

February 3, 2025

The Honorable Jeff Wu
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to MedicarePhysicianFeeSchedule@cms.hhs.gov

RE: Nomination as potentially misvalued codes during CY2026 rulemaking:

Fine Needle Aspiration - CPT codes 10021, 10004, 10005, 10006

Dear Acting Administrator Wu:

The American Association of Clinical Endocrinology and the American Thyroid Association appreciate the opportunity to request nomination of the Fine Needle Aspiration codes as potentially misvalued.

We strongly feel that since these codes were redefined for CY 2019, that they were severely undervalued, and we are now presenting new evidence for your consideration. We urge CMS to restore the RVU values for these codes to the amounts recommended by the AMA – RUC for 2019.

Several organizations have repeatedly pointed to this code set as misvalued, and in the CY2025 Physician Fee Schedule Final Rule, CMS devoted 4 pages to this topic, and yet gave no explanation whatsoever as to the rationale behind failing to make any change.

We will provide additional evidence of site of service changes, increasing average cost due to site changes, and highlight the errors of the previous valuation including the discrepancies with the comparator service that CMS used in its initial assessment in 2019

Who we are:

AACE represents more than 5700 clinical endocrinologists who participate in Medicare, Medicaid, and commercial insurance plans. These clinicians work in private practice,

academic practices, and health systems across the nation. We work to improve quality of endocrine care for patients and reduce health care cost. Our mission is *elevating the practice of clinical endocrinology to improve global health*. Our vision is *achieving healthier communities through endocrine innovation, education, and care*.

The American Thyroid Association (ATA) is dedicated to transforming thyroid care through clinical excellence, education, scientific discovery, and advocacy in a collaborative and diverse community. ATA is an international professional medical society with more than 1,700 members from private practice, academic health centers and other practice and research settings globally.

I. Fine Needle Aspiration Procedures

Fine Needle Aspiration is the primary tool for evaluating thyroid nodules that are suspicious for thyroid cancer. When properly used, it avoids the need for thyroid surgery, which is far more invasive and expensive.

We have become increasingly alarmed about the negative impacts of the reduction of RVU for the “Fine Needle Aspiration” CPT code set 10005, 10006 and 10021 that began with the 2019 Physician Fee Schedule, and we ask that CMS review its previous decision to reduce payment for these codes now that we have further experience with the new valuation.

The specific codes in question are:

10021 - Fine Needle Aspiration without guidance , first lesion

10004 - Fine Needle Aspiration without guidance , additional lesion

10005 Fine Needle aspiration biopsy, including ultrasound guidance first lesion

10006 Fine Needle aspiration biopsy with imaging guidance, each additional lesion

While the FNA procedure can be performed on many sites, 73.9% of the claims for CPT 10005 in 2022 were for thyroid, and 85.5% of claims for 10006 were for thyroid, making this predominantly a thyroid procedure.

The reduction in RVU for these procedures has resulted in reduced access to thyroid FNA procedures as many outpatient thyroid physician offices discontinue them altogether. This has caused a shift in the procedures to the hospital-based radiology locations resulting in a net increase in cost to Medicare. In 2022, the Place of Service continued to shift away from the lower cost Physician Office (non-facility) at 43.5% to Outpatient Hospital (On Campus) at 50%.

Hospital-based radiology locations are typically less focused on the optimal care of thyroid nodules, and the procedures are often performed by radiology Physician Assistants without comprehensive training in thyroid nodule assessment that is typically seen in endocrinology or thyroid specialist offices.

Commented [WB1]: Need to update with 2022 numbers

Finally, we have convincing evidence that new endocrinologists and thyroid specialists in training are being discouraged from learning the FNA procedure in fellowship because of the widespread sentiment by thyroid specialists that this procedure is so badly undervalued that it is no longer worthwhile to perform in a clinic setting. Most new endocrine and thyroid fellows no longer plan to perform this procedure after beginning their practice. This will further reduce access to this necessary procedure at the lowest cost place of service.

This is truly regrettable because we feel strongly that physicians specializing in thyroid disease provide the most cost-efficient way to evaluate thyroid nodules, can perform fine needle aspiration sampling with the lowest rate of complications and have the best insight about which nodules need to be sampled versus which thyroid nodules can be simply observed.

