MEDIClever
Outsourced Medical Reimbursement

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A Shortcut to Medical Device Reimbursement in Germany

You plan on getting your product approved in Europe and complete the CE mark process relatively quickly. You know Germany presents the largest market for medical devices in Europe and you already have a few German physicians interested in using your product. But, how can you get those German Sickness Funds (Payers) to pay for it - fast?

Here is one possible, intermediate mechanism, designed to serve as a gateway for introducing innovative medical devices into the German Inpatient reimbursement system.

1. The Problem

Just as in the US acute care hospital inpatient stays are reimbursed according to Medicare Severity Diagnosis Related Groups (MS-DRGs), in Germany they are reimbursed according to German Diagnosis Related Groups (G-DRGs).

In both cases, if your new device does not fit into an existing DRG, the hospital may not get paid for using it and thus may not want to use it. On the other hand, forming a new DRG code for your device (in the US or in Germany) requires data collection of procedure utilization. But since your device doesn't currently fit into an existing DRG, hospitals are reluctant to use it, and therefore it will never reach sufficient utilization to justify the creation of a new DRG code.

Sounds like a Catch-22, right?

To encourage entry of new and innovative technologies into the German healthcare system, there is a short-term, intermediate reimbursement mechanism that provides hospitals with the required financial incentive to use a new device, before it is properly reimbursed under the G-DRG system. However, it seems as if most US medical device companies are unaware of this mechanism that could shorten their time-to-market and even increase their chances of obtaining a relevant G-DRG code in the future.

In the next part I will provide a short description of the German G-DRG system, and then discuss the NUB mechanism.

2. German G-DRG System

The German DRG system, or G-DRG system, groups several parameters, such as: the patient's main and sub diagnosis (using ICD-10 diagnostic codes), performed procedures (using OPS procedure codes) as well as additional characteristics including the patient's age, complications and co-morbidities into a single G-DRG code and assigns each code with a price tag (with different adaptations that are outside the scope of this article).

The G-DRG system is a 'leaning system', relying on quantitative data supplied to the Agency for the Hospital Payment System (IneK) by the ~250 reporting hospitals throughout the year. The data gathered during 2010 is applied in the 2012 catalog.

3. NUB Reimbursement

Article 6.2 of the Hospital Remuneration Law (KHEntgG) allows hospitals to submit requests for reimbursement of "new and innovative diagnosis and treatment methods" that did not obtain a G-DRG code yet.

It should be emphasized that the device manufacturer is not the one applying for NUB reimbursement. Mediclever typically assists the manufacturer in preparing the application and then each relevant hospital receives a copy and submits it on its own.

3.1 Required Criteria

The NUB reimbursement request must fulfill the following criteria:

* The new and innovative method affects several existing G-DRGs.
* The new and innovative method can be clearly defined.
* The cost of using this new and innovative method affects the cost structure of the relevant procedure and the overall cost structure of the hospital.
* The requesting hospital's financial situation would be worse if the request is rejected.

3.2 The Application Process

Any hospital, interested in submitting a request for NUB reimbursement, should fill out a request form, which could be downloaded from the InEK site (www.g-drg.de). The application must be submitted by October 31st and provide information regarding the substituted (old) method, date of first applying the new method, number of patients treated and expected number of patients that will be treated according to this new and innovative method. Furthermore, a cost analysis comparing between the old and new methods should be added.

InEK checks all submitted applications and replies with a value of 1 to 4 for each application by January 31st.

* Value 1:
  - The innovative method corresponds with the requirements and will be reimbursed.
  - Usually, InEK will not have a national database that enables a uniform reimbursement rate, therefore each hospital and local GKV negotiation committee will negotiate the reimbursement rate.
  - InEK will also check if the innovative method can be adapted into the G-DRG framework
* Value 2:
  - The innovative method does not correspond with the requirements.
  - The hospital is not allowed to negotiate reimbursement with any Sickness Fund.
* Value 3:
  - InEK is overloaded and cannot reply to the submitted application until the deadline of Jan 31st.
  - The hospital may negotiate NUB reimbursement with interested Sickness Funds
* Value 4:

- The application was not clear or did not explain clearly why NUB reimbursement is needed.
- The hospital may negotiate NUB reimbursement with interested Sickness Funds.

3.3 Benefits and Disadvantages

* Benefits:
  - Obtaining NUB reimbursement takes a relatively short time. This could lead to immediate increase in procedure and sales volume.
  - There are no risks in receiving a rejection and a negative reply will not affect chances of obtaining another reimbursement mechanism in the future.
* Disadvantages:
  - NUB reimbursement only applies to submitting hospitals and requires bilateral negotiations between each hospital and the local Sickness Funds.
  - Each agreement is only valid for one year, but may be renewed, relatively easy, unless it has become a part of the G-DRG system.

In a recent research conducted by the Institute of Health Economics (IFG), it was suggested that hospital submissions will be available throughout the year and innovative methods that received a value 1 reply will automatically be reimbursed until included in G-DRG and apply to all relevant hospitals.

3.4 Statistics

For 2010, out of 13,865 requests for 546 new methods, 7,480 (representing 87 new methods) were assigned with Value 1, 6,005 (representing 444 new methods) were assigned with Value 2, none with Value 3 and 245 (representing 11 new methods) were assigned with Value 4. (Source: InEK).

4. Summary

The German healthcare system is trying to cope with the built-in delays of integrating innovative diagnostic and therapeutic treatments into the system. Similar to the German NUBs, comparable reimbursement mechanisms exist in the UK and in some regions of Italy. Utilizing these mechanisms can help US companies obtain reimbursement in Europe faster, bring their products to market sooner and increase their chances of obtaining a specific DRG code at a later stage.

To verify the existence of relevant DRG codes or any other reimbursement mechanisms for your product in the US or any European country, to develop and implement an appropriate reimbursement strategy and for any additional questions, please contact:

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About the Author

Amir Inbar founded Mediclever (www.mediclever.com), which provides end-to-end reimbursement consulting services to life-science companies, selling pharmaceuticals and medical technology products in the US and Europe.

As an expert reimbursement consultant Amir has consulted for organizations ranging from incubator startups to large, publicly traded companies, assisting them to obtain reimbursement for their Drugs/Devices in the US and Europe.