



August 19, 2022

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Medicare Payment for Orthopoxvirus (e.g., Monkeypox) HCPCS code 87593

Dear Administrator Brooks-LaSure,

The American Clinical Laboratory Association (ACLA) is the not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, several of which are working closely with the Centers for Disease Control and Prevention (CDC) in supporting the U.S. Government response to monkeypox through significant expansion of clinical testing capacity. Answering the call to action, the five ACLA member laboratories partnering with the CDC rapidly deployed their teams and resources in order to increase the nation's testing capacity by 70,000 tests per week, above current demand.

We appreciate the Administration's leadership and partnership to enable a swift response to the monkeypox outbreak in recent months, ensuring patient access to monkeypox testing and treatment. I write today to follow up on ACLA's July 27th request to the Centers for Medicare & Medicaid Services (CMS) to ensure Medicare coverage and responsible payment for monkeypox testing and to encourage state Medicaid programs and private insurers to follow suit.

Background

Specifically, ACLA's July 27th letter (attached for reference) requests that CMS publish guidance declaring that monkeypox testing is covered by Medicare and recommending that State Medicaid Directors and commercial health plans take steps to ensure that monkeypox testing is covered and reimbursed appropriately. The communication also provided ACLA's recommendations for a Medicare payment rate for new Current Procedural Terminology (CPT®) / Healthcare Common Procedure Coding System (HCPCS) code 87593, *Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each*, which became effective on July 26th. Soon after the approval of the CPT code, ACLA contacted each Medicare Administrative Contractor (MAC) to share the association's recommendation for pricing CPT code 87593. ACLA also shared this communication with CMS staff. ACLA recommended a crosswalk to the CPT code used to report polymerase chain reaction (PCR) testing to detect the Zika virus (CPT code 87662) with a 1.5 multiplier, to arrive at a payment rate of \$76.97 ($\$51.31 \times 1.5 = \76.97).

To determine this recommendation, ACLA members noted that there are additional resources required for PCR testing to detect the monkeypox virus above and beyond many other infectious disease pathogens. The 1.5 multiplier necessarily takes into account the increased personal protective equipment (PPE) (disposable gloves, gowns, head covers and respirators), use of a Biosafety Level-3 facility for employees who have not been vaccinated for monkeypox, increased reagent use, intensified waste disposal procedures for specimens (that need to be autoclaved before disposal with some required to be shipped to CDC at the laboratory's expense), and substantial requirements for reporting communicable disease test

results to federal and state public health authorities.


Inadequate Payment Determinations

As ACLA awaits a formal response to the July 27th letter, on August 16th we began to hear from some of the MACs that are tasked with setting payment rates for this new code. First Coast Service Options and Novitas announced that they have set a rate of \$51.31, while Noridian has notified the association via email that they have set a payment rate of \$35.09.^{1,2} Both of these rates do not align with ACLA's recommendations and do not account for the inputs required to run a monkeypox test. This raises significant concerns that an inadequate payment rate may impact patient access to testing for a pathogen that is currently declared a public health emergency (PHE) in the United States.

ACLA member laboratories that offer monkeypox testing have been instructed by MACs, Medicaid Agencies, and other payers to hold claims until there is clarity on a payment rate for CPT code 87593. ACLA is concerned that the inadequate payment rates set by the MACs may impact current and future access to monkeypox testing, not only from ACLA member laboratories but also from other health care entities that want to offer the test to serve their communities. CMS's action in the early days of the COVID-19 pandemic to ensure adequate reimbursement for PCR testing was instrumental in ensuring adequate laboratory testing capacity and to encourage laboratories all over the country to offer COVID testing. The same type of action is needed to ensure adequate access to monkeypox testing and to support the rapid advancement of new test methodologies. **We urge CMS to ensure the Medicare program consistently supports appropriate coverage, payment, and billing policies consistent with the standard of care and instruct MACs, through a CMS Ruling or other mechanism, to pay claims for monkeypox testing at the reasonably derived ACLA recommended rate to support sufficient testing capacity and patient access.**

ACLA, and ACLA members are committed to continuing robust partnership with the Administration in support of the nation's monkeypox response. I thank you for your consideration and would be pleased to discuss this significant issue and the broader efforts of ACLA members at your convenience.

