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October 31, 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:

On behalf of the Coalition for 21st Century Medicine (C21), we appreciate the opportunity to comment on the above-captioned proposed rule. In particular, C21 strongly supports the establishment of the Medicare Coverage of Innovative Technology (MCIT) pathway to facilitate beneficiary access to life saving technologies. C21 members are developing clinical laboratory tests that would be eligible for coverage under the MCIT pathway following FDA market authorization.

C21 comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. C21's mission is to improve the quality of healthcare by encouraging research, development, and commercialization of innovative diagnostic technologies that will personalize patient care, improve patient outcomes, and substantially reduce healthcare costs. For fifteen years, C21 has worked with CMS on the development, promulgation, and implementation of policies intended to facilitate appropriate patient access to high-quality clinical laboratory tests.

In furtherance of this goal, C21 offers the following comments on both the MCIT pathway and the reasonable and necessary definition in the proposed rule for the agency's consideration:

I. C21 Supports the Medicare Coverage of Innovative Technology Pathway to Facilitate Beneficiary Access to New Technologies

A. Summary of Support for MCIT

C21 strongly supports the proposed MCIT pathway. We believe the MCIT pathway addresses the concerns identified in the President's October 3, 2019 Executive Order[1] – that delays between FDA clearance or approval of new technologies and Medicare coverage inappropriately limit beneficiary access to new life-saving items and services. C21 has worked with CMS, Medicare contractors, FDA, and Congress over the past decade to expand access to advanced diagnostics.

CMS is proposing the MCIT pathway to provide up to four years of national coverage to FDA cleared or approved breakthrough devices. Specifically, the agency's proposed regulations would provide for up to four years of national coverage for devices that are FDA-designated breakthrough devices and are FDA market authorized – that is, cleared under section 510(k) of the Food, Drug and Cosmetic Act, approved under Premarket Approval (PMA), authorized under a De Novo classification, or otherwise authorized. Such coverage would be limited to the device's FDA approved or cleared indication for use. Additionally, the product would need to be within a Medicare benefit category, and not be otherwise excluded from coverage through law or regulation. The proposed coverage would last for four years from the date of FDA clearance or approval, unless ended early at the manufacturer's request or due to a National Coverage Determination (NCD) or change in law or regulation.

We agree that the rigorous review and validation required for FDA clearance or approval after designation as a breakthrough device suffices to demonstrate that the device is reasonable and necessary while additional evidence is developed. C21 does not believe that CMS needs to mandate or incentivize additional studies during the MCIT period, as manufacturers of breakthrough devices that receive FDA clearance or approval have undertaken robust pre-market studies and, typically, also conduct post-market studies as part of the regulatory product life-cycle. The MCIT period should provide sufficient opportunity for device manufacturers to address with CMS and/or their local Medicare Administrative Contractor (MAC) any additional evidence that should be developed outside of an FDA post-market study in order to support coverage after the end of the MCIT period.

C21 also supports the voluntary opt-in approach proposed for the MCIT. Although we anticipate that most manufacturers of breakthrough devices will elect to participate in the MCIT in order to establish consistent national coverage for an initial period, we agree that it is appropriate for the agency to allow manufacturers to make that choice by affirmatively opting into the program. We recommend that CMS be flexible with respect to the establishment of deadlines for opting into the MCIT.

C21 agrees that CMS should defer to FDA to determine what type of medical devices are eligible for breakthrough device designation. Given the questions raised by the references in the Proposed Rule and its accompanying press release, we recommend that CMS clarify in the Final Rule that any medical device, including any in vitro diagnostic, that receives breakthrough

[1] White House, Executive Order 13890, "Executive Order on Protecting and Improving Medicare for Our Nation's Seniors," Oct. 3, 2019, *available at* https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/.

designation from FDA and is both 1) subsequently FDA cleared or approved and 2) otherwise eligible for MCIT coverage, would be included in the MCIT program.

Finally, to the extent possible under existing authorities, C21 encourages CMS to make available any information it has (or may obtain in the future) regarding individual devices granted breakthrough status (e.g., intended use, evaluation criteria, and supporting data), as well as aggregate program performance metrics (e.g., number of applications, approval status, and review time). Historically, stakeholders have very limited visibility into FDA's process and rationale for "breakthrough" designation decisions, and the availability of such information will facilitate reimbursement and business planning.

