

2022 PROGRESS REPORT

Specialty Drug Patient Support Programs



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Forward

In this progress report, AssistRx shares our insights released over the past year about the current state of patient support programs in the specialty pharmaceutical space. Specifically, you'll learn the challenges patients, caregivers and healthcare providers have faced over the past year concerning therapy access, affordability and adherence. You'll also discover ways life sciences organizations can address these challenges through new technologies and patient support program models.

We also cover our latest insights on the unique challenges faced by orphan & rare disease products and retail & specialty-lite products. These product segments have unique characteristics that should be considered in program design and delivery. This report expands upon those considerations and possible solutions.

WHITE PAPER

State of Specialty Therapy Initiation



Introduction

Specialty therapies are the fastest-growing, largest segment of the total pharmacy market in the United States.¹ In 2019, 32 of the 54 novel agents approved by the U.S. Food and Drug Administration (FDA) and 80 of the 135 expanded indications were for specialty medications. In 2019, specialty medications accounted for 75% of the approximately 7,000 prescription drugs in development.² Further, a growing elderly patient population combined with a growing number of chronic and complex diseases is driving more specialty therapies to the market. By 2023, its projected that 65% of new drug launches will be specialty therapies.³

Specialty therapy initiation—or the process of getting patients from diagnosis to prescription fulfillment—is complicated by several factors, including access hurdles put in place by payers, such as prior authorization (PA) requirements, step therapies, etc. These complications are further compounded by manual, time-consuming tasks undertaken by healthcare providers (HCPs) to meet payer requirements. **In fact, the average time to therapy using standard specialty therapy initiation methods is 15 days.**

This report details the needs reported by HCPs and what specialty pharmaceutical stakeholders can do to meet these needs. Specifically, to reduce administrative burden and improve access to therapy for specialty patients, HCPs require a comprehensive specialty therapy initiation solution that streamlines all tasks required for initiation: e-Consent, e-PA, e-Benefit Verification (e-BV), access to financial assistance programs and more.

1. <https://www.pharmacytimes.com/view/taming-the-trend-managing-costs-of--specialty-pharmaceuticals-for-insurers>
2. https://payorsolutions.cvshealth.com/sites/default/files/cvs-health-payor-solutions-a-look-at-specialty-pharmacy-dynamics-briefing-july-2020_ph.pdf
3. <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>

AssistRx Survey

AssistRx surveyed HCPs regarding their current experience initiating specialty therapy. The survey was conducted at the 2021 Healthcare Advocate Summit among hundreds of HCPs involved with medication access, navigation and reimbursement.

The survey consisted of eight questions inquiring about HCPs' top responsibilities, sources of information, tasks that take up the most of their time, tasks they feel need the most improvement and their most valued solution features. Survey respondents included care coordinators, clinical staff, doctors, nurse practitioners, office staff and pharmacy teams. Sixty-three percent of respondents were care coordinators and office staff, and 27% were clinical staff and nurse practitioners.

HCPs using iAssist were able to get their patients on therapy **10 days faster** than HCPs using fax.

This represented a **45% reduction** in time to therapy compared to manual methods.

Survey Findings

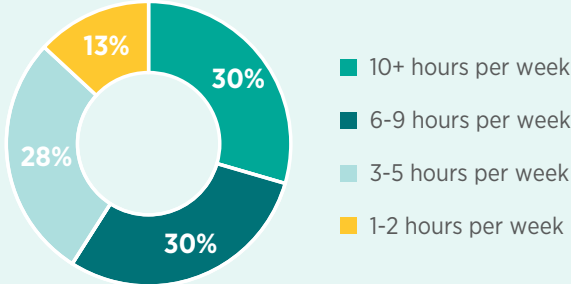
Survey responses revealed that capturing patient consent, obtaining patient coverage and reviewing financial options with patients are HCPs’ top three responsibilities. These tasks are followed by completing PAs and program enrollment. While completing PAs and program enrollment are lower on HCPs’ responsibility list, more than 60% of HCPs reported that the follow-up alone for these two tasks takes more than six hours per week. Thirty percent of HCPs reported that the follow-up alone for these two tasks takes more than 10 hours per week. **For the standard 40-hour work week, that means 25% of HCPs’ time is spent on follow-up.**

There are many factors that shed light on why follow-up on PAs and enrollments is so time-consuming for HCPs in the specialty pharmaceutical space. These factors include but are not limited to:

1. Lack of visibility to comprehensive information,
2. Siloed sources of information and
3. Use of manual methods.

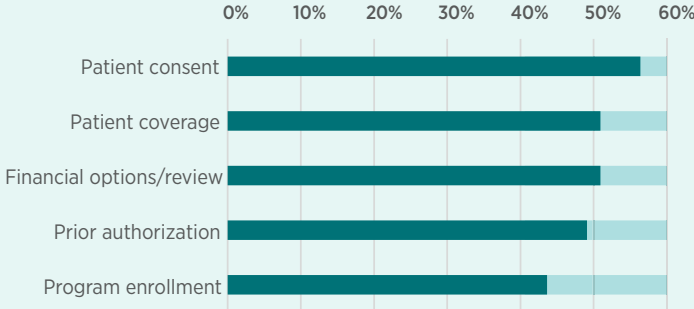
The following findings dive into HCPs’ specific challenges caused by the three aforementioned factors, as well as ways to overcome these obstacles.

How much time does your practice spend on follow-up inquiries for enrollments and prior authorizations in a typical work week?



Survey Question Type: Single-answer multiple choice

What responsibility do you have in initiating specialty therapy?



Survey Question Type: Multiple-answer multiple choice. Includes “Other” answer option with comment field”

Lack of Visibility to Comprehensive Information

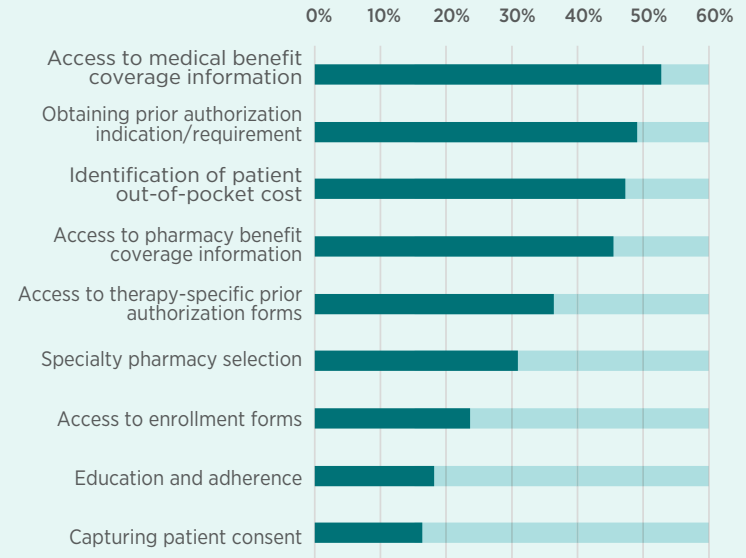
It should come as no surprise that HCPs spend much of their time on PAs and enrollments. PA burden has been a common gripe in the specialty pharmaceutical industry for years, with estimates that HCPs spend up to two business days each week completing PAs.⁴

Many PSP vendors that facilitate digital PA submission have entered the market to address this access barrier. However, submitting PAs is not the holistic challenge for HCPs. In fact, this challenge is predicated by the obstacles HCPs face in gaining comprehensive patient coverage information.

With iAssist, abandonment rates were **reduced by 57.3%**.

Patients routed through a fax-based process were **80 times** more likely to abandon therapy compared to those who were initiated through iAssist.

What areas of specialty therapy initiation need the most improvement?



Survey Question Type: Multiple-answer multiple choice.
Includes "Other" answer option with comment field

4. <https://www.ama-assn.org/system/files/2021-04/prior-authorization-survey.pdf>

Therapy Initiation Requirements

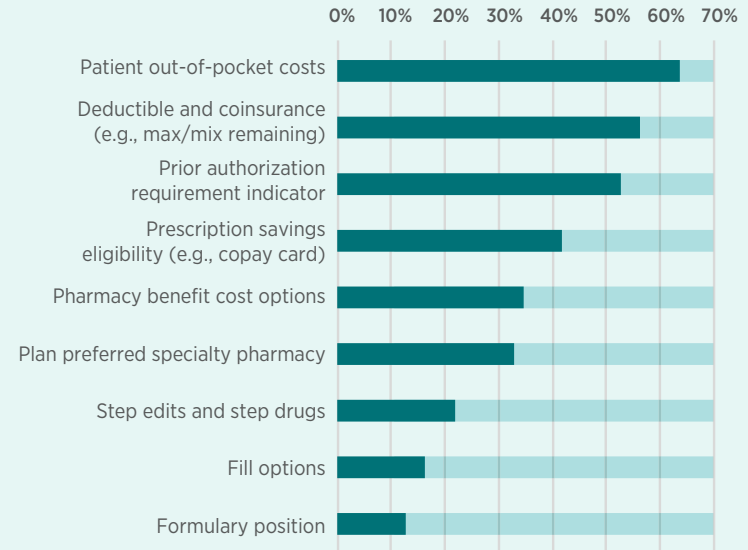
According to survey respondents, specialty therapy initiation steps needing the most improvement include obtaining medical and pharmacy benefit information, PA indication/requirement, therapy-specific PA forms and patient out-of-pocket (OOP) cost.

As expected, access to medical benefit coverage information was the top reported area needing improvement. The medical benefit space has always lagged behind the pharmacy benefit space when it comes to electronic exchange of information. **Interestingly, nearly half of respondents reported obtaining PA indication/requirement as an area needing the most improvement.** This task was followed closely by identification of patient OOP cost (47%) and access to pharmacy benefit coverage information (45%).

The specialty pharmaceutical market is ripe with e-BV and e-PA service providers, yet HCPs indicated access to patient coverage and PA information needs the most improvement. HCPs also indicated that the most important features in a BV solution are patient OOP cost, deductible and coinsurance, PA requirement and financial assistance program eligibility.

Solutions such as real-time benefit check (RTBC) typically feature comprehensive patient benefit information and PA requirements. e-PA tools typically feature PA indication, form generation and electronic submission. Unfortunately, these solutions are sometimes disjointed, not as robust as purported, are based on algorithms rather than current data or have limited reach to payer-covered lives. Further, few solutions can deliver all of this information accurately, comprehensively and in a digestible format.

Choose the 3 features most important to you in a benefit coverage verification service.



