cost or with a Credit

In FY 2008 CMS implemented the policy to reduce reimbursement to a hospital for device placement for certain MS-DRGs where the implantation of the device subsequently failed or was recalled. At that time, CMS reduced the amount paid to the hospital when they received a credit equal to 50 percent or more of the cost of the device. In FY 2012 this was clarified to mean if a hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly. For FY 2022 CMS is not proposing to add any additional MS-DRGs to the policy for replaced devices offered without cost or with a credit. CMS finalized to continue the current list of MS-DRGs.

### Add-On Payments for New Services and Technologies for FY 2022

#### 1-Year Extension

When technology granted an add-on payment by CMS begins in the second half of the year, CMS will typically extend the new technology add-on payment for a third year. CMS is extending the add-on payment for several technologies, one specific to interventional radiology providers is the Eluvia™ Drug-Eluting Vascular Stent System.

One Year Extension for Technologies for which New Technology Add-on Payment Would Otherwise Be Discontinued in FY 2022						
Technology	FDA/Newness Start Date	NTAP start date	NTAP Status for FY 2022	Previous Final Rule Citations	Maximum NTAP Amount for FY 2022	Coding Used to Identify Cases Eligible for NTAP
<i>Eluvia™ Drug-Eluting Vascular Stent System</i>	<i>09/18/2018 commercially available in US 10/4/2018</i>	<i>10/1/2020</i>	<i>One-year extension; 3-year anniversary date (10/04/2021) will occur prior to the second half of FY 2022</i>	<i>(85 FR 58645 Through 58636)</i>	<i>\$3,646.50</i>	<i>X27H385, X27H395, X27H3B5, X27H3C5, X27J385, X27J395, X27J3B5, X27J3C5, X27K385, X27K395, X27K3B5, X27K3C5, X27L385, X27L395, X27L3B5, X27L3C5</i>

## New Applications

Each year CMS reviews applications received per the deadline for new technology requesting an add-on payment to the DRG. There are specific criteria which must be met in order to qualify for the additional payment:

- (1) the medical service or technology must be new;
- (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and
- (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

## Newness Criterion

With regard to the newness criterion, technology is no longer considered “new” for the purposes of the add-on payment if it is substantially similar to one or more existing technologies, even if it recently received FDA approval or clearance. In addition, if it has been on the market for more than 2 to 3 years, it is no longer considered “new”.

To differentiate how CMS defines what is new technology and the criteria it must meet to evaluate if potentially similar to existing technology CMS created the following guidelines. If technology meets all of the following it is considered similar to existing technology and not “new” for an add-on payment:

- (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome;
- (2) whether a product is assigned to the same or a different MS-DRG; and
- (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population.

## Cost Criterion

The second criterion is related to cost. CMS will evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS-DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS-DRGs if the new medical service or technology occurs in many different MS-DRGs). CMS does provide access to the data files utilized for this analysis.

Applicants are expected to submit significant sample of data to demonstrate the technology meets the high-cost threshold. The sample size is expected to be significant to allow for CMS be able to do an initial validation and analysis of the data.

### Substantial Clinical Improvement Criterion

The third and final criterion is the technology must represent an advancement that significantly improves the diagnosis or treatment relative to already existing technologies. Some of the criteria which may support the clinical improvement include:

- The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;
- The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;
- The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or
- The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished sources with the United States or elsewhere may be sufficient to establish the improvement.
- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

The following are new technology add-on payment applications outlined in the FY 2022 IPPS proposed rule which may include technologies utilized or beneficial to interventional radiology.

