



February 6, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, Maryland 21244-1816

Re: Calendar Year (CY) 2027 Potentially Misvalued Service Nomination for Ultrasound-guided Carpal Tunnel Release Described by Current Procedural Terminology (CPT®)¹ Code 64728

Dear Administrator Oz,

Sonex Health, Inc. (Sonex) thanks the Centers for Medicare & Medicaid Services (CMS) for the agency's ongoing work to identify and redress potentially misvalued services and, more generally, to set appropriate reimbursement under the Medicare Physician Fee Schedule (PFS). Sonex respectfully nominates CPT code 64728 (Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance) as potentially misvalued. We request that CMS evaluate this code in the CY 2027 PFS rulemaking and establish payment that appropriately accounts for the intensity and complexity of the physician work associated with this procedure.

Sonex is a U.S.-based medical device innovator and the manufacturer of the UltraGuideCTR™, a single use device used in conjunction with real-time ultrasound imaging to perform the new, minimally invasive ultrasound guided carpal tunnel release procedure (described by new Category I CPT code 64728).² We appreciate CMS's discussion of this new code's valuation in the CY 2026 PFS Final Rule but continue to believe it is misvalued for at least three reasons, discussed further below:

- (1) The anomalous relationship between the valuation for CPT code 64728 and other CPT codes for carpal tunnel release procedures;
- (2) "[I]ncorrect assumptions were made in the previous valuation of the service," including a misleading survey and flawed crosswalk assumptions; and
- (3) Analysis of work relative value units (RVUs) from reliable data sources support increased valuation.

This new ultrasound-guided approach to perform carpal tunnel release procedures is life-changing for patients, facilitating patient access in multiple settings of care (including the physician office) and enabling patients to return to daily activities and work within days (not weeks or months, as is the case with recovery from open and endoscopic surgical carpal tunnel release approaches), and without the need to use opioids to manage post-procedure pain and discomfort. That said, the clinical challenges

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² CPT code 64728 (Decompression; median nerve at the carpal tunnel, percutaneous with intracarpal tunnel balloon dilation, including ultrasound guidance).

of providing the benefits of a minimally invasive carpal tunnel release procedure are borne by the physicians who must perform a lengthier and more intensive service.

Unfortunately, the current valuation fails to fully account for the documented clinician effort that goes into providing this service. This undervaluation compromises patients' access to this important new procedure to end their daily suffering from carpal tunnel syndrome. Sonex respectfully requests that CMS recognize CPT code 64728 as potentially misvalued and increase the assigned work RVUs to reflect the intensity required to perform continuous real-time ultrasound imaging and visualization throughout the entirety of this procedure.

I. BACKGROUND

A. Ultrasound-Guided Carpal Tunnel Release Offers Real Relief for Chronic Pain

Carpal tunnel syndrome can be a debilitating, painful condition that interferes with the ability of Medicare beneficiaries to engage in the normal activities of daily living. Carpal tunnel release procedures are the standard of care for relieving the symptoms of pain, numbness, and tingling caused by carpal tunnel syndrome when non-surgical options fail to provide relief. For beneficiaries who rely on walking aids or mobility devices, carpal tunnel syndrome can be particularly problematic and unsafe as it impacts their ability to grip the walker/cane or propel a wheelchair.

When conservative therapy fails, the only way to relieve the debilitating symptoms of carpal tunnel syndrome is to undergo a procedure to release compression of the median nerve by transecting the transverse carpal ligament which is the cause of this condition. For several reasons, patients often delay undergoing a carpal tunnel release procedure that they desperately need due to the side effects and extended wound healing processes required following either of the open and endoscopic surgical carpal tunnel release approaches.

