

**A Qualitative Analysis of Pharmaceutical Manufacturer Funded Patient Access Services
for Newly Launched Drugs**

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Abstract

Objectives. To quantify and describe the extent to which manufacturer-funded patient support services are included with novel drugs that were launched in 2019. The nature of these patient services – whether they provide financial or clinical support for patients and providers- will be described and categorized. Any trends, patterns, and gaps in the area of branded pharmaceutical products and manufacturer funded programs resulting from this study can serve as the foundation for future research.

Methods. Analyzed and catalogued all patient support services associated with novel drugs approved by the U.S. FDA and launched by pharmaceutical manufacturers in the United States (n=40). Drug-specific data came from the Drugs@FDA database while information on product-related services came from patient and healthcare professional websites for the specific pharmaceutical product. Descriptive statistics (mean, median, proportions) were used to characterize the programs.

Results. Overall, 90% of all novel drugs in 2019 included some form of manufacturer sponsored patient service. Results were distributed among the 8 therapeutic areas of the drug's main indication, among the 2 modes of administration, and across the price quartiles. Patient administered drugs were more likely to offer a patient support service.

Conclusion. Improving medication adherence may be a motivating factor for the pervasiveness of patient support services offered by manufacturers. There does not appear to be a single factor or trait that could predict the likelihood of having patient support services. More data on program utilization and costs along with patient and health system outcomes are needed in order to draw more meaningful conclusions on the impact of manufacturer sponsored patient support programs.

The Problem with Medication Nonadherence

Medication nonadherence is a widespread problem. Thirty to fifty percent of medications prescribed for adults with chronic illnesses are not taken as prescribed.¹ The WHO and Consumer Health Information Corporation conducted a survey that found roughly half of all patients take their medicine improperly.² Nonadherence is related to 125,000 deaths and 10% of hospitalizations in the United States each year.¹ Unaddressed nonadherence leads to untreated or undertreated conditions, complications, and productivity loss.² Further, consequences of nonadherence contribute \$100 billion to annual health care service costs due to recurring hospitalizations and medical interventions.¹ Commonly cited reasons for not taking medication as directed include: forgetfulness, concern over drug side effects, costs of the drug, inability to get prescription filled or picked up, belief that the drug is not necessary, or lack of knowledge over how to use the drug.²

Why is this issue important?

Taking the medicine at the appropriate dosage at the appropriate intervals is necessary for the drug to deliver “maximum effectiveness because medications taken in the dosages and at the intervals prescribed would ... work better”.² Despite differing priorities among the stakeholders in the healthcare system, improving medication adherence is one priority in which health systems, drug manufacturers, payers, providers, and pharmacists can align on.²

What is the pharmaceutical industry doing in response?

Drug companies are funding patient access services to remedy adherence issues, either directly or by contracting services with third party providers. The services aim to overcome adherence obstacles related to patient education, financial concerns, insurance coverage restrictions, and prescription fill and dispensing barriers.² These include financial assistance

programs such as vouchers, coupons, copayment assistance to manage costs of medication and navigate insurance policies.³ Clinical related support services include patient include clinical and treatment related education and support for patients, caregivers, and healthcare providers.⁴

Examples of industry funded programs

Sanofi, one of the top ten largest multinational pharmaceutical companies in the world, has a patient support service for diabetic patients on insulin known as the COACH program. COACH provides disease education, insulin product support, and lifestyle education, all with the goal of controlling glycemic levels, which is a clinical indicator for diabetes management.⁵ Patients enrolled in COACH were 1.8 times more likely to adhere to the treatment protocol compared to matched non-participants.⁵ Other outcomes for program participants included positive levels of persistence, reduced clinical and healthcare utilization, and improved patient quality of life.⁵

AbbVie, another top ten pharmaceutical company, provided access and financial assistance components in a program associated with its anti-inflammatory medication (adalimumab), intended to treat a variety of immune-related conditions.⁶ The program encompassed copayment and coinsurance assistance, nurse ambassador support, instructions on syringe disposal, mobile phone reminders for patients, follow-up calls, and self-injection training.⁶ There was a 14 percent lower discontinuation rate for patients in the intervention. Program participants also experienced cost savings with a 23 percent reduction in 12-month medical costs (excluding costs of treatment) and 22 percent reduction in disease related costs.⁶

Other reasons for patient access programs

There may be additional factors behind the rise of patient access programs other than to address medication adherence. One possible reason is that patient access services may enhance a

new pharmaceutical product's differentiating value, which consequently increases the likelihood of the product's commercial success. Amerisource Bergen, a drug wholesaler and distributor, suggests that manufacturer-sponsored patient support programs may be needed in order to improve access to medications that are increasingly complex.⁴ Deloitte's Life Sciences Consulting Practice recommends that drug manufacturers should include patient services beyond the product itself as part of a commercialization strategy.⁷ McKesson, another drug wholesaler and distributor, defines patient access support services as solutions that the drug manufacturer provides for patients and providers to ensure access to new drugs, as they have "significant impact on overall brand and patient experience".⁸ Again, this implies the importance of patient support programs to successful product commercial launches.

