Submitted Electronically
CMS-1834-P
https://www.regulations.gov/document/CMS-2025-0306-0002

August 26, 2025

TO: Robert F. Kennedy, Jr., Secretary, Department of Health and Human Services
Mehmet Oz, M.D., Administrator, Centers for Medicare and Medicaid Services

ADDRESS: Centers for Medicare and Medicaid Services,
Attention: CMS-1834-P,
P.O. Box 8010,
Baltimore, MD 21244-8010

CC: David Rice, Director
Mitali Dayal, Deputy Director
Division of Outpatient Care, Hospital and Ambulatory Policy Group (HAPG)
Centers for Medicare and Medicaid Services (CMS)
David.Rice1@cms.hhs.gov
Mitali.Dayal2@cms.hhs.gov

Subject: Support for reassignment of CPT Code 76978 and CPT Code 76979 from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast)

Dear Secretary Kennedy and Dr. Oz:

The Board of Directors of the International Contrast Ultrasound Society (ICUS) respectfully submits this letter in support of the reassignment of CPT Code 76978[i] and CPT Code 76979[ii] from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast). The procedures described by these two CPT codes are non-cardiac contrast enhanced ultrasound (CEUS).

CEUS is a safe, cost-effective, noninvasive, radiation-free imaging modality.[iii] Multiple prospective[iv] and retrospective[v] studies and meta-analyses[vi] demonstrate that the sensitivity and specificity of CEUS are equivalent to that of computed tomography (CT) and magnetic resonance imaging (MRI).[vii] Studies also show that CEUS often reduces the need for downstream testing and interventional procedures[viii], and may speed up the time to diagnosis, lower overall diagnostic

imaging costs, streamline workflows, and improve patient outcomes and save lives – even in the sickest patients.[ix]

The purpose of this letter is to describe the important clinical and economic benefits of non-cardiac CEUS to patients and the broader healthcare system, and to demonstrate why an exception for low volume services and reassignment to APC 5572 are warranted. We also wish to call your attention to the clinical coherence, for resource utilization purposes, of these non-cardiac CEUS procedures with other contrast enhanced imaging procedures that currently are assigned to APC 5572.

International Contrast Ultrasound Society

ICUS is a non-profit medical society focused on the safe and appropriate utilization of CEUS where medically indicated in order to improve patient care and outcomes. Our members include radiologists, oncologists, hepatologists, and other physicians, nurses, sonographers and ultrasound imaging professionals. ICUS webinars provide CEUS education and training for novices and advanced practitioners, and are offered live and on demand. ICUS also provides white papers and expert testimony to the United States Food and Drug Administration from time to time, and coordinates with other professional organizations in the development of CEUS educational programming and evidence-based professional consensus statements and guidance documents.

CEUS and its benefits to patients and the healthcare system

CEUS utilizes standard ultrasound equipment which is portable and widely available in many medical centers. Ultrasound-based imaging may be administered at the bedside, avoiding the need to transport patients to a CT or MRI imaging suite. In addition, ultrasound-based imaging often avoids delays associated with CT or MRI and allows for real time diagnoses without exposure to ionizing radiation.

CEUS also utilizes commercially available ultrasound contrast agents (UCAs) that are administered intravenously during an ultrasound scan. UCAs traverse the microcirculation unimpeded, enhancing visualization of perfusion of tumors and other tissue, and vascular structures in various organs.

UCAs are among the safest of all contrast media. They do not contain iodine or gadolinium, and have not been shown have an effect on thyroid or renal function.[x] In addition, UCAs do not cross the placental barrier, and since CEUS avoids exposure to ionizing radiation and iodinated contrast media it is considered an ideal imaging option for pregnant patients.[xi]

We also note:

- **Real-Time Dynamic Imaging:** CEUS enables dynamic assessment of perfusion in real time. Its ability to capture arterial phase hyperenhancement and subsequent washout patterns is critical for accurate lesion characterization.

- **Higher Temporal Resolution:** CEUS permits visualization of contrast-enhancement patterns during all vascular phases (arterial, portal-venous, and late), resulting in higher temporal resolution than achieved with other imaging modalities.[xii]

- **Improve Patient Access to Timely Diagnosis:** The rapid, real-time and noninvasive nature of CEUS facilitates early and accurate diagnosis, reducing diagnostic delays and ensuring that patients receive prompt evaluation and appropriate management.

- **Enhanced Diagnostic Accuracy:** CEUS has demonstrated high sensitivity and specificity for diagnosis of lesions including hepatocellular carcinoma (HCC), the most common primary liver cancer.

