

Is employment group insurance financing of expensive gene therapies threatened in the United States?

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Abstract

Despite the potential of gene therapy to transform the lives of patients with rare genetic diseases, serious concern has been raised about the financing of the high up-front costs for such treatments and about the ability of the employer-sponsored insurance system in the United States, particularly in small firms, to pay for discoveries of this type. In this paper, we provide a conceptual framework and empirical evidence to support the proposition that, at present, private group insurance financing of cost-effective gene therapies is not only feasible and competitively necessary in the labor market for employers, regardless of group size, but also that, currently, the number of US workers in small firms who might be stressed by very high-priced claims is a tiny fraction of the group market for genetic treatments. The current system of employer-paid self-insurance supplemented by stop-loss coverage should be able to facilitate the use of new cost-effective gene therapies. Other alternative methods of financing that have been proposed may not be urgently needed. There are, however, some concerns about the long-term resilience of this system if stop-loss premiums continue to have high growth.

Key words: gene therapies; rare diseases; financing; employer; insurance; self-insured.

Introduction

Biopharmaceutical breakthroughs in the form of one-time gene therapies hold the potential to allow patients with rare genetic diseases to lead healthy lives without disability. However, innovation has come with a cost: prices for gene therapies can exceed \$1 million per patient treated.

When the first discoveries in gene therapy appeared in the mid-2010s, concerns were raised about whether health insurance plans in the United States could sustain payment of such large one-time costs per patient treated, especially as more treatments appear over time.^{1–3} This development, it was said, presented a challenge to the conventional view of prescription drug insurance that serves as a prepayment financing device for moderately costly drugs and other maintenance drugs to treat chronic conditions, so that pooled claims vary little from period to period. A large, if rare, expense (as with the new gene therapies) was thought to pose a novel problem for drug insurance with financial or budget constraints, and alternative payment methods to spread cost over time or to pool individual risks were extensively discussed. Given the growing number of gene therapies already on the market—12 to 30 for genetic diseases,^{4,5} and many more drugs under development for a variety of rare diseases—these concerns about a mismatch of insurance to treatment continue up to the present day.^{6,7}

The million (or even billion) dollar question behind many of these concerns focuses on US employers and employees—that is, whether there is a sustainable way for the private group insurance market, particularly in small self-insured firms, to cover such treatments.^{8,9} This question thus asks both about

financing, given short-term expectations about drug introductions, and about the longer-term resilience of private group health insurance if increasingly more such treatments are introduced over time.

From the viewpoint of insurance theory¹⁰ and empirical evidence, we conclude that these concerns are overstated for the vast majority of workers in competitive labor markets with group insurance in the United States. After all, the primary goal of insurance, in theory, is converting a large, unexpected, unaffordable, but rare expense into a moderate insurance premium, by spreading an individual large expense over many premium payers.

In addition, employers competing for risk-averse workers will offer such protection against financial risk if they are to match what other employers (large or small) offer. In fact, group health insurance had its origin and its most stable financing in paying very large bills, primarily hospital bills, such as those for large expenses associated with serious illness with long intensive care unit stays. The essence of the economic theory of why insurance creates value is its ability to convert large uncertain losses into small certain premiums, and employers who compete for workers seek to provide such value through group insurance. While employers appropriately should not cover treatments whose benefits fall short of their costs (ie, are not cost-effective), they and their workers will gain by covering high-value treatments.

Concern remains, however, about those workers and their dependents who are covered by self-insured employer plans. The great majority of workers in self-funded plans are in large groups where pooling of high claims is feasible. However,

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Table 1. Number and percentage of full-time civilian workers by firm size and health insurance financing (2019).

Population	Firm size	Number (millions)	Marginal % ^a	Cumulative % ^b
All full-time workers	All	116.3	100.0%	100.0%
In “small firms”	<200 FTE workers	39.0	33.6%	33.6%
In firms that offer private group insurance	<200 FTE workers	28.4	72.8%	24.4%
In firms that self-insure ^c	<200 FTE workers	5.1	17.9%	4.4%
With stop-loss coverage	<200 FTE workers	3.0	59.2%	2.6%
Without stop-loss coverage	<200 FTE workers	2.1	40.8%	1.8%

Source: Special tabulations of the 2019 Medical Expenditure Panel Survey Insurance Component (MEPS-IC). “Civilian workers” include workers for private-sector employers and state and local governments.

Abbreviation: FTE, full-time equivalent.

^aCalculated as the percentage of workers reported in the previous row.

