PUBLIC COMMENT PERIOD ON:

Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements. [CMS-1751-P]

Submitted electronically to https://www.regulations.gov/

September 14, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
U.S. Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Brooks-LaSure,

The American Headache Society (AHS) appreciates the opportunity to submit a public comment regarding the 2022 Medicare Physician Fee Schedule Proposed Rule.

For 60 plus years, AHS has been and continues to be the leading professional society of health care providers dedicated to the study and treatment of migraine, cluster and other headaches, as well as face pain. With over 1400 members and associates, the Society's education, research, and advancement programs engage medical professionals throughout their careers, from the world's most sought after thought leaders to those at the beginning of their professional work in headache medicine.

Telehealth and Other Services Involving Communications Technology

The AHS wishes to express gratitude for the flexibilities CMS enacted during the Public Health Emergency (PHE). According to the Kaiser Family Foundation, "Among the 33.6 million Medicare beneficiaries with a usual source of care who reported that their provider currently offers telehealth appointments, nearly half (45%) said they had a telehealth visit with a doctor or other health professional between the summer (July) and fall of 2020. This translates to just over 1 in 4 (27% or 15 million) of all community-dwelling beneficiaries in both traditional Medicare and Medicare Advantage using telehealth during this time period."[1] These accommodations allowed clinicians to adapt more easily to changing circumstances in order to maintain access and quality to care for patients who may have otherwise had their care compromised.

[1] Koma, W., Cubanski, J., & Neuman, T. (2021, May 19). Medicare and Telehealth: Coverage and Use During the COVID-19 Pandemic and Options for the Future. Available at https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future.

AHS supports patient access to telehealth services regardless of location; coverage for telehealth services by all subscriber benefits and insurance; equitable provider reimbursement; simplified state licensing requirements easing access to virtual care; and expanding telehealth research and quality initiatives as recommended by the American Academy of Neurology (AAN).[2] Telehealth and communication technology-enabled services (CTBS), such as telephone encounters, have become a lifeline connecting headache medicine patients with neurology healthcare professionals. The choice to use telehealth technology is determined by the needs of the patient, the ability to access and use the technology, and the clinical problem to be addressed. Patients and caregivers alike have benefitted from expanded access to telehealth services both before and during the PHE. Patients report that access to care has improved, and that in many instances, telehealth services are more convenient and comfortable, and provide more confidentiality.

Frequency of in-person visits for continued telehealth care

AHS is glad to see CMS evaluating all elements of telehealth policy as the technology and methodology evolve. We believe that removing obstacles to access to care is of upmost importance and therefore the requirement for in-person visits should be based on medical need. Migraine is highly disabling and travel to see their healthcare professionals may be difficult during attacks or even a potential trigger for an attack of symptoms. People living with headache disorders with socioeconomic vulnerabilities may be barred from the highest quality of care by unnecessary restrictions. AHS believes that patients and healthcare professionals are capable of jointly identifying when an in-person visit is appropriate and thus a blanket restriction is unnecessary. We believe that this timeframe should be eliminated or extended to as long as possible, at least to 12 months.

Audio-only telehealth services

AHS agrees with the recommendation to make permanent the flexibilities for audio-only telehealth visits. The use of audio-only telehealth has been a tremendous benefit for many older patients and others who struggled with audio/video technology for a variety of reasons. During the PHE, 56% of Medicare beneficiaries surveyed reported having a telehealth visit using a telephone only.[3] There is a substantial proportion of the neurology patient base who does not have access to or cannot operate computers or mobile devices that have video and audio capability. Furthermore, there are many patients who cannot afford broadband access or robust cellular data plans that would allow audio/video encounters to take place.

AHS is disappointed that office/outpatient services, CPT codes 99441-99443, were not added to the telehealth services list as these are critical to access to care for patients that cannot access audio-video services. Older adults and patients without access to high quality broadband would benefit from these services. CMS acknowledges in this proposed rule the utility of audio-only visits for mental health services as many of these services "primarily involve verbal conversation where visualization between the patient and furnishing physician or practitioner may be less critical to the provision of the service." AHS strongly agrees with this rationale and believes CMS should expand this to include other neurologic services that fit the same description such as headache and pain. AHS does not believe that any additional obstacles or documentation requirements should be placed on audio-only visits that are not currently mandated for audio-visual visits. Parity between these services is critical for ease of access and administration.

Originating Site

---

[2] Hatcher-Martin, J. M., Busis, N. A., Cohen, B. H., Wolf, R. A., Jones, E. C., Anderson, E. R., Fritz, J. V., Shook, S. J., & Bove, R. M. (2021). American Academy of Neurology Telehealth Position Statement. Neurology, 97(7), 334–339. https://doi.org/10.1212/WNL.0000000000012185.

[3] Koma, W., Cubanski, J., & Neuman, T. (2021, May 19). Medicare and Telehealth: Coverage and Use During the COVID-19 Pandemic and Options for the Future. Available at https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future.

AHS agrees with CMS's addition of a patient's home as a permissible originating site as well as the removal of the geographic restrictions in § 410.78(b)(4). This is an important step in modernizing virtual care delivery and should be used as the model going forward for inclusion of other appropriate telehealth services, including those related to the neurologic community and headache medicine.