At the time of the CY2021 PFS Final Rule, CMS stated “In the event that there is a new review of these services, as opposed to a reaffirmation of the previous review, we would look forward to receiving any additional information or new data.”

We are providing additional information and new data on the actual utilization of these codes since the change in RVU.

II. ORIGIN OF THE RVU PROBLEM

CPT Code 10021 for Fine Needle Aspiration was identified as part of the CMS OPPI/ASC cap payment proposal for CY2014, which intended to limit the practice expense (PE) payment in the PFS to the lower of either OPPI or ASC payment schedules. Although the OPPI/ASC cap proposal was not implemented in the final CY2014 rule, AMA RUC forwarded practice expense only recommendations to CMS for CY 2015. In the CY2016 Final Rule, CMS noted concern about implementing PE inputs without the corresponding physician work being reviewed.

Due to the need for clarifying language regarding the number of needle passes per lesion, and the realization that more than 75% of the procedures included ultrasound guidance for needle placement, the AMA RUC referred this concern to the AMA CPT Editorial panel for clarification.

For CPT 2019, the CPT Editorial Panel deleted CPT code 10022, revised CPT code 10021, and created nine new codes. Under the previous code structure, reporting FNA under image guidance with a certain modality for a single lesion would involve reporting deleted code 10022 and the corresponding image guidance code; under the current code structure only the new FNA code with bundled image guidance would be reported. FNA is most commonly performed under ultrasound guidance and uses the code 10005 for the first nodule sampled, and 10006 for any additional nodules.

The AMA RUC provided an assessment of the physician time and work involved and recommended an overall reduction in work value compared to previous years' codes.

CPT Code	Work RVU	Pre Time	Intra Time	Post Time	IWPUT
10021 (2018)	1.27	21	17	10	0.339
10021 RUC Recommended	1.20	10	15	8	0.53
10021 CMS Adopted	1.03	10	15	8	0.42
10005 (2018 Equivalent)					
10005 (RUC Recommended)	1.63	10	20	9	0.60
10005 (CMS Adopted)	1.46	10	20	9	0.52

IV – FURTHER REDUCTIONS TAKEN BY CMS

Despite the RVU reduction proposed by the AMA RUC, CMS further reduced the RVU in the CY2019 PFS. The primary procedure, 10005 was reduced from the RUC recommended 1.63 to the CMS adopted value of 1.46.

In the CY 2019 Final Rule, CMS stated “... that the recommended work pool is increasing by approximately 20 percent for the Fine Needle Aspiration family as a whole, while the recommended work time pool for the same codes is only increasing by about 2 percent.”

It initially appeared to AMA, and to us, that the work pool comparisons used with the AMA RUC recommended RVU overcounted the expected RVU by exactly double. In discussions with CMS in January 2024, we are assured that this was not the case, and this did not drive any reduction in RVU for the procedure.

Unfortunately, as can be clearly seen in the below excerpt from table 12 from the CY 2019 Final Rule, CMS utilization crosswalk numbers don’t add up, and the table itself appears to be in error. The source utilization for the two existing FNA codes 10021 and deleted code 10022 of a collective volume of 210,210, was greatly exceeded by the utilization destination column for 10021, 10004-10012 of a collective volume of 400,450. Those two numbers should have instead both totaled to an identical number, 210,210. CMS’ destination utilization for code 10005 alone was erroneously higher than the source utilization for deleted code 10022 *Fine needle aspiration biopsy, with image guidance*.

Table Excerpt from CY 2019 Medicare Physician Fee Schedule Final Rule:

TABLE 12—FINE NEEDLE ASPIRATION WORK POOL COMPARISON

HCPSC code	Utilization source	Utilization destination	Work RVU source	Work pool source	Work RVU destination	Work pool destination	Work pool RVU change	Work pool % change
10021	23,755	21,380	1.27	30,189	1.20	25,655	-4,513	-15
10004	0	2,376	0.00	0	0.80	1,900	1,900	
10005	0	270,753	0.00	0	1.63	441,327	441,327	
10006	0	30,621	0.00	0	1.00	30,621	30,621	
10007	0	6,857	0.00	0	1.81	12,411	12,411	
10008	0	873	0.00	0	1.18	1,030	1,030	
10009	0	60,665	0.00	0	2.43	147,416	147,416	
10010	0	6,831	0.00	0	1.65	11,271	11,271	
10011	0	83	0.00	0	C	0	0	
10012	0	3	0.00	0	C	0	0	
10022	186,455	0	1.27	236,798	0.00	0	-236,798	-100

It is now our understanding that while the Table 12 may have been in error, these numbers were not the basis for any CMS decision to lower the RVU.

