

Imaging Panda - US Head - National Access Management at Amylyx Pharmaceuticals

Interview conducted on March 08, 2023

Topics

Pharmaceutical Industry, Prior Authorization, Sales Strategy, Data Collection, Patient Education, Healthcare Industry, Medicare, Software Systems

Summary

A Tegus Client seeks information from the US Head of National Access Management at Amylyx Pharmaceuticals about how a FRM can help clinics get patients onto their therapy. The expert explains the challenges of determining which account to assist and the slow process of data collection from vendors. They also discuss the challenges of dealing with multiple data sources and the need to involve the right people at the right time to overcome barriers to therapy. The expert notes that having the right person in the office and understanding swim lanes are crucial to the process. They also discuss the importance of having the right software package to store information for reauthorization and refills, and the challenges of accessing and using that information.

Expert Details

US Head - National Access Management at Amylyx Pharmaceuticals; former National Director of Field Reimbursement at Sandoz, leaving in November 2021; and former Sr. Director - US Field Access & Reimbursement at Intercept Pharmaceuticals, Inc., leaving in June 2021. Expert can speak to their experience leading field reimbursement at Amylyx Pharmaceuticals, Sandoz, and Intercept Pharmaceuticals, Inc.

US Head - National Access Management at Amylyx Pharmaceuticals. The expert is responsible for the entire access and reimbursement market access group. They handled everything from creating the curriculum, working with peer marketing teams and vendors to create teaching materials, and also sourcing and hiring people for the company.

Prior to Amylyx Pharmaceuticals, the expert was the former National Director of Field Reimbursement at Sandoz, leaving in November 2021. The expert was a lead for the Field Reimbursement division on all matters related to strategy, leadership, management, operations, and financial support and oversight that aligns with strategy and business goals. They also provided leadership to link strategy to execution in order to deliver patient access to products and services.

The expert was the former Sr. Director - US Field Access & Reimbursement at Intercept Pharmaceuticals, Inc., leaving in June 2021. The expert was responsible for creating and executing strategy as well as meeting and exceeding goals for Ocaliva. They were also responsible for the expansion, buildout, recruiting and onboarding of 4 Area Directors and 24 Regional Access Managers (RAMs) and set vision and strategy to execute brand and market access strategies specific to the unique needs of each division.

Q: What are your current top 3 goals/focuses in your current role?

A: 1. Ensuring that we're creating and implementing strategy that ensures access for appropriate patients to get on our product
2. Educating our providers and advocacy groups on what the process is (focusing on our top 20%) both internally and externally

Q: What is the job title of your boss/the person right above you in your org? (e.g., Directly reporting to the VP of Market Access)

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A: Global Head of Market Access.

Q: What are the job titles of the people you manage/your direct reports? (e.g. Regional Account Manager)

A: 8 regional access managers (more like field reimbursement managers) and 2 associate directors.

Tegus Client

Hi, thanks for speaking with me. I am trying to get smart and really understand into the weeds of how a FRM helps assist clinics get patients onto their therapy. Before we get into the weeds here, can you just start by briefly describing your current role and your current day-to-day?

US Head - National Access Management at Amylyx Pharmaceuticals

I worked for a start-up biotech company. I've been involved with a number of start-up build-outs and have built out my own team of FRMs and directors. I've been with my organization for about one and a half years. And I've just expanded my team from five people to 10 people due to the demand for our product. And really, what I do is I oversee the U.S. operations for access and reimbursement.

Tegus Client

Perfect. So pretend I'm an expert in the field like I'm a fellow FRM, can talk to me at an expert level. And my understanding is, as an FRM, you can get looped into helping a clinic at any point in the patient journey, whether it's at the very beginning, trying to enroll a patient to your hub to helping a prior auth, to helping with the denial at any point.

And so talking about the perspective of Monday morning, you're going to work as an FRM, what are your steps to just assisting your stakeholders to help get a patient on to their specialty medication. And so we have it listed out in eight steps. And I'm going to go through it step by step, and I'm just going to ask you the same questions over in this gray box.

So let's just start with Step one. It's the beginning of your day, and you're trying to determine which account you want to directly assist. So you have a lot of accounts, you have to prioritize and make a decision there. And then from there, you got to figure out, how do you actually help them?

Where are you going to collect the information. And if you're going to have to work with a system like an IBM, do they have any procedures for setting up an employment base but just determining whatever you need to. In this step, what makes this step or parts of it challenging, inconvenient or frustrating for you?