^bCalculated as the percentage of all full-time workers reported in the first row (n = 116.3 million).

^cFirms with at least 1 self-insured plan.

since the self-insured employer pays the claims covered by the plan, small firms might be financially stressed by larger claims unless they have wealthy or diversified owners. Not only might a large claim bankrupt a small self-insuring employer, but its possibility might also be a reason for an employer to refuse to cover such treatments in the first place.

In this article, we first provide new research data from several sources to provide empirical evidence on the prevalence of workers in such potentially stressed small firms. We then comment that, based on data from the last decade, these concerns currently are of small importance nationwide, because the number of workers with group insurance coverage in small firms that makes employers vulnerable to financial stress from large claims is a tiny fraction of all workers. Efforts to design plans for a tiny fraction of the market would have a low return. Next, we show that the current chances that coverage of new cost-effective gene therapy will be omitted or denied even by small firms are minimal because almost all have stop-loss insurance. Finally, because of the key role of stop-loss coverage, we consider trends in the market for it and discuss the future of small employer coverage if many high-priced, but cost-effective gene therapies become available. Our conclusion that innovative high-cost treatments can be financed efficiently in group insurance, even small group insurance, is contingent on the continued functioning of stop-loss insurance markets for self-insured firms.

How many workers are in small firms at risk of financial stress due to gene therapies?

We drew on novel data from the Medical Expenditures Panel Survey Insurance Component (MEPS-IC) and the Kaiser Family Foundation (KFF) Health Benefits Survey of Employer Health Benefit Offerings to present estimates of the proportion of workers in the United States covered by group insurance, who work in small firms, and whose employers might, in principle, have difficulty financing an expensive gene therapy. Special tabulations of the MEPS-IC data were obtained for small firms of sizes that matched those reported in the published KFF survey results (KFF or KFF/HRET (Health Research and Educational Trust), various years). We then explored how those employers financed coverage for their workers.

Full-time workers in small firms with self-insurance
In 2019 (the last pre-pandemic year), there were approximately 116 million full-time civilian workers (private-sector

employers and state or local governments) in the United States based on special tabulations of the MEPS-IC data (Table 1). We assumed that this population is the potential market for private group health insurance since such benefits are usually not offered to part-time workers. Approximately 34% of all full-time workers, or 39 million people, were employed by small firms, defined here as having fewer than 200 workers. The MEPS-IC estimates indicate that approximately 73% of those small firm workers (~28.4 million people) are covered by private group insurance. (The majority of small-firm workers obtain group insurance supplied as “full insurance” by large insurance companies with premiums partly paid explicitly by workers and partly paid by employers as part of their total compensation expense; a few use Medicaid or the individual market.) The MEPS-IC data thus estimate that only 17.9% of small-firm workers with private group insurance equivalent to 4.4% of all civilian full-time workers (5.1 million) are in small firms that offer insurance with at least 1 self-insured plan.

An examination of trends over 2013–2019 in employer-reported prevalence of self-insurance across small firms of different sizes in the MEPS-IC data shows that self-insurance prevalence has remained quite stable over this period (Table 2, left panel “A”). This result from our data is similar to that from Fronstin.¹¹ Comparable data on the fraction self-insured from the KFF survey (Table 2, right panel “B”) show similar trends for the first part of the period, but in 2018 and 2019 indicate a growing fraction of respondents answering that they have self-insured coverage with “level premiums” (Table 2, last column). The protection from level premium plans (explained further in Appendix S1, Part 1) is often misinterpreted by employer respondents and makes interpretation of survey responses ambiguous.

Stop-loss coverage among small self-insured firms

Employers who self-insure are willing to accept part of the risk of above-average claims in return for the tax, regulatory, and possible rating advantages of self-insurance. However, the majority of these employers have access to and choose to purchase stop-loss insurance to limit their risk. Stop-loss insurance is a form of insurance where an outside insurer agrees to cover self-insured employer claims in excess of some pre-specified limits. It provides financing for unusually large claims or claim totals.

As shown in Table 3, the reported percentage of full-time civilian workers in small firms (up to 199 employees) with stop-loss protection reported in the MEPS-IC has been

Table 2. Percentage of workers in small firms with self-funded or level-funded plans (2013–2019).

