Session 66PD, Reimbursement Approaches for High Cost Technologies

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066: Reimbursement Approaches for High Cost Technologies

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Scope and limitations

This research report relies on illustrative scenarios and assumptions made by the authors to consolidate and summarize key considerations around the payment and allocation of risk for future high-cost curative therapies targeting rare diseases.

In practice, the disease-related metrics, costs and specific contracting terms of the alternate payment models may differ significantly from what has been modeled. This modeling was strictly limited to focusing on the primary payer's perspective; "primary payer" in this context refers to the entity funding the cure. Thus, the effect of a curative therapy on patient cost sharing, treatment centers, specialty pharmacies, providers or other relevant distributors or stakeholders was not considered.

For this study, a curative therapy is defined as (a) a therapy that improves a person's clinical state or cures a condition for a sustained period of time, and (b) is administered once.

The focus of this research is not on the quantitative values, but rather on the extent to which each of the proposed payment models can diversify or mitigate financial risk. Given the decision by the primary payer to cover a curative therapy, the study examines the extent to which alternate payment models can mitigate the inherent risks associated with an up-front cost for a treatment with long-term durability, using a consistent set of assumptions.

Relevance of the topic

Reimbursement Approaches for High Cost Technologies

Curative therapies, such as gene therapies and CAR-T cell therapies, are beginning to be approved in the U.S. and Europe. These therapies are expected to provide high value to patients, especially for patients diagnosed with rare diseases or patients who have few treatment options currently

Due to the unique nature of curative therapies, the current mechanisms for providing payment of medical and pharmaceutical treatments could strain payer's budgets. For this reason, payers, third parties and manufacturers should consider ways to mitigate, share, or distribute the financial risks associated with these therapies

- We were engaged by the SOA to explore this topic. We anticipate the report will be published in July 2018 ("Evaluating Payment Models for High-Cost Curative Therapies")
- Today we will review some of the insights of the report and discuss potential applications and complexities

Goal of the research report

To evaluate alternate payment models that could be instituted in the real world to pay for these high-value and high-cost curative therapies, using a common set of assumptions and evaluation framework

Context of the research report

Price is established

- Does not intend to inform the potential price to be paid for a future cure in the disease areas selected

Coverage of the therapy is approved

The modeling performed relies upon a defined set of assumptions, regardless of payment model

- Does not intend to inform the impact of curative therapies on future claim costs, premiums, or trend

What kinds of therapies are we talking about?

Characteristics of high-value therapies include:

- Curative or regenerative
- Limited duration of treatment (e.g. single-administration)
- Extended duration for clinical benefit

Examples of high-value therapies include:

- Gene therapy, cell therapy (CAR T-Cells), regenerative medicines, etc.
  - Often genetic: many are orphan and ultra-orphan disease states
    - Not exclusively so (e.g. Hepatitis C)
  - Certain cancer treatments

The number of people who may be candidates for treatment will expand

KEY

Condition
$Launch price, ~ Indicated #

Condition
~ Diagnosed #

US approved gene or cell therapies

- Spinraza $750k, ~9k
- Kymriah $475k, ~4k
- Yescarta $373k, ~10k
- Luxturna $850k, ~1.5k

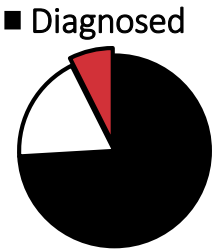
Pipeline conditions: gene therapy*

- Cystic Fibrosis ~30k
- CCALD ~13k
- Beta thalassemia ~1k
- Leber's ~6k
- Hemophilia A ~16k
- Glioblastoma ~24k
- SMA ~8.5k
- Hemophilia B ~4k

PAST

For context, 36,000 organ transplants occur per year, ranging from $400k-$1.4M (for single organ transplants)**

FUTURE



Not all of the diagnosed patients are indicated for treatment. A minimum clinical threshold (i.e. lower level of disease progression) or approval for second- or third-line therapies is a common limitation

*Not exhaustive. Source: Based on 2018 pipeline report. Medical Marketing and Media.

