In Chapter 10, we discussed how the Payer Value Story is used to rationally translate benefits and related evidence to the payer system requirements for Market Access and Pricing. In this chapter we will describe more in detail how we can effectively structure and communicate our payer value story for maximum impact in payer negotiations.

How do we convince a payer to make a Market Access or Pricing decision that is favorable to our strategic objectives? How do we make sure that our payer audience is

1. interested to even listen to, or read our proposal and claims;

2. sufficiently concerned about the clinical challenges in the disease area under consideration that provides the basis for the treatment solution that we will offer now or in the future;

3. inclined to have a positive mindset with respect to our specific offering, so that he/she is open to consider our claims and give us some benefit of the doubt where the supporting evidence is not perfect;

4. willing to engage in dialog and a practical deal to address or overcome any evidence gaps and other concerns that the payer may have, rather than outright reject our proposition over skepticism against a budget concern background?

The framework in this chapter will provide a structured solution to addressing the above questions, building on the BEST PRICE framework that was discussed in Chapter 10.
Value Dossier

Many companies are putting significant efforts in creating a Value Dossier. This dossier is intended to provide guidance to national and local teams on the value strategy that should be followed and provides the supporting data to strengthen the brand’s claims and hopefully enable positive negotiation results. The American Academy of Managed Care Pharmacy (AMCP) has structured a proposed design of a new drug dossier for the purpose of Managed Care formulary review. The “AMCP Dossier” is very comprehensive in its inclusion of all relevant clinical and economic data. However it is also structured so as not to allow the manufacturer to “tell the story.” As such, the AMCP dossier format is designed to minimize the probability of success in convincing a payer of added value of a new treatment. It ignores the fact that Managed Care management is able to critically judge the value of an offered innovation without imposed limitations on what can be submitted. The AMCP dossier format should, where possible, be ignored and at least not serve as our framework for value communication and company dossier structure. Certainly there are more suitable structures that allow us to tell the story and build the supporting arguments with clinical evidence.

So how can we make sure that we provide a compelling story and ensure that we have a willing audience to listen to us or read a dossier? Our TEMPLE Framework may be helpful in achieving that objective.

TEMPLE Framework

The TEMPLE Framework is based on the concept that we need to create both an early interest and a strong rationale for meaningful claims that our new drug brings to payers and other important players in the drug prescribing decision process. Most of us like to read a good book, but dread reading a poorly written, less than compelling “dossier.” A benefits dossier for an AMNOG submission in Germany easily counts 30,000 pages, hardly a Stephen King novel. The mindset of anybody who starts to study a dossier is probably not one of great expectation and enthusiasm. Therefore, relying on a collection of unstructured information and data to instill payer enthusiasm is not a great strategy. Short of hitting a payer over the head, it is not easy to impress a payer with a 1,000+ pages dossier. Therefore we need to create a well-structured and credible story that ties into payer concerns and interests. Further, we need to use pre-payer marketing strategies to carefully prepare the audience for our
ultimate claims and actual dossier for review. The TEMPLE Framework clearly distinguishes between branded messages that can only be communicated after FDA/EMA approval and unbranded messages that can be communicated much earlier. Starting the process early is important, since many of the improvement claims are dependent on a thorough understanding of the unmet needs and shortcomings of existing treatments.

Figure 11.1 shows the TEMPLE Framework for Payer Value Messaging and its components: Elevator Message, Pillar Messages and Detailed support messages and evidence. The philosophy is that the elevator message is to be a high-level succinct statement that creates interest and launches the claim. The pillars form the essential support to make the elevator claims “stand,” considering the anticipated general understanding of the typical payer. Detailed messages create more robustness for each of the pillars to support the claims with scientific data.
ELEVATOR MESSAGE

A brief and compelling “elevator message” style value proposition is essential to a good value story. The notion is that if you cannot raise interest in a brief statement, then a lengthy dossier will certainly not do it. The elevator message needs to communicate the essential claims of the drug that are of interest to the payer and that address an unmet need. We cannot expect that the message alone will be enough to sway a payer into a positive market access or pricing decision, but should rather peak their interest to hear or read the full story. The elevator message needs to be a reasonable high level summary of the claims made and supported in the pillar messages. Overstating a claim in an elevator message is a short lived victory.