The question becomes whether these patient services are rendered for the benefit of the patient or intended to influence pharmacists to use specific manufacturer's products.³ As pharmaceutical products shift to more specialty launches in recent years, these related patient services may become more relevant with the increased complexity in both treatment and insurance coverage of these specialty products. Consequently, successful patient access to treatment may play a larger role in the commercial success of high cost products.^{9,10}

Are patient access services uniformly provided across all branded products?

While industry sponsored programs purport to alleviate the resource and time constraints of the medical professional and improve patient medication adherence, a complete picture of the utilization and impact of these programs is still unclear.¹¹ Do these patient services exist solely for the purposes of improving treatment adherence? Life science consultants recommended that drug manufacturers consider services to address all points of the patient journey; however, these programs may not be uniformly implemented across all pharmaceutical products.⁷ Lamkin et al¹²

suggests patient support programs may benefit specialized and expensive drugs more, since those drug manufacturers face the dual patient access barriers of high cost and unpleasant side effects. However, there is no such summative information on the extent and nature of manufacturer funded patient support programs for branded pharmaceutical products.

Criticism of manufacturer funded patient services

It is unclear whether manufacturer sponsored patient access services are improving patient adherence enough to compensate for some of the problems inherent with these programs. Services with clinical educators like pharmacists or nurses who provide education and counseling for specific drugs may not have the patient's best interest in mind. These programs involve clinicians counseling patients through call centers on topics related drug usage, drug-side effects, etc. These call centers may create a conflict of interest since the clinicians are not free to discuss unbiased medical judgements with patients, as their primary duty is customer retention for the pharmaceutical manufacturer.¹² There is criticism that these programs only exist for high margin, expensive, and on-patent drugs. If patient adherence is truly the goal, then should not the strategy be extended to lesser priced generics as well?

Other criticisms of pharmaceutical manufacturer sponsored programs are directed to the increased administrative burden for providers to enroll patients into these access programs. Some involve a complex and manual application and enrollment process in order for patients to receive support.¹³ Additionally, there is no single standardized process or program for different drugs at different companies, which for patients on multiple products, may be even more complicated to navigate.¹³

There are also financial consequences to patient access services. While out-of-pocket expenses may be defrayed for patients, it results in incentivizing patients to choose the more

costly therapies instead of generic drugs, since patients are more insulated to costs.¹⁴ Payers do not view such programs favorably since they make patients less sensitive to prices, which also causes manufacturers to raise list prices.¹⁴ There is no full transparency of data or even program benefits provided by the pharmaceutical manufacturers that is publicly available. The ability of patient access services to improve access and to reduce health care costs are debatable.¹⁵ There is a need for more transparency and research in order to evaluate the utilization and benefits from these various programs.¹⁵

Objectives

To date, there is no comprehensive, systematic survey of all patient and provider support services related to branded pharmaceutical drugs for a given year. This paper will attempt to quantify and describe the extent to which manufacturer-funded patient services are included with novel drugs that were launched in 2019. The nature of these patient services will be described and categorized. Any trends, patterns, and gaps in the area of branded pharmaceutical products and manufacturer funded programs resulting from this study can serve as the foundation for future research.

This qualitative study may be informative for more in-depth evaluations on the costs and benefits of these manufacturer funded programs. Understanding the impact that these programs may have on patient health outcomes, medication adherence, and hospital and health system costs can even lead to more accountability in respective program funding and utilization. Further research may determine whether such patient and provider access services are adding value to patients, payers, and other stakeholders in the healthcare system or creating an additional stream of financial waste by funding such programs.

