ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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 Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit comments in response to the proposed rule regarding Medicare Coverage of Innovative Technology (MCIT) and the new definition of "reasonable and necessary". Both of these topics are of interest to the Alliance but we have concerns that CMS has included both of these very significant but completely different topics together in one proposed rule. We believe that the proposed definition for reasonable and necessary is a very complex issue. Therefore, **the Alliance recommends that CMS issue a separate proposed rule regarding the definition of reasonable and necessary in which the Agency provides significantly more information to stakeholders and addresses the gaps that are contained in this proposed rule. The Agency should then issue another proposed rule so that stakeholders can provide comments**.

The Alliance is a nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote evidenced-based quality care and access to products and services for people with chronic wounds. Our comments focus on provisions within this proposed rule which impact wound care. Our specific comments follow.

Innovative Technologies

The Alliance applauds CMS for its decision to move forward in providing the pathways to move innovative technologies to market faster. This benefits the entire wound care community and especially the Medicare beneficiaries whom our members treat. While the Alliance is generally supportive of proposals which address bringing innovative technologies to market, this proposed rule does not provide enough details for us to offer substantive and meaningful comments. There are significant gaps in this proposal both procedurally and operationally that need to be addressed. As such, the Alliance has provided questions in areas that we believe gaps still exist and would encourage the Agency to provide detailed clarifications and guidance in

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order to ensure transparency and clear direction to all stakeholders. These questions include but are not limited to:

1. Would this proposal defer CMS' responsibility to determine whether an item is reasonable and necessary to FDA's judgment as to whether something is a breakthrough device? Should CMS explain in more detail why it is deferring to an FDA decision but not to one regarding medical necessity? What happens if a device loses its breakthrough status?
2. Will the proposed MCIT pathway be expanded to include non-breakthrough devices? All PMA devices, including non-breakthrough devices, have FDA marketing approval and, in many cases, the clinical trials supporting non-breakthrough devices are more robust because they include more patients, have longer follow up, etc.
3. CMS makes no mention of coding and reimbursement for these devices or how CMS intends to coordinate that process with day-one coverage after FDA market authorization. CMS should provide more details as to the notification process and the required timing to coordinate coverage, coding and payment so everything is effective on day one as proposed.
4. CMS should provide more detail on how it intends to interact with manufacturers during the four-year MCIT period so that manufacturers can obtain a clear understanding of what CMS expects in terms of additional clinical data to support continued coverage.
5. If there is no NCD in effect when the MCIT pathway provides eligibility, will the device still be covered at the local level? CMS should be more explicit as to what actions it or the MACs might take with respect to coverage after the MCIT pathway eligibility expires.
6. Does this proposal affect Medicare coverage of breakthrough devices that are used during an otherwise non-covered inpatient stay (e.g., due to medical necessity)?
7. We believe that CMS needs to explain the relationship between the MCIT pathway and the NCD process. For example, why would a breakthrough device be deemed medically necessary under MCIT but then have to go through the NCD pathway after four years? This information is absent from the proposal.
8. If CMS is granting coverage to a product from day one, what is the timetable for the Agency to coordinate review of the product with the FDA?
9. How will CMS determine what the reimbursement rate will be for the technology?

Definition of Reasonable and Necessary

CMS proposes to codify existing language in its Program Integrity Manual, but with modifications, including a reference to commercial insurers' coverage policies. The Alliance's clinical association members are familiar with the reasonable and necessary provisions which are contained in the program integrity manual (PIM). The Alliance can not take a position on this proposal since we believe that there are not enough details provided in this proposed rule. Some of our members believe that we should codify only the portion of the proposed rule that is already contained in the PIM,while others believe that it is not necessary to codify a definition that already exists in the PIM and has been followed for so many years. The Alliance has the following concerns as well as questions which we believe need to be addressed before CMS moves forward with this proposal.

Our concerns include but are not limited to the following issues regarding the commercial payers:

- There is no transparency into the evidence reviewed by commercial payers in reaching their analyses. Many commercial payers use external Health Technology Assessment (HTA) organizations' recommendations to develop their coverage policies. We have concerns with these reviews since they are often "black boxes" with no public process for input or transparency of the evidence or reason for the assessment findings.
- Many commercial payers will adopt the policies of other commercial payers, without performing an independent review of the evidence.
- There is the perception that CMS will cherry pick the commercial payers which have the most restrictive policies.
- Most commercial payers are not early adopters and will follow Medicare coverage policy language.

