**Precision Medicine Podcast, Season 3, Episode 44**

## **Dr. Gabriel Bien-Willner Part 2: Helping Payers Adapt to the Paradigm Shift of Precision Medicine**

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**Karan Cushman, Producer:**
Welcome to Season Three of the Precision Medicine Podcast sponsored by Trapelo. This is the podcast where experts come to discuss the problems oncologists, reference labs, and payers face as precision medicine grows and consider solutions for advancing the quality of patient-centered cancer care. Be sure to subscribe at precisionmedicinepodcast.com to get the latest episodes delivered straight to your inbox.

You are listening to Part 2 with Dr. Gabriel Ben Willner, Chief Medical Officer at Palmetto GBA and Director of the MoleDX Program. In this segment, we continue the conversation on the growing difficulties that payers face in navigating the explosion of precision medicine and related diagnostics tests and treatments. And in the second half, we discuss solutions for improving processes and adapting to this paradigm shift in the practice of medicine.

 ***(Continued from Episode One)***

***Jerome Madison, Precision Medicine Podcast host:***

*You mentioned that Palmetto was looking for a subject matter expert, and I'm sure you've heard this. And being in the industry for a while, I hear from providers who lament dealing with their insurance companies and that they don't have that expertise, and they have to explain why they need access to a drug that there's a clear indication for. In fact, on our podcast with Robin Toft talks about a talent crisis in this space where there's just not enough experience, skill and knowledge for leaders, for companies that are leading companies into this precision medicine future, if you will. But other than just kind of the talent and the know-how, what have been some of the challenges from the payer perspective that you've seen, and that payers have had to navigate as this precision medicine space, the explosion of diagnostic test has grown over the last few years.*

***Gabriel Bien-Willner:***

*Sure. So the MolDX program was really created to try to navigate the challenges. So let me go through some of what that is. That the talent aspect of this is very palpable. So the way Medicare works is that the determinations, the policies are written by CMDs or contracting medical directors. So I told you I had two titles basically within Palmetto GBA, but I have a third title in this role. I am the chief medical officer for Palmetto and the MolDX director, but I'm also a contract medical director for CMS, which means the Centers for Medicare Medicaid services. What this means is that I'm authorized by CMS to speak on their behalf and make decisions for them. The way that the Medicare program works is the CMDs are hired by the MACs to make these policies, and they have to be physicians.*

**Part 2 Episode Begins:**

**Dr. Gabriel Bien-Willner:**

There are, I would say, several other, probably even bigger problems that resulted in the creation of this program. One is that payers communicate with providers and understanding what services were rendered and why they should be paid for based on the claim submission process. And so, what happens is a provider does some service, and then they bill Medicare for that service by telling them what service was performed and that's usually in laboratory settings by using a CPT code. CPT codes are created by the AMA, and they also use an ICD-10 code, which is a descriptor of a general code set that describes conditions. It's not really a diagnostic code set but more or less could be seen that way. And so, that's how you communicate with the payer what you did and why you did it. And for many services that's sufficient. But in molecular diagnostics, it really doesn't work well.

If you look at the CPT code set, the CPT code set doesn't explain a specific test option or a specific test for a specific intended use. Sometimes the CPT code defines a gene. Sometimes it defines a procedure that was performed. Sometimes the CPT code defines one of maybe fifty different genes—doesn't matter which one. And so, if the payer wants to understand what service was rendered, CPT codes are often a very poor way of doing that. And so, it's very easy for the payer to say, "I don't understand why this test was done," and then they just don't pay for it. Another major reason is that even other laboratory tests, molecular diagnostics is very heavy in laboratory developed tests. Laboratory developed test is one where the lab itself is creating its own assay. Now, utilizing the physicians’—who are running these laboratories—ability to practice medicine, this is totally appropriate that they create their own tests that are necessary for their own patient population.

But because there's not general standardized procedures or equipment or chemicals that are used in these tests, two different labs performing the same CPT-coded test, may be performing two entirely different tests for two entirely different intended uses. Furthermore, because some of these tests are very highly complex, it's not clear to the payer if the test is even being performed to whatever standards are necessary to ensure that the test is reasonable or necessary.

So yes, there is CLIA, yes, there is CAP, but those operate at the lab level, not on the specific assay level a majority of the time. And because these tests have become so complicated, the payer wants to ensure that whatever they're paying for has been validated and is being used properly. So these are all considerations that maybe aren't relevant in other areas of medicine or even other laboratory tests. If all NGS tests, for example, were FDA-approved kits, that last thing I mentioned may not be relevant. But that's not how most of these services are rendered. And I would argue that's probably a good thing. But it still means that the payer has one more challenge to try to overcome before deciding whether they should be covering a test and how much it should be paid for.

