

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 Ha-Te'ena St., Modin 71799

E-mail: il@mediclever.com Phone: +972.50.837.1711

## Reimbursement by Distributors

### 1. Overview

In many cases, when we ask the CEO of a medical device company how they are planning to obtain reimbursement for their product in Europe, they answer: "we have an excellent distributor who will take care of it".

The purpose of this article is to show:

- When may a company obtain reimbursement through a distributor and when it should not.
- In cases where the company may rely on its distributor to obtain reimbursement:
  - Which steps of the process may be relegated to the distributor and which steps must be kept under the company's lead.
  - How should the company preserve its interests and avoid being driven into a controlled position by its distributor.

### 2. When may a company obtain reimbursement through a distributor

## a. Using existing reimbursement mechanisms

The first question to be asked is whether the relevant device can be reimbursed through existing reimbursement mechanisms (codes, coverage and payment levels).

- If new reimbursement mechanisms have to be developed for the device, the reimbursement task should not be relegated to the distributor.
  - Distributors are experts at distributing, not at reimbursement. In some cases, according to the local law, the company only has one opportunity to apply for reimbursement. If it fails in this first trial, it is banned from applying again forever!
- If existing reimbursement mechanisms could be utilized without any modifications, transferring the responsibility for reimbursement to an experienced distributor may be considered.

### b. Steps that should always remain the company's responsibility

Even when the distributor assumes responsibility for reimbursement, if a Billing Guide should be issued, it is the company that should be responsible for it, not the distributor. A Billing Guide has two purposes:

1) Serve as the <u>only</u> source from the company that instructs the local healthcare providers on reimbursement issues. When to bill, who to bill and how much.



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 Ha-Te'ena St., Modiin 71799 E-mail: il@mediclever.com

E-mail: il@mediclever.com Phone: +972.50.837.1711

2) Reduce the company's exposure to fraud and abuse claims if a healthcare provider or a distributor fails to appropriately use (mistakenly or deliberately) the correct reimbursement mechanism.

# c. Preserving the company's interests

In some cases, even when existing reimbursement mechanisms may be utilized, an appropriate confirmation should be received from the relevant authority. If the distributor applies for this confirmation, he could phrase it in a manner that would grant the authority to himself (rather than the company), which will provide him with control over the company's products and make it difficult for the company to replace him with another distributor.

In some cases, we applied on behalf of our clients to correct the application and replace the distributor's name with the company's. This resulted with unnecessary delays for the company in replacing the distributor and launching the product in Europe.

## 3. Summary

The issue of reimbursement should only be transferred to an experienced distributor in case existing reimbursement mechanisms can be utilized. In such case, the company should still be responsible for the issue of its Billing Guide and make sure that any applications made by the distributor do not conflict with the company's interests.

To verify the existence of relevant reimbursement mechanisms for your product in any European country and for any additional questions, please contact:

Amir Inbar, CEO Mediclever Ltd. www.mediclever.com amir@mediclever.com

#### About the Author:

Amir Inbar founded Mediclever, which provides a cost-effective solution to manufacturers of medical technology products interested in obtaining reimbursement for their products in Europe.

As an expert reimbursement consultant Amir has consulted for organizations ranging from incubator startups to large, publicly traded companies, resulting in reimbursement for their products across various European markets.