Managed Care and the Impact of Glaucoma

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Abstract

Changes in the healthcare system, population demographics, and treatment alternatives have contributed to an emerging awareness of glaucoma among managed care organizations. Early diagnosis and treatment are essential to thwarting the personal and economic consequences of end-stage glaucoma. Despite recognition of the need for early intervention and therapy, the literature suggests a great need still exists for improvements in lowering intraocular pressure, managing appropriate follow-up, and improving adherence to current glaucoma medication regimens. As the elderly population continues to increase, these issues will intensify and present further problems for the healthcare system. The purpose of this introductory manuscript is to highlight the literature on the clinical and economic impact of glaucoma and its importance to the managed care community. The remainder of the supplement will focus on the current management of glaucoma and the potential role of neuroprotection in this patient population.

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Managed care organizations (MCOs) continually encounter new challenges as novel therapies are developed, diseases become more treatable, and the structure of the healthcare system continues to evolve in terms of reimbursement and population demographics. One such case is in the area of ophthalmology, particularly in the treatment of glaucoma, where the addition of the prostaglandin analogues and alpha$_2$ agonists to the armamentarium introduced more treatment options for glaucoma. In addition, the Health Plan Employer Data and Information Set (HEDIS®) requirements set forth by the National Committee for Quality Assurance (NCQA) were updated in 2005 to include glaucoma screenings. Moreover, the advent of Medicare Part D introduced managed care to a new population with more age-related conditions such as glaucoma. Appropriate management of this new population requires health plans to understand the consequences of disease and the benefits of available treatments for glaucoma.

Impact of Glaucoma

Glaucoma affects approximately 2.5 million persons in the United States older than age 55. Many of these cases are thought to be undiagnosed, with as many as half of these patients unaware that they have the disease.[1,2] Moreover, the prevalence of glaucoma is increasing. It is estimated that by 2010, there will be 60.5 million people worldwide with open-angle glaucoma or angle closure glaucoma, with 79.6 million cases projected worldwide by 2020. Of these cases, approximately 74% will be open-angle glaucoma.[3] In the United States, the number of individuals with potentially treatable open-angle glaucoma is expected to reach 3 million by 2020.[4] Left untreated, glaucoma leads to blindness. It is the second most common cause of legal blindness in the United States and the leading cause of legal blindness in African Americans.[5] Moreover, glaucoma-related blindness is largely preventable with early detection and appropriate treatment regimens.[6]

Although there are several different types of glaucoma, the most common form is primary open-angle glaucoma (POAG), which accounts for more than 90% of cases in the United States.[7] Risk factors associated with open-angle glaucoma include elevated

intraocular eye pressure (IOP), older age, race (African American), diabetes, and a positive family history of glaucoma.[5] Glaucoma usually affects both eyes, although each eye may be affected to a varying degree. In the early stages, glaucoma is rather insidious; patients with open-angle glaucoma rarely exhibit symptoms. Consequently, glaucoma is often an incidental finding during a routine eye examination or during an examination performed for other reasons. In patients who are symptomatic, glaucoma usually manifests itself as a gradual loss of peripheral vision. Unfortunately, this vision loss often occurs after 40% or more of the optic nerve fibers are damaged. Optic disc changes may be detected before patients experience symptoms of visual loss, further supporting the need for regular ophthalmic examinations that include glaucoma screenings.[5] According to the American Academy of Ophthalmology (AAO), the most effective way to diagnose glaucoma early is to screen for elevated IOP or disc changes as part of a regular comprehensive eye examination.[8]

As a treatable risk factor, lowering IOP has been the primary target for glaucoma therapy. Patients are usually prescribed ophthalmic drops as the initial treatment of choice for glaucoma. The mechanism of action of these topical eyedrops is to reduce IOP by either decreasing aqueous production or increasing aqueous outflow. Several therapeutic classes of glaucoma agents are available; if one drop is found to be ineffective, the patient can be switched to a medication from a different class or have a second medication added to the regimen to adequately control the glaucoma. Without adequate control, irreversible vision loss can occur. Moreover, the consequences of poorly treated glaucoma are not limited to just the eye. Research has demonstrated that any degree of vision loss is associated with increased medical costs as well as an increased risk of depression, injury, skilled nursing facility utilization, and long-term care placement.[9] In most cases, however, glaucoma can be controlled and vision loss prevented with early detection and effective treatment.[6]