**Jerome Madison, Precision Medicine Podcast host:**

Yeah, you've mentioned before that payers, alluding to the codes that might not be adequate in the communication process, but payers need more specificity on what was done and why. Like if we can put that in the context of how to communicate that to payers, what would be the best situation, come up with another code or is there other information that needs to be submitted with a claim? How do we address that to make that process more clear and streamlined for payers?

**Dr. Gabriel Bien-Willner:**

Yeah, it's a great question. And this is something that really…what I think the one thing that made MolDX work from the beginning is that they sort of solved that problem—and this is before I got there, so I really can't take any credit for this—is they realize that they could create a second code set and require providers to put this code, which they call Z-code, on the claim. And so what a Z-code is, is a unique identifier for each and every test. So if you have an NGS test, that's a 5-50 gene panel for breast cancer at lab X, and you have a 5-50 gene test that's for colorectal cancer in lab Y, those would both be billed with the same CPT code 81445, but the payer doesn't know the difference.

And now they've got two different patients. One has breast cancer, one has colon cancer. And without this kind of specificity with the coding, the payer is going to be confused. Why is a patient with breast cancer getting the same test as a patient with colon cancer? So they would be confused every time, and that's why you have things like pre-authorization, that sort of come up as a remedy for that. Where they would have to look at a lot of information to figure out… a payer would have to figure out in advance, “Hey, this is actually a different test, this is why it was ordered,” and then sort of approve it. Whereas what MolDX has done is we created this code set, and the way it works is if you have a new test, and it's a molecular diagnostic test, you go to the DEX website.

DEX is a program that we actually operate now, and you register your test. You tell us what's in that test, what genes you're sequencing for, assuming it's a sequencing test. You give us a lot of information about the methodologies, the intended uses, and then when you submit that, we give you a unique Z-code. So now when you are performing a test, and it's a 5-50 gene-sequencing test for breast cancer, and you submit the Z-code, we know exactly what tests you performed. And given the ICD-10 code, we know exactly why you performed it. And so, we don't need to do pre-authorizations. We've already been able to delineate that it's the proper test for that patient.

**Jerome:**

Yeah. You mentioned the prior authorization kind of being the process that's in play there. And obviously from the provider side, that is kind of another big hurdle that they have to jump to make treatment decisions. How big of an administrative or financial obstacle is prior authorization for payers?

**Dr. Gabriel Bien-Willner:**

So, the Medicare program in MolDX program does not use pre-authorization. So, it's none from our perspective. There are, I believe, some initiatives in Medicare in general that have attempted this or are attempting it, but, in general, Medicare doesn't do that. Medicare, if you submit a proper claim, it pays within 15 days. And a lot of our reviews are post-pay reviews, meaning that if you improperly billed or were given improper payment, we'll tell you often after the fact. Our efforts are made to preclude improper payments by creating systemic edits that prevent those kinds of claims from getting through.

So, whereas I think in a private payer setting, they take longer to process claims because they want to make sure that they're paying for something that's reasonable, including this pre-authorization process on the Medicare side it really isn't a thing we do. And so we have to be very creative to try to prevent those problems in other ways. So, I could tell you that from my exposure to private payers, it's a big problem for them. And it's obviously a huge resource sink to have to do that. But for Medicare, really, it's not really an issue.

**Jerome:**

Yeah. As you establish policies, how do you keep providers abreast of the changes in the payer preferences that have evolved?

**Dr. Gabriel Bien-Willner:**

Well, the reality is that all of the policies that are written are living, breathing documents, and they need to reflect the evidence of the time when the decision was rendered. We rely on the published evidence to tell us that there is support for the use of a service. And we look at basically three factors in that determination. One, is that the test demonstrates analytical validity. Two, that it demonstrates clinical validity. And three, that it demonstrates clinical utility.

We can go into details as to what that means in specifics but the evidence can change over time. So we can make a decision that is now no longer true because additional evidence has come out to show that the test that we're paying for actually doesn't improve clinical outcomes in patients and doesn't have clinical utility. Or a test that we decided to not cover has now come out and demonstrated clinical utility and so now should be covered. There are formal processes that are in place to change policy, these are called reconsideration of current policies. And so, there's an established formal way of changing our minds. And the key thing that will get us to change our mind is evidence.

