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November 2, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically at www.regulations.gov

Re: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" [CMS-3372-P]; 42 CFR Part 405; RIN 0938-AT88

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the *Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"* proposed rule[1] published in the Federal Register on September 1, 2020.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicaid beneficiaries.

In this rule, CMS is proposing regulatory standards to be used in making reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act (the Act) for items and services that are furnished under Part A and Part B. This proposed rule would also establish a new Medicare coverage pathway for new, innovative medical devices designated as breakthrough by the Food and Drug Administration (FDA).

Below we offer comments and recommendations on both of these proposals.

[1] Available at https://www.federalregister.gov/documents/2020/09/01/2020-19289/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and

Codification and Definition of "Reasonable and Necessary"

To date, the factors used in making "reasonable and necessary" determinations based on section 1862(a)(1)(A) of the Act have not been established in regulations for Medicare coverage purposes. The Secretary has authority to determine whether a particular medical item or service is "reasonable and necessary" under section 1862(a)(1)(A) of the Act.

When making coverage determinations, CMS policies consider whether the item or service is safe and effective, not experimental or investigational, and appropriate. These factors are found in Chapter 13 of the Medicare Program Integrity Manual (PIM) at section 13.5.4—*Reasonable and Necessary Provisions in LCDs* as instructions for Medicare contractors.

Proposal: Codification and Definition of "Reasonable and Necessary"

CMS is proposing to codify in regulations the Program Integrity Manual definition of "reasonable and necessary" with modifications, including to add a reference to Medicare patients and a reference to commercial health insurer coverage policies.

CMS proposes that an item or service would be considered "reasonable and necessary" (new language *in italics*) if it is:

1) safe and effective;
2) not experimental or investigational; and
3) appropriate *for Medicare patients*, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
    - 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;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

Under criterion number 3, CMS is proposing to add language that an item or service would be "appropriate for Medicare patients" *if it is covered in the commercial insurance market* (except where evidence supports that there are clinically relevant differences between Medicare beneficiaries and commercially insured individuals). An item or service deemed appropriate for Medicare coverage based on commercial coverage would be covered on that basis without also having to satisfy the bullets listed above. CMS proposes 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.

Role of "Commercial Coverage" in CMS' Coverage Determinations in Medicare

ASCO urges CMS to affirm that the proposed addition of commercial plan coverage as a criterion for Medicare coverage would function as an additional consideration for coverage, not as a substitute. Additionally, the absence or paucity of commercial coverage for a specific item or service should not serve as a basis for CMS to deny Medicare coverage of such an item or service. If coverage is lacking in the commercial market, CMS should revert to consideration of the original criteria under requirement number 3 as they currently exist in the Program Integrity Manual.

While CMS proposes 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, the agency is also soliciting comment on whether to grant coverage for an item or service to the extent it meets the first and second factors and the commercial coverage criterion for the third factor.

CMS is also soliciting comment on whether to grant coverage for an item or service to the extent it meets the first and second factors and the commercial coverage basis for the third factor. Under this approach, CMS would only use the current definition of "appropriate" from the current PIM when the exception for clinically relevant differences between Medicare beneficiaries and commercially insured individuals applies (or if the commercial coverage basis is determined by a proportion like a majority and there is insufficient commercial coverage information available). The agency notes that referring to commercial coverage in this way may expand or narrow the circumstances under which it will cover a particular item or service and therefore solicits comment on whether, under such an approach, it should grandfather its current coverage policies for items and services.

ASCO does not agree with any approach to the use of commercial coverage policies that could narrow coverage under Medicare, or that would permit CMS or the MACs to narrow coverage without their own independent review and analysis of the evidence. ASCO emphasizes that it is critical for CMS and the MACs to view the addition of "commercial insurance coverage" to the criteria for Medicare coverage as just that: an *additional* and possibly speedier pathway to coverage. Consideration of commercial coverage could lead to more rapid coverage by Medicare if coverage emerges on the private market prior to CMS' usual determination of reasonable and necessary. As we emphasize above, this additional "commercial insurance" criterion should act as an additional, potentially more rapid pathway to coverage. It should not absolve CMS of the requirement to determine in timely fashion if an item or service is "appropriate" (criterion 3) for Medicare coverage if commercial coverage is sparse or does not (yet) exist.

