

August 31, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: [CMS-4203-NC] RIN 0938-AV01 Medicare Program; Request for Information on Medicare

Dear Administrator Brooks-LaSure,

Thank you for this opportunity to provide comments on strategies to improve the Medicare Advantage (MA) Program.

ASRS is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

We are focusing our comments on three key recommendations:

- **Rescind the August 2018 memo permitting MA plans to implement step therapy.** Nearly every MA beneficiary with chronic retinal disease is subject to step therapy, which subverts retina specialists' clinical judgement and requires patients with vision-threatening conditions to undergo inferior treatments before being able to receive the treatment originally prescribed by their physician.
- **Remove or significantly scale back MA plans' ability to require prior authorization.** In this comment letter, ASRS is presenting preliminary data indicating the overwhelming majority of retina specialists' prior authorization requests for intravitreal injections are approved, but more than half of patients experience a delay in care because of insurer utilization management tactics.
- **Provide more readily available and thorough information to beneficiaries about MA plans' utilization management tactics and provide beneficiaries clear comparisons between how their care would be covered under Part B.** Patients are often unaware of hurdles to receiving care such as step therapy and prior authorization until they are denied or must wait for the treatment their physician prescribes. Conversely, they are not always aware of how coverage may differ if they remained with Part B.

STEP THERAPY

ASRS strongly opposes step therapy, or “fail first,” policies by any insurer, but we find them particularly objectionable for MA plans because they inequitably deny beneficiaries the same coverage they would receive under traditional Medicare Part B. Furthermore, step therapy interferes with the doctor-patient relationship and overrules retina specialists’ clinical judgement.

ASRS recommends CMS reinstate the original 2012 memo¹ that prohibited MA plans from implementing mandatory step therapy policies. In that memo, CMS correctly cites regulations requiring MA plans to “provide coverage of, furnishing, arranging for, or making payment for all services that are covered by Part A and Part B of Medicare,” and further notes that MA plans may not impose coverage determinations that are more stringent than original Medicare. By rescinding this memo in 2018, CMS has created an inequitable two-tier system whereby plans that have imposed step therapy are requiring more restrictive coverage decisions—requiring a patient to try and fail a plan’s preferred agent before covering the physician’s originally prescribed treatment—than the beneficiary would have encountered if they had been covered by original Medicare. **ASRS supports CMS’ efforts to ensure all beneficiaries have equitable access to all treatments covered under Medicare, but believes allowing step therapy to continue in MA threatens that access.**

Step Therapy for anti-VEGF Treatments

Over roughly the last two decades, treatment for chronic retinal disease—including age-related macular degeneration (AMD), diabetic retinopathy, diabetic macular edema (DME), and retinal vein occlusion (RVO)—has been revolutionized by the advent of anti-vascular endothelial growth factor treatments (anti-VEGF). Previously, there were very few treatments for these blinding conditions, but now anti-VEGF treatments allow patients not only to maintain, but in many cases, improve their vision. However, since 2018, MA plans looking to cut costs have increasingly implemented step therapy protocols for anti-VEGFs that overrule the physician’s clinical decision-making and threaten beneficiaries’ sight.

Retina specialists have several options for treating chronic retinal disease. The two most commonly used anti-VEGFs are aflibercept (Eylea) and ranibizumab (Lucentis), which are FDA-approved to treat the conditions listed above. Bevacizumab (Avastin) is also used, but is off-label and must be repackaged for ocular use. There are other FDA-approved agents that are either very new to the market or less frequently used. In addition, ranibizumab biosimilars have just become available in the last few months.

Because repackaged Avastin is cheaper than the FDA-approved products, MA plans have generally imposed step therapy policies for retinal disease that require a patient to begin treatment with Avastin and fail before the FDA-approved products are covered. It is well-established that branded anti-VEGF

¹ “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services” September 17, 2012, Medicare Drug and Health Plan Contract Administration Group.

drugs are superior to and/or safer than Avastin in various treatment groups.^{2,3,4} Substantial majorities of patients eventually need to be switched from Avastin to a branded product because they have experienced sub-optimal results with Avastin.