The CY2019 PFS Final Rule stated “... that the recommended work pool is increasing by approximately 20 percent for the Fine Needle Aspiration family as a whole, while the recommended work time pool for the same codes is only increasing by about 2 percent.”

We presume that this reflected a real concern that the Physician Work RVU was increasing from the 1.27 from the 2018 CPT codes to the higher value of 1.63 recommended by RUC.

V – REASSESSMENT OF RVU WORK CHANGES USING 2023 CLAIMS DATA

Neither the CY2019 Table 12, or the accompanying commentary in the CY2019 Final Rule, addresses the fact that the new CPT 10005 bundled the prior CPT codes 10022 and 76942, which had a combined work RVU of 1.94, and RUC was revaluing this combined code 10005 at 1.63.

CY2019 Table 12 does not include the Work RVU for any of the source imaging procedures bundled into the new codes, regardless of whether there is overcounting or not.

We respectfully submit for your consideration revised tables, using actual 2022 claims data, on the impact of the revised RVU. This utilization crosswalk includes the RVU for both components of the new CPT 10005 (previously 10022 plus 76942) as source RVU, and the fact that the source CPT 10022 would be billed multiple times for any additional nodules. These revised tables are included as an appendix.

Looking at the entire FNA family of CPT codes, these show a reduction in Work RVU Pool of 15.9% if the AMA RUC numbers had been adopted, and a reduction in Work RVU Pool of 23.8% based on the actual CMS RVU used today.

This is in stark contrast to the assessment that the “recommended work pool is increasing by 20% “ found in the CY2019 PFS final rule. (See Attachments 1, 2 and 3.)

VI - TIME AND INTENSITY OF THIS SERVICE

CMS stated in the 2021 Physician Fee Schedule final rule that the utilization crosswalk was not the principal reason CMS rejected the RUC recommendations, but that it was due to the interservice time measurement. CMS chose to compare the high work intensity Fine Needle Aspiration codes (which are performed hundreds of thousands of times per year) to an obscure low intensity neonatal transfusion code which has limited time measurement data and is rarely billed to Medicare.

At the time of the CMS RVU decision, CMS identified the neonatal transfusion code (36440) as being a comparable code, based on the exact match in service times.

This was a very poor choice crosswalk for several reasons.

- a. CPT 36440 is rarely used code, that is almost never billed to Medicare.

Claims for CPT 36440

2015	0
2016	0
2017	0
2018	0
2019	1
2020	1
2021	0
2022	0

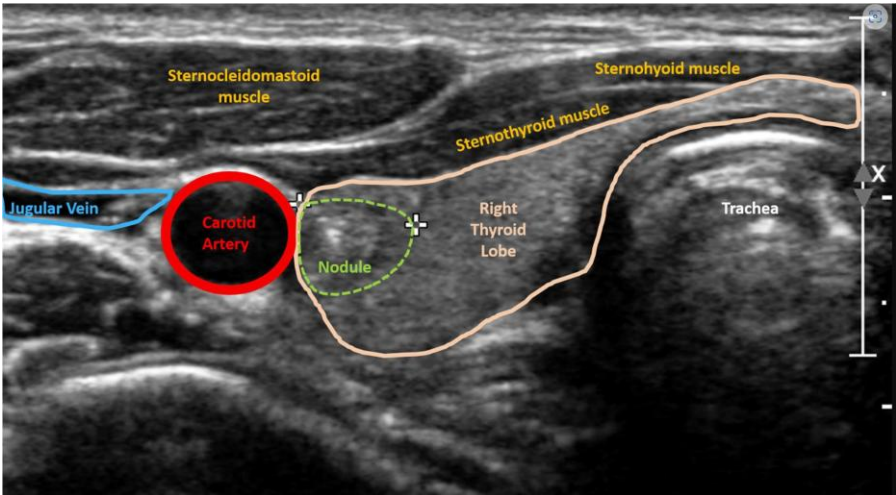
There are literally 2 claims in the last 8 years.

