



ASSOCIATION FOR MOLECULAR PATHOLOGY

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September 13, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA <http://www.regulations.gov>

Re: CMS-1751-P: 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

Dear Administrator Brooks-LaSure:

The Association for Molecular Pathology (AMP) appreciates the opportunity to comment on the calendar year (CY) 2022 Medicare Physician Fee Schedule proposed rule (CMS-1751-P). AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

Our comments in this letter focus on the following subjects included in the proposed rule:

- Pathology Clinical Consult Codes (CPT codes 80XX0, 80XX1, 80XX2, and 80XX3)
- Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs

Pathology Clinical Consult Codes (CPT codes 80XX0, 80XX1, 80XX2, and 80XX3)

In October 2019, the American Medical Association (AMA) Relative Value Update Committee (RUC) identified CPT code 80500 (*Clinical pathology consultation; limited, without review of patient's history and medical records*) through its screen for services with utilization of over 20,000 and referred the code to the CPT Editorial Panel because the descriptor was vague. In October 2020, the CPT Editorial Panel replaced the CPT code family of 80500 and 80502 with four new codes, 80XX0, 80XX1, 80XX2, and 80XX3, to report pathology clinical consultations. In addition, separate guidelines were created to document the appropriate level of service for reporting of these codes. The new code family describes pathology clinical consultations by degree of

complexity and/or time of service, broken down by 20-minute increments each for codes 80XX0, 80XX1 and 80XX2, along with an add-on code 80XX3 reflecting additional 15–30-minutes above that spent on CPT 80XX2.

AMP offers the following comments on CMS' proposed values for the revised code family.

80XX0

AMP respectfully disagrees with CMS' proposal of a work RVU of 0.43 instead of the RUC recommended physician work value of 0.50 for CPT code 80XX0. We believe that in calculating the work RVU of 0.43, CMS is not considering magnitude estimation and is disregarding the compelling evidence criteria which was presented and deemed to be met during the RUC review.

First, AMP believes that CMS is ignoring valid survey data. The surveyed pathologists have a keen understanding of the mental effort, psychological stress, and technical skill that make up physician work and time. The surveyed pathologists also have a deep understanding of the differing complexity levels of various pathology clinical consultations. The RUC's RVU recommendation of 0.50 was based on the survey's 25th percentile work RVU. CMS' RVU valuation of 0.43 skews the relationship between the value of services in this family.

Second, AMP believes that CMS has disregarded the compelling evidence criteria in support of the increased value, when arriving at a RVU valuation of 0.43. Since CMS began using the resource-based relative value scale (RBRVS), the Agency has used the compelling evidence criteria in rulemaking for the purpose of reviewing RUC recommendations. AMP stipulates that the pathology clinical consultations code family was classified as work neutral. However, the RUC provided the Agency with substantial, compelling evidence that these evaluated services' previous valuations were based on flawed methodology. The nature of physician work has changed substantially based on changes to the field's technology and the demographic composition of the patient population meeting the standard for compelling evidence in this case.

Given these factors, AMP believes that CMS should adopt the RUC-recommended work value developed with input from practicing physicians. AMP would ask the Agency to accept and implement the RUC recommended physician work value of 0.50 for CPT code 80XX0 for CY 2022.

80XX1

AMP applauds and urges CMS finalize the proposal to implement the RUC recommended physician work value of 0.91 for CPT code 80XX1 for CY 2022.

80XX2

AMP respectfully disagrees with CMS' proposal of a work RVU of 1.71 instead of the RUC-recommended value of 1.80 for CPT code 80XX0. We believe that in calculating the work RVU of 1.71, CMS is not making an appropriate CPT code comparison for the pricing of 80XX2, considering magnitude estimation and disregarding the compelling evidence criteria that were met.