Survey Question Type: Multiple-answer (select 3) multiple choice. Includes "Other" answer option with comment field

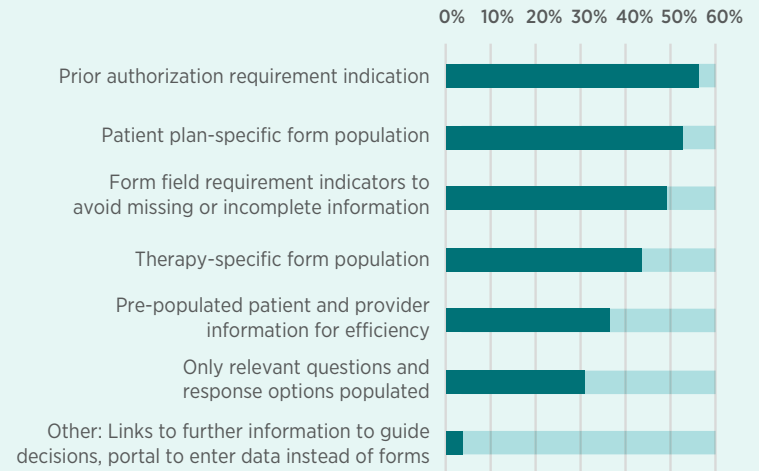
Benefit Verification and Out-of-pocket Cost

Life sciences organizations can present this information to their HCPs through multiple access channels, including a therapy initiation platform, brand website, EHR and the hub. Regardless of channel, coverage information needs to be relayed not only within the HCP’s workflow and at their time of need, but also in an accurate, comprehensive and digestible way.

Regarding accuracy, the method to achieve accurate information varies by PSP—some more successful than others. BV methods include predicting coverage based on algorithms using historical coverage data or establishing direct integrations with payers and PBMs. Both have their pros and cons. Using algorithms, sometimes referred to as artificial intelligence (AI) or its subset machine learning (ML), can deliver accurate coverage information, but require a significant amount of historical data to do so. These algorithm-based solutions may be much less effective at delivering accurate and comprehensive information if there is little data to work from. Additionally, relying on historical information may deliver skewed results if product- and patient-specific coverage trends have recently changed. **Direct integrations, on the other hand, deliver real-time data directly from the source.** This means information is up-to-date and available immediately. However, a PSP vendor needs significant payer reach for this method to be effective. Integrations must facilitate access to a large percentage of payer-covered lives, and they must be holistic in order to deliver accurate and comprehensive information.

Regarding digestibility, HCPs’ ability to absorb and relay coverage information was highlighted in a recent Journal of the American Medicine Association (JAMA) Network study. **The study found that only 21% of HCPs could accurately estimate OOP costs, even when given all the necessary information about a product’s price and a patient’s health plan.**⁵ This means that the presentation of coverage information to the user must be less complex and easier to facilitate informed cost conversations with patients.

Choose 3 features most important to you in a prior authorization service.



Survey Question Type: Multiple-answer (select 3) multiple choice. Includes “Other” answer option with comment field

5. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2785905>

Siloed Sources of Information

PA Requirement

One of the data sets HCPs value most in BV solutions is the PA indication/ requirement. Life sciences organizations should meet this desire by selecting a solution that not only delivers comprehensive coverage information, but also triggers a real-time e-PA submission when a PA is in the way of a fill.

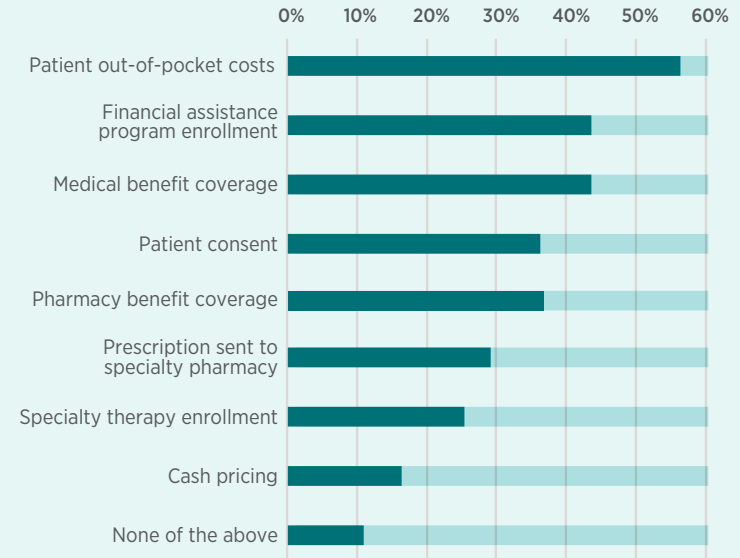
In fact, according to our survey, the features HCPs value most in PA solutions are PA indication, patient plan-specific form population, therapy-specific form population, field requirement indicators, pre-populated patient and HCP information, and population of only relevant questions and response options.

Unfortunately, many PSP e-services on the market today cannot generate a patient plan- and therapy-specific e-PA form for completion and real-time submission. Additionally, access to these capabilities typically requires a disruption in the HCP's workflow, as demonstrated in another survey question.

Fifty-seven percent of HCPs use web-based platforms rather than their EHR to complete a PA. However, when using a standalone platform or website, the HCP may need to re-enter information, complete unnecessary fields and/or double check that all required fields are completed before submission.

Further, if the PA is denied, the HCP may need to call the payer to understand next steps. It is this siloed and complex process that causes 30% of HCPs to spend more than six hours on PA and enrollment follow-up.

Which of the following tasks do you use web-based platforms outside of the EHR/EMR/PM/HIS to complete?



Survey Question Type: Multiple-answer multiple choice.
Includes "Other" answer option with comment field

Affordability

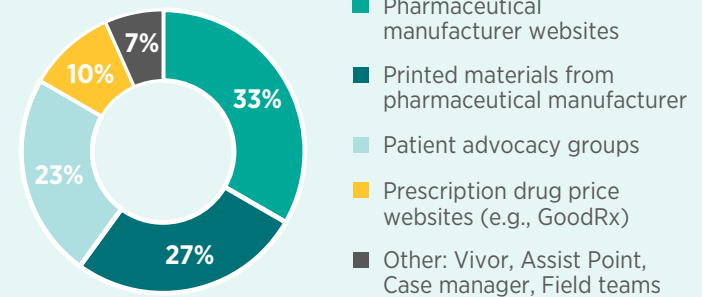
Another therapy initiation task that may disrupt the HCP workflow is identifying patient affordability options, which is HCPs' second top responsibility according to our survey. Like completing PAs, many HCPs (44%) indicated they need to complete financial assistance program enrollment outside of their EHR.

In fact, survey respondents reported they use eight different sources of financial assistance program availability. Each brand may have its own HCP-facing website and/or be featured on the manufacturer's HCP-facing website. Navigating to financial assistance program information is a different experience per brand/manufacturer website. The same can be said for patient advocacy group websites. HCPs using printed manufacturer materials run the risk of losing print forms, using outdated forms or faxing forms with missing, inaccurate or incomplete information. Unfortunately, even the most capable PSP providers cannot compile and present access to the thousands of affordability programs available for today's specialty therapies. This siloed process is likely not only time-consuming and frustrating for HCPs, but also leads to therapy switching if a financial assistance program cannot be found for the prescribed product.

Patients who started therapy through iAssist had a **0.20% abandonment** rate and **0.02% discontinuation** rate.

With iAssist, patients were **78 times** less likely to abandon therapy than those initiated through fax.

What primary resource do you utilize to identify financial assistance programs (e.g., PAP, copay assistance)?



Survey Question Type: Single-answer multiple choice.
Includes "Other" answer option with comment field

Manual Processes

The siloed nature of the specialty pharmaceutical space causes HCPs to leverage various systems, turn to multiple resources, and rely on a multitude of channels (e.g., phone, fax) to follow up on just one patient case. The sector's inability to deliver comprehensive information in a timely manner prevents informed decision making and delays therapy initiation.

The industry has made tremendous strides to develop innovative digital solutions for tasks and processes that used to be entirely paper-based. Cumbersome fax, pen and paper tasks can now be completed with a few clicks. However, HCPs still bounce between systems, online- and paper-based resources, and many, many phone calls.

Several PSP providers have developed digital solutions that enable HCPs to perform electronic consent, prescribing, enrollment, BV, PA and more. Some of these providers have combined these electronic services into one platform. Yet, these platforms are typically focused on a small group of disease states, feature some but not all therapy initiation tasks, include limited services for medical benefit products, or don't have the integrations to deliver information (e.g., PA approval, pharmacy dispense) back to the user.

Whether following a process that is paper-based or a process that features digital solutions but requires a swivel chair, both have manual components that can lead to errors, duplicative efforts, rework and the back-and-forth. These challenges result in delayed access to therapy, lower adherence, poor HCP and patient experiences, and a continuation of factors that drive up the cost of care.

iAssist By the Numbers

795,000+

AssistRx patients served annually

80,000+

registered HCP users

77,000+

connected specialty pharmacies

80%

patient lives found

~30 seconds

patient coverage returned

Conclusion and Solutions

Survey responses clearly indicate that HCPs struggle with lack of access to comprehensive coverage information, available affordability programs, and PA indication and form generation. These challenges continue to prevail in the specialty pharmaceutical space due to limited data returns, siloed systems, and fragmented, manual processes.

HCPs need a comprehensive and automated solution that eliminates manual processes. All therapy initiation tasks required by today's HCPs should be housed in one place and in one simple workflow, removing the swivel chair. HCPs should have real-time visibility to patient status and the corresponding ability to make informed decisions.

By leveraging a comprehensive specialty therapy initiation solution like iAssist, life sciences organizations can offer HCPs access to all e-support services needed to get a patient started on therapy, including manufacturer-sponsored patient support programs, for all products and all in one place.

Founded in 2009 by specialty pharmaceutical industry veterans, AssistRx has the expertise and technology capabilities to build nimble solutions like iAssist that meet the ever-evolving needs of HCPs, patients and the market. Life sciences organizations partner with AssistRx to increase patient uptake, gain visibility and improve patient treatment outcomes.

Introducing iAssist

iAssist is a multi-category, multi-therapy initiation platform that delivers comprehensive, real-time specialty therapy initiation solutions to address the unique needs of HCPs and patients. This Surescripts-certified and HIPAA-compliant platform features real-time capabilities, such as e-Consent, e-Prescribe, real-time e-coverage solutions like Advanced Benefit Verification and e-Medical Benefit Verification, real-time e-PA and electronic appeals, and immediate screening and enrollment into affordability programs.

An all-in-one, automated solution, iAssist simplifies the process of getting patients on specialty therapy, accelerates speed to therapy and streamlines enrollment into crucial patient support programs.

As a connected, data-driven solution, iAssist empowers HCPs to proactively track their patients and support them through real-time visibility into each step of the therapy initiation process.

**Experience the intelligent way
to initiate and advance specialty
therapies by visiting assistrx.com.**

CASE STUDY

Therapy Initiation through iAssist

How iAssist powers access, speed to therapy and adherence.



Experience the intelligent way to initiate specialty therapies.

As the only platform that delivers comprehensive, real-time specialty therapy initiation solutions, iAssist simplifies the process of getting patients on specialty therapy. This free, Surescripts-certified and HIPAA-compliant platform is the only multi-therapy, multi-category solution that supports all healthcare providers' (HCPs) prescribing and program enrollment needs through one easy-to-use workflow.

ACCESS:

iAssist simplifies and speeds patient access to therapy.

SPEED TO THERAPY:

Patients supported by iAssist start therapy sooner.

Challenge

- HCPs prescribing a multiple sclerosis drug through manual methods faced lengthy patient initiation processes and corresponding high abandonment rates.
- Fax and other manual enrollment methods had missing, incomplete and illegible information, which led to rework and back-and-forth.
- Reactionary therapy initiation processes delayed access to therapy driving higher abandonment rates.

