Suggested minimal evidence for CAMP coverage

Recent local coverage determinations by three of the Medicare Administrative Contractors (MACs) in the US this month, removed coverage for >70 cellular, acellular and matrix-based products (CAMPs, also known as cellular and/or tissue-based products), and limited the use of those products that survived delisting to four applications.[1,2] The terms 'Group 2, covered' and 'Group 3, uncovered' entered the wound care lexicon. Undoubtedly, there are more cuts to come. At this point, there are no products safe from arbitrary exclusion. My first reaction to this seemingly capricious decision was to rail against the MACs. Calls for resistance from clinicians and patients flooded the offices of the MAC medical directors.

After the anger and disbelief faded, an overwhelming question emerged: 'How did we get here?' The first products performed well in clinical trials. I have no doubt that CAMPs promote wound healing; however, the number of products lumped into the CAMP category soon exploded. Their varied US Food and Drug Administration pathways did not require evidence and the promise of astronomical reimbursement fuelled overuse. Tales of companies promising clinicians millions of dollars in fees arose. It was only a matter of time before the Government intervened.[1,2]

I am not sure I will ever understand the differentiation between Groups 2 and 3, but the decision affected >200 products. It must have been a difficult decision; of the hundreds of CAMPs, less than a dozen have clinical trials supporting their efficacy. In addition, unlike other areas of medicine, their continued use is not supported by real-world registry data.

How did we get here? It is my fault. The fault of the wound care community. The fault of wound care societies and organisations. Captivated by cultured foreskin, pieces of placenta, animal parts from unexpected anatomical locations and synthetic matrices, we ignored the lack of clinical evidence. We believed the laboratory analysis of chopped up CAMPs showing growth factors and stem cells. We listened intently to the stories of secret processing. Most importantly, we finally had a product that made money. In the end, we provided no guidance on the minimal amount of evidence required to recommend a CAMP for patients. It is no wonder the MAC decision appears haphazard.

The time has come to stop blaming MACs and manufacturers, and publish recommendations on the amount of clinical evidence necessary to recommend the use of a CAMP. Principally, all products reimbursed as a CAMP must have a randomised clinical trial with >100 patients followed by a real-world registry. A series of manuscripts following this commentary will detail the suggested requirements for clinical trials and registries for CAMPs. **JWC**

References

1 CMS.gov. Billing and coding: skin substitute grafts/cellular and/or tissue-based products for the treatment of diabetic foot ulcers and venous leg ulcers (Article A54117). https://tinyurl.com/m9vzts9h (accessed 21 September 2023)

2 CMS.gov. Local Coverage Determination. Skin substitute grafts/cellular and/or tissue-based products for the treatment of diabetic foot ulcers and venous leg ulcers (Article L35041). https://tinyurl.com/mrxx5vw4 (accessed 21 September 2023)

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