After CPT code 80500 was referred to the CPT Editorial Panel, the family was revised and the two-code family of CPT codes 80500 (*Clinical pathology consultation; limited, without review of patient's history and medical records.*) and 80502 (*Clinical pathology consultation; comprehensive, for a complex diagnostic problem, with review of patient's history and medical records*) was replaced with a new family with three base codes and one add-on code with different reporting requirements. In this proposed rule, the Agency is proposing to compare the time of 80XX2 to the deleted CPT code 80502. AMP believes this is an inappropriate comparator due to the

different code descriptors and granularity added to the family with the addition of a third code as well as the add-on code. For example, the code descriptor for 80502 described a clinical pathology consultation for a “complex diagnostic problem”, whereas new code 80XX1 describes a clinical pathology consultation for a “moderately complex clinical problem” and 80XX2 for a “highly complex clinical problem”. The comparison between the two code descriptors supports that these services are not equivalent and as a result former CPT code 80502 cannot be used to commensurately evaluate CPT code 80XX2.

Second, AMP believes that CMS has again disregarded the compelling evidence criteria, when arriving at a RVU valuation of 1.71. Since the implementation of the RBRVS, the Agency has used the compelling evidence criteria in rulemaking for the purpose of reviewing RUC recommendations. CMS stipulates that the pathology clinical consultations code family was classified as work neutral. However, the RUC provided the Agency with substantial, compelling evidence that these evaluated services’ previous valuations were based on flawed methodology. The nature of physician work has changed substantially based on changes to the field’s technology and the demographic composition of the patient population meeting the compelling evidence criteria. The Agency continues to not address these systemic flaws and ignores this compelling evidence by proposing a work value of 1.71 for this service.

Finally, AMP believes that CMS is ignoring survey data, which was gathered from pathologists who are performing the services described in CPT code 80XX2. The surveyed pathologists have a keen understanding of the mental effort, psychological stress, and technical skill that make up physician work and time. The surveyed pathologists also have a deep understanding of the differing complexity levels of various pathology clinical consultations. The RUC’s RVU recommendation of 1.80 was based on the survey 25th percentile work RVU. CMS’ RVU valuation of 1.71 shows a worrisome disregard for survey data and magnitude estimation. This disregard skews the relationship between the services in this family.

Given these factors, AMP believes that CMS should adopt the RUC-recommended work values developed based on a valid survey and requests that the Agency accept and implement the RUC recommended physician work value of 1.80 for CPT code 80XX2 for CY 2022.

80XX3

AMP applauds and supports CMS’ proposal to implement the RUC recommended physician work value of 0.80 for CPT code 80XX3 based on the valid RUC survey for CY 2022.

Clinical Laboratory Fee Schedule: Laboratory Specimen Collection and Travel Allowance for Clinical Diagnostic Laboratory Tests and Use of Electronic Travel Logs

Last year, CMS established that Medicare would pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID-19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients and indicated that this policy would cease after the end of the public health emergency. Despite receiving stakeholder input, broadly supportive of making this payment permanent, CMS has still decided to terminate this payment at the end of the public health emergency.

It is the position of AMP that CMS should continue payment for laboratory specimen collection and travel allowance following the conclusion of the public health emergency in order to recognize and support the full spectrum of laboratory services. The COVID-19 pandemic has forced laboratories to scale up in terms of personnel and services offered. This upscaling has allowed laboratories to offer services that enhance patient

care while also offering a high standard of safety to employees. The pandemic has also driven significant adoption of telemedicine, which necessitates travel to patients for specimen collection. In some cases, this allows patients who cannot travel to get the full range of necessary care. COVID-19 and its many variants are now endemic in the United States, and although the public health emergency may one day end, the virus will continue to be communicable and pose a threat to community health. The continuance of this payment is necessary for laboratories to continue providing these much-needed services. Should CMS proceed and terminate these payments, AMP recommends that CMS continue to track the delivery of this service after the public health emergency ends, through HCPCS codes G2023 (specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source) and code G2024 (specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) (Coronavirus disease [COVID19]), from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, any specimen source). CMS should monitor and collect data on the use of these codes and then make an evidence-based decision on appropriate payment for these services.

Thank you for the opportunity to provide these comments. Should you have any questions, please do not hesitate to contact Sarah Thibault-Sennett, Senior Manager, Public Policy & Advocacy at sthibaultsennett@amp.org.

Sincerely,

Samuel K. Caughron, MD
Chair, Economic Affairs Committee
Association for Molecular Pathology