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VIA ELECTRONIC SUBMISSION

April 16, 2021

Ms. Elizabeth Richter
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3372-IFC
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"; Delay of Effective Date; Public Comment Period [CMS–3372–IFC]

Dear Acting Administrator Richter:

BioUtah appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS) Interim Final Rule delaying the effective date and requesting comments on the January 14, 2021 final rule on Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary" (IFC).[1]

BioUtah strongly supports the MCIT program in the final rule and urges CMS to implement the final rule without further delay so that Medicare patients can have access to these important breakthrough devices.

We share the administration's goal to promote innovation and make U.S. Food and Drug Administration (FDA)-designated breakthrough medical devices and diagnostics (breakthrough devices) widely available to Medicare beneficiaries. We also commend CMS for recognizing the need to bridge the divide between FDA approval or clearance of innovative medical products and obtaining coverage from Medicare. Throughout this letter, references to "device(s)" is intended to include diagnostics.

The final rule would create immediate and predictable national Medicare coverage for breakthrough devices that receive FDA approval or clearance. Coverage would last for four years from as early as the date of FDA market authorization (after review of a premarket notification (510(k)), De Novo request, or premarket approval application for the product).

BioUtah is Utah's only trade association dedicated solely to supporting the state's diverse life sciences industry, which includes medical device manufacturing, diagnostics, biotechnology and biopharmaceuticals - all dedicated to developing and delivering life-enhancing and life-saving products.

In our November 2, 2020 letter on the proposed rule, we provided comments on specific aspects of the MCIT program. Today, on behalf of our Utah-based medical device companies, BioUtah offers general comments on the importance of the MCIT program as well as comments focused on the following concerns raised in the March 17, 2021 IFC.

[1] 86 Fed Reg 14542, et seq, March 17, 2021; see https://www.govinfo.gov/content/pkg/FR-2021-03-17/pdf/2021-05490.pdf.

- Operational Issues
- FDA-Breakthrough Device Volume
- Medicare Patient Benefit/Protection

I. GENERAL COMMENTS

Utah's life sciences hub is among the fastest growing in the nation. From large established global companies to promising startups, our industry innovates and develops the medical devices and advanced diagnostics that often improve patient outcomes and reduce healthcare costs. In the case of testing, breakthrough diagnostics can help guide optimal treatment decisions that save lives. A number of medical innovations being developed by Utah medical device companies address some of our most serious healthcare conditions, such as lung cancer, Parkinson's, degenerative disc disease, breast cancer, chronic kidney disease and more.

For companies who are working to develop the next generation of breakthrough devices, approval or clearance from the FDA comes after years of research, hard work and commitment. However, under the current process, once FDA approval or clearance is achieved, it can still take several more years to obtain Medicare coverage. This "gap" not only delays the availability of innovative devices for Medicare beneficiaries, but it also hits startups and pre-revenue companies particularly hard. Without timely and predictable coverage, it can be difficult for smaller companies to begin to generate revenue and attract the investor interest and funding needed to commercialize their breakthrough devices. As a result, even after FDA market authorization, commercialization of potentially life-saving treatments for seniors could be delayed and unavailable to Medicare patients and providers.

The MCIT program in the final rule provides coverage certainties that are essential to spur continued investment in medical innovation while ensuring that Medicare's seniors, including patients in our most vulnerable communities, have the opportunity to immediately benefit from novel medical devices.

Importantly, over the years, policies with bipartisan support have demonstrated a commitment to expediting Medicare coverage to bring innovative medical devices to market faster. For instance, *The 21st Century Cures Act*[2] signed into law on December 13, 2016, under the Obama administration, was designed to accelerate medical device development and bring new innovations more efficiently to patients who need them. More recently, CMS has simplified the pathway for breakthrough devices to receive inpatient new technology add-on payments (NTAP) and hospital outpatient transitional pass-through payments (TPT). The MCIT program, in essence, represents years of discussion by lawmakers, CMS, FDA and stakeholders, and has been sufficiently vetted through a public notice and comment period.

II. OPERATIONAL ISSUES

While BioUtah recognizes CMS' concerns about underestimating operational hurdles to implementation of the MCIT program, we believe the challenges raised, including establishing coding and payment amounts, and making benefit category determinations, do not warrant further delay of the MCIT program for several reasons.

