Cost Sharing in Insurance Coverage for Precision Medicine: Preliminary Notes

Mark V. Pauly

Introduction

Most medicines (and other treatments) work well for some otherwise apparently similar patients but not others. One of the factors that determines effectiveness is the genetic makeup of the patient or the disease. While physicians for centuries have honed the skill of determining which patients are good candidates for which treatments, the advent of "precision medicine" adds a tool in the form of a genetic test to predict effectiveness or its absence of a treatment regimen. The main advantage of such a test is avoiding the cost, side effects, and false hope for those for whom the treatment is less likely to work.

Insurance coverage is now near universal in the United States but does not cover everything a physician or patient might think useful. Coverage is incomplete, both to avoid insurer administrative cost, and inefficient stimulation to low or no-value use. In this paper I will outline some intentionally simple theoretical models of the ideal role of insurance in such settings. I will then contrast those theoretical prescriptions with what appears to be current practice in public and private insurance coverage. Coverage of treatment will not usually be a major issue, but coverage of testing will be an interesting question. Coverage decisions involve both the binary decision whether to cover a test and/or treatment at all (presumably in part as a function of its cost effectiveness), and the continuous question of what level of positive cost sharing to impose given that there is to be some coverage some of the time. The accuracy and completeness of information flow from patient and physician to insurer will turn out to be important, as will the pricing of test and treatment and the perspective taken.

A benchmark model

We begin with a simple case in which the patient already presents with a disease which (absent any other information) is expected to have an identical course, cost and outcome. However, it is known that there is a perfect genetic test which can indicate whether a drug will produce a major health improvement or have no health effect, depending on the result of the test. Only the test is predictive of health outcomes, and health outcomes given positive test results are uniform. Both the test and the drug are sold in perfectly competitive markets. (This model is based on Pauly (2015))

If the expected value of the test plus treatment regimen is positive and exceeds the expected costs of the combination, the optimal level of insurance is full coverage of both test and treatment if insurer administrative costs are zero. This can be represented by the fundamental cost effectiveness equation: cover in full if $C(T) + C(R) <$ (QALYS added) x (dollar value of a QALY) for every insured person. If the person is risk-averse, nearly full coverage may be optimal even if benefits fall slightly below cost because of the value of risk reduction.

An Important digression.

We will explore in detail later in the paper the pricing of test and treatment when either or both markets are not competitive (as opposed to P=MC). However, we should note here that it is very likely that the price of the treatment, especially if it is a drug treatment under patent protection and/or FDA exclusion, is likely to exceed marginal cost by a wide margin. This means that if we use price rather than

marginal cost in the benchmark model, we are much more likely to find the test is "efficiency" improving because it helps to avoid a treatment which, in addition to possible side effects, carries a very high *price* offset. However, this saving is not true saving from a societal perspective because (at least in the short run and without more complexity) the financial benefit from precision medicine to the insurer or the patient substantially overstates the benefit to society because the avoided price is well above the value of the resources saved. We will tussle with this issue toward the end of the paper, but it is important here to note that mispricing of drugs can engender a significant overuse of precision medicine tests even for treatments with small side effects. Empirical treatment of all who present with observable symptoms may well dominate the test-and-then-treatment regimen.

Heterogeneity and deviations from the benchmark model.

In the general theory of optimal coinsurance, the key determinant of the level of cost sharing if it is to take on a value between zero and one is the shape of distribution of marginal benefits (otherwise known as the demand curve). If patients are identical, with identical marginal benefits from care at any quantity of care or level of patient characteristics (so there is a perfectly horizontal demand curve for everyone at risk), we either get optimal coverage being 100% or zero. So the rest of this sector explores alternative forms of heterogeneity of effect or knowledge.

Different predictive test values. Suppose that instead of a binary result ("good" vs. "bad") the test can indicate different values of expected improvement in health. Consider a population whose expected net benefit from the test-plus-selective-treatment strategy yields positive expected net benefits. Cost sharing for the test should be zero. But if the test result indicates positive benefit from treatment but benefit below the value which (given the cost of treatment) yields net benefit, then there should be no coverage of the treatment. Hence as a function of the test value, the insurance should pay in full for some patients and nothing for others, not even for those who will (let us assume) definitely get positive benefits, just not enough. This is an efficient design but one which may yield complaints about equity since some who have been found to be potential beneficiaries from treatment would be denied treatment.

