

September 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1784-P
Submitted electronically to regulations.gov

**RE: CY2024 Medicare Physician Fee Schedule Proposed Rule
Undervaluation of Fine Needle Aspiration procedures**

Dear Administrator Brooks-LaSure:

The American Association of Clinical Endocrinology and the American Thyroid Association appreciate the opportunity to submit comments in response to CY2024 Medicare Physician Fee Schedule (MPFS).

AAACE represents more than 5700 clinical endocrinologists who participate in Medicare, Medicaid, and commercial insurance working in private practice, academic practices, and health systems across the nation, working 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.

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 Biopsy without imaging guidance

10004 Fine Needle aspiration biopsy without imaging guidance, each 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, 73.5% of the claims for CPT 10005 in 2021 were for thyroid, and 84.4% 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.

Additionally, hospital-based radiology locations are typically less focused on the care of thyroid nodules, and the procedures are often performed by Physician Assistants without comprehensive training in thyroid nodule assessment.

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. The majority of new endocrine and thyroid fellows do not plan to perform this procedure after beginning their practice. This is truly regrettable because we feel strongly that physicians specializing in thyroid disease provide the most cost-efficient way to evaluate thyroid nodules, are able to perform a 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.

ORIGIN OF THE RVU PROBLEM

The reduction in RVU coincided with restructuring of the fine needle aspiration code family for CY2019, primarily to bundle image guidance into the new FNA procedure codes. 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.

Despite the RVU reduction proposed by the AMA RUC, CMS further reduced the RVU in the CY2019 PFS. 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." Unfortunately, as can be clearly seen in the below excerpt from table 12 from the CY 2019 Final Rule, CMS utilization crosswalk estimate was inaccurate. 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

HCPCS 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	30,169	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 appeared to have been the understandable intent to have a cost neutral utilization crosswalk from the preceding CPT code set when transitioning to the new CPT codes.