Step edits requiring the use of Avastin are contrary to accepted clinical practice and prevent patients from accessing the most effective treatments. Furthermore, they demonstrate that insurance companies are more interested in controlling costs than ensuring their beneficiaries have access to products that have been through the rigorous FDA approval process.

Step Therapy Impacts on Patients

Patients are the most harmed by step therapy policies. For patients with chronic retinal disease, who are likely suffering from vision impairment that may prevent them from performing daily activities, step therapy often means they will have to receive several monthly intravitreal injections of Avastin without experiencing any improvement. Many patients do not respond to treatment until they can receive the FDA-approved drugs. In addition to patients suffering from impaired vision, the treatment burden often falls on family members or caregivers who must take time from their jobs to accompany the patient to an appointment to receive an ultimately ineffective treatment.

ASRS has been collecting examples from patients who have been negatively impacted by step therapy and have presented a selection of the cases we have gathered below. ASRS members note that these stories are representative of their experiences with patients every day.

- *Jack, Long Island, NY:* Jack is a **99-year-old** World War II veteran who began experiencing vision impairment last year. His vision loss was so severe, he was unable to continue working in his family business or use a computer. After seeing a retina specialist who prescribed Eylea, Jack's insurance company denied the drug and required step therapy. He experienced no improvement with Avastin and had to wait months until he received Eylea, which cleared his vision quickly. Requiring patients of such advanced age to undergo step therapy is cruel and should be prohibited. A full telling of Jack's story is available here: <https://www.youtube.com/watch?v=7fex-EjoGal>
- *Patient, St. Louis, MO Area:* A patient with central retinal vein occlusion (CRVO) and cystoid macular edema in the same eye was treated by an ASRS member retina specialist several years ago. Treatments with Avastin did not clear the edema and he had permanent vision loss. Three years later, the same patient presented with CRVO in the fellow eye. Due to the poor response to Avastin previously, the doctor tried to get approval to use Lucentis, but it was denied due to step therapy. Because he knew the Avastin was unlikely to work, the retina specialist was forced

² Wells, J A, et. al. Diabetic Retinopathy Clinical Research Network. "Aflibercept, Bevacizumab, or Ranibizumab for Diabetic Macular Edema: Two-Year Results from a Comparative Effectiveness Randomized Clinical Trial." *Ophthalmology*. 2016 Jun;123(6):1351-9.

³ Major Jr, J. C., Wykoff, C. C., Croft, D. E., Wang, R., Mariani, A. F., Lehmann, A. E., & Brown, D. M. (2015). Aflibercept for pigment epithelial detachment for previously treated neovascular age-related macular degeneration. *Canadian Journal of Ophthalmology*, 50(5), 373-377.

⁴ Avery, R. L., Castellarin, A. A., Steinle, N. C., Dhoot, D. S., Pieramici, D. J., See, R., ... & Visich, J. E. (2014). Systemic pharmacokinetics following intravitreal injections of ranibizumab, bevacizumab or aflibercept in patients with neovascular AMD. *British Journal of Ophthalmology*, 98(12), 1636-1641.

to use a sample, which brought the disease in the new eye under control. In many cases, insurers know that a physician will not allow an adverse event to occur and take advantage of the limited supply of samples to avoid paying for any treatment, even the relatively low cost of Avastin.

- *Patient, Maryland and South Carolina:* This patient splits her time between Maryland and South Carolina. Because of her mother's previous poor response to Avastin, the patient's retina specialists in both states agreed that Lucentis would be a better option. As she has moved back and forth between her homes, the MA plan has repeatedly denied Lucentis and required a re-start with Avastin—in violation of the 2018 memo permitting step therapy. She has lodged a complaint with Medicare and is seeking assistance from her U.S. Representative.

Existing Healthcare Disparities Exacerbated by Step Therapy

Not only does step therapy divide patients into those who are able to access their physician's prescribed treatment and those who must fail on another treatment first, but it has the potential to worsen the impact of existing disparities in retinal disease. For example, the higher rate of diabetes in the nation's black, Hispanic and indigenous populations compared to white patients is well-documented. Correspondingly, racial minorities also suffer from diabetic retinopathy at a higher rate than white patients.⁵ Making matters worse, this population also is hindered by a lack of screening and less accessible and reliable transportation causing them to be less likely to see a retina specialist before the disease has progressed to a more severe state.⁶ Adding step therapy as a further barrier to care for these patients potentially leads to worse visual outcomes. Since diabetic retinopathy patients tend to be younger than AMD patients, they may still be working, and losing sight may imperil their employment prospects and lead to further health conditions and thereby, costs.