B. Request Explicit Inclusion of Clinical Laboratory Tests in MCIT

The proposed regulations at § 405.603(a) would allow any "***FDA-designated breakthrough devices***" meeting the other criteria for the MCIT to be included in the new coverage pathway. This regulatory language includes FDA cleared or approved molecular diagnostic tests based on analytes such as DNA, RNA, or proteins – along with other clinical laboratory tests – that receive breakthrough designation as devices and are both 1) subsequently FDA cleared or approved and 2) otherwise eligible for MCIT coverage. This is confirmed in CMS' fact sheet accompanying the Proposed Rule, where the agency states that ***"[t]he proposed MCIT pathway would only be available for FDA-designated breakthrough devices (which includes some diagnostic tests) that have subsequently been market authorized***."[2] The accompanying Press Release states that the MCIT "could include devices harnessing new technologies like implants or ***gene-based tests*** to diagnose or treat life-threatening or irreversibly debilitating diseases or conditions like cancer and heart disease."[3] Based on the proposed regulations, all clinical laboratory tests designated by FDA as breakthrough devices that meet the other MCIT criteria should be eligible to opt in to the MCIT pathway.

C21 ***strongly supports*** CMS' proposal to include clinical laboratory tests in the MCIT pathway. We believe that it is critical for clinical laboratory tests that are FDA cleared or approved as breakthrough devices to be eligible for coverage under the MCIT. Clinical laboratory testing is one of the central areas in which scientific breakthroughs have the potential to transform treatment and prevent inefficient care. CMS has recognized the clinical value of such testing in NCDs for colorectal cancer screening and Next Generation Sequencing for advanced cancer patients, and in its support for centralizing expertise on molecular diagnostic tests through the MolDX program to provide a coverage pathway for these assays.

Inclusion of clinical laboratory tests in the MCIT is consistent with the agency's emphasis on the value of diagnostic testing to drive better-informed and more efficient patient care. In addition, the MCIT criteria, as proposed, would already restrict coverage under the MCIT to those clinical laboratory tests submitted to FDA for premarket clearance or approval. This is a voluntary process for clinical laboratory tests, as the FDA has made clear that it "will not require premarket

[2] CMS Fact Sheet, "Proposed Medicare Coverage of Innovative Technology (CMS-3372-P)," Aug. 31, 2020, *available at* https://www.cms.gov/newsroom/fact-sheets/proposed-medicare-coverage-innovative-technology-cms-3372-p.
[3] CMS Press Release, "CMS Acts to Spur Innovation for America's Seniors," Aug. 31, 2020, *available at* https://www.cms.gov/newsroom/press-releases/cms-acts-spur-innovation-americas-seniors.

review of laboratory developed tests absent notice-and-comment rulemaking."[4] Although we note that in the Preamble to the Proposed Rule, CMS solicits comment as to whether the MCIT should include "diagnostics," our understanding is that this is intended to refer to drugs used in diagnostic imaging (e.g. PET imaging agents). However, to avoid any unintentional confusion, we respectfully urge CMS to ***clarify explicitly in the Final Rule that clinical laboratory tests are eligible for the MCIT if they meet the criteria for inclusion***.

C. Support Interpretation of "Benefit Category" Requirement in Accordance with Objective to Provide Additional Coverage Pathway

CMS' proposed regulations would apply the MCIT to any FDA cleared or approved breakthrough device that is "within a benefit category" and is not excluded by statute, regulation, or NCD. In the Proposed Rule, CMS suggests a broad approach to whether a device is "within" a benefit category for purposes of the MCIT. The agency takes the position that "coverage would occur unless the device does not have a Medicare benefit category or is otherwise excluded from coverage by statute." CMS lists "certain wearable devices" as examples of devices that would not be included under the MCIT because they lack a benefit category.[5]

C21 ***supports*** the agency's position that a clinical laboratory test (whether diagnostic or screening) should be included in the MCIT as long as it is within a benefit category. This interpretation would align with the intent of the MCIT to provide a new avenue for consistent coverage of FDA cleared or approved breakthrough devices. C21 believes that clinical laboratory tests that are FDA cleared or approved as breakthrough devices should be eligible for coverage under one or more of the applicable benefit categories including: diagnostic laboratory tests (§ 1861(s)(3)), other diagnostic tests (§ 1861(s)(3)), diagnostic services furnished to hospital outpatients (Social Security Act § 1861(s)(2)(C)), specific single cancer screening tests such as colorectal (§§ 1861(s)(2)(R) and 1861(pp)) or prostate cancer (§§ 1861(s)(2)(P) and 1861(oo)), and/or additional preventive services (§ 1861(ddd)).