Solution

- iAssist workflow enabled HCPs to access and complete real-time patient consent, coverage determination, PA forms and submissions, and screening and enrollment for support programs such as PAP and copay.
- Through an automated workflow, HCPs proactively and electronically completed all therapy initiation steps in under four minutes.

Results

10 HCPs using iAssist were able to get their patients on therapy **10 days faster** than HCPs using fax.

45% This represented a **45% reduction** in time to therapy compared to manual methods.

Challenge

- HCPs prescribing a dermatology drug serving a non-motivated patient population faced a 60.4% abandonment rate.
- Primarily using fax and other manual methods to initiate therapy, HCPs were challenged with process churn and back-and-forth.
- Due to delays in therapy initiation, many patients abandoned or discontinued therapy.

Solution

- Automated iAssist workflow streamlined the steps to get patients on therapy, and facilitated electronic and proactive submission of all required information in one place.
- HCPs were able to get their patients started on therapy faster by a reduction in rework, back-and-forth and inefficient processes.

Results

57% With iAssist, abandonment rates were **reduced by 57.3%**.

80x Patients routed through a fax-based process were **80 times** more likely to abandon therapy compared to those who were initiated through iAssist.

Speed and adherence made easier with iAssist.

iAssist moves patients to therapy faster through automation, reduces therapy delays through real-time e-support services, and delivers patient status information from prescription through therapy access.

ADHERENCE:

iAssist patients are more likely to start and stay on therapy.

Challenge

- HCPs prescribing a women's health drug faced a 13.0% abandonment rate and 5.1% discontinuation rate even though the patient population was highly motivated.
- Many HCPs used fax and other paper-based processes to initiate therapy, which led to process churn and back-and-forth.
- Due to therapy initiation delays, many patients abandoned or discontinued therapy.

Solution

- iAssist workflow enabled HCPs to access and complete real-time patient consent, coverage determination, PA forms and submissions, and screening and enrollment for support programs such as injection training.
- This automated, all-in-one workflow reduced rework, back-and-forth and inefficient processes.

Results

0.2% Patients who started therapy through iAssist had a **0.20% abandonment** rate and **0.02% discontinuation** rate.

78x With iAssist, patients were **78 times** less likely to abandon therapy than those initiated through fax.

Experience the intelligent way to initiate and advance specialty therapies with iAssist.

Affordability

WHITE PAPER

Affordability Programs: Supporting Patients and Healthcare Providers While Building Brand Loyalty



Introduction

The number of patients who struggle to afford their medications has grown over the past decade not because of population growth, but due to the increasing shift of cost share onto the patient. While affordability programs can help patients gain access to and remain on therapy, poorly delivered affordability programs can create frustrating experiences and even not help patients get on therapy. On the other hand, exceptional affordability programs can create differentiated experiences and foster brand loyalty.

Definitions

While affordability programs have been around for decades, the purpose of these programs remains the same: to alleviate the financial distress of eligible patients who need access to therapies. Various affordability programs are offered by different organizations for disparate purposes.

Typically, affordability programs fall into these categories:

Copay assistance programs cover all or part of an insured, eligible patient’s out-of-pocket cost for a brand name drug.

Free drug programs, such as patient assistance programs (PAPs), quick start and bridge, support patients that meet program eligibility criteria.

Alternate funding programs support eligible patients with affording their medications, as well as financial assistance for transportation, housing, childcare and more.



A Growing Need

Prescription drug costs are one of the largest concerns in the specialty pharmaceutical industry: two-thirds of prescribers say the cost of therapy is one of the top three issues facing healthcare today, along with healthcare provider (HCP) burnout and growing chronic disease populations.¹

Fortunately, affordability programs are on the rise to address this concern. For example, copay assistance dollars for commercially insured plans tripled from \$6 to \$18 billion between 2014 and 2020.² These dollars were spread across 669 programs among 253 life sciences organizations — a 48% increase since 2016.

However, while affordability programs continue to grow, the number of Americans who cannot afford their medications is growing at a faster rate.

Six in ten adults currently take at least one prescription medicine, and **eight in ten adults say the cost of prescription drugs is unreasonable.**³

According to a 2021 report, the average specialty drug price rose more than three times faster than the rate of general inflation.⁴ The average annual cost for a chronic disease specialty therapy was \$84,442 in 2020. Yet, the cost would be \$39,068 if the retail price increase for this drug was limited to the rate of inflation from 2006 to 2020.⁴

Prescribers report that 25% of patients request less expensive medication, and pharmacists say **10% of patients walk away without their medication due to cost.**¹ This underscores the adherence challenges patients face due to financial hardship.

Impact on Patients

Patients experiencing higher cost-share tend to reduce use of prescribed therapies. A 2021 study found that 18 million Americans are unable to pay for at least one HCP-prescribed medication.⁵ Over half of Americans are “concerned” or “very concerned” that the cost of healthcare services and prescription drugs will continue to rise to the point they can no longer afford them.⁶

Increasing prescription costs also negatively impact patients beyond their wallet. **Thirty percent of adults claim to have not taken their medicines as prescribed in the past year because of cost.** This includes 16% who report not filling a prescription, 22% who took an over-the-counter drug instead, and 13% who cut pills in half or skipped a dose.³

Not only are cost-burdened patients skipping dosages, but they’re also skipping needed care. **Eighteen percent of American households forgo some degree of needed healthcare** because they are unable to afford it.⁷

The quality of life of patients who choose to remain adherent and pay for the cost of their care is at risk, too, as over one-third of adults report reducing spending on recreational activities to pay for healthcare or medicine.⁷ Additionally, one in eight adults report cutting back spending on food to afford care.⁷

8 in 10 adults say the cost of prescription drugs is unreasonable

10% of patients walk away without their medication due to cost

18% of American households forgo some degree of healthcare

Impact on HCPs and Life Sciences Organizations

It isn't only patients affected by this gap. Few or no available affordability programs for a specialty therapy could foster a perception of lack of access among HCPs. If affordability programs do exist but are not delivered effectively, HCPs may encounter poor experiences and opt for a different therapy that they've found to have reliable access and affordability.

Even if HCPs are aware of therapies' affordability programs, many still believe they have limited power to resolve cost concerns, as 73% find it "somewhat difficult" or "very difficult" to access a patient's out-of-pocket (OOP) cost.¹ Technology solutions like e-benefit verification and real-time benefit check are meant to address this challenge, and many HCP offices transitioned from manual to digital methods throughout the pandemic. Yet, although two-thirds of HCPs report their office has increased its use of technology over the past 18 months, many claim the most frustrating tasks are still finding medication pricing, following up on prior authorizations (PAs), and communicating with insurers and pharmacists.¹ Life sciences organizations can alleviate some of HCPs' frustrations by deploying real-time e-coverage and e-PA solutions regardless of affordability program PA requirements. However, while implementing

technology helps improve program delivery, a truly differentiated affordability program needs to offer the right solutions at the right touchpoints to address the unique needs of patients, HCPs and the product profile.

Designing Affordability Programs that Build Brand Loyalty

In order to build trust with patients and HCPs and capture their brand loyalty, life sciences organizations need to design an affordability program that delivers differentiated experiences at every stage of the patient journey. Whether patients or HCPs are interacting with the program for the first time or completing PAP re-enrollment, the experience must be reliable, supportive and tailored to their unique needs and preferences.

Fortunately, there are solutions on the market like e-consent and electronic copay and PAP enrollment to help life sciences organizations do just that. These tools can help create differentiated experiences and drive program efficiency; however, the key is to implement these solutions with the right balance of technology and talent. When designing an affordability program, life sciences organizations need to

have a comprehensive understanding of their stakeholders and when it's best to support them with technology only- or with technology- and talent-enabled solutions.

Here is a checklist to review when designing an affordability program:

Mostly Technology-enabled Affordability Programs

- Straightforward therapy journey
- Tech-savvy, highly-motivated and somewhat educated patient population
- Tech-savvy HCP population familiar with specialty drug processes
- Payer mix having electronic capability

Mostly Talent-enabled Affordability Programs

- Complex therapy journey and/or combination therapy
- Non-tech-savvy, high adherence risk patient population with low literacy rates
- Non-tech-savvy HCP population with low specialty drug familiarity
- Payer mix having limited electronic capability

The AssistRx Solution

AssistRx understands that affordability programs are a branding opportunity for life sciences organizations. By delivering a seamless experience, timely patient access and ongoing support, HCPs gain trust and positive associations with the organization and brand(s). By delivering meaningful experiences to patients and clearly annotating that they are providing this support — not the patient's HCP or hospital — patients also develop positive associations with the organization and brand(s).

This is why life sciences organizations choose AssistRx to support their affordability programs. We built our proprietary e-Support Services because we understand how automated, digital solutions help reduce therapy delays, enable patient adherence and provide visibility to the patient journey from prescription through therapy access. Our e-Support Services empower patients and HCPs with real-time, self-serve solutions that accelerate patient onboarding and ensure timely access to crucial support services.

Our partners also choose AssistRx because of our expertise in designing patient support programs with the right balance of technology

and talent tailored for our partners' patients, HCPs and products. Some HCPs prefer manual methods. Some patients cannot or prefer not to use technology. This is where talent should step in to provide support. Meeting HCPs in their workflow and patients in their lifeflow, our talented Patient Solutions teams and modular e-Support Services best support patients and HCPs through many access channels (e.g., branded engagement websites, brand(s) websites, our therapy initiation platform, iAssist, and our people — powered by the AssistRx Patient Solutions CRM).

Anchored in a perfect balance of technology and talent, our solutions increase patient uptake, empower life sciences organizations and HCPs with visibility to enhance the patient experience, and improve patient outcomes.

AssistRx e-Support Services:

- AssistRx e-Support Services
- e-Consent
- e-Signature
- e-Prescribe
- e-Coverage Solutions
 - e-Eligibility
 - e-Medical Benefit Verification
 - Advanced Benefit Verification
- e-Prior Authorization
- e-Enrollment
- Financial Assistance Access
 - e-Copay
 - e-PAP
- Pharmacy Selection
- Status Messaging

References

1. Surescripts. Covid-19 Heightens the Need to Improve Interoperability, Provide Price Transparency and Relieve Provider Burnout. August 11, 2021. https://surescripts.com/docs/default-source/default-document-library/surescripts-data-brief-covid-survey-pharmacists-prescribers-2021.pdf?sfvrsn=e56c77ca_2
2. Drug Channels Institute. The 2021 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, p. 177. March, 2021.
3. Hamel L, Lopes L, Kirzinger A, et al. Public Opinion on Prescription Drugs and Their Prices. April 5, 2022. <https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/>
4. AARP. AARP Report: Average Specialty Drug Price Reached \$84,442 in 2020, Rising More Than Three Times Faster Than the Prices of Other Goods and Services. September 28, 2021. <https://press.aarp.org/2021-9-28-Average-Specialty-Drug-Price-Reached-84,442-2020-Rising-Three-Times-Faster-Prices-Other-Goods-Services>
5. Witters, Dan. In U.S., an Estimated 18 Million Can't Pay for Needed Drugs. September 21, 2021. <https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx>
6. Witters, Dan. 1 in 6 U.S. Workers Stay in Unwanted Job for Health Benefits. May 6, 2021. <https://news.gallup.com/poll/349094/workers-stay-unwanted-job-health-benefits.aspx>
7. Witters Dan. In U.S., An Estimated 46 Million Cannot Afford Needed Care. March 31, 2021. <https://news.gallup.com/poll/342095/estimated-million-cannot-afford-needed-care.aspx>

CASE STUDY

Improving Program Health through Tech-enabled Affordability Programs



Experience the intelligent way to initiate and advance specialty therapies.

