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RESEARCH ARTICLE

Impact of Funding Assistance on Choice for On-Label Intraocular Pharmaceuticals

Cassie Papproth[1], Chase Miller[1], Harrison Sciulli[2], Esa Malik[2], Christina McCrossin[2], David Miller[2]

[1]*Creighton University School of Medicine.*
[2]*Retina Associates of Cleveland Inc, Beachwood, OH, USA.*

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Corresponding Authors: David Miller, Retina Associates of Cleveland Inc, Beachwood, OH, USA.

Abstract

Purpose: Understanding the economic impact on intraocular pharmaceutical choices is critical for retinal specialty care. This study assesses the impact of consistent Chronic Disease Foundation (CDF) funding on the maintenance of on-label pharmaceuticals.

Methods: A retrospective cohort study was conducted at a single, private retinal practice. Retina Associates of Cleveland's Practice Management System was used to track CDF patients' intraocular pharmaceuticals during the stable-funded period, September 16-29, 2022, and during transition to a non-funded period, November 16-29, 2022. Pharmaceuticals were tracked, and the change rates were analyzed. Outcomes tracked included maintaining on-label medication, switching to a different on-label medication, switching to free sample injection, or switching to off-label bevacizumab. Patients starting on free sample injections were excluded.

Results: During the non-funded period, 79% of patients switched to either free sample injections or off-label bevacizumab. In contrast, only 1% of patients switched medications during the stable-funded period.

Conclusion: Consistent funding significantly reduces the likelihood of switching from on-label to off-label medications or free samples, highlighting the magnitude financial assistance has in maintaining on-label treatment plans.

Keywords: Retinal Vascular Diseases, Chronic Disease Foundation (CDF), Anti-VEGF Therapy, Intraocular Pharmaceuticals, Financial Assistance Programs, Treatment Adherence.

1. Introduction

The treatment of retinal vascular diseases, such as wet Age-Related Macular Degeneration (AMD) and diabetic retinopathy, has been transformed by the development of intraocular pharmaceuticals. Among these are anti-Vascular Endothelial Growth Factor (VEGF) therapies, which have greatly improved patient outcomes[1]. Currently, there are several FDA-approved intraocular agents (on-label), including anti-VEGF intravitreal therapies such as aflibercept, brolucizumab, ranibizumab, and faricimab, as well as other classes of agents like dexamethasone implants. Additionally, bevacizumab, which is not FDA-approved (off-label), is another mainstay therapy for retinal vascular diseases at a significantly lower cost[2]. Bevacizumab, though not FDA-approved for intraocular use, remains popular due to its affordability compared to on-label drugs. It provides a viable alternative for patients who cannot afford the high cost of on-label therapies.

While these intraocular pharmaceuticals are revolutionary, they can impose a significant financial burden on both the healthcare system and patients due to their high cost and the need for multiple treatments[3]. Patients with chronic retinal diseases receiving intravitreal injections face substantial out-of-pocket costs, ranging from $1,300 to $2,000 per injection[4]. Bevacizumab, a medication not FDA-approved as

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an intraocular pharmaceutical, is often used as an alternative to FDA-approved treatments due to its lower cost or third-party payer requirements.

Patient assistance programs are in place to mitigate the cost of medications for patients. These programs play a crucial role in ensuring access to necessary treatments, especially for chronic conditions. While many of these programs are sponsored by pharmaceutical companies, some independent patient assistance programs offer benefits for patients with Medicare, Medicaid, or private insurance. The Chronic Disease Fund (CDF) is a national non-profit charitable organization that helps ease the burden of chronic illnesses, such as wet AMD, by providing financial assistance to patients undergoing treatment[5]. CDF funding allows patients to afford the use of on-label pharmaceuticals that they otherwise may not be able to access due to financial barriers. This assistance plays a key role in reducing the economic strain on patients and promoting adherence to optimal treatment plans. Patients must be enrolled by their physician and meet requirements for assistance with the qualifications of the funding organizations.

This funding allows patients to receive on-label pharmaceuticals at significantly reduced personal expense. From November 16-29, 2022, the CDF faced a non-funded period due to exhaustion of available funds. This unexpected funding gap forced patients to assume the costs themselves, offering a unique opportunity to assess how funding assistance affects treatment choices.