D. Responses to CMS' Technical Questions

CMS also raises several technical questions regarding the implementation of the MCIT provisions of the Proposed Rule. Below please find C21's response to certain of these questions.

1. <u>C21 supports the two-year lookback for MCIT inclusion</u>

C21 ***agrees*** with the agency's proposal for a two-year lookback period, and believes it strikes an appropriate balance to allow coverage of recently FDA cleared or approved breakthrough devices that may face the type of coverage gap that the MCIT was proposed to avoid, while not disturbing existing local coverage policies for devices that have been on the market for a longer period of time. C21 further agrees that the date of FDA clearance or approval is the appropriate

[4] FDA, "Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests," *available at* https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html.
[5] 85 Fed. Reg. 54,329 (Sep. 1, 2020).

start of the lookback period, as opposed to the date of designation by FDA as a breakthrough device.

2. Recommend five years of MCIT coverage period

C21 ***recommends the extension of the MCIT period to five years***. In many disease states in which a test might be designated as a breakthrough device, such as oncology and transplantation medicine, studies often measure outcomes in five-year intervals. For instance, a study to provide evidence for a test that informs cancer treatment might track five-year disease-free survival. Making the MCIT period five years instead of four years would align with these outcomes measures, improving the ability of device manufacturers to generate robust evidence to inform post-MCIT coverage.

In particular, to the extent CMS expects to begin reviewing clinical evidence in support of post-MCIT coverage one to two years before the end of the MCIT period,[6] a longer period of MCIT coverage is necessary. On the current time frame, additional studies to demonstrate clinical utility would have to be completed in the two-year period following the breakthrough device's clearance or approval. This may not allow for adequate time to understand the evidentiary needs of CMS and the MACs, design and initiate a study, complete the study, and publish peer-reviewed results. A five-year MCIT period is likely to be particularly important to ensure an appropriate window to generate evidence for technologies that may require years of patient follow-up to demonstrate utility.

3. Maintain coverage following the expiration date of the MCIT period, unless modified

After the conclusion of the MCIT period, ***coverage under the MCIT should be deemed to remain in effect until an NCD or LCD that modifies such coverage takes effect***. When the MCIT ends, the existing Medicare coverage rules become applicable. CMS has a longstanding position against revising an existing coverage policy without stakeholder notice and comment, especially where the effect is to restrict coverage.[7] It follows that coverage under the MCIT – the existing coverage policy at the end of the four-year (or five-year) period – should remain in effect until changed by CMS or a MAC through the NCD or LCD process.

Along with being consistent with CMS' existing policy, this approach would avoid provider and beneficiary coverage uncertainty at the end of the MCIT period, and would relieve CMS and the MACs of the burden of establishing coverage policies on a strict timetable even when they do not believe that a change to coverage under the MCIT is warranted. C21 does not believe that maintaining the MCIT coverage as the default at the end of the four-year period, unless modified through the NCD or LCD process, would present a disincentive for manufacturers to develop clinical evidence in support of MCIT-participating devices. CMS and the MACs would retain the ability to restrict coverage through an NCD or LCD. Thus, manufacturers will continue to have an incentive to develop clinical evidence to support maintaining and/or expanding the MCIT coverage.

[6] *See* 85 Fed. Reg. 54,331 (Sep. 1, 2020) ("Manufacturers that are interested in a NCD are encouraged to submit a NCD request during the third year of MCIT to allow for sufficient time for NCD development.").
[7] *See* Medicare Program Integrity Manual, chapter 13, section 13.2.4.

E. Recommended Modifications to Text of Proposed Regulation

To effectuate our recommended changes, C21 also recommends specific revisions to the regulatory text:

1. Clarify that MCIT applies to on-label indications of a device not addressed by an NCD

The proposed regulations at § 405.603(e) state that devices are eligible for the MCIT pathway only if they "are not the subject of a Medicare national coverage determination." The agency states that it is proposing to exclude devices subject to an NCD because for these devices, "once the device has been reviewed by CMS for the FDA-required approved or cleared indication for use; CMS has made a coverage determination based on the available evidence for that technology."[8]

However, in certain cases, CMS' NCD only addresses ***some*** of a breakthrough device's labeled indications. In these circumstances, the agency's rationale for excluding devices subject to an NCD from the MCIT applies only to those indications ***within the scope of the NCD***. Indications outside the scope of the NCD are not analyzed by CMS. If excluded from the MCIT, these indications – which are not included in CMS' coverage analysis – would continue to be subject to the coverage gaps that the MCIT seeks to remedy.

