**The importance of reimbursement - A lot more than just the money**

Getting your product thought the FDA process is an important but it is only a small piece of the puzzle getting reimbursement from CMS and insurance companies is 10 times more complicated process. Going out to the market with a product which has no reimbursement might end up with a product which does not sell.

When coming to design a product, manufactures should consider not only the FDA clearance requirements but also how to comply with existing reimbursement codes to accelerate time to market and improve chances for market adaptation.

Many tend to think that if a device is going through the FDA De NOVO path, they necessarily will be required to promote a new CPT code. But in real life, the fact manufacture has invented a new mechanism or technique does not necessarily mean it cannot fit into an existing CPT code if it defines the result and not the process. On the other hand, in some cases even if you can fit into existing CPT code it does not always mean you should, if in the long term a new CPT code will result in significantly higher revenue.

To choose correctly if to use existing CPT code or promote a new one is a strategic decision and this is the reason it is never too early to consider reimbursement strategy, in fact should come long time before design freeze.

**Building a financial valuable product**

To ensure claims for reimbursement are being accepted it is not enough to comply with CPT codes requirements. Significant part of the reimbursement strategy should focus on: 1. Seamlessly integrating into the healthcare organization reimbursement processes; 2. Provide the necessary information required to submit reimbursement claim; 3. Improve compliance with reimbursement requirements; 4. Automate reimbursement process to reduce workload and claims denials.

Findings show that 30% ($262B) of the claims are denied even though 63% of those claims were recoverable. Human errors and missing data are the main cause for claims denials resulting with an additional cost of $118 per claim, $8.6B appeals-related administrative costs. Medical devices which will be designed with reimbursement automation capabilities such as reporting the time physician spent on remote patient monitoring during a month, the time a patient used the device during the month, the time spent on patient training, time physician spent on operational tasks related to RPM during the month and automatically allocating CPT code once reimbursement criteria is met will dramatical reduce the workload and human errors resulting with higher claims acceptance rate and are expected to improve adaptation rate of the device.

One of the challenges medical devices manufactures are facing when coming to add reimbursement automation capabilities is how to continuously comply with the reimbursement requirements which are constantly changing? While allocating internal resources is costly in inefficient, choosing from day one to use a medical-grade cloud platform which include reimbursement automation capabilities might end up to be cost-effective and more efficient.

**Real World Data & Real-World Evidence, what is the difference and the effect on reimbursement.**

Read World Evidence is a subset of Real-World Data so we can look at both together as all of the data and knowledge received from and about the device collected from the moment it goes to the market.

The difference is that Real-World Data is all of the evidence, regardless of how reliable or realistic they are. Real-World evidence on the other hand is a subset of the Real-World Data with the sufficient quality to be reproduceable, some will say it is data at a higher standard and this is the reason 3 years ago the FDA started to consider accepting Real-World evidence to approve extension of an FDA approved product for additional indication (label expansion). Label expansion (for FDA submission) require clinical data. You have 2 options, you can either do clinical trials which currently is still considered to be the "Gold Standard" even though it is unrealistic compering to how we practice medicine in real-life. The other option is to consider real evidence in case the device is already in the market and people are using it for this specific indication even though it is not part of the RCT as long as the real-world evidence is considered to be reliable (i.e enough data, collected over time, repeatable, demographic diversity…). In those cases, the FDA will consider accepting Real-World evince instead of performing clinical trial.

Exactly the same thing applies to reimbursement. We should consider accepting reliable Real-World evidence as justification for reimbursement rather the traditional "Gold Standard".

In the eye of product design, adding connectivity for post-market data collection (as Real-World evidence) will simplify the label expansion submission process, cut costs and time.

**The transition from Fee for service to value-based care and the effect on reimbursement**

Fee-for-service (FFS) is a payment model where services are unbundled and paid for separately. In health care, it gives an [incentive](https://en.wikipedia.org/wiki/Incentive) for physicians to provide more treatments because payment is dependent on the quantity of care, rather than quality of care, and discourages the efficiencies of [integrated care](https://en.wikipedia.org/wiki/Integrated_care) and not taking into consideration or asking for evidence of the effectiveness of the treatment. The outcome is poor care and increasing costs of services.

Value-based healthcare is a healthcare delivery model in which providers are paid based on patient health outcomes. They are rewarded for helping patients improve their health, reduce the effects and incidence of chronic disease, and live healthier lives in an evidence-based way. The benefits of value-based care systems are lower costs, better patient outcomes, reduced risks and higher patient satisfaction.

The American healthcare system is in the process of shifting from FFS to Value-based care which is going to affect the reimbursement requirements and processes. It will require healthcare providers to submit evidence on patient outcomes and satisfaction on top of objective data.

Supporting value-based care model will require collecting and documenting patient data, evidence (i.e indication of the improvement of patient condition or adherence to treatment protocol) and using patient reported outcomes measures (i.e using questioners to prove patient condition improved after treatment). It will also expect to increase the demand for patient-based care where treatment is defined based on reported results and with usage of algorithms and preventive care where care providers are equipped with tools to prevent further deterioration.

Using connected medical devices is the most efficient tool to not only collect real world evidence and patient data but also to improve adherence to treatment protocol (in case the device includes follow up and notification capabilities), enable to remotely monitor patients and provide patient-based care as well as prevent deterioration.

As the transit from FFS to value-based care is still in early stages and guidelines are not yet clear, using a medical-grade cloud platform is the safest way to ensure future compliance with reimbursement requirements and simple integration of supporting features (i.e automatic PROMs tools).