MEDIClever Reimbursement Consultants

www.mediclever.com

UK Office: Mediclever Ltd.
27 Old Gloucester St.,
London WC1N 3AX
E-mail: uk@mediclever.com
Phone: +44.208.099.7435

Israel Office: Mediclever Ltd.
6 Te'ena St.,
Modiin 71799
E-mail: il@mediclever.com
Phone: +972.50.837.1711

A Shortcut to Medical Device Reimbursement in France

[This is a second article in this series. The first article, "*A Shortcut to Medical Device Reimbursement in Germany*", can be downloaded at: http://www.mediclever.com/resources/5.pdf

You plan on getting your product approved in Europe and complete the CE mark process relatively quickly. You know France presents the 2nd largest market for medical devices in Europe and you already have a few French physicians interested in using your product. But, how can you get the French payers, aka health insurance funds (*caisses d'assurance maladie*) to pay for it - fast?

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

1. The Problem

Reimbursement for a hospital inpatient stay in the US is determined according to a Medicare Severity Diagnosis Related Group (MS-DRG). Similarly, reimbursement for a hospital inpatient stay in France is determined according to a Homogeneous Group of Stay (*Groupe Homogène de Séjour, GHS*). In both cases, if a new device does not fit into an existing DRG/GHS the hospital may not be properly reimbursed for its added cost and thus may not want to use it.

On the other hand, forming a new GHS code to reflect the added costs associated with your new device requires data collection of procedure utilization. But since your device doesn't currently fit into one of the French GHS codes, hospitals are reluctant to use it, and therefore it will never reach sufficient utilization to justify the creation of a new GHS code.

Sounds like a Catch-22, right?

To encourage entry of new and innovative technologies into the French healthcare system, innovative devices may be added to the "add-on list" ("*liste en sus*"), which provides hospitals with the required financial incentive to use a new device, before it is properly reimbursed under the GHS 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 influencing the payment rate of a relevant GHS code in the future.

In the next part I will provide a short description of the French GHS system, and then discuss the *liste en sus* mechanism in detail.

2. French GHS System

The French DRG system, or GHS system, groups several parameters to classify each patient's stay in a Homogeneous Group of Patients (*Groupe Homogène de Maladies, GHM*). Thereafter, each GHM is associated with its financial counterpart, the GHS.

The GHS system is a 'leaning system', relying on quantitative data supplied to the Technical Agency of Information on Hospitalization (*Agence technique de l'information sur l'hospitalisation, ATIH*) by ~45 reporting hospitals throughout the year. The data gathered during 2011 is applied in the 2013 GHS catalog.

3. Liste en Sus

To get listed on the liste en sus, the product needs to get listed on France's list of reimbursable products (*Liste des Produits et Prestations Remboursables, LPPR*), under the product's trade name (rather than under a general description).

The validity of the request for inclusion on the LPPR is evaluated by the national Committee for the Evaluation of Medical Devices and Health Technologies (*Commission Nationale d'évaluation des Dispositifs Médicaux et des Technologies de Santé, CNEDiMTS*), which bases its decision in particular on the dossier requesting reimbursement that is typically submitted by the manufacturer.

The device's reimbursement tariff, in addition to the hospital GHS tariff, is then negotiated between the healthcare products pricing committee (*Comité Economique des Produits de Santé, CEPS*) and the manufacturer.

Inclusion using the brand name is intended to be temporary. In fact, as soon as a competitor appears for the innovative product, inclusion using the generic description form could be justified.

4. Application for Inclusion on the Liste en Sus

In the case of an initial request for inclusion, the guidance of CNEDiMTS is based in particular on assessment of the product's Expected Service (*Service Attendu, SA*) and, if sufficient, on assessment of the Improvement of Expected Service (*Amélioration du Service Attendu, ASA*).

4.1 Assessment of the expected service (SA)

Assessment of the SA is by indication and is essentially based on an assessment:

- of the risk/benefit ratio;
- of the role of the device within therapeutic strategy;
- of its benefit to public health

4.2 Assessment of improvement of expected service (ASA)

If the expected service is sufficient to justify listing for reimbursement, the guidance of CNEDiMTS will also be based on the ASA in relation to a comparable product, considered to be the current gold standard, whether or not this gold standard is reimbursed. This assessment classifies the added clinical value as major (I), substantial (II), moderate (III), minor (IV) or absent (V) for each indication for which the committee considers that there is evidence to justify listing.

4.3 Setting the Tariff

Determination of the tariffs mainly takes into account SA, and ASA, when appropriate additional studies requested, tariffs and prices of comparable procedures or products, as well as services included on the list, the volume of anticipated sales and predicted and real conditions of use.

According to the law, the whole process should not take more than 6 months. However, some companies reported much longer time periods.

4.4 Maintaining the Listing

To remain on the list with the assigned level of reimbursement, the manufacturer should resubmit its applications every three years in order to demonstrate real-life data generated by post marketing studies, supporting claims that were used at the basis of the initial application.

If the post marketing study is either not performed, or incomplete, or there is insufficient evidence to show that the product performs as well in actual life, the so-called “service rendu” rating may drop, and with it the reimbursement level.

5. Statistics

Out of the 148 reviews provided by CNEDiMTS during 2009, 76 (51.3%) were provided for products submitted for the first time, 12 (8.1%) concerned requests for modifications, 51 (34.5%) concerned renewals and 9 (6.1%) were classified as other requests[1].

Out of the 88 reviews that concerned first submittals and modification requests, 62 were granted a ‘sufficient’ SA grade, while 26 were granted a ‘non-sufficient’ SA. For the assessment of improvement of expected service (ASA), only 2 products received ASA level I (major) and 4 received ASA level II (substantial).

[1] *HAS Annual Report 2009 (http://www.has-sante.fr/portail/upload/docs/application/pdf/2011-02/has_rapport_activite_2009_2011-02-25_11-31-57_229.pdf)*

6. Benefits and Disadvantages

6.1 Benefits:

* Inclusion on the *liste en sus* could lead to immediate increase in procedure and sales volume.

* As opposed to the equivalent NUB process in Germany, the manufacturer and not each individual hospital, negotiates the added reimbursement, which is then applicable for all hospitals, for up to 3 years.

6.2 Disadvantages:

* The process requires review of at least two separate agencies (CNEDiMTS and CEPS), which lengthens the process and requires substantial resources from the manufacturer's side.

* On an annual average, only 3 to 4 new products receive an ASA level of I or II that justifies separate reimbursement.

7. Summary

The French healthcare system is trying to cope with the built-in delays of integrating innovative diagnostic and therapeutic treatments into the system. Similar to the French *liste en sus*, comparable reimbursement mechanisms exist in Germany, the UK and in some regions of Italy. Utilizing these mechanisms can help US companies obtain reimbursement in Europe faster and bring their products to market sooner.

To verify the existence of relevant GHS codes, to develop the appropriate dossier for inclusion in the *liste en sus* or for the inclusion of your product under any reimbursement mechanisms in the US and Europe, please contact:

Amir Inbar, CEO, Mediclever Ltd.

www.mediclever.com

amir@mediclever.com

About the Author

Amir Inbar founded Mediclever Reimbursement Consultants (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.