We recommend that CMS revise the regulatory language to provide that an otherwise eligible breakthrough device that is subject to an NCD is excluded from the MCIT only with respect to those indications that are within the scope of the NCD.

2. Commencement of MCIT coverage as of effective date of Final Rule for previously cleared or approved devices

Currently the proposed regulations at § 405.607 provide that the coverage period under MCIT begins "on the date the breakthrough device receives FDA market authorization." We believe that CMS' objective of providing "predictable national coverage… that will generally last for a set time period"[9] is best served by ***allowing FDA-designated breakthrough devices that were cleared or approved prior to the effective date of the Final Rule the full period of coverage***. This will provide manufacturers of breakthrough devices cleared or approved prior to the effective date of the Final Rule the full four (or five) years of MCIT coverage in which to develop additional evidence of improvement of health outcomes, rather than restricting them to a shorter period of coverage, which could result in more rushed evidence development. In addition, providing the full period of coverage would avoid frequent fluctuations in coverage that could be burdensome for providers, patients, and MACs.

3. Confirmation that Devices Included in MCIT are Reasonable and Necessary

In the Proposed Rule, CMS proposes that "breakthrough devices per se meet the reasonable and necessary standard in order to increase access and to reduce the delay from FDA market

[8] 85 Fed. Reg. 54,334 (Sep. 1, 2020).
[9] *Id.*

authorization to Medicare coverage."[10] We agree with CMS' proposal. However, we urge the agency to anchor in the regulatory text the determination that devices that qualify for the MCIT are reasonable and necessary.

To effectuate the proposed changes set forth above, as well as those set out in Section I.D.2, C21 has included recommended revisions to the proposed regulatory text to read as follows:

42 C.F.R. § 405.603 Medical device eligibility

The MCIT pathway is available only to medical devices that meet all of the following:

*(e) That are not the subject of a Medicare national coverage determination**, provided that a medical device shall be considered to be the subject of a Medicare national coverage determination only with respect to FDA approved or cleared indications addressed by such national coverage determination**.*

42 C.F.R. § 405.603 Coverage of items and services.

*Covered items and services furnished within the MCIT pathway **are reasonable and necessary and** may include any of the following, if not otherwise excluded from coverage*

42 C.F.R. § 405.607 Coverage period.

(a) Start of the period*. The MCIT pathway begins on the date the breakthrough device receives FDA market authorization **or [effective date of the Final Rule], whichever is later**.*

(b) End of the period*. The MCIT pathway for a breakthrough device ends as follows:*

*(1) No later than ~~4~~ **5** years from the date the **MCIT pathway begins for the** breakthrough device ~~**received FDA market authorization**~~.*

*(2) Prior to ~~4~~ **5** years if a manufacturer withdraws the breakthrough device from the MCIT pathway.*

*(3) Prior to ~~4~~ **5** years if the breakthrough device becomes the subject of a national coverage determination or otherwise becomes noncovered through law or regulation**, provided that a national coverage determination shall only end the MCIT pathway for a breakthrough device with respect to FDA approved or cleared indications addressed by such national coverage determination**.*

II. Proposed Regulatory Standards for "Reasonable and Necessary" Determination

In the Proposed Rule, CMS proposes to define the term "reasonable and necessary" to mean an item or service that is (a) safe and effective; (b) not experimental or investigational; and (c) appropriate for Medicare patients. When determining whether an item or service is

[10] 85 Fed. Reg. 54,333 (Sep. 1, 2020).

"appropriate" for purposes of criterion (c), CMS proposes that such item or service must either (i) 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 (ii) be covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.

C21 offers the following comments regarding this aspect of the Proposed Rule.

A. **Recommended modifications to text of proposed regulation**

1. Clarification that the proposed "reasonable and necessary" definition applies to all items and services furnished to Medicare beneficiaries – not just investigational devices.