Year	A. Percentage of full-time civilian employees in small firms that offer private insurance with self-insured plans ^a			B. Among covered workers, percentage in a self-funded plan or in a self- or level-funded plan ^b	
	MEPS-IC			KFF/HRET	
	Firm size			Firm size: 3–199	
	<50	50–199	3–199	Self-funded	Self- or level-funded
2013	11.9%	17.9%	14.7%	16%	NA
2014	12.9%	21.6%	17.2%	15%	NA
2015	12.6%	23.9%	18.2%	17%	NA
2016	15.6%	23.3%	19.4%	13%	NA
2017	14.7%	22.1%	18.4%	15%	NA
2018	13.2%	21.5%	17.4%	13%	19%
2019	14.5%	21.5%	17.9%	17%	24%

Source: Special tabulations of the 2013–2019 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and rates reported in the 2013–2019 KFF/HRET survey reports.
 Abbreviations: KFF/HRET: Kaiser Family Foundation/Health Research and Educational Trust; NA, not available.
^aFirms with at least 1 self-insured plan.
^bFirms with a level-funded plan pay claims from the plan trust fund and also pay for stop-loss coverage.

Table 3. Percentage of full-time workers in small firms with self-insurance who have stop-loss coverage (2013–2019).

Year	MEPS-IC		Kaiser/HRET	
	3–199 workers	50–199 workers	3–199 workers	50–199 workers
2013	49.1%	63.3%	62%	73%
2014	53.0%	64.2%	75%	79%
2015	57.8%	68.9%	64%	68%
2016	55.0%	70.6%	72%	76%
2017	54.5%	68.5%	60%	73%
2018	52.7%	63.6%	72%	89%
2019	59.2%	68.6%	NA	NA

Source: Special tabulations of the 2013–2019 Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and rates reported in the 2013–2019 KFF/HRET survey reports.
 Abbreviations: KFF/HRET: Kaiser Family Foundation/Health Research and Educational Trust; NA, not available.

generally stable over time between 2013 and 2019, reaching a level of 59.2% of self-insured small-group (up to 199) workers in 2019. (This is the basis for the calculations for the last 2 rows in Table 1.) However, the same measure in KFF reached a level of 72% in 2018, as shown in Table 3, with an even higher reported percentage (89%) for groups between 50 and 199 workers. (This measure was not reported by Kaiser/HRET in 2019.) Part of the explanation for the difference in the estimates from the 2 surveys appears to be imprecision in employer-respondent understanding of the survey questions, as discussed in Appendix S1, Part 1.

The range of estimates of the proportion of workers in self-insured small firms with stop-loss coverage from the latest available MEPS-IC (59.2% in 2019) or KFF (72% in 2018) surveys implies that the percentage of all small-group workers with self-insured coverage where the employer is fully liable for very large claims in 2019 was only 1.4 to 2.1 million workers, a range of 28% to 41% of workers in small, self-insured

firms. Even at the high end of this range of estimates, the fraction of the overall private insurance market at risk for large claims is small indeed (last row of Table 1). According to these data, at most, 1.8% of the total potential group insurance market (2.1 million workers) with group insurance coverage were in firms without stop-loss coverage that might not be able to cover large claims for gene therapies or other high-priced treatments. Moreover, the fraction of workers in groups that actually would experience large claims for a gene therapy for a rare condition would represent both a tiny share of the overall insurance market and of the market for the genetic treatment. For example, the annual number of expected cases of childhood blindness for the genetic treatment Luxturna (Spark Therapeutics, Inc., Philadelphia, PA, USA) is fewer than 10 nationwide. (See Appendix S1, Part 2, for sample calculations.) Hence, the need for special help or alternative financing models for employers at risk of such claims would therefore only be required by a small fraction of the market for group insurance.

What are the chances that coverage of gene therapy will be omitted or denied by small firms in anticipation of financing challenges?

Discussions of alternative payment models for one-time gene therapies with a high up-front cost have also been motivated by fears that financing challenges for high-priced gene therapies would inhibit employer willingness to include coverage for rare but expensive treatment. To fully explore these issues, we need to probe employer choices about the insurance they offer their workers. Would anticipation of financing challenge deter employers from including coverage for such treatments?

We address this question in the sections that follow based on the following 2 key underlying assumptions. One assumption is that treatments that will be covered are priced to be cost-effective and are evaluated as such by workers. Specifically, we assume that the gene therapies that might appropriately be covered by group insurance have been determined to be cost-effective, given the cost they add to expected claims and the value workers attach to the health benefits. Here “cost-effective” means that benefits to workers, as evaluated by the wages foregone to cover insurance, exceed in monetary amount the net additional claims cost of coverage.