The issues the Alliance recommends that CMS address include but are not limited to the following:

1. What implications does the MCIT pathway have for coverage by and payment to Medicare Advantage plans?
2. CMS should be more specific in how it would apply the new reasonable and necessary criteria to specific items and services by giving examples.
3. CMS should provide more detail on how these proposed criteria might result in different coverage decisions than have been made using the current criteria.
4. Aside from coverage of drugs and devices, these criteria may apply to all medical services such as diagnostic tests, surgical procedures, and office visits. CMS should provide additional detail as to how these criteria will be applied to those services.
5. CMS should provide more detail on how it will apply the "appropriate setting," "meets, but does not exceed the patient's need," and the "at least as beneficial as" criteria? For example, will Medicare make place-of-service specific coverage decisions, cover only the minimal amount of care a patient needs, and/or require head-to-head comparative clinical trials for coverage of items and services as it implements these three criteria?
6. If no commercial plans explicitly cover an item or service or if some plans explicitly non-cover an item or service, will CMS also non-cover that item or service? What if some commercial plans cover and others non-cover?
7. How will CMS take into account the heterogeneity of the commercial insurance market? For example, how will CMS account for regional and plan coverage differences in its analysis of commercial insurance? Even if CMS limits its reference policies to the five payers with the largest market penetration, coverage would vary significantly by city, state and plan. Employers in the local, regional and national commercial marketplace drive coverage decisions. How will CMS set rates over time? What data will CMS be looking for? And how will CMS determine the coverage policy for the technology?
8. Are current commercial payer coverage policies s valued more than past ones, even if they have better coverage for breakthrough devices? Is there a mechanism for incorporating the more beneficial coverage of past coverage policies?
9. How and what evidence will be used to determine that clinically relevant differences exist between Medicare and commercial beneficiaries? Will these criteria be transparent?
10. How will commercial coverage of maintenance care impact decision-making?
11. Given that intensity of care can vary for the Medicare-eligible population, how will the intensity of care be adjusted?

12. How will the needs of the Medicare-eligible population be considered as they relate to the risk present in this population that may not exist in a commercial payer population?

13. How does CMS propose to properly survey plans for the best coverage, when many commercial plan policies are not publicly available? What is CMS's authority, if any, to compel insurers to disclose their policies, and how does CMS plan to facilitate this disclosure? How will this information be made available to providers and the public in order to verify the information that resulted in CMS' coverage decision?

14. How is CMS planning to define "clinically relevant differences between Medicare beneficiaries and commercially insured individuals"?

15. How will CMS determine whether the commercial policy decision is based on evidence-based criteria or cost-saving measures?

16. Which commercial policy will apply when one commercial payer covers a service, and another does not?

17. Given that commercial insurance policies often are updated multiple times per year, how will CMS determine when coverage decisions are made? Is there a plan in place for CMS to obtain and review commercial policy updates and incorporate into the definition?

As stated above, given that CMS has placed two significant but different issues within one proposal, the Alliance recommends that CMS issue a separate proposed rule regarding the reasonable and necessary definition, and in doing so provide significantly more information to stakeholders as well as address the gaps in this proposed rule. The Agency should then issue another proposal in which stakeholders can provide comment.

Stakeholder Feedback on Technical Questions

CMS has also asked for stakeholder feedback on a number of questions related to the additional of the commercial payer language within the reasonable and necessary defintion. The Alliance has not taken a position on whether the new definition should be codified or whether it should contain the ability for CMS to use commercial payers for Medicare coverage purposes but offer our suggestions on the questions posed.

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

   If CMS moves forward with this provision, CMS should give specific consideration to commercial payer policies that are transparent in explaining the evidence and rationale behind the policies. Any payer that is not transparent should not be utilized.

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?

   While plans with geographically limited scopes, or relatively small beneficiary populations, should not be categorically excluded from consideration if these are based upon evidence and applicable to

the Medicare population, CMS should give specific consideration to using commercial payers that are national in scope to make coverage more consistent across the U.S.

3. 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?

   Given the stated intent by CMS to increase and not restrict coveage, CMS and/or the local MACs should adopt the least restrictive coverage policy from a commercial payer. If multiple policies could be considered the "least" restrictive, then CMS should consider the least restrictive policy. CMS should also look at the combination of the policies that are least restrictive, and implemented in the least restrictive cumulative manner.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director