US Head - National Access Management at Amylyx Pharmaceuticals

So there are a lot of things that make it frustrating. Number one, post-COVID, is the availability of the account to either half-time, make time or actually want to see you. Because many of these accounts are short staffed, and they don't have the time to put in to see you virtually or live. And part of that is, they don't really understand how an FRM can help them with resources and education to eventually make their life a little easier.

Tegus Client

Got that. And I just want to understand this a little bit, why is that so challenging?

US Head - National Access Management at Amylyx Pharmaceuticals

One of the main reasons it's challenging is because in this industry, everyone looks at the sales rep as being the person that goes into these accounts. As the industry has evolved, the sales rep plays less of a role. And once the pen has put the paper to write a script, that's really when the FRM comes in to ensure that the account is following a process from enrollment to fulfillment.

Tegus Client

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Got it. And again, when you think about Step one still, what makes this step slow or time consuming for you?

US Head - National Access Management at Amylyx Pharmaceuticals

I mean, a lot of it depends on the account that you're calling on. And to answer Step one Part A, determine which account to directly assist, really, what I have my FRMs do and what I did was I used the 80/20 rule. My top 20% of my customers are going to represent 80% of the enrollments that come in to a hub. So I want to make sure that they're on top of what they need to do, that they're being provided with the proper resources.

And then I'm there to answer any questions possible. The second part of it is there may be emerging accounts that could become top producers that don't understand the process. Those accounts are accounts where I'm going to focus on to educate them, to understand where they're lacking, and then where I can offer proper resources in education.

Tegus Client

What makes Step one slow?

US Head - National Access Management at Amylyx Pharmaceuticals

So on the emerging accounts, it's a matter of getting those accounts to understand the value that you can provide to that. And when I say value, it's not a monetary value. It's an educational value. I don't see that. There's a lot of ambiguity in what FRM does, which is not easily understood or seen.

So the FRM has to spend time to help that customer internally or externally, for that matter, understand where their value is. And that makes it a bit frustrating because something that may seem fairly obvious may not be, and the FRM really has to go back to basics to start to build that foundation in that case of the value they provide.

Tegus Client

Got it. So you're saying it just takes a lot of time to educate these emerging accounts how you can help. Am I understanding that correctly?

US Head - National Access Management at Amylyx Pharmaceuticals

That is correct in the emerging accounts. And then with your larger accounts, that big 20% that represents 80% of your business, depending on whether you're discussing a medical benefit or a pharmacy benefit, there are nuances that are involved in each of these steps. When you have an enrollment, okay, is the enrollment form completed?

The provider may think that they've completed the enrollment form, but they're missing a check box or they're missing a date or they're missing number of refills. And so it becomes a bit monotonous almost to have to reeducate accounts on things that seem obvious that are commonly missed. So you have to do that.

And then there are the process after that. If it gets sent to a specialty pharmacy or when it gets into a specialty pharmacy, depending on what type of product it is. If it's a specialty product, a rare disease, orphan product, there's a prior authorization involved. The staff are overworked.

They don't have time to do these prior authorizations. So how can you educate them on making life a little easier for them? There are resources that are out there that help that. So you have to get that customer to focus and become engaged to want to do this when they don't have the time to do it.

Tegus Client

And what aspects of Step one are wasteful or can contribute to lower efficiency for you?

US Head - National Access Management at Amylyx Pharmaceuticals

That's an interesting question because there are usually not enough assets to effectively and efficiently help customers. So from my perspective, I'm constantly searching for assets to better provide educational value.

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Tegus Client

Let's move on to Step two then. So in Step two, you've now determined which account you're going to assist. Now you actually have to do all of the data collection to understand the case. So you have to collect info on the patient's case from your vendors, whether it's your hub, whether it's your patient assistance programs, whether it's your SPs. You need to gather information on the payer coverage, whether it's directly from the policy.

Whether it's from the benefit verification. And then also finally, gathering info about the case from the account staff. Maybe you don't have all the information, maybe the enrollment form isn't complete, so we have to gather more info from the accounts themselves. That's what we're talking about in Step two. What makes this step or parts of the challenging, inconvenient or frustrating for you?

US Head - National Access Management at Amylyx Pharmaceuticals

That's a great question. So when you're looking at a Step two Part D, gathering info from our vendors, a lot of times, the info will come from our data aggregators that will take all this information and reorganize it and then spit it out into our data. So it depends on what kind of data packages the pharmaceutical companies buy.