Creating a strong elevator message is an iterative process. It is useful to consider from the start what the most compelling claims are, based on the benefits analysis, but it also makes sense to review after creating the more detailed pillars and supporting messages. At that stage we should consider whether we have really built a strong case or whether we have left compelling claims out.

Particularly in early stages of the story development, we should not get hung up on exact wording, but rather focus on having the most important elements in place. Engaging in wordsmithing too early can detract from considering the bigger picture. This is not just true for the elevator message, but for all elements of the payer value story.

PILLAR MESSAGES

It is unlikely that an elevator message in itself will create sufficient buy in from a payer to support a favorable decision. However that is also not the intent. A more realistic goal is to create genuine interest and/or get an endorsement that if a claim can be met, this would be a meaningful improvement, hence warranting a closer review of the dossier.

Payers are very different from treating physicians in their decision-making process and evidence requirements. A physician who hears 10 different messages related to a new drug, may be intrigued by one or two of them. If these messages are highly relevant for specific patients and if the physician has no other concerns, then he/she may try the new drug on appropriate patients. When successful he/she may expand usage to a broader set of patients. National and regional payers are much less likely to “try” new drugs. They expect a
complete dossier that will enable them to make a balanced decision for price and/or reimbursement based on the evidence provided by the manufacturer and experience of consulting KOLs. Therefore a Payer Value Story and Dossier needs to provide a complete picture of the appropriate use of a new drug, not just an incentive to “try.” Hospital payers have some more flexibility. When good reasons exist, they can organize a pilot program in a hospital and make a more formal formulary and treatment protocol decision later.

The TEMPLE Framework example in Figure 11.1 uses the following typical Pillar Message Topics:

1. **What is the Burden of the Disease?**
   Why is this disease area one where I should be concerned about having effective treatment available to patients? What is the financial and human cost of suffering because of this condition? Is or should this be considered a public health priority?

2. **What are the Problems with the current Standard of Care?**
   Why are the current drugs and other treatments not sufficiently effective or safe to provide an effective treatment to patients? Why should I consider new treatment options?

3. **What are the Implications of Treatment Failure?**
   What are the health consequences of treatment failure with the current options available? How do these consequences impact patient (drug and medical) treatment and care requirements and cost?

4. **What solution does Product X provide?**
   What is the impact of Product X on the treatment problems for the disease? How do clinical, humanistic, economic and public health benefits provide a favorable proposition to payers, their healthcare systems and the general public?

The four pillar messages provide the high-level flow of the payer value story in support of the elevator message. They bridge the gap between the foundational understanding of the payer and the elevator message that we are trying to support. There is no particular reason why there could not be three or five pillars, but four seems to generally work well to outline the high-level value story in logical steps. It is important to note that pillars 1, 2 and 3
are unbranded and therefore are to be communicated prior to launch (within certain legal constraints). This is very important, since building support for the recognition of an unmet need is a process that will take time; more time than may usually be available between market authorization and launch of our new drug. Pillar 4 is the branded message for which communication is commonly restricted to post-marketing approval timing.

![Figure 11.2 Example of a payer value story](image)

Below each pillar we require more detailed messages and supporting evidence to make the story credible and address the obvious evidence requirements for each message and its sub-messages. Many of these messages may refer to substantial data packages. Despite the ultimate need for detail, it is important to thoroughly consider a simple format for the high-level messages. Dossier weight is a poor substitute for substance and unfortunately, many value dossiers ignore this important aspect. Of course a value dossier can only be as good as the asset value that it represents. Great innovations make creating a payer value story easier, but a poor value dossier can harm even the best drug innovation. An example of a payer value story with Elevator Messages, Pillar Messages and Sub-Messages is shown in Figure 11.2. Unfortunately, this real-life example had to be significantly blinded to honor client confidentiality,
but the intent of the example is to show the structure of the payer value story, with a short elevator message, four pillar messages and usually three to six sub-messages for each pillar that link to the data and references.