Recommendations for Glaucoma Care and Patterns of Care

In 2005, the NCQA instituted glaucoma screening as a measure in its HEDIS requirements. The addition of this measure is significant because HEDIS measures are important quality assurance considerations for MCOs. The HEDIS glaucoma measure captures the percentage of Medicare members who received a glaucoma examination in the past 2 years by an eye-care professional.[10] Under the current reimbursement system, Medicare pays for 1 comprehensive eye examination every 12 months for high-risk patients. To be considered at high risk, patients must have diabetes, a family history of glaucoma, or be an African American older than 50 years of age. Patients pay 20% of the Medicare deductible amount for the eye examination after the yearly Part B deductible is satisfied.[11]

The AAO has published a Preferred Practice Pattern (PPP) for the treatment of glaucoma. The PPP outlines the major recommendations for glaucoma care and provides guidelines concerning glaucoma screenings and follow-up intervals.[8] To evaluate the effect of these recommendations, Fremont et al assessed conformance with the AAO practice patterns in a managed care population.[12] A total of 395 patients, who were enrolled in 6 managed care plans, were assessed for processes of care at initial and follow-up visits; control of IOP; time intervals between visits; visual field tests; and adjustments in therapy. Overall, recommended processes of care were followed in 80% to 97% of follow-up visits. IOP was controlled in approximately 66% of follow-up visits for patients with mild glaucoma and in 52% of visits for patients with moderate-to-severe glaucoma.

Intervals between visits were consistent with preferred practice recommendations, but adjustments in therapy occurred in only half of visits where IOP was 30 mm Hg or higher (average IOP for the study was ~20 mm Hg). Patients with mild optic damage had IOP controlled in both eyes in less than half of follow-up visits, whereas patients with moderate-to-severe optic damage had IOP controlled in one third of follow-up visits. The probability of an adjustment in therapy for POAG at follow-up was a function of how well IOP was controlled at the visit, with medication increases occurring more often when the IOP was uncontrolled. However, the proportion of visits in which the therapy was increased was surprisingly low (44.6% of visits where the IOP was 26-29 mm Hg, and 49.3% of visits where the IOP was ≥30 mm Hg).[12]

A retrospective database study of patients enrolled in a large MCO found that 83% of patients with newly diagnosed glaucoma or suspected glaucoma had a claim for a follow-up office visit, and 46% had at least 1 claim filed for a visual field test during a median follow-up time of 440 days.[13] According to recommended treatment patterns, even patients with suspected glaucoma whose risk factors are very low should be seen at a minimum of 18 months, whereas patients with diagnosed glaucoma should have a follow-up visit every 6 months.[13] Among the managed care patients evaluated in this study, 10% to 20% (depending on the methodology used) did not receive a follow-up visit at the recommended frequency.

Treatment variations have also been observed in patients diagnosed with or suspected to have glaucoma. Friedman et al found that women were less likely than men to undergo treatment (topical ocular hypotensives, argon laser trabeculoplasty, or surgery) even though they were more likely to be diagnosed with glaucoma.[14] Although women were less likely to be treated than men, they were monitored for glaucoma at comparable rates to men. Among all patients, individuals with a confirmed glaucoma diagnosis were 7.5 times more likely to receive topical medications and 9.4 times more likely to undergo surgery than patients with a suspected diagnosis. Factors other than gender and diagnosis associated with a greater likelihood of treatment were older age, geographic region, and longer follow-up periods. For example, patients older than 65 years were almost twice as likely to receive medication as those aged 50 to 59 years, while patients in the Northeast region had lower treatment rates than other parts of the country.[14]

Adherence and Persistence

For glaucoma therapy to be effective in lowering and controlling IOP, the proper regimen must be prescribed and used appropriately. Appropriate use involves compliance (adherence and persistence) with the regimen on the part of the patient, which can be problematic in those with glaucoma. As newly diagnosed patients are often asymptomatic, the use of medication does not provide the patient with immediately obvious benefits, such as pain relief or improved vision. This perceived benefit absence can lead to decreased patient compliance. Medication compliance in an elderly population is also affected by other factors, such as difficulty with self-administration of eyedrops, increased frequency of administration side effects (eg, irritation, burning, or blurred vision), unaffordable out-of-pocket expenses for medicines, or simply forgetting to administer the medication.[15]

Measuring adherence with ophthalmic medications is difficult in the elderly population. Assessments of medication adherence are often based on administrative paid claims databases rather than on more direct patient evaluation. Use of paid claims databases can be a potential problem for dosage forms such as eyedrops, where the quantity-dispensed field may contain inaccuracies related to claims-filing procedures (eg, claims for a 2.5-mL bottle may be reported as 2 mL or 3 mL if a whole number must be entered into the field, or the number of bottles dispensed may be entered instead of the number of milliliters). Inconsistencies between the claim and actual medication use can also be related to variation in factors such as the number of drops per milliliter dispensed, vial overfill, and estimates of reported days' supply. After adjusting for the influence of these factors on compliance, Wilensky et al found that patients considered to be new therapy starts and taking IOP-lowering prostaglandin/prostamide medications had an average adherence rate of 76%. Such a rate indicates that opportunities exist to improve adherence and decrease the long-term consequences of glaucoma.[16]