How those assets and information are distributed. Because how that's distributed will go a long way in determining what information an FRM is going to have and how they are going to be able to know what coverage there is for the patient. And they're going to know how they're going to provide that information to the account in terms of, okay, where are we in this step along the journey? When does the SP call the patient to have products scheduled to be delivered, things of that nature. So a lot of it depends on the vendors that we get our data from. And I wouldn't say easier, but more seamless.

Tegus Client

Got it. And what makes Step two slow or time-consuming for you?

US Head - National Access Management at Amylyx Pharmaceuticals

In the case of the organization I'm with right now, we have had unprecedented demand. So we've blown past our forecast. And so the unprecedented demand has slowed things down because we just can't handle the volume that we're getting. And that happens a decent amount of times. The other thing that slows things down again is not having the proper data from our data aggregators and from our IT vendors. And the other thing that slows things down to is the receptiveness of the customer to schedule time for you to communicate what you need to communicate to that with them.

Tegus Client

What actually makes this step slow for you or time-consuming?

US Head - National Access Management at Amylyx Pharmaceuticals

The actual time it takes to accumulate all of the information I need to be able to provide value and educate my customers. There could be a lot of data. There could be a little bit of data, and each has its own benefits and not benefits. If I've got 50 accounts that are my top accounts, it takes time to sift through that data.

To make sure that I've got the right information, put it into the right place to be delivered to the customer at the right time, understanding where that patient is along that journey from enrollment to fulfillment. So if you multiply that by the number of accounts and then take the number of patients within that account that are going through that process, that could be very, very time-consuming.

Tegus Client

And could you maybe just give an example or two of the types of data that you're trying to aggregate so that you can figure out how to provide value?

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Sure. So once an enrollment form is completed, it gets into a hub, an internal or an external hub. They both handle it the same way. They'll QC all the data to make sure everything is correct. If the data is not correct, then it has to be sent back to the provider, and the provider office has to address what's missing on there.

They'll be given information either by the FRM or by the hub on what's missing could be a signature. It could be a date it could be any of these things. Then it depends on the receptivity of that particular office to take care of that. Once that's done, it gets sent back in, and then it moves to the next step. The next step is going through insurance benefits, making sure that the benefits for that particular patient are active benefits, whether it's a Medicare patient or a commercial patient or a dual-eligible patient.

Going through that, determining what the benefits are, communicating those benefits with the office and with the patients. Once that's done, then it moves to the next step, where a prior authorization more than likely is needed for a product. And that would entail a customer to a provider's office to get all of the information from the patient charts in terms of why that particular patient needs to be put on product X.

Have they tried and failed a product depending on the criteria of that insurance company. Do they need to have a step therapy? There are a lot of other things that are involved there. So once they meet, if they don't meet that criteria, then the script in the case will get denied and you have to go and repeat.

Tegus Client

And my understanding is that today, you have access to pretty good tools here. You have a portal with the hub, they have access to electronic benefit verification. You have a different tools like Policy Reporter to help you understand the policy. You have access to a bunch of different resources to make that step a lot more seamless, so why is it still so time-consuming?

US Head - National Access Management at Amylyx Pharmaceuticals

It's time-consuming because it takes a human to input the correct data. So Policy Reporter is not always accurate. DRG is not always accurate. So getting the proper criteria for formularies for particular products may not always be the most accurate and friendly. And you mentioned also that a lot of these specialty pharmacies have portals, yes and no. CVS does not have a portal, at least not for the product that I have in my company right now. Whereas, some of our other SPs do have portals, which make it easier, but it's not foolproof.

Tegus Client

And what aspects of Step two are wasteful or can contribute to lower output?

US Head - National Access Management at Amylyx Pharmaceuticals

Having too much data from multiple sources can overkill a situation. So if you're getting the same data from three different data sources, it could lead to confusion and spending more time trying to figure out what could be figured out through one particular data source. And I do see that happen.

Tegus Client

Can you maybe just give an example, I'm not sure I fully understand.

US Head - National Access Management at Amylyx Pharmaceuticals

Okay. So you have data that comes in through your hub. You also have data that comes in through a data aggregator. Usually, those two types of data match up. At times, they don't match up. When they don't match up, how do you know which source is correct and which source is not? So you've got to take time to go work through the hub to see how they have obtained their information, where they've obtained their information. And then the same thing on the data side. I've got to work with my commercial operations team to determine what was the process for them to gain this data, when did they gain this data? How much time has it lapsed between getting the data and delivering the data?

Tegus Client

So it can be wasteful because if you have multiple sources and they don't match up, you really have to then

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figure out what's your real source of truth. So you're trying to minimize the amount of time to figure out what's your source of truth.