** Source: Milliman 2017 Transplant Report

Regenerative Medicine Clinical Trials (Globally)

959
Clinical trials underway worldwide by end of Q1 2018

Ph. I: 320
Ph. II: 549
Ph. III: 90

Number of Clinical Trials Utilizing Specific RM/AT Technology: Q1 2018

Gene Therapy
Total: 319
Ph. I: 110
Ph. II: 174
Ph. III: 35

Gene-Modified Cell Therapy
Total: 284
Ph. I: 121
Ph. II: 152
Ph. III: 11

Cell Therapy
Total: 332
Ph. I: 84
Ph. II: 211
Ph. III: 37

Tissue Engineering
Total: 24
Ph. I: 5
Ph. II: 12
Ph. III: 7

According to the Q1 2018 ARM quarterly report:

- 54% of the companies investigating regenerative medicines are located in the U.S.
- 53% of current clinical trials are in oncology
- 10% are cardiovascular disorders
- 6% are diseases of the central nervous system

*Source: Q1 2018 Alliance Regenerative Medicine Quarterly Data Report. https://alliancerm.org/wp-content/uploads/2018/05/ARM_Q1_2018_Web_Version.pdf

Curative therapies and FDA approval

Many gene therapies are being developed for rare diseases, and could meet the FDA's criteria for fast track or accelerated approval due to the current unmet need.

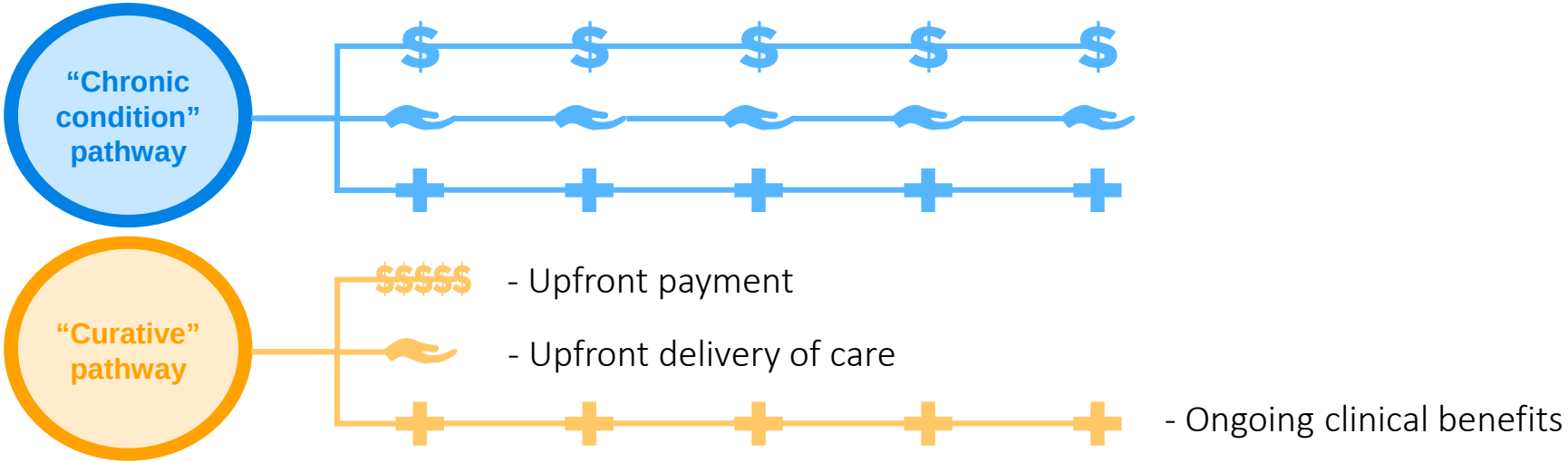
- According to Global Genes, 95% of rare diseases do not have any FDA approved therapies[1]
- Clinical trials for rare diseases may have few patients enrolled, which could make it difficult to generate robust clinical evidence of efficacy or durability

Development of gene or cell therapy as a competing treatment option

- These treatments options can be highly invasive
- Alternate treatment options could be more "traditional"
- Of course, alternate treatments don't have to be cheaper, but may be recurring which is consistent with what we currently accept as "trend"

➢ Due to the low number of enrolled patients in clinical trials, it may be harder to prove (or disprove) efficacy for these therapies.

Maintenance vs curative therapies



Current funding mechanisms for healthcare services are structured to cover costs at the time the service is incurred.
These may not be well suited for the potentially substantial one-time cost impact associated with curative therapies.

Considerations for payment

The decision by payers to enter into an alternate payment arrangement to fund a one-time high cost curative therapy depends on many factors, including:

1) The total expected budget impact and expected duration of clinical benefits;
2) The payers' ability to capture future financial benefits and financial offsets linked to this new treatment;
3) The degree of uncertainty around efficacy.