Believing access to therapy can transform lives, AssistRx is passionate about designing and deploying affordability programs that expand access and improve adherence. Our proprietary e-Support Services facilitate immediate screening, approval and enrollment into affordability programs such as patient assistance programs (PAPs) and copay assistance programs. Learn how our e-PAP and e-Copay solutions improved access, affordability and adherence:

Accelerated Access to Therapy for Oral Oncology Drug

Challenge

Manufacturer of an oral oncology therapy challenged with lack of visibility into the patient journey, fragmented patient and healthcare provider (HCP) experiences, and long turnaround times (TAT) for copay and PAP screening, enrollment and dispense. The previous vendor's inability to integrate resulted in suboptimal conversion rates, gaps in care and lower adherence rates.

Solution

AssistRx deployed a dual-role CRM to facilitate real-time, case level collaboration between the client and AssistRx teams. We also deployed SP integrations to improve visibility and conversion. Consolidating all program services to AssistRx's tech- and talent-enabled solutions improved efficiencies and experiences.

Our patient engagement website and iAssist drove self-serve, real-time copay and PAP enrollment through automated eligibility screening and card generation. Ongoing PAP audit also identified patients who obtained coverage and transitioned them to paid-for script.

Results

In first month post-launch, **AssistRx reduced TAT for free drug dispense by 77%**, and increased PAP conversion with **15% ineligible patients converted to external foundation support**. Over the first four months, we increased the ratio of tech-first copay program enrollments by 22%, reaching **70% copay program enrollments starting tech-first**.

Immediate Free Drug Access for HIV Prevention Therapy

Challenge

Manufacturer of HIV prevention therapies challenged with facilitating timely access to patients for pre- and post-HIV exposure. This patient population also faced access challenges from lack of internet, non-traditional work hours and/or transient status. These access gaps delayed or prevented patients from obtaining HIV prevention therapies, putting more patients at risk.

Solution

AssistRx deployed an iAssist workflow for HCPs and a self-serve branded access website for patients and caregivers. Both solutions featured e-Consent, real-time screening and e-enrollment into PAP and download of a PAP voucher.

These solutions reduced therapy initiation barriers by implementing multiple access channels, 24/7 access, real-time PAP approval, and immediate PAP voucher download for the patient to bring to the pharmacy.

Results

Over 2021, there were nearly **66,000 submissions, 5,000+ unique prescribers, and 50% tech-first enrollments** — 8% of which were made after hours or on weekends. Our solution not only facilitated immediate access to tens of thousands who may not have received timely access but also improved program efficiency through a tech-first approach.

Tech-enabled Reverification Improves Program Efficiency

Challenge

Manufacturer of a portfolio of neurology products struggled with manual PAP reverification efforts and high FTE counts.

Client needed a seamless, electronic solution to speed the reverification/re-enrollment process and transition patients who had obtained commercial coverage.

Solution

AssistRx deployed its Advanced Benefit Verification (ABV) tool—an e-coverage solution that goes above and beyond other real-time benefit check solutions in the market—across the product portfolio.

In under 30 seconds and using just 5 patient identifiers, ABV performs automated batch reverification to identify patients who've obtained commercial coverage.

Results

ABV identified **~20% patients** in each product's PAP had new insurance. Of this population, **~58% were no longer eligible for PAP** based on program business rules. These patients were transitioned to commercial script, resulting in **\$2M+ in cost savings**, lower FTE count and an ongoing automated solution.

AssistRx By The Numbers

AssistRx e-Support Services include e-Consent, e-Prescribing, Advanced Benefit Verification (ABV), e-Medical Benefit Verification (e-MedBV), e-Prior Authorization (e-PA), e-Copay and e-PAP, e-Enrollment and more.

These modular e-Support Services can be integrated into several AssistRx patient- and HCP-facing solutions like iAssist, branded engagement websites, manufacturers' existing brand websites, CoAssist, and Patient Solutions CRM, CaseAssist.

e-Consent

Improves patient consent capture by **90%**.

ABV

Returns comprehensive patient coverage in **under 30 seconds** using just **5 patient identifiers** for **80% payer-covered lives**.

e-MedBV

Returns comprehensive patient coverage in **under 30 seconds** using just **5 patient identifiers**.

e-PA

Pulls correct PA form using the product and patient's plan, generates only relevant questions and response options, enables real-time submission including document upload, returns payer decisions **within minutes** for **80% payer-covered lives**.

Adherence

The image features a dark gray background with the word "Adherence" in white text on the left side. On the right side, there are two thin white lines that curve and cross each other, creating a decorative graphic element.

WHITE PAPER

Enhancing Patient and Healthcare Provider Experiences: Stratification and Engagement Strategies in Our New Normal



Introduction

A one-size-fits-all approach to designing patient solutions programs (PSPs) limits the effectiveness of the therapy initiation process and quality of support offered to patients and their healthcare providers (HCPs). The impact of the COVID-19 pandemic's resulting industry, economic and societal changes has underscored the importance of delivering solutions to patients and HCPs at targeted touchpoints, tailored to their respective lifeflow and workflow. Appropriately stratifying patients by adherence risk and life stage, and stratifying HCPs by technology savviness and specialty drug familiarity, is key. This stratification allows life sciences companies to meet them where they are through the right balance of technology and talent needed to speed the therapy initiation process and improve support through the patient journey.

Unique Stakeholders Require a Stratified Approach

The industry standard for total time to therapy from point of prescription to specialty pharmacy dispense is 14-15 days. With the adoption of e-support services, such as e-prescribe, e-enrollment, e-benefit verification (e-BV) and e-prior authorization (e-PA), the process timeframe can be decreased by 50% or more. This results in increased speed to therapy and improved clinical outcomes for patients who can start their prescribed therapies earlier.

Unfortunately, not all stakeholders take advantage of e-support services. **Physicians report phone and fax as the most commonly used methods for completing PAs.**¹ Additionally, new-to-market therapies do not immediately have the infrastructure in place to support e-BVs, e-PAs, e-enrollment and other processes that require established formulary. As a result, HCPs resort to phone calls and paper-based submissions that lead to back-and-forth and rework due to missing, incomplete or inaccurate information.

\$1,655 is the current average annual deductible, which is double the average of a decade ago

To enhance the HCP experience with the correct balance of technology and talent, it is important to stratify HCPs initiating therapy by technology savviness, office workflow, familiarity with specialty drugs and processes and the volume of patients the HCP sees who could be prescribed your drug. Offices that typically prescribe lesser complex therapies, serve a high volume of specialty patients, have strong technology savviness and familiarity with specialty drugs are good candidates for a more technology-enabled approach. Offices that follow more manual processes, and typically prescribe more complex therapies or have little familiarity with specialty drugs may need a more talent-enabled approach. Once appropriately stratified, your patient support program (PSP) can support the automated processes enabled by e-support services with talented, experienced staff. Thus, staff can focus on more complex cases or supporting the offices who need their support, rather than on administrative tasks. While you may need more staff at program launch, you will be able to reduce the number of full-time employees (FTEs) or refocus those FTEs on value-add touchpoints as your product evolves in its lifecycle.

Patients and caregivers also require a substantial level of understanding and stratification to achieve the best possible treatment outcomes and brand loyalty. Putting the needs of the patient first is more important now than ever because patients are becoming the healthcare industry's largest payers. **The average annual deductible is now at \$1,655, double the average of a decade ago.**² In 2018, patients accounted for 30% of healthcare revenue on the backend, driven by the increased utilization of high-deductible health plans as well as higher copays. These trends have fueled consumerism,³ resulting in better patient healthcare literacy and a more competitive market.

Patients have more resources available to research the market and their treatment options. **Nearly 85% of patients believe they can take responsibility for their own health and access the online resources they need, and the need for life sciences companies to inform patients is more important than ever.**⁴ This is why stratification is key. While some patients are highly motivated and technology-savvy, others may have cognitive or psychiatric challenges and minimal internet access. Further, those highly motivated and technology-savvy patients may still prefer a phone call over digital engagement with your brand. Life sciences organizations must be able to engage patients in their preferred channel and at their point of need.

Strategic Methods to Stratify Healthcare Providers

Some HCPs may be slow to adopt innovations in technology, continuing to rely on methods long abandoned by other industries – such as the fax machine – because they are hesitant to learn and adopt new procedures. The fax machine is well known as a HIPAA-compliant method of transmitting protected health

information (PHI), and a software malfunction or error in a healthcare setting can have far-reaching negative impacts. This lack of trust and change-averse culture within the industry has resulted in a wide range of tech savviness and preferred workflows among HCPs. For example, on the opposite end of the spectrum are the HCPs entering the industry who have never used a fax machine and grew up with an expectation that the best technologies are user-friendly. These tech-savvy offices will want to do everything themselves, while the change- and risk-averse offices will always use fax and may need help along the process due to the lack of visibility facilitated by technology. A great PSP will not require a behavior change from either of these audiences. Instead, they will be able to flex and make the process as simple, seamless and reliable as possible for HCPs across the spectrum.

HCP office setting and familiarity with specialty products will also have an impact on how PSPs should interact with HCPs. A small group practice that mostly refers out prescriptions to the specialty pharmacy is vastly different from a large medical center that has its own specialty pharmacy and patient advocate teams. HCPs with a low level of familiarity with specialty products and the nuances associated with them will require more assistance from your PSP to guide them through the process. Meanwhile, HCPs who are specialists, often within these large medical centers or academic settings, will be able to move patients quickly through the process, leveraging e-support services where available to get their patients on therapy faster.

Another aspect of a HCP's familiarity with specialty products will be the volume of patients they see who can be prescribed a specialty product. A large, technology-savvy office with a high volume of patients may only serve two or three patients who require a specialty drug. These offices will still need support from your PSP. On the other side of the spectrum, rare and orphan disease products are prescribed at such a low frequency that even specialists will need help recalling the available patient support programs for the orphan drug.

Your PSP should help you consider the nuances you can bring to your program's set of services, as well as how they drive value for the patient and HCP. Some of this can be achieved by people and some can be achieved by technology. Your PSP should be able to guide you on when and how to integrate technology. As you consider which partner is best for your program, look for PSPs that have developed these offerings before. These PSPs will be the ones who can provide a consultative approach to your program and help you optimize for the patients and HCPs who leverage their services – whether technology- or talent-driven.

Enhance the Patient Experience by Recognizing their Unique Patient Journeys

The ultimate end-user of your PSP is the patient. While many patients with the same diagnosis will have similar needs, how well your program addresses their unique challenges and preferences will impact the success of your product.

