How to Implement a Private Payer Reimbursement Strategy

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When and How to Develop a Reimbursement Strategy

• The short answer is as soon as possible
• Now we’ll explain the how and why
Why is it so important?

• Reimbursement is critical to the success of a product

• We have had many clients who have developed a wonderful device only to find there was no coverage or inadequate reimbursement for the device, resulting in a wonderful device no one wanted to buy!

• Simply put, reimbursement will determine whether or not providers will be willing to buy the product
What needs to be addressed in the reimbursement strategy?

• The reimbursement strategy should address each of the relevant target markets
  – Medicare
  – Medicaid
  – Commercial (including unions & self-insured companies)
• Prior to making a purchase, providers will want to know what they can expect in terms of reimbursement in each of these markets
How do providers make a purchase decision?

• Providers will evaluate:
  – The amount of time it takes to perform the procedure
  – The opportunity cost of seeing another patient
  – The sales price
  – The administrative impact of the device on their practice (clinical and administrative staff time)

• Their bottom line is “what is the price of this device relative to my expected return?”
What do payers look at?

• How much will the device/procedure cost in terms of claims expense?
• Does this procedure substitute for something that is more costly?
• Will it reduce other health care costs in the near term (e.g. hospital admissions)?
• Will it reduce future costs through early detection, etc.?
• Does the clinical literature support the manufacturer’s claims regarding efficacy, safety and cost savings?
When do we begin developing the reimbursement strategy?

- It is really never too soon to begin developing your reimbursement strategy
- At least 12 months before product launch, you should begin to identify all the potential reimbursement issues including:
  - Coding (is there an existing code or do we need a new one?)
  - How it will be reimbursed (e.g. through a separate procedure rate, bundled into an existing rate, etc.)
  - Does the existing clinical literature enable us to make the case to the payers?
- Identify the gaps and develop an action plan for each issue
When do we begin developing the reimbursement strategy?

• At least, six months before launch:
  – Begin researching reimbursement levels for comparable products
  – Begin informal discussions with the payers to see how they are likely to react
  – Determine if additional data will be needed to support your case
  – Begin developing the “value story”
    • Collect all the relevant clinical literature that will be needed to support the request for coverage
    • Develop the economic argument in support of the device or service
When do we begin developing the reimbursement strategy?

• At least six months before launch:
  – Incorporate the reimbursement information into the final pricing strategy - make sure pricing and reimbursement are consistent
  – Develop a strategy for educating field staff and your customers on reimbursement issues
When do we begin developing the reimbursement strategy?

• Beginning three months before launch:
  – Formalize the information that will be presented to the payers including the clinical literature and economic data
  – Implement the provider strategy, making sure you have a way to respond to inquiries and resolve issues
  – Continue working with the payers to ensure that their coverage and reimbursement policies result in a favorable outcome
When do we begin developing the reimbursement strategy?

- 12 months
  - Identify issues
  - Develop action plan

- 6 months
  - Research comparables
  - Initiate informal payer discussions
  - Finalize pricing
  - Finalize reimbursement strategy

- 3 months
  - Implement provider strategy
  - Meet with payers
  - Educate field staff
  - Resolve billing issues

Product Launch
What to do if, despite your best efforts, the payers say NO

• DON’T PANIC!
What to do if, despite your best efforts, a Private Payer says NO

Formal Appeals Process:

• In the case of the private payers, there generally is no formal reconsideration process for new technology reviews

• The manufacturer will have to work with the payer and its Medical Director(s) through an informal process to present the evidence needed to make the case
What to do if, despite your best efforts, a Private Payer says NO

• Individual patients who have been denied prior authorization for a specific procedure can appeal to the private payer; Each payer has its own internal appeals process that the patient must follow

• Once the internal appeals process has been exhausted, most States require that there be an external process as well, which is generally handled by an outside independent review organization

• An affirmative decision for a specific patient does not mean that the coverage decision will be reversed but it does begin to build the case for future discussions with the payer
What to do if, despite your best efforts, a Private Payer says NO

Informal appeals process:

• The first step is to try and obtain as much information as possible as to why a negative decision was issued
• If possible, speak directly to the Medical Director at the relevant payer
• Enlist the support of the provider community in contacting the Medical Director to explain why a change is needed
What to do if, despite your best efforts, a Private Payer says NO

- Most likely, you will be told that the literature was not adequate to support an affirmative coverage position
- If this is the case, have your clinical experts develop a point-by-point response
- Provide the Medical Director with additional information that might not have been available prior to rendering their decision
- If you cannot convince them, consider the need for additional studies designed to address the payers’ specific concerns
What to do if, despite your best efforts, Medicare says NO

- Medicare has a formal process in place for reconsideration of both National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)
- The only opportunity for a manufacturer to overturn an NCD (which is binding on all the carriers) is to submit a reconsideration request
What to do if, despite your best efforts, Medicare says NO

• The reconsideration request will only be considered if it is accompanied by additional medical or scientific evidence that was not considered as part of the initial review or if you are asserting that the data was misinterpreted
• The reconsideration process takes about 90 days and the existing NCD remains in effect during this period
• Medicare beneficiaries who have been denied a service have an additional opportunity to appeal, initially to the Departmental Appeals Board and ultimately through the Federal district court
What to do if, despite your best efforts, Medicare says NO

• If you are dissatisfied with an LCD, manufacturers can submit a request for a reconsideration
• As with an NCD reconsideration, the information submitted will be held to the same standard that was applied for the initial determination
• The carrier has 30 days to determine if the request is valid; if so, they have up to 90 days in which to make a decision on whether a revision is warranted
What to do if, despite your best efforts, Medicare says NO

• In our experience, carriers are willing to entertain additional information submitted through the reconsideration process and will, in fact, make changes if deemed appropriate
• It is also extremely helpful if you can engage in a dialogue with the local carrier Medical Director and if you can enlist the support of providers who can also request a reconsideration
What to do if, despite your best efforts, Medicare says NO

• Medicare beneficiaries who have been denied a service because of an LCD can also file an LCD challenge
• The challenge is reviewed by an Administrative Law Judge (ALJ)
• If the ALJ rules in favor of the beneficiary, it may trigger a change in the policy
• If the ALJ upholds the original policy, the beneficiary may appeal to a Departmental Appeals Board and ultimately the courts
Summary/Conclusion

• The key component in your reimbursement strategy is to make sure that the information is in place to convince the Medical Directors that the new technology is:
  – Safe;
  – Has an impact on clinical outcome as documented in peer reviewed, scientific literature; and
  – Short of a significant leap in outcome or quality, will not result in additional costs

• Without the supporting evidence, it will be very difficult, if not impossible to implement a successful reimbursement strategy