

2016- 2017

ISASS BOARD OF DIRECTORS

President

Hee Kit Wong, MD, Singapore

Treasurer

Jeffrey Goldstein, MD, USA

Michael Ogon, MD, PhD, Austria

Marek Szpalski, MD Belgium

Jack Zigler, MD, USA

Frank Phillips, MD, USA

Domagoj Coric, MD, USA

Immediate Past President

Gunnar B. J. Andersson, MD, PhD, USA

ISASS Past Presidents

Luiz Pimenta, MD, PhD, Brazil

Steven Garfin, MD USA

Jean-Charles LeHuec, MD, France

Thomas Errico, MD, USA

Chun-Kun Park, MD, PhD, South Korea

Karin Büttner-Janz, MD, PhD, Germany

Hansen A. Yuan, MD, USA

Founding Members

Stephen Hochschuler, MD, USA

Thierry Marnay, MD, France

Rudolf Bertagnoli, MD, Germany

(the late) Charles Ray, MD, USA



September 6, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Comments to CMS-1654-P (Medicare Program: Payment Policies under the Physician Fee Schedule; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; etc.)

Dear Acting Administrator Slavitt:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to submit comments in response to CMS-1654-P.

ISASS is a global, scientific, and educational society of spinal surgeons and scientists organized to provide an independent venue to discuss and address the issues involved with surgical aspects of the basic and clinical science of spinal care. Thank you for the opportunity to provide comments on the proposed rule.

CY 2017 Proposed Codes

Several new Category I spine codes will take effect in the 2017 code set. ISASS participated in the CPT and RUC processes for these new codes and is disappointed that CMS did not agree with the RUC recommended work RVU for several of the codes. Our detailed comments and recommendations for these new codes follow.

Insertion of Spinal Stability Distractive Device (CPT Codes 228X1, 228X2, 228X4, 228X5)

Code	Descriptor	RUC-Recommended Work RVU	CMS-Proposed Work RVU
228X1	Insertion of interlaminar/interspinous process stabilization/distractive device, without fusion, including image guidance when performed, with open decompression, lumbar; single level	15.00	13.50
228X2	Insertion of interlaminar/interspinous process stabilization/distractive device, without fusion, including image guidance when performed, with open decompression, lumbar; second level	4.00	4.00
228X4	Insertion of interlaminar/interspinous process stabilization/distractive device, without open decompression or fusion, including image guidance when performed, lumbar; single level	7.39	7.03
228X5	Insertion of interlaminar/interspinous process stabilization/distractive device, without open decompression or fusion, including image guidance when performed, lumbar; second level	2.34	2.34

CMS Rationale:

- CMS believes that the RUC recommendations for CPT codes 228X1 and 228X4 overestimate the work involved in furnishing these services. CMS believes that a crosswalk to CPT code 36832 (Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)), which has a work RVU of 13.50, is a more accurate comparison because CPT code 36832 is similar in total time, work intensity, and number of visits to 228X1. CMS believes this is supported by the ratio between total time and work in the key reference service, CPT code 63047 (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar). Therefore, CMS is proposing a work RVU of 13.50 for CPT code 228X1.
- For CPT code 228X4, CMS believes that CPT code 29881 (Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed) is an appropriate crosswalk based on clinical similarity as well as intensity and total time. CPT code 29881 has an RVU of 7.03; therefore, CMS is proposing a work RVU of 7.03 for CPT code 228X4.
- CMS is proposing to accept the RUC-recommended work RVU for CPT codes 228X2 and 228X5 without refinement.

ISASS Comments:

- ISASS appreciates CMS accepting the RUC-recommended value for 228X2 and 228X5, however we strongly believe that the CMS proposed values for 228X1 and 228X4 do not appropriately capture physician work.
- ISASS would like to point out that the RUC recommendations for 228X1, 228X4 and 228X5 already fall below the 25th percentile of RUC survey responses.
- For 228X1, the RUC recommended a crosswalk to CPT code 29915 (Arthroscopy, hip, surgical; with acetabuloplasty (ie, treatment of pincer lesion)). CPT code 29915 has identical intra-service time, very similar total time, very similar intensity, and a similar amount of time for post-op visits. As illustrated in the table below, the RUC's crosswalk code is a much better comparator than the CMS crosswalk under virtually every point of comparison. CMS did not propose adjusting the intra-service or total time for 228X1 and did provide any information as to why it feels CPT code 29915 is not an appropriate crosswalk.

