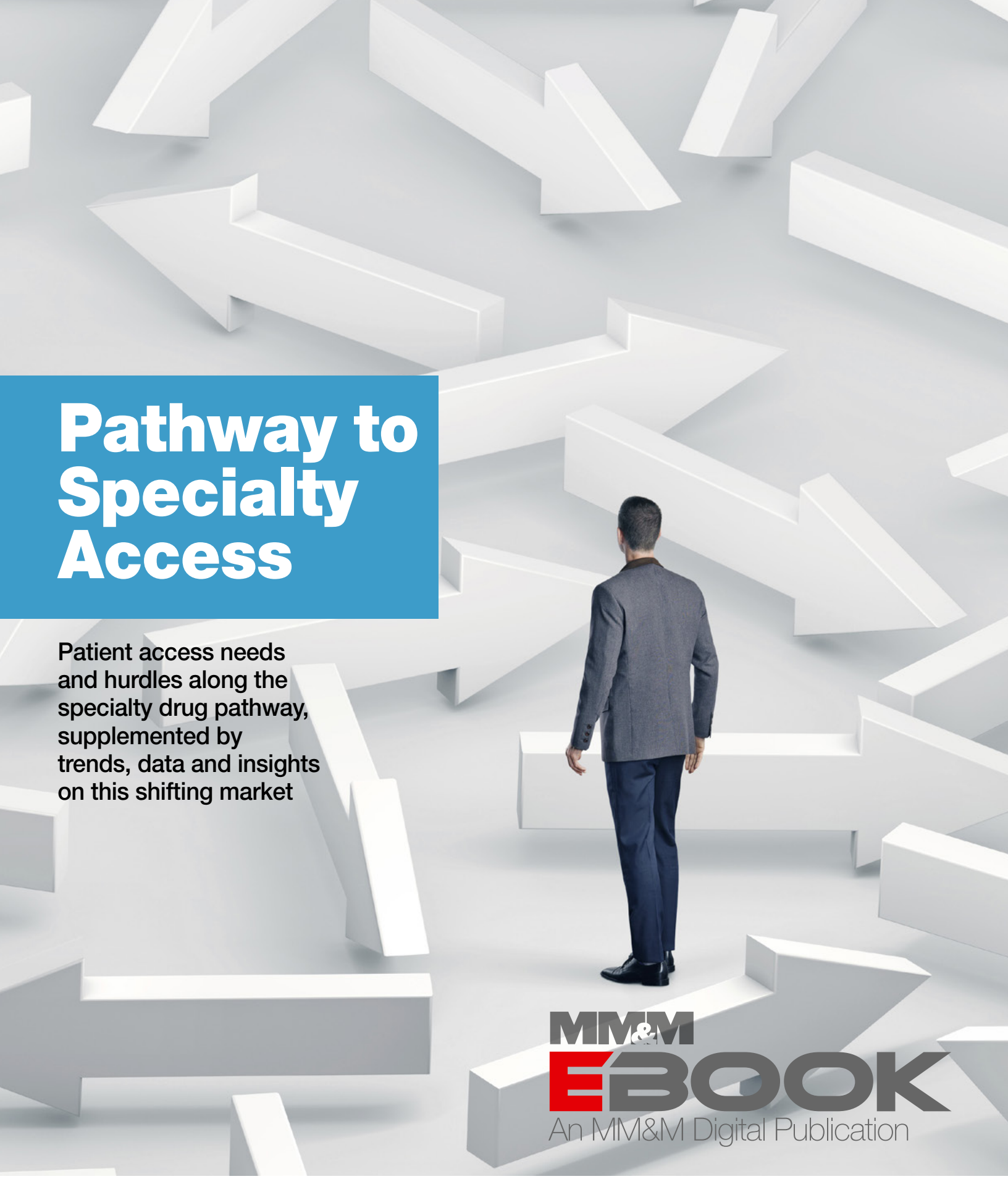

Pathway to Specialty Access

Patient access needs and hurdles along the specialty drug pathway, supplemented by trends, data and insights on this shifting market

