Clinical Guidelines

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Purpose of Clinical Guidelines

The purpose of the clinical guidelines is to assist in the day to day UM management and triage of members. While the guidelines are a great asset in determining medical care for a member, they

are not an absolute standard that is bound to. Numerous factors can influence what type of medical care is appropriate for a member and if a member needs care different from the clinical guidelines, the Medical Director has the ultimate authority on how to best plan the treatment for a member. Criteria is reviewed objectively and based on medical evidence that is consistent with national Medicare coverage guidelines, as well as, the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines. Additionally, Ocular Benefits complies with state laws regarding an ophthalmologist upon request. A provider may request a member to see an ophthalmologist if the provider feels it is within the member's best interest even in cases where a member would normally be triaged to an optometric physician. The clinical guidelines are reviewed quarterly with updates and revisions added to policy as necessary.

1.0 OVERVIEW – Management of Capsular Opacity by YAG Capsulotomy

1.1 Introduction

These guidelines are based on the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines. Papers reviewed for the development of these standards were *Cataract in the Otherwise Healthy Adult Eye*, produced by the American Academy of Ophthalmology, and, the *Guidelines for Cataract Practice*, produced by the American College of Eye Surgeons.

The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have experienced the functional impairment of Posterior Capsular Opacification.

1.2 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with functional impairment due to cataract, they are organized into the following subjects:

a) The definition of Posterior Capsular Opacification (PCO)

b) Responsibilities and Obligations

c) Diagnosis and Prognosis

d) Indications and Goals for Laser Posterior Capsulotomy

e) Contraindications for Laser Posterior Capsulotomy

f) Pre-operative Evaluation

g) Complications of Laser Posterior Capsulotomy

h) Post-operative Care

2.0 POSTERIOR CAPSULAR OPACIFICATION

Opacification of the posterior lens capsule occurs frequently after all forms of extracapsular cataract surgery. As the opacification increases, the patient begins to notice a decrease in visual function that can lead to functional impairment.

Visual functional disability resulting from capsular opacification is the indication for posterior capsulotomy. The occurrence is seldom significant during the first three postoperative months unless there is residual opacity of the capsule at surgery or a significant inflammatory reaction. The rate of clinically significant capsular opacification increases from the first to fifth years post-operatively and may reach as much as 50%.

The management of functional impairment due to posterior capsule opacification resembles that for cataract, except that the risk/benefit ratio is altered by a generally perceived lower risk. Considerations of management include the following:

- Diagnosis
- Prognosis
- Indication for surgery
- Contraindication for surgery
- Surgical technique and complications
- Postoperative care and long-term follow-up

3.0 Responsibilities and Obligations

The physician team has well established and firm responsibilities to the patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis, and understanding in the evaluation of the patient's disability, needs and concerns. The physician team is also responsible for completeness in informing and educating the patient regarding their disease, its potential treatment and the ultimate challenge in providing appropriate and competent treatment. The obligation of the physician team continues until postoperative rehabilitation is complete.

The ophthalmologist who performs the capsulotomy has an ethical and legal responsibility to coordinate postoperative care for the patient. The postoperative period is considered to extend 90 days from the end of the procedure. Should complications develop, the ophthalmologist or optometric physician has the obligation to provide appropriate care to the patient or to refer the patient to another Eye Care physician provider.

The patient has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, and to follow instructions, comply with prescriptions, and notify the physician should evidence of complications arise.

The plan also has responsibilities to the doctor/patient relationship: the responsibility to attempt to understand information regarding the disease and its treatment, and to authorize appropriate treatment for the best possible clinical outcome for the patient.

4.0 DIAGNOSIS AND PROGNOSIS

4.1 Diagnosis

Opacification of the posterior capsule may occur in any patient who has previously undergone extracapsular cataract surgery. In most instances the patient will have enjoyed considerable improvement in visual function following the cataract procedure and then a progressive decline in acuity and contrast with progressively increasing glare. In the context of this history, tests can demonstrate the reduced contrast sensitivity and increased glare effect.

4.2 Prognosis

Pinhole testing frequently may demonstrate a major improvement in resolution and macular function testing may demonstrate a normal response. Examination of the eye will demonstrate a physical change in the posterior capsule and may demonstrate a distortion in the view of fundus details with the ophthalmoscope.

5.0 INDICATIONS AND GOALS

5.1 Indications for Posterior Capsulotomy

Posterior capsulotomy is indicated when the following subjective, objective and educational criteria are met.

- Subjective: The patient's visual function is decreased to the point of interference with needed or desired activities of daily life.

- Objective: The examination confirms the diagnosis of opacity of the posterior capsule, distortion of optics and has established a good prognosis for relief of symptoms through treatment.

- Educational: The patient has been educated regarding the diagnosis and prognosis and informed of the potential risks and benefits of the capsulotomy procedure.

As with cataract surgery, posterior capsulotomy may occasionally be indicated for reasons other than the improvement of visual function, i.e., to provide better visualization of the posterior pole for diagnosis, evaluation or treatment of:

- Retinal detachment
- Macular disease
- Diabetic retinopathy
- Glaucoma and other conditions affecting the optic nerve
- Tumors of the posterior segment

- Other conditions requiring funduscopic examination

Other special tests may be indicated by additional concurrent diagnosis. Tests such as fluorescein angiography, B-Scan, Ultrasonography, formal visual fields, etc., are examples of such tests. The justification for these tests should be apparent from documentation in the patient's record.