This period provides unique insight into the impact of funding assistance on the choice of intraocular pharmaceuticals. During this time, patients assumed financial responsibility for the portion of their treatment formerly covered by the CDF. This unexpected financial burden impacted treatment choices for patients and physicians, complicating the previously chosen treatment regimen. The purpose of this study is to compare the rate of pharmaceutical choice changes over this defined non-funded period (NFP) to a control group during a CDF stable funding period (SFP).

2. Materials and Methods

A retrospective cohort study was conducted at a large retina specialty practice, Retina Associates of Cleveland. Institutional Review Board approval was not sought for this study, as there was minimal risk to the privacy of patients, and data were de-identified. The requirement for informed consent was waived, but all patient data were handled in compliance with HIPAA regulations to ensure privacy and confidentiality. We tracked intraocular pharmaceutical use among patients during two distinct periods: a stable funded period (SFP) from September 16-29, 2022, and a non-funded period (NFP) from November 16-29, 2022. The pharmaceutical choice at the immediately preceding injection visit for both the SFP and NFP was recorded to track changes in each group. Pharmaceuticals tracked included aflibercept (AFL), brolucizumab-dbll (BROL), faricimab-svoa (FAR), ranibizumab (RAN), dexamethasone implant (DEXA), and off-label bevacizumab (BEVA).

Patients' use of pharmaceuticals was categorized as maintaining their treatment plan, switching to a different on-label pharmaceutical (OLP), switching to an off-label pharmaceutical, or receiving a free sample injection (FSI) during both the SFP and NFP. The percentage of patients that maintained their prior drug choice was calculated for both periods and compared to those who switched to a different OLP, a FSI, or off-label bevacizumab (BEVA). Additionally, we calculated the percentage of patients who switched from an OLP to either a FSI or off-label bevacizumab (BEVA) for both periods. The rates of treatment retention and changes between the two periods were calculated and analyzed using statistical methods. A one-sided t-test was used for statistical analysis, with a significance level set at $p < 0.05$.

Patients were excluded if they stopped treatment during either period or received medication not investigated in this study. Additionally, patients initially starting on free sample injections were excluded from this study.

3. Results

During the NFP, 2,507 pharmaceutical injections were administered practice-wide, to a total of 331 patients in the CDF. Of those 331 patients, 260 had received injections in a prior visit with foundation funding. Nine of the 260 patients had started on a free sample injection in the visit prior to the NFP and were excluded. The remaining 251 patients were tracked to determine their pharmaceutical injection choice immediately prior to the NFP and during the NFP. Of the 251 patients tracked, 205 (82%) had a documented change in inventory type between the SFP immediately preceding and during the NFP. For detailed pharmaceutical switching data during the NFP.

Table 1. *Non-Funded Period*

Initial Drug Use	Maintained same drug	Different on-label drug	Free sample injection	Off-label bevacizumab
aflibercept (n=193)	36 (19%)	2 (1%)	84 (44%)	71 (37%)
brolucizumab-dbII (n=9)	0 (0%)	1 (11%)	6 (67%)	2 (22%)
faricimab-svoa (n=30)	10 (33%)	0 (0%)	10 (33%)	10 (33%)
ranibizumab (n=13)	1 (8%)	0 (0%)	9 (69%)	3 (23%)
dexamethasone (n=6)	2 (33%)	0 (0%)	3 (50%)	1 (17%)
Total=251	49 (19.5%)	3 (1.2%)	112 (44.6%)	87 (34.7%)

In the observed SFP from September 16-29, 205 patients received intravitreal injections with foundation funding. Of these, four were started on a FSI and excluded from this study. The remaining 201 patients were tracked to determine their pharmaceutical injection choice immediately prior to the SFP and during the SFP. Pharmaceutical injections over the course of the funded period were tracked, with 21 (10%) having a documented change in inventory type during the observed funded period. For detailed pharmaceutical switching data during the SFP period.