The ultrasound-guided carpal tunnel release procedure offers patients a minimally invasive alternative to traditional open and endoscopic surgical carpal tunnel release approaches. Continuous ultrasound imaging pre-, intra-, and post-procedure allows physicians to visualize and assess all pertinent anatomy in the carpal tunnel, and visualize both the device and the anatomy while inserting and guiding the UltraGuideCTR device through a 4 to 6mm percutaneous incision in the crease of the wrist (preserving the base and palm of the hand for physical activities and personal hygiene). This procedure can be performed in multiple settings of care and does not require general or regional block anesthesia and their attendant requirements such as discontinuing medications and arranging for day-of-procedure transportation. The minimal percutaneous incision can be closed with a Steri-Strip (no sutures required) and mitigates scarring as well as the need for patients to take opioids to manage post-procedure pain. Critically, patients return to normal activities and work following the procedure within three to six days. The fast recovery time also makes this a practical option for patients suffering from bilateral carpal tunnel syndrome (of which there is a high incidence), who would not be able to undergo simultaneous bilateral release procedures using the traditional open surgical approach due to needing to maintain functionality in their non-operative hand to perform basic personal hygiene and daily activities while the other hand heals from the surgery.

B. Minimally Invasive Does Not Mean Easy or Fast

All these benefits of the ultrasound-guided procedure have a trade off in terms of the time, skill, and intensity required of the physician performing the procedure. Minimally invasive does not mean easy or fast; in fact, it is exactly the opposite.

Open carpal tunnel release is the most invasive approach but the easiest and fastest for the physician to perform as the large palmar incision allows the surgeon to directly visualize the transverse carpal ligament and surrounding anatomy through the incision. A surgical endoscopic carpal tunnel release procedure is less invasive but requires more time, skill, and intensity. Insertion of the endoscope requires dilation of the carpal tunnel anatomy to accommodate the scope's circumference, and the scope allows the physician to see only the anatomy directly in front of the camera lens, not any anatomy or anatomic anomalies above, below, or on either side of the endoscope. This limited visualization and oversized endoscope increase the risk of temporary nerve irritation, which can leave patients with lingering numbness or weakness that disrupts daily life.

Ultrasound-guided carpal tunnel release, the least invasive approach, is the most intense for the physician to perform. Unlike other image-guided procedures and the other surgical carpal tunnel release approaches, a physician providing ultrasound-guided carpal tunnel release is performing nearly all the work themselves. Because physicians perform this procedure on wide-awake patients in a procedure room, they do not have the staff support typically available in an operating room. There is no technician performing the imaging; it is the physician who must continuously manipulate the ultrasound probe in one hand and identify critical anatomy on the screen, while simultaneously guiding the device through the carpal tunnel anatomy, avoiding critical nerves, nerve branches, and blood vessels, to the correct location to safely transect the transverse carpal ligament. This service requires immense technical skills and mental fortitude.

And, it is not only the intra-procedure work that is complex or intensive; the physician's role also is substantially greater for pre- and post-procedure work than with other carpal tunnel release approaches. For example, the physician is typically the one providing pre-procedure education and counseling, positioning and preparing the patient, performing detailed ultrasound imaging to evaluate the patient's anatomy and plan the procedural approach, delivering the local anesthetic using ultrasound to guide the needle positioning, and then, following the procedure, confirming complete release of the ligament under ultrasound, applying a pressure dressing, and delivering comprehensive post-procedure instructions to the patient.

Sonex welcomes the opportunity to share more with CMS about this service, and we would be happy to facilitate CMS representatives observing an ultrasound-guided carpal tunnel release procedure in the D.C. metropolitan area.

II. CPT CODE 64728 IS MISVALUED

Despite the complex physician work involved in performing the ultrasound-guided carpal tunnel release procedure, the work RVUs established in the 2026 PFS rule fail to appropriately value the service, jeopardizing access to the procedure for Medicare beneficiaries. Although CMS considered the time associated with the service when reviewing this code's valuation as part of the 2026 rulemaking, we are concerned that insufficient attention was given by both CMS and the American Medical Association's (AMA) RVS Update Committee's (RUC) to the intensity aspect of the valuation.