	Code	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Facility Post-Op Time	Office Post-Op Time	Total Time	IWPUT
	228X1	63	90	30	19	69	271	.1065
RUC Crosswalk	29915	63	90	20	19	78	270	.1083
CMS Crosswalk	36832	65	90	30	19	62	266	.0947

- For 228X4, the RUC recommended a crosswalk to CPT code 29880 (Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed). CPT code 29880 is very similar in intra-service time and is closer to the survey code in both intra-service time and physician intensity. Other than those differences, all other time components of CPT code 29880 and CPT code 29881 are identical. As illustrated in the table below, the RUC's crosswalk code is a better comparator than the CMS crosswalk under every point of comparison. CMS did not propose adjusting the intra-service or total time for 228X4 and did provide any information as to why it feels CPT code 29880 is not an appropriate crosswalk.

	Code	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Facility Post-Op Time	Office Post-Op Time	Total Time	IWPUT
	228X4	63	43	30	19	39	194	.080
RUC Crosswalk	29880	58	45	15	19	62	199	.0647
CMS Crosswalk	29881	58	40	15	19	62	194	.0637

ISASS Recommendation:

CMS should accept the RUC-recommended work RVU of 15.00 for CPT code 22X81 and the RUC-recommended work RVU of 7.39 for CPT code 22X84.

Biomechanical Device Insertion - Intervertebral, Interbody (CPT Codes 22X81, 22X82, 22X83)

Code	Descriptor	RUC-Recommended Work RVU	CMS-Proposed Work RVU
22X81	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges) when performed to intervertebral disc space in conjunction with interbody arthrodesis, each interspace	4.88	4.25
22X82	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges) when performed to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect	5.50	5.50
22X83	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect	6.00	5.50

CMS Rationale:

- CMS believes that the RUC-recommended work RVU for CPT code 22X81 overestimates the work in the procedure relative to the other codes in the family. CMS is proposing a work RVU of 4.25 for CPT code 228X1 based a crosswalk from CPT code 37237 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery (List separately in addition to code for primary procedure)), which it feels is similar in time and intensity to the work described by CPT code 22X81.
- In reviewing the code descriptors, descriptions of work, and vignettes associated with CPT codes 22X82 and 22X83, CMS determined that the two procedures, in addition to having identical work time, contain many clinical similarities and do not have quantifiable differences in overall intensity. Therefore, CMS is proposing the RUC-recommended work RVU of 5.50 for both CPT code 22X82 and CPT code 228X3.

ISASS Comments:

- ISASS appreciates CMS accepting the RUC-recommended value for 22X82, however we strongly believe that the CMS proposed values for 22X81 and 22X83 do not appropriately capture physician work.
- ISASS would like to point out that the RUC recommendations for 22X81 and 22X82 already fall below the 25th percentile of RUC survey responses. In addition, if CMS finalizes its proposed value for 22X83, it too, will fall below the 25th percentile of RUC survey responses. Further, ISASS has concerns with the language of the descriptors of all three codes. It is unclear whether RUC survey respondents understood that 22X81 and 22X82 include insertion of biomechanical devices with AND without integral instrumentation. Clearly, inserting a device with integral instrumentation takes more time and work than inserting a device without integral instrumentation. ISASS does not believe that these three new codes are the best way to categorize and report insertion of biomechanical devices; the language of the descriptors will likely confuse surgeons and coders when the new codes are implemented in January 2017. The language of the descriptors of these new codes should be reevaluated by the CPT Editorial Panel.
- For 22X81, the RUC recommended a crosswalk to CPT code 57267 (Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)). CPT code 57267 has an identical amount of intra-service time and total physician time relative to 22X81, whereas CMS' proposed crosswalk has physician times which are not identical. As illustrated in the table below, the RUC's crosswalk code is a better comparator than the CMS crosswalk. CMS did not propose adjusting the intra-service or total time for 228X4 and did provide any information as to why it feels CPT code 29880 is not an appropriate crosswalk.