Interference with the Doctor-Patient Relationship

While the potential harm patients can suffer as a result of step therapy is the most troubling issue to retina specialists, the constant overruling of their clinical judgement by insurance companies is exasperating and contributes to the well-publicized crisis of physician burnout. Step therapy robs retina specialists—who have completed an additional fellowship beyond their ophthalmology residency—of their autonomy and replaces it with the judgement of the insurance company which is likely not employing retina specialists to make these policies. ASRS members report they are weary of constantly explaining to patients that their insurance coverage will not allow them to begin with the drug they know to be the most effective and that the patient must undergo several treatments of a less-effective drug first. Step therapy indicates to patients that they do not have the authority to work with their physician to pursue the most appropriate treatment for their disease, and instead, that authority is solely the insurance company's.

To ensure MA beneficiaries have the same access to care that beneficiaries with Part B have, ASRS continues to urge CMS to prohibit MA plans from using step therapy.

⁵ Kaelber, DC. "A Descriptive Study of Diabetic Retinopathy Disparities among Millions of Patients." Association of Research in Vision and Ophthalmology Annual Meeting. May 2022.

⁶ Barsegian, A. Boleslav, K. Lee, J. Salifu, M. McFarlane, S. Diabetic Retinopathy: Focus on Minority Populations. *Int J Clin Endocrinol Metab.* 2017; 3(1): 034–045.

PRIOR AUTHORIZATION

It is well-documented not only in previous comment letters from ASRS, but across medicine, that MA plans' use of prior authorization in recent years has expanded to include nearly every procedure and treatment and has become a major source of administrative burden for physician practices. Not only are the burdens prior authorization places on practices becoming well-known, new data indicates that it is also ineffective at reducing the cost of care. We recognize that Medicare, and thereby plans participating in the MA program, must be good stewards of the Trust Fund and some use of prior authorization for certain services may be warranted, but data show it is unnecessary for retinal disease.

ASRS Intravitreal Injection Prior Authorization Tracking Project

Over the past year, ASRS through its Practice Management Committee, has undertaken a study to measure how frequently, and under what circumstances, prior authorization requests for intravitreal injections are approved. The initial study included 2,361 intravitreal injections performed at nine different clinical sites across the United States. The study tracked the date of service, diagnosis, prescribed drug, payer, decision on the prior authorization, reason for denial and time spent by the practice obtaining the authorization. Preliminary results were presented at the 2022 ASRS Annual Meeting.⁷

Key among the findings was that 96.3% of prior authorization requests were approved with the most common reason for denial being step therapy. Avastin—which is generally the first required drug with step therapy and should not be subject to prior authorization—was approved 99% of the time. Despite the overwhelming success rate for all treatments, 56.8% of patients experienced a delay in care due to prior authorization. The study found that on average, practices spent 47 minutes on each prior authorization request, but that some cases stretched days or weeks to complete. (Complete results included in Appendix A.) The authors of this study are currently preparing it for publication and seeking further analysis related to step therapy.

While these data are only preliminary, they paint a clear picture that retina specialists are providing clinically-appropriate care and that MA plans are needlessly bombarding them with authorization requests. In fact, it is the MA plans that are not being judicious stewards of Medicare dollars. By requiring authorization, and therefore that the patient would have to return another day, they are potentially requiring unnecessary visits. ASRS recommends that CMS limits MA plans' ability to require prior authorization for services that are so frequently approved.

OIG and Congressional Action

It is not only physician practices that are raising concerns with MA plans' use of prior authorization. A recent report from the HHS OIG found that a significant percentage of MA claims denied through prior authorization would have been covered under original Medicare.⁸ This again violates the regulations

⁷ Dang, S. "Anti-VEGF Injection Prior Authorization Impacts on Retina Practices." 2022 ASRS Annual Meeting, July 16, 2022.

⁸ "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care." HHS Office of the Inspector General. April 2022.

mentioned in the previous section of this comment letter that MA plans are prohibited from instituting more stringent coverage criteria than original Medicare. We agree with the OIG's recommendations that CMS increase its oversight of plans' use of prior authorization.