Sincerely,



Susan Van Meter, President
American Clinical Laboratory Association

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CC: Dr. Meena Seshamani, Deputy Administrator
Daniel Tsai, Deputy Administrator
Robert Fenton, Coordinator, National Monkeypox Response
Dr. Demetre Daskalakis, Deputy Coordinator, National Monkeypox Response

¹ First Coast Service Options, Inc. Billing new monkeypox vaccine and laboratory codes. Retrieved August 17, 2022 from: https://medicare.fcso.com/Billing_news/0498060.asp

² Noridian. Monkeypox vaccine and laboratory codes. Retrieved August 18, 2022 from: <https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00267510>



July 27, 2022

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Medicare and Medicaid Coverage for Monkeypox Testing

Dear Administrator Brooks-LaSure,

The American Clinical Laboratory Association (ACLA) appreciates the leadership of the Administration in launching a multifaceted response to the emerging public health threat posed by the spread of the monkeypox virus. ACLA, the not-for-profit association representing the nation's leading clinical and anatomic pathology laboratories, and several ACLA member laboratories are working closely with the Centers for Disease Control and Prevention (CDC) in supporting the U.S. Government response to monkeypox through significant expansion of clinical testing. As was the case from the earliest days of the COVID-19 pandemic, ACLA member laboratories have been an important component of the nation's response, among the first laboratories to validate and scale novel COVID-19 tests. To date, ACLA members have collectively performed over 200 million COVID-19 laboratory tests. Public and private health insurance coverage for tests is essential to ensuring widespread patient access to necessary testing, whether it is for COVID-19, monkeypox, or other diseases or conditions. I write today to encourage the Centers for Medicare & Medicaid Services (CMS) to ensure Medicare coverage for monkeypox testing is extended to all beneficiaries swiftly and to urge CMS to encourage state Medicaid programs to cover monkeypox testing immediately.

Currently, five ACLA member laboratories, in partnership with the CDC, have ramped national testing capacity for monkeypox to 70,000 tests per week collectively, largely by leveraging the agency's 510(k) cleared assay. This capacity is in addition to that of the nation's public health laboratories' capacity of 10,000 tests per week. This robust testing capacity is well beyond current demand. Leaders from the five member laboratories had an opportunity to meet with CDC Director Dr. Rochelle Walensky last week to discuss best practices for communication and coordination and how the commercial laboratory community can best support the federal government's response efforts, ensuring all Americans who need a test are able to access testing. ACLA and its members are grateful for the opportunity for this public-private partnership, again serving a significant role in the nation's response to a serious public health concern.

ACLA also appreciates the ongoing collaboration with the CMS on patient access to testing. I write today to share recent developments related to coding and payment for monkeypox testing and to recommend robust coverage to ensure widespread access to testing. **Specifically, we encourage CMS to communicate to Medicare Administrative Contractors (MACs) and to the health care community that monkeypox testing is covered under the Medicare laboratory test benefit category when the testing is reasonable and medically necessary for**

the beneficiary, and to also encourage State Medicaid programs to cover the testing as a laboratory benefit.

A. Background

Monkeypox is a rare disease caused by infection with the monkeypox virus. It is part of the same family of viruses as variola virus, the virus that causes smallpox. To date, there have been about 3,500 confirmed cases of monkeypox in the United States, although the number of total infections most likely is far greater.¹ On June 22, the World Health Organization declared monkeypox a “public health emergency of international concern,” with more than 16,000 infections identified in 75 countries.² The Department of Health and Human Services has activated a multi-pronged response to the outbreak, increasing the availability of testing, treatments, vaccines, and educational resources throughout the country. The CDC guidance on testing for monkeypox recommends that a person who thinks he or she has monkeypox or has had a close personal contact with someone who has monkeypox should visit a healthcare provider to determine if testing is indicated.³

B. Coding

Early this week, the American Medical Association (AMA) CPT[®] Editorial Panel approved a new CPT code to describe performance of PCR testing to detect the monkeypox virus, pursuant to an expedited code request application submitted by ACLA.⁴ The code is effective as of July 26, 2022. The code and its descriptor are:

87593	Orthopox virus (<i>e.g.</i> , monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each
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This describes a procedure in which DNA is isolated and a polymerase chain reaction (PCR) is performed for detection of orthopox genus or member species. Issuance of the code is critical to tracking the availability of testing and for reimbursement purposes, and we are pleased that the AMA CPT Editorial Panel moved quickly to respond to ACLA’s request for the code.

¹ Centers for Disease Control and Prevention, About Monkeypox, *available at*: <https://www.cdc.gov/poxvirus/monkeypox/about.html>.

² WHO Director-General's statement at the press conference following IHR Emergency Committee regarding the multi-country outbreak of monkeypox, Jul. 23, 2022, *available at*: <https://www.who.int/news-room/speeches/item/who-director-general-s-statement-on-the-press-conference-following-IHR-emergency-committee-regarding-the-multi--country-outbreak-of-monkeypox--23-july-2022>.

³ Centers for Disease Control and Prevention, Frequently Asked Questions, *available at*: <https://www.cdc.gov/poxvirus/monkeypox/faq.html>.

⁴ In mid-June, ACLA met with Jason Bennet, Director of the CMS Technology, Coding, and Pricing Group, and several of his CMS colleagues to discuss creation of a HCPCS Level II code to describe testing with the CDC kit. ACLA has not pursued a HCPCS code further, in light of the fact that the AMA CPT Editorial Panel expedited consideration of ACLA’s request for a Category I CPT code. We appreciated CMS’s engagement with ACLA on the creation of a HCPCS code nonetheless.

