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The Role of Stop-Loss Insurance and Reinsurance in Managing Performance-Based Agreements

16 September 2019

CONTENTS

Introduction2

Stop-Loss Insurance/Reinsurance: Roles and Operational Aspects3

Benefits and Challenges of Durable and Curative Therapies4

Modifications to Secondary Insurance to Accommodate Durable and Curative Therapies4

Alternative Mechanisms to Manage Durable and Curative Therapies5

Conclusions6

References6

INTRODUCTION

Over the last decade, rising healthcare costs and the availability of expensive new treatment options has led to a substantial increase in the number of patients with large insurance claims. For the insurance carrier Sun Life, members with annual claims greater than \$1 million grew from 114 to 192 between 2013 and 2016, an increase of 68% [1]. Employers with <100 and 5000+ covered lives had million-dollar plus claimants <1% and 33% of the time respectively [1], suggesting incidence of about one such claimant per 10,000-15,000 covered lives per year. Somewhat smaller claims are also increasing in frequency, with the top 5% of the noninstitutionalized population being responsible for over half of national healthcare expenditures [2].

For entities with a relatively small number of covered lives, claims of this magnitude can be a serious financial issue. A single million-dollar claim for a self-insured employer with 100 covered lives might exceed the total plan costs for all covered lives in a typical year lacking such a claim. Such an expenditure could have significant repercussions for company profit, and might even threaten the viability of the company itself if sufficient reserves or other protections are not available. For larger companies, unexpected claims may not threaten the viability of the company, but may result in undesirable balance sheet liabilities or profit volatility driven by factors outside the core company business.

In order to avoid these issues, healthcare payers often pass on excess risk that they cannot tolerate to secondary payers. If the primary payer is itself an insurance plan, this protection is known as reinsurance, while if the primary payer is a self-insured employer, it is commonly known as stop-loss insurance.

Since 2017, new classes of treatments have reached the market that promise to provide durable or even curative benefits. Kymriah and Yescarta are CAR-T therapies that may provide longer-term benefits for some blood cancers, while Luxturna and Zolgensma are gene therapies. These treatments carry high prices, ranging up to about \$2 million, with other treatment and supportive care substantially increasing the total cost in some cases. Another forty gene therapy products are expected to reach the market within the next five years [3]. Most of these treatments will be approved based on small clinical trials that provide limited evidence on the level and long-term durability of benefits, making multiyear performance-based contracts an important option.

As these new treatments become more common, the frequency and nature of expensive healthcare claims will continue to evolve. The goals of this paper are to examine reinsurance and stop-loss contracts and how they will be impacted by durable and curative therapies, while suggesting ways in which these secondary insurance products could evolve in order to be able to accommodate the needs created by these therapies.

STOP-LOSS INSURANCE/REINSURANCE: ROLES AND OPERATIONAL ASPECTS

Insurance arose as a means of protecting against the financial consequences of events that could jeopardize a family or company's survival, such as house fires, death of a primary breadwinner or an industrial accident. Policies protected against the occurrence of specific events, and pooled premiums created reserves to cover payouts. Premiums needed to be at least as large as expected payouts, so for insurance to be useful, only rare and unexpected events could be covered; insurance cannot make events with a high expected cost more affordable. Furthermore, enough policies must be written to make the number of payouts across all insured groups reasonably predictable and balanced to the inflow of premiums.

Over time, health insurance evolved to take on a broader role in the reimbursement of individual health needs, with much of the expansion in the US occurring through employer-provided healthcare after World War II. [4] [5] Routine preventative care and other predictable costs became covered, though with increasing limitations as the cost of care increased. Due in part to restrictions placed on commercial insurance plans by the Employee Retirement Income Security Act (ERISA), it became more economical for many companies to self-insure rather than purchase insurance, and the percentage of employees subject to such plans rose from about 5% in the early 1970s to approximately 63% today. [5] [4] [6] Self-insurance started with larger companies, but smaller companies also adopted self-insurance to take advantage of opportunities to control their expenses. The rise of small-group products such as level-funded health plans has accelerated this trend by easing the transition to self-insurance for smaller companies.

