Amendment to Reimbursement of Wound Care Products in Germany expected March 2017 (Will it impact your business?)

Authors: Anette Skowronsky & Andrew Adams
Mrs Skowronsky has more than 20 years clinical and business experience in wound care reimbursement in Germany. A pharmacist by profession, she is active as a freelancer for various companies including B.Braun, Covidien or Smith & Nephew and professional bodies including BVMed Bundesverband Medizintechnologie e.V., Berlin.
Mr Adams. Managing Director of Wound Market Consulting, with more than 25 years’ international experience in the wound care industry.

An amendment to the law in Germany regulating the provision of reimbursed devices for healing (including wound care products) and for aids to living is expected to take effect from March 2017…

Background
In Germany patients have a legal right to receive wound dressings as part of their insured treatment. A “dressing” is defined for these purposes as a product which covers the wound, absorbs wound fluid. Historically, companies with wound care products which have these features but whose primary claim of benefit is different (such as regulating levels of proteases or antimicrobial properties) have sought to have their products recognized as “dressings” for the purpose of reimbursement. At the same time and under the same rules, the German patient has been denied easy access to some other wound care products because their physical configuration, for example solutions and sprays, may not have allowed them to be considered “dressings”.

The Intention of this amendment with regards to wound care...

- To continue to reimburse classic “dressings” & for them to continue to be included in the benefits provided to insured patients by the statutory health insurance Funds (GKV)
- To include those products in the definition of “dressings” whose primary benefit is keeping the wound moist by covering the wound. This will still exclude sprays & liquids.
- To differentiate between the eligibility for reimbursement of “dressings” and other wound care products claiming other and additional benefits to the wound.
- To reimburse only those “non-dressing” wound care products which can prove with clinical and economic evidence that their use will lead to a material improvement in care outcomes.
Reimbursement - Germany

Anticipated practical impacts of the amendment...

- Clearer distinction between the reimbursement of classic “dressings” and other wound care products.
- Inclusion of dressings whose primary benefit is covering the wound and keeping the wound moist in the same reimbursement process as that for classic “dressings”.
- Demand for better quality evidence of improved care outcomes from new wound care products applying for reimbursement.
- Longer and more expensive pathway to reimbursement for wound care products not defined as “dressings”.
- Products which currently fall under the old regulations will remain reimbursed for one year after the new law comes into force.

A little more detail...

The precise differentiation of what constitutes a “dressing” and what other wound care products with additional claims will in future be regulated by the Federal Joint Committee (Gemeinsame Bundesausschuss (G-BA))¹.

The amendment to the law on devices for healing and aids to living² (Heil-und Hilfsmittelversorgungsgesetz – HHVG) will involve the following paragraph (Clause 1a) being added to the Social Law Volume V after paragraph 31 clause 1 (our translation)

> “1a Dressing materials are products including fixation materials whose primary action consists of covering parts of the body with a superficial injury, of absorbing bodily fluids or of both actions. The features of the dressing are not especially relevant if the product also keeps the wound moist as its supplementary action. Products also included under this definition are those which are used, if necessary multiple times, to make unique bindings of parts of the body which have no superficial injury in order to stabilise, immobilise or compress those parts.”

Wound care devices which are not considered by the G-BA to qualify as “dressings” will have to go through its efficacy and health economic assessment procedures in order to be listed as eligible for reimbursement by the GKV.

The G-BA’s goal is to ensure that only those products are reimbursed which deliver an improvement to care, and that all insured members of the GKV can have access to them.

One consequence of this amendment is that the G-BA will have to determine in which cases substances or preparations for substances, which as medical devices according to Section 3 No.1 or No.2 of the medical device law¹ are intended for use on humans, will be included exceptionally in a pharmaceutical category of reimbursement. Examples of these so-called “dressing-similar” products are wound cleansing solutions such as “Ringer’s” solution applied during or after surgery.

Currently only those “dressing-similar” products which have been recognised as providing an improvement to care will be recognised as reimbursable by the GKV. According to Section 40, Paragraph 1 of Chap. 4 of the Operating Procedures of the G-BA (latest version 23.08.2016) the case for the medical necessity for the use of a medical device has to be supported by studies of the highest possible level of evidence for that device and where appropriate further literature on equivalent devices. The actual type and content of this application procedure is at present being considered in various specialist committees and consultation has been sought from industry bodies. A decision on the future application procedure for wound dressings has not yet been taken.
Notes:

1. Source: Proposal for an amendment to Federal law; Proposal of a law for the strengthening of the provision of devices for healing and for aids to living. (The Law on the provision of devices for Healing and Aids to living) Heil- und Hilfsmittelversorgungsgesetz (HHVG)

2. The Statutory Health Insurance Funds (Gesetzliche Krankenversicherungen) are an obligatory health insurance for all those not otherwise categorised as being self-insurers or having other adequate health insurance cover. They insure the majority of the population and so recognition by the GKV as a reimbursable product is essential for the widespread adoption of a wound care product for use in the community.

3. The G-BA is a joint committee of public health agencies authorised to make binding regulations arising from health reform bills passed by lawmakers, along with routine decisions regarding healthcare in Germany.


Contact us today to discuss how we can grow your wound care business...

DESIGNING for REIMBURSEMENT:
We can assist you with long-range planning for reimbursement, ensuring that your product portfolio contains product designs which meet the various national requirements.

EVIDENCE for REIMBURSEMENT:
Our clinical research specialists bring long experience to bear on designing and managing studies to deliver clinical and health economic evidence tailored to national reimbursement environments.

APPLYING for REIMBURSEMENT:
Our specialist teams work in North America and Europe to deliver effective reimbursement strategies for your advanced wound care products.