- Ultimately, the model selected to fund a one-time curative therapy will be specific to the type of payer funding it, the characteristics of the disease areas, and the financial risks that the payer is willing to share with third party entities.

Innovative payment models: Today

Population health / outcomes based

- Entresto: *"Novartis will reduce the price of Entresto to payers, if the rate of heart failure hospitalization of patients on Entresto exceed a pre-specified threshold."*
- Symbicort: *"Under the contract, Highmark said it will track whether the symptoms of its plan members using Symbicort are in line with the results of AstraZeneca's clinical trials. If the drug doesn't live up to its promise, AstraZeneca will provide Highmark with some savings."*

Patient level / performance based

- Kymriah: *"[Novartis'] contract with CMS includes a clause that allows for payment based on outcomes: The company will only receive payment for patients who have received this treatment and show significant improvement within a month after the infusion."*
- Repatha: *The agreement with Amgen "guarantees [Harvard Pilgrim] and its members will receive a full refund of their costs for the drug if a member is hospitalized for a myocardial infarction or stroke after taking Repatha for six months or more and maintaining an appropriate level of compliance on the drug."*

Coverage based

- Praluent: *"To help ensure more affordable and timely access to patients most in need, Sanofi and Regeneron Pharmaceuticals, will offer U.S. payers that agree to reduce burdensome access barriers for high-risk patients a further reduced net price for Praluent® (alirocumab) Injection in alignment with a new value assessment for high-risk patients from the U.S. Institute for Clinical and Economic Review (ICER)."*

Alternate payment models explored

The research report explores the following alternate payment models:

- Industry pooling
- Multiyear insurance
- Annuity payments
- Annuity payments with effectiveness guarantee
- Health currency
- Financial bonds
- Financial bonds with effectiveness guarantee

For today's presentation, we will be focusing primarily on the perspective of commercial insurers in the United States

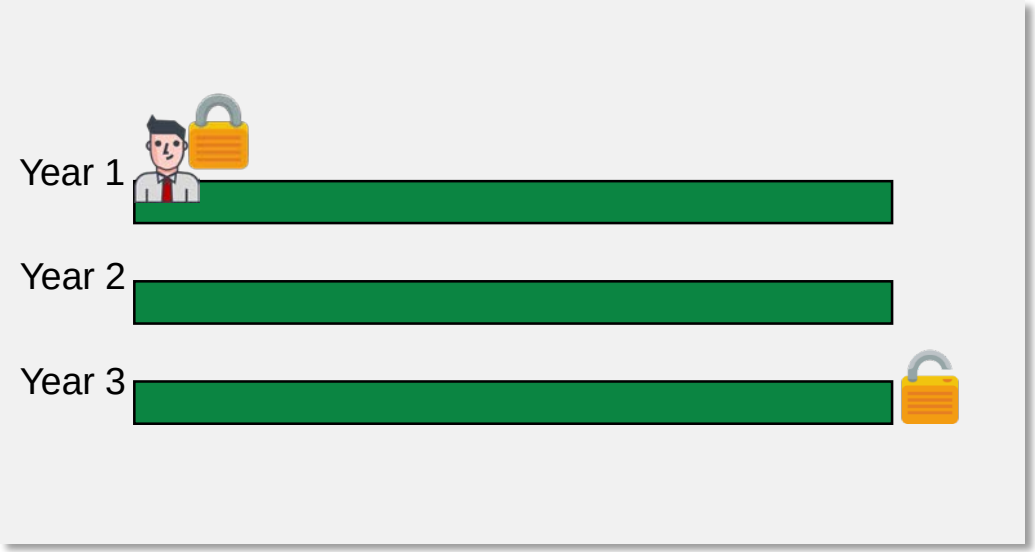
Payment models that do not pay the cost of the therapy in an explicit way (e.g., bundled payments or disease capitation) or that share the financial burden with secondary insurers (e.g., reinsurance or stop-loss insurance) were not considered for this study. We acknowledge these approaches could also be used as alternate payment models. Rather, our focus is on risk-sharing approaches between payers and third-party entities, such as manufacturers, other payers or financial institutions.