5.2 Contraindications for Posterior Capsulotomy

There are no absolute contraindications to the performance of a posterior capsulotomy in an appropriately evaluated and informed patient who meets the criteria for posterior capsulotomy. Incisional capsulotomy may be selected in those patients who cannot comply with the requirements for a YAG capsulotomy by reason of physical or mental impairment, or membrane thickness which would preclude successful laser surgery. In younger patients with lens cell proliferation, e.g., Elschnig's Pearls, causing the posterior capsule opacity, it may be desirable to preserve the posterior capsule and remove the lens material causing the functional impairment.

Routine or prophylactic posterior capsulotomy is not appropriate.

6.0 PRE-OPERATIVE EVALUATION AND MEDICATIONS

6.1 Preoperative Medical Evaluation

In addition to visual acuity, tests of glare, contrast sensitivity and potential acuity may be of particular value in assessing the functional impairment due to posterior capsular opacification and the benefits of posterior capsulotomy. Fluorescein angiography may be indicated when there is clinical evidence of macular disease and/or the degree of capsular opacity appears insufficient to account for the level of functional impairment. B-scan ultrasonography is indicated when the degree of opacification is of a severity that the posterior pole cannot be visualized and/or the degree of functional impairment is severe and seemingly unexplained by the degree of opacification. The reasons for these tests should be documented in the patient's record.

6.2 Preoperative Medications

Laser posterior capsulotomy ordinarily requires only optional topical anesthesia and optional pupillary dilation. The risk of these medications is small; however, it remains the responsibility of the operating surgeon to assess the medical suitability of the patient for the procedure and the use of these agents in the perioperative period.

7.0 SURGICAL TECHNIQUE

7.1 YAG Posterior Capsulotomy

Nd: YAG posterior capsulotomy laser surgery, the most common technique, is performed in the office or ambulatory surgical center under biomicroscopic magnification. A contact lens may be used to enhance visualization of the posterior capsule and to stabilize the eye during the procedure. The energy used and the size and location of the opening are controlled to minimize the risk of complications.

8.0 COMPLICATIONS

8.1 Complications

The complications of laser posterior capsulotomy may be very serious although they are extremely uncommon. Retinal detachment, hyphema, dislocated intraocular lens and corneal decompensation are in the serious category. Cystoid macular edema and damage to the intraocular lens are less serious effects and the occasional elevation of intraocular pressure post-surgery is often prevented by prophylactic use of appropriate medications. It is the responsibility of the operating surgeon or optometric physician to ensure that the patient is adequately informed of the potential complications prior to the procedure.

The operating surgeon has a unique and intimate knowledge of the laser procedure performed and, therefore, the expectation of the patient's postoperative condition. However, individual differences in patient response may lead to variations in outcome, even resulting from an uncomplicated laser procedure. If complications develop the surgeon or optometric physician will arrange for appropriate treatment, perhaps to include referral to other Eye Care physicians. In unusually complicated circumstances, this may extend beyond the normal postoperative period.

9.0 POSTOPERATIVE CARE

9.1 Postoperative Care - Immediate

Patients who have undergone capsulotomy must be observed for an appropriate time for evidence of elevated intraocular pressure. If the pressure is elevated, appropriate treatment must be instituted and the patient followed until the problem is resolved. Immediate postoperative care is the responsibility of the operating ophthalmologist

9.2 Postoperative Care - Non-immediate/1 Week

Because most complications following posterior capsulotomy occur in the late postoperative period, the re-examination schedule should be established according to the patient's needs, the experience of the surgeon and other associated conditions of the eye. Non-immediate postoperative care is the responsibility of an optometric physician.

The examination should include measurement of visual function, intraocular pressure, slit lamp examination of the anterior segment including the intraocular lens, if present, the capsular opening and a fundus examination as deemed appropriate by the examining physician. The patient should be instructed for the symptoms of retinal detachment and the need for immediate attention if they occur. Patients also should be informed of other long-term risks and the need for periodic eye examinations.

10.0 PATIENT TRIAGE

10.1 Patient Triage Management

Optometrists and Ophthalmologists are licensed and governed by the their respective state department of health and their respective state boards of medicine. Most of the provider practices on Ocular Benefit's panel have Optometrists and Ophthalmologists on staff. Patients who have been previously diagnosed with posterior opacity will be triaged to an optometric physician or ophthalmologist to determine their best corrected acuity. Patients who cannot be adequately corrected will be triaged to an ophthalmologist for a YAG laser posterior capsulotomy evaluation.

1.0 OVERVIEW – Management of Age-Related Macular Degeneration (ARMD)

1.1 Introduction

These guidelines are based on the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines. Papers reviewed for the development of these standards were, *Age-Related Macular Degeneration,* produced by the American Academy of Ophthalmology and *Care of the Patient with Age-Related Macular Degeneration*, produced by the American Optometric Association.

The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have been diagnosed with age-related macular degeneration.