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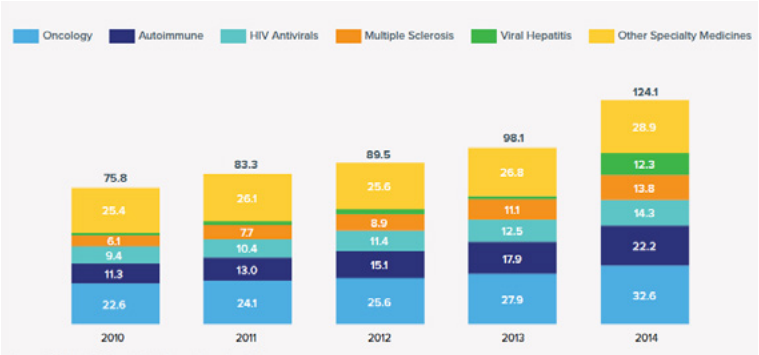
The Changing Landscape: Specialty meds in the current market

Specialty medicines continue to be a hot category, one in which spending has surged behind products that treat medicine's most complex diseases. But for patients, gaining access to the specialty drugs they need can be a bewildering journey. **James Chase** finds out how stakeholders are working together along the specialty pathway to eliminate barriers to access and assist patients

In the consumer world, if you shatter your phone or your dishwasher quits or you want to upgrade your TV, it's pretty straightforward to research what you need, gauge what it's going to cost, find the best deal, make a purchase, figure out how to use it and obtain any support you might need along the way.

Not so in healthcare. Particularly in specialty care.

Spending on Specialty Medicines US$Bn



Source: IMS Health, National Sales Perspectives, Dec. 2014

Specialty medications are traditionally high-cost, complex products, often injectables, prescribed to treat what are usually debilitating chronic conditions. And, for patients, gaining access to—and covering the cost of—the specialty drugs they need can be a bewildering journey, with numerous checkpoints and potential roadblocks at every turn, compounding the emotional strain of a diagnosis.

The specialty surge

Medicine has never had so many specialty products. According to IMS Health data, spending on specialty medicines increased $54 billion over the past five years, contributing 73% of overall medicine spending growth in that period.

And in 2014 alone, specialty medicines grew by 26.5% to $124.1 billion and now account for one-third of all medicine spending, up from 23% just five years ago. Much of this recent growth has come from innovative drugs for the treatment of hepatitis C, cancer and multiple sclerosis, along with 30% higher spending on diabetes treatments.

The single biggest driver was the more than 161,000 patients who started treatment for hepatitis C in 2014, including $11.3 billion from four new hep.-C treatments offering drastically improved outcomes. Overall, nearly 10 times as many patients were treated for hep. C last year than in 2013.

This caught many payers by surprise, forcing budget holders to weigh the cost and the value of new cures, such as Gilead's Sovaldi, which hit the headlines as much for its price tag of $80,000-plus for a 12-week course as it did for its breakthrough efficacy. Sovaldi, in fact, was the highest-grossing drug in the US last year, with $7.8 billion in sales.

In 2014 42 new active substances (NAS) were launched altogether, up from 36 in 2013, and the most since 2001, with more than half of these being specialty drugs. Specialty medicines accounted for $19.2 billion or 78% of the $24.5 billion total new brand spending in 2014. The drug R&D pipeline, too, has shifted toward specialty medicines over the past decade, with 42% of the late-stage pipeline now specialty–up from 33% 10 years ago.

The number of orphan drugs (targeting patient populations of less then 200,000) also peaked in 2014 with 18 launches, including nine new treatments for diseases afflicting fewer than 10,000 patients. A total of 61 orphan drugs have now launched in the past five years, with cancer remaining the most common orphan category.

Reimbursement data, too, is consistent with the specialty drug wave. The Pharmacy Benefit Management Institute reports a 12.2% increase last year in the average per member per month pharmacy gross cost.

Pharma's newfound responsibilities

Given the complex, often-chronic nature of specialty conditions, and the difficulty in treating them, patients

"It's much more than just bringing a pill to market. We're moving beyond patient centricity to patient inclusion."

—Cathryn Clary, MD, *head of US medical and chief scientific officer, US general medicines, Novartis*

Spending on specialty medicines increased **$54** billion over the past five years, contributing **73%** of overall medicine spending growth in that period

—IMS Health

taking specialty treatments tend to require more support along the way. And pharma companies find themselves having to step up from their traditional roles as transactional manufacturing organizations to become service providers, particularly as the healthcare landscape continues to shift toward outcomes-based reimbursement. And that means truly putting patients at the center and engaging fully in their treatment programs by surrounding the patient experience, rather than just their brands.

