

Diabetes Patient Assistance Programs: Insights and Recommendations for Increased Access

As prescription drug prices become unattainable for many, patient assistance programs (PAPs) are becoming increasingly important. As advocates for patients with diabetes, we wanted to learn more about how patients were using these resources. How are patients learning about PAPs? How is the application process affecting patients? Who is ultimately able to access PAPs?

PAPs exist to help people who have difficulty affording their prescription medications and/or other supplies. According to the Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS), “pharmaceutical manufacturers may sponsor patient assistance programs (PAPs) that provide financial assistance [...] to low income individuals to augment any existing prescription drug coverage.”¹ PAPs have varying qualifications and requirements for admission that differ based on the PAP administrators’ preferences, the type of drug or supply needed, and the patient’s income level or household size, but all PAPs have one ultimate goal: to provide patients with the medications they need.

Based on the conclusions from our survey, we have come up with recommendations for foundations who offer PAPs on how they can make their programs more accessible and more effective. PAPs serve an incredibly important purpose in our healthcare environment, and improvement in their operation will mean improved outcomes for the patient community.

I. Patients who have diabetes rely on a variety of different PAPs.

Patients with diabetes can take advantage of many different PAPs depending on what medications they use to control their disease.

AstraZeneca manufactures the drugs Bydureon, Byetta, Farxiga, Kombiglyze, Onglyza, Symmlin, Xigduo. The AZ&Me Prescription Savings Programs provide free medications to patients who qualify. In order to qualify, patients must be a U.S. citizen, have an active Green Card, or be a Work Visa holder, and not be covered by insurance (except in certain Medicare circumstances). The AZ&Me program does not publish the maximum household income requirement. If accepted into the program, patients have access to their medications for one year. Patients can reapply each year.

¹ <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html>

Eli Lilly and Company manufactures the insulins Humalog, Humalin, and Basaglar as well as the oral medication Jardiance. The Lilly Cares Foundation has a PAP to help patients who may have trouble affording their insulin. The PAP is for patients with no prescription insurance coverage. Lilly Cares offers insulin and the diabetes drugs Glucagon and Trulicity at no cost. To qualify for Lilly Cares, a patient must be a U.S. resident, must not have prescription coverage, must not be enrolled in Medicaid or VA benefits, and must have a household income less than 400% of the federal poverty level (FPL). In order to apply for Lilly Cares, a patient must complete the Lilly Cares application and their healthcare provider must fill out, sign, and mail/fax in the application along with proof of income and other documentation. If accepted into Lilly Cares, patients receive their medication in three month increments through their healthcare provider's office. In August of 2018, Lilly opened its Lilly Diabetes Solutions Center, which is "a new patient-focused helpline with representatives who will identify personalized solutions to address insulin affordability[.]"²

Janssen manufactures the drugs Invokana, and Invokamet XR. The Johnson & Johnson Patient Assistance Program provides free medications to patients who qualify. This PAP is available to patients who are uninsured, are being treated as an outpatient by a U.S. licensed doctor, and live in the U.S. or a U.S. Territory. Patients must have a household income of under 300% of the FPL. If patients are accepted into the program, they will be given a card to pay for the medication at a pharmacy. No medication will be sent to the patient or the patient's healthcare provider.

Merck manufactures the oral diabetes drugs Januvia, and Janumet. The Merck Patient Assistance Program, Merck Helps, provides medication for free to eligible patients. Patients must be uninsured or have special circumstances of financial and medical hardship. Patients must also be a U.S. resident, have a prescription from a healthcare provider, and have a household income under 400% of the FPL. If accepted into the program, patients can receive medication through their healthcare provider's office or direct to their home for up to one year. Patients can reapply each year.