Patients are used to a personalized consumer experience in other industries. The best brands will understand this expectation, and, in addition to providing resources to their patients in their lifeflow, will proactively communicate with patients at their point-of-need using their preferred method of communication.

To demonstrate the importance of program design, consider the patient's journey. First, the patient or, often, their family members begin to believe that there is something wrong. As they progress through their journey, they likely experience lab work and scans, followed by a diagnosis. Depending on the patient and the family, there's some research shortly before or after diagnosis on what treatments are available, cost, what support programs are available, etc. And the patient continues forward until the point where a decision is made to go for treatment or to delay or not pursue treatment.

If your product is a first- or second-line therapy, you'll likely need to stay in touch with this patient along their decision-making journey, and then provide treatment education, support program education, therapy reminders, etc. If your product is a fourth-line therapy, you only have the survivors left. You have the people who have decided to fight. These patients are compliant, but they are sick and worried that they are becoming a burden to their family. They and their caregivers need a very different type of support than a first-line product.

Additionally, you'll need to design your program around your patient population challenges. A second-line multiple sclerosis product patient population will have very different challenges than a plaque psoriasis patient population. The first population may have cognitive challenges, require transportation assistance, refresher injection trainings and require more high-touch adherence support at a more frequent cadence. The plaque psoriasis population may be able to take advantage of self-serve options, such as online PAP or copay enrollment, enrollment into text refill reminders—all driven by e-support solutions.

To determine exactly what your patient population requires from your PSP, you'll first need to stratify them by a number of factors, looking at their patient journey holistically. **Social determinant data—including environment, socioeconomic status, race, gender, and other factors—and behavioral data have emerged at the forefront of patient engagement, and can impact life stage and quality of life score assessments.**⁵

Factors to Consider for Patient Stratification

- Adherence risk captured on the welcome call:
 - PSPs should offer personalized welcome calls to patients that provide an introduction to the medication and the program, as well as perform a risk assessment to identify the patient's historical compliance and adherence.
 - Follow-up touchpoints and patient communication preferences are established during this call. Content and frequency are based on historical compliance and barriers to care.
 - The most widespread medication adherence scale, the Morisky Medication Adherence Scale, is shown to correlate strongly with many fiscally important long-term outcomes.⁶
- Quality of life score (QOLS) – Quality of life measures have become a vital part of health outcomes appraisal, providing a meaningful way to determine the impact of healthcare when a cure is not possible.⁷ Patients with lower QOLS may require more interventions from your PSP, since they are likely to have competing life circumstances, such as strained interpersonal relationships or financial hardships that distract from adherence. Further, this score can help quantify otherwise qualitative measurements of the therapy's impact.
- Life stage – A successful PSP will also stratify patients by life stage. The needs of a Medicare-insured, 70-year-old patient will be much different than a working mother in her 30s. Populations will have different cognitive challenges, support systems, transportation needs and more. Designing PSPs around the challenges specific to diagnosis and life stage can help determine whether high-touch adherence support is necessary or whether patients are apt to take advantage of self-serve options, such as online PAP or copay enrollment or

enrollment into text refill reminders. Further, patients' engagement preferences will evolve as they evolve in their life stage. For example, a pediatric patient will be able to start managing their therapy regimen as they mature. Thus, adherence outreach via email to the patient's caregiver can transition to text reminders to the patient. Further, adolescents and young adults, though often grouped together as ages 15-39, are not a one-size-fits-all population. Navigation programs can better assist when targeted to appropriate developmental ages, such as adolescents 15-18 years, emerging adults 19-25 years and young adults 26-39 years.⁸

- Prescriber, payer and specialty pharmacy – In addition to all the personal elements that can impact the patient journey and their clinical outcomes, patients are also directly impacted by the nuances of their prescriber, payer and specialty pharmacy. For example, some payers may typically deny PAs and require appeals before approving the therapy, certain specialty pharmacies may fill prescriptions less quickly than others, and some physician offices may struggle to submit PAs correctly. It is important to stratify patients on this basis, too, in order to guide stakeholders through the process, set expectations and drive pull-through.

Equally important is how, once you've appropriately stratified patients, you communicate with them at targeted touchpoints. These touchpoints will be at the patient's point of need, and executed leveraging their preferred communication methods noted during the welcome call. **Patient education and ongoing communication are critical for patient understanding and medication persistence, especially with mindful consideration that challenges can ebb and flow over time.**⁹

Examples of Patient Point-of-Need

- Point of prescription – HCPs should have the resources available to them to communicate prescription cost at various pharmacies, PSP offerings, any patient assistance programs the patient may qualify for and answer any questions about their medication.
- First administration – If your product is an HCP-administered product, your PSP should confirm with the patient that they can make their appointment and with the office that the medication is ready. If your product is a self-administered product, such as self-injectable, your PSP should provide or coordinate with a third-party adherence vendor to perform injection training and first dose observation, if required. Regardless of the method of administration, your PSP clinical resources should be able to communicate the importance of starting and remaining on therapy, the process, potential side effects and determine any patient needs.
- Onset of side effects – Side effects for some therapies can have such a large impact on patients that they decide to forgo their treatments. To plan for this, your patients should be educated—by their HCPs, your PSP and through your patient-facing engagement site—of the side effects and when they can expect to begin experiencing them. A 2019 study found when learning about side effects, patients want to know how likely they are to experience side effects and the timelines associated with them. They are also interested in learning the long-term benefits of therapy.¹⁰
- Drop-off point – Many therapies have a known drop-off point—for example, first refill. This moment deserves a communication of its own to ensure continued adherence. This touchpoint can help your patient work through any adherence risks and ensure they have all the resources available to continue therapy. Further, possible drop-off should be identified early for timely intervention. For example, if a

therapy isn't refilled, this status can trigger a phone call, text or email to the patient to determine the reason behind the drop and next steps. Another point of drop-off is the point of apparent clinical efficacy. When patients begin seeing and feeling the positive effects of therapy, their first instinct may be to discontinue medication because they feel that they are no longer sick. Your PSP should include the point where most patients begin feeling these positive effects as a targeted touchpoint to remind patients they need to continue therapy to sustain positive outcomes. In a meta-analysis that analyzed different text-messaging designs, it was determined that **text messaging doubled the odds of medication adherence and improved overall adherence rates by 17.8%**. Overall, text messaging appears to be a promising tool for promoting medication adherence.⁹

Text messaging doubled the odds of
medication adherence and improved overall
adherence rates by **17.8%**

The AssistRx Solution

Because of the wide range of patient and HCP expectations, comfort with electronic services and the impact the COVID-19 pandemic has had on industry and individual economic and social circumstances, life sciences organizations need to stratify both sets of stakeholders accordingly, and implement targeted touchpoints to ensure their patients get the best outcomes from therapy. By following the best practices detailed in this white paper, organizations build patient journeys that improve adherence and build brand loyalty for their products.

A key part of the successful delivery of a specialty program is engaging with knowledgeable patient solutions and technology providers that can support the product in the market. Your partner should have the infrastructure and expertise necessary to support your program, staff that care passionately about your patients, and experts that can recommend the appropriate services. As your product moves through its lifecycle, your vendor should be able to flex and evolve to meet the needs of the product's patient and HCP populations.

AssistRx partners with the nation's largest life sciences organizations to deliver patient solutions programs anchored in the perfect balance of technology and talent. Our solutions increase patient uptake, empower life sciences organizations and HCPs with visibility to enhance the patient experience, and improve patient outcomes. Through our interoperable, agnostic technology, we offer patients and HCPs real-time e-Support Solutions that facilitate informed decision making and timely access to therapy. These solutions, combined with passionate and talented personnel, deliver services that fit into the patient lifeflow and HCP workflow across access channels.

AssistRx e-Support Services:

- e-Consent
- e-Prescribe
- e-Coverage Solutions
 - e-Eligibility
 - Advanced Benefit Verification
 - e-Medical Benefit Verification
- e-Enrollment
- Financial Assistance Access
 - e-Copay
 - e-PAP
- Specialty Pharmacy Selection
- Status Messaging

Accessed Through Various Channels:

- Existing Brand(s) Website
- Branded Patient & HCP Engagement Website
- iAssist, the AssistRx specialty therapy initiation platform
- CoAssist, the AssistRx tech-first therapy initiation and fulfillment solution
- AssistRx Patient Solutions CRM

As a chosen service provider, we serve as an extension of our clients, and leverage our patient support expertise and leading technology to provide unique and comprehensive solutions for programs of all sizes. With solutions that span the patient journey, we continually provide holistic and actionable insights that drive brand performance and improve the experience for patients and HCPs caring for them.

References

1. 2019 AMA Prior Authorization Physician Survey available at: <https://www.ama-assn.org/system/files/2020-02/prior-auth-2019.pdf>.
2. 2019 Employer Health Benefits Survey, Kaiser Family Foundation available at <https://www.kff.org/health-costs/report/2019-employer-health-benefits-survey/>
3. Jones Sanborn, Beth. "Patients Are the New Payers in Healthcare." *HealthcareITNews*, 6, Feb. 2018, <https://www.healthcareitnews.com/news/patients-are-new-payers-healthcare>.
4. Morrison, Anton. "The Evolving World of Pharma Marketing." *Pharmacy Times*, 28, May 2020, <https://www.pharmacytimes.com/news/the-evolving-world-of-pharma-marketing>.
5. Heath, Sara. "Using Risk Stratification in Patient Engagement Strategies." *Patient Engagement HIT*, 19 July 2017, <https://www.patientengagementhit.com/news/using-risk-stratification-in-patient-engagement-strategies>.
6. Uchmanowicz, B., Jankowska, E. A., Uchmanowicz, I., & Morisky, D. E. (2019). Self-Reported Medication Adherence Measured With Morisky Medication Adherence Scales and Its Determinants in Hypertensive Patients Aged ≥60 Years: A Systematic Review and Meta-Analysis. *Frontiers in pharmacology*, 10, 168. <https://doi.org/10.3389/fphar.2019.00168>
7. Burckhardt, C. S., & Anderson, K. L. (2003). The Quality of Life Scale (QOLS): reliability, validity, and utilization. *Health and quality of life outcomes*, 1, 60. <https://doi.org/10.1186/1477-7525-1-60>
8. Pannier, S.T., Warner, E.L., Fowler, B. et al. Age-Specific Patient Navigation Preferences Among Adolescents and Young Adults with Cancer. *J Canc Educ* 34, 242-251 (2019). <https://doi.org/10.1007/s13187-017-1294-4>
9. Medication Adherence: The Elephant in the Room. Jennifer Kim, PharmD, BCPS, BCACP, CPP; Kelsy Combs, PharmD; Jonathan Downs, PharmD; Frank Tillman III, PharmD Candidate. *US Pharm*. 2018;43(1)30-34.
10. Patient Counseling Approaches to Enhance Medication Adherence, Cortney M. Mospan, PharmD, BCACP, BCGP, *US Pharm*. 2019;44(6):15-18.

CASE STUDY

Driving Patient Adherence Through Tech + Talent



Introduction

Patient adherence to any specialty therapy can be challenging. High out-of-pocket (OOP) costs, complex dosing regimens, difficult methods of administration and/or significant side effects are just some reasons patients struggle with remaining adherent to their medications.

