EVERTON L. ARRINDELL, M.D.
CARL C. AWH, M.D.
BRANDON G. BUSBEE, M.D.
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ERIC W. SCHNEIDER, M.D.
PETER L. SONKIN, M.D.
AKSHAY S. THOMAS, M.D.
R. TRENT WALLACE, M.D.

TENNESSEE RETINA

CENTENNIAL PROFESSIONAL PLAZA
345 23RD AVENUE NORTH, SUITE 350
NASHVILLE, TN 37203
(615) 983-6000 PHONE
(615) 983-6010 FAX
WWW.TNRETINA.COM

December 10, 2019
Andrea Willis, MD, MPH, FAAP
Vice President and Chief Medical Officer
BlueCross and BlueShield of Tennessee, Inc.
6021 Brentwood Chase, Dr.
Brentwood, TN 37027

Dear Dr. Willis,

We are writing in strong objection to the recent BCBST requirement that patients will have to use specialty pharmacies in order to receive commonly used injectable medications for vision-threatening retinal diseases. Our position is supported by the American Society of Retina Specialists (ASRS), the largest international organization of retina doctors, who share our concern that this policy will risk the vision of patients by delaying treatment, limit the option of providing same-day treatments, increase the financial burden for patients, and waste medications we cannot use when patients do not handle them correctly.

Our repeated efforts over the last few weeks to discuss this issue with you and others at BCBST have been rebuffed. Efforts made by the ASRS last week to arrange a conference call have also been ignored. Therefore, we are including with this letter several documents that would have been shared with you in person. They include:

a) The letter previously sent to BCBST last month from the American Society of Retina Specialists (ASRS);
b) A detailed explanation of the process that our practice has carefully developed for the safe and effective acquisition and administration of injectable drugs;
c) A letter to our patients informing them of the policy change, and our concerns of the impact that this policy will have on their care; and
d) A letter to employers who have chosen the BCBST plans affected by this policy.

We do not believe that patients should be forced to risk their eyesight as this policy is implemented, and we feel that our patients deserve to be informed of how they will be impacted by this proposed policy. We further believe that employers need to be informed of unanticipated costs and potentially disastrous consequences associated with their choice of employee health plans. Therefore, we plan to send the included letters to BCBST patients and employers on Friday, December 13, 2019, if this policy is not rescinded.

Our primary focus is to maintain high-quality retinal care for all of our patients. We ask that you reconsider your policy in light of the concerns raised.

Sincerely,

Franco M. Recchia, MD Carl C. Awh, MD
On behalf of Tennessee Retina, PC
Cc: all relevant contacts at BCBST

ASRS American Society of Retina Specialists

November 18, 2019

Andrea Willis, MD, MPH, FAAP
Vice President and Chief Medical Officer
BlueCross and BlueShield of Tennessee, Inc.
6021 Brentwood Chase, Dr.
Brentwood, TN 37027

Dear Dr. Willis:

On behalf of members of the American Society of Retina Specialists (ASRS) we write to express our concerns regarding the BlueCross and BlueShield of Tennessee requirement to use a network of specialty pharmacies to deliver commonly used retina drugs (Avastin, Eylea, Lucentis and Beovu). This presents significant logistical and administrative issues for both the two large retina practices in Tennessee that treat an average of 150 patients per day at multiple clinic locations including outreach clinics, as well as small retina practices that may not have much experience utilizing specialty pharmacies. We would greatly appreciate the opportunity to meet with you to discuss how your policy will interfere with patient care.

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.

Patient Considerations

The typical patient population cared for by retina specialists is comprised of patients with diabetes, cardiovascular disease and elderly persons with wet age-related macular degeneration (AMD). Most patients with wet AMD need anti-VEGF injections in their eye within a specific treatment window to prevent permanent and irreversible damage to the retina and vision. To provide the highest quality of patient care retina specialists often treat patients on the same day they are seen. To provide same day treatment, retina specialists require an office stock of medicines to optimize treatment decisions and outcomes at the point of service.