"Patients want to be partners, they don't want to just be told what to do, and so we are really trying to deeply understand them," said Cathryn Clary, MD, head of US medical and chief scientific officer, US general medicines, Novartis, at the company's recent R&D day. "It's much more than just bringing a pill to market. We're moving beyond patient centricity to patient inclusion."

Drew Miller, creative director, Frog Design, urged delegates at *MM&M*'s recent Transforming Healthcare event to reevaluate models of relationships with patients and to look beyond the moment of treatment interaction. "The old models aren't working anymore," he says. "You need to know where a product fits into a patient's life and make it fit seamlessly. You need to smooth out problems and meet unmet needs."

Monique Levy, VP, research at Manhattan Research, puts it a little more bluntly. "The thing that's lying at pharma's feet is helping with the complex paths and choices that patients have to make," she says. "It's a huge opportunity that some are missing because they think it's risky, or too complex, or they don't think it'll generate sales. But if I'm diagnosed with MS or diabetes, why do I have to go to PatientsLikeMe and cobble together stories of other patients' outcomes and experiences?"

Bill Hinshaw, EVP and head, US, Novartis Oncology, highlights the difference between talking about medical science and human experience within his category. "Cancer is not about a group of cells replicating," he says. "This is about the impact on patients' lives and their families."

But aside from some notable exceptions, the industry's patient-engagement efforts to date have often fallen short. Recent research from WEGO Health finds that 55% of patient advocates believe pharma isn't working collaboratively with patients, with 45% feeling the industry doesn't understand their real needs. Worse still, 46% claim that pharma does understand but that it just doesn't do enough to address those needs.

Clearly there is a vast undermet need for greater access to specialty medications and better support services for patients. The answer, for pharma, surely lies in an integrated, coordinated patient-centric approach. ■

"You need to know where a product fits into a patient's life and make it fit seamlessly."

—Drew Miller, MD, *creative director, Frog Design*

$7.8
billion in 2014 sales: Sovaldi was the highest-grossing drug that year

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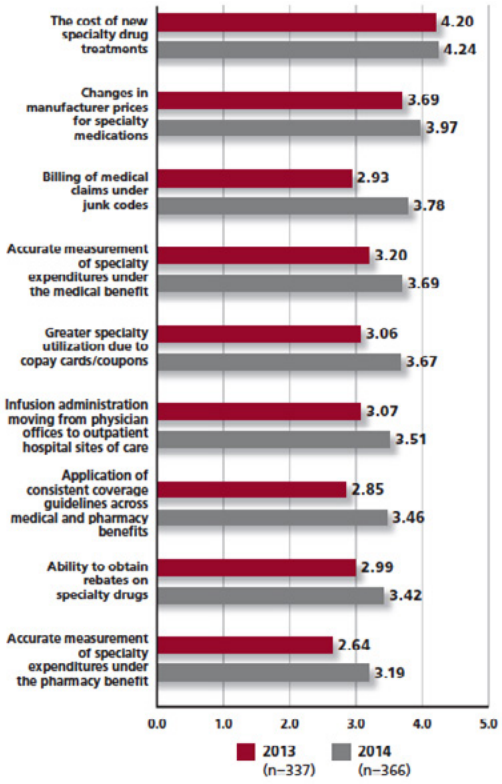
Diagnosis and Drug Access:
Easing the long-term patient's path

Given the complex, often-chronic nature of specialty conditions, healthcare must step up to support the patient. The hand-holding must begin from the time of diagnosis, and working with payers is a big part

The human response

When Ian Talmage was diagnosed with cancer, back in 2002, and given just six weeks to live, he recalls feeling "terrified." Nevertheless, as a distinguished pharmaceutical marketing executive, Talmage was confident he would be able to seek answers to his questions from the industry he had embraced and trusted for more than 30 years. He was wrong. His enquiries failed to yield a single response.

Problems Related to Specialty Medications



Year-over-year significance testing not performed.
Scale is 1 ("not a problem at all") to 5 ("a very big problem").
Source: Pharmacy Benefit Management Institute 2015 Specialty Drug Benefit Report (n=366 employers)

"One of the things that became very clear to me is that I wasn't in control of what I was doing," he says. "I was moved to a point where enormous fear took over. I was seeking information. I was looking for dialogue. I wanted advice."

Fortunately, Talmage was able to beat the odds and is presently SVP global marketing for Bayer HealthCare Pharmaceuticals in Germany.