	Code	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Facility Post-Op Time	Office Post-Op Time	Total Time	IWPUT
	22X81	0	45	0	0	0	45	.108
RUC Crosswalk	57267	0	45	0	0	0	45	.1084
CMS Crosswalk	37237	1	45	1	0	0	47	.0934

- The RUC correctly recognized the differences in time and intensity between 22X82 and 22X83 and recommended values according to the clinical differences of the procedures. 22X82 describes insertion of a biomechanical device following resection of the vertebral body with the goal of achieving arthrodesis of the unstable spinal segment. The purpose of the device is to provide immediate stability while long-term stability is achieved through arthrodesis. 22X83 describes insertion of a biomechanical device with no intention of achieving arthrodesis. Therefore, the surgeon must place and secure the stand-alone device to provide long-term spinal stability without arthrodesis. The RUC-recommended work RVU for 22X83 accounts for the added intensity of the procedure resulting from patients with higher complexity and more inherent spinal instability as well as the precision necessary to place and secure the stand-alone device.

ISASS Recommendation:

CMS should accept the RUC-recommended RVU of 4.88 for CPT code 22X81 and the RUC-recommended work RVU of 6.00 for CPT code 22X83.

Endoscopic Decompression of Spinal Cord Nerve (CPT Code 630X1)

Code	Descriptor	RUC-Recommended Work RVU	CMS-Proposed Work RVU
630X1	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	10.47	9.09

CMS Rationale:

CMS believes the recommendation for 630X1 overestimates the overall work involved in performing this procedure. CMS notes that RUC-recommended crosswalk has a higher intra-service time than reflected in the survey data for 630X1 and believes CPT codes 630X1 and 47562 are similar in intensity, but not time. CMS believes reference CPT code 49507 (Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated) (work RVU of 9.09) is similar in intensity and has an identical intra-service time compared to CPT code 630X1. Therefore, CMS is proposing a work RVU of 9.09 for CPT code 630X1 based on a crosswalk to CPT code 49507.

ISASS Comments:

- ISASS strongly believes that the CMS proposed value for 630X1 does not appropriately capture physician work.
- ISASS would like to point out that the RUC-recommended work RVU already falls below the 25th percentile of RUC survey responses. If CMS finalizes the proposed work RVU at 9.09, the value will fall below the minimum RUC survey response.
- The RUC recommended a crosswalk to MPC code 47562 (Laparoscopy, surgical; cholecystectomy). CPT codes 630X1 and 47562 have similar physician time, however the specialty societies argued and the RUC agreed the intensity of 630X1 was greater, offsetting the 10 minute difference in intra-service time between the two codes. The difference in intensity between these procedures is based upon 630X1 involving decompression around neural elements and the spinal cord, where opportunity for complications and for loss of function is high. The IWP/UT of the RUC-recommended value is comparable to other spinal decompression procedures.
- ISASS would like to highlight the importance of intensity when assigning work RVUs. While time is the most objective measure and CMS seems to rely heavily on intra-service and total time when valuing codes, CMS cannot ignore or diminish the importance of

intensity, especially for minimally invasive procedures such as 630X1, which involves the use of an endoscope to directly visualize and decompress the neural structures of the spine. Intra-service intensity may slightly vary at different points during open surgical spine procedures, however, intensity typically remains high throughout the entire intra-service period for minimally invasive surgical spine procedures. For 630X1, the entire procedure is performed through an endoscope and intensity remains high from the time the surgeon enters the cavity, visualizes the neural structures, performs the decompression, and removes the instruments from the cavity. Proposing reductions in RVUs based strictly on time is inappropriate because it diminishes the importance of the intensity of physician work.