A. Anomalous Relationships with Other Codes Indicates Code 64728 Is Misvalued

There is a stark lack of relativity between the work valuation for CPT code 64728 and other carpal tunnel release procedures. Such “anomalies in relative values within a family of codes” are strong evidence that a code is misvalued and warrants reexamination.³

As discussed above, ultrasound-guided carpal tunnel release is the least invasive and most intensive of the three carpal tunnel release procedures. Open, or mini-open, surgical carpal tunnel release procedures typically involve a 3-5 cm incision in the base of the palm of the hand to directly access and visualize the critical anatomy, which the surgeon can access quickly but leaves patients with long recoveries, pain, and scarring. Endoscopic procedures are less invasive but still require dilation of the carpal tunnel anatomy prior to inserting the endoscope camera and cutting blade. Both the ultrasound-guided and endoscopic carpal tunnel release approaches require the physician to visualize the anatomy of the carpal tunnel through imaging technology (via ultrasound or endoscopic camera, respectively) and to adjust the position of the devices in response to what they see before the cutting blades are actuated to transect the transverse carpal ligament. Unlike other surgical procedures that may involve imaging, in the 64728 procedure, the ultrasound probe is continuously maneuvered by the physician throughout the entire procedure to generate multi-planar 2D ultrasound images. There is no imaging technician helping; the physician is simultaneously adjusting the ultrasound probe to generate the 2D images on an external screen, identifying the critical anatomy, including nerves, nerve branches, and blood vessels, inserting and advancing the operative device, and then ultimately positioning the device, inflating balloons on the device to create additional safe space in the carpal tunnel, actuating a recessed blade in the device to transect the transverse carpal ligament, and then confirming a complete transection of the ligament all while avoiding very sensitive immediately adjacent nerves, nerve branches and blood vessels.

Yet, for all this additional work, the work RVUs for code 64728 are completely misaligned with the valuation of the other services, as shown in Table 1 below. This not only results in inappropriate payment, but risks pushing Medicare beneficiaries to the more invasive surgical approaches that involve weeks of recovery time, additional therapy and other costs, and potential opioid use for pain management—or cause them to forgo treatment altogether and continue suffering from chronic and often debilitating pain.

Table 1. Comparison of work RVUs for open, endoscopic, and ultrasound guided carpal tunnel release

CPT Code	Procedure	Time, Intensiveness, Invasiveness	Work RVUs
64721	Open carpal tunnel release	Least intensive; least amount of time; most invasive	4.85
29848	Endoscopic carpal tunnel release	More intensive than open; more time than open; less invasive than open	6.23
64728	Ultrasound guided carpal tunnel release	Most intensive as it requires contemporaneous ultrasound; least invasive	2.70

³ 90 Fed. Reg. 49,266, 49,298 (Nov. 5, 2025).

B. Incorrect Assumptions Contributed to the Misvaluation of Code 64728

CMS's discussion of CPT code 64728's valuation in the CY 2026 PFS rulemaking indicates that "incorrect assumptions were made in the previous valuation of the service," including a "misleading vignette, survey, or flawed crosswalk assumptions."⁴

First, the valuation relied on a flawed crosswalk.

CPT code 64728 was valued in substantial part based on the recommendation of the AMA RUC to crosswalk to code 51102 (Aspiration of bladder; with insertion of suprapubic catheter). CMS acknowledged the procedures' "significant clinical differences" but nevertheless concluded that they "share highly similar work times along with comparable intensity."⁵ However, CMS never discussed the procedures' relative intensities, only their times. Given the absence of *any* comparison of the procedures' intensities, the assumption that they have "comparable intensity" clearly was flawed.

Moreover, the "significant" differences between these procedures have a marked impact on their relative intensities. Critical elements of the 64728 procedure that are not part of a 51102 procedure include: (1) using one hand to hold and manipulate an ultrasound transducer to provide continuous real-time intra-procedure long- and short-axis images, while using the other hand to insert, navigate, and position the operative device; (2) using continuous real-time imaging to visualize and identify critical anatomy, including nerves, nerve branches, and blood vessels in the carpal tunnel, and safely and accurately advancing and positioning the device in the confined space of the carpal tunnel; (3) actuating the device to transect the transverse carpal ligament; and (4) probing and scanning post-transection to confirm a complete release of the transverse carpal ligament.