### Aidoc Briefcase for PE

Aidoc Medical Ltd. (Aidoc) is the applicant for Briefcase for PE, and indicates it is an FDA cleared, artificial intelligence (AI)-based solution for triage and notification of suspected pulmonary embolism (PE) cases. According to Aidoc, this *“device assists hospitals and radiologists by flagging and communicating suspected positive findings of PE in computed tomography (CT) pulmonary angiography (CTPA) examinations, which prompts the radiologist to assess relevant Digital Imaging and Communications in Medicine (DICOM) imaging*

*files, allowing suspect cases to receive attention sooner than otherwise would have occurred, which in turn improves clinical outcomes.”*

Following the CTPA the images are forwarded to the applicant’s cloud-based engine where they are analyzed by an AI algorithm. If a PE is suspected by Briefcase for PE, the radiologist is alerted via the user interface with the Aidoc Worklist Application which is installed on the radiologist’s desktop. The radiologist can then review and communicate to the ER the findings, all occurring much faster than by more manual review.

CMS does have concerns regarding the application. CMS is unclear about statements by the applicant that Briefcase for PE differs from the predicate device Briefcase for ICH, but CMS believes it would be used for a different population.

The applicant submitted a final inflated average case-weighted standardized charge per case of \$87,483, which exceeded the average case-weighted threshold amount of \$71,312. Since this is greater than the average-weighted threshold amount the applicant maintains Briefcase for PE meets the cost criterion. CMS indicated they would like more information on how the applicant selected the MS-DRGs (175 and 176) for the analysis and the cost per case calculation.

Regarding clinical improvement, the applicant indicated because Briefcase for PE notifies the radiologist to open and reads the CTPA studies with high probability of PE sooner, the mortality rate and length of stay are reduced related to PE. CMS stated the following concerns about the information submitted to support this. The applicant only submitted clinical literature that compares the technology to unassisted FIFO workflows and not against existing electronic (for example, EHR “stat” orders) or manual (for example, verbal communication to radiologist) forms of prioritization, or other types of existing risk stratification tools or features currently available in EHRs. In addition, the applicant did not present data relative to false negatives, false positives, or how workflows are prioritized when multiple cases present at the same time.

Lastly, CMS noted the applicant does not measure the effect on treatment outcomes, instead stating the faster treatment results themselves proves there are better outcomes. CMS is uncertain that without this data it can be supported it will/would lead to substantive clinical outcomes.

After additional comments by the applicant, CMS believes the Briefcase for PE is not substantially similar to an existing technology and meets the newness criterion. CMS also believes it meets the cost criterion. CMS continues to have concerns regarding the substantial clinical improvement criterion has been met. Due to this, CMS is not approving the application for new technology add-on payments for FY 2022.

### Ellipsys® Vascular Access System

Avenu Medical, Inc. is the applicant who has requested an add-on payment for the Ellipsys® Vascular Access System for FY 2022. Per Avenu Medical, *“Ellipsys is a device that enables percutaneous creation of an arteriovenous fistula (AVF), which is used to access the bloodstream for hemodialysis for the treatment of end-stage renal disease (ESRD). According to the applicant, to create the fistula, a physician inserts a crossing needle through the perforating vein and into the proximal radial artery in the forearm. A specialized catheter is then used to bring the artery and vein together. The two vessels are “welded” together with thermal resistance energy, creating an anastomosis. According to the applicant, the only means of creating an AVF was through*

*open surgery before the approval of Ellipsys, and percutaneous AVF (pAVF) offers a number of advantages over surgical AVF (sAVF)."*

The applicant believes the Ellipsys is not substantially similar to other current therapies and due to the fact, it uses a new mechanism of action, it supports the newness criterion for the add-on payment. CMS however believes the mechanism of action is similar to the original version of the Ellipsys system which was approved by the FDA on June 22, 2018. The current instructions for use (IFU) include a step for balloon angioplasty done concurrently, but CMS indicated it is not clear this changes the mechanism of action for Ellipsys. Per the FDA summary, all characteristics remain unchanged to the manner in which it creates a percutaneous anastomosis, other than the already mentioned balloon angioplasty.