- b. CPT 36440 is a pediatric procedure done on neonates. CPT 10021 is never done on neonates. This is a dissimilar code as far as the physicians who perform the code, and the patients having the procedure.
- c. The training and experience level needed to properly perform these procedures significantly differs. A neonatal transfusion could be performed by an intern or resident in the neonatal ICU. Thyroid fine needle aspiration is learned at the endocrinology fellowship level of training, or as an otolaryngology or radiology senior resident.
- d. The work intensity is vastly different. The neck around the thyroid is filled with other structures including arteries, veins, nerves, muscles, esophagus, and trachea that complicate the procedure.
- e. CPT 36440 is facility only, does not require any clinical staff pre-service time, and has no associated practice expense inputs.

Fine needle aspiration is a much more complex and potentially hazardous procedure. The thyroid has the carotid artery, jugular vein, lymphatics, nerves, trachea, and the esophagus

in contact with the thyroid. The nodules that are sampled are commonly touching the carotid artery, jugular vein, or both. A deviation of only 1 – 2 millimeters can be disastrous if these blood vessels or other structures are accidentally punctured. The thyroid can be moving due to respiratory disease, patient swallowing, or patient anxiety.

There is significant physician work and a high level of clinical expertise necessary to select the proper nodules for sampling and to pre-plan the needle path. True competence requires significant training and a relatively high number of proctored procedures. None of this exists with neonatal phlebotomy.



The AMA RUC used similar intensity procedures to calculate its RVU recommendation.

70470 (CT head or brain)	1.27	5	15	5	.0697
99283 (ER visit)	1.34	5	18	7	.0595
40490 (lip biopsy)	1.22	14	15	5	.0577
78451 (myocardial imaging)	1.38	10	15	5	.0621
95865 (needle EMG larynx)	1.57	10	15	7	.080
53855 (urethral stent insertion)	1.64	7	15	10	.0839

VI. UNEXPECTED CHANGES SINCE THE IMPLEMENTATION OF THE NEW RVU

Despite vigorous objections by the impacted specialty groups, CMS implemented the lower RVU value.

We now present evidence as to the damage done to patient access, increasing overall costs, and degrading the physician workforce capable of competently performing this procedure.

VII. CONCERNS REGARDING PATIENT ACCESS SINCE IMPLEMENTATION

Claims for thyroid FNA have fallen 18% from CMS projections, suggesting that this is creating an access problem for correct diagnosis of thyroid cancer. It is implausible that the number of suspicious thyroid nodules has decreased, or that thyroid cancer has decreased.

Given that FNA is for diagnosis of thyroid cancer, a significant reduction in thyroid FNA would be expected to cause an increase in diagnosis of thyroid cancer at later and more advanced stages. This delay in treatment will cause increased morbidity, mortality, and costs.

Commented [WB2]: Do we have any coding data to look at this ?

VIII. SHIFT FROM OUTPATIENT TO FACILITY LOCATIONS AND INCREASED COST TO MEDICARE

In 2018, the most common single location for a thyroid FNA was the physician office setting, with 47.1% of claims for CPT 10022. Claims for the multiple POS that include hospital facilities amounted to 52.06% of claims. By 2023, the hospital facility claims had increased to 57.5% of claims for the RVU family.

The reduction in payment for the FNA code family has caused non-facility outpatient practices to discontinue the procedure. From an economic perspective, one might think that a switch to a lower cost location makes sense. However, in this case the procedure is now being performed in a *vastly more expensive* location costing 524% more.

CPT Code	2023 National MPFS Total Non-Facility Payment	2023 National MPFS Total Facility Payment	2023 HOPPS Facility Fee (APC Code 5071)	2023 Combined Payment when in Hospital Outpatient Setting (MPFS + OPPS)	Site of Service % Differential (Hospital Outpatient vs Non-Facility)
Office	\$ 137.92			\$ 137.92	
Facility		\$ 73.87	\$ 648.97	\$ 722.84	524%

FNA

If we consider the site of service change from Office to Facility that was seen between 2018 and 2023, with the additional cost of \$584.92 at the Facility location, Medicare experienced an additional 5.44% of the 130,977 CPT 10005 procedures in hospital facilities, a shift of 7,125 procedures. **At cost of \$584.92 each this is a net increased expense to Medicare of \$4,167,642 due to physicians in non-facility locations abandoning the procedure.**