Insurance-like models

These approaches support the view that existing insurance mechanisms, or subtle variations of them, could be adopted as potential payment methods. Therefore, the payment associated with a one-time curative therapy is borne up-front

Industry pooling

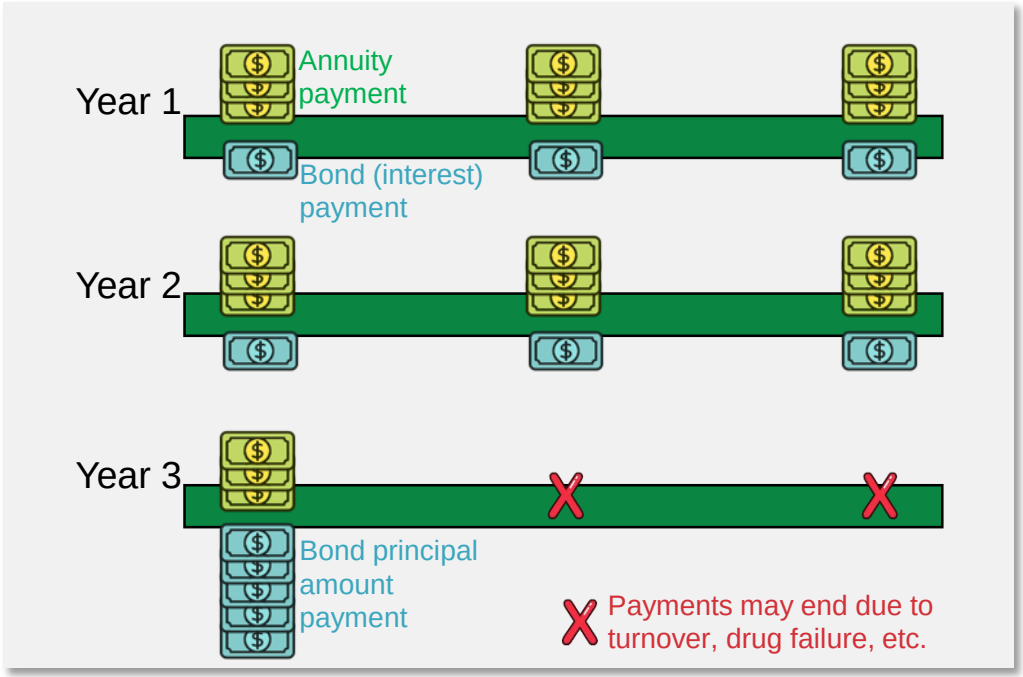
Multiyear insurance



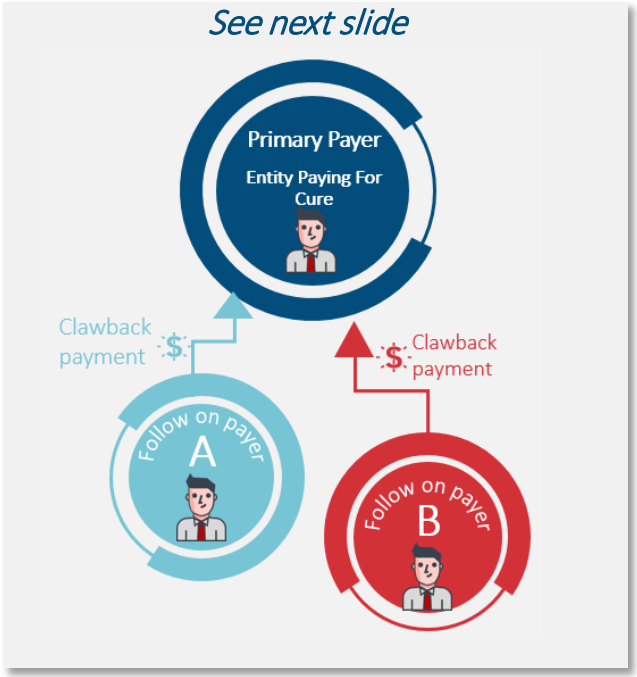
Debt-like models

These approaches draw on the concept of outstanding balance, and/or amortize costs over time