Requiring specialty pharmacy drug delivery for our patient population would result in the patient needing to return for a second visit while the prior authorizations are verified, the specialty pharmacy order is placed, confirmed, shipped and received. Not only does this requirement risk a poorer outcome for the patient and increase their costs in terms of time and additional copays, access to our care is effectively limited. From the communication, it is unclear whether this process is waived for patients with emergent conditions that require immediate injections. If the process is not waived, what barriers will staff have to navigate to make the drug available on short notice? If your intention is to ship the drug ahead of an anticipated appointment, your policy will result in wasted drugs when patients become ill and cannot return, move out of the area or switch care to another doctor.

20 North Wacker Drive
Suite 2030
Chicago, IL 60606

phone 312 578 8760
fax 312 578 8763
www.asrs.org

Since retina patients are typically elderly and may have disabilities such as low vision, they often rely on family members or other caretakers to transport them to and from appointments, which adds another level of complexity to maintaining the patient's treatment schedule. In some cases, this can result in now-shows or at last minute scheduling changes. In these events, will practice staff be responsible for repacking and sending refrigerated unused doses back to the specialty pharmacy if it is not used? Currently, unused office stock medications are used for other patients. This new process would mean that medications may go to waste at additional cost to you.

Specialty Pharmacy Related Concerns

Many specialty pharmacies are required to contact the patient prior to dispensing the medication. Patients are generally scheduled for their next appointment at the time of their injections. Our members have found that that patients using specialty pharmacies arrive at the office for their next appointments, only to find that the drug has not been shipped due to the inability of the specialty pharmacy to reach patient for authorization. Will the onus of approving the shipment of these medications be placed on the patient, the practice or both? Again, if the drug is not available at the patient's appointment this adds to the treatment burden, wasting patient and physician time.

In the cases where there are delays with shipping, or the medication is received and the temperature monitor in the shipping package indicates the drug has exceeded the safe storage temperature range, how will the specialty pharmacy replace the medications?

Practice Management Concerns

Working with specialty pharmacies requires substantial uncompensated time that is not currently encountered when drugs are ordered from distributors. This new requirement means that an office staff has a very short window to obtain prior authorization from Magellan RX for hundreds of patient prescriptions. Following the prior authorization, the staff would have to set up authorizations for one of the listed specialty pharmacies for each patient. Are these processes automated so that refills will be requested from the pharmacy, or will the practice have to submit a new prescription each time? Once the order with pharmacy is placed, will the practice also have to follow up with the pharmacy prior to the patient's appointment?

Upon successful receipt of the medication from the specialty pharmacy, **each medication** would have to be logged into an inventory tracking system, labeled, and filed into the proper place of a medication-grade refrigerator, which is monitored and alarmed in order to ensure that the medication is not compromised prior to injection. Temperatures for this medication are also logged.

At the patient's scheduled treatment location and time, staff would need to assure the correct patient receives their specific syringe/vial. For patients on "treat and extend" protocols, where OCTs are required at the time of the injection to determine the presence or absence of retina edema, the retina specialists determines whether to keep or extend the interval for the next injection. Will office staff now have to store that patient's drug in a specific place until the medication is needed or ship it back? All of these new administrative processes will have to be determined for the BCBSTN patients and none are reimbursed according to your policy. If this policy is enacted, the practices will expect to be reimbursed to pay for the additional administrative burden.

In short, the logistics of this new program has the potential to be disastrous for offices who take care of many elderly patients. We strongly urge you to reverse this policy for patients receiving anti-VEGF drugs

as we believe it places an unrealistic burden on physician practices and increases barriers to providing efficient and appropriate medical care.

Thank you for considering our request. Please contact ASRS Director of Practice Management, Monica Horton at monica.horton@asrs.org or 312-578-8760, to schedule a meeting to further discuss this issue in treating our retina patients.