ISASS Recommendation:

CMS should accept the RUC-recommended RVU of 10.47 for CPT code 630X1.

Final Work RVU - CPT Code 27279

ISASS submitted comments to CMS on the final 2015 Physician Fee Schedule in December 2014 requesting refinement of the interim final work RVU for CPT code 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) (“MIS SIJ fusion”). ISASS requested refinement of CPT code 27279 in December 2014 because our members strongly felt that the work valuation that was assigned to this code through a crosswalk methodology was undervalued at 9.03 work RVUs. CMS accepted our request for refinement and ISASS participated in the 2015 Multi-Specialty Refinement Panel and presented data on two separate paired comparison surveys utilizing Rasch methodology¹ in addition to a separate study by Garber et al.² to Refinement Panel in August 2015.

Despite the data from the first paired comparison survey conducted by ISASS in December 2014 suggesting that the work RVU for CPT code 27279 should be 14.36, the second paired comparison survey conducted by ISASS and the Society for Minimally Invasive Spine Surgery (SMISS) in March and April 2015 suggesting that the work RVU for CPT code 27279 should be 14.1, and the study by Garber et al. suggesting that MIS SIJ fusion requires more physician time and effort than open primary lumbar microdiscectomy and that the work RVU for MIS SIJ fusion should be at a minimum equal to the work RVU for open primary lumbar microdiscectomy (13.18), CMS finalized the interim final work RVU for CPT code 27279 at 9.03 RVUs in the final 2016 Physician Fee Schedule rule.

Since the release of the final 2016 Physician Fee Schedule rule, another study comparing the work intensity of MIS SIJ fusion and lumbar microdiscectomy has been published by Frank et al.³ The authors reviewed the charts of 96 patients who underwent MIS SIJ fusion and lumbar microdiscectomy (13.18 work RVUs) analyzing the times associated with pre-operative, intra-

¹ Lorio MP, Martinson M, Ferrara L. Paired comparison survey analyses utilizing Rasch methodology of the relative difficulty and estimated work relative value units of CPT code 27279. Submitted to *Int J Spine Surg*.

² Garber T, Ledonio CGT, Polly DW. How much work effort is involved in minimally invasive sacroiliac joint fusion? *Int J Spine Surg*. 2015;9:58. doi:10.14444/2058.

³ Frank CJ, Kondrashov D, Meyer SC, et al. Work intensity in sacroiliac joint fusion and lumbar microdiscectomy. *Clin Outcomes Res*. 2016;367-376.

operative and post-operative services. Physicians estimated intra-operative work intensity using a visual analog scale. The results show that MIS SIJ fusion has higher pre-operative time, intra-operative intensity, and post-operative time than lumbar microdiscectomy. For your reference and review, I have attached the Frank et al. study in addition to the ISASS paired comparison surveys study (Lorio et al.), the Garber et al. study. ISASS asks that CMS review this information when taking any future action to adjust the work RVU of CPT code 27279.

Collecting Data on Resources Used in Furnishing Global Services

Many surgical spine procedures are valued and reimbursed as part of global packages that include the procedure and the services typically furnished in the periods immediately before and after the procedure. Citing concerns with lack of data to verify and update the values of codes with global packages, CMS finalized a policy to transform all 10- and 90-day global codes to 0-day global codes beginning in 2018. Under this policy, CMS would have valued the surgery or procedure to include all services furnished on the day of surgery and paid separately for visits and services furnished after the day of the procedure. Subsequently, Congress enacted Section 523 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) prohibiting CMS from implementing this policy and requiring the Agency to gather data on visits in the post-surgical period that could be used to accurately value these services.

As part of CMS-1654-P, CMS is proposing a three-pronged data collection strategy to gather information on the frequency of, and inputs involved in furnishing global services, including the procedure, pre-operative visits, post-operative visits, and other services for which payment is included in the global surgical payment for 4,200 codes with a 10- or 90-day global period. Specifically, the data collection effort would include:

1. Comprehensive claims-based reporting about the number and level of pre- and post-operative visits furnished for 10- and 90-day global services;
2. A survey of a representative sample of practitioners about the activities involved in and the resources used in providing a number of pre- and post-operative visits during a specified, recent period of time, such as two weeks; and
3. A more in-depth study, including direct observation of the pre- and post-operative care delivered in a small number of sites, including some ACOs.