First, these issues have already been considered in prior notice and comment with the agency noting that "a detailed description of coding and payment is beyond the scope of the MCIT rule and resides in other payment rules." (86 FR 3002).

[2] P.L. 114-255, December 13, 2016.

Second, the MCIT pathway is not a significant departure from CMS' experience with expediting coding and payment for innovative devices, including devices with breakthrough designation, through the NTAP process and the TPT device designation process. Additional details and instructions concerning MCIT operations could be addressed through sub-regulatory guidance.

Third, it takes months to years for companies to receive FDA approval or clearance, even after an innovative medical device has received breakthrough status. An August 2020 study, *Early Experience with the FDA's Breakthrough Devices Program*, found that FDA review time (from the date of submission to the FDA) among publicly disclosed high-risk breakthrough devices ranged from 146 to 301 days, with median review time of 181.5 days.[3]

We believe that this long lead-time offers companies a significant opportunity to engage with CMS on questions around coding, site of service, appropriate payment system, MS-DRG or APC placement or other issues. Even if there is insufficient time to develop permanent codes and national payment amounts for MCIT-eligible products, CMS can draw on existing processes to operationalize coding and payment (e.g., assignment of temporary codes, use of miscellaneous codes, holding of claims for some time-period until permanent coding is in place). These options could be improved through the new Technology, Coding, and Pricing Group[4] CMS established late last year to harmonize coverage, coding and payment processes for innovative technologies, including breakthrough devices.

To the extent possible, we urge CMS to leverage existing approaches in developing guidance to implement the benefit category, coding, and payment processes. We believe this will decrease administrative burdens and provide clarity for both companies and providers.

III. NEW INFORMATION: BREAKTHROUGH DEVICE VOLUME

BioUtah believes that the regulatory impact analysis published as part of the MCIT final rule correctly captured the anticipated volume of MCIT utilization, sufficiently reflects stakeholder input and should not impede timely implementation of the MCIT program.

CMS has requested feedback on whether recent public data suggests a larger number of FDA market-authorized breakthrough devices may be eligible for MCIT than initially assumed.

In the IFC, CMS cited "new information" from the FDA, which reported that more than 400 devices have been designated as breakthroughs to date. This is misleading. Opponents (including insurance companies) fail to distinguish between FDA breakthrough designation and FDA approval or clearance and thus, suggest that the MCIT program will result in a massive spending increase. In reality, only those breakthrough devices that have then been approved or cleared by the FDA would receive MCIT coverage. To date 23 breakthrough devices have been approved by the FDA that would conceivably be MCIT eligible.[5]

Volume considerations must also take into account the fact that garnering breakthrough designation from the FDA is merely the first step in a lengthy process before FDA approval or clearance. The device, in many cases, still has to go through clinical trials and other rigorous data development before submission to the FDA. This

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[3] Johnston, James L.; Dhruva, Sanket; Ross, Joseph; and Rathl, Vinay; "Early Experience with the FDA's Breakthrough Devices Program," Nature Biotechnology, Vol. 38, August 2020, p. 933-938.

[4] See https://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_CM.

[5] The FDA has now approved, authorized, or cleared 23 breakthrough devices through the PMA, De Novo or 510(k) pathway..." See https://www.fda.gov/news-events/fda-voices/reflections-record-year-novel-device-innovation-despite-covid-19-challenges.

can take years. Even once submitted, there is additional review time before approval or clearance by the FDA. The time involved in submission review combined with the fact that many FDA-designated breakthrough devices will never be approved or cleared, should reduce the number of approved or cleared breakthrough devices to a much smaller number. Utilization - i.e. whether a device or diagnostic test is provided to a Medicare beneficiary will be determined in consultation with the patient's physician and healthcare team.

Furthermore, some breakthrough devices will move through the NCD process, instead of the MCIT pathway. Also, breakthrough devices must fit within a Medicare benefit category to be covered under MCIT. Because there are breakthrough devices that do not have a Medicare benefit category, not all devices that receive FDA market authorization will even enter the MCIT pathway, further constraining volume. Still others will not be relevant to a Medicare population. All these factors would likely limit the volume of devices that enter the MCIT pathway on a yearly basis.