1.2 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with age-related macular degeneration (ARMD), they are organized into the following subjects:

a) The Definition of Age-Related Macular Degeneration
b) Responsibilities and Obligations
c) Diagnosis and Prognosis
d) Available Treatment Options
e) Goals
f) Patient Triage

2.0 AGE-RELATED MACULAR DEGENERATION

2.1 Definition of Age-Related Macular Degeneration

Age-Related Macular Degeneration (ARMD) is an acquired retinal disorder which is characterized by any of the following fundus changes: pigmentary atrophy and degeneration, drusen formation, serous and hemorrhagic retinal and/or pigment epithelial detachments, choroidal neovascularization and subretinal fibrosis or disciform scar. Two forms of ARMD exist. Nonexudative (dry) ARMD, and exudative (wet) ARMD.

2.2 The Natural History of ARMD

In most instances, ARMD occurs in patients over age 55. It can result in progressive, sometimes significant, irreversible loss of central visual function from either fibrous scarring or diffuse, geographic atrophy of the macula. Most patients with severe vision loss have exudative ARMD. However, patients with atrophic ARMD may experience a gradual but significant loss of visual function or may progress to the exudative stage of the disease. These GUIDELINES specifically deal with ARMD present in the otherwise healthy adult patient.

More than 1.6 million Americans over age 60 have advanced ARMD.

3.0 RESPONSIBILITIES AND OBLIGATIONS

3.1 Responsibilities and Obligations

The physician team has well established and firm responsibilities to the patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis, and understanding in the evaluation of the patient's disability, needs and concerns. The physician team is also responsible for completeness in informing and educating the patient regarding their disease, its potential treatment and the ultimate challenge in providing appropriate and competent treatment. The obligation of the physician team is to improve vision or minimize visual loss and functional impairment related to ARMD.

The patient has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, and to follow instructions, comply with prescriptions, and notify the physician should evidence of complications arise.

The plan also has responsibilities to the doctor/patient relationship: the responsibility to attempt to understand information regarding the disease and its treatment, and to authorize appropriate treatment for the best possible clinical outcome for the patient.

4.0 DIAGNOSIS AND PROGNOSIS

4.1 Diagnosis

In order for the patient to consider a decision regarding treatment options, full information must be given regarding the correct diagnosis of ARMD and the prognosis following the anticipated treatment.

The purpose of the comprehensive baseline ARMD evaluation is to confirm the diagnosis, establish baseline status and determine appropriate action.

4.2 Prognosis

The progression of vision loss in non-exudative ARMD is variable and must be evaluated on an individual basis. The ophthalmoscopic appearance of the macula cannot be directly correlated with the degree of visual acuity loss. Foveal involvement appears to occur early in the atrophic process, but the average interval from first observation to legal blindness is 9 to 10 years. Patients with exudative ARMD have a worse prognosis than do patients with non-exudative disease. Patients who present with an exudative lesion in one eye and no evidence of exudative disease in the other eye are at a significant risk of developing exudative disease in the fellow eye and becoming legally blind.

5.0 TREATMENT OPTIONS

5.1 Goal of Treatment

The goal of treatment in ARMD is to minimize visual loss and functional impairment in these patients through appropriate detection, treatment and follow-up recommendations.

5.2 Medical Management

Treatment is not indicated for most patients with ARMD. While there is no generally accepted treatment for dry ARMD, research sponsored by the National Eye Institute has recently shown that a combination of zinc, vitamins C and E, and beta-carotene may also reduce the risk of advanced ARMD by 25 percent. When treatment is not indicated, the prognosis should be explained. Patients should be educated and instructed to look for signs of decreased vision, scotoma and morphopsia by self-assessment with an Amsler grid. Patients deemed stable on the basis of reporting no noticeable change in visual function should be examined yearly.

Patients at risk for severe vision loss from exudative ARMD need immediate consultation with a retina specialist, if available, or a general ophthalmologist experienced in retinal disease. Fundus fluorescein angiography is indicated to determine if the patient would benefit from laser treatment. Timely intervention may reduce the risk for significant vision loss.

5.3 Laser Treatment

Choroidal neovascularization in the exudative form of ARMD is the major cause of severe visual loss in patients with ARMD, and it is the one form of the disease proven amenable to laser photocoagulation. In the past, Photo-dynamic therapy (PDT) with the injection of Visudyne (vertiporfin) has proven to be an effective laser treatment option for those patients with sub-foveal neovascularization.

5.4 Intravitreal Injections

The intravitreal injection of Macugen **(**pegaptanib sodium) was the treatment of choice for wet macular degeneration. The IV injections are performed every six weeks per eye for up to two years. In addition, there are ongoing studies with the anti-cancer drugs Avastin and Lucentis, which are very promising. Avastin is currently only FDA approved as an anti-colon cancer drug, but, studies indicate that Avastin is a good treatment modality for macular degeneration. Treatments are every 4-6 weeks. Physicians are using Avastin "off-label" for the treatment of wet macular degeneration. The current protocol for Avastin is:

Day 1: Consult, F/A, OCT, extended ophthalmoscopy.

Treatment 1: Intravitreal Injection of Avastin

Treatment 2: Six weeks later. OCT and Intravitreal Injection of Avastin.

Treatment 3: Six weeks later. OCT, F/A, Intravitreal Injection of Avastin.

Treatment 4: Six weeks later. OCT, Intravitreal Injection of Avastin.

Average treatments per patient is 4-5. Some patients require as little as 2 treatments, some may require as many as 7. Second eye treatments sometimes performed same day as initial eye.

In addition, Lucentis, has been FDA approved and Medicare approved for the treatment of the wet form of macular degeneration. Treatments are also every 4-6 weeks. The treatment of macular degeneration will certainly be in flux while new drugs are being developed for the aging population.

