POINT OF CARE TESTING ASSOCIATION

June 20, 2025

VIA Electronic Mail to: clfs_inquiries@cms.hhs.gov

Sarah Shirey-Losso
Director, Division of Ambulatory Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C4–01–26
Baltimore, MD 21244

RE: CY 2025 Gapfill Preliminary Determinations

Dear Ms. Shirey-Losso:

On behalf of the Point of Care Testing Association (POCTA), we are pleased to provide comments on the CY 2025 Clinical Laboratory Fee Schedule (CLFS) Gapfill Preliminary Determinations. POCTA is a collaborative effort among manufacturers of point of care (POC) diagnostic technologies that enable clinicians to monitor chronic conditions, diagnose illnesses, and provide timely information for patients in a variety of care settings, from physician offices to pharmacies to community centers to non-hospital facilities. POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. POCTA works to develop reimbursement and regulatory policies that can improve health outcomes by supporting access to POC testing. **For the reasons outlined below, we urge CMS to increase the rates for the five neurodegenerative testing codes (82233, 82234, 83884, 84393, 84394) to $130.25 (i.e, 0358U TIMES 0.5).**

POCTA appreciates the MACs' thoughtful consideration of the materials submitted to date, as well as the MACs' acknowledgment of the additional resources required to perform these tests as compared to the non-specific immunoassay code to which CMS initially proposed crosswalk. That being said, POCTA maintains that $130.25 – i.e., the amount calculated by 0358U TIMES 0.5 – more accurately reflects the resources required to furnish these services than the rates reflected in the preliminary determinations.

Under the gapfill regulations (42 CFR § 414.508(b)), CMS may consider not only laboratory charges and payment amounts, but also "resources required to perform the test" and rates for "**other laboratory tests that may be comparable or otherwise relevant**." As outlined in the following table, 0358U is a relevant and appropriate comparator, and its use as a benchmark would be appropriate given the similar resources and methods required to run these tests; the 0.5x multiplier is justified by the lower number of targets involved (2 to 1 = 50% reduction):

Characteristic	0358U[1]	82233, 82234, 83884, 84393, 84394
In general		
Code descriptor	Neurology (mild cognitive impairment), analysis of ß-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative	Varies
Intended use	Evaluation of patients presenting with mild cognitive impairment for Alzheimer's and other causes of cognitive decline	Evaluation of patients presenting with mild cognitive impairment for Alzheimer's and other causes of cognitive decline
CLFS rate	$260.50	TBD
Pre-analytic		
Specimen type(s)	Cerebrospinal fluid (CSF)	Cerebrospinal fluid (CSF), plasma
Analytic		
Methodology	Immunoassay (chemiluminescent enzyme)	Varies (e.g., immunoassay)
Automated?	Yes	Yes
Target(s)	β-amyloid 1-40, β-amyloid 1-42	β-amyloid 1-40, β-amyloid 1-42, neurofilament light chain, phosphorylated tau, OR total tau
Number of targets	2 ***(0.5x multiplier intended to reflect that new codes only report one target, not two)***	1 ***(0.5x multiplier intended to reflect that new codes only report one target, not two)***
Measuring resolution	Picograms/ml	Picograms/ml
Post-analytic		
Quantitative results reported?	Yes	Yes
Qualitative result reported (based on ratio)?	Yes	No

Establishing rates at POCTA's recommended level would also produce more consistent ratesetting across codes describing similar services. Because these tests utilize highly similar resources and produce similarly useful clinical information, failing to align their pricing could unintentionally

[1] Information in this column pulled from Evaluation of Automatic Class III Designation for Lumipulse G B-amyloid Ratio (1-42/1-40) Decision Summary (DEN200072) (last visited June 20, 2025).

create incentives to order certain tests over others based on reimbursement differences, rather than clinical appropriateness.

We understand consistency to be an important consideration for CMS, but are concerned that the preliminary gapfill rates do not achieve this important objective. Specifically, the MACs propose a rate for neurofilament light chain testing ($70.48) that is nearly $50 lower than the rate CMS finalized ($116.23) for a specific laboratory's neurofilament light chain test (0361U[2]) last year; it is unclear how the MACs priced a seemingly similar service so much lower this year than they did last year.[3]

Establishing all NDD rates for single analytes at $130.25 – i.e., at 50% of the tests for two NDD analytes – would further CMS's critical objective of providing better consistency across similarly-situated codes.

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We thank you in advance for your consideration of these comments. If you have any questions about these recommendations, we would be pleased to meet virtually to discuss at your convenience. Please contact Mike Ryan at 202.756.8088, or via e-mail to mryan@mwe.com, if we can be helpful to CMS in any way.

Sincerely,

Mike Ryan
On behalf of the Point of Care Testing Association

[2] Neurofilament light chain, digital immunoassay, plasma, quantitative
[3] Code 0361U describes Mayo Clinic's digital immunoassay for neurofilament light chain. Other laboratories running a test for the same analyte via digital immunoassay (e.g., link), however, would be required to report with 83884 – and receive nearly $50 less if the preliminary determination for that code is finalized – when the sole difference between the tests would be the laboratory running the test.