Novo Nordisk manufactures the insulins Levemir, Novolog, Novolog Mix 70/30, and Novolin, as well as the diabetes drugs GlucaGen and Victoza. The Novo Nordisk Foundation has two PAPs. The first is Reduced Rx, a collaboration with CVS Health. Reduced Rx provides Novolin insulin for \$25 per vial at CVS Caremark retail pharmacies to help patients who are uninsured or enrolled in a high deductible health plan. The second PAP Novo Nordisk offers is the Novo Nordisk Patient Assistance Program, which provides free medication to people who are U.S. citizens, have a household income less than 300% of the FPL, and do not have private prescription coverage, VA prescription benefits, or any government program such as Medicare or Medicaid (there is an exception for those Medicare beneficiaries who have entered the

²<https://investor.lilly.com/news-releases/news-release-details/lilly-diabetes-solution-center-now-open-help-people-insulin>

coverage gap in Medicare Part D and patients who have applied for and been denied Medicare Extra Help/Low Income Subsidy). If accepted into the Novo Nordisk PAP, patients receive their medication in three month increments via their prescribing healthcare provider's office.

Sanofi manufactures the insulins Apidra, Lantus, Soliqua, and Toujeo. The Sanofi Foundation for North America has one PAP, the Sanofi Patient Connection Program, that provides these products to patients at no cost. The Patient Connection Program is only for patients who have no insurance coverage for their prescribed medication; patients who have high deductible plans do not qualify for the PAP. In order to be eligible for the PAP, a patient must be a U.S. citizen or resident and be under the care of a licensed healthcare provider authorized to prescribe, dispense, and administer medication in the U.S., must have no insurance coverage or no access to the prescribed produce or treatment via their insurance, must not be eligible for Medicare or Medicaid, and must have a household income of less than 250% of the FPL.

II. Findings

Our survey confirmed some ideas we held before embarking on this research, but also gave us valuable insight into the application process which were not anticipated. Overall, we found four main insights: first, applicants had about a fifty percent chance of being helped by the PAP. Those who did not receive help were turned away because they did not qualify for the PAP (as opposed to finding assistance elsewhere or giving up on the application process). Second, most patients are not learning about PAPs at the pharmacy counter, but instead are learning about them from the internet and from their healthcare providers. Third, patients had generally good experiences with the application process, except when they were asked to provide additional documentation. Some patients found the qualifications for PAPs difficult to find and understand. Fourth, some patients did not receive their medications in a timely manner even with PAP assistance. These findings formed the basis for our conclusions and informed our proposed solutions to make PAPs more accessible to patients.

A. PAP applicants had about a 50/50 chance of getting assistance from the PAP. Most patients who did not receive help did not meet the PAP's qualifications.

About fifty seven percent of PAP applicants received assistance through a PAP.³ About seventy four percent of those who were left without help report that they did not receive assistance because they did not qualify for the PAP.⁴ This number is much higher than is acceptable, especially considering what hardship patients experience without financial assistance. Patients who do not receive assistance from a PAP face hard choices. About thirty three percent paid for their medication out of their own pocket with financial hardship. Another nineteen percent

³ "Did you receive assistance through a Patient Assistance Programs (or PAP)?" Yes 56.58%, No 43.42%. 76 total responses. Mean 1.43, Standard Dev. 0.50, Variance 0.25.

⁴ "Why did you not receive assistance through a Patient Assistance Program?" Did not qualify 73.53%, healthcare professional did not complete paperwork 8.82%, other 8.82%, application too complicated 5.88%, could not provide financial documents 2.94%, I do not have a healthcare professional to complete paperwork 0%. 34 total responses. Mean 1.74, Standard Dev. 1.52, Variance 2.32.

rationed their medication, which is dangerous and can have lethal consequences. Another thirty five percent either received medication from someone else with the disease, received medication from their healthcare professional or low-cost clinic, or simply stopped taking their medication altogether.⁵ When even one patient is left with a choice between facing financial hardship and rationing their medication, changes need to be made.

B. Very few patients are learning about PAPs at the pharmacy counter, which is where they're facing a cost crisis.

Patients are learning about PAPs from the internet and healthcare providers, but not at the pharmacy counter. About forty three percent of patients discovered a PAP via the internet. Another thirty nine percent were informed of a PAP by their healthcare provider. In contrast, a tiny seven percent of patients were informed of a PAP at their pharmacy.⁶ The pharmacy is the most common place where patients face the cost of their medications, yet patients are not receiving education about their options for affording their medications at that time.