5.4.1 Second Opinion

Second opinion may be useful in unusual cases of questionable diagnosis or prognosis. However, a second opinion does not relieve the examining physician of the responsibility for a thorough history and ocular examination and the determination of both diagnosis and prognosis.

6.0 GOALS

The generally accepted paradigm of age-related macular degeneration management is to identify patients at risk of visual loss related to ARMD, minimize visual loss and functional impairment in these patients through appropriate detection, treatment and follow-up recommendations, help patients identify resources for visual rehabilitation and to educate patients about the disease and engage them in managing the disease.

7.0 PATIENT TRIAGE

7.1 Patient Triage Management

Optometrists and Ophthalmologists are licensed and governed by their respective state departments of health and their respective state boards of medicine. Most of the provider practices on Ocular Benefits' panel have Optometrists and Ophthalmologists on staff. Initial consults of previously undiagnosed ARMD patients may be triaged to optometrists or ophthalmologists. Patients previously diagnosed with ARMD may be triaged to optometrists or ophthalmologists for evaluation, diagnosis and management. Patients with complicated ARMD histories and/or post- laser ARMD patients will be triaged to an ophthalmologist.

1.0 OVERVIEW – Management of Cataract

1.1 Introduction

These guidelines are based on the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines. Papers reviewed for the development of these standards were *Cataract in the Otherwise Healthy Adult Eye*, produced by the American Academy of Ophthalmology, and, the *Guidelines for Cataract Practice*, produced by the American College of Eye Surgeons.

The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have experienced the functional impairment of cataract.

1.2 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with functional impairment due to cataract, they are organized into the following subjects:

a) The Definition of Cataract and Visual Function
b) Responsibilities and Obligations
c) Diagnosis and Prognosis
d) Surgical Intervention
e) Anesthesia
f) Post-operative Care
g) Complications
h) Patient Triage

2.0 CATARACTS AND VISUAL FUNCTION

2.1 Definition of Cataract and Visual Function

Cataracts become significant to the patient when they interfere with visual function. Interference with visual function is the disability experienced by the patient with cataract. A multitude of

additional factors bear on the degree of disability experienced by any individual patient. The functional consequences of lens opacification include: loss of driving privileges, the hazard of falling in low light surroundings, inability to maintain an independent lifestyle, and loss of self-confidence extending to withdrawal and even depression.

2.2 The Natural History of Cataract

In most instances, cataract development is considered part of the aging process. These GUIDELINES specifically deal with cataracts present in the otherwise healthy adult patient.

3.0 RESPONSIBILITIES AND OBLIGATIONS

3.1 Responsibilities and Obligations

The physician team has well established and firm responsibilities to the patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis, and understanding in the evaluation of the patient's disability, needs and concerns. The physician team is also responsible for completeness in informing and educating the patient regarding their disease, its potential treatment and the ultimate challenge in providing appropriate and competent treatment. The obligation of the physician team continues until postoperative rehabilitation is complete.

The patient has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, and to follow instructions, comply with prescriptions, and notify the physician should evidence of complications arise.

The plan also has responsibilities to the doctor/patient relationship: the responsibility to attempt to understand information regarding the disease and its treatment, and to authorize appropriate treatment for the best possible clinical outcome for the patient.

4.0 DIAGNOSIS AND PROGNOSIS

4.1 Diagnosis

In order for the patient to consider a decision regarding surgical intervention, full information must be given regarding the correct diagnosis of cataract and the prognosis for return of visual function following the anticipated treatment.

The history of visual functional disability will be carefully evaluated, including the effect on both distant and near vision and the effect of varying ambient light circumstances. Many patients have a striking reduction in visual function with Snellen acuity reduced to less than 20/50, and a generalized interference with activities of daily life. Other patients may be disabled by less striking reductions in visual function. For example, an airline pilot may be prevented from performing his/her job, although the Snellen acuity is better than 20/50.

4.2 Prognosis

Tests of macular function have been developed to aid in the analysis of prognosis for cataract surgery, i.e., whether the patient will see well following removal of cataract. Two basic types of tests are available: subjective and objective.

The most commonly utilized macular function tests are subjective, high brightness tests which present to the retina a high intensity image of appropriately sized Snellen style opti-types. In eyes with Snellen acuity of 20/200 or better, these tests often allow a very useful evaluation of macular function which, when used in conjunction with the history and ocular examination, aid the physician in counseling the patient regarding the expected improvement from cataract surgery.

The corneal endothelium is peculiarly sensitive to the trauma of surgery and its condition should be evaluated prior to any intraocular operation. Specular photo micrography or video micrography can be used as an objective test to measure and record the evaluation of corneal endothelial cells if corneal dystrophy or guttata is observed on slit lamp exam.

5.0 SURGICAL INTERVENTION

5.1 Goal of Treatment

Functional rehabilitation through improvement of visual function is possible in the vast majority of cataract patients and is the goal at each stage of treatment.

5.2 Pre-surgical Management

In most circumstances, cataract surgery is elective. For the patient with gradually developing cataracts, management consists of reassurance, support and education about the cause of visual disability and its prognosis. During the development of nuclear sclerosis, myopia is induced and changes of spectacle lens prescription will often improve visual function. The use of strong bifocals, appropriate lighting, occasional magnification and other visual aids may satisfy the changing vision requirements as a cataract progresses. Therapeutic dilation of the pupil assists the occasional patient to see around central posterior subcapsular cataract, however, it may also increase glare and visual discomfort. During the early stages of cataract development, measures such as these may allow the patient to temporize before deciding on surgical intervention. On the other hand symptomatic anisometropia, loss of driver licensure, or disabling glare may force a patient's decision.