Specialty therapy adherence among patients experiencing mental health challenges and/or cognitive impairments can be even more challenging. According to a 2022 HCPLive article, patients on a complex antipsychotic polypharmacy therapy regimen having frequent dosing and a complicated administration may be deterred from adhering to therapy.¹ Further, studies of chronic disease patients found that these patients are typically taking multiple therapies and facing lower adherence rates.¹

Improving adherence among specialty patients having mental health challenges and/or cognitive impairments may require more than technology solutions. The human element may be required for certain touchpoints in the patient's journey. Patients facing severe depression, memory loss and/or paranoia may be best served by an individual who displays empathy and holds extensive experience in supporting this patient profile. Patients who are transient and/or supported by multiple caregivers may need a single point of contact to coordinate their care.

This is why AssistRx built our solutions to be nimble, modular and able to be tailored to life sciences organizations' needs. We know cookie-cutter patient support programs do not best serve patients. Successful patient support programs require the perfect balance of technology- and talent-enabled solutions tailored to the patient, healthcare provider (HCP) and product profile.

1. HCPLive. Real-World Insights Into Unmet Needs Among Patients With Schizophrenia. March 14, 2022. <https://www.hcplive.com/view/real-world-insight-into-the-unmet-needs-among-patients-with-schizophrenia>

Challenge

A manufacturer of an oral therapy indicated for Huntington's Disease (HD) and Tardive Dyskinesia (TD) was challenged with patient adherence among its patient population having movement challenges and cognitive disorders. Patient cognitive challenges required significant communication outreach with the patient, multiple caregivers and the patient's HCP. Additionally, the therapy had a complex titration and ongoing maintenance regimen.

Solution

AssistRx built a comprehensive patient support program that included a branded patient- and HCP-facing engagement website, our Patient Solutions clinical and non-clinical teams – powered by our CRM, and our non-commercial pharmacy.

Call center nurses delivered site of care coordination, patient transportation support, patient and caregiver education, targeted adherence outreach at identified points of dropoff, and coordination if re-titration was needed. Case managers delivered proactive education to HCPs about prior authorization requirements such as Letters of Medical Necessity, as well as coordination with specialty pharmacies to drive conversion. Pharmacy teams facilitated free drug dispense, dose monitoring, and coordinating with HCPs if re-titration was required.

Results

Specialty pharmacy triage improved to 1.2 days due to HCP education efforts and the efficiencies gained from using electronic methods. Clinical and non-clinical team member support **improved refill rates by 73% for TD patients and 84% for HD patients.**

Orphan and Rare Disease Products

WHITE PAPER

Orphan Drugs: Unique Challenges Faced by Patients and Healthcare Providers and How to Best Support Them



Introduction

The number of recognized rare diseases in the United States has increased in recent years, resulting in growth in the orphan drug market. To successfully capitalize on the orphan drug market, life sciences organizations need to understand the challenges healthcare providers and patients face. By empathizing with and becoming a trusted resource to this community of providers and patients, life sciences organizations can not only improve patient adherence and treatment outcomes, but also build positive brand association and loyalty.

Current State of Rare Disease in the U.S.

Orphan drugs are most often used to treat or prevent a rare disease. In 1983, The Orphan Drug Act was passed to encourage increased development of therapies to treat patients who had been neglected due to small patient population sizes. Further, the Orphan Drug Act gave hope to these patients and their families, as many had been excluded from the blockbuster treatments existing at that time.

Since then, the U.S. has seen a dramatic increase in the number of recognized rare diseases. For context, there were **5,857** cataloged rare diseases in 2009; today this number is over **7,000**.^{1,3}

With continued scientific advances and a growing commitment of policy makers to adopt precision medicine, the amount of recognized rare diseases will continue to grow.³ Rare disease patient populations are also becoming more targeted due to these scientific advances – about a quarter of orphan drug approvals target populations smaller than 5,000 patients.⁴ Thus, while the number of recognized rare diseases continues to grow, the size of patient populations treated by various orphan drugs continues to decline. These trends further complicate an already complex space, resulting in a growing need for educational, access and adherence resources.

A rare disease is a condition that affects fewer than 200,000 people in the U.S. The current state of rare disease in our nation includes:

- Over 7,000 rare diseases¹
- More than 30 million people affected by rare diseases¹
- 95% of rare diseases do not have any treatment options²

5,857 cataloged rare diseases in 2009

7,000+ cataloged rare diseases today

Growth of Orphan Drugs in the U.S.

According to a 2017 study, the orphan drug share of new drug approvals increased from **10%** of all drug approvals in 1998 to **44%** in 2017.⁵

New orphan drug approvals increased from

10% in 1998 to **44%** in 2017

Additionally, based on consensus forecasts, the value created by orphan research and development (R&D) drugs is 20 percentage points higher than non-orphan drugs.⁶

Given the increase in approvals of orphan drugs, it is not surprising that orphan drug sales are expected to increase. In fact, worldwide orphan drug sales are forecasted to grow at a compound annual growth rate of **12.3%** from 2019 to 2024, which is approximately double the rate forecast for the non-orphan drug market.⁷

Orphan drug sales forecasted to grow at

2x the rate of non-orphan drug sales

By 2024, the value of the global orphan drug market is predicted to reach \$242 billion and capture one-fifth of worldwide prescription sales.⁷ Fueling this growth is the Food and Drug Administration's (FDA) objective to approve more orphan drugs to drive down price. During the 37th annual

J.P. Morgan Healthcare Conference in 2019, FDA Commissioner Scott Gottlieb announced that to meet this objective, the FDA is approving like therapies. As the amount of orphan drugs increase and are approved by the FDA, life sciences organizations face more competition, underscoring the need to build brand loyalty among patients, caregivers and providers.

Additionally, orphan drugs are being prescribed for conditions that aren't orphan conditions and can be treated with other therapies. In 2017, **seven of the top 10** best-selling drugs were orphan drugs that were widely prescribed for non-orphan indications and off-label uses.⁵

7 of the top **10** best-selling drugs were orphan drugs widely prescribed for non-orphan indications and off-label uses

In summary, the development and use of orphan drugs in the U.S. is growing rapidly to support both rare disease patients and patient populations outside of this space. While the rare disease community celebrates advancements in therapy and growing treatment options, many providers, patients and caregivers continue to face significant access challenges.

Understanding Challenges Faced by Providers

Physicians and their teams face unique challenges in the orphan drug space. A research study conducted among 1,632 healthcare professionals who diagnose and treat rare disease patients found that **88%** of healthcare providers agree there is need for more professional content on rare diseases.

88% of surveyed providers agree there is need for more professional content on rare diseases

According to the study, both primary care physicians and specialists treat an average of 12 diagnosed or suspected but undiagnosed rare disease patients.

Because the patient population is small and physicians don't often treat these patients, it is difficult for them to keep up with new drugs on the market and expanded indications. Not only are these therapies not on their radar, but there are limited resources for physicians to turn to for more information on these therapies and the rare diseases they treat.

It is also challenging for physicians and office staff to stay up to date on available support programs. Awareness of a program is only half the equation, however. Staff must also recall how to access the program, including website or portal information, required forms and patient information, program processes and much more. Like physicians, staff also have limited resources to turn to for guidance. This can negatively impact patient access and treatment outcomes.

Challenges faced by these providers include:

- Lack of networking opportunities or access to experts related to specific rare diseases
- Lack of awareness among their professional specialty
- Lack of means to collaborate with colleagues with knowledge/experience in diagnosis and/or treatment
- Lack of proper training and education
- Lack of means to coordinate care with other clinicians handling the same case⁸

It's important for life sciences organizations to understand these challenges in order to develop educational resources to meet this need and become a supportive, trusted resource. Supplying these resources helps not only build trust and positive brand association among and providers also ultimately facilitates better care for patients. Additionally, it is important to understand the challenges patients face in order to develop solutions that will further build brand loyalty.

Understanding Challenges Faced by Patients

While providers in this space tend to struggle with staying up-to-date on specific rare diseases, patients in this space are very informed. As such, these patients and their caregivers may have to fight misconceptions, and they take on the role of their own advocate by routinely seeking information about their disease from sources other than their provider. At the same time, these patients and their caregivers must also navigate financial, logistical, emotional and treatment-related challenges.

A typical rare disease patient faces:

- Lack of resources to learn about their disease and therapy options
- Lack of access to appropriate specialists, diagnostic testing and timely diagnosis
- Significant medical costs, including physician visits, travel, testing and more
- Lack of tools to manage appointments, transportation and therapy regimen
- Disease state-related symptoms and treatment side effects
- Lack of emotional support for the patient and their family and friends

Patients visit **7.3** physicians before receiving a diagnosis and often experience symptoms for **4.8 years** on average before they are diagnosed

Lack of Educational Resources and Emotional Support

Many patient advocacy groups and disease state-specific non-profit organizations exist to support rare disease patients. Although patient advocacy groups can take many different forms, most are dedicated to sharing resources, raising awareness about the rare disease and advancing research. These advocacy groups often share some mutual goals with life sciences organizations. They want to empower patients to make informed decisions, which presents an opportunity for organizations to partner with advocacy groups to provide them with educational materials they can share with patients. They also want to provide patients and their caregivers with an outlet to connect with other patients and their families who are navigating the same journey. These groups are very helpful and influential in the rare disease space, and it behooves manufacturers to connect with them to better support patients and their families.

Lack of Access to Appropriate Specialists and Timely Diagnosis

Patients with rare diseases often struggle to receive timely diagnosis and support. According to a recent study, patients visit **7.3** physicians before receiving a diagnosis and often experience symptoms for **4.8** years on average before they are diagnosed.⁹

The writers of this study state that the “lack of understanding of where to refer patients is as much to blame for delayed diagnosis as a lack of rare disease knowledge, and highlights the need for more robust physician education regarding targeted referrals”. This leads to the conclusion that patients are seeking help from providers, but providers struggle to recognize the disease and refer the patient to the appropriate specialist.

The overwhelming process of finding an accurate diagnosis and therapy to treat the disease sometimes requires extensive travel by the patient, which can be physically draining, especially if their condition has regressed. This underscores the advantages of telehealth, which can have numerous advantages as well as the potential to improve a patient’s outcome.

Significant Medical Costs

Rare disease patients are also grappling with significant medical costs to access their medication, physician appointments, testing and other therapies associated with their disease state. According to a 2019 orphan drug report, the mean orphan drug cost per patient of the top 100 U.S. orphan drugs was almost 4.5 times greater than the non-orphan drug cost.⁷ The mean cost of an orphan drug per patient per year was found to be **\$150,864** versus **\$33,654** for a non-orphan drug.⁷

\$150,864 mean cost of an orphan

drug per patient per year versus

\$33,654 for a non-orphan drug

Combination therapies are becoming more common to treat rare diseases as well, and recent studies have shown that personalized combination therapies deliver better treatment outcomes. A 2019 study found that of the cancer patients who were highly matched with combination treatments that targeted multiple alterations, 50% saw their disease respond compared to 22% that were unmatched or less well matched.¹⁰ The unfortunate part of this equation, however, is that the cost of therapy is significantly higher and navigating coverage and financial assistance options becomes much more complex for the patient.