Table 2. *Stable Funded Period*

Initial Drug Use	Maintained same drug	Different on-label	Free sample injection	Off-label bevacizumab
aflibercept (n=150)	144 (96%)	5 (3%)	1 (0.7%)	0 (0%)
brolucizumab-dbII (n=12)	9 (75%)	2 (17%)	1 (8%)	0 (0%)
faricimab-svoa (n=17)	15 (88%)	1 (6%)	1 (6%)	0 (0%)
ranibizumab (n=12)	9 (75%)	3 (25%)	0 (0%)	0 (0%)
dexamethasone (n=4)	3 (75%)	1 (25%)	0 (0%)	0 (0%)
bevacizumab (n=6)	0 (0%)	6 (100%)	0 (0%)	x
Total=201	180 (89.6%)	18 (8.9%)	3 (1.5%)	0 (0%)

Between the two observed time periods, the NFP saw approximately 8 (82%) times more patients switch pharmaceuticals compared to the funded period (10%) ($p = 0.0007$). In analyzing switching from on-label medication to a different on-label medication, the percentages were similar at 1% for the NFP and 8% for the funded period ($p = 0.21$). The number of patients switching from on-label pharmaceuticals to either FSI or BEVA was 199 (79%) for the NFP and 3 (1%) for the funded period, respectively ($p = 0.00017$).

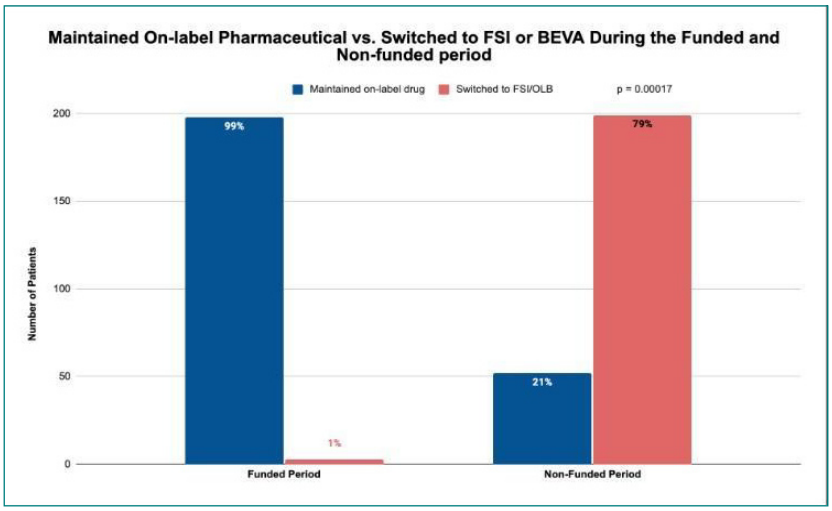

Figure 1. *Patients who switched to a free-sample injection or off-label bevacizumab versus maintaining on-label pharmaceuticals during funded and non-funded periods. The non-funded period rate of pharmaceutical change was 82% versus 8% during the funded period.*

4. Discussion

This study found a statistically significant difference in the maintenance of pharmaceutical choice in patients during the NFP compared to the SFP. During the NFP, changes in treatment courses predominantly involved switching from on-label medication to either a FSI or BEVA. Both FSI's and BEVA are more cost-friendly compared to on-label medications[6].

This result, while expected given the high cost of on-label intravitreal medications, is the first to quantify the magnitude of financial assistance on pharmaceutical choice. Retinal vascular diseases are chronic, often

requiring indefinite treatment, which makes cost a crucial factor for patients and providers. Thus, cost plays a major role in the treatment of these diseases. The cost of intraocular injections can vary depending on the pharmaceutical but typically ranges from $50 (BEVA) to $2,500 (OLP) per injection[4]. Compared to other intraocular injections, off-label BEVA is often considered the most economically affordable option at an average cost of $50-60 per dose[2]. Due to the high cost of injections like aflibercept, brolucizumab-dbll, ranibizumab, faricimab-svoa, and dexamethasone implants, many patients without financial support are often unable to afford the more expensive pharmaceuticals. This limits a patient's choice, physician recommendations, safety of treatment, and possibly the patient's long-term visual health. For instance, off-label BEVA has been shown to be less effective in diabetic macular edema, require more frequent injections, and is also associated with more particulate matter[7-9].

The alternatives to bevacizumab (BEVA) include free samples of on-label pharmaceuticals (OLP). However, the availability of free samples is often limited, and relying on them is not a sustainable solution for patients.

One limitation of our study is the relatively small sample size, which could overestimate the effect of CDF funding on pharmaceutical choices. Larger-scale studies are needed to validate these findings. Future studies should investigate the retention rate of treatment over a longer period or survey patients and physicians on the significance of CDF funding in treatment choices.

This study demonstrates that CDF funding significantly impacts the consistency of intraocular treatments and gives a magnitude of these programs on pharmaceutical choice, with eight times more patients switching medications when funding was not available.

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