Hence, the question we address is whether there are ways for group insurers to finance cost-effective treatments even when their price is high and, if so, what are the best or most promising ways to do so (largely involving comprehensive stop-loss insurance for all high-cost treatments). That group coverage and stop-loss insurance now finance expensive treatments such as organ transplants suggests that there are ways to do so.

There will be gene therapies (at both high and low prices) that are effective but not cost-effective, producing modest improvements in health at high cost. However, we will not be concerned with the financing of such treatments since employers should not choose to cover them. This is a coverage decision rather than a financing one; with efficient insurance, covering and paying for them should not be of concern.

Our second assumption is that employers choose the type and financing of insurance offered in a competitive market for labor to maximize profits and/or minimize total compensation costs. Since health insurance is part of the worker’s

compensation package, this assumption generally implies that employers will be concerned with the total cost of compensation (employer-paid health insurance, other benefits, and money wages less any explicit insurance premiums), along with the effect of the package they choose on their ability to attract and retain workers they hire in competitive labor markets where both larger and smaller firms compete for workers.^{12,13}

Employer choice of self-insurance

Many firms, regardless of size, choose to self-insure rather than buy full insurance from an external insurer. One reason for choosing to self-insure is that state regulations and state taxes do not apply to self-insured plans, which are instead regulated by federal rules. Another is that (in theory) the employer or the entity an employer chooses to manage the self-insured plan may have more control over coverage determination and price negotiations with providers (and the claiming of discounts) than with external insurance (although the employer is constrained by the terms of the plan document). A third reason is that a group with workers who are lower-than-average users of costly care may have a lower cost of coverage in a self-insured plan than in a community-rated insurance plan.¹⁴

Administration of self-insured plans fosters financial protection

An employer that self-insures its coverage must establish a trust or account into which payments for care are made; that account is then used to pay claims. It must also have a plan document that specifies what is to be covered and what is not; exceptions must be explicit in the plan document. Most commonly, this process is designed and managed by a separate third-party administrator (TPA) or insurer, which has already established relationships with health systems and other providers of care to specify prices and transfer funds. The employer retains ownership of the funds in this account, except for any part of the premium paid explicitly by workers. In some cases, small groups may use software to pay claims without a TPA.

A firm stressed for cash flow might consider foregoing the stop-loss premium (even though it is typically small [$<5\%$] relative to the amount paid per worker into the plan trust) to conserve funds. However, providers would be reluctant to treat patients covered by insurance that might not pay claims. Moreover, avoiding stop-loss premiums puts the employer at risk for much larger future payments: going without stop-loss insurance does not make expenses go away. Possibly in some small towns, where the self-insured firm and the local hospital are known to each other, the hospital would admit workers covered by insurance that might not be able to guarantee payment. However, such employer behavior would be constrained by the requirements for plan administration. The TPAs would refuse to administer insurance where default could occur, because doing so would have negative implications for their provider contracts.

Any self-funded firm that uses a TPA will therefore be required as a condition of its contract with the TPA to have stop-loss insurance. This is because the TPA, in turn, contracts with network hospitals that will accept only insured patients. Hence, stop-loss insurance will be a must.

The great majority of small firms that self-insure do indeed use TPAs to pay claims rather than have the firm's HR (human resources) management review each claim and write checks. One should expect that almost no agents, brokers, or consultants would recommend or even be responsible for a firm without stop-loss insurance (Siemers R. Special communication with Aegis Risk, LLC. 2022).

Within the limits of any federal regulations, how would a profit-seeking employer decide what to cover and to what extent? Cutting benefits for cost-effective care, even if it is expensive, would harm a small employer's ability to compete for workers. If its benefits fell below those of other competitive employers, including less-challenged large employers, it would have to pay higher money wages. The existence of a tradeoff between benefits and money wages has strong empirical support,^{13,15,16} depending on the state of the labor market and the size of the premium increase.

Dealing with high-cost claims by self-insured employers

Self-insured firms large and small had to develop a mechanism for dealing with high-cost claims even before gene therapy appeared. Organ transplants, complex cancer cases, and other services could result in bills in the mid-6 figures. Unless coverage was specifically excluded by the plan document, such care would almost always be covered by self-insured firms with stop-loss insurance. For exceptional cases, some pretreatment review and more in-depth analysis of medical necessity would be undertaken. Sometimes, disputes would arise that need to be resolved or litigated. But generally, the insurance will pay. Private insurers are constrained from denial of coverage by the terms of their contracts—there has to be a reason for rejection (other than high price), such as absence of medical necessity. Appendix S1, Part 3, shows novel data that indicate that, despite managed-care restrictions about experimental drugs, medical necessity, or step therapy, the great majority of drugs in all categories are covered by insurance.