Annuity payments & Financial Bonds



Health currency



Example: The health currency

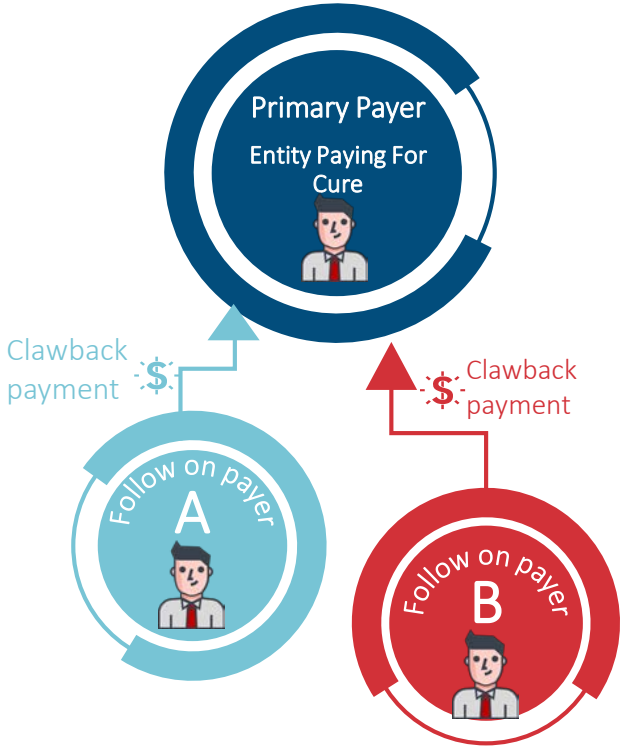
The health currency is a novel payment model.

- It has not yet been implemented in practice.
- It allows a primary payer to recoup some of the future cost savings if the member leaves.

How it works? A primary payer receives a clawback payment—a pre-defined % of the foregone expected savings related to the cure—after a successfully treated patient leaves the primary payer's book of business.

Clawback payment calculation:

Clawback % * ((Expected cost of care – Expected premium to primary payer)$_{\text{no cure scenario}}$ - (Actual cost of care – Actual premium to follow-on payer))$_{\text{with cure scenario}}$



There may be barriers to implementation, particularly as members cross over to a different payer channel

Health Currency: Case Study

The health currency offers the largest potential for revenue collection through its clawback feature.

Most beneficial when there is (A) high turnover or (B) when there is a large cost difference between the annual cost of care of members in the pre-cure and post-cure scenarios.

		YEAR 1 (CURE)	YEAR 2	YEAR 3 (TURNOVER)	YEAR 4	YEAR 5
A	Expected cost of care to primary payer (if no cure)	$150,000	$155,000			
B	Expected cost of care to follow-on payer (if no cure)			$160,000	$165,000	$170,000
C	Actual residual cost of care to primary payer (post-cure)	5% * 150,000 = $7,500	5% * 155,000 = $7,750			
D	Actual residual cost of care to follow-on payer (post-cure)			5% * 160,000 = $8,000	5% * 165,000 = $8,250	5% * 170,000 = $8,500
E	Expected premium to primary payer (pre-cure and post-cure)	$6,250	$6,500	$6,750	$7,000	$7,250
F	Expected premium to follow-on payer (pre-cure and post-cure)	$7,000	$7,250	$7,500	$7,750	$8,000
	Clawback @10% of forgone future savings ((B – E) – (D – F))*10%	$0 (Member is still with primary payer)	$0 (Member is still with primary payer)	(($160,000 - $6,750) - ($8,000 - $7,500)) * 10% = $15, 275	(($165,000 - $7,000) - ($8,250 - $7,750)) * 10% = $15,750	(($170,000 - $7,250) - ($8,500 - $8,000)) * 10% = $16,225

Modeling base-case assumptions

The net present value of the total expected financial exposure to the primary payer over 10 years corresponds to the sum of expenses minus revenues:

1) **Cost of cure** (expense): This corresponds to the hypothetical amount charged by the manufacturer for a single administration cure.

2) **Annual residual cost of care** (expense): This corresponds to the weighted average of the cost of care of a patient who achieves a curative state and one who does not achieve a curative state.

3) **Annual premium and other revenue** (revenue): This corresponds to the annual revenue stream to the primary payer, which is embedded in the alternate payment model.

Model assumptions	Base case value - hemophilia	Base case value – cystic fibrosis
1. Annual membership turnover	15%	15%
2. Residual cost of care (post-cure)	5% of no-cure cost	5% of no-cure cost
3. Curative therapy efficacy	90%	90%
4. Hypothetical cost of cure	$500,000	$500,000
5. Discount rate	3%	3%
6. Bond coupon rate	3% (set equal to discount rate)	3% (set equal to discount rate)
7. Mortality load	250%	1000%
8. Annual cost of care (no-cure cost)	$185,976*	$46,878*
9. Healthcare trend rate	5%	5%
10. Base annual premium	$6,250	$6,250