Study Data and Methods

Data and study population

The study population for the review are the novel drugs classified as new molecular entities (“NMEs”) and approved in 2019 by the US Food and Drug Administration’s Center for Drug Evaluation and Research (CDER).¹⁶ Novel drugs are defined as new molecular entities or new therapeutic biological products that were not previously approved and marketed in the United States.¹⁶ Excluded from this sample are new and expanded uses of previously approved drugs and diagnostic entities, new formulations, biosimilars, and new dosage forms.¹⁷ Also excluded are vaccines, allergenic products, blood products, plasma derivatives, cellular and gene therapy products, and other products, as they were approved by in 2019 by the Center for Biologics Evaluation and Research.¹⁷

Drug characteristics

Drug characteristics were described across these parameters: 1) brand or trade name, 2) active ingredient, 3) approval date, 4) application type, 5) sponsor, 6) route of administration, 7) FDA approval pathways, 8) FDA approved use on approval date, 9) Risk Evaluation and Mitigation Strategies (REMs), and 10) list price at market launch. The CDER webpage for 2019 approvals contains information on the novel drug’s trade name, active ingredient, approval date, and the FDA-approved use on the approval date.¹⁶ The Drugs@FDA database includes all materials related to a product’s application such as the application type, application sponsor name, route of administration, FDA approval pathways, and any required Risk Evaluation and Mitigation Strategies (REMS).¹⁸ The drug application type distinguishes the drug between a small molecule (New Drug Application) and a large molecule biologic (Biologic License Application). REMS are drug safety programs required by the FDA and developed by the

manufacturer for certain medications with significant safety concerns in order to ensure the appropriate and safe use of certain drugs.¹⁹ The determination for a top ten pharmaceutical company is based off of total annual revenue in 2019.²⁰ Finally, drug list prices were found on the GoodRx website.²¹ List prices were standardized to allow for comparisons across different drugs by calculating the estimated cost for one month of treatment based on the list price for a single dose or unit.

Program identification and characterization

For each drug, I searched on its patient and healthcare professional websites to identify and describe the types of access programs offered by the drug company. The primary outcome of interest were the specific type of programs and services offered by the drug company. Once the program information were extracted, they were sorted into 4 broader categories: 1) clinical support, 2) financial support, 3) case management, and 4) technology solutions. Services and programs offered were categorized according to the dimension of patient access barriers they addressed. Services that fall under clinical support address potential disease state or treatment regimen barriers through treatment counseling services to clinician hotlines. The financial support category includes services that address insurance, coverage, and payment barriers such as prior authorization and coverage, patient out-of-pocket spending, or patient assistance for the under- and uninsured patient population. Financial support programs also extend to physicians, where they receive access and reimbursement guidelines or insurance prior authorization and appeals support. Case management programs were its own category since they encompass a range of end-to-end services. A dedicated case manager supports the patient throughout the treatment journey via check-in calls to appointment reminders to insurance and benefits

navigation. Lastly, technology solutions are either mobile applications or online portals that provided access to clinical or financial support services.

Data systematization and analysis

Abstracted drug and program information was recorded into a Microsoft Excel spreadsheet. The analysis of programs included only programs that were readily accessible on the product and/or company webpage. The results were reported using descriptive statistics including median, mean, and proportions.

Limitations

This study does not include data on patient outcomes, program utilization, or costs incurred by the drug manufacturers for funding patient service programs. Thus, the results of the study cannot draw conclusions on the cost-effectiveness of the programs on medication adherence, patient outcomes, or financial savings for the patient and health systems. There is also no data to support whether program expenses contribute to the initial list prices.

Study Results

Drug Characteristics

48 new molecular entities (NMEs) were approved by the FDA in 2019. Of which, 4 were diagnostic products and 4 were not yet commercially marketed in the United States at the time of study, so those 8 entities were excluded from analysis (exhibit 1). The remaining 40 novel drugs included for analysis were sponsored by 32 different pharmaceutical companies. 9 of those manufacturers were among the top 10 manufacturers in the United States by revenue.²⁰

33 drugs (83%) of the 40 approved and launched novel drugs have a specialty designation. While the definition of a specialty drug is not explicitly set by the U.S. FDA, it is usually characterized by the product attributes which include manufacturing difficulty, condition

and treatment complexity, rare disease status, high monthly cost, and limited distribution through specialty pharmacies.²² 3 of the 40 novel drugs (8%) were required by the U.S. FDA to include manufacturer directed Risk Evaluation and Mitigation Strategies for controlling and monitoring drug use.^{19,22} The estimated monthly cost of treatment ranged from \$5 to \$270,000, with a median price of \$8,000. 25 drugs (63%) were patient administered in the form of tablets, capsules, self-injectable, or topical creams. 15 drugs (37%) were physician administered through injections or intravenous infusions.