Sincerely,

Robert L. Avery, MD
Chair, Practice Management Committee
American Society of Retina Specialists

John T. Thompson, MD
Chair, Health Policy Council
American Society of Retina Specialists

cc:

Caroline Carney, MD, MSc, FAMP, CPHQ
Chief Medical Officer
Magellan RX

Jill Blim
ASRS Executive Vice President

Tennessee Retina (TNR)

A summary of TNR's current drug management process and an assessment of the likely risks and effects on patient care that will result from the BCBST specialty pharmacy policy

OVERVIEW:

- Intraocular injection of physician-administered drugs has transformed the treatment of blinding retinal diseases. Timely treatment stabilizes or improves vision in a majority of patients with neovascular macular degeneration, diabetic macular edema, retinal vein occlusion, and other conditions encountered in the BCBST patient population.
- Utilization of injectable drugs has increased through the years as efficacy, treatment options and patient volumes have increased.
- The development of injectable drugs for retinal diseases has improved the quality of life for millions of patients worldwide. Economic analysis has shown that, while these medications are costly, the benefits to society far outweigh this cost. However, the benefits diminish as adherence to treatment diminishes (Mulligan et al, JAMA Ophthalmol 2019). In other words, any barrier to treatment reduces a patient's chance to benefit from treatment.
- Tennessee Retina has developed a sophisticated, reliable method for managing drugs in a manner that allows timely and safe treatment in 9 locations throughout Tennessee.
- A shift to the BCBST policy of using a specialty pharmacy will necessitate changes that will compromise patient outcomes due to delays in treatment and potential safety issues with drugs.
- The liability for adverse outcomes related to the BCBST specialty pharmacy policy should be recognized, acknowledged, and accepted by BCBST.

DRUG MANAGEMENT PROCESS

Goals:

- To ensure availability of the appropriate drug for each patient at each TNR practice location
- To ensure safety of physician-administered drugs
- To responsibly purchase, store, transport, track, and utilize expensive drug inventory
- To appropriately bill for and be reimbursed for the substantial labor and material costs associated with managing physician-administered drugs.

Summary of process to manage physician-administered drugs

1. **Order** buy and bill drug from distributors. Performed weekly at 6 TNR offices. Managers review drug inventory on hand, reconcile it with upcoming patient appointments and diagnoses, and order drug sufficient to meet projected clinical needs. This is done for up to 7 different physician-administered drugs.
2. The various drugs typically arrive the following day in temperature-controlled packaging. All locations have clinical staff specially trained and experienced in the handling of these special medications.
3. A specially trained technician first moves the drug boxes to a secured storage area and places them in designated climate-controlled refrigerators with constant temperature monitoring systems and alarms to ensure that drugs are maintained according to FDA guidelines.
4. A specially trained technician then compares the drug received to the packing slip and manually enters the number of units received, the lot number, and the expiration date into a proprietary third-party drug inventory management system.