What is the future of small employer coverage of high-cost treatments and purchase of stop-loss insurance if we end up with the problem of “too much of a good thing”?

It appears that the self-insurance market is highly competitive, with many options available to employers. However, there has been a recent trend for high growth rates of premiums for stop-loss coverage. As shown in Table 4, according to a survey conducted by Aegis LLC, stop-loss premiums grew over the period 2012–2022 at a much faster rate (138%) than average premiums for complete coverage paid by self-insured large firms (43%) reported in the KFF/HRET survey. This trend is consistent with the finding that recent increases in medical care costs seem to have disproportionately affected patients with high-cost and chronic conditions.¹⁷ Overall, the high rate of increase for stop-loss premiums, driven by above-average increases in growth in the cost of large claims, is obviously of concern to all employers regardless of size. However, there is no evidence that this trend has, as yet, led to less demand for stop-loss coverage. The alternative of choosing full insurance has total premiums reflecting the same trend. The alternative of dropping stop-loss coverage because the premium has risen is to choose to be at risk for a large claim that would be financially catastrophic for the firm, something that

Table 4. Trends in annual insurance premiums for stop-loss insurance and self-insured large firms (2012–2022).

	Average annual premium for \$200K individual stop-loss	Average annual family health insurance premium for self-insured large firms
2012	\$444	\$15 907
2017	\$660	\$19 521
2021	\$996	\$22 510
2022	\$1056	\$22 814
10-y percentage increase (from 2012 to 2022)	138%	43%

Source: The annual stop-loss premiums were obtained from the Aegis, LLC, 2012–2022 survey reports. The annual family health insurance premiums were obtained from the Kaiser Family Foundation (KFF/HRET) 2012–2022 survey reports.

employers will avoid if they are risk averse or seek to avoid bankruptcy costs. Thus far, the group insurance system with stop-loss coverage has been able to finance expensive treatments (such as organ transplants) that have diffused at a moderate rate.

Some stakeholders fear that the number of new effective drugs introduced at high prices could eventually lead to total spending so high that paying for them is unsustainable. The US health care system, they claim, “was not built for expensive therapies”¹⁸ and “we don’t have an unlimited amount of money to spend on health care.”¹⁹ In the context of employment benefits, “unsustainable” would mean an unsustainable reduction in the level of monetary compensation for workers. If the monetary value of health benefit added is linked to worker values of health and if they are willing to sacrifice monetary wages for those benefits, a treatment that is high cost but is cost-effective is one that workers should be able and willing to buy. That is, if a new treatment is cost-effective for workers, that means that they are better off paying for it and obtaining the additional value of health added rather than using their compensation for other types of consumption. Since they are better off buying than not buying, paying for that care must be sustainable via a combination of increased insurance premiums and lower growth in monetary wages (compared with not covering that care).

Conclusion

There are some limitations to our research and analysis. The novel MEPS-IC data we analyzed may be imprecise because employers are uncertain about stop-loss coverage. The stop-loss market, although currently functioning well, faces some challenges. It is possible (although unlikely) that drug firms rather than stop-loss insurers are more efficient at raising capital to help small firms cover large expenses. Finally, some genetic treatments may be priced so high that coverage of them is unattractive (not cost-effective), even if they can be made affordable.

However, our research indicates that the percentage of workers in the private group insurance market who are currently in plans where employers would face challenges of financing a rare but high-cost gene therapy is tiny—1.8% of all full-time workers with group coverage, and probably less. The administrative difficulties that would be faced by small self-insured firms without stop-loss coverage are so great

that, in reality, very few firms lack such coverage. If effective treatments for gene therapy are priced to be cost-effective (given the value workers place on the health benefits of treatment), small firms offering health insurance will choose to cover those treatments.

Overall, there should be continued attention paid to the challenges facing small firms faced with large potential claims for novel and highly effective treatment. At present, the current system of employer-paid self-insurance supplemented by stop-loss coverage appears to be able to sustain financing of new, cost-effective gene therapies with currently available market-based institutional arrangements. Other alternative methods of financing that have been proposed may not be urgently needed. There are, however, some concerns about the long-term resilience of this system if stop-loss premiums continue to have high growth.

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Supplementary material

Supplementary material is available at *Health Affairs Scholar* online.

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Conflicts of interest

Please see ICMJE form(s) for author conflicts of interest. These have been provided as supplementary materials.

Notes

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