**Jerome:**

You've really helped us understand the challenges from the payer side that are presented with the growth of precision medicine. But, as you look forward, what are some of the solutions or ways that we can address these challenges as precision medicine grows from a payer perspective?

**Dr. Gabriel Bien-Willner:**

So, thanks Jerome for that. I think a lot of the challenges that we're seeing are really a consequence of a paradigm shift in the practice of medicine. And honestly, a lot of this was going to be unavoidable, and we're feeling the growing pains of a change in the way we do things. I think that there's a lot that can be done to improve and smooth out the process. I think I mentioned that the Z-codes are a specified code set for lab developed tests, certainly would help a lot in the communication between provider and payer. There's certainly a lot of other things that could be done to improve that. One is to also work more closely together on the CPT code set to make them better fit the payer needs. I can give you lots of examples. For example, Tier 2 codes are a listing of individual genes or processes that the payer really can't do anything with.

Then there's also the fact that they're really, as you mentioned earlier, there's just not that many experts out there in the field. There's just this gap. And that's for a variety of reasons. One is it's a new field, there's few people that are invested in this field and have expertise just because it's new and only, I happen to be at the cutting edge in academia before leaving and going into industry and then into the payer space. How many people were in the space with me? I mean, I probably know almost all of them just because it's such a new and small field. When I started going to, for example, the Association for Molecular Pathology, AMP, is the key body really in this space. I remember going to AMP meetings as early, as like 2009, and it was a pretty small meeting, 500 people or so. And now it's 3, 4,000. Medicine has recognized that this is really the future.

Precision medicine is the future. And yet why aren't there more people involved? Why isn't there more education? There's a lot of reasons. One of them is, we talked about the lack of subject matter expertise, but that's also tied to the fact that there wasn't the payers paying for these services. So if there's a service out there that the payer is not paying for, then who's going to be performing those services? Why would people go into molecular genetic pathology when there's no molecular pathology jobs to be had at the end of the rainbow? So now that these tests are becoming more accepted and they're being performed, and when they start to get reimbursed, that will open up more positions for hiring molecular genetic pathologist. And that, in turn, will push people to get some specialization in molecular genetic pathology. And so, I think it's all of these things are working together.

There's not one magic bullet that's going to make this work. It's a bunch of little things that need to fall into place. And unfortunately it takes a lot of time having the payers understand the test and make good policy. That's one of those things, having the physicians get actionable reports is another. There's another thing we haven't talked at all about. So these are highly complex tests that are looking for very niche things. Looking at molecular genetics, which is the driving force behind oncology, cancer is a genetic disease. And yet how many oncologists are actually experts in genetics? Virtually none. Not that none of them are. Of course there are some that are very brilliant geneticists, but in general, the practice of oncology doesn't require, or didn't in the past, require expertise in genetics or genomics. And so what we have is right now, we have this big gap in understanding. We have the laboratories that are becoming very proficient in creating test results, looking for specific genetic aberrations.

And then you've got oncologists who are practicing medicine and wanting to identify the best therapeutic intervention for their patient. And somewhere in the middle is the interpretation of very complex genomic signatures and turning that into a directive for the oncologist. Right now, nobody's doing a good job of filling that gap.

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**Dr. Gabriel Bien-Willner:**

So, I could tell you when I was running my 650-gene panel in industry, the real driver of that business, the reason why we were successful was because we weren't putting out a report with a list of genes. We weren't putting out canned text, only canned text about what the evidence shows about each gene. What was really valuable…there was… we were writing a consultation on every patient, reviewing the oncology notes for those patients, looking at the genetic signatures of those tumors and telling the oncologist, based on our expertise, what they should think about doing, what their different choices were and what the rationale was for each potential therapeutic intervention that they may be considering.

And that really helped the oncologist. And I could tell you with feedback that I got from my clients who are the oncologist, it helped them make better decisions. So, what is the future of this field? Is it one where the oncologist is now also an expert in genetics and genomics and can interpret the test results better? Is it that the laboratory understands the clinical implications better of all the resultant mutations that they identify? Or is it somewhere in between where there's a new specialty of molecular oncology that fills that gap? So, I think that's what we have yet to figure out. And I think there's been challenges there as well.

**Dr. Gabriel Bien-Willner:**

For example, next generation sequencing tests are considered part of the clinical lab fee schedule, meaning that they are laboratory tests. And yet there's a lot of professional expertise that has to go out in reviewing that evidence to make an actionable report for a physician.