Would consumers tolerate such a design in their ex ante decisions about what insurance they prefer? (Ignore the politically determined Medicare.) Compared to covering some or all of the lower net benefit cases, the insurance premium will be lower. But will people prefer a cheaper insurance that could put them in this situation where better health is available but kept just out of reach? Clearly there will be a difficult adjustment to the proposition that you determined that the value of health was no greater than some dollar amount but now that prior decision means you will not get life-saving care. As my father used to say to me whenever I had a problem, "you should have thought of that beforehand." But one key point in this case is that coverage is still binary, all or none. It just raises equity and political issues.

Multiple but heterogeneous indicators of expected benefits. This case applies both to test and treatment but we will first discuss the situation with testing. Assume that there are indicators that can be detected by patient or physician which help to predict what the test result would be. Indicators might be family history, presentation of symptoms, uninsurable costs, or other information. Depending on the level of these indicators, the expected net benefit of the test plus treatment could be high or low—there could be an array of values of net benefits (before considering the cost of testing). The distribution of this array could take many forms, from highly variable (elastic) to near uniform (inelastic). If insurers or other external planners could obtain complete information about these levels, the test would still ideally

be free of out of pocket cost for those with favorable values, would be conditional on those values, and so would not be covered at all for those with less favorable values.

The need for cost sharing greater than zero but less than one would arise if the third party could not obtain this information accurately—if physicians or patients would neglect to mention or lie about these indicators, permitting someone with expected benefits less than cost to go on to treatment. This information asymmetry would then create moral hazard, and positive cost sharing could in principle lead low expected benefit patients to select out of the test plus treatment regimen (Finkelstein 2014) The role of cost sharing (as in the classic case) would be to persuade those with low net benefits to self-select out of the opportunity for testing which will have benefits worth less than their cost. How large the level of cost sharing would ideally be would depend on the distribution of these unobserved net benefits. Holding risk characteristics constant, the more potential patients would opt out of testing if there were an increase in the user charge for it, the higher that charge should be.

The same argument applies if there are other sources of predictive information for effective treatment given a positive test result. There will be an incentive to dissimulate in order to obtain care of positive gross benefit but negative net benefit if cost sharing is zero. In addition, if people attach different monetary values to health outcomes, the treatment will be inefficient for those with low values. Since these values are known only to the patient, positive cost sharing will be required. The better alternative would be to offer a plan that does not cover the test-treatment combination at a lower premium and allow people with lower health values to choose this plan (Pauly 2005) But those with lower net benefits for a whole host of other reasons could not feasibly be accommodated by a range of plans and so would prefer insurance with cost sharing if they did not know before buying insurance what their expected benefits would be.

Other reasons for cost sharing. The cases just discussed furnish the primary and most consequential reason for "interior" cost sharing of tests or treatments in precision medicine, but there are some other possible rationales. If the cost of either test or treatment is very low, the administrative expense of paying claims may not justify the benefit of a tiny reduction in risk. If the plan has standard coinsurance rates that it applies across the board to categories of clinical services in the interest of administrative simplicity, it may choose to apply them rather than make coverage even more complex than it really is. We also abstract at this point from the problems raised by Filipova-Neumann and Hoy (2014) that a test may change subsequent incentives to engage in preventive behaviors (like monitoring through other tests), but we will consider this later. If patients underestimate the benefits of tests or treatment, there may be a case for value based cost sharing (Pauly and Blavin 2008)

Situations and solutions.

While positive cost sharing can improve efficiency by reducing moral hazard in the heterogeneous-hidden information case, the extent to which it will do so depends on how responsive demand is to such charges. The more responsive is to use insurance coverage, the lower the ideal level of cost sharing. This proposition becomes more complex in the case of interrelated demands such as we have here—design needs to take into account both price responsiveness of demand for tests and price responsiveness of demand for treatment. But one baseline finding is that if neither testing nor treatment responded to cost sharing, there would be no point in modest cost sharing—just make care free. Later we will see what empirical evidence we have on this question.

