Wound Market Consulting

The International Wound Care Market Specialists

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GERMANY:

Reimbursement: Changes and Transitional Measures

"Other wound care products"; i.e those with claims beyond protecting the wound and managing wound moisture, will continue to be reimbursable up to and including December 2024; thereafter in order to remain reimbursable these products will need to have had a dossier of evidence supporting their claims assessed and approved by the G-BA (the Federal Health Committee).

The G-BA has published application forms and indicated how it will rate the quality of evidence but has not yet defined exact criteria for reimbursability. This situation has led to a call by the German MedTech Association (BVMed) for a dialogue with stakeholders and the establishment of practical and reliable systems of assessment.

The G-BA is already accepting advance notices of requests for consultations on the inclusion of "Other wound care products" in Appendix V, Annex 3 of the Medicines Directive. The consultations themselves can only be requested when the G-BA's decree enabling these consultations has been approved by the Federal Ministry of Health; a decision which is currently still pending, Manufacturers can contact the G-BA office informally at the following email address: medizinprodukte-wundbehandlung@g-ba.de.
Further information has been provided by the G-BA (in German) here: https://www.g-ba.de/service/fachnews/106/

German proposals for reforms to the Medical Device Regulation.

The German MedTech Association (BVMed) is joining forces with its counterpart for diagnostics Verband der Diagnostica-Industrie (VDGH) to present a joint position paper proposing solutions to the bottlenecks in the implementation of the Medical Device Regulation.

Proposed changes include eliminating the five-year recertification period and simplifying procedures for innovation, orphan devices and rare disease diagnostics. The November BVMed conference in Berlin on the practical implementation of the MDR noted the absence of the "golden mean" to be struck between concern for patient safety and recognition of technological progress and called for a critical analysis of the MDR system's rules and procedures, including those applied to cost benefit calculations.

ENGLAND

National Wound Care Strategy Leg Ulcer Best Practice Bundle: Stakeholder Engagement

In 2023, NHS England Nursing Authority commissioned NWCSP to develop a Leg Ulcer Best Practice Bundle. The initial stakeholder survey closed in December. The Best Practice Bundle is intended to complement the wider NWCSP Leg Ulcer Recommendations by supporting providers, commissioners and practitioners with the means to implement change that will have the most impact. It brings together five evidence-based elements of care, which when performed collectively, will significantly improve healing rates, reduce recurrence rates and limb loss, improve patient experience and reduce the use of NHS resources and costs. A 2017 survey of the costs of wound care to the NHS found that the average annual cost in 2017 values of treating a venous leg ulcer which healed was £2036.67 [approx €2,400) and an unhealed venous leg ulcer was £7,886.05 (approx €9,280)[1]

WOUND CARE CONFERENCES:

France	**SFFPC: Annual Congress:** 21st – 23rd January 2024. **Click here.**	**Czech Republic:**	**Czech Society for Wound Treatment:** 18th – 19th January 2024 **Click here.**	**Finland**	**XXVII National Wound Days** 1st – 2nd February 2024 **Click here.**	**United Kingdom**	**Wound Care Today:** 6th – 7th March 2024 **Click here.**	**EWMA & Society of Tissue Viability** 1st 3rd May 2024 **Click here.**

[1] Guest JF,Fuller JW, Vowden P. Cohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018:update from 2012/13. Doi:10.1136/bmjopen-2020-045253

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FRANCE

Medicines and dressings dispensed individually

The Ministry of Health is proposing that certain medicines and medical devices such as wound dressings may be dispensed 'individually' in quantities smaller than one pack, proportionate to the intended period of treatment /use. Certain medications in pharmacies can be dispensed "individually". This is intended to reduce waste and provide a means of managing temporary shortages of drugs. The change may have a similar effect on the usage of dressings to that seen through the direct supply systems for wound care products in several European countries. The proposal is yet to be approved by Government decree.

For further information, click here.

POLAND

Industry News

WARMIE, the manufacturer of a programmable sensor for monitoring temperature changes and Polmedi, a telemedicine system used in wound management have recently announced their merger to become the Polmedi Group. They aim to raise financing of up to €2 million for international expansion and development, specifically for the iWound 3.0 telemedicine system and the certification and launch of the WARMIE Sterile sensor which can be placed in a wound to monitor temperature and alert the patient and clinicians to the presence of infection. Discussions are currently taking place with potential investors.

For further information, click here.

USA

FDA's Proposed Rule on Antimicrobial-Containing Wound Products-Consultation ends 28th Feb.2024

In November 2023, the FDA took a significant step in addressing the growing concern of antimicrobial resistance (AMR) by publishing a proposed rule on classifying specific wound dressings and washes containing antimicrobials acting as protectants or preservatives based on the level of AMR to those antimicrobials. The proposal envisages the allocation of devices to one of two classifications; most of the products will be classified as Class II (subject to special controls in combination with general controlsand requiring a premarket notification) whilst those containing a medically important antimicrobial with a high level of AMR which are unclassified preamendment devices will be classified as Class III and subject to a Premarket Approval (PMA).

The aim is to regulate these products to mitigate their potential impact on AMR. The FDA emphasises the importance of policies and regulations that preserve the effectiveness of antimicrobials for human use, advocating for proper labeling and recommending clinical trial designs to assess efficacy.

The FDA is seeking public input, interested parties are encouraged to submit electronic or written comments by 28th February, 2024, to ensure their input is considered in the development of the final rule and order. For further information and to submit a formal comment can be found here: Federal Register: Effective Date of Requirement for Premarket Approval Applications for Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Cream, or Ointment; and Liquid Wound Washes Containing Medically Important Antimicrobials

The continuing debate over CAMPs Coverage and Reimbursement

Acoording to a paper in the November 2023 issue of the Journal of Wound Care* the dramatic increase in the number and cost of cellular, acellular and matrix like wound care products - "CAMPS" on the US market has led to controversy over their reimbursement rates when used in the doctor's "private office" i.e. in the community. Manufacturers are supposed to report their nett selling prices to the private office under what is known as Part B Medicare (outpatient drug) and the Medicare reimbursement administrators ('MACs') set an average selling price (ASP) which becomes effectively the reimbursement rate. Until the ASP is set the MACs reimburse a wholesale price + a small margin or the actual price paid. In the third quarter of 2022 30/68 CAMPs cost a disproportionate $256 m due to failures to report their average sales pricing (ASP) and this has caused MACs to try to limit the use of CAMPS by restricting what is covered by insurance and the number of applications of the products. Three MACs had to withdraw initiatives to limit use and the Centers for Medicare and Medicaid Services (CMS) have not implemented a mooted proposal to package ('bundle') the cost of CAMPs products with the reimbursement of the medical procedures associated with their use. The paper points out the clinical efficacy of CAMPs and makes a plea for consistent reporting of prices to Medicare.

* *Feight J.,Forsyth A, Tettelbach W."Navigating obstacles impacting the sustainability of Medicare-funded wound care pricing " JoWC Vol 32, (11) 2023.*