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October 14, 2021

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P2
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" [CMS-3372-P2]

Dear Administrator Brooks-LaSure:

On behalf of the Point of Care Testing Association ("POCTA"), we appreciate the opportunity to comment on the Rule, **Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" [CMS-3372-P2]**. POCTA seeks to facilitate access to safe, effective, and cost-effective clinical diagnostic laboratory testing furnished at the time of treatment. Point of care testing enables physicians to monitor chronic conditions, diagnose illnesses, influence outpatient procedure treatment decisions, and provide timely information to patients.

POCTA has strongly supported the establishment of the Medicare Coverage of Innovative Technology (MCIT) pathway to facilitate beneficiary access to life saving technologies and is disappointed by the proposed repeal of the aforementioned rule. Although we support the proposed repeal of the definition of "reasonable and necessary", we urge CMS to finalize and implement the MCIT pathway consistent with the current Final Rule. POCTA also recommends that CMS implement reforms to the NCD process to increase access for Medicare beneficiaries to all FDA-approved devices, including clinical diagnostic laboratory tests.

POCTA offers the following comments for your consideration.

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I. Pathway for expedited coverage consideration

POCTA believes that it is critical for clinical diagnostic laboratory tests furnished at the point of care and are designated as FDA-approved breakthrough devices be eligible for national coverage in a timely manner. *In vitro* diagnostic testing is one of the central areas in which scientific breakthroughs have the potential to transform treatment and improve patient outcomes. Clinical laboratory tests provide critical lifesaving and cost saving technology to

evaluate Medicare beneficiaries for treatable and life-threatening disease. Point of care testing has been essential to managing the COVID-19 crisis by providing convenient, rapid diagnostic testing. Inclusion of these tests in an expedited coverage pathway, whether MCIT as set forth in the current Final Rule or similar regulatory process, avoids coverage uncertainty for FDA-cleared / authorized / approved diagnostic laboratory tests that are designated as breakthrough devices, while enabling CMS and the Medicare Administrative Contractors (MACs) to conserve resources and avoid duplicating analysis done by FDA to determine the safety and effectiveness of devices. Inclusion of these tests in an expedited pathway is also consistent with the Agency's recognition of the value of diagnostic testing to drive better-informed and more efficient patient care.

In this Proposed Rule, CMS expresses its concern that the MCIT pathway as currently defined is not in the best interest of Medicare beneficiaries as the current rule "may provide coverage without adequate evidence that the [d]evice would be a reasonable and necessary treatment for the Medicare patients that have the particular disease or condition that the device is intended to treat or diagnose." While proposing a repeal for the rule as currently constructed, the Agency discusses using existing pathways or conducting future rule-making.

POCTA has supported the MCIT pathway, including national coverage for a period of up to four years. **In accordance with that position, we disagree with this Proposed Rule which would rescind implementation of the MCIT pathway.** A four-year period of national coverage would facilitate generation of additional evidence of clinical utility to support continued coverage following the end of a transitional national coverage period.

Should CMS finalize its decision to repeal the MCIT pathway, we urge CMS to consider other alternatives such as expedited national coverage whereby device manufacturers can submit an expedited request for coverage consideration for breakthrough devices to show CMS that:

(a) There are sufficient data with Medicare beneficiaries in the FDA clearance/approval package or otherwise publicly available in the clinical literature; and

(b) The data on performance of the breakthrough device in Medicare beneficiaries are consistent with the data for the intended use population overall as included in the directions for use approved by the FDA.

In evaluating the data submitted by the applicant to support coverage in the Medicare-eligible population, we ask that the Agency consider the data in light of relative risk of the device to the Medicare populations. Many *in vitro* diagnostic devices, such as clinical diagnostic laboratory tests furnished at the point of care, have a substantially lower risk profile than surgically inserted or implanted devices.

A process for expedited review of an application for coverage could be modeled after the transitional pass-through device payment status under the Hospital Outpatient Prospective Payment System whereby organizations can submit a request on a quarterly basis with a decision as early as four months following submission.

Complete application for expedited coverage by the first business date in:	Earliest effective date for national coverage begins on:
March	July 1
June	October 1
September	January 1
December	April 1

It is critically important that Medicare beneficiaries have access to innovative devices and technologies, such as point of care clinical laboratory tests, which play a pivotal role in diagnosis and treatment. For example, the scientific advances resulting in nucleic acid amplification, antigen and antibody testing for SARS-CoV-2, have substantially contributed to the management of the pandemic. As such, we urge CMS to finalize the MCIT pathway as currently defined or establish a comparable pathway to allow for expedited coverage for breakthrough devices.

II. Repeal of "reasonable and necessary" definition

POCTA agrees that CMS should not create a pathway to coverage based on private payer policies.

In the September 1, 2020 Proposed Rule, CMS proposed to define the term "reasonable and necessary" to mean an item or service that is —(1) safe and effective; (2) not experimental or investigational; and (3) appropriate for Medicare patients. When determining whether an item or service is "appropriate" for purposes of criterion (3), CMS proposed that such item or service must either (a) meet all of the following criteria – be furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member; be furnished in a setting appropriate to the patient's medical needs and condition; be ordered and furnished by qualified personnel; be one that meets, but does not exceed, the patient's medical need; and be at least as beneficial as an existing and available medically appropriate alternative, or (b) is covered by private payers, unless evidence supports that there are clinically relevant differences between Medicare beneficiaries and privately insured individuals..