5.3 The Decision for Surgical Intervention

The patient will make the elective decision regarding cataract surgical intervention. The decision will be based on full information regarding the correct diagnosis, the prognosis for improvement and a detailed discussion of the potential risks and benefits of the procedure.

5.3.1 Second Opinion

Second opinion may be useful in unusual cases of questionable diagnosis or prognosis. However, a second opinion does not relieve the examining physician of the responsibility for a thorough history and ocular examination and the determination of both diagnosis and prognosis. In the large majority of elective cataract surgery patients, routine second opinion is not beneficial and significantly increases the cost of appropriate care to the patient and to third party payers.

5.4 Indications for Surgery

The purpose of cataract surgery is to reduce and ideally eliminate functional impairment caused by the presence of a cataract. Only rarely is cataract surgery performed for other reasons.

Cataract surgery is indicated when the cataract reduces visual function to a level that interferes with daily activities of the patient. The severity of the interference can range from simple glare recognized in intense lighting to reduced ability to perform recreational activities and reading, difficulty with driving, loss of employment, and prevention of independent living.

The appropriateness of cataract surgery at any level of disability depends on a complete assessment of the overall visual function and the needs of the well informed patient. Surgery for cataract is considered when medical, optical and environmental measures have proven inadequate for the patient's personal visual requirements.

The patient should consider the decision to intervene with surgery on the basis of the physician's recommendation based on full subjective, objective and educational criteria. The indication for surgery, however, is founded on the patient's requirement for better vision and the patient's personal reasons. Surgery is not necessary solely because the cataract is present. The ultimate decision regarding the desirability and timing of cataract surgery is determined by the patient, the referring physician and the ophthalmologist who is to perform the surgery after a complete evaluation confirms the subjective and objective findings of visual disability related to the cataract.

The indications for surgery are considered for two levels of visual impairment, with 20/50 as the divider.

5.4.1 Visual Disability with the Snellen Acuity Reduced to 20/50 or Worse

Cataract surgery is justified and appropriate when the following subjective, objective and educational criteria are met.

- Subjective: The subjective criterion is impairment of the ability to carry out needed or desired activities. The patient's decision depends on a personal assessment of visual disability (e.g., impact on driving, reading, watching television, special occupational or vocational needs) and perception of the impact of the disability on lifestyle such as loss of independence or loss of income.

- Objective: Visual function cannot be improved to 20/50 Snellen acuity or better. Evaluation of diagnosis and prognosis has established that cataract is the responsible factor in

visual functional disability. The patient's mental status and medical health should permit surgical intervention to be performed safely.

- Educational: The patient is educated about the diagnosis, prognosis, risks and benefits of cataract surgery, including the alternatives to treatment. The patient determines that the expected improvement in the visual function outweighs the potential risk, cost and inconvenience of surgery.

5.4.2 Visual Disability with the Snellen Acuity of 20/40 or Worse

Cataract surgery is justified and appropriate when the following subjective, objective and educational criteria are met:

- Subjective: The subjective criterion is impairment of the ability to carry out needed or desired activities. The patient's decision depends on the assessment of his or her visual disability (e.g., impact on driving, reading, watching television, special occupational/vocational needs) and perception of the impact of the disability on lifestyle, such as loss of independence or loss of income.

In this category it is expected that a greater disparity of visual function will be seen with varying special activities and environmental circumstances. The patient may experience severe difficulties with reading, while distance visual function is adequate. Conversely, visual function in the controlled living room environment may be acceptable, while the glare of night time driving or open sunlight may be disabling. Careful historical information may clearly demonstrate these special factors in the visual functional disability experienced.

The patient may recognize reduced visual function and describe it in any of the following categories:

- Visual function disability fluctuates as a result of environmental factors, dim illumination or glare.

- There are bothersome distortions of vision such as monocular diplopia, or multiple ghost images.

- There is a significant disparity of visual function between the two eyes.

- Binocular vision is prevented by disparate image sizes with anisometropia.

- Objective: Visual function can be improved to 20/40 or worse under Snellen acuity standards.

However contrast sensitivity and/or glare testing demonstrates a greater reduction of visual function which is consistent with the patient's subjective experience. The patient should demonstrate a specific disability due to glare and acuity decreases to 20/50 or worse in a brightly lit room, or on glare testing with the Mentor Brightness Acuity Tester (BAT) on "low" or "medium" setting, or equivalent. The patient's mental status and medical health should permit surgery to be performed safely. In this category the objective criterion is based on the evaluation of visual function based on factors other than Snellen visual acuity.

- Educational: The patient is educated about the diagnosis, prognosis, risks and benefits of cataract surgery, including alternatives to treatment. The patient determines if the expected improvement in visual function outweighs the potential risk, cost and inconvenience of surgery. As a general rule, the better the Snellen visual acuity, the greater the need for verification and documentation of other aspects of visual function. Similarly, the better the Snellen visual acuity, the more significant the various risks become as measured against the potential benefit. Consequently, the importance of education is greatest for those patients where the visual functional disability is least.

