

MEMO

To: CMS

From: RAND (Hannah James, Jodi Liu, Lane Burgette)

Date: June 11, 2026

Re: Options to Address Potential Misvaluation of HCPCS 97610

Issue Summary

CMS asked RAND to identify services that may be misvalued under the Physician Fee Schedule (PFS). This memo examines HCPCS 97610 (low frequency non-contact ultrasound wound management); our analysis suggests that HCPCS code 97610 is potentially overvalued under the Physician Fee Schedule (PFS) due to inflated supply cost inputs. These inputs result in a substantially higher nonfacility practice expense (PE) payment rate compared to the facility-setting payment rate, resulting in a significant site-of-service payment differential.

Key Findings

- The CY2026 nonfacility PE payment rate for HCPCS 97610 is \$389, compared to a total facility-setting payment of \$207 – **a payment differential of \$182.**¹
- The nonfacility PE payment rate reflects a direct PE input of **\$320 in supply costs** for a disposable “kit, low frequency ultrasound wound therapy (MIST),” which has a list price of **\$100**, and we estimate an approximate average sales price of **\$86**.
- Utilization is highly concentrated in the nonfacility setting (181,037 services furnished in nonfacility versus 814 in facility settings), where payment is currently 88 percent higher.
- Estimated nonfacility PE payments for HCPCS 97610 are **\$69.7 million** per year across all FFS beneficiaries. With reduced supply costs or rates aligned with OPPS, total payments would be \$27.4–39.3 million.²

Proposed Updates to Practice Expense Inputs

We recommend considering the following options:

1. **Reduce Supply Cost Inputs:** Update the disposable kit supply cost to \$86 (1a) or \$100 (1b) per service, consistent with the implied sales price and observed list price.
2. **Align Nonfacility PE with OPPS:** Cap the nonfacility PE payment rate to the OPPS payment rate (2a) or service-level OPPS geometric mean cost (2b).

	NF PE	Reduce supply cost (1a)	Reduce supply cost (1b)	Align with OPPS payment rate (2a)	Align with service-level OPPS geometric mean cost (2b)
Supply cost per service	\$320	\$86	\$100	N/A	N/A
Estimated payment rate ³	\$389	\$151	\$165	\$205	\$217
Total annual nonfacility ² payments (millions)	\$70.5	\$27.4	\$29.9	\$37.1	\$39.3

¹ Payment rates are from the CY 2026 NFRM PFS Addendum B and OPPS Addendum B.

² Estimated payment rates and total payments reflect illustrative scenarios and would change based on actual PFS rate setting; reducing the supply direct PE input also affects the indirect allocation, which is not reflected here. Reduced payments would be reallocated to other services under budget neutrality requirements. Total payments are based on CY2024 nonfacility FFS volume from the Integrated Data Repository (IDR).

³ For options 1a and 1b, the estimated payment rate reflects the revised disposable kit supply cost plus unchanged work, other direct PE, malpractice, and indirect PE components (~\$65 per service). Supply cost is N/A for options 2a and 2b, which cap the total nonfacility PE rate to an OPPS benchmark rather than revising PE inputs directly; the estimated payment rate for these options is the applicable OPPS benchmark.

Conclusion

HCPCS 97610 demonstrates a misalignment between PFS nonfacility PE and OPPS payment rates, driven primarily by inflated supply cost inputs in PFS rate setting. Revising PE to reflect actual supply costs or aligning payments across settings would improve payment accuracy and mitigate site-of-service distortions. See the Appendix for additional detail on market context, device and supply pricing, and the implied sales price methodology.

APPENDIX

Market Context

Sanuwave Health, Inc. (a publicly traded company) manufactures the UltraMIST® system, a non-contact, low-frequency ultrasound wound therapy device marketed for services billed under HCPCS 97610. The system requires their proprietary per-service disposable applicator. While at least one alternative product (Arobella Medical's Qoustic® Wound Therapy System) has FDA-clearance for similar services, there is limited publicly available information indicating that this alternative product accounts for a material share of Medicare utilization under this code.

Device and Supply Pricing and Market Reach

In a [public investor presentation from December 2025](#), Sanuwave reported an approximate \$35,000 acquisition cost for the UltraMIST system and a list price of approximately \$100 per disposable applicator kit. The company states that practices typically recover the cost of the device after approximately 90 services, which it estimates corresponds to 10–13 patients. As of year-end 2024, Sanuwave reported over 1,000 UltraMIST systems deployed in the field.

Medicare Volume and Providers

In the 2024 Medicare fee-for-service (FFS) professional claims in the IDR, there were 181,037 claims for HCPCS 97610 in nonfacility settings and 814 in facility settings. There were 745 unique billing providers (based on National Provider Identifier [NPI]) that billed HCPCS 97610. Among the 718 billing NPIs with at least one service billed in a nonfacility setting, providers on average billed for 252 services during the year. Notably, only 16 billing NPIs accounted for 51 percent of the total nonfacility volume; these high-volume providers billed an average of 5,775 services during the year.

Commercial Coverage Landscape

Citing limited clinical evidence supporting the use of this service, some private payers classify non-contact ultrasound wound therapy as investigational or not medically necessary and do not provide routine coverage.⁴

⁴ Example commercial coverage policies: [Anthem](#) ("investigational and not medically necessary"), [Aetna](#) ("experimental, investigational, or unproven"), and [Blue Cross Blue Shield CA](#) ("investigational").

Implied Sales Price for the Disposable Kit

Using publicly available manufacturer disclosures and Medicare claims data, we estimated an implied sales price of \$86 per disposable kit on average. Sanuwave reported \$21.0 million in U.S. consumable and parts net revenue for calendar year 2024. Although we do not have information about the total number of kits sold by Sanuwave, we estimated total volume by assuming each of the 745 unique billing NPIs in Medicare claims have approximately one of the ~1,000 UltraMist systems in the field, such that the 181,851 Medicare claim lines account for 74.5 percent of total volume ($\$21.0 \text{ million} / [181,851 / \{745 / 1,000\}] = \86). This estimate assumes that the 181,851 Medicare claim lines account for approximately 74.5 percent of each billing NPI's total volume across all payers. Given that many commercial payers do not routinely cover non-contact ultrasound wound therapy (see Commercial Coverage Landscape), the Medicare share is likely high but cannot be verified with available data. If any of these providers perform the service for Medicaid or Medicare Advantage patients, total volume would be higher, resulting in a lower implied sales price than our estimate. This approach also assumes each of the 745 billing NPIs has access to approximately one UltraMIST system. To the extent that any NPIs share systems (e.g., multiple providers working from a single facility-owned device), this assumption would overstate total Medicare volume relative to total systems, resulting in a higher estimated implied sales price than the true average. We believe this assumption is reasonable given that the service is predominantly billed by independent nonfacility providers, but we cannot verify this with available data. The actual sales price would also be expected to vary due to volume-based or other supplier discounts, commercial utilization, and other factors.

Payment Comparison

The total facility-setting payment of \$207 reflects the OPPS payment rate (\$205) plus the facility practice expense component of the PFS facility rate (\$2) for HCPCS 97610. Together, these represent the full Medicare FFS payment for this service when it is furnished in a facility setting: the OPPS payment rate is paid to the facility, and the facility PE component is paid to the billing physician.