**KOL AND PHYSICIAN ENDORSEMENT**

Probably the most important step towards gaining payer endorsement is to gain support from key opinion leaders (KOLs) in the field with respect to the medical necessity of the new treatment. KOLs will not be able to comment on cost issues, but they can influence payers by informing them of the importance of a new treatment, the impact on individual patients and the impact on patient prognosis of not allowing the treatment. In order to achieve this, it is crucial to work closely with KOLs to define data and other information needs to come to this conclusion.

Physicians are primarily interested in medical value. Price and cost usually only play a role in absence of reimbursement or at high patient co-pay, although medical societies such as ASCO and AHA have stated an intent to incorporate cost or “financial toxicity” as one of the perspectives in guideline development. In some markets, for example Germany, physicians have become more cost-sensitive as a result of practices in the healthcare system. German drug budgets of the 1990s have created a lot of anxiety among physicians because of the potential impact of over-prescribing on the physician’s retirement benefit. Although only few, if any, cases exist where physicians have actually been penalized, the drug budgets (nowadays called “cost guidelines”) and prescribing audits have been very effective in creating some cost-sensitivity among the physician community.

Absent of cost-driven guidelines or budget incentives, most physicians tend to want to prescribe the best treatment option for the patient, irrespective of cost. In the United States, increases in co-pays and co-insurance rates have altered the situation for some therapeutic areas. For Medicare Part D and Exchange plans, co-insurance rates of 33 or 50 percent are not unusual. Specifically drug categories with relatively close substitutes, such as gliptins in diabetes, have seen increases in substitutions as a result of patients’ complaints, sometimes aided with pharmacists’ suggestions. Specialty drugs have traditionally seen less substitution, but high co-insurance rates and the imminent emergence of biosimilars have created large incentives for substitution, particularly for TNF inhibitors, where multiple options are now available.
An important question to answer is related to patient selection. “What is the right patient for this new treatment?” “Given cost, should every patient within an indication be a candidate for the new treatment?” Often, a new treatment is crucial for a selection of patients (for example, treatment resistant), but not for others. Before banking on a KOL endorsement for “medically necessary” coverage of a new drug, one should carefully evaluate for which patients the support would stand under pressure from payers.

**PAYER VIEWS ON THE VALUE STORY AND DOSSIER**

What are payers looking for in a dossier? Payers, as holders of the budget, tend to resist new more expensive treatments, particularly when they don’t see a strong push from the community. The natural stance for payers will frequently be: “Why would I pay more?” Some of the controlled payer systems, such as in France and Japan, link the approved price to a selected reference drug, with an awarded price premium based on the demonstrated innovation and patient benefits. Since the government regulators are also paying the bill, and are rewarded on the basis of their budget control results, innovativeness premiums tend to be hard to obtain unless compelling arguments are delivered. Hospital payers will often feel squeezed between capitated reimbursement rates and the value of an improved treatment. In that setting they likely demand to see an impact on their performance metric, such as for example re-hospitalization rates, since they impact US Medicare reimbursement.

Whether skeptical vis-à-vis a new drug treatment or not, payers normally follow an agreed-upon path for reviewing a drug. The review path is very consistent with the system’s formalized ways of awarding market access and price. This is why it is important to address the fundamental elements of the approval process in each of the payer systems and the global payer segments that characterize them.