Basically some experts got to look at all of that data and turn that into a clinical report that has utility for the ordering physician. And so, that professional work is not well captured in the code set. It's not well reimbursed when it is billed, because the payers still quite haven't figured out how much of this is just a lab thing and how much of this is a professional work thing. So, I think that's another problem is really this knowledge gap. Who is going to take these raw data or these lists of mutations and convert them into a report that informs the oncologist on what they should do and why they should do that? I went off on a tangent on that I know, but I think that's another important point.

**Jerome:**

No, that was fantastic. Everything you said was exactly what we are looking for and what we could use. One last question before I ask social media, do you see this, the demand for clinical genomics going into other disease states that you guys are going to have to look at developing policy in the future?

**Dr. Gabriel Bien-Willner:**

Yes, absolutely. Cancer isn't the only genetic disease or the only genetic disease that could benefit from a better understanding of the genetic implications or drivers of disease. We're seeing it in a host of other... we're writing policies, not just in cancer. There's a reason why cancer is first; why cancer is the best studied of these, and that's because cancer patients don't have good therapeutic interventions. I mean, we spent a lot of time, a lot of money in developing a lot of cancer therapeutics, but in general cancer patients still die of their disease. And so, if you're an oncologist, you may not like that statement and say, "Hey, look, we are a lot better in this particular disease than we were 50 years ago." Forget the precision medicine field. Let's talk a little bit before that, because I would say that when we get into precision medicine and targeted therapies, we are all speaking the same language, but the reason why it's moved faster in oncology is because those patients are really, really sick and could from benefit anything that could improve their condition.

Other diseases are going to lag behind because there's less urgency on doing so is my opinion, but it doesn't mean that it's not just as relevant. And so, we're already seeing movement in these tests in a host of other fields. Another obvious one is infectious disease. But also in transplant services, we have policies there. In immunology we're seeing a lot of this. In endocrinology we're seeing this. Cardiology we're seeing this.

So, it's going to probably spread out to probably many, if not most, other specialty areas with different degrees of penetration of how important or relevant it is to…managing those patients in their care. And also to say things that may be general to the entire population would be things like pharmacogenomics, where we can understand, forget about the disease that's the issue, it's which specific drugs may be considered for those patients, which may be completely independent of the diseases that the patients have. Where there's known metabolic issues that patients may either not benefit from a drug or have adverse effects related to those drugs and risk that's based solely on genetic signature.

**Jerome:**

Dr. Gabriel Bien-Willner, Chief Medical Officer at Palmetto GBA and the Director of the MolDX program. Before we let you go, for those that follow you or want to get in contact on social media for speaking opportunities, how can they connect with you?

**Dr. Gabriel Bien-Willner:**

Thanks Jerome. So, I do have a LinkedIn account, so you can look me up there. I don't know what the handle is for that. Just look up my name, you'll see it. I do have a Twitter account and a Twitter handle, although I don't use it as much, but it's, I think it's just gbwillner @, and then a string of texts, which is bwpgprecisionmed.com. And actually that reflects the company that I own.

**Jerome Madison, Host:**

And you can also get in touch on the homepage at precisionmedicinepodcast.com or wherever you get your podcasts.

**Dr. Gabriel Bien-Willner:**

Thank you for having me. This was a lot of fun.

**Karan Cushman, Producer:**

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**About Our Guest**

**Gabriel A. Bien-Willner MD, PhD, FCAP**

###### **Medical Director, MolDX and Chief Medical Officer, Palmetto GBA**

Dr. Bien-Willner is the Medical Director of the MolDX program at Palmetto GBA, a Medicare Administrative Contractor (MAC). MolDX seeks to understand the molecular testing landscape to implement payer controls, coverage, and to set policy for affiliated MACs, which currently cover 28 states. He is a leader in the Precision Medicine space and practices as a Board-certified Anatomic Pathologist and Molecular Genetic Pathologist.

Throughout his career, Dr. Bien-Willner has been active in research, development, and advancement of molecular diagnostic services, specifically next-generation sequencing. He has worked closely with clinicians to develop clear clinical diagnostic and treatment pathways for directing Precision Medicine programs at community cancer centers. Dr. Bien-Willner received his M.D. and Ph.D. degrees from Baylor College of Medicine with a Ph.D. in Human Molecular Genetics. He completed his residency and fellowship at Washington University in St. Louis before attaining a faculty appointment there. He held several leadership roles in laboratory and biotech companies before joining Palmetto GBA.