In addition, ASRS supports bipartisan legislation currently in Congress, the Protecting Seniors Timely Access to Care Act, which would streamline and reform the prior authorization process. This bill has overwhelming bipartisan support and has already passed the House Ways and Means Committee. While we continue to seek its enactment, we believe that CMS already has the authority to implement the provisions included in the bill, such as requiring standardized, electronic prior authorization requests; exempting services with high approval rates from prior authorization; and instituting peer-to-peer reviews in the appeals process. ASRS recommends CMS implement those provisions immediately.

Inequitable Impacts of Prior Authorization

As noted above, the treatment burden for chronic retinal disease can be significant. Those burdens are made worse, however, by MA plans' use of prior authorization. By requiring a patient to come back for a follow-up visit to the retina specialist to receive treatment, or make multiple visits to receive a mandated ineffective treatment, MA plans disproportionately burden patients who can least withstand it. Travel to unnecessary additional visits becomes much more difficult for elderly and vision-impaired patients who may not be able to rely on public transportation. For patients that do have family or caregiver support to accompany them to the retina specialist, coming back for additional visits delayed by prior authorization means the escort may potentially miss work and have to take unpaid leave. For some populations who may be more susceptible to retinal disease, such as those racial minorities mentioned above with diabetic retinopathy, prior authorization further delays interventions that may already be coming later due to existing healthcare disparities and could lead to worse outcomes.

Unlike many entrenched and systemic issues mentioned above that lead to poorer health outcomes for some populations, CMS can alleviate the inequitable burden of prior authorization by limiting MA plans' ability to use it. ASRS recommends CMS take action immediately.

IMPROVE BENEFICIARY ACCESS TO PLAN INFORMATION

ASRS is pleased that CMS has recently prioritized beneficiary protections in its policies related to MA. Recently, ASRS has supported in our comments, proposals by CMS to create a Star Rating measure related to beneficiary complaints and to increase oversight of third-party marketing organizations that often use deceptive marketing practices to attract beneficiaries. We encourage CMS to continue with these efforts and expand on them to ensure that beneficiaries are making the most informed choice when selecting a type of Medicare coverage. ASRS urges CMS to consider the following suggestions:


- *Require MA plans to provide clear explanations of the utilization management practices they employ.* Beneficiaries who have not encountered prior authorization or step therapy in Part B or other plans may not be aware of what they may mean for their care. MA plans must be required to give potential beneficiaries a full description, including clinical examples, of how they may limit a patient's access to certain services.

-
- *Streamline the Star Ratings Program to focus on the beneficiary experience:* While adding more star rating measures can be helpful to address certain issues, if there are too many or they are too focused on specific issues, it can diminish the overall weight of key indicators and leave beneficiaries with an inaccurate picture of the plan's performance. ASRS recommends that CMS focus on limited metrics from beneficiary feedback, such as how they have been able to access care, the affordability, and the clarity of information provided by the plan.
 - *Provide clear comparisons with coverage under Medicare Part B:* Like any other insurance product, selecting an MA plan is a prospective process based on limited information with no way to know what the future will hold. Beneficiaries with existing conditions may have some idea of what services they are likely to need, but they and anyone else will have no way to predict accidents or the onset of new disease. Providing a beneficiary with some sort of retrospective analysis of the cost of care they received in the preceding year could be helpful in demonstrating how each type of coverage would impact them. A side-by-side accounting of the premiums, out-of-pocket expenditures, and limitations, such as step therapy, of a beneficiary's MA policy, compared to what they would have encountered under Part B for the same care could assist beneficiaries when choosing their coverage during open enrollment.
 - *Limit direct-to-consumer advertising of MA plans:* ASRS is concerned that the current marketing practices of many MA plans, including television commercials, bombard beneficiaries with overly-positive depictions of their plans. These commercials focus on additional benefits, such as gym memberships or dental benefits, and neglect to mention drawbacks such as limited provider networks and utilization management. ASRS urges CMS to direct beneficiaries to reputable, unbiased information sources for beneficiaries considering their Medicare coverage options. Thirty-second television advertisements are not the appropriate source of that information.
 - *Ensure beneficiaries have broad access to and accurate information about specialists included in the network.* ASRS has long recommended that CMS strengthen its network adequacy standards to ensure that MA beneficiaries have access to all types of specialists and sub-specialists. Because retina specialists must designate ophthalmology as their primary specialty, it is difficult for beneficiaries to ensure that if they need the care of a retina specialist that one will be available to them in-network. We recommend CMS use expanded metrics, including taxonomy codes, to ensure beneficiaries have access to a full complement of sub-specialists. In addition, CMS should provide oversight of plan directories to ensure networks are not only adequate, but the information is accurate and up-to-date.