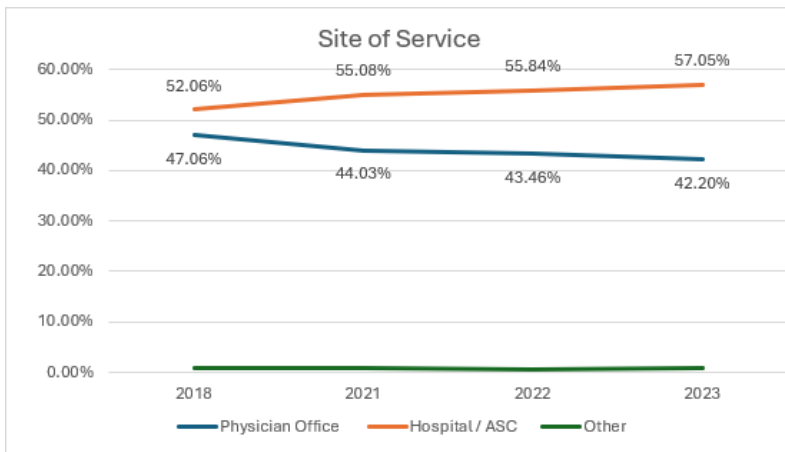
These calculations do not include any consideration of medically unnecessary FNA performed due to increasing referral to radiologists vs thyroid clinicians. We find that experienced thyroid clinicians are more likely to cancel a medically unnecessary FNA when they encounter a request that does not meet current FNA guidelines.

IX. CONTINUED SHIFT IN SPECIALTY AND SITE PERFORMING THE SERVICE

Most endocrinologists are in office-based practices, and not hospital facilities. As they increasingly stop offering this procedure in their offices, the patients are referred to hospital-based radiology practices which are staffed by radiologists.

Ultrasound guided fine needle aspiration does NOT need to take place at a hospital facility, which is far more expensive, a greater infection risk, and far less convenient.

In the past, most ultrasound FNA procedures were done in physician offices, with the plurality of procedures done by endocrinologists. Reviewing the 2023 Medicare claims data for all sites, endocrinologists performing now only 17.2% of all fine needle aspirations. The site of service is now in a hospital facility 57.5% of the time.



While radiologists are generally excellent at the technical components of this, there are several concerns about this additional referral. The radiology provider who performs this procedure is generally not familiar with the patient's history and risk factors for suspected thyroid cancer. Their

FNA

training in thyroid cancer is more focused on the imaging and the procedure, and not viewing the problem from a whole patient point of view. Endocrinologists and surgeons have much more extensive clinical insight about the presentation, diagnosis, and treatment of thyroid nodules and thyroid cancer than radiologists. Many of these referrals for FNA come from Primary Care Providers who are not as experienced with this disease state and then referred to generalist radiologists who are less experienced with this disease state.

A significant number of thyroid FNA requests that come to endocrinologists and thyroid surgeons are found to not meet the clinical criteria for the procedure, and thus the procedure is canceled. It is uncommon for radiology providers at a hospital to cancel a FNA procedure. Thus, additional medically unnecessary FNA procedures are expected to occur with a clinical pathway for PCP to radiology compared to referrals from a PCP to a thyroid specialist.

To whatever extent the RVU reduction pushes a higher number of FNA to radiology providers, it will result in an increased number of medically unnecessary procedures.

X. REDUCTION IN SPECIALIST WORKFORCE TRAINED TO PERFORM THE PROCEDURE

The RVU reduction has become common knowledge in endocrinology training programs, to the extent that fellows are often told that ultrasound guided FNA is a poor use of their time. FNA competence and expertise is increasingly absent as a fellowship training requirement by many fellowship programs.

The impact of reduced numbers of thyroid and endocrine specialists who are fully capable of performing FNA in their offices will result in acceleration of these problems, with reduced access and increased costs for many years to come.