5. The inventory system assigns a unique drug tracking number to each dose of drug and prints a 2D barcode used to track the inventory during every step of the drug's life-cycle. This tracking code creates a chain of custody that is interfaced with our E.H.R. and practice management systems.
6. Our specially trained staff perform daily inventory checks and review the temperature logs to ensure safe handling of the drugs. At any given time, TNR is responsible for several thousand drugs in 9 locations throughout middle Tennessee and Kentucky.
7. One to two days before a given clinic, our billing staff runs benefits verification for all scheduled patients to ensure that all patients have: 1) a drug authorization on file for the correct drug; 2) copay assistance on file (if needed); 3) valid insurance for the expected date of service; and 4) an estimate of the patient's financial responsibility for the scheduled appointment.
8. The morning of clinic at our seven main offices, technicians take out blocks of unassigned drug from the secured storage room and place them in special refrigerators at the clinical stations. For the two satellite offices where we don't order and store drug, technicians come to the main Nashville office first and transport blocks of unassigned drugs before clinic begins. Medications are transported in specially designed carriers to ensure drugs stay within pre-set temperature ranges. Movement of medications within and between offices is tracked in the inventory system.
9. During clinic, a TNR physician examines the patient and determines if the patient should be treated with an injectable drug that day, and decides on the optimal drug. If so, only then is a drug taken from inventory for use.
10. The technician takes an unassigned dose of drug from the refrigerator, confirms that it is not expired, and manually and electronically assigns that dose to the patient and to the specific eye(s) in both the inventory system and the EHR.
11. The physician then treats the patient with the appropriate medication at the time of the patient's visit.
12. At the end of each clinic, a technician reconciles all drug used with the inventory system and the EHR to ensure that all doses of drug are accounted for. Details of drug usage are then relayed to the billing system.
13. Unused, unassigned drug is returned to inventory at the site or to the central supply at the main Nashville office.
14. The inventory system is used for the vigilant tracking of expiration dates and lot numbers. Tracking of expiration dates eliminates waste of medication by ensuring that doses are used long before the expiration date. Tracking of lot numbers provides an extra measure of safety to our patients in at least two ways: (1) patients receiving injections in both eyes are treated with doses from different lot numbers to avoid the low, but potentially serious, risk of bilateral infection in case a particular lot was contaminated during manufacture or distribution; (2) in rare cases of unforeseen adverse events, specific lot numbers can be quarantined and not administered to subsequent patients until the adverse event is properly investigated.
15. The standard process outlined above is used for patients with <u>scheduled</u> appointments for whom treatment could be anticipated.
16. For patients for whom treatment was <u>not</u> anticipated, but who are determined to need "same day" treatment based upon exam findings, <u>additional steps</u> are necessary. It is well-established in the peer-reviewed literature and among retinal community that prompt treatment reduces the risk of long-term irreversible vision loss. This scenario is typical for new patients who have been referred urgently for vision loss, as well as for established patients whose disease has suddenly progressed and who need immediate treatment. (One example is a diabetic patient

being treated in one eye who show signs and symptoms of new vision-threatening disease in her fellow eye.) In these cases the following steps are performed:

a. The clinic technician contacts an Authorizations Specialist in the TNR billing department and requests a "same day" drug authorization.
b. Our Billing Specialist performs an eligibility check based on the patient's insurance, diagnosis, and recommended treatment.
c. Some insurance companies have cumbersome authorization processes which force delays in treatment by several days. However, most insurance companies accept same-day phone calls for urgent cases and can authorize the drug over the phone.
d. The payers who accept phone calls will normally authorize a new treatment within 5-30 minutes. This same-day turnaround is critical to helping to preserve the patient's vision and reduces burden on patients and caregivers by avoiding the need to schedule a separate office visit for treatment.

17. Overnight, all signed off examinations from the EHR are interfaced with information from the billing system for coding review and submission to payers. For drug injection claims, our Coding Specialists perform a three- way match to ensure that the dose of drug that is billed to the payer matches the dose assigned to the patient in both the inventory system and the EHR.

Specific processes needed for copay assistance programs

1. Given the high cost of some FDA-approved drugs, and the limitations levied on them by their insurance companies, many of our patients cannot afford the cost of the care necessary to preserve their vision. Manufacturers and foundations offer copay assistance programs to help these patients.
2. When a patient is diagnosed and in need of treatment, our financial counselors help him/her to complete an application for copay assistance.
3. Once approved, the copay assistance providers act similar to a secondary or supplemental insurance provider. The patient normally pays a minor amount out of pocket at the time of service ($0-$10). After the primary and secondary insurance carriers pay their portions of the charge, the claim is passed to the copay assistance program, which pays any remaining balance of the authorized amount on the patient's behalf.
4. While there are annual limits for these assistance programs, virtually all patients receive sufficient financial support to make their out-of-pocket costs for their injectable medications manageable.