If the current device which the applicant is seeking the add-on payment is substantially similar to the original version of Ellipsys, CMS believes the newness period for the technology began on June 22, 2018. Additional 510(k) clearance was received for a minor change to packaging components on January 25, 2019 and minor technological differences in power control unit and minor enhancements to the catheter design on October 5, 2018. The applicant did indicate the most recent FDA approvals are needed to support this application. The 3-year anniversary to the De Novo clearance would put the date of June 22, 2021 during FY 2021 and no longer considered new and not eligible for consideration. CMS is seeking comments on whether the change in the Ellipsys IFU supports a change to the device's mechanism of action.

Currently there are two ICD-10-PCS codes for procedures using Ellipsys, 031B3ZF (Bypass right radial artery to lower arm vein, percutaneous approach); and 031C3ZF (Bypass left radial artery to lower arm vein, percutaneous approach). Both codes are available for use with the WavelinQ™ EndoAVF System ("WavelinQ") as well. Due to this, the applicant is seeking a code specific to and only for reporting when the Ellipsys is utilized beginning with FY 2022 reimbursement.

Regarding the cost criterion, the applicant calculated a final inflated average case-weighted standardized charge per case of \$119,158, which exceeded the average case-weighted threshold amount of \$91,190 by \$27,967. The applicant indicated because the ICD-10-PCS codes available for Ellipsys were effective October 1, 2019, there is no claims data from 2019 available. The most common MS-DRGs for the patients admitted with chronic kidney disease receive an open subclavian artery bypass to upper arm vein, in addition to radial lower arm fistulas, which the applicant used to support the cost criterion. The applicant indicated Ellipsys may provide an alternative to these cases in some instances where AVF placement in the radial arteries is possible, but the surgeons are unfamiliar with the procedure. CMS questions the use of this proxy as *"Ellipsys should not replace radiocephalic fistulas, per standard guidelines that recommend wrist fistulas first; and it would be more likely that surgeons would use Ellipsys over upper arm fistulas than a subclavian fistula, which is used rarely in standard practice."* CMS is seeking comments on whether the cost criterion has been met.

Regarding the clinical improvement, the applicant stated the Ellipsys provides substantial clinical improvement over the following:

- (1) percutaneous AVF with the WavelinQ™ (4F) EndoAVF System;
- (2) percutaneous AVF (pAVF) with the prior version of Ellipsys; and

(3) surgical AVF (sAVF).

The applicant indicated the Ellipsys has improved outcomes of technical success and cumulative patency over the WavelinQ. There was no head-to-head clinical trial data available to support this, but the applicant provided one retrospective study which provides a direct comparison between the two different systems.

CMS indicated only one of the studies submitted by the applicant supports substantial clinical improvement for Ellipsys has a comparator arm (retrospective study). None of the studies were created to demonstrate superiority of the Ellipsys. The statistical outcomes in the one retrospective study submitted by the applicant did not reach statistical significance for primary patency, technical success, maturation rates, time to cannulation, or fistula success, and CMS noted the potential for bias with the single operator/single site study design.

After consideration of the comments from stakeholders and the applicant, CMS does not believe the newness criteria was met as the “newness” expired during FY 2021 and was not valid for inclusion in FY 2022. Due to this, the Ellipsys® Vascular Access System was not approved for new technology add-on payments for FY 2022.

INDIGO Aspiration System with Lightning Aspiration Tubing

Penumbra, Inc. is the applicant for the INDIGO Aspiration System with Lightning Aspiration Tubing. The applicant indicates the INDIGO® with Lightning is a mechanical thrombectomy aspiration system used in the treatment of pulmonary embolism, deep vein thrombosis and peripheral arterial thromboembolism that optimizes thrombus removal by differentiating between thrombus and blood. The application states it performs clot detection and removal using smart technology to allow the physician to know when the catheter is in the thrombus and when in patent flow, this results in blood loss reduction through intermittent aspiration mechanical thrombectomy. It is indicated for the use of removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and treatment of pulmonary embolisms.