This is the reality of the human response to a diagnosis. Even in a less dramatic scenario, such as diabetes, the initial diagnosis can send patients into a tailspin. "Patients are diagnosed and told, 'Hey, go take this product, lose 20 pounds and eat better,' and they go home and they have no idea what to do," says Jeremy Shepler, senior director, diabetes marketing, Novo Nordisk. "And the doctor doesn't really have anything to give them."

And that's "only" the emotional effect of diagnosis. An arguably greater strain is gaining access to the medications they need—and figuring out a way to pay for them. Patients could use a little help at this point.

Take your patient by the hand

"The second somebody is diagnosed with cancer or MS, or just about any illness, pretty much their reaction is, 'Oh my God, I have MS or I have cancer,'" confirms Dianne Higgins, RN, director of nursing services, TrialCard.

Higgins heads up TrialCard's version of a patient-support hub, which the company calls Product Access Support Services (PASS). It's essentially a series of patient-centric access and support programs for different pharmaceutical products each aiming to integrate and coordinate all the stakeholders in the healthcare ecosystem with the twin objectives of minimizing barriers and optimizing access.

Higgins says the program provides comprehensive support from when the first script is written through to sourcing a specialty pharmacy, arranging delivery of the drug, training in administration (for, say, an injectable), offering adherence support and motivation, collecting real-world outcomes data and coordinating the various stakeholders.

"We take the patient's hand and walk them through the journey," she says. For most of these programs, TrialCard appoints a case manager as the go-to person for all stakeholders, which can be a nurse or a pharmacist or a social worker, depending on the product and category.

The process starts when the physician—who would

"We don't have a preferred specialty pharmacy, so we will choose which one is most appropriate and can get the drug into the patient's hands as quickly as possible."

Dianne Higgins, RN, *director of nursing services, TrialCard*

80%

of rare-disease patients give drug-makers an overall approval rating for working with payers to assure drug access

—*MM&M* survey on access to specialty medicines

usually hear of the program via the product sales force—faxes the initial script to TrialCard. Higgins's team then immediately reaches out to the patient in a live interaction to verify their insurance coverage, activate patient-assistance or co-pay programs if appropriate and seek approval on behalf of the patient, if necessary.

At the same time, that communication will be shared with the provider to keep it updated. Then TrialCard will source a specialty pharmacy and facilitate the shipping of the product to the patient's home, following up personally with the patient to make sure he or she received the drug.

"We don't have a preferred specialty pharmacy," says Higgins, "so we will choose which one is most appropriate and can get the drug into the patient's hands as quickly as possible."

The payer checkpoint

The specialty surge presents something of a conundrum for payers. Many of the new treatments represent significant breakthroughs in efficacy or mechanism—and in some cases even cures—for previously undertreated diseases. However, the majority of these treatments are expensive.

Caught cold by effective but pricey new treatments like Sovaldi for hep. C, payers have continued to tighten management strategies to deal with the influx of specialty claims. In a recent *MM&M* survey on access to specialty medications, nearly 80% of payers reported they require prior authorization to verify a diagnosis while around one-third require step therapy (trying less expensive treatments before a costlier one). What's more, 92% plan to make those strategies more stringent in the next two years.

In the same survey, many physicians were less than impressed by these measures. "We shouldn't have to beg," one noted. And as one patient put it, "There's really no reason anybody would want to take these type of medications unless they need them."

Having said that, 80% of rare-disease patients gave an overall approval rating to the job that drugmakers do working with payers to ensure access. And almost a third of patient respondents felt that a lack of clinical knowledge on the payer side was hindering access: "The most difficult part of working with insurance providers is that they're uninformed about what a medication actually is"; "companies could work with payers to let them know that this medication, if taken proactively, can actually lower costs in the long run and that this medicine is a necessity … versus a luxury"; "when insurance is calling the shots on whether you receive coverage or not, and they know nothing about the drug or the condition, this becomes a travesty"; "health insurance companies are understaffed in terms of clinicians and researchers who understand new drugs and how they make a life-or-death difference in the treatment of many diseases."

Unsurprisingly, co-pay programs play a major role in the affordability of specialty medicines, particularly some of the new products. IMS Health notes that in some specialty classes, such as MS and rheumatoid arthritis, coupon usage rates can be as high as 70% with terms that reduce out-of-pocket spend to nominal levels as little as $5 a script. The newest class of diabetes drugs, SGLT-2s, also have a high coupon usage, compared to a very low rate for conventional insulins. ■

"There's really no reason anybody would want to take these [meds] unless they need them."