Please note that we are not commenting on the associated codes that include Xray, CT, or MR imaging guidance, specifically codes 10007 through 10012. These are rarely performed by thyroid specialists and are primarily used at sites other than thyroid. (See attachment 4). The differences between each member of the CPT FNA” family” 10004 – 10021) would argue against lumping all of them together for RVU purposes, as they involve different specialties, different organs, and different disease types.

XI. CONCERNS VOICED BY SPECIALITY SOCIETIES

The American Thyroid Association published a Policy Statement in the journal “Thyroid” reporting that “as the result of changes to the 2019 CMS Physician Fee Schedule has led to a cascade of negative consequences impacting the care of patients with thyroid nodules and cancer.”¹ We are attaching a copy.

¹ THYROID Volume 34 Number 11, 2024 <https://doi.org/10.1089/thy.2024.0442> Eldeiry, et al. “Impact of Changes in Fine Needle Aspiration Biopsy Reimbursement on Clinical Care of Patients with Thyroid Nodules in the United States”

FNA

SUMMARY

The low valuation of the Fine Needle Aspiration RVU for CPT codes 10004, 10005, 10006 and 10021 has resulted in increased overall costs, reduced access, and reduced quality of care. We are seeing damage to the physician workforce capable of competently diagnosing and performing this procedure, which will further reduce access and increase costs for the foreseeable future.

The underpinnings of the reduction in RVU were flawed and have not been corrected or explained. The RVU crosswalk CPT code chosen by CMS is not comparable to Fine Needle Aspiration in any respect other than service time. There was absolutely no similarity in the amount of provider training, procedure risk and intensity, or patient population, and it is almost never billed to Medicare. The physician work previously associated with the imaging component appears to have been ignored in the current valuation.

From an RVU perspective, the Fine Needle Aspiration codes are not really a 'family', other than a fine needle is required somewhere. They involve different organs, for different reasons, different age groups, require different clinical training and experience, and are predominantly performed by different specialties. Until the valuation reduction drove the procedure into the hospital, most ultrasound guided FNA were done outside hospitals.

Thyroid fine needle aspiration should be an outpatient procedure. There is absolutely no reason for it to require a hospital. Needlessly pushing ultrasound guided FNA into the inconvenient, high-cost, hazardous scenario of the hospitals should be rejected as nonsense.

CMS must act quickly to repair this problem to avoid further expense and reductions in quality.

CONCLUSION

We respectfully request that CMS consider the CPT codes 10004, 10005, 10006, and 10021 to be misvalued, and restore the work RVU to the values recommended by the AMA RUC.

We hope that you will share our serious concerns about reduced access, increased costs, and depletion of the provider talent pool willing to perform FNA procedures. Left unresolved, this problem will intensify, and we ask for prompt intervention by CMS to correct this in the CY2025 Physician Fee Schedule. This action would be harmonized with CMS stated goals of improving access to care and reducing overall cost to the healthcare system. This would also help in maintaining a larger pool of clinical expertise to competently serve Medicare patients.

We continue to observe significant changes in practice patterns, and changes in site of service. Our concerns about the evidence of errors in the current valuation appear to be acknowledged by CMS, but otherwise ignored. We continue to plea for reconsideration.

Unless corrected, we expect an extinction event for outpatient non-facility fine needle aspiration within the next few years, with a permanently high total cost of the procedure.

FNA

AACE is committed to providing the highest quality care for our patients and the communities we serve. We are available for any further discussion or fact-finding should this be necessary. If you have any questions, please contact William Biggs, MD, FACE, at william@amarilloaco.com.

Sincerely,



Scott D. Isaacs, MD, FACP, FACE
sisaacs@aace.com
<https://www.aace.com/>

President, American Association of Clinical Endocrinology
Elevating the practice of clinical endocrinology to improve global health

ATTACHMENTS:

- 1 - Table 12 with 2022 Claims Data and CMS adopted RVU
- 2 - Table 12 with 2022 Claims Data and AMA proposed RVU
- 3 - Translation table for procedure codes from 2018 to 2022
- 4 – Comparison of CPT FNA family by imaging modality
- 5 - Results of FNA provider survey by ATA and AACE
- 6- THYROID Volume 34 Number 11, 2024 <https://doi.org/10.1089/thy.2024.0442> Eldeiry, et al. "Impact of Changes in Fine Needle Aspiration Biopsy Reimbursement on Clinical Care of Patients with Thyroid Nodules in the United States"