While self-insured companies with sufficiently large pools of employees might have modest variability in plan expenses, smaller companies can be subject to significant expense fluctuations if they happen to have a few very expensive events; a \$2M claim has a much smaller impact on a large organization with \$100M in overall drug spend than a small group typically spending \$6M. As described above, the frequency and magnitude of these large healthcare expenses has increased over time, and this can endanger a company's existence or curtail its ability to make important investments. In order to avoid such issues, smaller companies that self-insure typically pass on a portion of their healthcare risk to larger groups (insurers or reinsurers) through stop-loss insurance. Stop-loss insurance comes in many forms, but generally takes on the role originally played by insurance: It protects against large, rare, unexpected claims and/or unexpectedly high frequency of smaller claims by allowing a company to pay another party to assume the covered risks in return for their expected cost plus a risk charge. As the insurer or reinsurer contracts with a large number of companies, it has a sufficient pool of covered individuals to smooth its own risk profile.

Stop-loss insurance can be designed in a variety of ways to manage risks, but is not as useful for predictable costs. If an individual has high expenses each year because of a chronic condition or has a known upcoming large expense (such as a gene therapy treatment), a reinsurer will not typically take on those costs for the same premium that would be required for a typical employee. Doing so would likely lead to large losses for the reinsurer or costs passed on to other customers through higher average premiums, which would lead to progressive challenges wherein only customers with high expected expenses would consider the premiums reasonable and maintain coverage, leading to progressively rising premiums (an adverse selection death spiral).

In order to avoid such issues, contracts between insurers/reinsurers and employers are careful to specify which expenses are covered and which are not. For example, specific individuals with known conditions that lead to predictably high expenses may be excluded from coverage ("lasered"), at least for particular known costs. If an individual develops an expensive condition, they might be covered for the first year (unpredicted expenses) and then lasered from subsequent years. This permits the stop-loss contract to focus on protecting against unexpected high costs.

"Specific stop-loss" contracts generally cover all or a portion of the expenses for individuals that exceed some threshold (the deductible or attachment point). For example, if the attachment point was \$250,000 and the reinsurer agreed to cover 90% of all claims for covered individuals above that level, the health payer would be responsible for \$350,000 for a covered individual with \$1,250,000 in claims during the covered period: The first \$250,000 and 10% of the remaining \$1,000,000. Specific stop-loss contracts may be combined with "aggregate stop-loss" contracts, which further limit total losses across all of the individuals in a plan.

Contracts differ with regard to what claims are covered and when the claims must be incurred and paid relative to the covered period. Exclusions can be at the individual level as noted above, but may also exclude categories of therapy, new therapies, unapproved therapies, or whatever other categories are agreed to by the two parties in order to manage desired risks at an acceptable cost. Many policies last for 12 months and some require claims to be incurred and paid during that period, though often there are provisions to manage claims that are incurred and paid during different plan years (it would be undesirable for claims incurred in December and paid in January to be uncovered in either year). Between plan years, assessments of the patient pool experience may lead to modifications of plan terms or employee lasering, though sometimes multiyear agreements may restrict changes between years. Insurers and reinsurers may tailor these terms or provide other services (such as assistance in care management) based on the needs of an employer.

BENEFITS AND CHALLENGES OF DURABLE AND CURATIVE THERAPIES

Gene therapies are a good example of the durable and curative therapies category. Using a variety of technologies, they seek to make targeted changes in patient DNA in order to correct defects that lead to congenital disease. Prior to the advent of gene therapy, these diseases could at best be treated symptomatically, and often there remained significant unmet need (morbidity and/or mortality) even with chronic treatment using the best standard of care. While gene therapies often will not be able to correct prior disease damage, they carry the promise of being able to prevent any further damage with as little as a single treatment.

As gene therapies are targeted to a specific genetic defect, the treatable population for a particular therapy is often small, typically leading to orphan status with regulatory bodies and challenges in identifying enough patients to run large clinical trials. They also often have accelerated routes to market through fast-track status because of their high potential benefit. As a consequence, these therapies can come to market based on relatively small, short trials that provide limited evidence regarding which patients will benefit and what the magnitude and duration of their benefit will be.

The sparsity of clinical evidence can provide pricing challenges relative to traditional treatments. Most traditional pharmaceutical treatments are dosed chronically, with the treatment period aligned with the period of benefit. This creates a natural mechanism wherein treatment (and cost of treatment) stop if a product is no longer producing benefit (See Figure 1a). By contrast, gene therapies may be administered once and have an extended and uncertain level and duration of benefit (See Figure 1b). If the upfront payment reflects the full potential value of a cure that may benefit patients for the rest of their life, more moderate benefit than expected would lead to a substantial overpayment for the treatment. By contrast, if a conservative price is placed on the treatment to reflect potential product failure, the reward for the innovator company might be inappropriately small, which might decrease the incentive to develop high-value curative therapies. While understanding of value may accumulate over time, a surge of pre-existing (prevalent) patients might be treated soon after product launch at the period of maximum uncertainty.