—anonymous patient in a recent *MM&M* survey on access to specialty medicines

80%

of payers report that they require prior authorization to verify a diagnosis

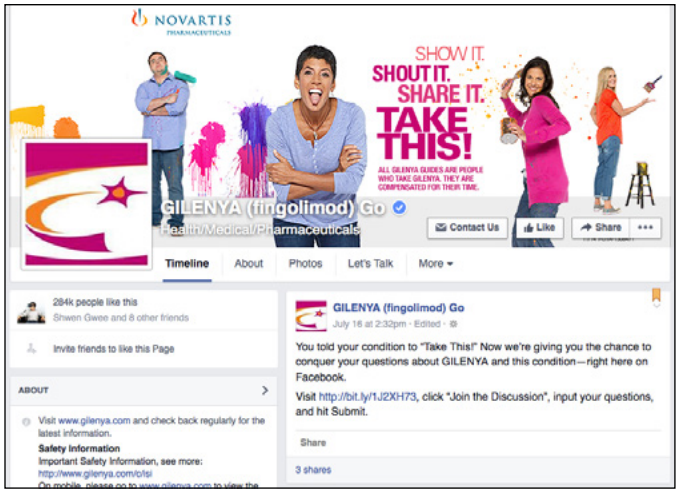
—*MM&M* survey on access to specialty medicines

Postdiagnosis: Engagement, support and adherence

As the locus of support shifts from access to adherence, ongoing education becomes paramount. Industry's latest attempts at improving compliance: comprehensive disease-state programs incorporating an array of offerings

Once the patient starts on a specialty medication, the focus shifts from access to adherence. It's in everyone's interest to make sure the patient follows the treatment regimen, not only in terms of the patient's individual experience but also to reassure the payer that an expensive treatment option isn't going to waste.

Because specialty diseases are often chronic, maximizing adherence and outcomes requires ongoing education and support services. And patients expect the makers of their drugs to provide these.



For Novartis the "social-media ecosystem" cannot be ignored

"Consumers want to be heard, to feel their questions and concerns are of significance, and not that they are there to make money for pharma companies," says MarlaJan DeFusco, lupus patient, health activist and author of Luck Fupus. "The majority of patients aren't demanding or expecting cures, but we deserve to feel better. Pharma needs to ask consumers about their specific needs. Involving the patient is a surefire way to instill trust."

Digital channels have enabled patient programs to become more sophisticated over the past couple of years. Of course, technology alone is of little use without the right combination of content, context and relevance with which to engage patients.

"They expect clear, balanced and actionable information that is accessible wherever they are," says Sandra Shpilberg, VP, strategic marketing and commercial planning, Nora Therapeutics. "Instead of expecting a patient to search for a website containing passive, published information, we should be helping them find us in the context of their daily activities."

To that point, some pharma companies are looking beyond the app and are developing comprehensive disease-state programs that incorporate an array of integrated offerings. Novartis is one.

"We believe in delivering the right drug to the right patient at the right time, which involves having technology, tools and educational support available to patients," said Cathryn Clary, MD, head of US medical and chief scientific officer, US general medicines, Novartis, at the company's recent R&D day.

The 2011 launch of Gilenya was Novartis's first foray into MS, and the company pulled out all the stops to get to know its patients. "We had a lot to learn," admits Clary. "They wanted support and they wanted to be educated, but they also wanted to be inspired."

Novartis rose to the challenge, developing a robust and groundbreaking "social-media ecosystem"—it was the first drug on Facebook and the company claims to respond to posts within 24 hours—and an elite "social care" group that monitors social media for problems. The company also offers nursing support for the duration of treatment and access to a network of Gilenya Guides—patients that help and support other patients.

Novo Nordisk's Cornerstones4Care diabetes program is similarly advanced, offering patients individually tailored educational modules and alerts, access to a personal Diabetes Health Coach and a YouTube channel fronted by web video celebrity Michael Stevens.

"We know that 24% to 36% of first prescriptions aren't filled, so first it drives them through that nonadherence," says Jeremy Shepler, senior director, diabetes marketing, Novo Nordisk. "Once we get them through injection training, they then focus on the lifestyle component. And we follow up with timely calls like, 'Hey it's day 28, have you filled your next prescription?'" ■

"Involving the patient is a surefire way to instill trust."