5.4.3 Visual Disability Due to Cataract in the One-Eyed Patient

A one-eyed patient is defined as one who has permanent legal blindness of the fellow eye.

The referring physician and the ophthalmologist who will perform the surgery has the obligation to inform and educate the patient of the risk of total blindness when considering potential benefits of cataract surgery. The same criteria apply for both levels of visual disability. The worse the vision in the fellow eye, the greater the need for caution when considering cataract surgery in the eye upon which will be operated.

5.4.4 Other Indications for Cataract Removal

There are three other indications for cataract removal:

- Lens-induced disease
- The need to visualize the fundus.
- To repair ocular trauma and in association with foreign body removal from the eye.

Documented evidence of the presence of lens-induced diseases (phacomorphic glaucoma, phacolytic glaucoma, etc.) may necessitate cataract removal. Because of the risk of permanent damage to vision and possible loss of the eye, cataract extraction may be urgent.

It is necessary to visualize the fundus to: 1) adequately manage ocular conditions that would otherwise lead to worse or permanent visual loss in an eye that has the potential for sight (e.g., the diabetic patient with significant risk of reduced visual acuity from diabetic retinopathy requiring visualization through clear media for diagnosis or laser therapy), or 2) when other special investigations demonstrate intraocular pathology where further attention is important and requires clear media.

5.5 Contraindications for Surgery

Surgery should not be performed under the following circumstances:

- The patient does not desire surgery.
- Glasses or visual aids provide functional vision satisfactory to the patient's needs and desires.
- Surgery will not improve visual function.
- The patient's lifestyle is not compromised.
- The patient is known to be medically unfit for safe surgical intervention.

5.6 Second Eye Surgery

Indications for surgery on the second eye are similar to those for the first eye surgery.

When an individual who has already had cataract surgery in one eye has or develops a cataract in the second eye, the patient and the physician are confronted with the same issues regarding the decision for surgery that were present during the evaluation of the cataract in the first eye. In addition, the disabilities caused by a visual deficit in the second eye are significant, e.g., loss of binocularity and stereopsis. Restoration of binocular vision enhances visual functions such as acuity, stereopsis, and the visual field, thus justifying surgery in the second eye.

Surgery in the second eye is justified and appropriate when the subjective, objective, and educational criteria outlined in the discussion on Indications for Surgery are met.

There are no scientific data to indicate an optimal or minimal time interval for surgery on the second eye.

Other factors to consider are:

- The patient's ability to provide informed consent for surgery on the second eye after he/she has been able to evaluate the visual results and postoperative course of surgery on the first eye.
- The passage of an adequate time for the detection and treatment for the most immediate vision-threatening complications of cataract surgery.
- Vision in the operated eye has recovered sufficiently so that the patient is not at risk of injury due to functional impairment during the second eye cataract surgery and the immediate postoperative period, or in the event that vision has not recovered or is not recoverable, there is time to arrange for adequate assistance so the patient is not at risk of injury due to functional impairment following second eye cataract surgery.

The following factors may influence the patient's and physician's judgment regarding the timing for surgery on the second eye:

- The nearest available facility for surgery and the appropriate postoperative care.
- The patient has a need (e.g., occupational) for good binocular vision within a limited time after the first eye surgery.
- The patient is symptomatic due to anisometropia.

Early spectacle correction or decrease in the duration of the postoperative course alone are not always adequate justification for performing surgery on the second eye before the patient and the physician have had a sufficient opportunity to evaluate the results from the surgery on the first eye. The final choice must remain in the hands of the patient combined with responsible counseling by his/her physician.

Evidence is now accumulating that earlier intervention leads to a more rapid rehabilitation time, and a shorter presurgical disability time, and also results in a lower complication rate. Cataracts which have been allowed to progress to a very advanced stage present several problems. These include:

- Hypermature and mature cataracts present a higher incidence of capsular rupture with vitreous loss and subsequent additional retinal complications.
- Dense nuclear cataracts may present increased danger to the corneal endothelium by requiring longer phacoemulsification times, or by their physical contact with the endothelium during extracapsular removal.

5.7 Surgical Techniques

Ophthalmologists should use their best judgment in selecting the surgical techniques for individual patients with cataract. This decision about the appropriate technique should be made by the ophthalmologist who is to perform the surgery in accordance with his/her training and experience and after discussion and explanation with the patient.

6.0 ANESTHESIA

6.1 Anesthesia for Cataract Surgery

The choice of general, local or topical anesthesia may affect visual outcome indirectly, through the effects of nausea, vomiting, coughing or sudden movement during the perioperative period. Many cataract patients are elderly with multiple medical problems, and thus at increased risk for morbidity during a period of general anesthesia.

On balance, properly managed local anesthesia is simpler and safer than general anesthesia, especially in patients with significant cardiac or pulmonary problems.

General anesthesia may be preferred, however, in the following situations:

- Extreme patient anxiety.
- Inability of the patient to cooperate with the surgical team.

- Inability to provide satisfactory local or topical anesthesia.
- Known allergy to local or topical anesthetic medications.
- The presence of disorders that may be better managed under general anesthesia, e.g., severe back pain, postural problems, etc.

Local and topical anesthesia involves decisions regarding patient monitoring and local anesthesia involves the choice of technique (peribulbar, retrobulbar, periocular, orbital epidural).