- **Enhanced Clinical Workflow:** With its ease of use and immediate availability, CEUS can streamline clinical workflows as it reduces time to treatment initiation.

It is important to acknowledge that significant numbers of patients cannot tolerate contrast MR or CT, and for them CEUS may be the only advanced imaging option available. For example, patients with impaired renal function may be contra-indicated for iodinated contrast. In addition, gadolinium-based contrast media toxicity may be a concern for patients with kidney disease due to the risk of developing systemic nephrogenic fibrosis and possible renal complications. Still other patients may be allergic to iodinated contrast. Since UCAs do NOT contain iodine or gadolinium, CEUS often represents a viable imaging option for these patients - who may have a pressing need for advanced imaging to evaluate potentially serious diseases, including cancers

Clinical similarity

We note that contrast enhanced CT and MRI procedures are currently assigned to APC 5572. For resource utilization purposes, non-cardiac CEUS procedures are clinically similar to contrast enhanced CT and MRI procedures, in that they all use intravenously injected contrast agents to enhance images of internal body structures. Assigning CPT 76978 for non-cardiac CEUS to APC 5572 will create clinical coherency that does not exist under the current APC assignment for CPT 76978.

Low volumes and underutilization

While CEUS is widely used for abdominal imaging outside the United States, current under-reimbursement in the United States may contribute to underutilization, even where CEUS is clearly recommended by multiple national and international guidelines.[xiii] This may be particularly problematic for patients who do not have access to alternative advanced imaging options such as CT and MRI -- including low income, rural and under-insured patients as well as those who cannot tolerate contrast media containing iodine or gadolinium.

Policy considerations

Medicare payment policy establishes a framework for understanding the financial incentives that drive behavior in the healthcare system.[xiv] Due to the dominance of Medicare as a payor, its structure and policies also anchor the decisions of private payors and delivery systems.[xv]

Medicare coverage policy should use payment to favor use of cost-effective imaging and to take advantage of existing clinical guidelines.[xvi] Such an approach would give providers a financial incentive that is aligned with best-practice medicine.[xvii]

Conclusion

We strongly support reassignment of CPT Code 76978 and CPT Code 76979 from APC 5571 (Level 1 Imaging with Contrast) to APC 5572 (Level 2 Imaging with Contrast). Current low volumes associated with CPT Code 76978 and CPT Code 76979 do not reflect clinical best practices as described in multiple national and international guidelines and an extensive body of peer-reviewed publications. Reassignment of these two CPT codes will help improve patient access to CEUS consistent with the best interest of patients, while reducing overall diagnostic imaging costs and streamlining workflows. And, although CEUS offers distinct clinical benefits over contrast enhanced CT and MRI, for resource utilization purposes they should be assigned to the same APC 5572 in order to establish clinical cohesiveness.

Thank you for your time and consideration of this important matter.

Very truly yours,

The International Contrast Ultrasound Society Board of Directors

Steven B. Feinstein, MD, FACC, FESC; Stephanie Wilson, MD, FRCPC; Petros Nihoyannopoulos, MD, FRCP, FESC, FACC, FAHA; Michael Main, MD; J. Brian Fowlkes, PhD, FAIUM, FAIMBE, FAAPM, FASA, FIEEE; Richard G. Barr, MD, PhD, FACR, FSRU, FAIUM; Jordan Strom, MD, MSc, FACC, FASE; Andrew Appis, MD; Maria Cristina Chammas, MD, PhD; Dirk-André Clevert, MD; Kassa Darge, MD, PhD, DTM&P, FAIUM, FSAR; Pintong Huang, MD, PhD; Orpheus Kolokythas, MD, FSAR; Yuko Kono, MD, PhD, FAIUM, FAASLD; Andrej Lyshchik MD,PhD, DSc, FAIM, FSRU; Wilson Mathias, Jr., MD, FACC; Christina Merrill, BSc, CRGS, CRVS, RDMS, RVT; Sharon L. Mulvagh, MD FRCP(C), FACC, FASE, FAHA; Fabio Piscaglia, MD, PhD; Arnaldo Rabischoffsky, MD; Roxy Senior, MD, DM, FRCP, FESC, FACC; Maria Stanczak, MS, RDMS, RVT, R.T(R)(M); Joan Olson, B.S., ACS, RDCS, RVT, FASE; Jessica Stout, RDCS, FASE; Viktor Zhelov, MD (Honorary); Barry Goldberg, MD (Emeritus); Beverly Gorman, RDCS (Emeritus); Edward G. Grant MD, FACR (Emeritus); Paul A. Grayburn, MD, FACC (Emeritus); Tom Porter, MD (Emeritus)

---

[i] Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion.