—MarlaJan DeFusco, *health activist and author*

24%

of first prescriptions aren't filled, with the rate as high as 36%

—Jeremy Shepler, *Novo Nordisk*

Real-World Evidence: Knowledge is power

In addition to smoothing the patient pathway to access and adherence, pharma is learning that demonstrating success to payers is a win–win prospect. The key involves collecting real-world evidence of patient performance

Real-world data is now a "must have" in specialty categories. The obvious reason is that manufacturers need to continuously track product performance, particularly in specialty categories where patient populations may be smaller and breakthrough treatments are often "fast-tracked" to market. However, there are other drivers.

1. Demonstrating value

As healthcare transitions to outcomes-driven reimbursement, payers will increasingly demand real-world data, especially with costly specialty products. A recent *MM&M*/MediMedia Managed Markets survey of payers reported that 56% expect to use data analysis to improve formulary decisions in the next two years.

"For the payer and reimbursement, proving your value—in addition to just the fact that it works and it's safe—is critical," says Greg Madison, president and CEO, Keryx Biopharmaceuticals.

For dialysis patients with chronic kidney disease, Keryx recently launched Auryxia, a breakthrough phosphate binder that reduces the number of potentially harmful injectables patients require during dialysis. Because the drug is only administered in centers, access is essentially governed by formulary decision makers. With clinical trials having shown a reduced need for injectables, along with a 24% reduction in hospitalizations, Madison already has a strong case for cost savings. But if he can supplement it with real-world evidence, further opportunities would beckon. "We just have to up the proof with data," he says.

Novo Nordisk's Shepler has been working with real-world data to prove the value of the Cornerstones4Care program in diabetes. "We already know patients in the program fill 1.4 more prescriptions through the co-pay card, relationship marketing, timely reminders and things like that," he says. "But what we haven't been able to prove is the implication on the A1C data, which is the true measurement of diabetes control. But we're very close to being able to do that."

2. Monitoring the conversation

It has become an essential responsibility of pharma companies to monitor online conversations about their products—not least for warnings of possible adverse events. But the value-add is that it can also lead to positive experiences in facilitating treatment access.

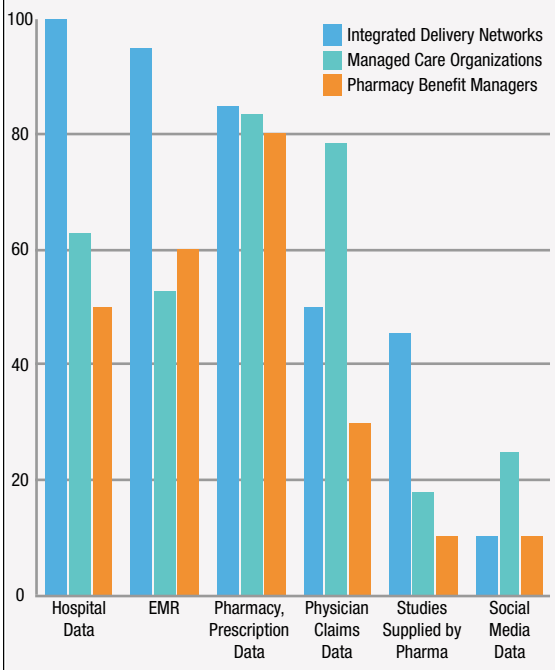
Novartis's Gilenya team recently spotted a Tweet from a patient who revealed that her COBRA insurance wouldn't be covering her medicine for a few weeks and that she would have to stop taking Gilenya until her coverage returned. "We saw that, we Tweeted back, and over a weekend we were able to get her more Gilenya," said Novartis's Clary. "Those are the kinds of services that we are talking about."

3. True patient insights

For companies to truly go "beyond the pill," they must measure not only clinical efficacy but understand the entire patient experience.

Most Frequently Used Real-World Data Sources

Payers' and IDNs' use of different types of RWD



Figures represent % of each organization using the different data sources;
Source: 2014 IMS Health Payer RWE survey, n=70 US payers and IDNs

"We are helping marketers make a strategic shift from their classic vertical product focus to personal product service platforms powered by technology."

—Larry Mickelberg, *partner, chief digital officer, Havas Health, and president, Havas Lynx US*

56%

of payers expect to use data analysis to improve formulary decision making in the next two years

—*MM&M*/MediMedia Managed Markets survey

Real-World Evidence: Knowledge is power

Havas Lynx is helping its clients inject a bit of innovation into the way they learn about disease populations. "We are helping marketers make a strategic shift from their classic vertical product focus to personal product service platforms powered by technology," explains Larry Mickelberg, partner, chief digital officer, Havas Health, and president, Havas Lynx US.