SUMMARY OF TNR'S DRUG MANAGEMENT PROCESS: The current process has evolved over time in response to the need to deliver timely, safe, and effective drug treatments for patients with sight-threatening retinal conditions. TNR has made continual large investments to refine the systems, processes, and staff necessary to deliver the optimal drug to the correct patient at the point of service, thereby maximizing the possibility of preserving and protecting patients' vision. Our current process is flexible and patient centered.

THE BCBST SPECIALTY PHARMACY POLICY

BCBST's policy creates critical problems by trying to insert individually assigned specialty pharmacy drugs into the current drug management process. Because BCBST will no longer compensate TNR for the above described drug management process, the responsibility of ordering, receiving, storing and

transporting the drug to each visit will fall to the patient. This will result in the following impacts to patients:

1. **Financial burden on the patient.**
    a. Our current process forces the practice to carry the high cost of drug inventory while the primary, secondary and copay assistance payers adjudicate the claim. The Specialty Pharmacy will require patients to pay deductibles up front (thousands of dollars), as well as the patient's portion of each drug ($350-$400) and then the patient will be solely responsible for getting reimbursement from copay assistance sources.
2. **Administrative burden on the patient.**
    a. The patient will have to call the specialty pharmacy ahead of each appointment and order the drug.
    b. The patient will have to receive the drug from the carrier and immediately unpack and store the drug according to the FDA guidelines.
    c. The patient will have to procure an appropriate syringe and injection needle.
    d. The patient will have to remember to bring the drug to the appointment in a suitable insulated container.
    e. The patient will have to apply for copay assistance and renew annually.
    f. The patient will have to track spending on drug compared to the annual copay assistance limits the manufacturers or foundations authorize each year.
    g. If a dose of drug is not used at a given appointment (frequently happens due to changes in the status of the eye, determined during the examination), the patient will have to keep the drug and coordinate with the specialty pharmacy to return the drug or store it until the next visit.
3. **Drug efficacy and safety are compromised.**
    a. Our current safety controls have been developed to maintain the safety and efficacy of the drug. It is unlikely that patients will consistently understand or comply with the FDA guidelines, and TNR has no control over the custody chain of the medication before the office visit.
    b. There may be malpractice/liability issues created by BCBST by involving a specialty pharmacy with anti-VEGF drugs. Given the chronic nature of most retinal diseases, adverse outcomes will inevitably occur in some patients. Without a documented chain of custody of medications and without the vigilant oversight that TNR typically provides, the liability for a drug-related adverse event will fall on the patient, BCBST, and the specialty pharmacy.
    c. In the interest of the safety of our patients, we do not treat both eyes of the same patient with doses from the same lot, in case that lot was somehow compromised during manufacturing or distribution. What internal controls have the specialty pharmacies implemented to guarantee that patients receiving bilateral injections will receive medications from different lots?
4. **Administrative and financial burdens on the practice.**
    a. Our inventory, EHR and billing systems are all integrated and developed to track drugs managed by our current processes. Inserting undocumented drug into this process will require manual intervention in our EHR and billing systems in order to properly document the dose of drug that is used.
    b. We intend to have every patient sign a waiver that releases our practice from any liability associated with any drug provided by a specialty pharmacy. Such a waiver will

require physician and staff time for adequate patient education, documentation, and record-keeping.

