PRICING A CURE: GETTING PAID FOR THE ULTIMATE PERFORMANCE

HURON'S POINT OF VIEW

As our scientific understanding of disease marches forward, a growing number of programs aim to radically improve upon standard of care. Looking at gene therapy alone, we see almost 100 clinical-stage programs in developed countries, pursuing over 75 indications. Many manufacturers will be impacted either as the owners of curative assets, or as incumbents in the indications impacted by them.

In this article, we recommend key actions manufacturers should consider when pricing, launching and/or defending against a curative therapy, specifically exploring:

- Pricing a cure, and its difference in comparison to pricing other therapies
- Opportunities to learn from current proxies, such as those in Hepatitis C
- The payer perspective
- Manufacturer implications

HOW DOES ONE PRICE A 'CURE'?

In considering the pricing of radical improvements to the standard of care, we define "cure" in two ways:

1. The total eradication of disease.
2. A drastic modification of disease, such that the experience for the patient, and physician, is transformed. For instance, in Hemophilia B, gene therapy is more likely to turn a severe case into a mild case than to result in a cure—but this would still represent a very substantial improvement in patients' lives.

When developing a price for a cure, the fundamentals of pricing decisions are not abandoned as traditional HECON levers are still in play, such as the level of impact on existing, unmet needs, size of cost off-sets (i.e. drug costs, office visits, ER visits, surgeries, hospitalizations), timing of cost off-sets, and Quality-adjusted Life Year (QALY) calculations.

For these metrics, a cure should drive convincing numbers given the expected level of impact on standard of care. It would be a mistake, however, to conclude that a manufacturer can price at whatever level the health economics calculations support.

Consider the following:

PAYERS' NEAR-TERM VS. LONG-TERM PERSPECTIVES:

Payers care little about a positive five- to 10-year ROI if budgets are busted early on. This is true both in the U.S. and outside the U.S., where there are differences among countries in their willingness to take a longer-term view. Additionally, the relative importance of this factor depends heavily on the number of patients qualifying for the curative therapy in a given year.

PUBLIC RELATIONS BACKLASH:

The public and media have repeatedly demonstrated little appetite for a long-term perspective, perhaps even less so than payers. Cost per patient per year, or even cost per dose, dominates the public dialogue. Sensitivity to drug pricing has been fueled by historical examples of pricing decisions seemingly divorced from clinical value. The public is on alert and stands ready to presume manufacturers guilty, perhaps even when HECON data seem unassailable.

THE PAYERS PAYING ≠ THE PAYERS BENEFITING:

In the U.S., where health coverage tends to change relatively frequently, it could easily be the case that the payer who funds the cure is not the payer who benefits from it. If enough patients qualify, it's reasonable to assume that benefit balances out across payers. However, when fewer patients qualify, an imbalance is more likely. Since gene therapies often target rare disease, this is an important consideration. Also, depending on a patient's average age, it might be commercial payers that cover the cost, and Medicare that reaps the benefits.

The experience of Sovaldi in Hepatitis C, which faced aggressive efforts by U.S. payers that restricted access and/or drove down price, provides evidence of these very considerations.

Keep in mind these actions have been taken on a drug that is supported by The National Institute for Health and Care Excellence (NICE), the U.K.'s historically conservative guidance body. Key drivers of this favorable evaluation include the elimination of high costs associated with treating chronic liver disease, estimated to be $270,000 over 10 years, as well as reductions in liver transplants, estimated to cost $577,000 each.[1] For Sovaldi, the incremental cost per QALY was often favorable versus commonly accepted thresholds.[2]