Exhibit 1: Characteristics of novel drugs in the study

Characteristics	Summary Measure n (%)
Approved and Launched in the U.S. Market	40
Manufacturers	32
Top 10 Manufacturers	9
Specialty Drugs	33 (83)
Associated REMS program	3 (8)
List Price at Market Launch (One-month of treatment)	\$5- \$270,000 (median = \$8,000)
Patient Administered (Oral or Self-Injection)	25 (63)
Physician Administered (Injection or Infusion)	15 (37)

Therapeutic Classes

The 40 approved drugs covered 8 different therapeutic areas (exhibit 2). Almost 75 percent of the drugs (n = 29) were approved for 3 therapeutic areas- rare diseases (47.5%), cancers and blood disorders (12.5%), neurological and psychiatric disorders (12.5%). The remaining 11 drugs were approved for infectious diseases (7.5%), women's specific health issues (7.5%), dermatological conditions (5%), auto-immune disorders (5%), and vision disorders (2.5%).

Approval Pathways

CDER designated 19 drugs (47.5%) as first-in-class (exhibit 2). First-in-class drugs have different mechanisms of action compared to existing treatments for the same indication. CDER

also designated 19 drugs (47.5%) as orphan drugs, which are for diseases affecting less than 200,000 individuals in the United States.¹⁶ 28 drugs (70%) were approved with at least one expedited regulatory pathway which include fast track, breakthrough, priority review, and accelerated approval. These pathways are intended to facilitate faster approval of certain novel drugs that demonstrate a potential to address unmet medical needs.¹⁶ Fast track-designated drugs (42.5%) demonstrated potential for treating unmet medical needs.¹⁶ Breakthrough drugs (32.5%) provided preliminary clinical evidence for the drug's potential to substantially improve on a clinical endpoint, compared to existing therapies.¹⁶ Drugs receiving priority review (67.5%) demonstrated the potential for significant advancement in medical care.¹⁶ Drugs receiving accelerated approval (22.5%) were permitted to use different clinical endpoints with shorter time durations that are reasonably likely to predict longer term clinical benefits.¹⁶

Exhibit 2: Therapeutic areas and FDA approval pathways of novel drugs

Therapeutic Area of Drug	No. (n = 40)	%
Rare Diseases	19	47.5
Cancers and Blood Disorders	5	12.5
Neurological and Psychiatric Disorders	5	12.5
Infectious Diseases	3	7.5
Women's Specific Health Issues	3	7.5
Dermatological	2	5
Autoimmune Conditions	2	5
Vision/Eye Diseases	1	2.5
FDA Approval Pathways	No. (n = 40)	%
First in Class	19	47.5
Orphan	19	47.5
Fast Track	17	42.5
Breakthrough	13	32.5
Priority Review	27	67.5
Accelerated Approval	9	22.5

Description of Patient Access Services

All of the patient access services can be classified into 4 categories: 1) clinical support, 2) case management, 3) financial support, and 4) technology solutions (exhibit 3). 6 of the 40 drugs (15%) had programs which the drug manufacturer contracted to a third party to administer—usually the specialty pharmacy or distributor (not shown in table below).

Clinical services focus on addressing and overcoming barriers that prevent a patient's ability to successfully start a new drug regimen or to adhere to a treatment course. Within the category, there were 5 different types of clinical services offered by drug manufacturers. 40 percent (n=16) of the novel drugs studied included patient education and counseling on the treatment and disease state management. Patient education and counseling also included guidebooks with treatment education for caretakers of patients. 20 percent of the novel drugs (n=8) offered samples, which were either given to the providers as free samples or as interim bridge support before a patient's insurance plan approved coverage of the drug. 13 percent of the novel drugs (n=5) studied included a clinician hotline available for the patient to call at any time. These call centers are typically staffed by pharmacists or nurses who could answer patient questions related to the treatment. Some call centers were available 24/7 for patients. 7.5 percent of the novel drugs (n=3) offered additional support for patients to direct them to independent national and local organizations such as patient advocacy and support groups and online communities, counseling services, or even other organizations that provide assistance with transportation and lodging for patients who require travel to their treatment-related appointments. 5 percent of the novel drugs (n=2) offered in-home support by clinical educators to provide training on self-injection and assistance on creating an administration therapy.