Figure 11.3 gives an overview of considerations and information needs by customer group in global payer segments and representative key countries. Payers universally make their decisions on the basis of unmet needs and either “value” versus a reference standard or cost-effectiveness. In any case, they have a mechanism to evaluate the value story in the context of existing treatment alternatives. Since reimbursement to patients and US patient co-pays are important to physicians, payers need to take reactions to their decisions by physicians and leading KOLs into consideration, as they will try to avoid controversial situations. There is no standard recipe towards assessing payer
Cost and budget impact is a prime concern for most new drugs or treatments. Particularly as healthcare cost has been rising rapidly in most countries, payers are struggling to find ways to fund broad access to healthcare at a reasonable cost. When considering cost, the payer may be interested in both the drug budget impact and an overall assessment on the treatment cost per patient. Many payers are responsible for management of a drug budget only. Particularly in many pricing and reimbursement controlled systems, drug budgets are managed as a silo, separate from other healthcare costs. P&R authorities are held responsible for controlling drug cost, regardless of the new therapies available or savings achieved in other healthcare sectors. Within the available budgets, they seek to negotiate access for compelling new treatments at the lowest cost and try to realize budget savings in competitive areas through voluntary or forced price concessions, discounts and rebates. New and innovative drug treatments can cause budget issues for drug budget holders, sometimes motivating them to delay negotiations and cost increases that are associated with reimbursement approval. Some healthcare systems have been notorious to do so in the past, resulting in European Union legislation to control pricing and reimbursement decision-making timelines. In most systems, payers feel compelled to provide
access for truly innovative treatments and want to avoid access restrictions, both for reasons of PR and workload associated with tight access control (such as a prior authorization and its equivalent in international markets).

Assessing the budget impact for a new drug is a difficult task as it is strongly dependent on the actual utilization patterns and physician acceptance of the drug. A common payer concern is the use of an expensive drug for patients for which it is not deemed medically necessary. For these expensive drugs, payers are increasingly enforcing use restrictions on the basis of the formal clinical indications and evidence-based guidelines, as they feel that pharmaceutical companies are promoting the use of its drugs beyond the indications where it has demonstrated its core value. Most national payers feel that they have little control over use of a drug within its approved label. They are then faced with the choice of either finding a way to contractually link overutilization or “inappropriate use” (France) or relying on regional payers to impose additional control measures (Italy, Spain).

The health economics discipline provides a rational way of allocating limited resources across a high number of needs. Unfortunately, it has also been used as an easy way for payers to delay or deny access for lack of demonstrated economic rationale. The two most important ways in which health economic evaluations tend to be used for pricing purposes consider cost-minimization and cost-effectiveness. Each of these is discussed in depth in Chapter 5.

Strong evidence of cost-minimization should make the access decision for a new drug a no-brainer, provided that the drug has a benefit and that the negotiating payer has a perspective and budget authority that is in line with the cost perspective used in the cost-minimization analysis. To illustrate this, a hospital administrator will be interested to see cost savings due to shorter hospital stays (when not affecting reimbursement), whereas the Australian drug budget holder may be less swayed. Whether the evidence is strong is a natural point of contention. Payers tend to distrust any health economic data provided by drug manufacturers, contending that promised savings in the past have often not materialized. For this reason, many payers want to see claims supported with real-life (naturalistic) data rather than claims that are only supported with clinical trial data and economic models. The real dilemma is that at launch it is usually impossible to have meaningful real-life data as clinical programs need to adhere to strict protocols prior to market authorization. FDA and EMA don’t tend to focus on a real-life data setting for regulatory evidence.
Cost-effectiveness measures are particularly useful for compelling health improvements that require additional spending. However, not every healthcare system accepts cost-effectiveness as a formal evaluation instrument. Australia, Canada, and the UK probably have the most established healthcare systems with respect to the use of cost-effectiveness measures as part of pricing and/or reimbursement approvals. In the UK, the National Institute for Care Excellence evaluates drugs and other treatments on cost-effectiveness and provides recommendations for treatment practices and healthcare coverage on that basis.