For one particular client, the agency looked at the socioeconomic and physical manifestations of a particular disease across the dimensions of home, work and play and identified partnership opportunities to help the brand create a new service-experience platform. "Some of the partners we identified were people like Verizon and Trip Advisor," he says. ■

"'Beyond the exam room' is going to be critical because that's where the digital health experience comes into play."

—Michele Polz, *head of patient insights, global commercial strategy, Biogen*

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Coordinated Approach: All stakeholders share concerns

The specialty access chain is only as strong as its weakest link. Coordinating everyone's—patient, payer, pharma, pharmacy—efforts across the board fosters the greatest possibility of success

Lynn O'Connor Vos, CEO of ghg (Grey Healthcare Group), paints a playful visual metaphor for "driving high-performance healthcare" by using the image of a car: Health-tech represents the engine, the payer is the driver, the HCP is struggling to stay in the front seat and the consumers are in the backseat trying to grab the wheel. "Pharma is in the trunk," confirms Vos.

Apart from being cute and clever, it conveys all too accurately the challenging dynamic between the various stakeholders along the patient journey. Namely, they don't always pull together seamlessly to give patients optimal access to the treatments they need.

Dianne Higgins, RN, director of nursing services, TrialCard, oversees Patient Access and Support Services (PASS) programs on behalf of pharma clients. The primary goals are to offer a coordinated approach to managing these stakeholders that minimizes barriers for the patient ("first and foremost"), for the provider and for the brand while optimizing patients access to medications and health outcomes.

One pathway to treatment success

Source: TrialCard

The program effectively takes the patient's hand and walks them through their journey. "We provide comprehensive reimbursement support, benefits verification, prior authorization and if an appeal process is needed, we will take care of all of that responsibility," says Higgins. "It's critical, because the cost is oftentimes overwhelming."

TrialCard names a case manager for each patient—usually a nurse but it can be a social worker or a pharmacist, depending on the disease—and they will engage with the patient, offering a gamut of adherence-focused support services from educational content and important updates (such as drug supply shortages) to online tools, reminders and other motivational interventions. The company also operates a 250-seat call center hotline to answer patients' questions on behalf of clients.

"When you have the opportunity to engage the patient in their therapy, either by phone or using technology—such as a Notebook or iPad interaction with an HCP or a health watch—you can really improve their long-term adherence," says Higgins.

The true value of a hub program lies in the ability to coordinate and integrate all of the moving parts in an way that removes barriers and optimizes access and, ultimately, outcomes.

Higgins says this extends to the collection and analysis of real-world evidence. "It's become so critical today because of the changing landscape," she says. "Many of the insurance carriers, and certainly Medicare, are becoming outcomes driven, so we have a team dedicated to addressing the analytics of every project."

John Hosier, former head of commercial operations of the Americas, Eisai, agrees that while these holistic programs clearly improve the patient experience, there is also a cost-saving message to share with the payers. "It's a cost of doing business now in MS," he says. "Everybody who plays in that space has to have an intense program. End-stage renal disease is very much the same way, and diabetes is starting to get there."

Michele Polz, head of patient insights, global commercial strategy, Biogen, says she believes that patients should remain at the center of such programs and that pharma companies should be doing more to understand them. "'Beyond the exam room' is going to be critical for us to understand because that's where the digital health experience comes into play," Polz told

"I would love to see our industry leading in the creation of the ultimate health channel that integrates the patient with pharma, research, medical providers and other patients to best support their health journey."

—Sandra Shpilberg, *VP, strategic marketing and commercial planning, Nora Therapeutics*

250

the number of seats in TrialCard's patient call center

—TrialCard

Coordinated Approach: All stakeholders share concerns

delegates at *MM&M*'s Transforming Healthcare conference earlier in the year. "How do you know what the patient is thinking every day? You can't get that from observing them in the HCP environment of focus groups from behind glass walls. We need to have conversations, not just observations."

And Sandra Shpilberg, VP, strategic marketing and commercial planning, Nora Therapeutics, believes pharma should be playing a pivotal role in galvanizing the various stakeholder groups. "I would love to see our industry leading in the creation of the ultimate health channel that integrates the patient with pharma, research, medical providers and other patients to best support their health journey," she says. ■