ASRS believes that implementing these reforms and providing additional oversight of plans will ensure that MA beneficiaries have equitable access to retina specialists' care. Patients with retinal disease are among the most elderly patients who often also suffer from multiple systematic co-morbidities. CMS should prioritize presenting clear, unbiased information about their coverage options to prevent them from experiencing required treatment with less-effect agents, delays in care, or loss of access.

Thank you again for this opportunity to provide comments. We look forward to working with CMS to improve the MA program for all beneficiaries. If you need additional information, please contact Allison Madson, vice president of health policy, at allison.madson@asrs.org.

Sincerely,

A handwritten signature in black ink that reads "Phil Ferrone". The signature is written in a cursive, slightly slanted style.

Philip J. Ferrone, MD, FASRS
President

Appendix A – Anti-VEGF Injection Prior Authorization Impacts on Retina Practices – *Initial Results*



Anti-VEGF Injection Prior Authorization Impacts on Retina Practices

Sabin Dang, MD
The Retina Institute, St. Louis Missouri

D. Wilkin Parke MD, Guneet S. Sodhi MD, David Eichenbaum MD, Jared Nielsen MD, Carl Danzig MD, Geeta Lalwani MD, Nader Moinfar MD, Nikolas London MD, Alan Kimura MD, Mike Jumper MD, Ken Lord MD, Veeral Sheth MD, Dante Pieramici MD, Anton Orlin MD, John Thompson MD, Charles Wykoff MD.

Financial Disclosures



- Regeneron: Speaker Bureau
- Bausch and Lomb: Research grant, advisory board

Introduction



Anti-VEGF administration is the most common procedure performed by retina specialists.



Increasingly, the process of obtaining authorization for these vision saving treatments is becoming more difficult.



With this study we aim to quantify the impacts and results of the PA process for these medications.

Methods

- A prospective, multi-center study was performed to collect data on PA requests for anti-VEGF medications.
- Sites were instructed to log the results of anti-VEGF PA requests on a standardized data form. Each site logged patients where a PA request was made on a specific date of service.

ASRS Prior Authorization (PA) Project

Thank you for participating in this project, please note all fields are required. We recommend keeping track of your selected PA manually, and then returning to this form when you receive final decision regarding the PA request.

 sabin@sabindang.com (not shared) [Switch account](#) 

* Required

Note: Only enter patients where a PA was required to treat the patient. Patients with authorizations on file should not be included