C. Patients generally reported having good experiences with the application process.

Our survey showed that patients felt that the application was easy to complete, the patient's medical professional helped with their portion of the application, patients received notification of the status of their application quickly, and patients could apply entirely online.⁷⁸⁹¹⁰ We were pleased to see that an overwhelming ninety three percent of patients were not asked to pay a fee to get their application processed or were not asked to pay a monthly fee for the PAP.¹¹ However, there were two areas in which patients were more closely divided on whether PAPs were meeting their needs.

⁵ "If you did not receive assistance through a Patient Assistance Program, how did you receive your medication(s)?" I paid for them out of my own pocket with financial hardship 32.69%, I rationed my medication 19.23%, I got my medication from someone else with the disease 13.46%, I got my medication from my healthcare professional or low-cost clinic 11.54%, I stopped taking my medication 9.62%, I used a co-pay card 5.77%, other 5.77%, I paid for them out of my own pocket without financial hardship 1.92%. 52 total responses. Mean 3.87, Standard Dev. 1.94, Variance 3.77.

⁶ "How did you learn about the Patient Assistance Program (PAP)? Internet search 42.86%, my healthcare provider 39.29%, friends/family/community 8.33%, pharmacy 7.14%, Blog 1.19%, insurance company 1.19%. 84 total responses. Mean 1.58, Standard Dev. 1.41, Variance 2.00.

⁷ "The application was easy to complete." Slightly agree 48.68%, strongly agree 18.42%, slightly disagree 17.11%, strongly disagree 15.79%. 76 total responses. Mean 2.40, Standard Dev. 0.95, Variance, 0.91.

⁸ "My medical professional helped with their portion of the application." Slightly agree 35.06%, strongly disagree 28.57%, strongly agree 27.27%, slightly disagree 9.09%. 77 total responses. Mean 2.39, Standard Dev. 1.17, Variance 1.37.

⁹ "I received notification of the status of my application quickly." Slightly agree 38.96%, strongly agree 23.38%, strongly disagree 22.08%, slightly disagree 15.58%. 77 total responses. Mean 2.36, Standard Dev. 1.07, Variance 1.16.

¹⁰ "I could apply entirely online." Slightly agree 37.66%, strongly disagree 33.77%, strongly agree 15.58%, slightly disagree 12.99%. 77 total responses. Mean 2.65, Standard Dev. 1.11, Variance 1.23.

¹¹ "Did you pay a fee to get your application processed or pay a monthly fee for the program?" No 93.33%, Yes 6.67%. 75 total responses. Mean 1.93, Standard Dev. 0.25, Variance 0.06.

1. **Some patients reported that the qualifications to apply to the PAP were not easy to find and understand.** About forty two percent of patients thought that qualifications to apply were difficult to find and understand.¹²
2. **Some patients had problems acquiring the additional documents needed to apply for the PAP.** About forty seven percent of patients reported that getting the additional documents needed to apply was difficult.¹³

D. Some patients did not receive their medications quickly.

Often, patients turn to PAPs when they are facing an urgent need for their medication. Many patients do not realize they will have an issue affording their medication until they are faced with the cost of the drug at the pharmacy counter. At this point, patients likely do not have a large amount of the needed medication on hand. This is why it is such a problem that forty four percent of surveyed patients reported that they did not receive their medications in a timely manner.¹⁴ When a patient is under pressure needs a drug immediately, the patient needs to know that they can access a PAP and get a quick turnaround in order to access their medication in time.

III. Proposed Solutions

A. Eligibility requirements for PAPs must be simplified and made more inclusive so that patients are not turned away in their time of need.