6.2 Monitoring Anesthesia

Monitored anesthesia by an anesthesiologist or anesthetist is strongly preferred to non-monitored care, particularly in the free-standing ambulatory surgical facility. The use of modern monitoring techniques is appropriate in cataract surgery given the age of the patients and the high incidence of associated medical problems. Good monitoring might affect visual outcome indirectly if it prevents sustained hypertension, hypotension or hypoxia. Monitoring by qualified anesthesia personnel is appropriate because the ophthalmologist is fully occupied in the surgical technique, and therefore unable to deal with emergencies in a timely manner. Monitored anesthesia includes physiologic monitoring with life support systems available.

6.3 Administering Anesthesia

Either peribulbar or retrobulbar injection (periocular, orbital epidural) is acceptable, and each has its own set of advantages and disadvantages. The injection should be administered by an individual physician, board certified registered nurse anesthetist, or licensed anesthesia assistant; an appropriately trained professional who has demonstrated competence in these techniques. The use of sedative drugs (reversible and with reduced side effects) is appropriate to minimize pain and discomfort while local anesthesia is being administered. Both peribulbar and retrobulbar anesthesia should be administered to properly monitored patients with intravenous access established and oxygen/ambu mask available. It should include use of the following monitoring techniques:

- EKG
- Pulse oximetry
- Blood pressure
- Respiration

7.0 POSTOPERATIVE CARE

7.1 Postoperative Care

The operating surgeon is responsible to the patient for the coordination of postoperative care. The number of postoperative office visits scheduled for the ophthalmologic and optometric physician offices should be determined according to the type of surgery performed and the individual needs of the patient. The cataract patient will be scheduled for postoperative care with an optometric physician as soon as one week after surgery, and no less than 3 weeks after surgery, unless otherwise indicated by complications or by lack of patient consent.

The postoperative patient is ordinarily examined on the first day following surgery, then again during the week following surgery. Additional visits are thereafter scheduled according to the patient's needs. However, through the entire convalescent period, immediate and appropriate care must be readily available to the patient at any time of day or night. The managing physicians continue to bear this ultimate responsibility.

From the patient's perspective, the period of postoperative care expands from the day of surgery until the goal of stable, improved visual function is achieved. In the absence of complications, most patients are prescribed a refractive correction by the managing optometric physician when the point of stability is reached. At that point, healing is sufficiently advanced so that the integrity of the eyeball has been reestablished and any intra or postoperative complications that may have occurred have been diagnosed and treated. If serious complications develop, the period of intensive treatment may extend well beyond the normal global period of postoperative care.

7.2 Patient Postoperative Education

The operating surgeon has the obligation to provide education and instruction to the patient regarding the following: resumption of activities, protection of the eye, the use of normal medications, the timing and scheduling of normal postoperative visits, the identifying signs and symptoms of possible complications, and detailed instructions for gaining access to emergency care. The patient of course has an obligation to actively participate in his or her care by following the surgeon's advice and instructions, and immediately notifying the surgeon should any evidence of problems arise.

7.3 Condition at Discharge

Following cataract surgery patients are normally discharged to their home or other local accommodation. The criteria for discharge after ambulatory cataract surgery include:

- Stable vital signs.
- Return to preoperative mental state.
- Absence of nausea and significant pain.
- Presence of a responsible escort or driver.
- An understanding of the postoperative instructions for the first 24 hours, including relief of pain, and method of gaining access to emergency care if needed.
- A written review of postoperative instruction.
- A clear understanding of the follow up appointment scheduled for the following day.

7.4 Postoperative Hospitalization

A small number of cataract patients may be hospitalized after surgery for either planned or unplanned circumstances.

7.4.1 Planned Postoperative Hospitalization

Possible indications for planned postoperative hospitalization include:

- The presence of medical conditions that will require prolong post-operative observation by nurses and or skilled personnel.
- The mentally disabled or demented patient who is functionally incapacitated and unable to maintain a level of self-care.
- Disabling loss of vision in the fellow eye in patients who have insufficient companionship and help in the home.

7.4.2 Unplanned Postoperative Hospitalization

Possible indications for unplanned postoperative hospitalization are as follows:

Postoperative complications of an ocular or medical nature are possible indications for unplanned postoperative hospitalization. Ocular complications can include hyphema, infection, wound dehiscence, endophthalmitis, uncontrolled elevated intraocular pressure, threatened or actual expulsive hemorrhage, retrobulbar hemorrhage, severe pain or other ocular problems requiring acute management of careful observation. Medical complications can include cardiac instability, respiratory instability, a cerebrovascular episode, diabetes mellitus requiring acute management, uncontrolled nausea or vomiting, acute urinary

retention, acute psychiatric disorientation, or other medical conditions requiring acute management or careful monitoring.

7.5 Postoperative Visits

The frequency of the examination during the postoperative period is determined by the surgeon's and the optometric physician's experience and the patient's needs. The office examinations provide the opportunity to:

- Provide routine postoperative care as healing progresses.
- Educate and support the patient during the postoperative period.
- Identify, diagnose and treat any complications that may arise.

The suggested guideline for normal follow up examinations of the patient without signs or symptoms of complication is:

- First visit, during the first day following surgery.
- Second visit, within two weeks after surgery.
- Additional visits, as necessary throughout the global period.

7.6 Postoperative Examination

The postoperative visits should include the evaluation of visual function, the condition of the postoperative eye with special emphasis on possible complications and screening for undiagnosed preoperative conditions and concurrent ocular diseases. These examinations would include external, slit lamp examination, intraocular pressure, and as necessary, ophthalmoscopy.

