AMERICAN CLINICAL LABORATORY ASSOCIATION

November 2, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P
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-P]

Dear Administrator Verma,

The American Clinical Laboratory Association (ACLA) appreciates the Centers for Medicare and Medicaid Services (CMS's) consideration of our comments on the abovementioned Proposed Rule.[1] As you know, ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. ACLA works to advance the next generation of health care delivery through policies that expand access to lifesaving testing services.

ACLA's comments focus on the proposed codification of the "reasonable and necessary" standard, and application of the Medicare Coverage of Innovative Technology (MCIT) pathway to clinical laboratory tests.

I. Codified Definition of "Reasonable and Necessary"

A standard for what is considered to be "reasonable and necessary" has appeared in the Medicare Program Integrity Manual (PIM) chapter on Local Coverage Determinations for many years.[2] CMS seeks to codify the standard as follows:

> *Reasonable and necessary* means that an item or service is considered—
>
> (1) Safe and effective;
>
> (2) Except as set forth in § 411.15(o) of this chapter, not experimental or investigational; and

[1] 85 Fed. Reg. 54327 (Sept. 1, 2020).
[2] Medicare Program Integrity Manual, Pub. No. 100-08, Ch. 13, Sec. 13.5.4.

> (3) Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it—
>
> (i) Meets all of the following criteria:
>
> (A) Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the functioning of a malformed body member;
>
> (B) Furnished in a setting appropriate to the patient's medical needs and conditions;
>
> (C) Ordered and furnished by qualified personnel;
>
> (D) One that meets, but that does not exceed, the patient's medical need; and
>
> (E) At least as beneficial as an existing and available medically appropriate alternative; or
>
> (ii) Is covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.[3]

A. "Safe and effective"

"Safe and effective" is the first criterion that has been included in the standard for "reasonable and necessary" in the PIM. Since this is the same standard used by the Federal Food and Drug Administration (FDA) to evaluate drugs and devices for marketing approval,[4] ACLA is concerned that this criterion could be interpreted as meaning that laboratory developed tests (LDTs) would need to be approved by the FDA as a condition for coverage by Medicare. Since any such interpretation would be inappropriate and likely would result in significant loss of access to medically necessary laboratory services for Medicare beneficiaries, this criterion should not be applied to LDTs in a manner that would require FDA clearance or approval as a condition of Medicare coverage.

While the "safe and effective" standard is appropriate for products distributed in interstate commerce that are designed for and intended to produce a direct therapeutic impact, LDTs are services, developed and performed by the same laboratory entity that do not create a direct therapeutic impact, but rather provide information to inform treatment decisions. LDTs are

[3] 85 Fed. Reg. 54338.
[4] *See* 21 C.F.R. § 860.7(b), Determination of safety and effectiveness.

qualitatively different from the tangible goods with direct therapeutic impact that the FDA may regulate as "devices" and to which the standard "safe and effective" appropriately applies. When CMS's predecessor agency set forth its interpretation of "reasonable and necessary" in the context of making National Coverage Determinations (NCDs), it recognized that "[n]ot all of the criteria are necessarily pertinent to every coverage issue and each criterion is not necessarily given equal consideration in reaching a final decision."[5] (Indeed, almost none of that proposed rule's discussion of what is meant by "safe and effective" is relevant to LDTs.)

While we recognize that this criterion has been included in the PIM for some time, it is important for CMS to acknowledge and clarify in the regulatory text that this first criterion will not be interpreted now or in the future to require LDTs to have FDA approval or clearance before Medicare can cover them. Codified regulations carry more weight than subregulatory guidance such as the PIM, and it is important that the regulation not be left open to this interpretation.

B. "As least as beneficial as an existing and available medically appropriate alternative"

In the proposed definition of "reasonable and necessary," whether an item or service is "appropriate for Medicare patients" turns in part on whether it is "as least as beneficial as an existing and available medically appropriate alternative." For the reasons below, we believe this criterion should be struck from the proposed regulation altogether.

To determine whether an item or service is appropriate for a Medicare patient, it is not necessary to determine whether it is more or less beneficial than other items or services. The proposed regulation's other criteria for appropriateness focus on an item's or services use for that particular beneficiary, which is sufficient to determine whether it is "reasonable and necessary". The other criteria are: being furnished in accordance with accepted standards of medical practice, being furnished in an appropriate setting, being ordered by qualified personnel, and meeting the patient's medical need. In contrast, the criterion at issue here compares an item's or service's benefit to other items or services. The availability and characteristics of other items and services should not be relevant. Also, an item or service that is far inferior to other available technology will not be "furnished in accordance with accepted standards of medical practice." It is not necessary to include this criterion.