US Head - National Access Management at Amylyx Pharmaceuticals

That is absolutely correct. Extra time being spent to figure that out could've been time that I was spending assisting another customer or working on another case.

Tegus Client

Well, then let's move on. So in Step three, you've now gathered the info that you needed to figure out what's going on. Now let's figure out what's going on. So you want to examine the barriers, whatever they are. You want to examine the options now that you figured out what the different barriers are on how to overcome those barriers, and then prepare any supporting materials that you need to share with the account to help them overcome the barriers. So in this step, what makes this step challenging and convenient or frustrating?

US Head - National Access Management at Amylyx Pharmaceuticals

So Medicare. Medicare government-sponsored program, there's very little that industry can do to provide value or assist customers. You can't provide them with a \$0 co-pay card because it's against government regulation. So the patient basically has a coinsurance or a co-pay that could be 1/4 to 1/3 of the cost of the product. And if it's a high-cost product, there's a barrier right there.

So you have to look at foundations that are out there that help patients in particular disease state therapies, but the patients have to have a certain income to be able to qualify to get monies from the foundation. So those are the things that make this challenging, frustrating because they are deserving patients that should be on product. But because of the government system that we have for Medicare, you've got to follow a certain process.

Tegus Client

And so am I understanding correctly that it's challenging actually figuring out the real options that you have to help a Medicare patient?

US Head - National Access Management at Amylyx Pharmaceuticals

Correct.

Tegus Client

And what makes this step, slow or time-consuming for you?

US Head - National Access Management at Amylyx Pharmaceuticals

You need to involve the provider and the patient. So making sure you get a hold of the provider, and the provider is providing you with the information you need, then getting a hold of the patient, which the hub would more than likely do, to find out income thresholds. Maybe they have to get a W2 or maybe they have to look at their last income statement, whatever it is, to see if they qualify for foundational support or low-income subsidy or some other aspects of programs available for a patient to get product.

Tegus Client

I just want to understand, why is that so time-consuming to get a hold of the provider or the patient to get this info?

US Head - National Access Management at Amylyx Pharmaceuticals

Do you answer 800 calls when they come into your cell phone? A lot of people don't. And I'd be honest with you, it's as simple as that. People don't answer a toll-free call that comes in. So the FRM has to let the customer know, please let your patient know that you're going to be getting a call from a toll-free number. If we know the toll-free number, we give you that number so that the patient hopefully will remember to pick up the phone. So there's a lot of time that gets wasted from that. That's the biggest reason.

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Tegus Client

And what aspects of this step can be unpredictable, unstable or cause it to go off-track?

US Head - National Access Management at Amylyx Pharmaceuticals

Can make it unstable? Lack of information provided from a provider and/or a customer to a support program or to a foundation. It's not that it would be unstable. It just takes more time to get the requisite information needed to be able to move a case forward, especially, like I said, if it's a Medicare patient or if it's an indigent patient.

If it's a patient that doesn't have the means, you have to explore other options that a company may have, like a patient assistance program, an interim access program that could help bridge that gap. Or if it's a patient assistance program that they don't qualify, whether it's because they don't have the income to qualify or whether the criteria from the insurance company gets denied, those are extra steps that get involved to try to get an appropriate patient onto product.

Tegus Client

Got it. And I realize that you said it's more slow and time-consuming. Why is it so time-consuming to get the patient to actually provide that information? I imagine this drug could really help them. They're sick, they should be pretty motivated here.

US Head - National Access Management at Amylyx Pharmaceuticals

So I'll tell you this. We have a product that's for ALS. And you would think that somebody with ALS or their caregiver would be picking up the phone the moment that it rings to be able to help get that person the product that they need. We have cases that have been aging 60, 90, 120 days because people don't pick up the phone, they don't answer an e-mail. There's a clock that's ticking for these individuals. They are unfortunately on death sentence. And we scratch our heads trying to figure that out ourselves. We just don't know.

Tegus Client

Let's move on to step four. So you've examined the options, and now, it's time to make a decision. Maybe you have more than one option, but now you actually have to decide how you can help the customer and maybe loop in anyone else that you need to. If you're going to loop in the sales rep who owns that account, if you're going to confirm that you have consent, whether it's HIPAA consent from the patient, the IDN's consent to allow you to kind of show up and help if you need to or just contact them. What makes this step challenging and convenient or frustrating?