Depending on the individual healthcare system and depending on the particular clinical and economic benefits of a drug proposition, health economic data may be beneficial in improving willingness-to-pay. However, this is not a given for every situation and a thorough evaluation is warranted before making any claims. Actually, the majority of healthcare systems has no way of assessing health economic data or chooses not to do so, because it is not consistent with its chosen approach towards pricing and reimbursement approval for prescription drugs. As shown in Chapter 8, only about 10 percent of global pharmaceutical sales take place in a system where market access decision-making is primarily driven by health economics.

More detailed discussions are found in Chapter 5: “Health Outcomes and Health Economics.”

VALUE STORY TESTING

It is extremely important to thoroughly test a drug’s value story. We must avoid making critical development and launch strategy decisions solely based on our perhaps rose-colored view of the world. Whether at a higher level, prior to Phase III clinical program decision making, or in all detail prior to launch, we need to ensure that the key points in our value claims are well in line with the KOL and payer customers’ priorities and frame of mind.

In testing our value story and its high level and detailed messages, we need to consider the dynamic interactions between payers and their advising clinical KOLs. Therefore, it is advisable to ensure that any value message can rely on the support of KOLs. Without a proper analysis of KOL input, we will be left with a distorted view on the acceptability or potential rejection of a message by payers.
A value message needs to be clear, relevant, credible and compelling/unique in order to be effective in affecting someone’s opinion. Let’s consider each of these dimensions separately in detail.

**Clear**

How easily can the message be read and understood? If multiple readings are required to understand the message, it will lose most of its power. We don’t need to show our literary strength to impress the reader. Keep sentences short. There is no shame in our children understanding the messages.

**Relevant**

Is the message content important for drug pricing or reimbursement decision making? Would our audience care about this point? Does it concern their responsibility?

**Credible**

Is the claim credible or can it be easily rejected? Is it likely in line with the customer perspective and logic? Are there any flaws in the reasoning or is it “water tight”?

**Compelling/Unique**

How convincing is the argument? Will it strongly support the decision at hand? For branded messages: Is it unique and differentiating versus existing and other emerging treatment options?

When carefully implementing these four dimensions in structuring our value messages, we should be able to prepare the most compelling argument possible, of course within the constraints of the available evidence package. Clever messaging cannot be a substitute for appropriate and convincing clinical and health outcomes data. It merely provides an opening for the data to make its way for serious consideration in the process and to help overcome initial emotional objections towards a new proposition.

Actual testing of a payer value story and its messages can be done in various ways. Interviews with payers and KOLs can be extremely useful, particularly in exploring receptivity to elements of a value story. It is important for the
final high-level version to be tested in a mixed audience of payers and KOLs. When not exposed to KOL opinion, payers may act differently from a real-life formulary review process. Therefore we need to ensure that we test story and messages for KOL acceptability and endorsement. Where the dialog between KOLs and payers is expected to be critical for the final evaluation, a mixed payer/KOL advisory board is often useful.

Payer/KOL research or advisory boards should ideally be organized by global payer segment, that is one for the US Managed Care, one for therapeutic referencing markets and one for health economics-driven markets. In reality it is difficult to entice payers from, for example, the UK, Canada and Australia, to meet for an adboard meeting. Having adboards for each individual country is usually cost-prohibitive as well during drug development. Frequently one US and one EU-5 adboard is the most pragmatic alternative, but it is important to consider differences between the review criteria and approval systems in the valuation of the results. Separate evaluations may be useful to address the acceptance of health economic arguments and models with health economists in markets where this is critical.

**OBJECTION HANDLING**

Objection handling is an important component of payer value story development. It is extremely important to be well prepared for a wide range of objections. With a good understanding of payers, we can anticipate most if not all of the objections and be well prepared for them. If recognized early enough in the process, we can still try to further strengthen our objection handling with additional data analyses or even some targeted trials prior to launch.

In some cases it makes sense to consciously address an issue through objection handling rather than in the actual value story. This is for example the case when this is not of importance for every payer. To illustrate this, we may have a comparator in our trials that is not the standard of care in each country. For some countries this is obviously not a challenge, for others we have to use the objection handler. Similarly, budget impact and cost-effectiveness will be different across countries, potentially resulting in different outcomes with respect to economic claims.