It is critical to note that Medicare has a basis in law with defined benefit categories, and rubrics for making determinations regarding coverage and reimbursement. Commercial insurance plans have different legal foundations. They may choose to cover services based in part on contractual arrangements, price negotiations, and choice of in-network providers. Effectively, this results in a system where commercial insurance providers may restrict coverage of some services on a basis that aligns with the contracts beneficiaries and providers have signed, but is unrelated to whether or not the item or service is reasonable and necessary under Medicare. There are several other reasons coverage may be

lacking in the commercial market for items/services that may be of benefit to Medicare beneficiaries. For example, the age mix of beneficiaries in commercial plans is definitionally much greater than beneficiaries in Medicare and certain items/services may be of greater utility in the Medicare population; an item/service may be new to the market and not yet covered by commercial payers; and private plans may be able to avoid covering costly items/services that are used by a very small proportion of their beneficiaries. If CMS delays covering an item/service until after it is covered on the commercial market, the agency may create a perverse incentive that delays coverage for all patients.

Coverage Restrictions

We agree with CMS' proposal to initially adopt the least restrictive coverage policy for the item or service amongst the commercial plan offerings CMS examines. CMS recognizes that plan offerings may impose certain coverage restrictions on an item or service, e.g. related to clinical criteria, disease stage, or number and frequency of treatment. As greater access to innovative treatments provides beneficiaries with more opportunity to optimize their health outcomes, CMS states that the agency would, when coverage is afforded on the basis of commercial coverage, adopt the least restrictive coverage policy for the item or service amongst the offerings examined. However, given the potential for unreasonable or unnecessary utilization, CMS also solicits comment on whether the agency should instead adopt the most restrictive coverage policy. ASCO understands that CMS must balance beneficiary access with careful stewardship of Medicare funds and concerns exist that less restrictive coverage may encourage overuse. CMS has well-established mechanisms for detecting, preventing, and correcting what the agency views as overuse (e.g. trends in use/billing, education, audits); therefore, matching coverage to the least restrictive available based on best available current clinical evidence and monitoring utilization in Medicare would provide the greatest beneficiary access while protecting against unreasonable or unnecessary utilization.

Process for Consideration of Commercial Plans

ASCO supports transparency in the process that CMS finalizes for consideration of commercial plans when determining coverage for Medicare patients. In the proposed rule, CMS seeks comment on the sources of data that could be used to implement this policy, and whether the agency should make this information public and transparent. Notwithstanding multiple outstanding questions related to which commercial plans or plan offerings should be considered when considering coverage for Medicare patients, by definition CMS will be looking at commercial plans in some form when making this determination. ASCO supports establishing a consistent process that is predictable and fair to all stakeholders; CMS should make public its process for selecting and reviewing commercial coverage and subsequent decision-making and solicit feedback from stakeholders on a regular basis. We note that the 21st Century Cures Act standards for local coverage determinations include "a summary of evidence that was considered by the contractor during the development of such determination and a list of the sources of such evidence." Any new process CMS establishes for consideration of commercial coverage should be at least equivalent to these standards.

Stakeholders' Demonstration of Coverage in Commercial Plans

All stakeholders wishing to gain coverage for an item or service should be able to demonstrate coverage in the commercial market for purposes of CMS' consideration of coverage under Medicare. The standard that CMS is setting for consideration of coverage under the new proposed criterion is that coverage in the commercial market should be established. In such a case, it is immaterial whether such coverage is brought to CMS' attention by beneficiaries, providers, innovators, or others, or whether CMS or its MACs identify such coverage through their own review of health insurance offerings.

Conclusion

In summary, we believe that careful and considered implementation of this proposal could speed Medicare coverage and enhance access to care for Medicare beneficiaries, a goal we all share. However, in addition to the points listed above, we do want to highlight the potential for other unintended outcomes and possible perverse incentives which would require careful monitoring as this proposal is implemented. For example, we cannot fully anticipate how MACs and commercial plans may factor this new criterion into their own decision making regarding coverage; it is possible that a situation may arise in which each entity waits for the other to make initial coverage determinations, thus delaying coverage for all patients. This proposal may also inadvertently create a "race to the bottom" where all payors refine their coverage to match the most restrictive available. If CMS finalizes this proposal, we strongly urge the agency to carefully monitor coverage trends and patient access post-implementation.