Currently, patients are required to meet several varying standards before they can receive assistance from PAPs. The fact that each PAP has different requirements is a challenge for many patients, especially those who change what medication they are taking. For example, someone switching from a Novo Nordisk insulin to a Sanofi insulin may have been eligible for Novo Nordisk's PAP because their income is below 300% FPL. However, that same patient might then be ineligible for Sanofi's PAP because their income is higher than Sanofi's 250% FPL cutoff. For patients who are non-medically switched (patients whose insurance plan changes which drugs are covered and therefore forces the patient to switch medications or pay much higher prices) this difference in qualifying income is especially egregious since the patient is not the one making a choice to switch medications.

¹² "The qualifications to apply were easy to find and understand." Slightly agree 38.96%, slightly disagree 23.38%, strongly agree 19.48%, strongly disagree 18.18%. 77 total responses. Mean 2.11, Standard Dev. 1.41, Variance 2.00.

¹³ "The additional documents needed to apply were easy to get." Slightly agree 33.77%, slightly disagree 23.38%, strongly disagree 23.38%, strongly agree 19.48%. 77 total responses. Mean 2.51, Standard Dev. 1.06, Variance 1.12.

¹⁴ "I received my medications in a timely manner." Strongly disagree 33.77%, slightly agree 33.77%, strongly agree 22.08%, slightly disagree 10.39%. 77 total responses. Mean 2.56, Standard Dev. 1.18, Variance 1.38.

We recognize that PAP administrators cannot simply offer free products without discovering a patients' needs and qualifications. However, we ask that administrators consider the following changes to their application process which would increase access to these programs for those who need them:

- Raise income requirements to include patients whose household income is lower than 500% of FPL. In 2019, for a family of four, 500% of FPL is only \$64,375.
- Publish a flowchart-style graphic that explains who qualifies for which programs. For example, a patient who has a high deductible health insurance plan may have only one PAP option but a patient who does not have any insurance may have multiple options. The chart would illustrate the options for different patient situations.
- Publish a comprehensive list of applicant qualifications and requirements, including what paperwork is needed, what is needed from a healthcare professional, any costs associated with the PAP application or membership, expected timeframe for a decision, expected timeframe for receiving needed medication, and where patients can turn if they encounter a barrier while applying (a helpline telephone number or email address).
- Provide a separate application available for situations in which a patient does not have a healthcare provider readily available.
- Provide a section for written explanation in the application process so that patients with unusual circumstances can explain their situation (for example, families that include multiple medication-needing patients, patients who lose their insurance coverage, etc.).

B. Pharmacists and pharmacy workers must be prepared to give information on PAPs when they see that a patient is having trouble paying for their medication or when a patient requests such information.

Often, patients discover that they cannot afford their medication at the pharmacy counter. This is why it is so important for pharmacists and pharmacy workers to be informed about different PAPs available and their requirements. As noted above, only about seven percent of patients are learning about PAPs at the pharmacy.

Pharmacists and pharmacy workers should be educated on what options are available to people who have trouble affording their medication. We recommend that PAP administrators develop educational programs that pharmacists can use to learn patients' options. We recommend that PAP administrators distribute these educational programs to pharmacy workers' professional associations so that it reaches the largest number of pharmacy professionals possible. Such organizations could include, but are not limited to, the American Pharmacists Association, the National Community Pharmacists Association, the American Association of Colleges of Pharmacy, the American Society of Consultant Pharmacists, the American Society of Health-System Pharmacists, and/or the American College of Clinical Pharmacy.

Pharmacists and pharmacy workers should have information at the ready about each available PAP. We recommend that PAP administrators develop printed materials that pharmacists can

distribute to patients. More information about printed materials is included in the recommendation below.

C. Healthcare providers outside of pharmacies must be prepared to give information on PAPs during office visits, when prescribing medications, or when a patient requests such information.

Healthcare providers should be having conversations about the cost of the medications they prescribe in office visits, and should be informing patients about PAP options if they qualify for them. We were pleased to find that about 39% of patients are learning about PAPs from their healthcare provider. We aim for that number to increase as providers receive more education about PAPs offered by administrators. Ideally, healthcare providers would be having conversations about PAPs with their patients in every office visit and information about PAPs would be available to patients in every waiting room.