C. Payment

Soon after the approval of the CPT code, ACLA reached out to each of the MACs to share our recommendation for pricing the tests. This communication has also been shared with CMS. ACLA recommends a crosswalk to the CPT code used to report PCR testing to detect the Zika virus (87662), with a 1.5 multiplier, to arrive at a payment rate of \$76.97 based on the 2022 Medicare clinical laboratory fee schedule. ACLA believes this would be a fair reimbursement rate for monkeypox testing, regardless of whether a laboratory uses the CDC test kit or a test developed by the laboratory.

The new CPT code 87593 describes a test procedure that is similar to the procedure represented by CPT code 87662. However, there are additional resources required for PCR testing to detect the monkeypox virus. The 1.5 multiplier would take into account the increased personal protective equipment (PPE) costs (disposable gloves, gowns, head covers and respirators), use of a Biosafety Level-3 facility for employees who have not been vaccinated for monkeypox, overall increased reagent costs, increased waste disposal cost for specimens (which need to be autoclaved before disposal), and requirements for reporting results to public health authorities that exceed current routine reporting requirements. There are significant costs associated with the increased time required to process specimens and perform the test, which effectively doubles the cost of highly skilled technical labor. For monkeypox testing, there are additional public health reporting fields being required that were not required for Zika or COVID-19. These requirements place additional burden on laboratories to format and submit the data for public health reporting.

D. Coverage

1. Medicare Coverage

Diagnostic tests that detect the monkeypox virus should be covered as a Medicare benefit when they are reasonable and medically necessary and used to guide a particular Medicare beneficiary's treatment. Presently, testing is ordered and performed on samples of skin lesions characteristic of monkeypox, rather than being ordered to screen patients via another sample type who may have been exposed to monkeypox but who do not have skin lesions. It is important that covered diagnostic testing be available to beneficiaries who personally have symptoms of the disease, both to allow for a definitive diagnosis and treatment and to facilitate notifying and monitoring others who may have been infected.

ACLA encourages CMS to **communicate to the MAC medical directors that diagnostic testing for a monkeypox infection is a covered Medicare benefit when it is reasonable and medically necessary for a beneficiary, considering the beneficiary's possible exposure and clinical symptoms consistent with monkeypox infection (i.e., skin lesions, lymphadenopathy, initial symptoms such as fever, malaise, headache, weakness, etc.)**. An unequivocal statement, shared uniformly with all of the MAC medical directors, would serve to mitigate uncertainty as to whether the testing is covered by Medicare. Further, ACLA asks that CMS **issue a Medicare Learning Network (MLN) Matters article or a similar communication to educate health care providers and the public about Medicare coverage and payment for monkeypox testing**. CMS issued this type of communication about Zika virus testing in 2016, even before a code was

issued and payment amounts were established.⁵ Together, these communications would encourage health care providers to order monkeypox testing for Medicare beneficiaries when it is medically necessary, allaying concerns that testing may be non-covered.

2. Medicaid Coverage

ACLA also believes that State Medicaid programs should cover monkeypox testing as part of the medical assistance services described at 42 U.S.C. § 1396d(a)(3)(A) and required under 42 C.F.R. § 440.210. Widespread Medicaid coverage will help achieve broad access to patients and providers. ACLA recognizes that each State Medicaid director has a fair amount of discretion to determine the amount, duration, and scope of mandatory benefits, as long as services are sufficient to reasonably achieve their intended purpose. **ACLA recommends CMS issue a State Medicaid Director letter that encourages coverage of the testing for Medicaid beneficiaries.**

3. Commercial Coverage

ACLA encourages the issuance of general advisory guidance to the broader payer community, including commercial plans, that supports the necessity of broad access to and coverage of critical diagnostic testing and therapeutics for monkeypox, thereby setting the course for a necessary robust response to this emerging public health threat. **We encourage CMS to issue broad guidance encouraging coverage and access to monkeypox testing without imposing restrictive utilization management policies (i.e., prior authorization, prohibitive cost-sharing, etc.).**

E. Conclusion

Thank you again for your leadership and for consideration of our recommendations to ensure widespread access to reasonable and necessary monkeypox testing for the Medicare and Medicaid populations. ACLA would welcome the opportunity to discuss our efforts to support the ongoing monkeypox response and our recommendations for coverage.

Sincerely,



Susan Van Meter, President
American Clinical Laboratory Association

CC: Dr. Meena Seshamani, Deputy Administrator
Mr. Daniel Tsai, Deputy Administrator

⁵ See MLN Matters Number SE1615, Medicare Coverage for Testing for Zika Virus (Jun. 26, 2016), available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1615.pdf>.