Costs Associated With Glaucoma

When direct medical costs and productivity costs are considered, the total financial burden of major adult visual disorders in the United States is estimated to be $35.4 billion, with more than $2.9 billion attributed to glaucoma alone. Outpatient medical and pharmaceutical costs accounted for the bulk of the glaucoma expenditure.[17] When assessing the benefits and cost of glaucoma therapy, several factors should be considered, including disease progression (early detection requires screening and early treatment, increasing costs on the front end), costs of glaucoma medications, and adherence to treatment regimens.[18]

To better understand the efficient and appropriate use of glaucoma medications, cost-effectiveness data can be enlightening. The following section

summarizes several studies that evaluate the relative cost and effectiveness of glaucoma therapies. For a more comprehensive analysis of the economic impact of glaucoma, the relative cost-effectiveness of glaucoma treatments, and limitations of the published literature, a recent review article by Schmier et al is recommended.[19]

Noecker and Walt used clinical trial data for bimatoprost and latanoprost to calculate the monthly cost to achieve a 1% reduction in IOP in glaucoma and ocular hypertensive patients. The authors determined that the incremental cost for each 1% lowering of IOP by bimatoprost over latanoprost was $0.29.[20] Some concerns with the design of this study have been raised in the literature. Kymes, in a letter to the editor, questions some of the model assumptions and the sensitivity analyses performed as part of the analysis.[21]

Using a US healthcare payer perspective, Goldberg and Walt compared the cost-effectiveness of glaucoma treatment with bimatoprost with other IOP-lowering medications in adult patients with chronic glaucoma or ocular hypertension. Total annual costs and cost per treatment success for 0.03% bimatoprost once daily were compared with the following: 0.5% timolol twice daily (generic), 0.005% latanoprost once daily, and the fixed combination of 0.5% timolol and 2.0% dorzolamide twice daily. (Treatment success was defined as moving a patient from an initial IOP range of 22 mm Hg to 34 mm Hg to a lower target IOP range of 13 mm Hg to 17 mm Hg.) Estimates were based on 2003 medical resource costs for physician visits. Drug acquisition costs and treatment success rates were obtained from published clinical trials. The outcome of interest was the percentage of patients achieving target IOPs. The authors found that a higher percentage of patients achieved target IOPs with bimatoprost than with each of the other medications. At most target pressures, the cost per treatment success for patients starting treatment on bimatoprost was less than that for patients started on other medications. The incremental cost of achieving additional clinical success (measured in 1 mm Hg interval decrements from 17 mm Hg to 13 mm Hg) for bimatoprost ranged from $800 to $1700, compared with timolol generics, and from $300 to $3100 for the combination of timolol and dorzolamide. Results of the analysis show that bimatoprost was more effective and less costly than latanoprost.[22]

Day et al evaluated differences in persistency and treatment costs for latanoprost, bimatoprost, or beta-blockers in open-angle glaucoma or ocular hypertensive patients. This study design was a retrospective, multicenter, parallel comparison of patients who were prescribed ocular hypotensive monotherapy between September 1996 and August 2002. Among the regimens for the first year of therapy, persistence was the greatest for latanoprost. There was a statistically significant difference between groups in final IOP for latanoprost (17.3 mm Hg), bimatoprost (18.0 mm Hg), and the beta-blockers (17.9 mm Hg). The average number of glaucoma-related visits was statistically greater for beta-blockers (3.3) compared with latanoprost (2.9) and bimatoprost (3.1). Moreover, the average number of therapy changes was statistically greater for bimatoprost (0.45) and beta-blockers (0.47) than for latanoprost (0.27). The cost of glaucoma-related visits and medications was lowest for beta-blockers ($119.30) and highest for bimatoprost ($163.80). The authors concluded that patients treated with latanoprost were more persistent, had lower average IOP, fewer glaucoma-related visits, and fewer medicine changes compared with bimatoprost or beta-blocker therapy. In contrast to these findings, the beta-blocker treatment group had lower overall cost.[23] However, study design limitations that could affect the findings regarding latanoprost efficacy and bimatoprost persistency have been debated.[24]