US Head - National Access Management at Amylyx Pharmaceuticals

What makes it convenient is that to overcome the barriers to therapy, and most companies have, and medical science leads on group, they've got nurse educators, they've got sales reps, they've got FRMs. So if there are any barriers to therapy that do occur, we can bring in the right people at the right time to educate the people in the account that have to work with those patients.

So let's say that there is a potential adverse event that usually happens in the second or third week with the product, we would bring in a medical science liaison or we would bring in a nurse educator so that they could educate the person that's going to be educating the patient on what to expect, how to expect it, how long it's going to last and how they can overcome it.

Tegus Client

What makes this step inconvenient, challenging or frustrating?

US Head - National Access Management at Amylyx Pharmaceuticals

Well, the inconvenient part and the challenging part is when that is explained or we think it's explained to the patient, and then the patient winds up taking the product, experiencing an adverse event and then discontinues the product. And the physician just basically takes the patient's word at, hey, I can't take this

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product anymore. I don't want to do it.

And the physician, maybe because he or she just doesn't have the time to go through finding out why the patients can't take the product anymore, they'll just say, okay, fine, we'll discontinue you and put you on something else or what have you. That becomes frustrating when the resources are available for us to provide that education so that patients can overcome barriers to that therapy.

Tegus Client

Got it. So it's challenging because this is a part of the medication, and obviously, it's tough for the patient. But you have resources available to help them with adherence and those resources aren't being used. Is that the challenging part?

US Head - National Access Management at Amylyx Pharmaceuticals

That is exactly the challenging part, whether it's a physical person from my company or any company that comes in, a nurse educator or an MSL or what have you that comes in or whether there are videos that can be given to the patient or a brochure that's given to the patient, and it goes all for naught. That's the frustrating part.

Tegus Client

I want to understand this a little bit better, why aren't the resources being used? Why is it so challenging to get these resources to be used?

US Head - National Access Management at Amylyx Pharmaceuticals

Look, it could be as simple as indifference in a physician, a staff member. Again, may not have the time, overworked, what have you. They'll hand the brochure to the patient and say, "Hey, read the ever so that you better understand the product that you're on." They don't take the time to explain it to them. It could be a number of different things. Could be that the patient doesn't really take the time to understand the barriers that could occur to the therapy that they have to work through. Those are two common examples.

Tegus Client

And what makes step forward or parts of it slow or time-consuming?

US Head - National Access Management at Amylyx Pharmaceuticals

If it's a sales rep, they don't have that HIPAA authorization to talk specifics with an account and a provider, whereas the FRM, in more cases than not do. Depending if consent has been signed, then it becomes easier to have that conversation about a specific patient. If consent is not signed, which happens about 15% to 20% of the time, then it becomes much more difficult to have that conversation because you can't talk specifics about a particular patient, about their history, -that may happen as a result of taking a product that could be avoided.

Tegus Client

Why is consent not given at such a high rate?

US Head - National Access Management at Amylyx Pharmaceuticals

It could be that patients are paranoid, a bit superstitious, they think that maybe that marketing people are going to call them or whatnot. Or just maybe they're private individuals, and they just don't want to offer up any consent. What we do is we try to explain to the provider why it's important for a patient to get consent so that then they can tell their patient why consent should be given. Because it allows us to better service the provider and the patient.

Tegus Client

And so when you don't have consent, what exactly slows down the assistance process?

US Head - National Access Management at Amylyx Pharmaceuticals

So to kind of give you a visual, it's like walking into a dark room. You don't know where you're going. If you don't have to consent, you don't know the patient. You don't know if it's male or female. You don't know their birthday. You don't know anything about their history. All you know is that they may have gotten the product, but you won't know if they've gotten the product unless you ask. So you really don't have any information about the process.

Tegus Client

Let's move on to Step five. So it's now time to actually share information. So you want to contact your account, share the strategies with them on how to overcome the barriers, whether it's a PA, a denial, an appeal, financial assistance, whatever. And so you contact them maybe in person maybe over the phone, you want to share any supporting materials, whether it's a link to the policy, a link to a medical exception letter.

And then if you need to loop anyone else in now that you've made account, whether it's letting your vendors know that, hey, we contacted the account. Expect this from them, let your sales rep know, I made contact with the account. This is how the meeting went. Obviously, you can't share any PHI with them, but just giving them a heads up. Which aspects of this step are challenging, inconvenient or frustrating?

