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Forecasting Access: How Employers Can Strategize for High-Cost Therapies in a Volatile Landscape

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Dr Randy Vogenberg explores how employers, providers, and manufacturers must collaborate more effectively to navigate the complex challenges of benefit design, patient access, and financial planning in the face of rapidly evolving and costly therapies like gene and cell treatments.

F. Randy Vogenberg, PhD, FASHP: I'm Randy Vogenberg, and I'm principal for the Institute for Integrated Healthcare. I'm also on the board leadership for the Employer Provider Council, which deals with employer organizations around the country as well as providers and collaborations with manufacturers.

Can you provide a brief overview of this program?

Vogenberg: This is an annual program that we've been doing for 15 years. I'm the co-founder and co-leader for the program, which is done with the Midwest Business Group on Health in Chicago each year.

For this year's program, obviously there's a lot of change that's going on and a lot of innovation that's happening in the marketplace. There's a lot of interest around advocacy and governmental intervention. What's going on there? What's happening with the technology of treatments, which runs the gamut of immunology, oncology, cell, and gene therapy and so forth? The other big issue is the coverage component. What's happening and what are some of the trends around that?

Embedded with a lot of this is the journey that the patient and the caregiver is on in terms of the treatment as well as the reimbursement, which is certainly relevant to the audience who reads the *Journal of Clinical Pathways*.

Given the increasing scrutiny on fiduciary responsibilities under ERISA, how should employers recalibrate their benefit design strategy when it comes to ultra-high-cost therapies?

Vogenberg: For the ultra-high-cost therapies, in insurance terms, we talk about them as a catastrophic claim. We think about oncology as an example—virtually most of the oncology claims end up being a catastrophic claim, particularly in the early treatment years. As it becomes more stable and under control, it becomes more of a chronic disease.

There are 2 different problems from an insurance perspective. Insurance is really designed to deal with acute issues. You have this scenario where there's an acute phase of therapy and then there's this chronic phase of therapy. The economic implications are somewhat different for employers, and it's also different to an employer who may be self-funded—which is what we think about with the large employers, the Fortune 500-type companies, as an example—or those that purchase an employee benefit plan from a carrier, which could be Blue Cross, UnitedHealthcare, Cigna, Aetna, and so forth.

The costs go up for both every year and they have to be adjusted. The biggest problem is predictability. How do you know what the treatment is going to be, and what are the costs associated with that? As you can imagine, in these fields that we're talking about, it's very difficult to help with that predictive requirement that's needed to understand what should we be covering, how we're going to finance the coverage, how we're going to allow for reimbursement, what will be on a formulary or not on formulary—all those key questions that are important, particularly to health care provider organizations.

How can employers more effectively engage with payers, pharmacy benefit managers (PBMs), and third-party vendors to ensure their teams are aligned and educated when it comes to new therapy launches?

Vogenberg: For years, the biggest complaint has been that employers don't know what to anticipate. Again, getting back to that predictability, how can you make plans? The problem, fundamentally, is one of timing.

Manufacturers are looking to launch a product. It'll be anytime during a year, and there are a lot of aspects that go into making that decision as to when they're going to actually launch, assuming they're going to be US Food and Drug Administration (FDA) approved. The employers every year—the example of a self-funded employer, a large employer that we were talking about—are

making decisions now, so by the summer, all the decisions are made about what they're going to do for coverage in the following year. For 2026, decisions are pretty much all done now.

If you're a drug company and it is March and you're going to launch your product, you're not going to have coverage because it will not have been included, and they would not have thought about this new, wonderful cell therapy that's going to be saving all these lives, and it's not going to cost you a half a million dollars or a million dollars—whatever it is. That's great if you're a patient. It's wonderful if you're a provider that you're able to offer that, but what does the insurance carrier do? The same problem occurs when you look at the fully insured who are buying from a carrier. Those rates are all set. Those are all usually done by September—same problem. They locked everything in, here's the coverage.

Typically, most manufacturers and providers are aware that for the first 6 months, there is probably going to be no coverage. There is a chance that there may be some coverage after that. But what we're seeing—because of the effect of the GLP-1s—is that the amount of monies that are available are getting smaller and smaller to allow for these new introductions of products later in the year, because we have a finite financial situation when we look at insurance coverage.