Although POCTA appreciated CMS' desire to clarify the factors used in making Medicare ''reasonable and necessary'' determinations, we did not support and continue to not support codification of the definition of "reasonable and necessary." In particular, we are concerned about the proposal to allow Medicare coverage to be based on commercial insurance policies.

The policy proposal to rely on commercial coverage is unnecessary since current law and regulations do not prohibit CMS and MACs from considering commercial policies today. While the two provisions were in the same rule, we believe that CMS can repeal the "reasonable and necessary" provisions and proceed with the implementation of the MCIT pathway consistent with current Final Rule.

Should CMS decide to reopen the "reasonable and necessary" definition in the future, **POCTA urges CMS to eliminate the requirement that an item or service must be "at least as beneficial as an existing and available medically appropriate alternative."** We recognize that this criterion is currently included in the Program Integrity Manual. However, POCTA is concerned about the codification of language that appears to impose a comparative effectiveness evidence requirement for coverage.

POCTA agrees that Medicare beneficiaries should receive high-quality care, and that poor performing items and services should not be covered. However, it is unclear whether many existing, well-established, FDA-approved items and services would have data establishing that they meet the "at least as beneficial" standard. It is difficult to conduct comparative effectiveness trials to show that one device is "at least as beneficial" as another. Equivalence designs typically require very large numbers of subjects, which may be technically and economically infeasible to run. For this reason, FDA typically accepts non-inferiority designs to show comparative effectiveness when a new technology is being evaluated in comparison to an established reference standard. POCTA is concerned, however, that such studies may not be considered sufficient under this "at least as beneficial" standard where non-inferiority is established when the lower bound confidence limit of an item or service's performance is less than a reference albeit within the range of a pre-set non-inferiority margin.

A criterion that could be interpreted to require performance data above and beyond what FDA requires in a premarket review could impede access to well-established items and services, including point of care clinical diagnostic laboratory tests. POCTA strongly urges CMS to delete this criterion from the regulation in the future.

III. Implementation of reforms to NCD process

Improved Medicare access to all clinically beneficial innovative technologies, including clinical diagnostic laboratory tests, can be achieved through adjustments to the timing, review and approval process for National Coverage Determinations (NCD) and by better coordination between CMS and MACs and between CMS and FDA. POCTA encourages CMS to implement the following practical reforms to the NCD process that will streamline and accelerate coverage of all FDA-cleared/approved and clinically beneficial devices, including clinical diagnostic laboratory tests.

1. **Shorten and standardize timeline between FDA approval and approval by CMS of a National Coverage Analysis (NCA) request.** Timelines required for notice of approval of an NCA coverage request by a manufacturer and for issuing NCD instructions for implementation are not currently subject to a specific timeline, and the time interval to CMS response has substantially increased. To address these issues, POCTA recommends that CMS establish a 60-day timeline for responding to formal NCA requests and a 90-day timeline for issuing implementation instructions following a final NCD. In conjunction with regulating and increasing the transparency of the NCA request to approval timeline, POCTA recommends that CMS keep the list of pending NCA requests updated in order to increase transparency regarding the number and nature of pending NCA requests.

2. **Address coverage of new indications in NCD language to eliminate requirement for NCD revision for each new FDA approved indication.** A revision to an NCD to add a new indication takes a year or longer (for each indication that is added). To assure beneficiary access for a new indication pending the finalization of an NCD, CMS should include language in an NCD to indicate that future FDA approved indications automatically will be covered. In cases where the above is not deemed appropriate, CMS should include language in the NCD indicating that new indications may be covered by the MACs on a claim by claim basis pending the finalization of a revised NCD.

3. **Omit trial design specifications from NCDs.** Trial design guidelines in NCDs often become outdated as the technology evolves. NCDs should be structured to avoid including elements that are variable and can become obsolete, such as trial design. Instead, the NCD should state that the clinical trial design must be approved by CMS.

4. **Require all NCDs with coverage with evidence development (CED) to specify a timeframe for the life of the CED.** CEDs are intended to be used judiciously and over a specific timeline. If no deadline is established for completion of a CED, the CED could continue indefinitely, even though all clinical evidence questions of coverage have been addressed. This problem can be solved by ensuring that a timeframe is specified in the NCD. If CMS eliminates the CED requirement in an NCD, the service or procedure should remain nationally covered under the NCD and not revert to local coverage at the discretion of the local MACs to ensure continuity of coverage.

5. **Prohibit concurrent NCA and LCD processes**. The ability of MACs to initiate an LCD for a technology at the same time manufacturers are initiating an NCA request leads to lack of clarity about coverage for providers. POCTA recommends that MACs not be permitted to begin an LCD process after a formal request is submitted and an NCA initiated. MACs could be instructed to check with CMS regarding the status of a future NCA before proceeding with an LCD.

6. **Expand use of parallel review.** Parallel review by CMS and FDA can substantially decrease the time between FDA approval and CMS national coverage. POCTA recommends that CMS and FDA loosen the criteria for technologies to qualify for parallel review and simplify the application process so that more technologies can benefit from this process.

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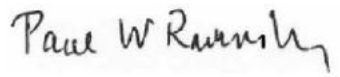
While we understand the Agency's concerns with certain aspects of the MCIT pathway, we believe that these concerns can be addressed as part of the implementation and urge the Agency to finalize and implement the MCIT pathway consistent with the current Final Rule. Thank you for your consideration of our comments. We would be pleased to discuss them with you in greater detail at your convenience. Please contact Paul Radensky at (202) 756-8794 or pradensky@mcdermottplus.com if you have any question.

Sincerely,



Paul Radensky, Counsel
Point of Care Testing Association