



20TH ANNIVERSARY

Sound Policy. Quality Care.

November 2, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-3372-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted online via regulations.gov

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” (CMS-3372-P)

Dear Administrator Verma:

On behalf of more than 100,000 specialty physicians, the undersigned members of the Alliance of Specialty Medicine (the “Alliance”) write in response to proposals outlined in the aforementioned proposed rule. The Alliance is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. To facilitate your review of our comments, below is a list of key recommended actions:

1. Finalize an expanded MCIT pathway that also includes innovative diagnostics, drugs, and biologics, in addition to FDA-designated breakthrough devices, allows for off-label use of products covered under MCIT, and provides coverage for up to 5 years;
2. Align Medicare physician coverage and reimbursement policies with MCIT final policies to address potential gaps in coverage;
3. Incentivize manufacturers to collect and regularly report data on outcomes based on the use of their products under the MCIT pathway; and
4. Finalize the proposed definition of “reasonable and necessary,” and clarify that the requirement for an item or service to be “safe and effective” does not necessitate FDA review, clearance, or authorization as a prerequisite for Medicare coverage.

Medicare Coverage of Innovative Technology (MCIT) Pathway

In response to Executive Order 13890, “Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors,” CMS proposes to establish a new Medicare coverage pathway for medical devices designated as breakthrough by the Food and Drug Administration (FDA), under which such devices would receive up to 4 years of Medicare coverage following the date of FDA market authorization. ***The Alliance supports CMS’ MCIT proposal, with the important amendments recommended below.*** We believe an MCIT pathway would allow for expanded access to specialty medicine, particularly with respect to cutting-edge items or services that could be furnished by physicians delivering care at the forefront of medical research. This proposed pathway – with our

recommended amendments – would not only promote innovation, but would also enable the Medicare program to keep pace with the rapidly-evolving health technology landscape, providing for automatic temporary coverage of breakthrough products while they make their way through the lengthy and complicated permanent coverage process. However, to maximize its potential, ***we urge CMS to expand the MCIT pathway to also include innovative diagnostics, drugs, and biologics that receive FDA market approval***, for example under FDA’s Breakthrough Therapy designation. Executive Order 13890 addresses “innovative products” broadly, and does not limit its scope to breakthrough medical devices only. Indeed, diagnostics, drugs, and biologics may face the same challenges regarding delayed and inconsistent coverage that exist for medical devices, and expanding the MCIT pathway to include these products would more robustly effectuate the goals of the Executive Order to accelerate innovation in the delivery of health care. ***We also request that CMS extend the MCIT coverage period from 4 years to 5 years.*** CMS notes that 4 years is approximately the amount of time it takes to complete a clinical study completed as part of an NCD. However, the proposed timeline does not take into account scenarios where studies may take additional time, nor the time required to advance an item or service through the CMS or contractor coverage determination process once the study is complete. We believe that this additional year will help to avoid any gaps in coverage that might arise.

The Alliance believes patients who require or are likely to benefit from cutting-edge technologies should have access to such technologies, without unnecessary administrative hurdles or coverage limitations. Use of such technologies should be dependent on physician judgement, paired with shared decision-making and informed consent by the patients. Consistent with this principle, ***the Alliance recommends that the MCIT pathway should not be limited to coverage under FDA approved or cleared indications only; rather, Medicare coverage should be made available for off-label use in a manner consistent with existing off-label policies and subject to physician judgement and informed patient consent.***

At the same time, ***we recommend that CMS incentivize manufacturers to collect and regularly report data on outcomes based on use of their products under the MCIT pathway***, in order to better inform decision-making and treatment recommendations. We note that studies on safety and efficacy of new technologies often focus on healthy populations, such that outcomes may not reflect their use among Medicare beneficiaries. Robust data collection, analysis, and reporting, therefore, can support appropriate use of innovative products over the MCIT period, as well inform long-term Medicare coverage determinations.

Finally, we note that there may be cases in which a new device, diagnostic, drug, or biologic is granted coverage under MCIT, but that corresponding reimbursement is not available for the physician service required to furnish or deliver the product. We believe this would create a gap in coverage that would undermine CMS’ goals and ultimately restrict beneficiaries’ access to the novel technologies the MCIT was intended to support. ***To address this gap, the Alliance recommends that CMS align Medicare physician coverage and reimbursement policies with MCIT final policies to ensure that the MCIT pathway truly increases access to innovative products consistent with the goals of Executive Order 13890.***

Defining “Reasonable and Necessary”

CMS proposes to codify its longstanding definition of “reasonable and necessary,” as detailed in the Program Integrity Manual, with modifications such that an item or service could be considered “appropriate for Medicare patients” if it is covered by commercial insurers, unless evidence supports that differences between Medicare beneficiaries and commercially insured individuals are clinically relevant. The Alliance supports this proposal, which – like the MCIT pathway – would advance the goals of Executive Order 13890. Allowing determinations of whether an item or service is “appropriate for Medicare patients” to be based on commercial coverage – in addition to the current appropriateness criteria – would expand Medicare beneficiaries’ access to new technologies, strengthen incentives for medical innovation, provide greater autonomy to physicians to exercise discretion and judgement in developing patients’ care plans, and remove unnecessary administrative burden.

The Alliance also appreciates CMS' proposal to adopt the least restrictive coverage policy for a given item or service among the commercial offerings examined; if adopted, this proposal would limit the use of utilization management tools like step therapy or prior authorization that might otherwise restrict patients' access to a broad array of accepted medical technologies and impose significant burden on physician practices. Finally, the Alliance requests that CMS further clarify that the revised definition of "reasonable and necessary" requiring that an item or service be considered "safe and effective" does not necessitate FDA review, clearance, or authorization as a prerequisite for Medicare coverage, given that FDA's process is narrowly tailored to the labeled indications or use, and Medicare coverage may be appropriate for "off-label" uses. We believe greater clarity will support beneficiary access to the full range of items and services that may be reasonable and necessary under the Medicare program.

We appreciate the opportunity to share feedback and recommendations for action. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,