US Head - National Access Management at Amylyx Pharmaceuticals

So the frustrating part is when you've contacted the account and you've shared the strategies for overcoming the barriers, and yet, you have the same errors that keep coming up, such as when you've educated them on an enrollment form and it could be missing a physician signature, could be missing a check market, a date, what have you.

What we don't know is we've educated the person who's responsible for it, but maybe they have three other people that work within that do it as well. Maybe they haven't been educated. Maybe there's turnover. So that's the frustrating part is that you're constantly reeducating and you're constantly seeing the same errors that come up.

Tegus Client

And what aspects of this step can be slow or time-consuming?

US Head - National Access Management at Amylyx Pharmaceuticals

The slow part and the time-consuming part is that if we want to stick with the enrollment form, when the enrollment form is sent in and it's not correct, then the hub had to contact the provider via a phone call or an e-mail, and they have to make sure that the enrollment form gets sent back to them, and that the missing information or the errors are corrected, and then the form gets sent back to the hub. That takes up extra time.

Tegus Client

And so am I understanding correctly that the enrollment form, whenever it's not properly filled, obviously, you have to just start all over with the clinic and tell them to fix it. Why is it not getting filled properly?

US Head - National Access Management at Amylyx Pharmaceuticals

That's a million dollar question. I've watched my FRMs do it. I've done it myself. We have enrollment forms. In most companies, they're color-coded. You've got to fill out this part, that part, the other part. You have to make sure that every check box is checked. We try to make it on one page so that nobody has to fumble through different pages or back and front.

So we've tried to do everything that's easy as easy as possible to make it as seamless as possible. I can't tell you why forms come in without a date. I can't tell you why they came in without a check mark. Maybe they're very busy, maybe they think they did it and they didn't.

I'll take it one step further. When prior authorizations have to be done, if you're dealing with an office that

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really has one person that handles all of the prior authorizations for all the products that prior authorizations are needed, it's going to take time and it's going to be delayed. It's just there's physically not enough staff in an account to do certain things. And I'm telling you this from specific experience that we have with our product right now.

Tegus Client

Got it. And if my understanding is correct that in other words, you want to minimize the amount of time that it takes to get a complete enrollment form.

US Head - National Access Management at Amylyx Pharmaceuticals

Absolutely. When I started in the industry, enrollment forms were four pages long. Customers were absolutely out of their mind, why do I have to fill out four pages? It's taking so much time. I've got to fax it in. And so over the years, different organizations have really condensed that enrollment form to be one page. And many times, there'll be a legitimate Rx, a prescription, that's on that first page of the form as well.

Tegus Client

Got it. And what's the real issue here? Is it on the PA side, is it you want to minimize the amount of time that the office takes to submit the PA? Or is it you just want to minimize the amount of time that it takes to just get a hold of the office to help them with the PA.

US Head - National Access Management at Amylyx Pharmaceuticals

Both. And we also want to minimize the time that it takes to get the materials that they need to submit for the PA. So what many organizations do now is they work with CoverMyMeds. And CoverMyMeds is an online site, which I'm sure you're familiar with, that actually assist the offices in getting their information and sending their information in.

Some of the specialty pharmacies that are out there also do the same thing, too. And if the specialty pharmacy cannot submit the prior authorization on behalf of the provider office, they send back the prior authorization simply so that the provider can hit the submit button and send it in themselves because some insurers don't want third parties to be involved.

Tegus Client

And what aspects of Step five can cause it to be unpredictable or go off-track?

US Head - National Access Management at Amylyx Pharmaceuticals

When you have one thing that comes up is when you have multiple people in a provider office that are handling these cases. Unless they're coordinated, unless they talk to one another, there could be confusion that's involved in that process as well. There could also be confusion from our side of the business, too. If we're not providing them with the information that they need or that they're looking for compliantly, that could cause confusion in the process.

The other thing that can cause confusion, too, is that if a sales rep goes in and starts getting involved in communicating the process, which is not their expertise. Their expertise is on the clinical side, but they go in thinking that they're helping the customer when they're actually probably confusing the customer, that can also lead to confusion.

Tegus Client

And I guess I just want to understand what actually is causing this to go off-track. Is it that you don't know who is the right person to speak with at the clinic? Is it that it's hard to coordinate your efforts across multiple different people between the FRM and the sales team? What's actually causing it to be off-track?

US Head - National Access Management at Amylyx Pharmaceuticals

Two things. One, you've got to have the right individual in the office that you're speaking with. If that person isn't in one day or is off doing something else and someone else comes in to take over for that process,

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there could be confusion that could cause the thing to go in a different direction.