C21 understands that CMS intends for the definition of "reasonable and necessary" to apply all items and services furnished to Medicare beneficiaries.[11] However, CMS proposes to add this definition to 42 C.F.R. § 405.201(b). This regulation is located in a 42 C.F.R. Part 405 Subpart B, which specifically addresses coverage for investigational devices.[12] Insofar as CMS intends for the definition of "reasonable and necessary" to apply to items and services more broadly – including to diagnostic testing services – C21 recommends that this definition be codified in a section of the regulations that applies more broadly (e.g., 42 C.F.R. Part 411[13]), and is not focused solely on investigational medical devices.

2. Modification to clarify that existence of commercial payer coverage policies would meet all three proposed "reasonable and necessary" criteria – not just "appropriateness".

Under the Proposed Rule, the availability of commercial payer coverage policies would only be relevant to the third "reasonable and necessary" criteria – i.e., appropriateness. As such, if CMS or a local MAC determines that an item or service is (a) not safe and effective or (b) experimental or investigational, the item or service would not be "reasonable and necessary", even if the item or service is covered by commercial payers.

[11] *See* 85 Fed. Reg. 54,331 (Sept. 1, 2020) ("In addition to codifying the above criteria, we propose to include a separate basis under which an *item or service* would be appropriate… that is based on commercial health insurers' coverage policies..." (emphasis added).)

[12] *See* 42 C.F.R. § 405.201(a) ("This subpart establishes that— (1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and (2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized as Category B (Nonexperimental/investigational) device. (3) CMS identifies criteria for coverage of items and services furnished in IDE studies.")

[13] *See* 42 C.F.R. § 411.1(b) ("This subpart identifies: (1) The particular types of services that are excluded; (2) The circumstances under which Medicare denies payment for certain services that are usually covered; and (3) The circumstances under which Medicare pays for services usually excluded from payment.")

However, it is unclear why the existence of a commercial payer policy would not also establish that an item or service is safe and effective, and not experimental or investigational. While commercial payers may not use the precise Medicare terminology, commercial payers would not publish a favorable coverage policy for an item or service unless they decided that the item or service was safe and effective, and not experimental or investigational.

While determinations of safety/effectiveness and experimental/investigational status are typically made based on a generalized understanding of an item or service's performance, "appropriateness" determinations are typically made at a patient-specific level.[14] Insofar as commercial payer policies similarly focus on a generalized (non-patient-specific) assessment of an item or service, it would be appropriate for the existence of such policies to be relevant to determinations of safety/effectiveness and investigational/experimental status as well.

As such, C21 recommends that CMS modify the proposed regulatory text to clarify that if an item or service is identified as covered in a commercial payer policy, all three "reasonable and necessary" requirements will be met unless CMS, or when CMS has not determined, a local MAC, may determine that there are clinically relevant differences between Medicare and commercial beneficiaries.

3. Recommended deletion of criterion that an item or service must be "at least as beneficial as an existing and available medically appropriate alternative".

C21 understands that the "at least as beneficial" criterion is currently included in the Program Integrity Manual. However, C21 is concerned about the codification of language that appears to impose a comparative effectiveness requirement for coverage.

C21 understands and agree 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. For example, the use of non-inferiority trials is well-established in FDA's review of drugs and biological products.[15] Similarly, in FDA's review of companion diagnostic tests, the agency typically requires the new test developer to establish non-inferiority to a "gold standard" methodology prior to granting premarket approval.[16] In non-inferiority trials, non-inferiority is established when the point estimate and 95% CI of an item or service's performance do not fall outside a pre-set non-inferiority margin. Therefore, non-inferiority trials do not automatically establish equivalent performance to the

[14] *See, e.g.,* 54 Fed Reg. 4,308 (Jan. 30, 1989) ("A service is considered appropriate if it is furnished in a setting commensurate with the patient's medical needs and condition, and furnished by qualified personnel.")

[15] *See, e.g.,* U.S. Food and Drug Administration, Non-Inferiority Trials to Establish Effectiveness: Guidance for Industry (November 2016), https://www.fda.gov/media/78504/download.

[16] *See* U.S. Food and Drug Administration, Regulatory Update: Next Generation Sequencing (NGS)-Based Oncopanels (June 26, 2018), https://deainfo.nci.nih.gov/advisory/joint/0618/03-Philip.pdf, at 23 (highlighting validation approach for NGS oncopanels offered as companion diagnostics).

comparator method[17] – and the data required to obtain FDA approval may not be sufficient to establish that an item or service is "at least as beneficial" as an alternative.