5. **Concerns for BCBST and the specialty pharmacy**
    a. There is obvious potential liability created by a policy that entails shifting the responsibility for acquiring, storing, and transporting drugs to patients. What is unclear is how the liability will be spread among BCBST, the specialty pharmacy, and the patient, since under this proposed policy, these are the principal entities involved in the handling of the drug.
    b. In our current process, drug wastage is minimized because our practice assumes the upfront cost of all medications and assigns a drug only after the patient is examined. The specialty pharmacy will need a reliable mechanism for allowing patients to return unused drugs in the case of missed appointments or a change in treatment plan. Without such a plan, expensive drugs will be wasted.
    c. It is not uncommon for retinal specialists to recommend a switch from one drug to another at the time of service, depending on the patient's individual exam findings and treatment response. The BCBST policy will render such same-day changes in therapy impossible or impractical, since patients will arrive with a dose of a drug obtained from the specialty pharmacy well in advance of each appointment. Given the lengthy process needed for specialty pharmacy drugs before the appointment, doctors will no longer have the opportunity to switch between drugs during the appointment, and patients will unnecessarily lose the opportunity to receive a potentially superior treatment.
    d. While bevacizumab (Avastin) is one of the drugs on the BCBST list, Avastin used for ophthalmologic indications must be compounded by a licensed pharmacy and dispensed in sterile, individual doses. None of the BCBST specialty pharmacies are compounding pharmacies. How will BCBST provide doses of Avastin to their patients, especially since some BCBST step therapies require the use of Avastin before using anti-VEGF drugs?
    e. To date, BCBST has not given TNR a comprehensive list of the employers and patients who will be affected by this policy. Without advance knowledge, our patients will be confused and likely enraged by this change that will negatively impact their quality of care and also transfer a considerable burden to them.

COMMENTS REGARDING THE PENDING BCBST SPECIALTY PHARMACY POLICY:

First and foremost, this proposed policy will jeopardize the vision and quality of life of many patients. This policy will delay patient care, limit physicians' ability to treat patients in a timely and efficient manner, and add waste to a system that has proven to work effectively.

This policy will shift a substantial financial burden to patients and will force them to learn and work through the complexities of a cumbersome specialty pharmacy system.

Finally, this policy will create outcome risks for patients and legal risks for any organization responsible for the drug until the patient brings it to each appointment.

TNR has an obligation to educate our patients, our patients' employers, and referring doctors about this policy and its many ramifications.

EVERTON L. ARRINDELL, M.D.
CARL C. AWH, M.D.
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345 23RD AVENUE NORTH, SUITE 350
NASHVILLE, TN 37203
(615) 983-6000 PHONE
(615) 983-6010 FAX
WWW.TNRETINA.COM

December 10, 2019

Dear Tennessee Retina patient;

Blue Cross Blue Shield of Tennessee ("BCBST"), along with the employer through whom you receive your health insurance, has implemented a new policy that will affect the way we treat your retinal condition.

Tennessee Retina strongly objects to this BCBST policy and has voiced our concerns and disapproval to BCBST. We are not the only doctors who feel this way. The American Society of Retinal Specialists, the largest organization of retina doctors in the world, recently sent a letter to BCBST expressing grave concerns over the policy, in the belief that the policy "places an unrealistic burden on physician practices and increases barriers to providing efficient and appropriate care."

Under this new BCBST policy, effective January 1, 2020, the FDA-approved drugs that we have used to treat your retinal condition will be supplied through a "specialty pharmacy network" and Magellan RX, a pharmacy benefit management (so-called "PBM") group.[1]

Under this new policy, as of January 1, 2020, it will be <u>your responsibility</u> to coordinate with Magellan RX and the specialty pharmacy to obtain the special medication that we have been using for your eye injections.[2] You will need to obtain this medication prior to each appointment.

Since, as a result of this new BCBST policy, <u>you will be required</u> to obtain and bring the medication yourself to your appointment, there are several changes that will impact you directly. These changes include but are not limited to the following:

- You will be responsible for the proper handling and storage of these highly sensitive medications. The medication may be affected by small changes in temperature or environment and become ineffective or contaminated if not properly stored and handled.
- Since we cannot guarantee the quality or sterility of your medication when it is handled by people other than us, we may have to refuse treatment if we suspect that the medication has been compromised.
- You will need to obtain an appropriate syringe and needle required for your injection, if Magellan RX and the specialty pharmacy do not provide these to you.
- You will be required to sign a waiver with our practice wherein you assume all responsibilities associated with the receipt, care, and transport of the drug.