Number two, again, with the sales rep, we have swim lanes. And so the swim lane for a sales rep is to work on issues for clinically convincing a physician about the merits of the product they're promoting. They don't get involved in the process. Once the physician is committed to the product, an enrollment can get submitted.

And that's when the FRM takes the baton from that point until fulfillment. So the sales reps are not trained on what happens throughout that process. They're trained on the clinical process. So if a sales rep is asked a question and they give an incorrect response, that could cause things to go off the rails.

Tegus Client

And is it that you just don't want them involved or you just don't want them saying the wrong thing? It's okay for them to get involved. But if they're going to do it, you just don't want them saying the wrong thing.

US Head - National Access Management at Amylyx Pharmaceuticals

That's correct. It's not that we don't want them involved. We want them to understand what the process is, but getting involved in the process could lead to providing an incorrect response. An example of that could be if there's a provider that's talking about a specific case for a patient that has Medicare, well, there are tens of different levels of Medicare within a plan.

Take Humana, for example, there are a lot of different types of Humana Medicare plans. There are a lot of different options that are involved. And so if you're not well versed on how to educate on that particular plan, which FRMs usually are, a sales rep can think they're providing value when they're providing misinformation. And that can cause a case to go off the rails.

Tegus Client

Now step six, so now you've shared the information with the account. And now it's time to actually verify if they understand it, how to overcome the barriers, whatever use strategies you've shared with them as well as just track their progress in overcoming the barriers. What makes this step challenging, inconvenient or frustrating?

US Head - National Access Management at Amylyx Pharmaceuticals

Well, so this step to me is like a teach back. What you've explained and what you've educated your provider on, you want them to repeat it back to you. What makes it challenging and frustrating is them not particularly listening to what you're saying, being distracted in terms of what you're saying or rushing you to say what you need to say for them to understand. Those are three things that occur a lot.

Tegus Client

I mean, these offices are pretty sophisticated. They're dealing with authorizations all the time. Maybe they're not dealing with a drug, but they're dealing with auths all the time. I'm just trying to understand, why is it so challenging to get them to actually understand what you're saying?

US Head - National Access Management at Amylyx Pharmaceuticals

So generally, a generalization is a prior authorization is a prior authorization. Yes and no. If you have a specialty product or a rare disease product, there's different criteria that's involved in a prior authorization. It's not simply, hey, I failed this product, and therefore, I can go on the next product. There are other steps that are involved. There's other documentation that's needed. So that's where that miscommunication or that obstacle comes in from not paying attention to what needs to be done.

Tegus Client

Got it. So it's really just challenging helping them understand the nuances of the documentation and the step-through, what exactly needs to happen.

US Head - National Access Management at Amylyx Pharmaceuticals

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Correct. And just a quick example would be diabetes medication. You've got your Ozempics or what have you, they more than likely need prior authorization, making sure someone has tried and failed metformin. So if they go on to a self-injectable diabetic product, a, they have to make sure that it's on the formulary of the insurance company; and b, they have to make sure that they tried and failed the stuff. So that's pretty simple.

But when you go to more complex product in a rare disease or an orphan space, there are a lot more variables that play into this that it may not just be having tried and failed a product. It could be a patient's condition that also leads them to skip a step, and this has to be documented. So that's where there are some differences within prior authorizations and understanding what's involved, you've seen one, you've seen one.

Tegus Client

And what aspects of Step six can just make this step slow or time-consuming for you?

US Head - National Access Management at Amylyx Pharmaceuticals

Again, getting time with the individuals in the office to just cross the Ts and dot the Is so that they understand what needs to be done. So there are no barriers to overcome. And then number two is making sure that we in the industry have the right tools and resources to provide to our customers so that they're not making these mistakes.

Tegus Client

Can you just explain that second one a little bit?

US Head - National Access Management at Amylyx Pharmaceuticals

It could come down to, again, a start-up company thinking that they've thought through the whole process and there might be a glossy step an algorithm that helps the customer to really visualize what the steps are. Maybe that doesn't exist. Maybe we've just gone through the steps of verbalizing it to a customer. So instead of showing it, we're just telling them.

Whereas, a lot of people are visual, and they need to see how that process works out. And it's not until like a month or two or three when we start seeing common errors come up that, oh, you know what, the marketing department really should come up with an algorithm that makes it really easy for that provider in the office to tape it up on their wall so that they see. Whenever this happens, I have to follow this process.