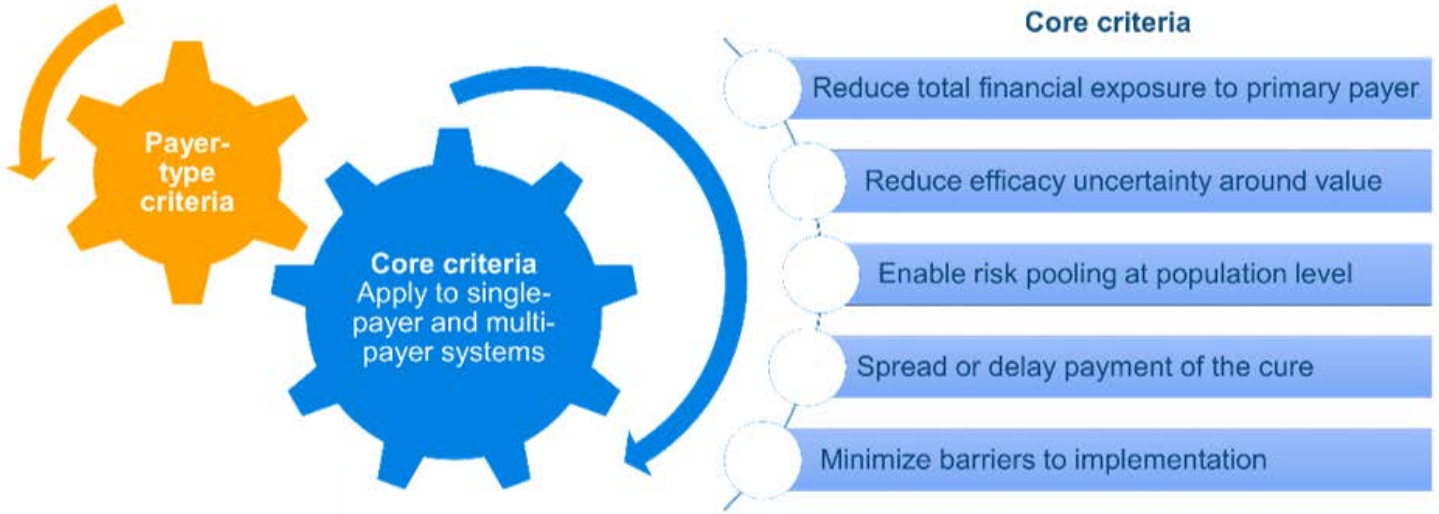
*Based on the 75th percentile of the distribution of the paid cost of care (from our analysis of the 2015 US Commercial data sample in the Milliman Consolidated Health Cost Guidelines Sources Database).

Evaluation framework

The research applied a common evaluation framework.

Disease areas modeled:
Hemophilia and cystic fibrosis, for illustrative purposes

Timeframe:
10-year net present value



Payer-specific considerations:

Single payer systems. A key concern is intergenerational equity, i.e. the future generation is not burdened with the costs from today

Multipayer systems. A key concern is the free rider problem, i.e. that the entity paying for the therapy does not accrue the financial savings of the clinical benefits due to member turnover

Assessment of payment models

Five core criteria were evaluated across each payment model

Payment models	Reduces total financial exposure to primary payer?	Reduces efficacy uncertainty about value?	Enables risk pooling at population level?	Spreads or delays payment of the cure?	Minimizes barriers to implementation?
Insurance-like					
Industry pooling	X	X	√	X	√
Multi-year insurance	X	X	X	X	√
Debt-like					
Annuity payments	√*	X	X	√	X
Annuity payments with effectiveness guarantee	√*	√	X	√	X
Health currency	√	X	X	X	X
Financial bonds	X	X	X	√	X
Financial bonds with effectiveness guarantee	√*	√	X	√	X