In order to collect claims-based data, CMS is proposing to require **ALL** physicians who furnish procedures with 10-day and 90-day global periods to report the number and level of pre- and post-operative visits using a new set of G-codes that distinguish between the setting of care and whether the services are furnished by a physician or by their clinical staff. Physicians would be required to report the following G-codes for every 10 minutes dedicated to a patient before and after a procedure or surgery:

Inpatient	GXXX1	Inpatient visit, typical, per 10 minutes, included in surgical package
	GXXX2	Inpatient visit, complex, per 10 minutes, included in surgical package

	GXXX3	Inpatient visit, critical illness, per 10 minutes, included in surgical package
Office or Other Outpatient	GXXX4	Office or other outpatient visit, clinical staff, per 10 minutes, included in surgical package
	GXXX5	Office or other outpatient visit, typical, per 10 minutes, included in surgical package
	GXXX6	Office or other outpatient visit, complex, per 10 minutes, included in surgical package
Via Phone or Internet	GXXX7	Patient interactions via electronic means by physician/NPP, per 10 minutes, included in surgical package
	GXXX8	Patient interactions via electronic means by clinical staff, per 10 minutes, included in surgical package

No separate payment would be made for these codes. CMS states they are not proposing to withhold payment for non-compliance at this time, but may do so in the future.

Problems with the Proposal

- Rather than using well-known, established E/M codes, CMS is creating new, poorly constructed G-codes to report patient visits in 10-minute increments.
- It is unclear how CMS will use the data collected from the G-codes and translate them into the existing E/M structure.
- The statute requires CMS to gather data from a representative sample, not the entire population of physicians who furnish procedures with 10- and 90-day global periods.
- It is not logistically feasible to require the collection of time per patient, at the minute level, for every task that a physician and his/her clinical staff perform on a daily basis.
- The data reported will be unreliable for reasons including:
 - It is likely that only large, urban, technologically rich practices will have the means to report data leaving the population of small and rural practices unrepresented.
 - The process is biased towards underreporting of time as any patient encounter not reported by a physician and his/her staff (i.e. due to system failure, lack of time for reporting, forgetting encounters, etc.) will undermine the accuracy of the data.
- The data will not capture the full range of services provided to patients and families by the physician and his/her staff during the post-operative period.

- The burden of reporting falls to the physician and his/her staff, which represents another unfunded regulatory mandate at a time when practices are devoting considerable time and resources to implement other major changes required by MACRA.

ISASS Recommendations

- The data collection process should not include all codes with 10- and 90-day global periods, as many of these codes are low volume and it would be difficult to find a meaningful sample. CMS should narrow the population of codes to high-volume, high-cost codes.
- Rather than collecting claims data from all physicians who report codes with 10- and 90-day global periods, CMS must create a representative sample to meet the statutory requirements of MACRA. Using geographical data, CMS should identify a representative sample including medium and small practices, not just large, more technologically rich practices.
- Rather than creating a new set of G-codes, CMS should utilize CPT code 99024 (Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure) to identify the number of post-operative visits associated with a surgical procedure.
- Rather than collecting the number and level of post-operative visits from claims-based reporting, CMS should instead collect the level of visit data as part of its planned survey of physicians.
- CMS should not penalize physicians who are unable to participate in this data collection effort and should reimburse physicians who do participate to account for the time and resources necessary to collect and report this data.

ISASS appreciates the opportunity to comment on the proposed rule. Thank you for your time and for your consideration of our comments. Please contact Liz Vogt, Director of Health Policy & Advocacy by email at liz@isass.org or by phone at (630) 375-1432 with questions or requests for additional information.

Sincerely,

Morgan P. Lorio, MD, FACS
Chair, Coding and Reimbursement Task Force
International Society for the Advancement of Spine Surgery