The other issue the prior discussion raises is the institutional arrangements which do or do not guarantee providing all information to insurers, and how much of an issue that is. Information the patient alone possesses can always be hidden from the insurer, but it does not seem that there is much of that kind of information to be kept hidden. More serious is information the physician has and whether the physician as the patient's agent chooses to keep it secret or whether the physician as insurer employee or contractor feels obliged to tell the insurer. This is another empirical matter to be investigated. Hence it will be important whether the testing-treatment process internalizes the transfer of accurate information or whether the two functions are performed in separate firms that need not communicate accurately with each other. The form of organizational structure will also affect pricing, as we shall see.

Insurance and pricing.

Often the seller of test or treatment has patent protection or other source of market exclusivity and is inclined to charge the monopoly price (which of course can much exceed marginal cost). What is optimal insurance design when either or both markets are not competitive?

There are three possible (non-competitive) situations here with respect to IP protection: (1) both test and treatment are patented; (2) testing is competitive but treatment is monopolized; (3) testing is monopolized but treatment is competitive. In case (1) there is also the issue of whether the same firm holds both patients.

If either the test or the treatment is monopolized alone, the equilibrium total price will be the same, since the monopoly rent can be collected at either stage of the production process, ignoring game theory issues which appear unlikely here. Adding monopoly control of one component when the firm already controls the other component will not add to profits since the monopoly price can only be collected once. If the firms are separate, the outcome is ambiguous and depends on bargaining.

The profit maximizing combination price for test and treatment when sold by a single firm is thus different from that if the two monopoly firms are separate. Compared to the absence of a test, the price of a treatment will increase when the test becomes available because its marginal effectiveness will increase. For example, if there is a 50-50 chance the treatment will work but the test picks out the half of the population where it will work, the treatment price will at least double (Pauly 2009). This increase in markup will also increase the bias in favor of testing as noted in the second paragraph in this note. There will also be an addition to the total cost to reflect the ability to avoid side effects of useless treatment for those who test negative. Compared to the price of a single firm monopolizing both test and treatment, the price under bilateral monopoly will be higher unless the seller of the treatment subsidizes the price of the test.

How do these pricing considerations feed back into the design of cost sharing in insurance, especially if prices sometimes vary?

The most important consideration here is the proof by Gaynor, Haas-Wilson, and Vogt (2000) that consumers cannot be made better off by monopoly pricing of insured services if insurance markets are competitive. While prices higher than marginal cost will discourage the use of care under a given level of proportional coinsurance, competitive firms will set coinsurance rates with competitive pricing that always make consumers better off than under "ideal" coinsurance with monopoly pricing (and higher

benefit payouts). As a general conclusion, the dollar amount of cost sharing will be higher under monopoly and may discourage both test and treatment, even with constant proportional coinsurance. We cannot predict the direction of the coinsurance percentage because the higher financial risk may cause it to fall just as the higher price may cause it to rise.

The other issue is whether monopoly pricing may make the entire therapeutic approach not cost effective from an insurer perspective (who must pay the price charged, not the marginal cost). The answer seems clearly affirmative and it is unclear if there is an obvious work-around this overpricing.

Adverse selection.

Regulation now forbids insurers from charging different premiums for the same nominal coverage except on the basis of age and location. Hence the ability of secret test results to contribute to adverse selection is severely constrained especially by ex post risk transfers. But there is nothing to prevent variation in coverage if there is interaction between test results and the amount or form of treatment.

The insurer will most want to retain for treatment patients whose test results suggest easy cases for high value treatment—for example, the future regimen will be unusually short, cheap, and effective. However, there will usually not be an opportunity to switch coverage between test and treatment. If there is, the prediction from the usual selection model is that the insurer will set higher coinsurance to attract the better risk if the risk transfers are imperfect. But we do not believe this will be a serious issue.

Current patterns of insurance coverage and cost sharing   [More work to be added to this section]

I first discuss cost sharing levels among those who have obtained coverage for test or treatment, and then the process of obtaining coverage.

The definitive paper on this subject is a 2007 study by Marc Williams (Williams 2007)The conclusion there is that there is considerable variation across insurers public and private in willingness to pay for tests based in large part on whether the test is said to be "experimental" or not but with varying judgements on this and other matters. The current situation is very little different from this setting, with some specific tests carved out for coverage by Medicare (details to be provided) and other insurance but still leave much to insurer discretion.