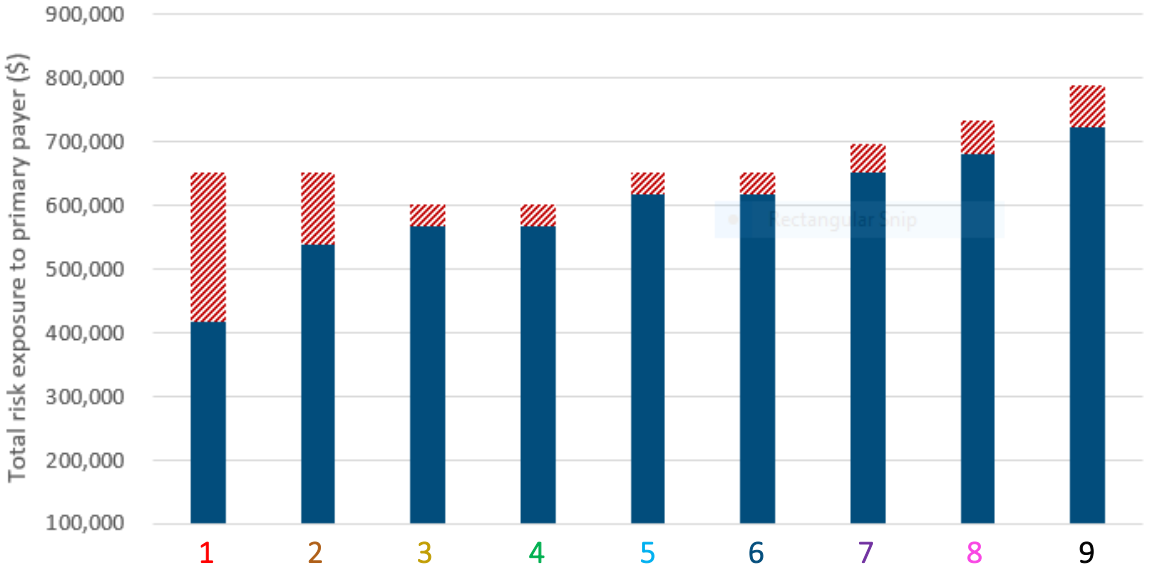
There is no single payment model that meets all the criteria. Depending on the concerns of the primary payer, certain payment models are better suited at mitigating, sharing, or spreading various risks

May add considerable administrative burden to payers and the partnering entities, particularly if patients are to be tracked and monitored. The health currency, which requires making retrospective payments, would require a high level of efficiency, surveillance and financial settlements at regular intervals. The use of a third party may be required, especially as members cross payer channels or move to payers with very different provider payment levels.

*It is theoretically possible that selected conditions for payment or effectiveness guarantee reduce the total financial exposure to the primary payer; yet in practice the manufacturer may decide to reflect this financial risk in the price of a curative therapy, or collect additional payments from follow-on payers

Comparison of payment models: Hemophilia example

- The health currency offers the lowest total risk exposure, due to the expected revenue from the clawback payment feature
- The price of the curative therapy scales the total costs incurred, but has little effect on the level of financial protection embedded in each payment model (i.e. the “ordering” of payment models)



1. Health currency (clawback @25%)
2. Health currency (clawback @10%)
3. Annuity payments (with effectiveness guarantee)
4. Financial bonds (with effectiveness guarantee)
5. Annuity payments (no effectiveness guarantee)
6. Financial bonds (no effectiveness guarantee)
7. Three-year term health insurance
8. Five-year term health insurance
9. Industry pooling

Expected Income/premium to primary payer by approaches

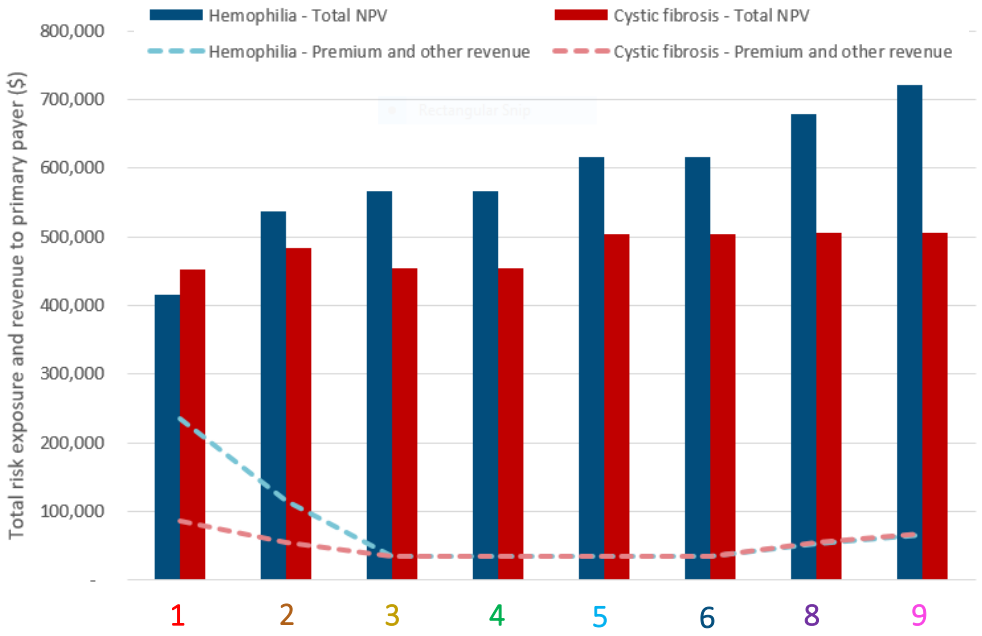
Total expected NPV risk exposure to primary payer by approaches