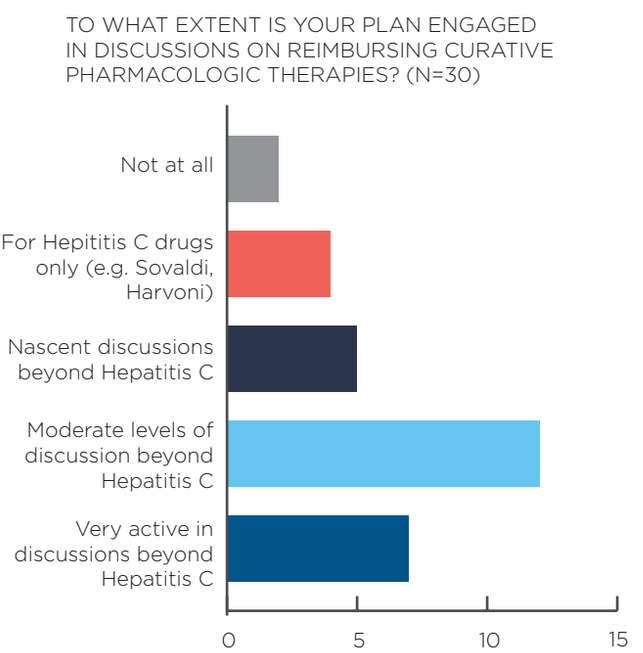
Ultimately, while a health economic analysis provides a starting point for the pricing decision, manufacturers must also account for additional factors when determining product pricing specifically, and go-to-market approach generally.

WHAT'S THE PAYER PERSPECTIVE?

Huron surveyed 30 large national and regional payers to explore this question. Below is a summary of the insights gained:

IS THIS TOPIC ON PAYERS' RADARS?

Eighty percent of respondents reported some level of discussions on reimbursing curative therapies beyond Hepatitis C drugs.



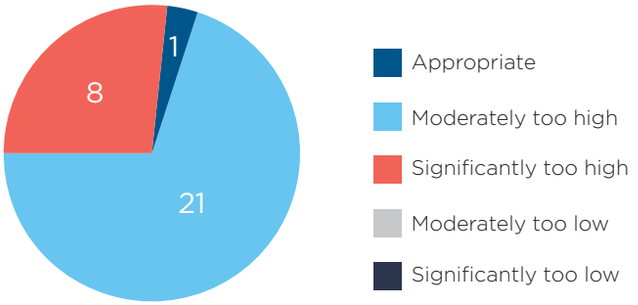
[1] Drug Health Patient Saf. 2014; 6: 37–45

[2] "NICE guidance recommends sofosbuvir (Sovaldi, Gilead Sciences) and simeprevir (Olysio, Janssen) for treating hepatitis C" (PR 02/2015)

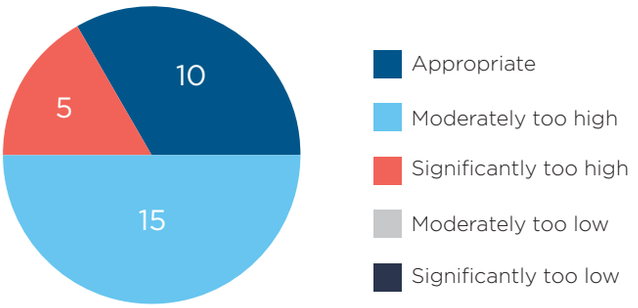
WHAT IS THE REACTION TO SOVALDI'S PRICE BY PAYERS, AND DOES THIS ANSWER CHANGE IF THEY COULD SPREAD THEIR COSTS OVER MULTIPLE YEARS?

Despite being shown some favorable cost per QALY data, virtually all respondents deemed Sovaldi overpriced. However, if costs could be spread over multiple years, a third of respondents felt the price becomes appropriate, underscoring the importance of the near-term perspective.

WHAT IS YOUR ORGANIZATION'S STANCE ON SOVALDI'S PRICE? (N=30)



[assume can spread payer cost over multiple years for each Sovaldi patient]
WHAT DO YOU BELIEVE YOUR ORGANIZATION'S STANCE ON SOVALDI'S PRICE WOULD BE?



ARE THERE CERTAIN METRICS PAYERS FEEL ARE ESPECIALLY IMPORTANT IN THE EVALUATION OF A CURATIVE THERAPY?

The most common theme was the need to see evidence of the cure, which for payers is reassurance that cost offsets should actually occur.

Some payers would want to understand membership turnover rates for the relevant population, highlighting their sensitivity to paying for the therapy and then not capturing the cost benefits of the cure.