Current patterns of coverage for treatment when coverage exists are fairly uniform: 20% coinsurance, with no upper limit on out of pocket payment in Medicare unless Medigap coverage is purchased. Testing is treated as a part B service and so for the most part are the follow-on treatments. For those with private high deductible insurance the frequency of people paying out of pocket will depend on whether they expect to cover the deductible anyway, which is highly likely in these cases of serious illness.

In contrast, coverage for testing is much more variable in the private insurance market and fairly restrictive in the Medicare market. Even before we get to coverage provisions, the issue is whether the test will be judged experimental or not. That all depends on the nature of the test and the current state of evidence. There is little evidence that cost effectiveness analysis with a benchmark value for life years added is used to determine coverage but rather coverage is based on clinical opinion on the clinical value of tests.

In Medicare there is a limited number of tests that will be covered (Medicare.gov 2016) but in general the Medicare law forbids payment for tests as "preventive" care that are uncovered unless recommended by the USPSTF (like mammograms). Conventional private insurers adopt a variety of policies and we know of no central compilation of the extent of out of pocket payment. There was a 2013 survey of 66 plan websites that determined what tests were covered at all (Graf, Needham, Teed and Brown 2013; also see Kaiser Foundation 2015)

We will be checking private insurer websites for information about the size of the coinsurance. At present, the assurance that genetic tests (outside of a limited set of categories) will be covered at all is limited. Note that at least in the short run, or if cost sharing takes the form of copayment for the treatment rather than coinsurance, an advantage of the test is to avoid cost sharing in cases where the treatment would not have been effective.

There is an alternative which is to include the test in the price of the drug (for which there is likely to be more than sufficient markup) but the drug company would have to run its own program of free or reduced priced testing and then charge the insurer a high price for the drug for the fraction for whom it is appropriate. We are not aware of the use of this model.

Policy Issues

In neither case do we have evidence on the extent of moral hazard. A priori we think it likely to be small but this may not be true in the case of less precise or less trusted tests or in the face of large revenues from testing. Still, the imposition of proportional coinsurance for thousand dollar tests and tens of thousands of dollars treatments for those without Medigap seems to be exposing beneficiaries to large financial risk with no welfare benefit, only a benefit to Medicare's budget or to an insurer's budget. Low income people who have bought high deductible insurance will have a challenge paying the $1000 or so cost of a test, but they should also have health savings accounts deposits to help with the cash flow problem. More importantly, those in the individual market can choose plans with low cost sharing requirements (gold plans) if they know they have a condition likely to require a test, but even those with higher deductibles will probably have the deductible eventually covered by cost sharing associated with treatment over the course of the year (or with the cost of whatever alternative treatment recommended for those who test negative). That is the marginal cost of either test or treatment is likely to be small and the financial risk is whatever would accompany a high cost illness, precision medicine or not.

In some cases, the test will be bundled with the treatment for those who qualify with a single copayment for the combination. If there is additional moral hazard in the decision about treatment this is non-optimal but may be offset by coordination of information.

We know of little evidence on requirements to disclose all information by physicians (eg, as a provision in an insurance contract) but we will be looking for such requirements.

Capitated and quasi-capitated risk sharing ACOs generally do not make much use of cost sharing but we will see. We will also look at how narrow networks treat testing and treatment.

Is there a way to offset the bias toward testing from overpriced drugs? Lakdawalla and Sood (2009, 2013) provide a theory where a monopoly insurer can solve this problem by setting cost sharing at (true) marginal cost after buying out the monopolist and adding the cost of purchase to the premium. The

savings from avoiding testing costs (whether price or marginal cost) can then also be built into the premium and can lead to a more efficient outcome with no testing, treatment of every patient and improved outcomes for some. Ex ante such a plan offers higher expected utility than one that pays the monopoly price for the treatment and treats selectively.

Conclusions.

1) Optimal cost sharing for precision medicine depends on data which we do not now have about demand responsiveness to price
2) Zero-one decisions on coverage given some assumed QALY threshold appear most important
3) There appears to be a serious issue if values of life vary and test-indicated treatment effectiveness varies
4) Current common practice of 20% coinsurance on covered tests and treatments seems to make little sense

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