Medicare Coverage of Innovative Technology (MCIT)

Proposed MCIT Coverage Pathway

ASCO supports the establishment of a pathway for immediate national Medicare coverage of FDA-market authorized breakthrough devices meeting the specified criteria and supports the voluntary, opt-in nature of this program. We also support CMS' proposal to put devices that are covered through the MCIT pathway on the CMS website so that all stakeholders will be aware of what is covered through the MCIT pathway.

The proposed MCIT coverage pathway is specifically for Medicare coverage of devices that are designated as part of the Food and Drug Administration's (FDA) Breakthrough Devices Program ("breakthrough devices") and are FDA market authorized. The MCIT pathway would be voluntary and device manufacturers would notify CMS of their intent to utilize this coverage option. In contrast to the current varied local coverage featuring between-MAC and within-MAC differences, the proposed MCIT would create a pathway for immediate national Medicare coverage of any FDA-market authorized breakthrough device if the device meets criteria outlined in the proposal.

CMS proposes that the agency would coordinate with FDA and manufacturers as medical devices move through the FDA regulatory process for Breakthrough Devices to ensure Medicare coverage on the date of FDA market authorization (unless CMS determines those devices do not have a Medicare benefit

category). National Medicare coverage under the MCIT pathway would begin immediately upon the date of FDA market authorization (that is, the date the medical device receives Premarket Approval (PMA); 510(k) clearance; or the granting of a De Novo classification request) for the breakthrough device.

ASCO supports this proposal as it would address the current patchwork of local coverage and could enhance access nationally for Medicare beneficiaries, thereby increasing clarity and consistency of coverage.

Additional Clinical Study Considerations

ASCO agrees with CMS that coverage of a breakthrough device by CMS should not alter a manufacturer's obligation to adhere to FDA's requirements regarding post-market data collection (or other study). Manufacturers of breakthrough devices will not be obligated or mandated by CMS to conduct clinical studies during coverage under the proposed MCIT pathway; however, some manufacturers may be required by the FDA to conduct post market data collection as a condition of market authorization, and nothing in this proposed rule would alter that FDA requirement. CMS encourages manufacturers to develop the clinical evidence base needed for one of the other coverage pathways after the MCIT pathway ends.

CMS seeks comment as to whether CMS should require or incentivize manufacturers to provide data about outcomes or should be obligated to enter into a clinical study similar to CMS's Coverage with Evidence Development (CED) paradigm. Given that the purpose of this new pathway is to provide more rapid access to coverage and that it may be rendered less appealing to manufacturers if additional data collection is always a condition of coverage, ASCO believes that such decisions should be made on a case-by-case basis and should not replicate any pre-existing FDA requirements. If a CED study is required, it would be important to extend coverage at least through two years following completion of the study. In cancer, many studies look at five-year outcomes. With a four-year MCIT period, the study would still be ongoing when the coverage ends. Once the study ended, it would take six to twelve months to complete the analysis and publish a manuscript; it then takes CMS at least nine months to complete an NCD (after opening an NCA).

Time Limits and Coverage Post-MCIT

Coverage for a previously covered breakthrough device supported by data should not be abruptly discontinued at the end of the four-year MCIT coverage period. CMS proposes to establish a four-year limit on how long a breakthrough device can be eligible for MCIT (that is, considered a breakthrough device for coverage purposes); the four-year period would start on the date of FDA market authorization. The agency believes that the time-limited characteristic of MCIT will drive some manufacturers to leverage this period of coverage to demonstrate the value of their device in the competitive marketplace and is particularly important for manufacturers of breakthrough devices that choose to further develop the clinical evidence basis on which the FDA granted marketing authorization.

At the end of the 4-year MCIT pathway, coverage of the breakthrough device would be subject to one of these possible outcomes:

(1) NCD, affirmative coverage (which may include facility or patient criteria);
(2) NCD, non-coverage; or
(3) MAC discretion (claim-by-claim adjudication or LCD).