Life sciences organizations have an opportunity here to provide patients and caregivers with educational materials and supportive communications that position the organization as a trusted resource. The key is to deliver this information at the right time and through the right channel in order to drive the most value. One channel currently experiencing growth in adoption is telehealth.

The Role of Telehealth

Telehealth allows patients to receive remote consultations through video chat, calls and emails. This technology has immense potential for patients with rare diseases, especially considering specialists who typically diagnose rare disease patients may be scattered throughout the United States. Some of these diseases have nonspecific symptoms that may be confused with more common diseases by non-specialists. Receiving an early diagnosis is an obstacle for these patients, and speaking to different specialists via telehealth services can help patients determine the root of their symptoms early.

COVID-19 is transforming the healthcare industry through increased support for telehealth. In 2019, only 8% of patients had tried telehealth¹¹. In recent months, interest in telehealth has grown tremendously. As an example, after the expansion of virtual health care staff by NYU Langone Health, virtual urgent care visits grew by 683% and non-urgent virtual care visits grew by 4,345% between March 2 and April 14, 2020.¹² Further, Frost & Sullivan forecasts a **sevenfold growth** in telehealth by 2025.¹³

Forecasted **600%**
growth in telehealth by 2025

Telehealth is especially important for patients with rare diseases in the COVID-19 environment because many of these patients are immunocompromised and are at risk going into a public office. Additionally, changes to telehealth utilization and payment reform brought on as a response to COVID-19 may become permanent with recently introduced legislation. For example, House Telehealth Caucus leaders introduced the

bipartisan bill, the Protecting Access to Post-COVID-19 Telehealth Act, in July of 2020, to eliminate restrictions on telehealth use in Medicare. Numerous payers have also expanded telehealth coverage to increase access to care during the pandemic.

Best Practices for Life Sciences Organizations

Life sciences organizations need to engage with providers and patients and offer multiple access points. To meet patients where they are, organizations should provide information and support via multiple channels, including virtual touchpoints, and partner with advocacy groups to reach patients and caregivers at their convenience. To meet providers where they are, it's critical to understand their channel preference and to supply them with materials to increase their knowledge and network. This will ultimately facilitate timely diagnosis and therapy initiation. The research study conducted among healthcare professionals who diagnose and treat rare disease patients also identified their preferences for resources and educational tactics.⁸

Research study respondents rated the following as extremely/very valuable tactics to best inform them:

- Single-topic or multi-topic medical journals online and in print
- Disease state websites/multimedia resource centers
- Disease-specific symposia at medical conference
- On-demand video and audio
- Expert key opinion leaders (KOLs) speaker programs⁸

Become a Trusted Resource

As demonstrated, research has confirmed the need for educational materials on rare diseases and orphan drugs. Offering educational resources to both providers and patients is how life sciences organizations can establish themselves as a trusted partner to the community. Serving the rare disease community in this way helps build positive brand association and brand loyalty with patients and providers. Brand loyalty and optimal treatment outcomes through access and adherence is critical in this space to ensure patients are staying as healthy as possible.

One best practice is to offer an access point for education in the form of video or podcast. This media could include information about the disease state, available resources and support groups, the therapy itself and testimonies from patients and their families.

For providers, having access to educational videos and podcasts on disease states and orphan drugs is a key strategy to increase awareness. The ability to review the media during down time or on a lunch break is especially helpful for healthcare providers. Further, this media is especially helpful in that it's easy for them to share with other stakeholders like office staff, another provider taking care of their patient or other providers in their network who treat this rare patient population.

Educational videos and podcasts have benefits for patients, too. They provide information in a digestible format that can be paused, slowed down, replayed and more. This is especially beneficial for patients affected by cognitive and/or sensory impairments. Videos also enable patients to share what they're experiencing with their care team, caregivers, other patients in the community, etc.

Partner with Advocacy Groups

Patient advocacy groups have grown in the last 10 years. In 2018, Kaiser Health News identified 1,215 U.S. nonprofits that function as a patient advocacy group.¹⁴ It's imperative for life sciences organizations to ally with these groups in order to understand the patients they treat, precisely develop solutions and support programs to meet their needs, and educate patients and caregivers about the resources available to them.

A recent study found that rare disease advocacy groups want to be treated as respected partners, not just as an intermediary between the industry and patients.¹⁵ This same study also found that while advocacy groups want to enhance patient-focused drug development, they also take pride in protecting their community members. Therefore, advocacy groups need to see evidence that a life sciences organization looking to partner with or seek access to their community truly cares about the patient journey before making a request like participation in a clinical trial or focus group. To do this, life sciences organizations should solicit feedback from advocacy groups on patients' most common challenges and needs, share appropriate educational materials with advocacy groups and include links to these organization's websites on the brand website.

The AssistRx Solution

No matter the disease state or size of a program, life sciences organizations must deliver a reliable, supportive and personalized experience that demonstrates to patients and providers they are an empathetic, trusted resource. By following the best practices detailed in this white paper, organizations can capture and retain brand loyalty for their orphan drug while also providing patients and providers the educational and support resources they desperately seek.

A key part of the successful delivery of an orphan drug program is engaging with knowledgeable patient solutions and technology providers that can support the product in the market. Orphan drugs are low-volume and high-cost products, so it's necessary to partner with a vendor that has the infrastructure to support a small program, staff that care about the program and experts that can recommend the appropriate services. Additionally, the vendor should be able to evolve with the product throughout its lifecycle in a way that makes sense for the product's patient and provider populations.

AssistRx does just that. Anchored in a perfect balance of technology and talent, our solutions increase patient uptake, empower life sciences organizations and providers with visibility to enhance the patient experience, and improve patient outcomes. Through our agnostic technology, we offer patients and providers real-time e-support solutions that facilitate informed decision making and timely access to therapy. These solutions can be integrated into multiple access channels to meet patients in their lifeflow and providers in their workflow.

AssistRx e-Support Services:

- e-Consent
- e-Prescribe
- e-Coverage Solutions
 - e-Eligibility
 - Advanced Benefit Verification
 - e-Medical Benefit Verification
- e-Enrollment
- Financial Assistance Access
 - e-Copay
 - e-PAP
- Specialty Pharmacy Selection
- Status Messaging

Accessed Through Various Channels:

- Existing Brand(s) Website
- Branded Patient & HCP Engagement Website
- iAssist, the AssistRx specialty therapy initiation platform
- CoAssist, the AssistRx tech-first therapy initiation and fulfillment solution
- AssistRx Patient Solutions CRM

Our solutions can also facilitate notifications or reminders that present the provider with information including, but not limited to, dosage or titration alerts, allergies, contraindications and more. In addition to notifications, these solutions present available support program information and requirements. The live chat feature can be staffed by both clinical and non-clinical staff to best support the provider.

To accommodate rare disease patients and caregivers who are likely knowledgeable about their disease state and therapy but may lack awareness of available support programs, we can stand up branded engagement websites or add onto the brand's existing website. These websites can feature many of the above mentioned patient-facing e-Support Solutions, as well as:

- Prescriber look-up
- Facility look-up
- Clinical and non-clinical field team staff calendaring tool
- Travel/lodging receipt upload and reimbursement
- Educational resources about therapy management, working with the patient's care team, etc.
- Information about other local/national support resources
- Live chat to provide immediate support by clinical and/or non-clinical staff

As a chosen service provider, we serve as an extension of our clients and leverage our patient support expertise and leading technology to provide unique and comprehensive solutions for programs with small patient populations. With solutions that span the patient journey, we continually provide holistic and actionable insights that drive brand performance and improve the experience for patients with rare diseases and providers caring for them.

References

1. U.S. Food and Drug Administration. Rare Diseases at FDA. February 20, 2020. <https://www.fda.gov/patients/rare-diseases-fda>
2. America's Biopharmaceutical Companies. Rare Diseases by the Numbers. <https://qa-innovation.mrmdigital.com/about-us/commitment/research-discovery/rare-disease-numbers>
3. Aitken M, Kleinrock M. Orphan Drugs in the United States: Providing Context for Use and Cost. October 2017. <https://rarediseases.org/wp-content/uploads/2017/10/Orphan-Drugs-in-the-United-States-Report-Web.pdf>
4. Aitken M, Kleinrock M. Orphan Drugs in the United States: Exclusivity, Pricing and Treated Populations. December 2018. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states-exclusivity-pricing-and-treated-populations.pdf>
5. America's Health Insurance Plans. The Rise of Orphan Drugs. September 2019. <https://www.ahip.org/resources/the-rise-of-orphan-drugs>
6. Pomeranz K, Siriwardana K, Davies F. Orphan Drug Report 2020. April 2020.
7. Pomeranz, Karen. Orphan Drug Report 2019. April 2019. <https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma%20Orphan%20Drug%20Report%202019.pdf>
8. Frontline Medical Communications. The Challenge of Diagnosing and Treating Rare Diseases. January 2014. https://www.frontlinemedcom.com/wp-content/uploads/RareDiseases_Infographic_May_2014.pdf
9. Engel P, Bagal S, Broback M, et al. Physician and Patient Perceptions Regarding Physician Training in Rare Diseases: The Need for Stronger Educational Initiatives for Physicians. 2013. <https://www.engagehealth.com/current-issues/insights-publications/physician-and-patient-perceptions-regarding-physician-training-in-rare-diseases-the-need-for-stronger-educational-initiatives-for-physicians/>
10. Sicklick J, Kato S, Okamura R, et al. Molecular profiling of cancer patients enables personalized combination therapy: the I-PREDICT study. April 22, 2019. <https://www.nature.com/articles/s41591-019-0407-5>
11. American Well. Telehealth Index: 2019 Consumer Survey. August 27, 2019. <https://static.americanwell.com/app/uploads/2019/07/American-Well-Telehealth-Index-2019-Consumer-Survey-eBook2.pdf>
12. Mann D, Chen J, Chunara R, et al. COVID-19 transforms health care through telemedicine: Evidence from the field. May 29, 2020. <https://academic.oup.com/jamia/article/27/7/1132/5824298?guestAccessKey=3621cf08-b2df-4027-b1f5-7dadadcd640f>
13. Frost & Sullivan. Telehealth – A Technology-Based Weapon in the War Against the Coronavirus, 2020. April 2020.
14. Kopp E, Lupkin S, Lucas E. Patient Advocacy Groups Take In Millions From Drugmakers. Is There a Payback? April 6, 2018. <https://khn.org/news/patient-advocacy-groups-take-in-millions-from-drugmakers-is-there-a-payback/>
15. Bodkin N, Darboné J, Wiggins S, et al. Connecting with Rare Disease Communities: Patient Advocates. 2018. https://www.covance.com/content/dam/covance/assetLibrary/whitepapers/Patient-Advocacy-White-Paper_WPCDS028.pdf

CASE STUDY

Supporting Rare Disease Patient Populations with Tech + Talent



Introduction

Catering patient access, affordability and adherence solutions to rare disease patient populations can be a challenging but rewarding endeavor. These patients face a lack of resources to learn about their disease, significant medical costs, lack of access to appropriate specialists/timely diagnosis, and more.