Medical Practice *

Your answer

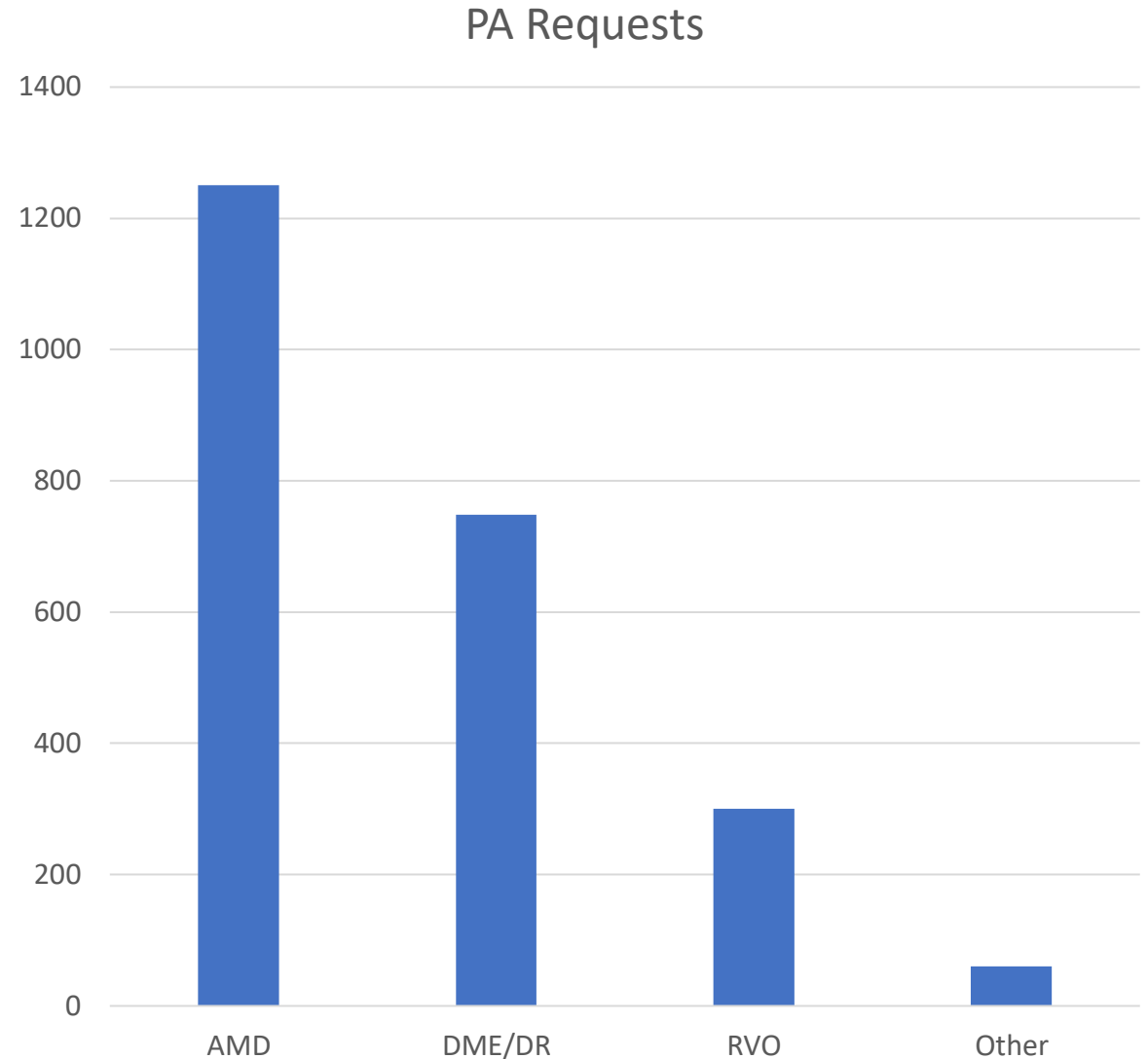
Date of Service *

MM DD YYYY

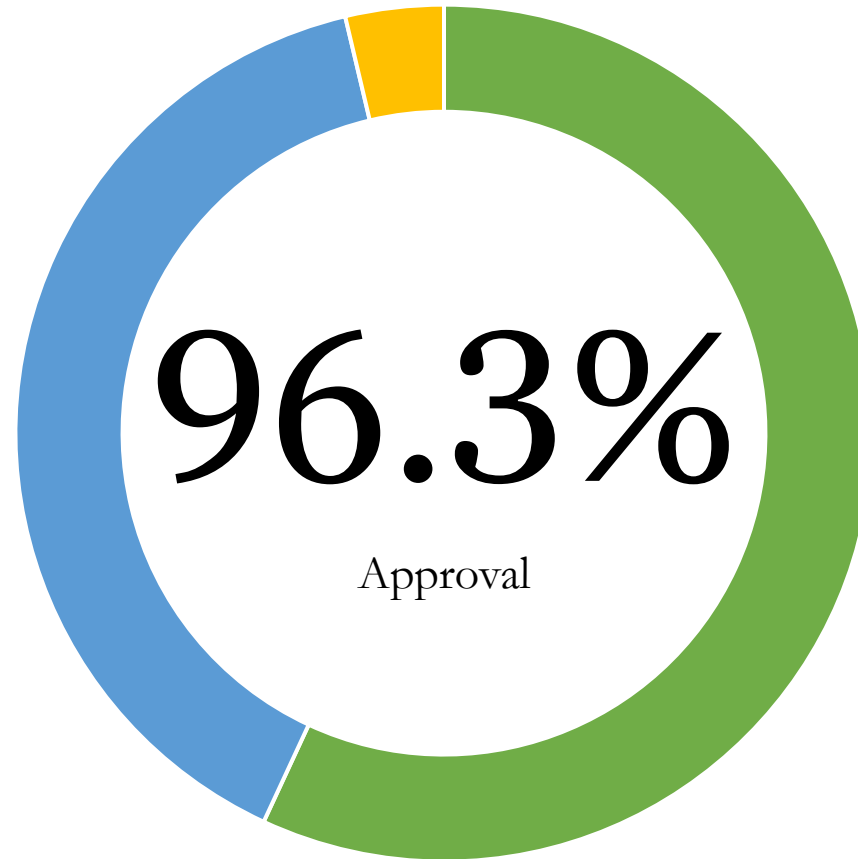
/ /

Results

- 2,361 intravitreal injections were logged over 9 clinical sites throughout the United States
- Three PA requests were excluded as they were performed prior to the date of service
- AMD was the most common diagnosis for PA in the data set, followed by DME/DR and RVO