Fiscella and Walt compared the cost-effectiveness of bimatoprost with latanoprost in the treatment of glaucoma or ocular hypertension. In this study, the estimated yearly costs and cost per treatment success for bimatoprost ophthalmic solution were compared with latanoprost ophthalmic solution. The treatment model was based on common clinical practice for newly diagnosed patients with glaucoma or ocular hypertension. Clinical success was defined as achieving a 20% reduction in IOP. After 6 months of treatment, the clinical success rates were significantly higher with bimatoprost than with latanoprost, while the average yearly cost per patient was similar for bimatoprost ($1151) and latanoprost ($1193). However, the cost per treatment success averaged $568 less with bimatoprost than with latanoprost. The authors attributed the

lower cost per treatment success to the greater efficacy of bimatoprost. This finding held even when responder rates were adjusted to account for patients who withdrew from treatment because of adverse events.[25]

If glaucoma is not treated adequately in the early stages, progression of the disease can result in appreciable resource utilization and costs for end-stage therapy. Visual rehabilitation care is often required for patients who advance to this stage, inflicting a significant economic burden on the healthcare system.[26] Other consequences associated with vision loss can also contribute significantly to the healthcare system burden. Javitt et al examined a Medicare population to determine the effects of vision loss on medical and pharmacy costs for eye-related and non–eye-related costs. Results from the study demonstrated that any degree of vision loss was associated with an increased risk for other costly outcomes, such as depression, injury, and hospital/ancillary unit admissions. Costs attributable to vision loss accounted for 27% to 41% of these excess costs. When findings were extrapolated to the entire Medicare population, it was estimated that blindness and vision loss were responsible for $2.14 billion in non–eye-related costs for 2003.[9]

In their recent review article, Schmier et al emphasize the need for more research on the costs of glaucoma and the cost-effectiveness of glaucoma treatments.[19] The need for this type of information will become even more important as the prevalence and economic burden of glaucoma increases and new glaucoma treatments emerge. Although the newer glaucoma therapies will certainly be more efficacious, they will likely be more expensive. Evidence of the value of these therapies, in the context of the total cost of glaucoma and its treatment, will be needed by those in managed care who make formulary and coverage decisions.

New Developments in Glaucoma

Until recently, treatment of glaucoma focused on lowering IOP as a treatable risk factor in the disease. However, the definition of glaucoma has evolved from one of elevated IOP to one characterized by an IOP-sensitive, progressive optic neuropathy. This change in definition has generated a refocus of treatment to include the role of neuroprotectants in glaucoma management. Neuroprotection is a potentially new treatment strategy for glaucoma patients that could have a profound clinical impact on patient care. In the context of glaucoma, neuroprotection refers to administering medications that interact with neuronal or glial elements within the retina or optic nerve to facilitate the survival of retinal ganglion cells.[27] In the future, medications that serve as neuroprotectants may be considered in conjunction with IOP-reducing therapy to provide what is being termed *complete therapy* for glaucoma patients. Such a combination could provide dually targeted treatment for patients with IOP-dependent glaucoma. It would also potentially reduce the rate of disease progression when IOP is not controlled or when progression occurs even with IOP at acceptable levels. Minimizing the consequences of glaucoma progression can ultimately reduce the economic and clinical burden of the disease to the patient and the payer.[9,26] When making managed care decisions, the costs of complete therapy will have to be weighed against the consequences of inadequate or incomplete therapy.

Conclusions

Given changes in the healthcare system, population demographics, and treatment alternatives, glaucoma is now a major consideration for MCOs. With the elderly population increasing, these issues will only escalate and present further problems for the healthcare system. Early detection and treatment of glaucoma is essential in preventing the devastating personal and economic consequences of end-stage glaucoma. Although early treatment has been shown to be beneficial, the literature suggests there is still a great need for improvement in lowering IOP, managing appropriate follow-up intervals, and adhering to glaucoma medication regimens. Research suggests that the addition of neuroprotective agents to traditional antiglaucoma agents (complete therapy) may improve glaucoma outcomes. As more treatments for glaucoma enter the market, MCOs will be faced with a myriad of therapeutic options. Weighing the cost of these options and the benefits of early treatment, combined with the need to address treatment and outcome deficits, will prove to be a challenge. Additional research is needed to help organizations better understand the cost and consequences of glaucoma treatment. Measures of therapeutic value, such as cost-effec-

tiveness comparisons, can assist MCOs in making formulary decisions as well as other decisions that impact patient care. The remainder of this supplement focuses on the current management of glaucoma and the role of neuroprotection as it pertains to complete therapy in this patient population.

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