



Reimbursement Landscape for Early Stage Pharma Companies



If an early stage company is developing a new medical technology, they may think that they can delay thinking about reimbursement until after the clinical studies or after FDA approval

Unfortunately, for an early stage company, potential investors want information early on the addressable market and the potential revenue. They want to know the possible return on investment and assess the risks of the technology. A

reimbursement landscape answers the question, 'how will we get paid and how much will we get paid' A reimbursement landscape is an essential part of the strategic plan. One of the biggest challenges relates to the reimbursement system in getting positive coverage, appropriate coding and reasonable and value based payment for a technology

What about waiting until you have clinical data?

Successful companies will tell you that is too late. A good reimbursement assessment will help the company identify the appropriate endpoints to be included as part of the clinical trial that include clinical outcomes and value to the clinician and payer.

What does a reimbursement landscape look like?

Reimbursement has three key components: codes, coverage and payment. A reimbursement landscape would provide you with the codes currently used, the current payments in Medicare/ private insurance market; and the relevant coverage statements and policies. A good assessment would look at similar products and describe what is currently done and the codes that are used for the product. In the current system of fee for service, a company needs to understand not only the product codes but the CPT codes used by physicians to be paid, or the bundled DRG codes. Yes, there is jargon in reimbursement! Coverage statements are listed in policies and are really statement of limitations. They describe how and when a product can be used. For many innovative products, prior authorizations are listed. This means that the provider will need to complete paperwork and provide evidence to the payor why this therapy should be used. The payer then can decide whether to authorize the use of that produce or procedure, or deny the use.

What about the future?

For a working reimbursement assessment that is part of the strategic plan, a company needs to look at trends and shifts and look to what some of the likely options are in the future. A company needs to look at alternative scenarios and consider how the competition and the whole health system will react and



change based on the new innovation. There are changes occurring in healthcare with a shift from fee for service to value based reimbursement. How might these changes affect your product?

CMS has an ambitious goal of transitioning 85% of fee for service payments to value based payments.

<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html>

The MACRA change on how physicians will be paid was announced October 14 2016 and will be implemented from January 1 2017

http://www.fiercehealthcare.com/practices/cms-releases-macra-final-rule-changes-medicare-payment-system-for-physicians?utm_medium=nl&utm_source=internal&mrkid=840287&mkt_tok=eyJpIjoiWTJFd1IqTmtObU15TW1VMylsInQiOiJQUjQDNMNGk1K2dkbWZGMGVFMUIrWUJlcHIBc1NONCtyeWI0Sk55WVFSTDBkVEgwUVNXXk3BzS2hEWVRQcHNJYmxhclNRRUp0VGhclzBNcEtPSINrNXhkYm9GT1N1b1luMGpTaUpcl0FCeVdw dGMwPSJ9

Policy makers are developing different systems and criteria to try and change pricing of drugs. Here in California, Proposition 61 is on the ballot as a measure that seeks to limit the price paid for prescription drugs by state agencies.

<https://www.americanprogress.org/issues/healthcare/report/2016/09/26/144760/negotiation-plus-a-framework-for-value-based-drug-pricing-negotiation/>

How might these moves effect your product and your potential competitors and the environment you will be in when your product is finally approved?

I recently spoke at a Women in Biotech meeting on reimbursement and pricing for drugs used in rare disease. These drugs need a different model. These are small market and the costs of developing a new drugs are the same or higher. In order to get a return on investment, these rare drugs are priced high, and some orphan drugs are among the most expensive in the world. At this meeting we had pharma companies, patients and patient advocacy speakers. Everyone recognized the need to develop these innovative products and that companies need a return on investment. What came as a surprise to some of the early stage companies was how early companies were investing in understanding the commercial and reimbursement aspects of a drug, even before the results are available.

So a reimbursement landscape assessment early in the process can help in developing a strategy and be part of the business plan, and don't forget to change it as circumstances change.