In terms of providing opportunity for public input on volume estimates, CMS acknowledged in the proposed rule that its assumption about MCIT volume includes its "impression from the FDA that the number of devices granted breakthrough status is increasing."[6] The agency also observed that "more manufacturers could potentially elect coverage under MCIT."[7] Therefore, we submit that stakeholders were given adequate information that the volume of breakthrough devices could exceed the CMS estimate.

IV. MEDICARE PATIENT BENEFIT/PROTECTION

BioUtah believes that the MCIT construct provides appropriate Medicare patient benefits as well as protections such that questions around clinical evidence and the value of breakthrough devices to Medicare beneficiaries should not delay implementation of the MCIT program. Through utilization of the MCIT pathway, we welcome the opportunity to collaborate with the agency to effectively respond to and strengthen the development of clinical evidence.

In the IFC, CMS indicates that after the close of the MCIT comment period some stakeholders raised concerns about the clinical benefit to Medicare beneficiaries of MCIT-eligible products absent specific evidence.

The safety and well-being of Medicare beneficiaries are priority one for BioUtah and our state's life sciences industry. We believe the final rule strikes the right balance between protecting our seniors and expanding access to innovative medical devices for this elderly population.

To that end, the final rule gives CMS authority to remove a breakthrough device from the MCIT pathway where a product safety communication or warning letter is issued by the FDA, or if the FDA revokes market authorization for a product. The rule goes further to provide CMS the ability to limit or withdraw MCIT coverage if there are significant questions of safety or clinical benefit that are unresolved after FDA market authorization, even absent FDA action. Under Section 405.607(b)(3), CMS may terminate MCIT coverage "prior to 4 years if the breakthrough device becomes the subject of a national coverage determination." The NCD process provides the proper channel for considering whether more restrictive coverage is appropriate.

The MCIT's four-year window for national Medicare coverage allows companies to launch their promising

[6] 85 Fed. Reg. at 54,336.
[7] 85 Fed. Reg. at 54,337.

innovative products and serve Medicare patients, but once the temporary coverage period ends, MCIT-eligible innovations will still need to prove they are "reasonable and necessary" for Medicare beneficiaries. We believe this program design will encourage companies to voluntarily develop the robust clinical data with Medicare patients that is necessary to support continued national coverage after temporary coverage expires. Moreover, we believe that clinical evidence development, including "Real World Evidence" could be advanced under this framework as companies collaborate with CMS while utilizing MCIT to ultimately pursue more permanent Medicare coverage under a NCD, local coverage determination or claim by claim decisions.

One final point. Besides the strong incentive the MCIT program provides to companies to develop Medicare focused clinical evidence, the breakthrough device designation has key safeguards of its own. A breakthrough device must provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating human disease or condition and must also meet at least one part of a second criterion, such as by being a "breakthrough technology" or offering a treatment option when no other approved or cleared alternatives exist. Then, after meeting these standards, to be MCIT eligible, the product has to be first approved or cleared by the FDA, indicating the device is safe and effective. This adds another layer of protection for beneficiaries. In short, for beneficiaries impacted by serious disease, the MCIT program will ensure access to the latest breakthrough medical devices while still building in important patient guardrails.

CONCLUSION

BioUtah appreciates the opportunity to comment on the IFC. We also greatly appreciate CMS' efforts to work with stakeholders to develop and finalize the MCIT program to accelerate the coverage of new, innovative breakthrough devices for all Medicare beneficiaries, including our most vulnerable and underrepresented.

We urge CMS to implement the MCIT final rule without further delay. We believe CMS can address the issues noted above through existing coding and payment processes, sub-regulatory guidance and collaboration with companies in the collection of clinical evidence to support long-term coverage.

BioUtah and our life sciences companies look forward to a continuing dialogue as the MCIT program advances.

If you have questions regarding these comments or if you require additional information, please contact me or Denise Bell, Vice President, Programming and Government Affairs at denise@bioutah.org.

Sincerely,

Kelvyn Cullimore
President and CEO
BioUtah