[ii] Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); each additional lesion.

[iii] Strom, JB, et al., Contemporary Safety of Ultrasound Enhancing Agents in a Nationwide Analysis, Journal of the American Heart Association, May 14, 2025; Kurt M, Shaikh KA, Peterson L, Kurrelmeyer KM, Shah G, Nagueh SF, Fromm R, Quinones MA, Zoghbi WA. Impact of contrast echocardiography on evaluation of ventricular function and clinical management in a large prospective cohort. J Am Coll Cardiol. 2009;53:802–810.

[iv] Kang, H.J., et al., Role of Contrast-Enhanced Ultrasound as a Second-Line Diagnostic Modality in Noninvasive Diagnostic Algorithms for Hepatocellular Carcinoma. Korean J Radiol, 2021. 22(3): p. 354-365.

[v] Terzi, E., et al., Contrast ultrasound LI-RADS LR-5 identifies hepatocellular carcinoma in cirrhosis in a multicenter restropective study of 1,006 nodules. J Hepatol, 2018. 68(3): p. 485-492; Zheng, W., et al., Evaluation of Contrast-enhanced US LI-RADS version 2017: Application on 2020 Liver Nodules in Patients with Hepatitis B Infection. Radiology, 2020. 294(2): p. 299-307; Huang, Z., et al., MR versus CEUS LI-RADS for Distinguishing Hepatocellular Carcinoma from other Hepatic Malignancies in High-Risk Patients. Ultrasound Med Biol, 2021. 47(5): p. 1244-1252.

[vi] Jin, H., et al., LI-RADS LR-5 on contrast-enhanced ultrasonography has satisfactory diagnostic specificity for hepatocellular carcinoma: a systematic review and meta-analysis. Quant Imaging Med Surg, 2023. 13(2): p. 957-969; van der Pol, C.B., et al., CT/MRI and CEUS LI-RADS Major Features Association with Hepatocellular Carcinoma: Individual Patient Data Meta-Analysis. Radiology, 2022. 302(2): p. 326-335.

[vii] Kang, H.J., et al., Role of Contrast-Enhanced Ultrasound as a Second-Line Diagnostic Modality in Noninvasive Diagnostic Algorithms for Hepatocellular Carcinoma. Korean J Radiol, 2021. 22(3): p. 354-365; Huang, Z., et al., MR versus CEUS LI-RADS for Distinguishing Hepatocellular Carcinoma from other Hepatic Malignancies in High-Risk Patients. Ultrasound Med Biol, 2021. 47(5): p. 1244-1252; Aube, C., et al., EASL and AASLD recommendations for the diagnosis of HCC to the test of daily practice. Liver Int, 2017. 37(10): p. 1515-1525; Zhou, Y., et al., Risk Stratification and Distribution of Hepatocellular Carcinomas in CEUS and CT/MRI LI-RADS: A Meta-Analysis. Front Oncol, 2022. 12: p. 873913; Li, S., et al., Diagnostic efficacy of contrast-enhanced ultrasound versus MRI Liver Imaging Reporting and Data System (LI-RADS) for categorising hepatic observations in patients at risk of hepatocellular carcinoma. Clin Radiol, 2021. 76(2): p. 161 e1-161 e10.

[viii] Kurt M, Shaikh KA, Peterson L, Kurrelmeyer KM, Shah G, Nagueh SF, Fromm R, Quinones MA, Zoghbi WA. Impact of contrast echocardiography on evaluation of ventricular function and clinical management in a large prospective cohort. J Am Coll Cardiol. 2009;53:802–810.

[ix] Strom, JB, et al., Contemporary Safety of Ultrasound Enhancing Agents in a Nationwide Analysis, Journal of the American Heart Association, May 14, 2025; Kurt M, Shaikh KA, Peterson L, Kurrelmeyer KM, Shah G, Nagueh SF, Fromm R, Quinones MA, Zoghbi WA. Impact of contrast echocardiography on evaluation of ventricular function and clinical management in a large prospective cohort. J Am Coll Cardiol. 2009;53:802–810; Main ML, Ryan AC, Davis TE, Albano MP, Kusnetzky LL, Hibberd M. Acute mortality in hospitalized patients undergoing echocardiography with and without an ultrasound contrast agent (multicenter registry results in 4,300,966 consecutive patients). Am J Cardiol. 2008;102:1742–1746; Kusnetzky LL, Khalid A, Khumri TM, Moe TG, Jones PG, Main ML. Acute mortality in hospitalized patients undergoing echocardiography with and without an ultrasound contrast agent: results in 18,671 consecutive studies. J Am Coll Cardiol. 2008;51:1704–1706.