APP incident to supervision requirement flexibility

AHS supports permanently modifying direct supervision requirements so that direct supervision can be performed via real-time interactive audio/video technology in certain cases. Virtual supervision, when appropriately utilized, can be an excellent way to maximize supervised team-based care across a more distributed geography. Providers have demonstrated throughout the PHE that this flexibility has allowed them to expand access without compromising patient care. Therefore, CMS should revise the definition of "direct supervision" to include immediate availability through the virtual presence of the supervising physician or practitioner using real-time, interactive audio/video communications technology without limitation.

Conversion Factor

AHS understands that the agency cannot waive its budget neutrality requirement without modification of existing legislation. Nor can CMS unilaterally add additional funds into the Fee Schedule. With that said, AHS strongly supports the new January 1, 2021 E/M coding and reimbursement structure but notes that the subsequent reduction of the conversion factor may detrimentally impact some clinicians. AHS is supportive of requests to Congress to waive budget neutrality, and add additional necessary funds into the Fee Schedule, provided that this would not result in a delay or in any way undermine CMS's decision to fully implement the new E/M coding and payment structure that started on January 1, 2021.

Principal Care Management (PCM)

AHS commends the agency's continued focus on the value of care management and coordination services, specifically with the recognition of comprehensive services for a single high-risk disease (that is, principal care management) which are commonly provided by neurologists. We are pleased CMS is proposing to accept the RUC recommended values of four new principal care management codes, 99X22, 99X23, 99X24, and 99X24 which will be effective in CY 2022. The agency is seeking stakeholder feedback whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of PCM when appropriate. We do not think this will be the case as specialty care providers, such as neurologists, often care for a single high-risk disease and did not previously meet the criteria for reporting other care management service codes that require the management of multiple conditions. As the patient population eligible for each service would differ, we do not anticipate an issue.

Billing for Physician Assistant Services

AHS supports the proposal to allow PAs to bill and be paid directly by Medicare. This change will bring parity between PAs and other NPs which will simplify the billing process for physician-led headache medicine care teams that are increasingly utilizing NPs. We also recognize CMS may be proposing this section to comport with new state laws.

With that in mind, we think this is an important moment to note that throughout the coronavirus pandemic, physicians, NPs, nurses, and the entire health care community have been working side-by-side caring for patients and saving lives. Now more than ever, we need health care professionals working together as part of physician-led health care teams. AHS opposes efforts that undermine the physician-patient relationship and physician-led health care teams during and after the pandemic. Nurse practitioners and PAs are integral members of the care team, but the skills and acumen obtained by physicians throughout their extensive education and training make them uniquely qualified to oversee and supervise patient care. Physician-led team-based care has a proven track record of success in

improving the quality of patient care, reducing costs, and allowing all health care professionals to spend more time with their patients.

Appropriate Use Criteria

AHS supports CMS for delaying the payment penalty phase until 2023. Please extend the educational and operations testing period for the Appropriate Use Criteria (AUC) program further. AHS appreciates that CMS recognized the impact that the ongoing PHE has had on providers' ability to participate in the current educational and operations testing period meaningfully. Delaying this program is necessary because during the PHE providers must ensure that resources are devoted to patient care, rather than compliance with burdensome regulatory programs. CMS acknowledges this, noting in the rule, "we recognize that practitioners have been heavily impacted in their own practice of medicine to respond to the PHE and provide treatment to patients which may have prevented them from focusing on and participating in the educational and operations testing period to prepare for the payment penalty phase."

Due to the PHE, providers are unlikely to have gained the experience they will need to fully participate in the AUC program after the education and testing period has elapsed. AHS believes that further implementation of this program is likely to have significant detrimental impacts on timely patient access to care, which is already hindered by the ongoing PHE. As such, AHS urges CMS to consider additional delays in the implementation of the AUC program. CMS should also consider whether the standalone AUC program is necessary or if programmatic requirements have become redundant due to provider participation in the Quality Payment Program.

Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan (section 2003 of the SUPPORT Act)

AHS supports CMS's decision to delay implementation of the statutory requirements related to the electronic prescribing for controlled substances for a covered Part D drug to January 1, 2022 because implementation takes additional time and resources. We further support this delay because the ongoing PHE may present additional challenges for some prescribers. Because of this, we support the new compliance date of January 1, 2023.

We also agree with CMS that electronic prescribing of controlled substances provides many advantages over the traditional processing of paper prescriptions. These advantages include improved workflow efficiencies; deterring and detecting fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes; enhanced patient safety through identity checks, safety alerts, medication menus, electronic history files, and medication recommendations that lower the risk of errors and potentially harmful interactions' and providing more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions. We agree electronic prescribing may reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilitates, other care sites, and pharmacies.

For the reasons outlined above, the American Headache Society and the American Migraine Foundation appreciate this opportunity to provide a comment to the Proposed Rule. AHS strongly urges CMS to consider our comments so that the Final Rule further reduces regulatory burdens on headache medicine clinicians and promotes the highest quality patient-centered headache medicine care.

On behalf of the American Headache Society,

Peter Goadsby, MD, PhD, FAHS, AHS President

Amaal Starling, MD, FAHS, AHS Advocacy Committee Chair

Jessica Ailaini, MD, FAHS, AHS Practice Management Committee Co-Chair

Bran Klein, MD, MBA, FAHS, AHS Practice Management Committee Chair