Contrary to the intent of the Proposed Rule, establishing 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 diagnostic tests. As such, C21 encourages CMS to delete this proposed criterion from the regulation.

Therefore, in summary, C21 recommends that CMS revise the proposed regulatory text to read as follows:

> *[insert appropriate regulatory section – e.g., 42 C.F.R. Part 411]*
> *Reasonable and necessary means that an item or service either –*
> *(1) Is considered –*
> *(i) Safe and effective*
> *(ii) Except as set forth in § 411.15(o) of this chapter, not experimental and investigational; and*
> *(iii) Appropriate for Medicare patients, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it 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 function of a malformed body member*
> *(B) Furnished in a setting appropriate to the patient's medical needs and condition;*
> *(C) Ordered and furnished by qualified personnel; and*
> *(D) One that meets, but does not exceed, the patient's medical need; or*
> *(2) Is covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant.*

B. Comments on aspects of proposed rule not requiring changes to proposed regulatory text

Above and beyond what appears in the text of the proposed regulation, the Proposed Rule outlines how CMS intends to implement the "commercial payer" component of this proposal. C21 offers the following comments on these aspects of this proposal.

[17] *See, e.g.,* U.S. Food and Drug Administration, Non-Inferiority Trials to Establish Effectiveness: Guidance for Industry (November 2016), https://www.fda.gov/media/78504/download, at 2 ("Active controlled trials that are not intended to show superiority of the test drug but rather to show that the new treatment is not inferior to an unacceptable extent were once called clinical equivalence trials. The intent of an NI trial, however, is not to show that the new drug is equivalent, but rather that it is not materially worse than the control. Therefore, the interest is one-sided. The new drug could be better than the control, and therefore at a minimum noninferior, but it would not be equivalent.")

1. Recommendation that the commercial coverage option not be considered a fallback option, only to be considered if the current "appropriateness" criteria are not met.

Under the Proposed Rule, CMS (or when CMS has not spoken, a local MAC) would only consider the existence of commercial payer cover policies if the current "appropriateness" criteria are not met. However, it is unclear why this analysis would need to proceed sequentially. There is no reason why providers of novel items and services should be required to wait for CMS and the local MACs to determine that the current appropriateness criteria have (or have not) been met if a commercial payer policy already identifies the item or service as covered, and CMS considers such designation to be persuasive.

As outlined above, C21 believes that the existence of a commercial payer coverage policy should be sufficient to meet all three "reasonable and necessary" criteria. However, if CMS disagrees, we encourage CMS to clarify that the appropriateness criteria can be met by pointing to the existence of a positive commercial payer coverage policy, regardless of whether the item or service described therein has first been analyzed under the existing "appropriateness" criteria.

2. Recommended clarification that "safe and effective" language not be interpreted to require FDA premarket review where items or services can be lawfully marketed without such review.

Under the Proposed Rule, CMS proposes to require that an item or service be "safe and effective" to meet the definition of "reasonable and necessary". While this language is similar to the language that FDA uses with respect to its review of certain FDA-regulated products and services, certain items and services – e.g., laboratory-developed tests (LDTs) – can be furnished without FDA premarket review. To confirm that such items and services will continue to be eligible for coverage even if they have not undergone premarket review, C21 encourages CMS to clarify that its reference to "safe and effective" is not intended to impose a requirement for FDA premarket review where the FDA does not itself require such review.

C. Responses to CMS' technical questions

CMS also raises several technical questions regarding the implementation of the "reasonable and necessary" provisions of the Proposed Rule. Below, please find C21's response to certain of these questions:

1. What is the best way to determine which commercial plan(s) to rely on?

CMS should recognize any commercial payer policy (or other evidence of coverage, as described below).

2. Should CMS limit its consideration of commercial plan offerings or covered lives to a subset of the commercial market in the interest of simplicity, including looking at geographic subsets, subsets based on number of enrollees, subsets based on plan type (HMO, PPO, etc.), or other subsets of plans—including utilizing a singular plan?

CMS should consider evidence of coverage from all commercial plans. Plans with geographically limited scopes, or relatively small beneficiary populations, should not be categorically excluded from consideration.

3. Given considerations such as the variation and distribution of coverage policies and access to innovations, should CMS only cover an item or service if it is covered for a majority, or a different proportion such as a plurality, of covered lives amongst plans? Or a majority, plurality, or some other proportion of plan offerings in the commercial market? Or should one commercial plan policy be sufficient?