Also, if included in the definition of "reasonable and necessary," this criterion could be interpreted to require a laboratory test developer to conduct clinical trials and present data comparing a test for which coverage is sought to other available tests, delaying access to cutting-edge diagnostics for Medicare beneficiaries. We also are concerned about the potential for this criterion to be interpreted to determine appropriateness based on relative costs of two tests. For

[5] Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302, 4307 (Jan. 30, 1989).

the foregoing reasons, we believe this criterion should be removed from the proposed regulation altogether.

C. "One that meets, but that does not exceed, the patient's medical need"

ACLA is concerned that the phrase "one that meets, but that does not exceed, the patient's medical need" could be interpreted to exclude innovative tests that are designed to provide more complete information to a treating health care practitioner earlier in the course of the disease, such as some blood-based cancer tests. These types of tests can lead to better patient outcomes and lower overall Medicare costs. We request that CMS revise this part of the proposed definition to read "one that meets the patient's medical need."

D. Commercial coverage criteria

In lieu of meeting all of the criteria in (3)(i) of the proposed regulation, an item or service can be shown to be "reasonable and necessary" by meeting criteria (1) and (2) and the criterion at (3)(ii), that the item or service "[i]s covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant." ACLA supports inclusion of this criterion if it is applied in a manner that helps to promote, rather than restrict, Medicare coverage of beneficial clinical diagnostics, and if evaluations under the criterion are transparent and fair.

1. Transparency is paramount.

We are heartened that CMS raised the issue of transparency of the commercial coverage policy evaluation process.[6] It is of utmost importance to ACLA members that when CMS or a MAC makes a determination about whether a laboratory test is "reasonable and necessary" based in part on one or more commercial coverage policies, the evaluation process is transparent. In a determination of whether a test meets this criterion, the evaluator should disclose the policy or policies evaluated, how and why they were selected, the metrics used in the evaluation, and the decision-making process. When an evaluator determines that a test is "reasonable and necessary" based in part on this criterion, this kind of transparency will give laboratories and other stakeholders valuable information about the factors considered in the evaluation that can be instructive in future requests for coverage or appeals. When an evaluator determines that a test is not "reasonable and necessary," the transparency may give a laboratory an opportunity to provide additional information or to address inaccurate assumptions.

[6] 85 Fed. Reg. 54332.

2. Determination of appropriateness for Medicare patients

We disagree with CMS's proposal that the "commercial market analysis would be initiated if an item/service fails to fulfill the existing factor (3) criteria defining appropriate for Medicare patients but fulfills (1) safe and effective and (2) not experimental or investigational.[7] Rather than wait for a MAC's determination of whether all three of the established "reasonable and necessary" criteria have been met, a stakeholder should be able to highlight the existence of one or more favorable commercial coverage policies in support of Medicare coverage of an item or service. This will save time, facilitate the evaluation process, and help the agency use scarce resources most efficiently.

3. Presentation of evidence of a commercial coverage policy

CMS and the MACs should rely solely on the requestor of coverage to provide evidence of commercial coverage of an item or service to support its appropriateness for Medicare patients. Beneficiaries, providers, innovators, and other stakeholders may provide CMS and the MACs with evidence of commercial coverage, but CMS and the MACs should confer with the requestor to ensure such evidence of commercial coverage is germane to the analysis of an item or service. The requestor will be the most familiar with how commercial policies treat certain items or services and the insurers' rationales, which can be of benefit to the Medicare program. Of course, if CMS or a MAC is aware of a salient commercial coverage policy that satisfies this criterion, it should not decline to determine that an item or service is "reasonable and necessary" simply because a stakeholder did not bring a commercial coverage policy forward.

CMS should consider it sufficient that a single commercial insurer covers an item or service for it to meet this criterion. The aim of the Proposed Rule is to increase Medicare beneficiary access to innovative technologies, and waiting until an item or service reaches a certain threshold of coverage among commercial payors (*e.g.*, number of payors, lives covered, geographic coverage) would have the opposite effect.

4. Exception when there are "clinically relevant differences"

As proposed, commercial coverage policies are relevant to appropriateness for Medicare patients "unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant." We urge CMS to revise the proposed exception to applicability of commercial coverage policies. We believe that Medicare beneficiaries should be compared to those covered by a commercial insurance policy who are similar to Medicare beneficiaries, and if there are clinically relevant differences between those two groups, the commercial coverage policy would not be used to support an item's or service's appropriateness for Medicare patients. We are concerned that, as written, the exception could be

[7] *Id.*

used to deny coverage when there are clinically relevant differences between Medicare beneficiaries and only *some* of the lives covered by a commercial policy. We suggest that CMS revise the exception to read: "unless evidence supports that differences between Medicare beneficiaries and comparable commercially insured individuals are clinically relevant."