CMS seeks public comment on whether the agency should open a national coverage analysis (NCA) if a MAC has not issued an LCD for a breakthrough device within 6 months of the expiration date of the 4-year MCIT period. ASCO supports this approach: if a device has been nationally covered for four years, abrupt discontinuation of coverage will cause confusion and lead to access barriers. When supported by data, CMS should continue national coverage of these devices, otherwise the MCIT pathway essentially leads to "provisional" coverage which may discourage its adoption by manufacturers. CMS should also require that MACs cannot issue a negative LCD or otherwise uniformly non-cover the device while the NCA is open.

Expansion of MCIT Pathway Beyond Breakthrough Devices

At this time, ASCO does not support universal expansion of the newly proposed MCIT pathway beyond breakthrough devices. CMS specifically seeks public comment on whether the MCIT pathway should also include diagnostics, drugs and/or biologics that utilize breakthrough or expedited approaches at the FDA or should also include all diagnostics, drugs and/or biologics. The agency also seeks data to support including these additional item categories in the MCIT pathway.

While ASCO supports the establishment of this pathway for breakthrough devices (including diagnostics that are cleared/authorized/approved by FDA as medical devices), we believe that the impact of this new pathway should be monitored and evaluated before CMS considers expanding it to include additional item categories. However, there may be limited circumstances where, for example, individual breakthrough drugs are not otherwise covered through other expedited pathways and CMS could consider the MCIT pathway to enhance beneficiary access.

Coverage for Use Consistent with FDA-approved or FDA-cleared Indication(s)

In general, ASCO supports CMS' proposal that MCIT devices must be used according to their FDA-approved or FDA-cleared indication for use. CMS proposes that to be part of the MCIT pathway, the device must be used according to its FDA approved or cleared indication for use because that is the indication and conditions for use that were reviewed by the FDA and authorized for marketing.

CMS states that data are unlikely to be available to support extending beyond the FDA required labeling for breakthrough devices on the date of marketing authorization and use of the device for a condition or population that is not labeled ("off-label") will not be covered as that use would not be FDA authorized. CMS specifically seeks comment on whether off-label use of breakthrough devices should be covered and, if so, under what specific circumstances and/or evidentiary support.

Given the proposed parameters for this pathway, ASCO believes that restriction to on-label use of the device is reasonable. However, there may be situations, for example, where additional compelling manufacturer data was not complete or mature at the time of FDA approval, or where a well-designed clinical trial shows clear benefit in a new or expanded population. CMS could, in these situations, use its discretion to expand coverage off-label. CMS should also expand coverage during the MCIT period to be co-extensive with FDA-approved labeling if the indications for use expand beyond those approved by FDA upon initial clearance/authorization/approval.

Application of "Reasonable and Necessary" Standard to MCIT

ASCO supports the application of the "reasonable and necessary" standard to MCIT as it aligns CMS and FDA standards in this new pathway, removes delay related to the usual process of CMS determination of whether an item or service is "reasonable and necessary," and ensures predictability in the MCIT pathway. CMS is proposing that breakthrough devices per se meet the reasonable and necessary standard in order to increase access and to reduce the delay from FDA market authorization to Medicare coverage. Specifically, CMS proposes that, under the proposed MCIT pathway, an item or service that receives a breakthrough device designation from the FDA would be considered "reasonable and necessary" under section 1862(a)(1)(A) of the Act because breakthrough devices have met the FDA's unique breakthrough devices criteria, and they are innovations that serve unmet needs. ASCO supports this proposal as it would streamline the MCIT process and asks that the agency finalize it.

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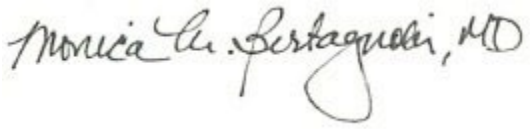
ASCO appreciates the opportunity to comment on this proposed rule. If you have any questions or would like additional details, please contact Karen Hagerty (karen.hagerty@asco.org).

Sincerely,



Monica Bertagnolli, MD, FACS, FASCO

Chair of the Board

Association for Clinical Oncology