We recommend that PAP administrators develop printed materials that healthcare providers can distribute to patients. Because diabetes is such a prevalent disease and because medications used to treat diabetes can be out of reach for many patients, we recommend that PAP administrators collaborate together to create one handout or pamphlet that encompasses all PAPs available to patients who have diabetes. The handout or pamphlet should not be drug-specific; it should include information from every company's PAP. The handout or pamphlet should have the following information included: a comprehensive list of applicant qualifications and requirements, including which medications are covered by the PAP, what paperwork is needed to apply, what is needed from a healthcare professional, any costs associated with the PAP application or membership, and where patients can turn if they encounter a barrier while applying (a helpline telephone number or email address).

D. Patients who are facing a medical crisis cannot wait to access their prescription medications.

As noted above, often patients often discover that they cannot afford their medication when they go to pay for it at the pharmacy counter. At this point, patients are unlikely to have a hoard of the medication on hand to 'fall back on'. We were unhappy to learn that forty four percent of patients reported that they did not receive their medications in a timely manner. Patients are frequently referred to PAPs because they are facing a crisis and have an urgent need for their medication.

Again, we recognize that plan administrators who offer PAPs cannot simply offer free products without discovering patients' needs and qualifications. In most cases, citizenship, income, and medical need must all be proven before help is offered. However, emergency situations require immediate answers. Our proposed solution is to offer a grace period. We recommend that each PAP institute a 30 day crisis grace period during which patients receive access to their needed medications while they gather all the paperwork needed to apply to the PAP. This grace period should be offered once every 365 days. During this grace period, we encourage PAPs to follow

up with the patient to assess their progress towards getting their paperwork together so that the patient is not again facing a crisis at the end of the 30 day grace period. The process of applying to the PAP should include a way for patients to indicate that they intend to use the 30 day grace period in order to get their medications quickly. Additionally, the definition of ‘crisis’ should include situations in which a patient is facing the possibility of rationing or going without a medication that keeps them healthy in the short- or long-term.

IV. Methodology and Sample

A. Methodology

This survey was distributed through nine nonprofit entities: the American Association of Diabetes Educators, Beyond Type 1, Children With Diabetes, the College Diabetes Network, the Diabetes Patient Advocacy Coalition, Diabetes Sisters, the Endocrine Society, JDRF, and the National Diabetes Volunteer Leadership Council. The survey was shared with the diabetes community through direct email solicitation, inclusion in newsletters, social media, and online community platforms. The survey was available from May of 2018 to March of 2019.

B. Sample

5049 people viewed this survey. 322 people started the survey, and 70 people completed it. About twenty one percent of people who began taking the survey finished it. Most people who could not finish the survey answered “No” to the question “have you ever applied to a Patient Assistance Program (or PAP)?”¹⁵

The age of survey respondents varied. About forty three percent were between the ages of thirty four and forty nine.¹⁶ Survey respondents also had varying insurance coverage. About thirty five percent of respondents were on an employer based plan, and about twenty nine percent were on a high deductible insurance plan.¹⁷

¹⁵ “Have you ever applied to a Patient Assistance Program (or PAP)?” No 58.16%, Yes 41.84%. 282 total responses. Mean 1.58, Standard Dev. 0.49, Variance 0.24.

¹⁶ “What is your age range?” 49-49 25.37%, 34-41 17.91%, 57-65 14.93%, 50-57 13.43%, 26-33 11.94%, under 18 8.96%, 65 and up 7.46%, 18-25 0.00%. 67 total responses. Mean 4.88, Standard Dev. 1.88, Variance 3.53.

¹⁷ “I am (Please answer all that apply):” On an employer based plan 35.16%, on a high deductible insurance plan 28.57%, on Medicare 15.38%, on Medicaid 6.59%, uninsured 6.59%, on an individual plan 6.59%, on a marketplace plan 1.10%. 91 total responses. Mean 3.91, Standard Dev. 1.65, Variance 2.73.