The INDIGO® with Lightning has several components reviewed by the FDA for separate components as well as the overall system. The applicant states the mechanism of action is different than existing technology due to the use of a mechanical pump to generate a vacuum for aspiration and the Lightning tubing. The other technologies referenced include the Inari Flowtriever (aspiration is provided through a syringe) for pulmonary embolism and the peripheral system and the Angiojet® (syringe based for aspiration) and Angiovac® (uses an extracorporeal bypass circuit created outside the body consisting of an outflow line, a centrifugal pump, a filter and an inflow line) both for thrombectomies.

CMS expressed concerns whether the technology of the INDIGO® with Lightning meets the substantial similarity criteria and whether it is “new.” CMS indicated the applicant did discuss how the INDIGO® with Lightning differs from others on the market from different manufacturers, they did not provide enough information on how it differs in its components from the existing thrombectomy catheters on the market to support a unique mechanism of action. Specially how it differs from other technology that also uses a pump, rather than syringe. Also, how the mechanism of action of the separator, which is part of the catheter portion of the device, is different from other thrombectomy systems that also deploy a device thru the lumen of the catheter to break up the thrombus.

Regarding the use of “smart technology,” CMS indicated it is unclear what mechanism of action is used by it and if this technology differs from other technologies also designed to limit blood loss during the procedure. It was not defined if the smart technology is part of the pump, which was given FDA 510(k) clearance on March 8, 2018 or within the tubing which was recently given FDA 510(k) clearance on April 22, 2020. If it resides in the pump, this exceeds the 3-year limit and would not be considered new. The tubing described in the FDA 510(k) application only supports minor differences from the predicate devices (e.g., length of tubing and shelf life). The dates for the original tubing FDA 510(k) were provided May 26, 2015 and May 3, 2018, neither would support the newness criterion. CMS invites comments on whether the INDIGO® with Lightning is substantially similar to other technologies and whether it meets the newness criterion.

Regarding the cost criterion, the applicant calculated a final inflated average case-weighted standardized charge per case of \$180,036, which exceeded the average case-weighted threshold amount of \$126,211 by \$53,825. CMS is inviting comments related to the cost criterion.

Regarding the substantial clinical improvement criterion, the applicant indicates the INDIGO® with Lightning supports this criterion because it results in lower rates of aspirated blood loss during procedure, low major bleeding event rate reduces blood loss, reduces ICU stays, and reduces procedure time. The applicant also indicated it allows for revascularization without thrombolytics and no recurrence of pulmonary embolism after 30 days.

CMS noted within the application, the applicant did not indicate which comparator they were using to support the substantial clinical improvement criterion. For example, CMS called out the following, “...whether INDIGO® is being compared to systemic thrombolysis, percutaneous catheter directed thrombolysis, or other aspiration thrombectomy catheters. Comparing INDIGO® to a medical treatment modality may not be appropriate since percutaneous interventions for PE and DVT have different clinical indications, risks, and benefits compared to medical or surgical interventions.”

CMS also had concerns as the applicant submitted mostly studies in support of INDIGO® without Lightning to substantiate the claims and application for INDIGO® with Lightning. Only one small study was provided to support INDIGO® with Lightning, comparing to earlier technology by the applicant and did not demonstrate superior outcomes for INDIGO® with Lightning. CMS also questioned whether there is enough evidence to support the “smart technology” over manual aspiration catheters to further support a substantial clinical improvement.

After consideration of comments by the applicant and stakeholder CMS does believe INDIGO Aspiration System with Lightning Aspiration Tubing (INDIGO® with Lightning) has a unique mechanism of action in the treatment of patients for pulmonary embolism, deep vein thrombosis and peripheral arterial thromboembolism and meets the newness criteria. CMS could not determine the INDIGO® with Lightning represented a substantial clinical improvement over existing technologies, due to this it was not approved for new technology add-on payment for FY 2022.