Wound Market Consulting
The International Wound Care Market Specialists

German Reimbursement Evaluation Process for a New Wound Technology which is not categorised as a dressing

The decision making body in Germany for all matters relating to the reimbursement for any drug, medical treatment or device is the Federal Government's Ministry of Health, and specifically the Federal Joint Committee (Gemeinsamer Bundesausschuss or G-BA), a statutory body set up by the Ministry and comprising representatives of medical practitioners, hospitals and health insurance funds. This is because 90% of the population receive their health cover from one of 202 Statutory Health Funds (SHFs), to which citizens must belong if not privately insured.

The G-BA determines whether and at what price any treatment or product will be reimbursed.
The procedure to obtain approval for reimbursement (and at what level) is as follows:

- An application must be made to the G-BA. This can come from either of the following:
    - the non-political members of the G-BA (namely the professional bodies representing the branches of the medical profession, patients' representatives and the funding bodies)
    - the manufacturers of a medical product/device essential for the introduction of a new treatment procedure, or from any provider of a new procedure who has a commercial interest in it being approved for reimbursement.

Application:

- The applicant must submit to the G-BA a dossier containing evidence of the new treatment's benefits.

Evaluation:

The G-BA will then follow a set procedure to evaluate the dossier, which invariably will involve an instruction to the Institute for Quality and Efficiency in Health Care ('Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen' or IQWiG), another independent statutory body, whose role is to review all available scientific evidence and research relating to the treatment, and to provide scientific advice to the G-BA on, firstly, the medical effectiveness of the treatment compared to current alternatives, and, if that test is passed, on its cost effectiveness.

- The IQWiG itself is an independent scientific body established as part of a range of reforms to the German Health sector in the early 2000s. It does not commission its own research, but instead reviews all published scientific material. All its reports are published on their website and there is a period allowed for comments from the public.
- Where a new treatment is so innovative that there is little published material or there has not been time for extensive trials, the supplier can apply to the G-BA for a controlled study to be carried out. There are precise stipulations for the application process and there must be sufficient evidence that the treatment warrants the study. The G-BA will (for a fee) advise companies how to make an application, and if successful, the G-BA will expect a cost contribution although substantial subsidies seem to be available for smaller companies.

Outcome:

- If the IQWiG gives a favourable report in terms of both clinical and cost effectiveness, the G-BA will make a decision which is also, in the interests of transparency, published on its website. The G-BA will then set the reimbursement price by reference to a pool of comparable treatments, making allowance for the extent to which the new treatment is superior or not to those already available. A detailed explanation of their methodology in this respect is available. There is an appeals procedure available if required.

Clear statutory procedures and transparency of process and of outcomes characterise the procedure and whilst the process can take time it would appear to be open and strictly evidence-based.

Cherwell Innovation Centre · Upper Heyford · OXON · OX25 5HD · United Kingdom
Tel: + (44) 1869 238040 Mobile: + (44) 7710 592 576 Email: enquiries@woundmarketconsulting.com