Craig Martin, CEO of Global Genes, speaks to these challenges: “People living with rare diseases are already inherently underserved. Although roughly 10% of the global population has a rare disease, people with rare conditions endure extended diagnostic odysseys and struggle to get their conditions recognized and prioritized.”¹

Accelerating speed to therapy and access to support services is critical for this patient population. A key component of an effective rare disease patient support program is engaging with a partner that is knowledgeable about the rare disease patient, caregiver and healthcare provider (HCP) experience, has a strong track record of supporting orphan/rare disease products, and delivers the right balance of tech- and talent-enabled solutions tailored to stakeholder needs.

Challenge

Manufacturer of a rare oncology therapy for ovarian and prostate cancer challenged with long turnaround times (TAT) for the brand’s PAP and copay assistance programs and a high FTE count due to lack of technology integrated into the program.

AssistRx Solution

AssistRx deployed an end-to-end, technology- and talent-enabled patient support program that included iAssist, branded patient and HCP engagement websites, AssistRx Patient Solutions clinical and non-clinical teams – powered by our Patient Solutions CRM, and free drug dispense from our non-commercial pharmacy, ARx Patient Solutions Pharmacy. This “tech-first” model drives program efficiencies and helps guide HCPs and patients through the process.

iAssist and branded engagement websites provided patients, caregivers and HCPs with 24/7 self-serve access to therapy initiation services. HCPs could use iAssist or the branded HCP engagement website to complete all therapy initiation steps, including e-Consent, e-Prescribe (iAssist only), Advanced Benefit Verification (ABV), e-PA, e-Copay, e-PAP and more – all in one workflow and in minutes. Patients and their caregivers could use the branded patient engagement website to complete e-Consent, e-Enrollment into support programs, and immediate e-Copay and e-PAP screening, enrollment and card/voucher generation.

Results

In just three months, **AssistRx solutions increased digital adoption for copay enrollment by 160%**. Copay program enrollments went from 80% hub-initiated and 20% tech-initiated to 48% hub-initiated and 52% tech-initiated. Our technology solutions also **reduced TAT for copay program enrollment by 12 days**.

By leveraging our ABV solution to perform PAP audit, we were able to immediately identify patients who obtained coverage and were no longer eligible for PAP, **converting 26% from the program to external third-party foundation support**.

Lastly, we were able to **reduce TAT for PAP dispense by 75%**. This is due to the efficiencies gained by leveraging technology and by having all PAP services under one roof.

1. Spinner, Jenni. Report shines a light on unique challenges of rare disease patients. February 24, 2022. <https://www.outsourcing-pharma.com/Article/2022/02/24/report-spotlights-unique-challenges-of-rare-disease-patients>

Retail and Specialty-lite Products

ARTICLE

Four Solutions Manufacturers Should Consider for Retail and Specialty-lite Products

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In the last decade,

the U.S. Food and Drug Administration (FDA) approved more drugs annually on average than it did in the prior two decades, resulting in increased competition for specialty and retail drugs alike. Specialty-lite drugs—or products positioned between retail and specialty products—are set to dominate growth in the space.

Not quite retail, specialty-lite drugs often require some specialty services, like access and reimbursement support. However, their often lower-than-specialty wholesale acquisition cost (WAC) limits the effectiveness and financial feasibility of full-time employee (FTE) models typically leveraged for specialty drug support. Additionally, life sciences organizations offering specialty-lite products are experiencing the same gross-to-net squeeze as their specialty drug manufacturer counterparts.

A Drug Channels Institute analysis of company reports found that the unweighted average gross-to-net gap in drug prices was -6.0% for 2020. Prices for brand-name drugs dropped, and drug makers sold their products for less than half of the list price. Factors driving this trend include distribution fees, discounts to hospitals, rebates and more. Regardless, the cascade effect of this gross-to-net squeeze can induce cost shifting onto the patient.

Compounding these factors, healthcare providers (HCPs) and patients are more often facing access challenges such as prior authorizations (PAs). According to an American Medical Association (AMA)-conducted survey, 83% of physicians across specialties and practice settings reported an increase in the number of PAs required for prescription medications and medical services over the last five years. Further, health plans report that “zero percent of primary care services are subject to

PA,” but according to AMA’s survey, 64% of primary care physicians (PCPs) disagree with this claim. Even low-WAC, primary care drugs are challenged by new/additional PA requirements.

Patient access, affordability and adherence challenges are just some of the obstacles faced by specialty-lite products. This underserved segment of the market needs a non-traditional model that supports patients and HCPs at an attainable cost. Life sciences organizations providing these products must strike the perfect balance between delivering differentiated patient support services and cost-effective solutions.

To meet the nuanced needs of this growing market segment, four new categories of patient solutions and pharmacy models are looking to disrupt the status quo. Vying for the attention of life sciences organizations launching specialty-lite products are:

1. Digital Pharmacies

Perhaps most visible within the industry and to consumers is the digital pharmacy. This model tends to focus on retail and lifestyle drugs. Driven by patients, digital pharmacies leverage an e-commerce model and lean on patients to self-serve throughout their journey. Digital pharmacies often encourage patients to use telehealth services and are usually cash-payment focused to give patients additional flexibility when evaluating affordability options.

In the February 2021 Drug Channels article, The Promise and Limits of Digital Pharmacies, it was asserted that digital pharmacies' biggest impact will come from forcing the industry incumbents to improve their business and patient-centric approach. However, it also said that it was unclear how far this "niche opportunity can expand into new-to-therapy prescribing for medically complex conditions." While digital pharmacies are not ideal for specialty-lite products, some of their characteristics—such as cash-payment dispensing and simplified prescribing for HCPs—are appealing to specialty-lite product brand teams.

2. Alternate Specialty-lite Pharmacies

While this model is similar to specialty pharmacies, alternate specialty-lite pharmacies focus on leveraging technology to speed access to therapy. Though these pharmacies deliver some electronic support services like e-benefit verification (e-BV) and e-PA, these services may have limited reach and technology-first functionality when compared to other solutions on the market. Further, leveraging a single pharmacy entity may create concern for steerage.

3. Hub-lite Services

This model provides some e-services like e-BV and e-PA, but hub-lite providers may struggle to evolve their service offerings alongside the specialty-lite drug's lifecycle without costly system and process changes.

4. Digital Patient Services

CoAssist answers to market demand for tech-first, cost-effective digital patient services with solutions and features tailored to the needs of specialty-lite programs. It is differentiated from digital pharmacies, alternate specialty-lite pharmacies and hub-lite services with the ability

to kick-off advanced and automated real-time e-support services at prescription intake from the EHR – an important distinction, as it meets HCPs within their established workflow. e-Support Services also include real-time e-BV, e-PA, e-Consent, e-Enrollment and more, which leverage multiple data sources and proprietary algorithms to outperform industry standards.

The CoAssist platform also features a limited pharmacy network, which helps alleviate the steerage concerns associated with the use of a single pharmacy. It also features its own consignment pharmacy to support the clinical decision and gain visibility to the patient journey CoAssist identifies the best affordability option for the patient, allowing for cash-dispense if optimal. Further, the CoAssist platform is supported by the necessary technology and expertise to evolve the program alongside the product lifecycle, providing the flexibility to enable different services at the launch phase versus at the near-loss-of-exclusivity phase.

CASE STUDY

Optimizing Program Performance Through CoAssist



Introduction

The specialty pharma industry is seeing a significant spike in specialty-lite drugs — or products positioned between retail and specialty products — coming to market. Often requiring some level of specialty services, while also having a lower-than-specialty wholesale acquisition cost (WAC), leveraging full hub program models is less financially feasible for this product segment. This “gross-to-net squeeze” challenges life sciences organizations to find the perfect balance between specialty support and cost-effective solutions. This is why AssistRx built CoAssist, a tech-first therapy initiation and fulfillment solution. CoAssist delivers tech-first specialty services, a select pharmacy network and a consignment option from CoAssist Pharmacy to meet the needs of today’s retail and specialty-lite therapies.

Challenge

A manufacturer was launching a new retail drug for iron deficiency targeting OB-GYNs and family practice physicians. Launching into a crowded market, the manufacturer needed to meet healthcare providers (HCPs) in their workflows, improve payer coverage, support patients until payer coverage was established and deliver differentiated experiences.

Solution

AssistRx deployed CoAssist to support the manufacturer’s needs, as well as the drug’s patient and HCP populations. Through CoAssist, HCPs could prescribe to CoAssist Pharmacy from their EHR, kicking off our proprietary e-Support Services at the point of prescription.

Through our non-commercial pharmacy, CoAssist’s selective pharmacy network and consignment option from CoAssist Pharmacy, we upheld the physician’s clinical decision and supported non-covered patients with cash dispense if that was their best affordability option. We also deployed our Payer Nudge Campaign to demonstrate prescription volume and persuade payers to add product to formulary.

Results

Nearly **90% of volume** was driven through CoAssist in the first nine months post-launch. CoAssist’s ability to accelerate speed to therapy through automated technology fostered best-in-class patient and HCP experiences. Additionally, our Payer Nudge Campaign significantly improved payer coverage. After one payer win, we were able to transition **more than 50% of that payer’s patients** from the program’s PAP to paid-for script.

The CoAssist Difference

- **Fully automated therapy initiation and fulfillment:** Real-time e-Support Services kicked off at the point of prescription from the EHR accelerate speed to therapy and increase patient uptake, while delivering differentiated experiences for patients and HCPs.
- **Patient-focused access to prescribed therapy:** Our innovative pharmacy model, comprised of our selective pharmacy network, a consignment option from CoAssist Pharmacy and free drug from ARx Patient Solutions Pharmacy, drives access at the best fulfillment option for all patient types while supporting the clinical decision and brand goals.
- **Configurable support throughout product lifecycle:** Scalable technology- and talent-enabled delivery, combined with legacy technology, pharmacy and patient solutions expertise, enables configurable support to improve treatment outcomes and program performance throughout the product lifecycle.

Closing

Over the past year, specialty pharmaceutical stakeholders have seen patient support programs evolving alongside the industry's growing adoption of technology and refocus of talent on value-add touchpoints.

As examined in this report, life sciences organizations are able to successfully evolve their patient support programs in line with these changes. Today's patient support programs can meet and exceed today's patient, caregiver and healthcare provider (HCP) needs and preferences with the right technology and the right talent. The key is implementing the right balance of the two. Life sciences organizations should seek a patient support provider that is not only nimble and technologically capable, but also forward-thinking and consultative. The chosen patient support provider should serve as an extension of the brand, ever seeking to improve program performance and patient treatment outcomes.

With a vision to transform lives through access to therapy, AssistRx has consistently partnered with our clients to create best-in-class solutions for patients, caregivers and HCPs. Through the powerful combination of our people and technology, we help life sciences organizations increase uptake, gain visibility and improve outcomes.



Informed access. Improved outcomes.

AssistRx has engineered the perfect blend of technology and talent to provide an intelligent therapy initiation and patient support solution to improve patient uptake, visibility and outcomes. Our solution integrates technology and therapy expertise to advance patient therapy in a more efficient and effective manner—delivering informed touchpoints that simplify a complex system to enable better results for today's patients.



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