Tegus Client

Then let's move on to Step seven. So let's say you now shared the strategy, whatever it is, let's say, it doesn't work. Maybe you recommended foundational assistance, patient's not eligible, and now, you have to figure something else out. What aspects of this are challenging or frustrating for you?

US Head - National Access Management at Amylyx Pharmaceuticals

The challenging and frustrating part for this is the provider and/or the patient not understanding why they don't qualify to be put on this particular therapy when the physician has said that they're an eligible patients, they're ideal for this, but circumstances beyond a clinical decision come into play. Insurance is not going to cover it, they don't have the proper amount of out-of-pocket or co-pay insurance or Medicare case.

So the initial strategy is not going to work. And so what are the other strategies that we have there? So we have a patient assistance program. We have an indigent patient program. And so people are going to have to then provide income information and other types of information to see if they qualify for these rigidly structured programs.

Tegus Client

Got it. And are you saying it's challenging because, again, it's just hard to get a hold of them or they just don't understand what's going on and why they now have to try something else?

US Head - National Access Management at Amylyx Pharmaceuticals

I think it's a combination of both, but I would say more so that they don't understand. And I also think that there's a little sometimes a bit of embarrassment, too, where a patient doesn't qualify or a patient gets rejected from their insurance company. They're like, "I have a job. I make X. How come I can't get this product?"

So they're a little embarrassed and get defensive over which leads to not providing maybe what information that's needed. Maybe somebody is not as inclined to provide personal financial information, whatever that may be, to see if they can go on to an alternative type of strategy to get product.

Tegus Client

Great, and in step eight for many of these medications, they're not one and done. You have to get a reauthorization. Patients are on them for quite some time. They might be on them for life, right? And so you have to store the information on the case until the next time you have to help the account. That's what we're talking about here. What makes this step challenging or frustrating?

US Head - National Access Management at Amylyx Pharmaceuticals

The challenging and frustrating part about this is the company not having purchased the right software package that will store all of the proper information that's needed for reverification or reinsurance. Things that are going to go on for patients that are going to be taking product for a particular amount of time.

That's really the big thing. And what's the word I want to use? Losing the information in the system or putting it somewhere where it's not supposed to be, that will make this a little frustrating, more time-consuming to try to find the information, where you put it.

Tegus Client

And I just want to understand it a little bit better. Sure, like you may not have the right software package, but what do you need that software to help you do?

US Head - National Access Management at Amylyx Pharmaceuticals

Well, I mean we're in a world now where we don't put things in file cabinets anymore, and the file cabinet is your computer software system. So if a patient is getting refills every month, you want to make sure that they're being refilled with their prescription every 30 days. If they're not being refilled with their prescription 30 days is a tracking system that says, okay, well, it's day 35, and a patient hasn't called to get their medication.

So the hub then would make a call to the patient, "Hey, we just want to let you know that you haven't called in to get you refill yet. is everything okay?" So things like that are why you want to have things stored in a software system. And you want to make sure that the information that's put in is accurate so that the patient is getting timely information according to how the physician wants them to get it.

Tegus Client

What makes this step slow or time-consuming?

US Head - National Access Management at Amylyx Pharmaceuticals

A lot of what makes it slow and time-consuming could be the level of education that the person, let's say, at the hub or the FRM has or doesn't have in terms of knowing how to access this information, what to look for, what steps to take.

Tegus Client

And are you saying it's time-consuming because the FRM doesn't know what they need to store or what they need to track for that next cycle?

US Head - National Access Management at Amylyx Pharmaceuticals

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That is correct as well. That's a component of it. Maybe they put in the correct information. Maybe they don't put any information at the right time. Maybe they put the information in somewhere different. So that when you go back, they go back or someone goes back to look for that information, i.e., for that refill, it's not where it's supposed to be, and then they have to take time to find out where it is, why this occurred and correct the situation.

Again, it's human error, and there's a level of understanding that happens or doesn't happen with that. And I've seen that over the course of 20 years, where you've got different levels of understanding and comprehension. And sometimes, you have a software system that kind of doesn't work right, and that's beyond your control.

Tegus Client

I just want to clarify, you're not talking about firsthand. It's not that you don't know where to store the information, but you're just talking about, in general, FRMs on your team, they may not know where to store the information.

US Head - National Access Management at Amylyx Pharmaceuticals

That's correct. Or you may have been taught how to do this, but it was taught to you incorrectly. And that information now has been lost in the system because it was put in somewhere where it's not retrievable. Those are, I wouldn't say common, but I've seen them happen often enough.

Tegus Client

Awesome. Well, you enjoy the rest of your day. Thank you so much.

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