We agree with the agency's general thinking that the existing criteria for when an item or service is "appropriate for Medicare patients" could be used in instances when the proposed exception regarding clinically relevant differences applies.[8]

5. Coverage restrictions

CMS proposes that when it evaluates commercial coverage policies that restrict coverage, it will adopt the least restrictive coverage policy for the item or service, to facilitate greater access to innovative treatments and provide beneficiaries with more opportunity to improve health.[9] ACLA agrees with this approach, which was reflected in the recent NCD for acupuncture for chronic low back pain.[10] In response to commenters who pointed to commercial coverage policies in support of Medicare coverage of acupuncture, CMS said: "We note that while there is variation in covered indications and frequency of service, a number of large private payors provide some coverage of acupuncture for certain indications."

Commercial insurers may non-cover an item or service for reasons that are at odds with the goal of making a test "widely available, consistent with the principles of patient safety, market-based policies, and value for patients."[11] CMS should remain focused on this goal and cover items and services as broadly as the least restrictive commercial coverage policy does.

6. Grandfathering

When an item or service is found to be "reasonable and necessary" based in part on commercial policy coverage, the policies' coverage restrictions could narrow the circumstances under which Medicare will cover the item or service, so the agency asks whether it should "grandfather" its current coverage policies. We believe that current Medicare coverage policies that are less restrictive than commercial coverage policies should be grandfathered, in service of the goal of broadening access to innovative technologies. However, an existing Medicare policy that is more restrictive than a commercial policy should not be grandfathered automatically. In

---

[8] *Id*.
[9] *Id*.
[10] CMS, Decision Memorandum for Acupuncture for Chronic Low Back Pain (Jan. 21, 2020), *available at* https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=295.
[11] Executive Order on Protecting and Improving Medicare for our Nation's Seniors, E.O. 13890 (Oct. 3, 2019).

fact, CMS and the MACs should be open to considering changes in existing policies when presented with one or more commercial policies that provide greater access to a laboratory test.

E. Location of the Definition of "Reasonable and Necessary"

In proposing to codify the "reasonable and necessary" standard, CMS is responding to Executive Order 13890, which directs the agency to clarify "the application of coverage standards, including the evidence standards CMS uses in applying its reasonable-and-necessary standard..."[12] Because the definition will have far broader applicability than just the MCIT pathway, it should be codified in a section of the Code of Federal Regulations relevant to all Medicare items and services, such as 42 C.F.R § 400.202, Definitions Specific to Medicare.

II. MCIT Pathway

ACLA supports creation of the MCIT pathway for Medicare coverage of FDA-cleared or -approved devices. We believe this pathway can expedite and improve Medicare beneficiaries' access to new technology and is an important addition to the existing NCD and LCD processes.

Our understanding is that clinical laboratory tests whose developers voluntarily submit them to the FDA and that meet the MCIT criteria would be eligible for Medicare coverage under the pathway. Innovative clinical laboratory tests are appropriate for inclusion in the MCIT pathway because they transform care and help clinicians choose the right treatment for the right beneficiary more precisely and efficiently. We ask CMS to confirm in the Final Rule that clinical laboratory tests are eligible for inclusion when they meet the MCIT pathway criteria. We also ask CMS to state explicitly in the Final Rule that while FDA designation and approval of an LDT as a breakthrough technology would be sufficient for Medicare coverage of that test, submission of an LDT to FDA for premarket clearance or approval is not a condition for Medicare coverage and remains voluntary.

The proposed regulation would apply the MCIT pathway to breakthrough devices that are not otherwise excluded and fall within a Medicare benefit category. ACLA supports CMS' proposed broad definition of "within a benefit category" as this aligns with the goal of the MCIT pathway to provide an additional coverage pathway for the most innovative clinical laboratory tests, including diagnostic and screening tests.

---

[12] *Id.*

ACLA agrees with the proposed two-year lookback period and believes that it may allow coverage of breakthrough devices that were approved or cleared by the FDA more recently and eliminate a coverage gap for those devices.

We ask that CMS extend the Medicare coverage period to five years, from the proposed four years.[13] The coverage period is to allow a breakthrough technology developer to gather clinical evidence and data regarding the benefit of the use of the technology "in a real-world setting."[14] For many disease states, studies track a patient's progress over five years (*e.g.*, rate of five-year disease-free survival after cancer diagnosis). Changing the coverage period to five years would align "real world" evidence collection with the coverage period and give the Medicare program a more complete understanding of the benefits of many kinds of innovative technology.

* * * * *

Thank you for your attention to ACLA's comments on the Proposed Rule.

Sincerely,

Sharon L. West
Vice President, Legal and Regulatory Affairs

[13] 85 Fed. Reg. 54334.
[14] *Id.*