15 of the 40 novel drugs (38%) provided a case management services. Case management and coordination services were placed into its own category because of the comprehensive nature of patient support included in case management. Once enrolled into a case management program, patients were assigned to a dedicated case manager. The case manager would initiate a benefits investigation on the patient's behalf to determine insurance eligibility and reimbursement and prior authorization support. They may also provide treatment education, medication dispensing and delivery support, routine check-ins, and appointment reminder calls. Case managers would also serve as a point of contact with healthcare practices and providers.

There were 5 different types of services offered by drug manufacturers under the financial support category. The most common financial support service was copayment support and patient assistance, which 32 of the 40 drugs (80%) provided. Patients eligible for copayment support would pay between \$0 - \$20 for one month's worth of medication. Manufacturers typically capped this copayment support to a certain amount each year. Patient assistance provided drugs free of charge; a separate nonprofit, usually within the manufacturer, would administer that benefit. Manufacturers provided both services in tandem; copayment support applied to commercially insured patients while patient assistance applied to uninsured or underinsured patients.

Financial support also included benefits investigation and navigation services for patients. 24 out of 40 drugs (60%) provided benefits investigation to determine a patient's insurance eligibility and whether their insurance policies included utilization restrictions such as prior authorization or step therapy. Prior authorization, also known as precertification or prior approval, requires that the patient's insurance plan approve the treatment in advance in order to determine payment coverage.²³ Prior authorization procedures vary among payers and create an

administrative burden that is expensive and time-consuming for the physicians who are responsible for obtaining them.²⁴ Step therapy requires patients to first use less expensive drugs for the same indication until the drugs are rejected due to lack of clinical result or adverse reactions.²⁴ In addition to being administratively burdensome, step therapy requirements are potentially disruptive to a patient's existing drug regimen if the patient switches health insurance plans and the policies for coverage change.²⁴ Consequently, 14 out of 40 drugs (35%) provided prior authorization and related insurance adjudication support for the patient's healthcare provider. To streamline the insurance support for patients, 8 out of 40 drugs (20%) also provided physician portals that were accessible online. These online solutions allowed physicians to simultaneously enroll patients into support programs, initiate benefits investigations, submit prior authorization documents, and also track the insurance access progress.

16 out of 40 drugs (40%) provided additional access, billing, and reimbursement support for prescribers. These were template letters that providers could use for obtaining prior authorization or for filing an appeal when insurers deny authorization. Coding and billing guidebooks were also included, especially for physician administered drugs, where the healthcare provider needs reimbursement for the product and the administration of the product. 6 out of 40 drugs (15%) provided field reimbursement specialists who would educate physicians and practices on billing and coding requirements for the product, chart documentation requirements, and insurer requirements. Lastly, in addition to physician portals, other types of technology solutions include mobile applications to allow physicians and practices to order inventory directly through the application or to speak to a sales representative about the product. 3 out of 40 drugs (8%) had mobile applications as part of technology services.

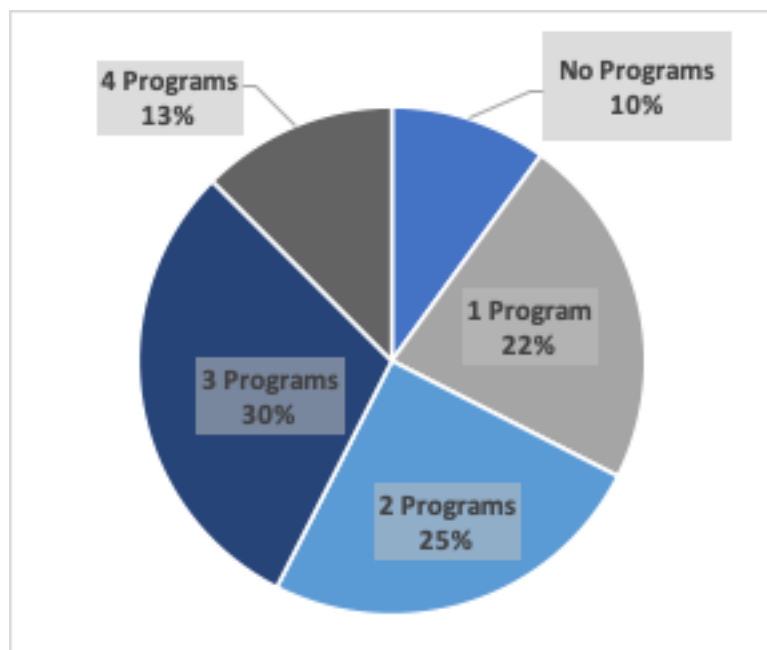
Exhibit 3: Patient access services, by broader program category