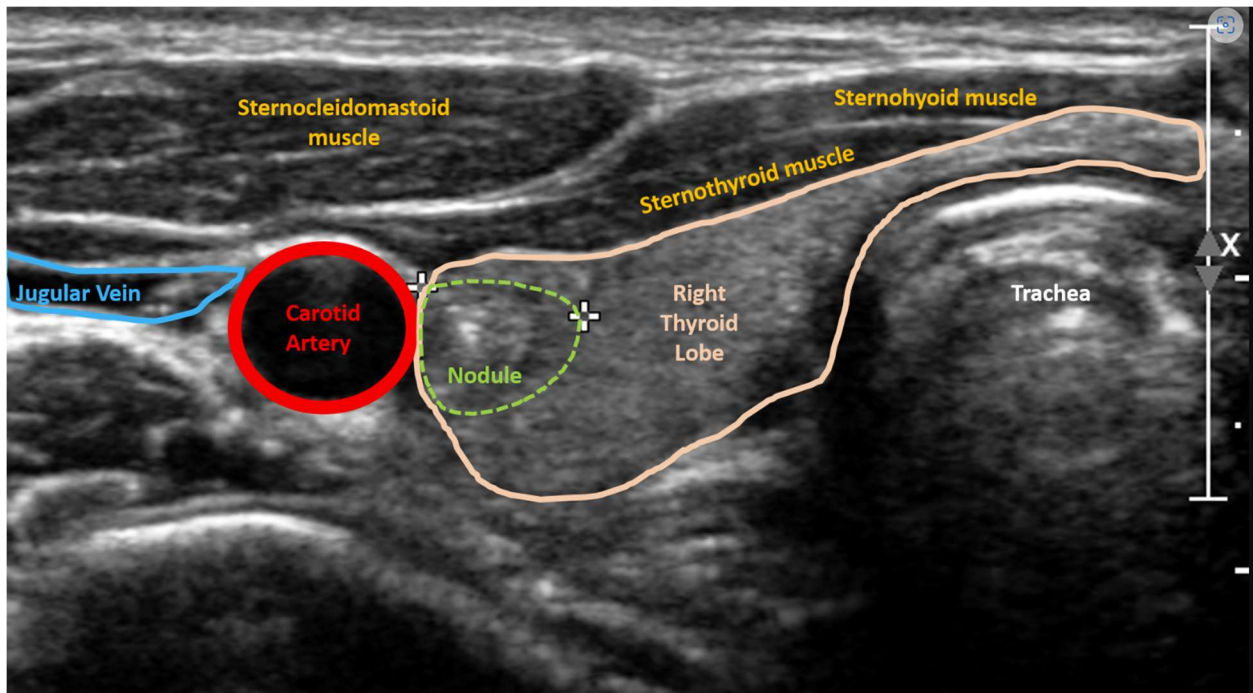
TIME AND INTENSITY OF THIS SERVICE

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.

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

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. However, it failed to recognize the difference in work intensity between the services.

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. There is significant physician work, and necessary clinical expertise, necessary to select the proper nodules for sampling and to pre-plan the needle path. 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

OUTCOME AFTER IMPLEMENTATION OF THE LOW 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.

RVU UTILIZATION CALCULATIONS WERE FLAWED

Although CMS claimed to not use the calculations as a basis for choosing a lower FNA RVU, these calculations were published as demonstrating budget neutrality when moving to the new CPT code set with new RVUs. We continue to believe that this influenced the choice for an inappropriately low intensity factor for these codes.

If we compare the actual RVU on claims from 2019 and 2021, versus the CMS published projections, we can see that in both years, the *actual work RVU was less than half of the CMS projected amounts*. Whether the utilization data was a factor in the CMS decision or not, it is clear that the actual RVU being billed for this code set is less than half of CMS projections, which supports our opinion that the codes are undervalued.

CPT Code	RUC Recommended Work RVUs	2019 Medicare Utilization Data	2021 Medicare Utilization	Work RVU Pool Based on actual CY2019 Claims	Work RVU Pool based on actual CY2021 Claims Data	CMS' Work RVU Pool Projections from CY2019 Final Rule Table 12 (due to double counting error)
10021	1.20	17,817	12,848	21,380	15,418	25,655
10004	0.80	530	287	424	230	1,900
10005	1.63	144,709	128,051	235,876	208,723	441,327
10006	1.00	33,761	30,901	33,761	30,901	30,621
10007	1.81	394	429	713	776	12,411
10008	1.18	31	29	37	34	1,030
10009	2.43	5,348	2,883	12,996	7,006	147,416
10010	1.65	95	53	157	87	11,271
10011	C	70	64		-	-
10012	C	31	34		-	-
Total Work RVU Pool				305,343	263,175	671,631
Total Work % of Projection				45.46%	39.18%	

SHIFT FROM OUTPATIENT TO FACILITY LOCATIONS

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 2021, the hospital facility claims had increased to 55.08% of claims.

INCREASED COSTS DUE TO SHIFT AWAY FROM OUTPATIENT SETTINGS

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 + OPSS)	Site of Service % Differential (Hospital Outpatient vs Non-Facility)
Office	\$ 137.92			\$ 137.92	
Facility		\$ 73.87	\$ 648.97	\$ 722.84	524%

If we consider the shift in location from Office to Facility that was seen between 2018 and 2021, with the increased cost of \$584.92 in the Facility location, Medicare experienced an additional cost of \$ 2,725,544 due to physicians in non-facility locations abandoning the procedure.

We expect this trend to continue, and accelerate, ultimately driving costs higher.

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 FNA is not an effective 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 reduced access and increased costs for many years to come.

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 reduce access and increase costs in the future.

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

CONCLUSION

Thank you for the opportunity to provide feedback on CY2024 Physician Fee Schedule.

We hope that you will share our serious concerns with the 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 CY2024 Physician Fee Schedule. This action would be synchronized 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.

AACE, ATA and the members of the two organizations are 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,

S. Sethu K. Reddy

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

A handwritten signature in black ink, appearing to read "Julie Ann Sosa".

Julie Ann Sosa, MD, MA, FACS

President, ATA



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