Wound Market Consulting
The International Wound Care Industry Specialists

Reimbursement - Germany UPDATE

Amendment to the law on devices for healing and aids to living approved by the German Parliament

(Possible Consequences)

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Current Position

- **Amendment to the law on devices for healing and aids to living approved by the German Parliament February 2017.**
- **Definition of Wound "dressings" eligible for reimbursement clarified.**
- **New process of assessing the "medical necessity" of wound care products which do not meet the revised reimbursement criteria not yet finalised.**
- **Products reimbursed under the old rules have one year's grace.**

Possible Practical Impacts of the Amendment

- **Pressure on advanced technologies to invest in more extensive and higher quality clinical evidence.**
- **"Traffic Jam" in the assessment of existing products which will lose their reimbursability under the new rules.**
- **New purchasing routes for anti-microbial dressings which no longer have reimbursement?**

A little more detail…

On February 16th the German Bundestag approved the changes to the law on devices for healing and aids to living (Heil-und Hilfsmittelversorgungsgesetz). The amended law is intended to improve the quality of care of patients in the community who are treated with or need to use medical devices and so includes the provision of wound care and wound care products. The amendments were needed because, amongst other things, due to a lack of a clear legal definition of the concept "dressing", there were different prices and products recognised for reimbursement by different Health Insurance Funds.

The new law has amended Section 31 of the Vth Book of Social Law. Those dressings which cover superficially damaged parts of the body and /or absorb bodily fluids are eligible for reimbursement as, additionally, are those which maintain a most wound environment. For all other dressings and wound care products their medical necessity must be proven before eligibility for reimbursement can be granted.

The Federal Joint Committee for Health (G-BA[1]) will develop and implement procedures for assessing products' reimbursability. Only those medical devices recognised by the G-BA as "similar to dressings" will be included in the reimbursable services of the Statutory Health Insurance Funds[2].

According to Section 40, Paragraph 1 of Chapter IV of the G-BA's Standard Procedures the medical necessity of the use of a medical device has to be demonstrated by studies of the highest level of evidence and by additional clinical literature. The type and content of the application procedure is at the moment being discussed in various specialist committees. A decision has not yet been made as to the precise application process.

Those products which have been eligible for reimbursement under the old rules and may not be under the new, will remain reimbursable for one year. This group concerns amongst others dressings with anti-microbial components, honey, collagens, active carbon etc. Liquids such as wound cleansing solutions will not be reimbursable. In the future it will be important for the manufacturer to assess critically whether the primary intended use of their products fulfils the criteria of covering a superficial wound and the absorption of fluids.

Consequences

With the amended law only coming into force from March and with the formal assessment process for advanced technology dressings not yet known it is not possible yet to say with any certainty what its impact will be.

The reimbursement status of anti-microbial dressings is particularly concerning. At present in many of the German Federal States, expensive anti-microbial dressings are not eligible for purchase as "practice consumables" to be used when patients visit a doctor or clinic but are prescribed for the patient's individual use. Any interruption in the reimbursed availability of such dressings may have a negative effect on the quality of care of chronic wounds in the community and may even result in an unwelcome increase in the use of systemic and topical antibiotics.

Under the previous version of the law manufacturers of advanced wound care technologies sought reimbursement for their products by emphasising their role in the protection of the wound and the maintenance of a moist wound environment. These product claims remain in the law's definition of a dressing but we can expect a much sharper focus by the G-BA on whether these benefits are the central purpose of the dressing or only secondary. We may see manufacturers developing further combination dressings in order to stay within the new definitions.

The restriction in the reimbursement of advanced technologies may reduce the confusing multiplicity of choice, although this is already restricted and managed through organisations' wound care formularies, but is unlikely to reduce the total cost of chronic wounds to the German economy unless the manufacturers take up the challenge to invest the very considerable sums needed to prove unequivocally how their products accelerate healing.

The risk is that products which today are recognised by frontline specialists in wound care as having value in the treatment package, tomorrow will not be available and the specialist and generalist will be thrown back on products which, to date, have not yet delivered the rates of healing needed to confront the rising number of chronic wounds.

Notes:

1. 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.

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.