Program Category	No. of Drugs n = 40	%
Drugs with No Associated Programs	4	10
Clinical Support Programs		
Clinical Education/Counseling	16	40
Free Sample	8	20
Clinician Hotline	5	13
Connection to Third Party Resources	3	7.5
At Home One-on-One Treatment Education	2	5
Case Management Programs	15	38
Financial Support Programs		
Co-pay/Patient Financial Assistance	32	80
Benefits Investigation	24	60
Access, Billing, and/or Formulary Guides	16	40
Physician Claims/Authorization/Appeals Support	14	35
Field Reimbursement Specialist	6	15
Technology Solutions		
Physician Portal	8	20
Mobile Application	3	8

How extensive were the services?

Of the 40 drugs, only 4 drugs (10%) launched offered no form of patient access service programs (exhibit 4). 3 of the 4 drugs were indicated for treating infectious diseases, and 1 was indicated for treating a rare skin disorder (not shown in exhibit). 19 out of 40 drugs (47.5%) included 1 or 2 categories of services. 12 out of 40 drugs (30%) included 3 categories of services. 5 out of 40 drugs (13%) included services spanning all four categories: clinical support, case management, financial support, and technology solutions. In comparing specialty drugs with non-specialty drugs, only 2 out of 7 non-specialty drugs (29%) provided clinical support services and 5 out of 7 non-specialty drugs (71%) provided financial support (not shown in exhibit). There were no case management services or technology solutions associated with non-specialty drugs.

Exhibit 4: Drugs with support programs, by category (n = 40)



How did patient service programs differ by route of administration?

Patient administered drugs dominated patient support services in 3 categories: 23 drugs out of 35 drugs (66%) offering financial support services, 10 out of 15 drugs (67%) offering case management services, and 16 out of 25 drugs (64%) offering clinical support (exhibit 5). Of the 10 drugs offering technology solutions, 5 were patient administered and 5 were physician administered.

How did patient service programs differ by therapeutic area?

Almost half of all program categories were drugs that were indicated for rare diseases (exhibit 6). 9 out of 15 drugs (60%) providing case coordination service were indicated for rare diseases. Rare disease indications constituted 60% (n=9) of case management programs, 50% (n=5) of technology solutions, 46% (n=16) of financial support programs, and 44% (n=11) of clinical support programs. Conversely, only 2 drugs indicated for infectious diseases provided financial support services and no services in any of the other categories. Drugs for cancer and

blood disorder indications and drugs for women's specific health issues provided services across all four categories as well. Within the financial category of patient support services, all therapeutic areas were represented. All of the therapeutic areas included a form of financial support service.