One potential solution to the uncertain benefit of durable therapies is to make some of the payment for the treatment conditional on longer-term performance. For example, instead of providing a single upfront payment at the time of treatment, the payment could be split into a series of payments over subsequent years with continuing payments being dependent on continuing benefit for the patient. Downstream payments would reflect the progressive resolution of risk regarding therapeutic performance based on the impact of the treatment on some agreed upon measurements that reflect true value at the patient or population level (potentially very challenging to define!).

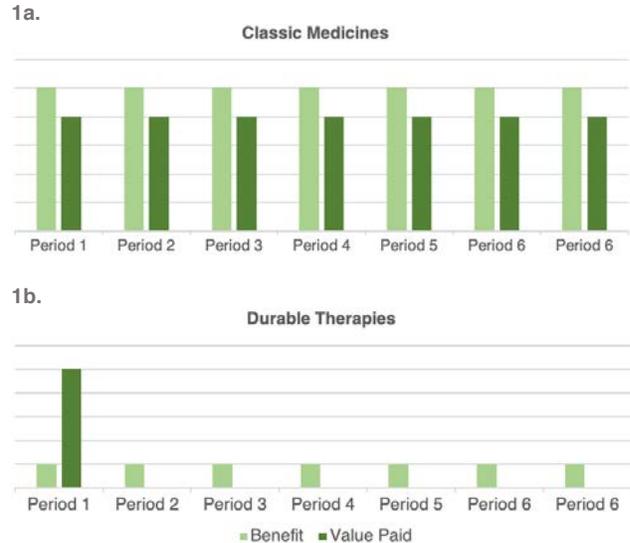


Figure 1. Durable therapies shift payments upfront relative to traditional medicines.

Having a series of payments over multiple years creates potential issues for both primary and secondary insurance. If the treated individual moves from the original payer (“patient mobility”), the new payer would likely decline to make payments contracted for by the original payer, leaving the original payer responsible for the contract. The original payer would then need to continue making payments or make some agreed upon terminal payment for an individual that is no longer covered and for whom they may not be able to obtain ongoing information regarding treatment benefit. Management of this patient mobility issue needs to be considered at the time of contracting and addressed in any HIPAA consent forms agreed to by the patient.

Even if the covered individual does not change primary payers, issues may arise with any secondary payer. As noted above, secondary insurance contracts are typically annual and require claims to be incurred and paid within the covered year, though many contracts have “run-out” periods permitting claims to be paid for a limited time after the end of the contract year. Traditional contracts, however, would not usually accommodate performance-based contracts that make payments for claims over several years.

MODIFICATIONS TO SECONDARY INSURANCE TO ACCOMMODATE DURABLE AND CURATIVE THERAPIES

There are a number of ways that one could contemplate modifying secondary insurance to enable performance-based agreements. Generally, this could include changes to terms of existing types of contracts (e.g. time periods over which they operate) or the creation of new types of specialized contracts. No option is ideal, with increased operational complexity being a typical challenge.

It is important to start by considering the challenges that would occur if multiyear performance-based agreements are

implemented in the context of traditional secondary insurance contracts. After the first year, the covered individual would be a known expensive patient, and the reinsurer would laser them out from further coverage. To counter this and to avoid having to pay deductibles for the individual each year (if not lasered), the employer would be incented to avoid performance-based contracts and instead pay the full cost of the treatment upfront, shifting more of the cost to the reinsurer. This would be suboptimal for both parties because it would lose the opportunity to reduce expenses if the treatment fails to achieve expected benefits. In addition, even if the primary payer's liability is limited for that particular patient, shifting costs to the reinsurer would force the reinsurer to increase risk charges for relevant policies to cover its expenses. Finally, there would be challenges regarding who would be responsible for payments if the primary payer changes insurance/reinsurance providers, similar to the patient mobility problem described above.

One change that might appear to help manage multiyear agreements would be to make secondary insurance contracts longer than one year. This option would force substantial changes in existing business practices, in that it would no longer be possible to modify terms in response to changing understanding of the underlying population, risk profile and available treatment options. In some cases, existing agreements limit changes that can be made in future years and this may be an option, but it would be of limited benefit for many types of performance-based agreements, which could last longer than a primary payer would want to be locked into a secondary insurance contract and would in any case not be able to manage patients treated late in a secondary insurance contract, whose performance-based agreements would last longer than the secondary insurance contract.