This becomes a big problem, and it puts the patient in the middle around how we're going to afford this cost of care. That's where employers have been trying to get a better idea as far in advance as they can. For a lot of the employers that I work with, we're looking at 2 to 5 years out, which is very much in line with new product development and pipelines that the manufacturers work on, but they don't communicate very effectively at all. There is no collaboration, and so one of the big conversations that was occurring across these multiple stakeholders in the conference was this need for better and more effective collaborations, because nobody is happy right now. Everybody has a problem.

We have to figure out how we can work more effectively together. That's one of the areas that I've been working on as well. How do we bring the different parties together in a safe harbor scenario that will have a beneficial effect on this patient and caregiver journey that they're going to be on with these new technologies?

Looking ahead, what trends in the specialty or gene therapy pipeline do you think will pose the greatest challenge to current employer-sponsored benefit models?

Vogenberg: The future is very murky and cloudy because of all the changes that are being brought forth in the Medicare program, as an example, that will likely take 18 to 36 months to have full effect.

That's within that time window that employers look at—that 2- to 5-year window—when they're making decisions and making plans. But with these new technologies, and we know the pipeline is massive, there is going to be a lot coming. It's become a pure financial issue.

From an employer perspective—who is either covering their own plan as a self-insured entity or they are buying coverage from a carrier—how do you anticipate what you're going to need for coverage? There are multiple levels of insurance coverage. Most providers don't really understand how insurance works from the benefit side, and so it gets very complicated very fast.

The bottom line is that there are going to be a lot of barriers for access to drugs. That's not going to go away fast. There will probably be some changes to prior approval that make it easier and simpler to try and minimize the paperwork. I think everybody agrees on that. But when it comes to the financial piece, what will actually be on a formulary? What may be built into the coverage? That's still a huge question mark. From the insurance side, there are a lot of questions about the financial mechanisms, because there are many mechanisms that could be used, more than 7 different scenarios. What's going to be the best one to use?

What we're learning is that, for each of these new novel therapies that are coming out, they are all going to be expensive—anywhere from inexpensive at $500 000 to as much as maybe $7 million when you get to a gene therapy. We need to have a lot more knowledge of that from the employer and the carrier perspective so they can figure out the best financial model that could be used to afford these products and to include them in the coverage.

Until that time, unfortunately, we're probably going to see a lot of scenarios for carve-outs and lasers, which means that there may be limited coverage or no coverage scenarios. Some of the models that are out there that have been tried just haven't really worked well, so a lot of those are going to be abandoned as we go forward over the next couple years.

The big question, from the employer side, is the impression or the understanding that the biotech pharmaceutical companies in general just aren't equipped to work in a world where there's a rebate involved. If you take away the rebate, how do you operate? So, that model without rebates is another huge question mark, because for most of these novel therapies, there are little to no rebates. There may be some patient assistance programs, but how do we solve for that within the context of the manufacturer's list price, for example, which has been elevated in importance because of the Medicare negotiations of Most Favored Nation pricing? This also gets very complicated.

We're left with more questions than answers. It's going to probably take us 12 to 24 months to sort through. If there is no information coming from the manufacturer, those will be done without input from a manufacturer, which increases the likelihood that there is not going to be coverage or that the coverage will be very poor, and it's going to put a burden on patients and providers.

Is there anything else you hope that audiences will take away from this program?

Vogenberg: The important issue is that there is a recognition of the importance of this patient and caregiver journey by the employers, and certainly the manufacturers as well, but I think a lot of it is misunderstood in terms of how it operates. That's where this collaboration needs to come into play to have a much better understanding of where the barriers occur and how we can start removing some of these barriers like we're going to see happen with prior authorizations (PAs).

We're also going to see a big shift in terms of the third-party PBM landscape. A lot of these novel therapies are going to be covered under the medical benefit, but a lot of the ancillary therapies are covered by the PBM. So, I think we're also going to see a movement toward having more harmony across medical and pharmacy benefits. This would be a major change, which is sorely needed at this point, and one that looks at patients more holistically. That will also help us with the claim financing issue.

So, expect a lot of shifting and changing to continue for the next 1 to 2 years at a minimum. Three to 5 years out, I think we're going to start getting in a much better place than where we're at today.