Total Expected NPV to Primary Payer, Hemophilia and Cystic Fibrosis:

The NPV for hemophilia is higher than CF for nearly all payment models due to the higher assumed residual costs, which are 5% of pre-cure expected costs

For this reason, the multi-year insurance and industry pooling fared better when used for cystic fibrosis, which on average is currently less expensive to treat than hemophilia (pre-cure)

The health currency (at 25% clawback) provided the most financial protection for both hemophilia and cystic fibrosis. However, the clawback is higher for hemophilia since it is applied to a larger expected forgone savings



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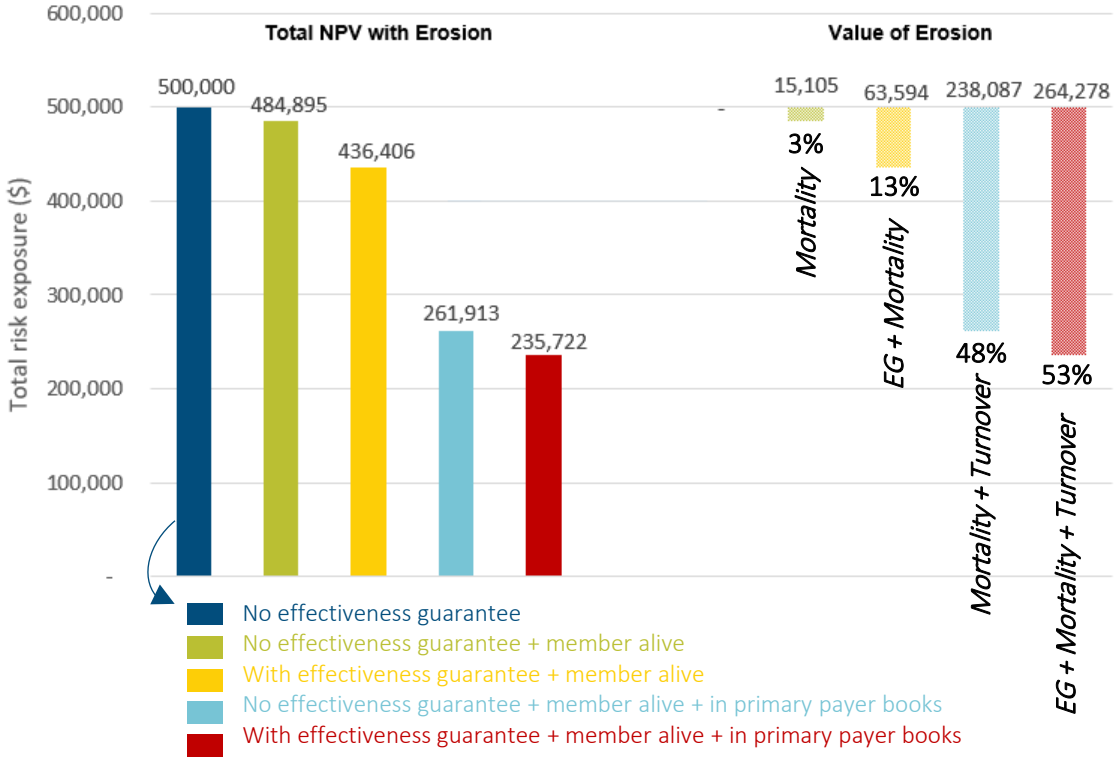
2. Health currency (clawback @10%)
3. Annuity payments (with effectiveness guarantee)
4. Financial bonds (with effectiveness guarantee)
5. Annuity payments (no effectiveness guarantee)
6. Financial bonds (no effectiveness guarantee)
7. Five-year term health insurance
8. Industry pooling

Risks of the Annuity Payment System

The annuity payment model spreads the upfront hypothetical cost of curative therapy over a defined long-term horizon.

Due to the spread of payments over time, the annuity payment model can incorporate various conditions for payment to mitigate risks.



EG = Effectiveness Guarantee

Key take-aways

- High value therapies could have significant clinical benefit but are likely to come with a high price
- The current healthcare payment systems were not designed to support exceptionally high cost therapies with a short duration of treatment but long period of clinical benefit
- No single payment model addresses all the risks associated with high-cost curative therapies, and some payment models will have a significant administrative burden

Questions?

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