Prior Authorization Results

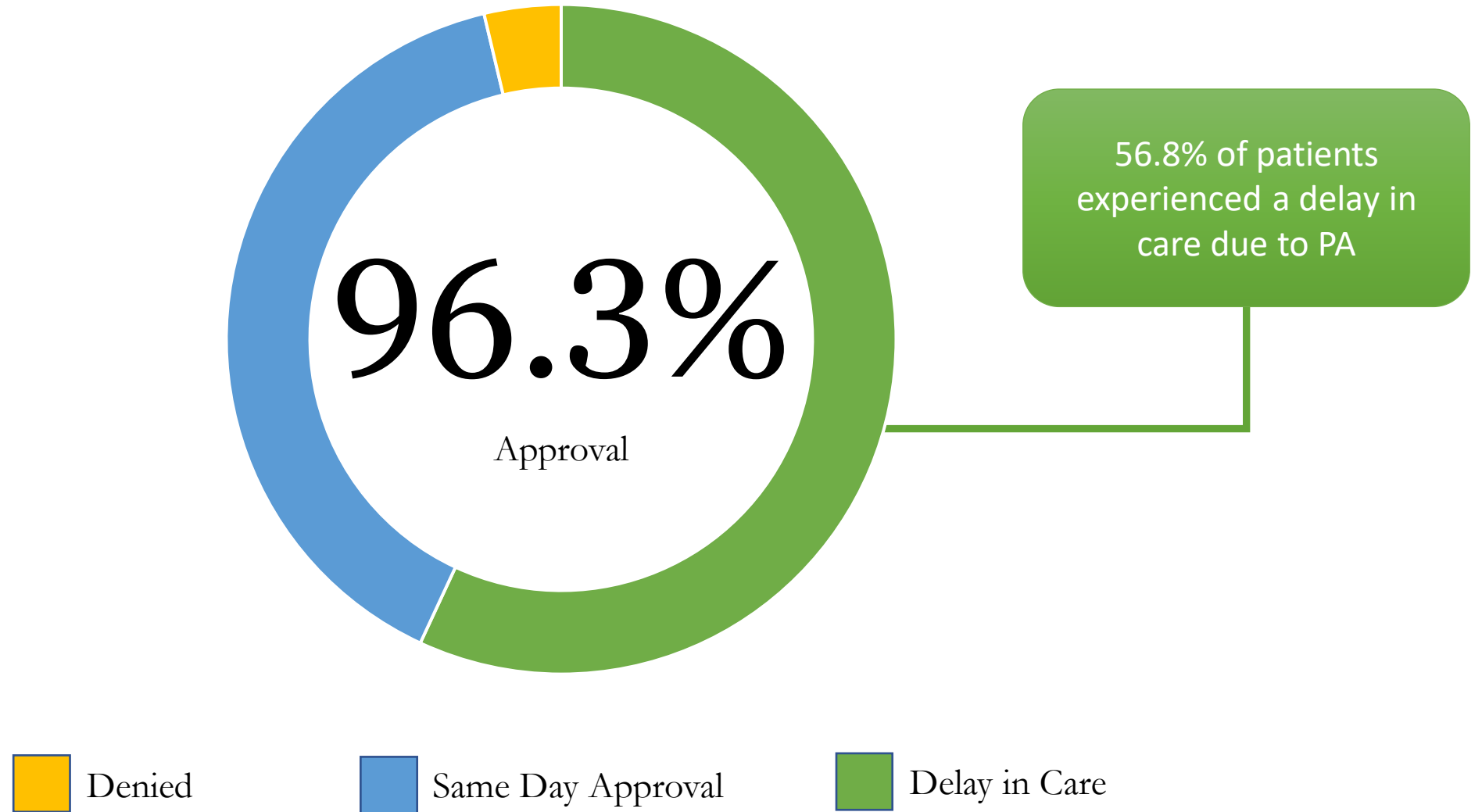


 Denied

 Same Day Approval

 Delay in Care

Prior Authorization Results

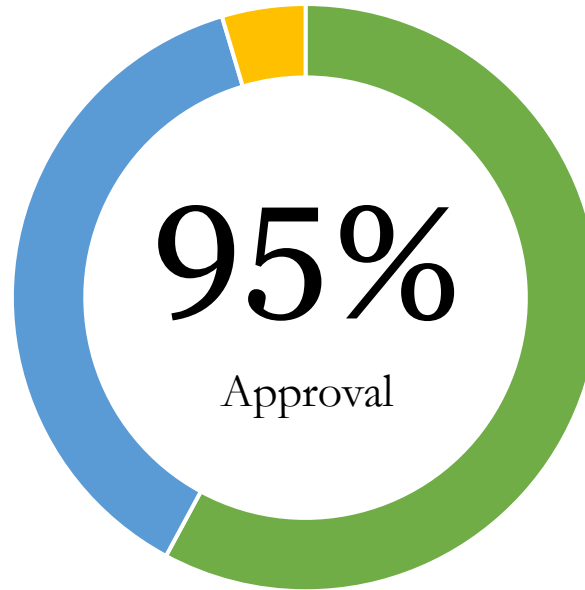


Prior Authorization Results by Medication

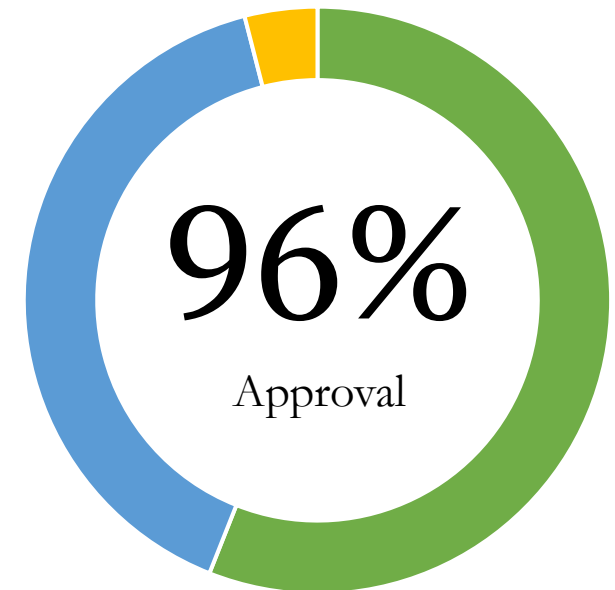
bevacizumab



aflibercept



ranibizumab



 Denied

 Same Day Approval

 Delay in Care

Reason for Denials

- Step therapy is the leading reason for denial, accounting for 73% of the 94 denials
- Uncovered diagnosis accounted for remaining denials (e.g. CNV secondary to POHS)



Administrative Burdens

47 minutes

Average time spent per PA request

12 requests

Required over 20 hours of active administrative staff time to obtain

7 patients

Waited more than 1 month to get their PA authorized

Conclusions



Retina specialists are highly accurate and selective in requesting prior authorizations



The prior authorization process results in a delay of care in a majority of patients



Significant administrative time, from the practice and carrier, were spent processing these requests, without evidence that it prevents unnecessary treatment



Thank You

sdang@rc-stl.com