[x] Strom, JB, et al., Contemporary Safety of Ultrasound Enhancing Agents in a Nationwide Analysis, Journal of the American Heart Association, May 14, 2025; Main ML, Goldman JH, Grayburn PA. Thinking outside the "box"-the ultrasound contrast controversy. J Am Coll Cardiol. 2007;50:2434–2437.

[xi] Sidhu, P.S., Clevert, D.A., Deganello, A. et al. Controversies in contrast-enhanced ultrasound (CEUS): pregnancy, paediatric, abdominal trauma, complex renal cysts, and endovascular aortic repair follow-up. Insights Imaging 16, 179 (2025). https://doi.org/10.1186/s13244-025-02055-w; Wilson, S.R., Barr, R.G. Contrast-enhanced ultrasound: the ideal contrast imaging study for pregnant patients. Abdom Radiol 48, 3553 (2023). https://doi.org/10.1007/s00261-023-04008-7.

[xii] See: Dietrich, CF, literature review: https://www.uptodate.com/contents/contrast-enhanced-ultrasound-for-the-evaluation-of-liver-lesions.

[xiii] See, e.g., World Federation for Ultrasound in Medicine and Biology (WFUMB): Guidelines and good clinical practice recommendations for contrast-enhanced ultrasound (CEUS) in the liver, update (2020); Dietrich CF, et al., How to perform Contrast-Enhanced Ultrasound (CEUS), Ultrasound Int Open. 2018;4(1):E2. Epub 2018 Feb 7; Sidhu P, Cantisani V, Dietrich C et al. The EFSUMB Guidelines and Recommendations for the Clinical Practice of Contrast-Enhanced Ultrasound (CEUS) in Non-Hepatic Applications: Update 2017 (Long Version). Ultraschall in Med. 2018;39(02):e2-e44. doi:10.1055/a-0586-1107 – Pubmed; Claudon M, Dietrich C, Choi B et al. Guidelines and Good Clinical Practice Recommendations for Contrast Enhanced Ultrasound (CEUS) in the Liver--Update 2012: A WFUMB-EFSUMB Initiative in Cooperation with Representatives of AFSUMB, AIUM, ASUM, FLAUS and ICUS. Ultraschall Med. 2013;34(1):11-29. doi:10.1055/s-0032-1325499 – Pubmed; Lee J, Minami Y, Choi B et al. The AFSUMB Consensus Statements and Recommendations for the Clinical Practice

of Contrast-Enhanced Ultrasound Using Sonazoid. Ultrasonography. 2020;39(3):191-220. doi:10.14366/usg.20057 – Pubmed; https://gravitas.acr.org/PPTS/GetDocumentView?docId=25; https://optn.transplant.hrsa.gov/media/wdlfb1a2/lic-_nlrb_proposal_winter-2025_public-comment.pdf; https://edge.sitecorecloud.io/americancoldf5f-acrorgf92a-productioncb02-3650/media/ACR/Files/RADS/LI-RADS/LI-RADS-CEUS-Nonradiation-TRA-v2024-Core.pdf; https://edge.sitecorecloud.io/americancoldf5f-acrorgf92a-productioncb02-3650/media/ACR/Files/RADS/LI-RADS/CEUS-LI-RADS-2017-Core.pdf;

[xiv] Findeiss LK. Medicare Payment Policy: The Basics. Semin Intervent Radiol. 2023 Nov 2;40(5):411-418. doi: 10.1055/s-0043-1775722. PMID: 37927527; PMCID: PMC10622233.

[xv] Findeiss LK. Medicare Payment Policy: The Basics. Semin Intervent Radiol. 2023 Nov 2;40(5):411-418. doi: 10.1055/s-0043-1775722. PMID: 37927527; PMCID: PMC10622233.

[xvi] Sistrom CL, McKay NL. Evidence-based imaging guidelines and Medicare payment policy. Health Serv Res. 2008 Jun;43(3):1006-24. doi: 10.1111/j.1475-6773.2007.00802.x. PMID: 18454778; PMCID: PMC2442247.

[xvii] Sistrom CL, McKay NL. Evidence-based imaging guidelines and Medicare payment policy. Health Serv Res. 2008 Jun;43(3):1006-24. doi: 10.1111/j.1475-6773.2007.00802.x. PMID: 18454778; PMCID: PMC2442247.