The most intense and complex aspect of the physician work for 64728 is continuously adjusting the ultrasound transducer to generate real-time multi-planar 2D ultrasound images throughout the procedure, interpreting those images to identify critical anatomical structures in the carpal tunnel, and simultaneously advancing and positioning the device to transect the transverse carpal ligament. The use of imaging is not standard for the 51102 procedure and, when performed, is billed separately, such that the intensity involved with continuous real-time imaging is not accounted for in the intensity of the valuation for the 51102 procedure. Additionally, the intensity required to insert a suprapubic catheter into an obstructed bladder is in no way comparable to navigating a device within millimeters of nerves, nerve branches and blood vessels to transect anatomy immediately adjacent to a critical nerve (i.e., the median nerve).

CPT guidance describes the two procedures as follows:

- 64728: "Using ultrasound guidance, make a 0.5-cm incision through the skin and distal forearm fascia in the marked region of the proximal wrist crease. Insert an elevator dorsal to the transverse carpal ligament. Use the elevator in several passes to remove the synovium from the dorsal surface of the TCL. Using ultrasound guidance, insert the device into the carpal tunnel just dorsal to the TCL. Use the transverse view to position the device between the ulnar edge of the median nerve and the ulnar artery, and the longitudinal view to position the device tip between the distal transverse carpal ligament and the proximal edge of the superficial palmar arch. Under continuous ultrasound guidance, inflate the device balloons to create space to protect key anatomy and visualize and confirm proper placement of the device. Reconfirm the absence of vital structures within

⁴ *Id.* at 49,298.

⁵ *Id.* at 49,375.

the anticipated transection pathway. Engage the cutting blade and transect the TCL in a distal-to-proximal manner. Perform additional release for any remaining fibers, checking the position of vital structures prior to each cutting blade activation. Recess the cutting blade, deflate the balloons, and remove the device. Reinsert the elevator and probe the TCL using ultrasound guidance to confirm a complete transection. Manually express excessive fluid from the wound and close using adhesive strips.”⁶

- 51102: “Prepare the lower abdomen and apply sterile drapes. Make a stab wound on the lower abdomen 1cm above the pubis with the tip of a scalpel, insert a trocar suprapubic tube into the bladder, inflate the balloon, and suture the tube into place. Clear urine is obtained immediately.”⁷

The assumption 64728 and 51102 have “comparable intensity” thus cannot be reconciled with their manifest clinical differences, including that 64728 involves continuous real-time imaging with simultaneous device manipulation while 51102 is billed separately from any related imaging.

Second, the valuation relied on a flawed and ultimately misleading survey.

CPT code 64728’s valuation also relied on a flawed survey and corresponding RUC-recommended RVUs which have no connection to the actual intensity involved in performing the procedure. By relying on the misleading RUC survey, code 64728’s valuation rested on incorrect assumptions about the physician work required.

Several irregularities permeated the RUC process for 64728. Notably, the RUC’s recommendation relied on survey data from physicians lacking any experience ever performing the 64728 procedure. The RUC survey was issued to two groups – a random survey was sent by the American Society for Surgery of the Hand (ASSH) (RUC Random Survey), which led the CPT and RUC process for this code, and a targeted survey was sent by the American College of Radiology (ACR) to a list of known physician performers of the service based on information supplied by Sonex (RUC Targeted Survey).⁸ The RUC Random Survey had a response rate of only 0.64% (just 22 responses out of 3,431 surveys issued) and reported median work RVUs of 3.00. The RUC Targeted Survey had a response rate of 15.1% (38 responses out of 252 surveys sent) and reported median work RVUs of 6.40, which is consistent with other independent sources of information on 64728’s time and intensity. Yet the RUC’s ultimate recommendation of just 2.70 work RVUs seems to entirely disregard the targeted survey results, instead reflecting an unfounded bias toward the survey with few responses and even fewer respondents with experience performing the procedure.