Whether to address some obvious objections immediately in the value story or to tackle them in the objection handling is often a part of strategy and to some extent preference. “Give a payer something to shoot at” may be an
approach that can work, but by leaving a weakness in the general story we may be risking an opportunity to get it right from the start. Most payers are very structured in their analysis, so trickery like this, with the intent of leaving other weaknesses uncovered, is not likely to work with many payers. A better reason to leave it somewhat open may be that it is simply not feasible to address this in the general value story and the objection requires a thorough evaluation in each case, for example with specific analysis of the environment of the specific payer questioning.

HOW DO WE USE THE VALUE STORY?

The payer value story is not just intended to be a document that is shipped to a payer. Rather it should be a much broader guidance to all pre-launch and peri-launch communications to payers and their influencers in each market. To illustrate the point, here are some examples on how the value story can be used:

- For a Pre-Phase III version of the payer value story: Help guide the design of the Phase III clinical and health outcomes trials, including patient inclusion/exclusion criteria, background therapy, trial comparator(s), primary and secondary end points, superiority (or non-inferiority) claims, length of patient follow-up, economic and other supplemental data gathered.

- Strategic guidance for the development of a Value Dossier and subsequent local P&R submission documents.

- Identify key medical facts and opinions that need to be supported by KOLs and directly or indirectly communicated to payers through articles, consultations, consensus meetings or other.

- Initiate additional data gathering work through clinical data searches, data registries, clinical trials, etc.

- Educate and train company staff to ensure preparation of the appropriate marketing and selling materials.

- Work with local country affiliates to “translate” the story and messages to the local environment and approval requirements and identify any specific local gaps to address.
• Prepare and execute regional or local mock negotiations sessions to validate the approach, test specific messages in a real-life situation and practice objection handling.

The above list is intended to be illustrative rather than all-inclusive. It is hopefully apparent that the payer value story is a very powerful and important aspect of the preparation of a drug asset for commercialization success.

VALUE DOSSIER CONTENT AND STRUCTURE

There is not a single correct way to structure a value dossier. Earlier in this chapter, we discussed the AMCP dossier format and its less than ideal structure to convey our value story. However, in many cases we cannot choose the format of our submission. In those cases it is important to consider other additional means of communicating our messages to our target customers, such as: press announcements, investor-focused communications, medical congress events, KOL discussions, peer-reviewed articles, etc.

A way of logically structuring a dossier that communicates the value story and provides supporting evidence is included below:

*Executive summary*

High-level value story and overview of dossier content.

*Burden of disease*

Medical and economic consequences of the condition, including direct and indirect medical cost and broader societal cost. Most payers will want to see direct medical expenses separated from indirect and broader societal cost.

*Tax Practices and unmet needs*

Prevailing treatment practices, shortcomings in current treatment alternatives and medical and economic consequences of shortcomings in current treatments.
Value proposition and improvement claims

Concise value proposition, that is elevator message with key improvement claims and supporting statements.

Clinical and health outcomes data

Complete overview of clinical and health outcomes data, logically structured to support value proposition and claims.

Health economics data and models

Budget impact models and cost-effectiveness models, as required to support value proposition and related claims. Data in this module should be entirely driven by payer-segment-based evidence needs.

Objection handling

Summary of most likely questions and objections to the value story and its related claims. Concisely formulated responses to each question.

Appendix

Detailed overview of all the available data and references clearly linked to the earlier dossier components where the data is referenced.

In this Chapter …

The TEMPLE Framework is used to develop an easy to understand and compelling payer value story for our drug. We discussed elevator message, pillar messages and detailed supporting messages and data as the components of our value story, as well as testing the story to be clear, relevant, credible and compelling/unique. Lastly, we discussed how to use the value story, handle objections and how to structure a value dossier.