Insofar as the intent of the Proposed Rule is to increase patient access to innovative technologies, CMS should take the most flexible approach possible, and establish that the item is "reasonable and necessary" if any individual commercial payer identifies the item or service as covered.

4. Should CMS adopt the most restrictive or least restrictive policy? Or if coverage restrictions are largely similar and present across a majority (or some other threshold) of offerings, should CMS adopt such restrictions?

CMS and/or the local MACs should adopt the least restrictive coverage policy from a commercial payer.

In the event that multiple policies could be considered the "least" restrictive (e.g., because the policies do not overlap 1:1 with respect to what they cover), the least restrictive policy should be considered the combination of the policies that are least restrictive, implemented in the least restrictive cumulative manner.

5. Should CMS grandfather its current coverage policies for items and services?

Existing Medicare policies that are less restrictive than commercial payer policies should be grandfathered. However, existing Medicare policies that are more restrictive than commercial payer policies should not be grandfathered unless there is evidence that the Medicare population is different from the private payer population and that such differences warrant different coverage policies.

6. What sources of data should be used to identify commercial payer coverage status? Should CMS make this information public and transparent?

CMS and/or the MACs should rely on payer policies published on publicly available payer websites. While certain third parties maintain databases of published payer policies, there is no guarantee that such databases include published policies from all commercial payers.

For those items and services that are not the subject of a published payer policy but are nonetheless covered by a commercial payer, CMS and/or the MACs should also be permitted to rely on non-policy documentation evidencing coverage (e.g., written correspondence affirming intent to cover an item or service on a case-by-case basis, contractual agreement with a recognized payer evidencing intent to cover an item or service, or redacted claims evidencing actual coverage (i.e., if item or service is clearly identified on the claim form with a unique

billing code, or the proprietary name of the item or service is clearly identified in an Explanation of Benefits)).

Interested stakeholders should be given the opportunity to proactively submit payer policies or the other above-referenced documentation to CMS and/or the MACs.

Any information that CMS and/or the MACs rely on when evaluating commercial payer policies should be made public via a transparent process (e.g., maintenance of an online database of controlling commercial policies).

7. To what extent should MACs have flexibility to address the above considerations?

CMS should encourage MACs to review commercial payer policies on a regular (i.e., monthly) basis to ensure coverage determinations and decisions comply with those of commercial payers.[18] (CMS should itself review such policies on a similar timeline, to the extent applicable.) Insofar as commercial payers may make changes to policies between MAC review cycles, Medicare coverage should be back-dated to the effective date of the updated commercial payer policy.

In addition, MACs should be given the flexibility to develop less restrictive coverage policies where supported by clinical evidence and/or professional society guidelines – i.e., commercial payer policies should serve as a floor, not a ceiling, for what is covered by Medicare.

However, CMS should clarify that insofar as a commercial payer may have a published policy that forms the basis of a positive coverage determination but also includes certain utilization controls, a MAC's reliance on such policy does not authorize the MAC to impose the utilization controls described therein unless MACs are explicitly authorized to impose such controls in the Social Security Act. For example, because MACs do not generally have authority to impose prior authorization requirements on items and services, the MACs could not impose such requirements even if a payer implements such controls.

8. If there is evidence to believe that Medicare beneficiaries have different clinical needs (and the process herein would not apply), what quantum of evidence should be sufficient? And should that process be handled through the NCD process or in another way?

CMS and/or the local MACs should have substantial clinical evidence (as such term may be defined in subsequent notice and comment rulemaking) of differences between the Medicare population and the commercial payer population to justify any deviations from the private payer standard. If CMS and/or the local MACs decide to rely upon this "claw back" standard, it should be handled via notice and comment rulemaking (if handled by CMS) or the current public process for the revision of LCDs (if handled by the MACs). Subsequently, if CMS and/or the local MACs chose to reverse this determination, they should have the authority to do so using an expedited process that will not unduly impact beneficiary access to such items and services.

[18] We recognize that this requirement would impose additional administrative costs on the MACs. CMS could account for this additional work by making it part of the MAC scope of work, such that the costs associated with such work would be reflected in a potential contractor's bid for a particular jurisdiction.

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Thank you for considering our comments. Please contact me at hmurphy@c21cm.org or (916) 835-5117 should you have any questions or if we can provide you with further information.

Sincerely,

Hannah Murphy