In the 2026 PFS Final Rule, CMS noted that the RUC has long used “a mixture of targeted and random survey respondents for their survey process, as the targeted survey respondents who have personal experience with the procedure in question tend to overestimate its intensity.”⁹ Even if this is true as a general matter, the survey data in this case were biased by the incorrect assumption that a minimally invasive procedure is less intensive to perform. This is a common misconception among those unfamiliar with the exceptional focus, precision, and technical skill required to perform many minimally invasive procedures. Given the overwhelming lack of experience from these respondents to the RUC Random Survey, the recommendations are based on assumptions about the procedure which, at best, clearly

⁶ CPT Changes 2026 at 99.

⁷ CPT Knowledge Base (last visited Jun. 26, 2026).

⁸ AMA/Specialty Society RVS Update Process, RUC Recommendations for CPT 2026: January 2025 Meeting at 3512 (Feb. 2025), available at <https://www.ama-assn.org/system/files/feb-2025-ruc-recommendations.pdf>.

⁹ 90 Fed. Reg. at 49,365.

reflect a lack of understanding of the increased intensity and time required to perform the service, notwithstanding that it is a minimally invasive procedure.

Even CMS has acknowledged problems with the RUC's recommendations, including "the use of surveys that have low response rates, low total number of responses, and a large range in responses, all of which may undermine the accuracy of recommendations relying on survey data."¹⁰ The RUC survey's low response rate means the survey sample is less likely to be representative and should not be relied upon.

C. Analyses of Work RVUs from Other Data Sources

Reliable sources of empiric data cast further doubt on the RUC valuation. An independent, randomized controlled trial (RCT) conducted at Walter Reed Medical Center found that the mean procedure time for the ultrasound-guided carpal tunnel release procedure is almost twice that of the mini-open carpal tunnel release, yet the ultrasound-guided procedure has just over half the work RVUs of the open procedure. Although the Walter Reed study did not specifically examine procedure intensity, these empiric results raise serious questions about the low work RVUs for the 64728 procedure and the RUC recommendations that gave rise to the valuation.

In the CY 2026 PFS Final Rule, CMS indicated it "would be interested in additional information from interested parties as to the generalizability of data from Walter Reed to the Medicare population."¹¹ We offer several considerations in response. The study included patients with an average age of about 50, so the study population included patients with ages similar to those of Medicare beneficiaries. Additionally, the time and intensity of the 64728 procedure are very similar regardless of patient age. Furthermore, as an RCT, the Walter Reed study arguably is more reliable than any survey. At a minimum, the Walter Reed RCT supports the conclusion that the RUC valuation did not accurately reflect the time and intensity to perform this service.

III. CONCLUSION

Considering the intensity of physician work involved in performing the 64728 procedure, it is clear that this CPT code is misvalued and, as such, Sonex is nominating it as a potentially misvalued code.

Per prior CMS rulemakings, Sonex is providing CMS with evidence of "[a]n anomalous relationship between the code being proposed for review and other codes," "in correction assumptions [that] were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions," and "[a]nalysis of other data on time and effort measures."¹² There is an anomalous lack of relativity between 64728 and other carpal tunnel release procedures. Incorrect assumptions were made during the previous valuation of 64728, including a misleading survey and flawed crosswalk assumptions. Analysis of reliable RCT data supports increased work RVUs for this procedure.

It is critical that CMS set payment rates appropriately for 64728 to facilitate appropriate Medicare beneficiary access to this service. We urge CMS to look critically at all available information and to revise and increase work RVUs to appropriately reflect the intensive work associated with this procedure. Given our concern about undervaluing the complexity of the service, we would be happy to facilitate CMS

¹⁰ 90 Fed. Reg. 32,352, 32,400 (July 16, 2025).

¹¹ 90 Fed. Reg. at 49,375.

¹² *Id.* at 42,299

representatives observing an ultrasound-guided carpal tunnel release procedure in the D.C. metropolitan area.

Thank you for your attention to this important matter. Please do not hesitate to contact me at bpaulson@sonexhealth.com if you have any questions.

Sincerely,

A handwritten signature in black ink, reading "J. Robert Paulson, Jr." in a cursive style.

J. Robert Paulson, Jr.
President & CEO
Sonex Health, Inc.