- If your medication or the supplies needed for your treatment have been compromised, this will cause delays in your care. We cannot be responsible for any negative effects on your health or your vision associated with such delays.
- Since your medication must be obtained in advance of your appointment, there will be no opportunity for unplanned emergency treatment on the same day as your appointment. For example, if your right eye is scheduled for treatment, but we discover that your left eye has developed a new problem that needs treatment, we will be unable to treat your left eye the same day. This is because the only drugs available to treat you will be the ones you receive in advance of each appointment through the specialty pharmacy. This delay in treatment is contrary to our preferred practice and may cause irreversible damage to your vision.
- If you need to reschedule your appointment to a later date, there is a chance that the medication that has been sent to you will expire before you can return. In that case, you will have to restart the process of obtaining replacement medication from the specialty pharmacy network.
- If you participate in a copay assistance program, you may be responsible to pay the specialty pharmacy for the drug when you order the drug. You will then be responsible for requesting reimbursement from the copay assistance program. Since the assistance programs help you to meet your deductible and cover the drug cost, you can expect to pay thousands of dollars out of pocket to meet your deductible. You may then pay between $250 and $400 per eye per visit after you meet your deductible.
- If you wish to participate in a copay assistance program, we can no longer assist you with your initial application and with your annual renewal. You will be required to manage this assistance directly with the specialty pharmacy.

If you share our disapproval with this new BCBST policy, we strongly suggest that you take the following steps:

- **Speak with your employer's Human Resources department and Benefits Manager** about how their choice of this insurance plan is not good for you.
- **Call Blue Cross Blue Shield of Tennessee** to express your concerns related to their policy about "provider-administered specialty drugs to be purchased through the BCBST Preferred Specialty Pharmacy Network." You can call the "Member Service Number" on the back of your insurance card.

To our knowledge, Blue Cross Blue Shield of Tennessee is the only major insurer in our area with this policy. We will continue to petition BCBST to reverse this policy on behalf of our patients and in the interest of maintaining high-quality retinal care.

Sincerely,

The physicians of Tennessee Retina

[1]You may have heard of Pharmacy Benefit Managers (PBMs) like Magellan RX in the news. PBMs have been the subject of investigation by the federal government, as well as the target of lawsuits in several states, because of allegations that PBM practices lead to higher drug costs and copays for patients.

[2]Why will handling the drug become your responsibility? Until now, we have been willing to purchase and store your eye medication. When we do this, we pay the upfront cost of the medication and accept the responsibility for storing, tracking, and transporting the medication to each of our nine offices. Federal law allows insurance companies to reimburse doctors a small percentage of the medication cost. This reimbursement is intended to cover the cost of medication management. It also helps to defray some of the costs associated with our staff assisting you with obtaining insurance pre-authorizations, applying for copay assistance programs, checking benefits to allow for same-day treatment, and other work directly related to using the medication. Under its new policy that now requires that all medications be obtained through a PBM/specialty pharmacy network, BCBST will cease paying us any additional reimbursement for your eye medication. Therefore, we will no longer accept the significant cost and responsibility of handling the medications. The BCBST policy leaves no option other than shifting the responsibility for handling the medication to patients.

EVERTON L. ARRINDELL, M.D.
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December 10, 2019

Dear Employer:

We are writing to inform you of a policy being implemented on January 1, 2020 by Blue Cross Blue Shield of Tennessee (BCBST) that we fear will compromise the medical care of some of your employees or of your employees' family members. As employers ourselves, we understand the challenges of balancing your costs with providing quality health insurance to your employees and their family members. We also understand that there may be hidden costs or unforeseen consequences that may not be immediately evident to you.

As retina specialists (medical doctors who have completed four years of post-graduate residency followed by two or more years of additional specialty training in medical and surgical treatment of retinal diseases), we care every day for patients with potentially blinding diseases. An essential part of our success in improving and maintaining vision for our patients is the use of medications that we inject into the eye. These medications (Lucentis, Eylea, Beovu, and Avastin) have significantly improved the quality of life for many of our patients.

