COALITION OF
Wound
Care
Manufacturers

November 2, 2020

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

*Comments Submitted Electronically to* **http://www.regulations.gov**

**Re: CMS 3372-P: Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"**

Dear Administrator Verma:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments in response to the Medicare Coverage of Innovative Technology proposed rule. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. Many of our members continue to create innovative technologies to treat patients with wounds and as such we are very interested in this proposal.

## ***Innovative Technologies***

The Coalition applauds CMS for its proposed rule to get innovative technologies to market faster. Providing automatic, national coverage for FDA-designated breakthrough technologies for four years streamlines a very lengthy process once a product is approved by the FDA. While the Coalition is generally supportive of this initiative we also believe that there are some questions that should be addressed including:

- How will CMS set rates over time?
- What data will the Agency be looking for?
- How will the Agency determine the coverage policy language starting on day one?
- How will the coverage policy be provided to stakeholders?
- Will language be provided prior to the first day of coverage? Will it be published in a bulletin or a coverage article and by whom?
- Will the coverage language be issued by the MACs or CMS?
- Will there be dialogue between the FDA and CMS throughout this process so if coverage is granted, the Agency will have already seen these products?
- What will be the process for MCIT-covered technologies to receive appropriate coding and payment?

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- How will payment of the device be determined and when?
- If an MCIT device were a DME item, would the payment methodology be through CMS gap-fill process?

There are many gaps in the processes that need to be addressed. In the meantime, the Coalition recommends that CMS does the following:

- Include biologics and diagnostic devices in the MCIT coverage pathway – some which may not have a benefit category already established.
- Provide procedural and operational details that are lacking in the proposed rule.
- Include a provision preventing the MACs from denying coverage of any technology eligible for new technology add-on payments (NTAP) or transitional passthrough payments (TPT).
- Establish a payment system for MCIT devices allowing for appropriate reimbursement. Without appropriate payment, the expanded MCIT coverage will be meaningless.
- Not utilize the gap filling methodology that has been used for DME for any type of device gaining coverage through the MCIT pathway.

## ***Reasonable and Necessary***

CMS has proposed to codify a definition of reasonable and necessary. In doing so, the Agency has added additional language to the definition already contained in the program integrity manual. The Coalition does not have a position on whether the Agency should codify the definition of "reasonable and necessary" as currently defined in the Program Integrity Manual. However, we are concerned about language which permits CMS to use commercial insurance medical policies for Medicare purposes. The Coalition is extremely concerned that CMS will cherry pick commercial payers that restrict coverage and therefore, at this time, we do not support any definition of "reasonable and necessary" that goes outside of what has already been published and adhered to in the Program Integrity Manual.

However, should CMS move forward including language in the rule permitting use of commercial plans for Medicare purposes, we recommend that CMS:

- Must be completely transparent about the details of that coverage information.
- Must be transparent about the evidence it uses to determine that individuals covered under commercial plans are clinically different from Medicare beneficiaries
- Not finalize this provision until significantly more information can be provided and the gaps in the policy addressed.
- Not be permitted to cherry pick the commercial payer with the most restrictive coverage policy to be used
- Must place language in the regulations which prohibit the Agency from using commercial policies restricting rather than increasing coverage for beneficiaries.

## ***Conclusion***

The Coalition appreciates the opportunity to offer our comments. We believe that CMS is trying to make innovative technologies available to beneficiaries, but believe that the Agency needs to provide significantly more information on operational and procedural issues before it can finalize

these proposals.

Sincerely,

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