FoCUS Project

Financing and Reimbursement of Cures in the US

RESEARCH BRIEF

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Impact of Actuarial Risk on Health Plans. The uncertain number of patients likely to be treated with an expensive novel therapy (actuarial risk) could represent a major financial issue for some payers (1). In this brief, we will present a high-level perspective on how treatment incidence and plan size affect the level of actuarial risk for a payer.

By **MIT NEWDIGS FoCUS Project**
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Expensive novel therapies can cause multiple challenges for health plans. High-priced treatments with a high incidence may create overall budget challenges, while treatments that have a high prevalent population may lead to "surge" effects wherein many patients seek treatment soon after regulatory approval. Even in the absence of these challenges, smaller plans may face risk due to deviations from actuarial assumptions regarding the number of new patients who will be treated in any particular year. Below, we explore where this uncertainty is most likely to create significant financial issues.

Consider a therapy with known cost in isolation. We distinguish absolute budget uncertainty (uncertainty in dollars) from relative budget uncertainty (uncertainty as a percentage of expected budget) and require both to be reasonably large for the therapy to cause potential actuarial risk issues. Budget uncertainty is the product of uncertainty in utilization and known cost per unit. Absolute budget uncertainty will rise with treatment cost and utilization level, while relative uncertainty will increase with *decreasing* incidence for rare conditions[1]. Thus, the treatments that are most

KEY TAKEAWAYS

1. Novel expensive treatments can have significant financial consequences for payers because of their expected absolute cost, surge in usage due to prevalent patients, or uncertain usage (actuarial risk)
2. Health plans with relatively few covered lives are unlikely to have usage of a particular rare product in a given year, but a single case could have large cost consequences if the risk is not managed
3. When considering a portfolio of comparable products, variability (actual costs as a percentage of expected costs) declines with increasing number of products
4. Analysis of retained risk is critical to determine what financial tools may be necessary to minimize reserve requirements and avoid extreme income statement outcomes

[1]Mathematically, this is because (with n=sample population and p=incidence) the standard deviation σ of treated patients is SQRT(np(1-p)) and the mean μ is np, so the ratio of uncertainty (as measured by the standard deviation or some multiple of it) and the expected utilization σ/μ is (1-p)/SQRT(np), which is approximately 1/SQRT(np) for small p.

Covered Lives	100	1,000	10,000	100,000	1,000,000	10,000,000
Years with:						
0 treated	99.9%	99.4%	95.1%	60.7%	0.7%	0.0%
1 treated	0.1%	0.6%	4.8%	30.1%	3.3%	0.0%
2 treated	0.0%	0.0%	0.2%	8.0%	8.3%	0.0%
3 treated	0.0%	0.0%	0.0%	1.1%	14.1%	0.0%
>3 treated	0.0%	0.0%	0.0%	0.2%	73.6%	100.0%
Expected Pts per Year	0.0005	0.005	0.05	0.5	5	50
St Dev	0.0224	0.0707	0.2236	0.7071	2.2361	7.0711

Table 1. Number of patients per year by health plan size.

likely to cause actuarial risk issues are those with high costs and low utilization, such as the evolving class of durable therapies (e.g. genetic therapies and CAR-T therapies) for rare diseases.

For these analyses, we will use as an example a hypothetical treatment with overall expected US sales of about $1 billion, a price of $600,000, and therefore US incidence of about 5 per million. As is shown in Table 1, small plans will rarely encounter a patient of this type in a given year, moderate-sized plans will be reasonably likely to see a patient, and large plans will see patients most years (and expect to see multiple patients).

Figure 1 shows cost per member per month by plan size. While expected costs remain constant regardless of plan size, uncertainty decreases as plan size increases. While small plans are unlikely to see a patient (as noted above), the consequences of a single patient could be financially devastating and appropriate safeguards such as stop-loss insurance are essential. By comparison, the largest plans see relatively modest (though still potentially meaningful) fluctuations relative to expected costs. Intermediate-sized plans still bear substantial risk, with significant potential impact on required reserves if unbuffered and potentially large swings in income occur from year to year.

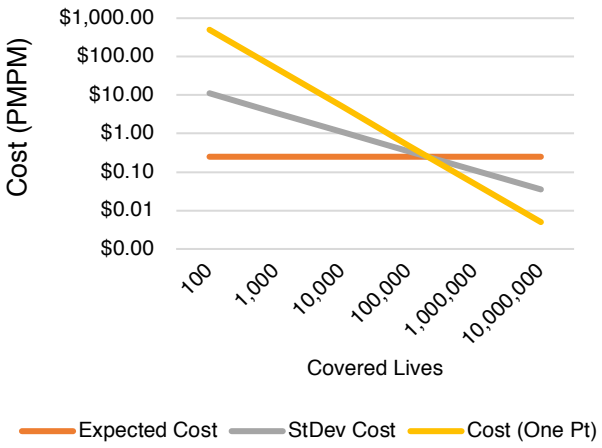

Figure 1. Cost per Member per Month by Plan Size.

The above analysis focuses on a single new treatment considered in isolation. In a portfolio of products, uncertainty will be dampened because it is unlikely that all products will take on comparably extreme utilization levels in the same year. Figure 2 shows simulated results for how portfolios with different numbers of uncorrelated new products with identical parameters would behave relative to a single product, as measured by the ratio between simulated and expected costs. As the number of products increases, the average portfolio risk declines. More generally, other existing products (drug and otherwise) will also moderate overall risk for plans. Note that a recent FoCUS research brief estimated that about 39 new gene therapies are likely to launch within the next five years (2), albeit not all of identical size; overall risk reduction will generally improve with the square root of expected number of patients for products of similar price.

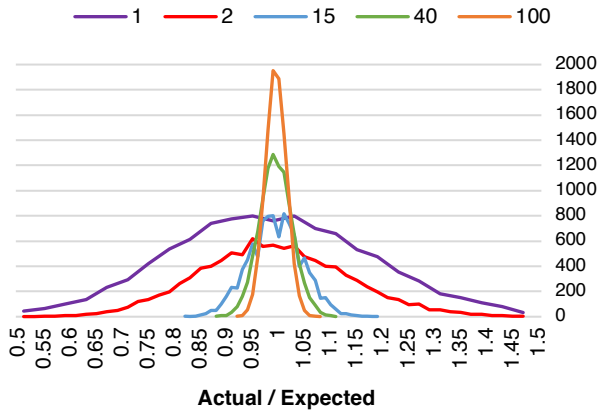

Figure 2. Distribution of Patients Treated Relative to Expected (10,000 simulated portfolios).

Analysis of actuarial risk is a critical process for any portfolio, and the introduction of expensive novel therapies can provide new risks. In particular, it is important to consider what risk is retained, either through reinsurance deductibles, patients not eligible ("lasered") from secondary insurance or high-priced product carve-outs; selective retention of high-risk patients removes the ability of the rest of the portfolio to buffer risk. Financing tools should be considered to mitigate overly high levels of unavoidable risk (1). Understanding the productivity of the gene therapy pipeline is an important first step in projecting the financial impact, challenges and solutions for each stakeholder.

REFERENCE

1. https://newdigs.mit.edu/sites/default/files/FoCUS%20Research%20Brief_2018F203-015_0.pdf
2. https://newdigs.mit.edu/sites/default/files/FoCUS_Research_Brief_2017F211v011.pdf

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About FoCUS

The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by durable therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement.

To learn more about the FoCUS Project, visit https://newdigs.mit.edu/programs-projects/focus