With its new policy, however, BCBST will require your employees under our care to use a pharmacy benefits manager (PBM) and a network of specialty pharmacies to deliver these medications.[1] We oppose this method of delivery commonly known as "white bagging" because it interferes with patient care and may increase costs to us, to your company, and to your employees. Additionally, we will be forced to require that your employees obtain their medications directly from the specialty pharmacy and bring their medications to each and every appointment with us.[2]

Our patients typically have diabetes and cardiovascular disease, and many are elderly persons with wet age-related macular degeneration (AMD) who require assistance from family members. Most patients require injections in their eye within a specific timeframe in order to prevent permanent and irreversible damage to their vision. To provide the highest quality of patient care, we prefer to treat patients on the same day they are seen. In order to provide same-day treatment, we need an office stock of medications. This approach optimizes our treatment decisions and outcomes and reduces unnecessary visits by patients and caregivers.

Under the new BCBST policy, however, patients will be forced to return for a second visit while the insurance authorizations are verified and the patient obtains the medication through the specialty pharmacy. This process:

- Risks damage to the vision of your employees or employees' family members by delaying treatment.
- Limits access and same-day appointments.
- Increases costs in terms of time and additional copays. If patients participate in a copay assistance program, they will be responsible for paying the specialty pharmacy for the medication when they order the medication. They will then be responsible for requesting reimbursement from the copay assistance program. Since the assistance programs help patients to meet their deductible and cover

the drug cost, they can expect to pay thousands of dollars out of pocket to meet their deductible. They will then pay between $250 and $400 per eye per visit after meeting the deductible.

- Wastes medications when patients become ill and cannot return, move out of the area, switch care to another doctor, or miss their scheduled visits due to last-minute scheduling changes.
- Requires your employees or employees' family members to schedule an additional appointment for urgent treatment, requiring additional time away from work.
- Will require your employees to acquire, store, and transport their medications themselves. These highly sensitive medications may be affected by small changes in temperature or environment and become ineffective or contaminated if not properly stored and handled. Use of contaminated medications can lead to blindness or death.

The logistics of this new BCBST policy have the potential to be disastrous for patients who require special medications not only for retinal disease, but also for other chronic diseases like rheumatologic (joint) diseases and cancer. This policy is also opposed by the American Society of Retina Specialists, the largest international organization of retina specialists, who has already sent a letter to BCBST to express its concern on behalf of patients and doctors. We strongly urge you to join us in advocating for your employees and their families by contacting BCBST to voice your concerns with this policy. Thank you for considering our perspectives on this policy. Please feel free to contact our Practice Administrator, Jack Flanagan at jflanagan@tnretina.com or 615-983-6000, to schedule a meeting to further discuss this issue.

Sincerely,

The physicians of Tennessee Retina

[1]You may have heard of Pharmacy Benefit Managers (PBMs) like Magellan RX in the news. PBMs have been the subject of investigation by the federal government, as well as the target of lawsuits in several states, because of allegations that PBM practices lead to higher drug costs and copays for patients.
[2]Why will handling the drug become the responsibility of your employees? Until now, we have been willing to purchase and store their eye medications. When we do this, we pay the upfront cost of the medication and accept the responsibility for storing, tracking, and transporting the medication to each of our nine offices. Federal law allows insurance companies to reimburse doctors a small percentage of the medication cost. This reimbursement is intended to cover the cost of medication management. It also helps to defray some of the costs associated with our staff assisting patients with obtaining insurance pre-authorizations, applying for copay assistance programs, checking benefits to allow for same-day treatment, and other work directly related to using the medication. Under its new policy that now requires that all medications be obtained through a PBM/specialty pharmacy network, BCBST will cease paying us any additional reimbursement for these eye medications. Therefore, we will no longer accept the significant cost and responsibility of handling the medications. The BCBST policy leaves no option other than shifting the responsibility for handling the medication to patients.