Finally, while almost half the respondents reported little-to-no consideration for quality-of-life metrics, some payers would want to see quantifiable impact of avoiding future therapy.

WHAT DOES THIS ALL MEAN TO A MANUFACTURER?

Potential actions depend on which side of the fence you stand. If you are the owner of the curative therapy, potential actions include:

1. Assess your health economic rationale sooner rather than later, including the expected annual impact on payers. Outputs will inform initial discussions with payers and other stakeholders, and potentially inform clinical trial design for later stage studies.
   - Is the drug likely to benefit different patients differently?
   - What are expected cost offsets and QOL improvements? Can they be substantiated?
2. Conduct research with payers, providers and patients to understand the landscape of current opinion:
   - Where are points of leverage to integrate into launch planning?
   - What are likely hurdles and risks that must be overcome or mitigated?
3. Test the waters on potential reimbursement mechanisms, for example:
   - What is the impact of spreading reimbursement over multiple years to ease the cost surge and better match timing of payer spend to timing of realization of cost offsets?

  - If payments are deferred, who assumes the carrying cost?
  - Does the spread of payments over multiple years help reduce payer concerns about covering the cost of therapy, only for the patient to leave them before realizing cost offsets?
- Are there other novel approaches to address concerns around paying for therapy but not realizing cost offsets due to membership turnover?
- What are the pros/cons of overlaying a pay-for-performance mechanism on the deferred payments, including any data collection challenges to support such a mechanism?
- Does the benefit of offering a single price per cure outweigh any downsides? The Fair Pricing Coalition made such a recommendation for Harvoni (a drug similar to Sovaldi), as different patients needed different doses to achieve a cure.[3]
- Is there a need to spread out the cost to the patient over multiple years as well?

4. To help mitigate public relations risks, develop an approach highlighting the uniqueness of a cure:
   - Distinguish it from typical improvements seen in disease management.
   - Distinguish it from historical predatory pricing.
   - Leverage and/or help build strong patient advocacy support based on the huge impact on patients' lives.
   - Make the technologic innovation tangible and exciting for the layperson.
5. From an organizational readiness perspective, ensure that clinical, commercial and access efforts are integrated as early as possible so that data generation can support launch access discussions to the extent possible.

IF YOU ARE THE INCUMBENT IN A RELEVANT INDICATION, POTENTIAL ACTIONS INCLUDE:

1. Systematically take stock of pipelines in current and future indications of interest. Where curative therapies exist, analyze the threat level to future revenues.
2. As many such threats will be in early clinical or preclinical stages of development, conduct research with opinion leaders to better understand the likely efficacy/safety profile of the disrupting drug.
   - What is the expected impact on key patient segments of interest? Is it likely to vary?
   - Even "cures" are likely to have limitations… identify them, and define if/how you can blunt the threat.

IF YOU ARE BOTH AN OWNER AND AN INCUMBENT, POTENTIAL ACTIONS INCLUDE:

1. If the curative therapy does not outright replace your incumbent therapy(ies), look to clearly define specific segments of use for each drug, consistent with the product value propositions.
   - Conduct research with opinion leaders to inform these decisions.
2. If therapy is not wholly curative but reduces use of your incumbent drug, explore clinical studies or other ways to link the two drugs together, creating more 2 support for your products overall.

Pricing a cure involves not only the traditional analyses, but also the consideration of additional factors such as the nearterm burden on payers. As

[3] "Fair Pricing Coalition Welcomes Approval of Gilead Sciences' Combination Tablet for Hepatitis C, Urges a Uniform Price for Curative Treatment (PR 10/2014)

we've seen in Hepatitis C, the public stands ready to heavily criticize high annual prices, even when health economics data support the price as appropriate.

Our market research indicates that the vast majority of payers are discussing this topic, even beyond Hepatitis C. Payers' responses underscore a focus on short-term costs and indicate that spreading those costs can provide at least some help.

There are actions manufactures should consider taking sooner vs. later to prepare for the potential arrival of curative therapies. Indeed, there are challenges associated with pricing a cure and/or managing the launch of a curative therapy (or defense against one). However, in a broader sense, this is a good problem for our industry to have as it is a byproduct of important breakthroughs in patient care.

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