Exhibit 5: Patient support services, by category and route of administration

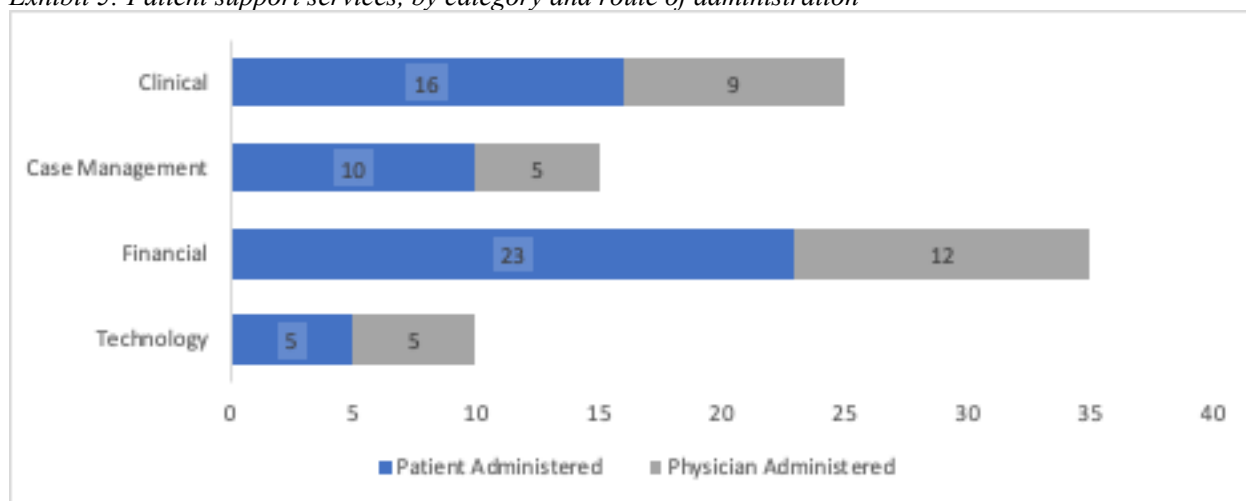
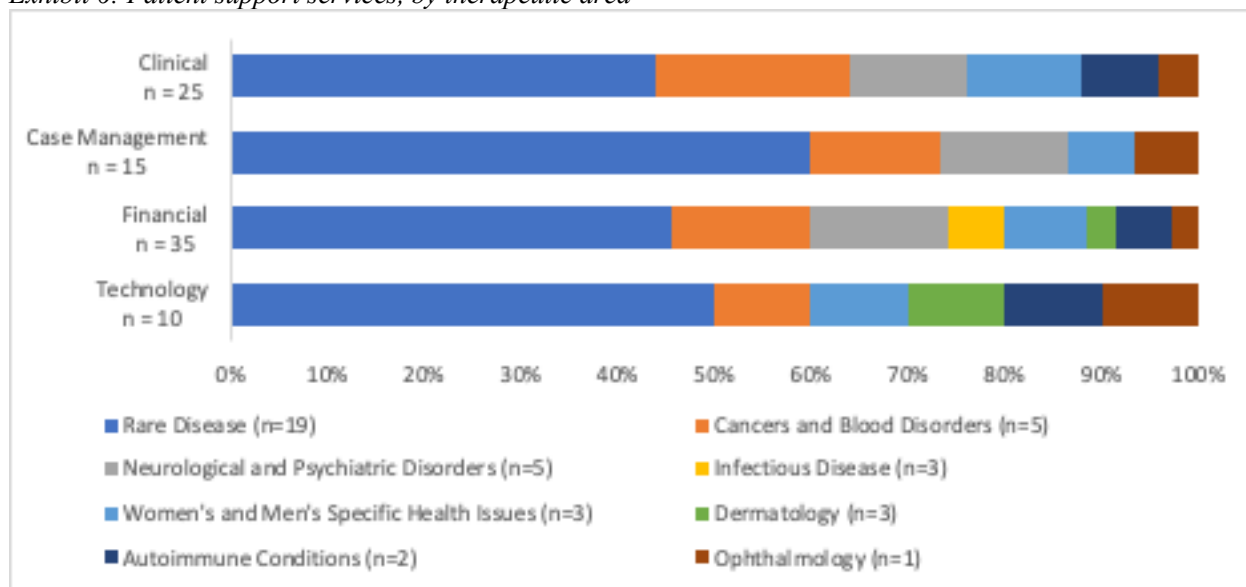


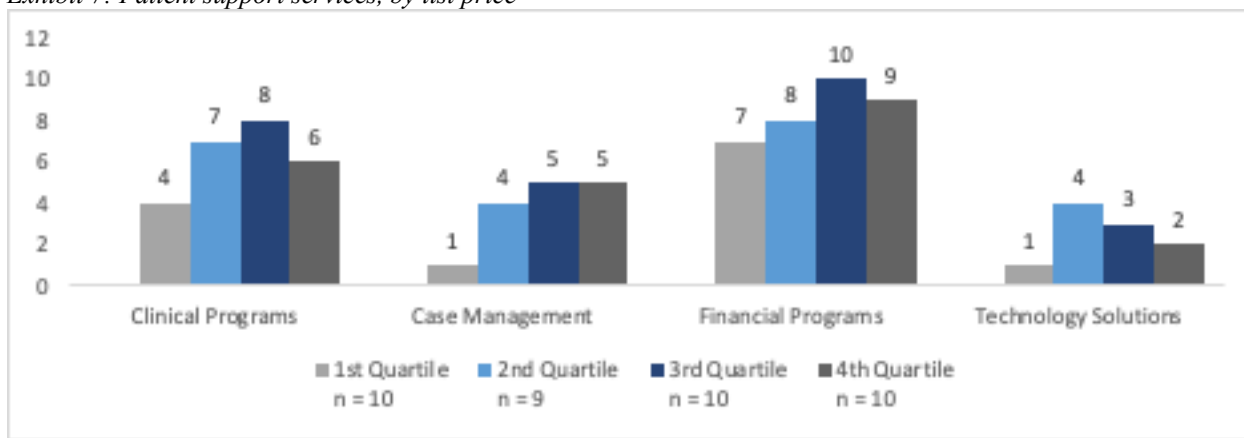
Exhibit 6: Patient support services, by therapeutic area



How do patient service programs differ by list price?

