ACOs – A New Reimbursement Strategy?

During the past few months we heard a few representatives of medical device companies, claim that their new and innovative devices would be sold directly to Accountable Care Organizations (ACOs), thus eliminating the need to develop a new HCPCS code or wait until payers issue new coverage policies to reimburse the use of their new device.

In order to examine this strategy and shed some light on ACOs and their impact on the healthcare industry, in the following paragraphs we try to clarify this new reimbursement and care delivery structure and examine its impact on developers of innovative medical devices.

1. Current Reimbursement and Care Delivery Structures

a. Description

Two examples for current reimbursement mechanisms, which may be replaced by ACOs, take place at the following settings:

- **Physician’s Office**: Procedures furnished outside of the hospital, at the physician’s office. Such procedures are currently reimbursed on a Fee-for-Service (FFS) basis, in which the physician receives a fee for each service performed (e.g., taking a chest X-Ray). This is probably the most traditional form of reimbursement.

- **Hospital Inpatient**: Procedures furnished to patients that are hospitalized for more than 24 hours (stay at the hospital overnight). Such procedures are usually reimbursed on a ‘Case-Mix’ basis, i.e., a ‘bundled’ lump-sum for treating a patient during a single encounter/episode (e.g., heart surgery), regardless of actual services provided (e.g., DRG, DTC).
The table below summarizes these current reimbursement and care delivery structures.

<table>
<thead>
<tr>
<th>Setting</th>
<th>Reimbursement Mechanism</th>
<th>Example</th>
<th>Unit of Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician’s Office</td>
<td>FFS</td>
<td>Taking a chest X-Ray</td>
<td>Pre-defined service</td>
</tr>
<tr>
<td>Hospital Inpatient</td>
<td>Case-Mix</td>
<td>Open heart surgery</td>
<td>Specific case or disease</td>
</tr>
</tbody>
</table>

**b. Drawbacks**

Both of the above reimbursement mechanisms (FFS and Case-Mix) have serious limitations.

- **FFS**: Since there is a direct link between volume and revenues there is a clear incentive for overproduction. Physicians may tend to conduct more tests, more imaging procedures and generally increase healthcare spending.

- **Case-Mix**: Reimbursement per case is fixed, so within a given case there are no incentives to provide unnecessary services. However, more cases do lead to more revenue and there is also an incentive to choose the most lucrative treatment even though this is not medically necessary.

Another incentive that leads to a risk is to lower the quality of care within a certain code in order to save costs¹.

The following matrix depicts these limitations:

<table>
<thead>
<tr>
<th>Quality of Healthcare Services</th>
<th>Healthcare Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower</td>
<td>Hospital Inpatient (Case-Mix)</td>
</tr>
<tr>
<td>Higher</td>
<td>ACOs (?)</td>
</tr>
<tr>
<td></td>
<td>Physician’s Office (FFS)</td>
</tr>
</tbody>
</table>

The introduction of ACOs aims to do both, lower healthcare spending, as well as increase the quality of healthcare services.

¹ Incentives in the Diagnosis Treatment Combination payment system for specialist medical care, A study about behavioral responses of medical specialists and hospitals in the Netherlands. Fleur Hasaart, July 2011.
2. ACOs

a. Definition

An ACO is currently defined as a medical provider panel (e.g., network of primary care and specialty doctors and hospitals) that shares financial responsibility for delivering quality care to patients by coordinating the allocation of service delivery to meet the healthcare needs of a minimum of 5,000 Medicare beneficiaries, for at least three years. However, some of the largest health insurers in the US, including Humana, United Healthcare and Cigna, already have announced plans to form their own ACOs for the private market.

b. Reimbursement Mechanism

As opposed to the traditional FFS/Case-Mix reimbursement mechanisms, ACOs would create savings incentives by offering bonuses when providers keep costs down. In addition, doctors and hospitals would have to meet specific quality benchmarks, focusing on prevention and carefully managing patients with chronic diseases. In other words, providers would get paid more for keeping their patients healthy and out of the hospital.

If an ACO is not able to save money, it could be stuck with the costs of investments made to improve care, such as adding new nurse care managers, and also may have to pay a penalty if they don't meet performance and savings benchmarks. ACOs sponsored by physicians or rural providers, however, can apply to receive payments in advance to help them build the infrastructure necessary for coordinated care – a concession the Obama administration made after complaints from rural hospitals².

c. Market Potential

As many as 270 ACO networks are expected to participate in the Medicare pay model that encourages physicians and hospitals to coordinate patient care in a way that improves quality and saves the program money. From 2012 through 2015, Medicare could save an estimated $1.8 billion and let groups share in $1.3

billion in bonuses for hitting savings targets, thus saving Medicare a net of about $500 million³.

3. Opportunities and Threats for Medical Device Makers

In theory, ACOs would be able to decide upon purchasing new and innovative medical devices, prior to securing a new HCPCS code or establishing a new coverage policy. This, of course, could substantially shorten the time to market. Reimbursement negotiations may be shifted away from payers back to hospitals and physicians, making them the main decision makers for the future procurement and use of products. However, this does not necessarily mean a simpler and quicker process.

Medical device developers would still need to demonstrate improvements in clinical outcomes (better than alternative treatment options) or reductions in overall healthcare costs to gain the ACOs attention⁴. “Manufacturers should perform a cost-benefit analysis on the expected clinical outcomes against the volume of ACO sales and utilization expected, which will require data in regard to how the manufacturer’s products are performing (clinical outcomes vs. cost savings) within an ACO”.

According to the Advanced Medical Technology Association, which represents medical device makers, ACOs could even encourage doctors to use less costly devices instead of what works best for the patient. “We are worried about the market power ACOs may wield…and it may present significant risks to patients,” said Ann-Marie Lynch, executive vice president of the Advanced Medical Technology Association. Her group is pushing for safeguards in the ACO rules to make sure new technologies are not discouraged and independent monitoring to make sure patients get appropriate care⁵.

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³ CMS redesigns Medicare ACOs to be more appealing to physicians, Charles Fiegl, amednews staff. Posted Oct 31, 2011 (http://www.ama-assn.org/amednews/2011/10/31/gvl11031.htm)


4. Conclusions

In spite of the seemingly shorter bureaucratic path towards reimbursement, selling new medical devices to ACOs may still require the same level of ‘evidence’ that were needed to convince payers and entail a similarly lengthy process. A detailed description of the suggested path can be downloaded here: [http://www.mediclever.com/resources/Reimbursement_Checklist.ppsx](http://www.mediclever.com/resources/Reimbursement_Checklist.ppsx).

To verify the existence of relevant reimbursement mechanisms in the US or Europe, to develop and implement an appropriate reimbursement strategy and for any other questions, please contact:

Amir Inbar, CEO
Mediclever Reimbursement Consultants
www.mediclever.com
amir@mediclever.com

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.

Mediclever's consultants have worked with organizations ranging from incubator startups to large, publicly traded companies, assisting them to obtain reimbursement for their drugs/devices in the US and Europe.