An alternative would be to retain the limitation that claims relate to treatments received during a year, but extend the period during which the resulting payments can occur. Ideally, this extension would only relate to payments from the initial claims, not additional treatments relating to the same event, though there might need to be consideration given to reimbursement for follow-up visits intended primarily to determine whether a patient continues to meet performance metrics. Such a change would increase operational complexity in that limited-term secondary insurance contracts would need to remain active for multiple years pending final resolution of costs, which would be particularly challenging if the primary and secondary payers no longer have other ongoing business.

ALTERNATIVE MECHANISMS TO MANAGE DURABLE AND CURATIVE THERAPIES

Given the operational and motivational challenges to the options described above, it is important to consider alternative mechanisms that might be useful for managing these therapies. Payments relating to durable and curative

therapies can be separated from more standard treatments and managed through separate contracts or vehicles.

For each of these options, overarching questions relate to the scope of treatments covered. Agreements can cover specific treatments, specific diseases, or categories of treatments (such as gene therapies). Managing each condition separately can create significant overhead given the number of treatments in the pipeline and the rarity of patients for each. In addition, it may increase the risk of adverse selection issues, where primary payers seek protection for specific conditions they believe may occur at higher frequency in their covered population. Secondary insurance cannot reduce the costs of known risks, though it can help in managing those risks in some circumstances.

Carveouts in other areas have been found to be generally effective means of transferring the risk for a specific condition to a third party. One of the most common types of carveouts has historically been a transplant carveout, but carveouts can address any high-cost and unpredictable condition. Carveouts have historically been used to plug gaps in stop-loss coverage, which often arise due to laserling, but are ideally designed in concert with existing coverage to provide a more holistic solution. As carveout coverage typically initiates from the first dollar of spend and can be designed to cover an entire episode of care, it may be ideal for managing durable and curative therapies in parallel with a traditional stop-loss policy. However, carveouts may have significant overhead if implemented for very rare treatments, so some collaborative effort may be required by primary and secondary payers to determine appropriate scope of coverage and structures.

Risk pools are an option that has been used in varying ways over the years. In its simplest form, it is the aggregation of risk across a larger pool of individuals, which is the traditional form of insurance risk mitigation. However, states have sometimes separated out patients with known expensive conditions into high risk pools, which are fundamentally more about finding ways to help pay for these conditions without causing substantial rises in premiums for the broader healthy population. While these have sometimes been successful when focusing on a small number of individuals, they have typically failed because of underfunding. [7] It is important to distinguish between risk pools that manage unknown risk (e.g. genetic conditions in newborns) and risk pools designed to mitigate the costs of known conditions.

More generally, one could contemplate new types of multiyear contracts that are specific for durable and curative therapies. These contracts could cover risk mitigation, financing through annuity-like payment structures, and even operational assistance in managing patients depending on the needs of the contracting party. While this type of contract does not exist in the market today, sample contracts could be developed to prototype these sorts of arrangements and understand what can be implemented without creating significant overhead at either the contracting or patient management stages. Business models organized around this

sort of approach have been suggested as “Orphan Reinsurer and Benefit Managers” (ORBMs). [8]

Management of durable and curative therapies needs to be viewed in the broader perspective of overall insurance costs and risks, and even overall corporate considerations beyond healthcare. In the past twenty years, there has been a substantial shift from boilerplate reinsurance contracts to tailored or “structured” solutions, which offer a greater range of options for stabilizing earnings and optimizing balance sheets. Contracts can be highly customized and may take into consideration accounting treatments and the need to maintain appropriate liquidity for expected future payments, such as through the use of special funding vehicles, factored payments, and risk swaps.

CONCLUSIONS

There is no simple uniform solution for managing the risks created by durable and curative therapies. It is important to consider the needs of a company based on its size, its overall risk profile and its risk tolerance, among other factors. Transparency regarding potential risks and known future costs is important for establishing an equitable relationship with a secondary insurer that provides long-term benefits for both parties, and this includes discussion of benefits from offsetting costs such as rebates from manufacturers and reduction in other chronic costs for a patient who receives a durable therapy.

In designing specific protection, the overhead burden is a significant consideration, both for writing and implementing a contract. It is not productive to write a series of contracts protecting against very remote risks, but it may be sensible to bundle a category of risks into one contract, particularly as the number of durable and curative therapies increases over the next decade. It is also not useful to write long-term contracts that will lead to difficulties in tracking patient data or have major impacts on more routine reinsurance products.

As the healthcare system evolves to encompass products with new properties, reinsurance will change to provide assistance where it will be beneficial. As novel products with durable benefits reach the market, it is important to experiment with new types of coverage in order to be able to provide appropriate risk protection where necessary.

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