When sorted by list price quartiles, over 50% of the distributions for each category were within the middle two quartiles and generally resembled symmetric distributions (exhibit 7). For both clinical and financial categories of support programs, there were the greatest number of drugs in the third price quartile (n=8 and n=10, respectively).

Exhibit 7: Patient support services, by list price



**Fetroja*, a physician administered intravenous infusion, did not have the list-price made publicly available and was excluded from the above analysis.

Discussion

The results from the examination of drug manufacturer funded patient support services among the novel drugs approved and launched in 2019 is generally consistent with literature that patient adherence is a motivator for the increasing number of programs provided.³⁻⁶

Furthermore, patient administered drugs were more likely to have an associated patient support service. Patient services were less likely to be offered for non-specialty drugs, which is consistent with literature that the rise of these patient services is in line with the rise of specialty drugs.⁹ Physician administered drugs can serve as a proxy to indicate drug complexity (such as infusions and injectables of biologics).^{9,10} However, the results do not appear to support research

that patient support services are associated only with more complex drugs, as seen by the greater number of patient administered drugs with patient support services.¹⁰

Furthermore, that only 10 percent of the drugs approved by the FDA and commercially launched in the U.S. in 2019 did not have any patient services associated with the product points to the widespread prevalence of these patient service programs. This poses the question whether medication adherence is the only motivator for providing such programs. Three of the four drugs without any patient support program were indicated for either a neglected tropic disease or for antibiotic purposes. In two of those cases, the drugs were likely to see higher utilization outside of the United States and could explain the lack of any patient access services.

Another finding that is consistent with research is that manufacturers invest the most resources into financial support services.¹⁰ These include physician support for prior authorization and benefit verification along with patient support through copayment assistance. As utilization restrictions vary from payer to payer and increases the administrative burden for the prescriber, it makes sense that manufacturers are motivated to minimize potential access barriers by providing these insurance and financial services for prescribers and patients alike.

Most surprisingly, the greatest number of patient services offered were not among the most expensive group of drugs but rather concentrated in the two middle list price quartiles. Less services were offered in both the lowest and highest quartiles. There may be two speculative reasons for this: that lower priced drugs may not require additional support for accessing drugs and that the highest cost drugs may be for diseases which there is less price sensitivity for.

The lack of a single trend or factor that can predict the likelihood of a manufacturer offering these services for newly launched drugs can only indicate that these programs will become more commonplace across the industry. The rise in manufacturer funded patient service

programs will likely be a continuing trend. As manufacturers continue to invest significant resources into funding these programs, patient support services will spread and become more sophisticated. Consequently, more rigorous evaluations that incorporate patient outcomes, budget impact, and even prescriber engagement and professional well-being will be needed to ensure that resources are being allocated efficiently and appropriately. Transparency of data associated will enable a better understanding of the utilization and impact of the services across financial and health metrics.

Conclusion

Pharmaceutical manufacturers are increasingly offering more patient access services for their new drug launches as a way to overcome patient barriers to access including medication nonadherence. However, medication nonadherence may not be the only motivator for these programs. Not offering any form of patient access services is an exception among the newly launched drugs in 2019. Meaningful research on the utilization of these services could not only help patients and prescribers streamline the process of navigating the medley of programs but also aid manufacturers in creating more effective and impactful programs.

Connection to MPH Goals

The competencies that this capstone allowed me to develop and strengthen were to: 1) prepare and deliver effective written communications for professional public health audiences, 2) identify, access, and display in tables or graphs data relevant to disciplines of public health, and 3) integrate and synthesize information to generate hypotheses and practice evidence-based decision-making in public health. The literature review and extensive qualitative study on the topic of pharmaceutical-sponsored patient access services allowed me to hone research, analytical, and writing skills. By taking the results of the data collection and analyzing and visualizing them in meaningful ways to generate additional inferences and discourse allowed me to strengthen the second competency related to data analysis and visualization. Lastly, I was also able to make apply and connect the learnings in my coursework at Bloomberg, from Economic Evaluation to US Pharmaceutical Policy to the findings of my research. Integrating the research conducted for the capstone along with previous/current coursework allowed me to deepen the understanding of the concepts that I learned in those courses.

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