The suggested components of postoperative examination include the following:

- Visual function, each visit.
- Intraocular pressure measurement, each visit.
- External examination, each visit.
- Slit lamp examination, each visit.
- Patient counseling/education, as necessary.

- Ophthalmoscopy appropriate to the patient's clinical circumstances.

Optical correction can be prescribed when the refraction is stable, usually 2 - 6 weeks after surgery, or earlier if warranted by patient needs.

8.0 COMPLICATIONS

8.1 Complications

The operating surgeon has a unique and intimate knowledge of the surgery performed and, therefore, the expectation of the patient's postoperative condition. However, individual differences in cataract and in patient response to surgery may lead to variations in outcome, even resulting from an uncomplicated surgical procedure. If surgical or postoperative complications develop the surgeon or optometric physician will arrange for appropriate treatment, perhaps to include referral to other Eye Care physicians. In unusually complicated circumstances, this may extend beyond the normal postoperative period.

Fortunately, serious complications are extremely uncommon with contemporary cataract surgery. However, they occur unpredictably and when inadequately treated may have a devastating effect on the outcome of the surgical procedure. Consequently, the patient must be educated and frequently reminded of the need for professional evaluation of any abnormal occurrences during the postoperative period.

Among the most serious complications are intraocular infections and secondary glaucoma. While the most serious and acute examples tend to be present within the first several postoperative days, such complications may arise even weeks or months later with potentially serious results. Consequently the scheduling of routine visits is a very general guide which should be expanded in the case of any unusual findings or complications and further expanded by raising the patient's level of suspicion regarding any untoward experiences.

9.0 PATIENT TRIAGE

9.1 Patient Triage Management

Optometrists and Ophthalmologists are licensed and governed by their respective state departments of health and their respective state boards of medicine. Most of the provider practices on Ocular Benefits' panel have Optometrists and Ophthalmologists on staff. Patients who have been previously diagnosed with cataract may be triaged to an optometrist or ophthalmologist to determine the best corrected acuity. Patients who cannot be adequately corrected will be triaged to an ophthalmologist for a cataract surgery consultation.

1.0 OVERVIEW – Management of Diabetic Retinopathy

1.1 Introduction

These guidelines are based on the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines. Papers reviewed for the development of these standards were *Diabetic Retinopathy,* produced by the American Academy of Ophthalmology and *Care of the Patient with Diabetic Mellitus*, produced by the American Optometric Association.

The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have been diagnosed with diabetic retinopathy.

1.2 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with diabetic retinopathy, they are organized into the following subjects:

a) The Definition of Diabetic Retinopathy
b) Responsibilities and Obligations
c) Diagnosis and Prognosis
d) Available Treatment Options
e) Goals
f) Patient Triage

2.0 DIABETIC RETINOPATHY

2.1 Definition of Diabetic Retinopathy

Diabetic Retinopathy is a complication of chronic diabetes mellitus. Eventually, nearly all patients with diabetes develop some degree of retinopathy.

2.2 The Natural History of Diabetic Retinopathy

Most patients with diabetes mellitus ultimately develop characteristic abnormalities of the retinal blood vessels. Diabetic retinopathy in its earliest stages is characterized by increased retinal vascular permeability, which can lead to fluid accumulation in the retina. Later, retinal ischemia may follow. In the more advanced stages, new vessel proliferation, vitreous hemorrhage, retinal detachment and neovascular glaucoma may develop. These GUIDELINES specifically deal with evaluating and managing patients with diabetic retinopathy.

Diabetic retinopathy is the leading cause of blindness in adults of working age (20-65 years). Nearly half of all people with diabetes will develop some degree of diabetic retinopathy during their lifetime.

Diabetic retinopathy currently affects over 5.3 million Americans age 18 or over, or just over 2.5 percent of this population. This represents a 10.5 percent increase in disease prevalence from 1990, when 4.8 million Americans were affected.

In general, the longer someone has had diabetes, the greater the risk of developing diabetic retinopathy. Eventually, almost everyone with juvenile onset diabetes will develop some signs of diabetic retinopathy. Of people who have diabetes for 25 years, 74% will develop some form of diabetic retinopathy.

Prior to age 40, diabetic retinopathy affects Caucasians more frequently than other races. In later years, Hispanics are the most commonly affected by the disease.

Of the 5.3 million Americans who suffer from diabetic retinopathy:

53% are female, 47 are male

74% are Caucasian (1.9% of the Caucasian population)

10.2 are Hispanic (1.7% of the Hispanic population)

10.3% are African American. (1.6% of the African American population)

Diabetic Retinopathy is most prevalent in the following 5 states:

Florida

Hawaii

New Mexico

Pennsylvania

West Virginia

3.0 RESPONSIBILITIES AND OBLIGATIONS

3.1 Responsibilities and Obligations

The physician team has well established and firm responsibilities to the patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis, and understanding in the evaluation of the patient's disability, needs and concerns. The physician team is also responsible for completeness in informing and educating the patient regarding their disease, its potential treatment and the ultimate challenge in providing appropriate and competent treatment. The obligation of the physician team is to improve vision or minimize visual loss and functional impairment related to diabetic retinopathy.

The patient has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, and to follow instructions, comply with prescriptions, and notify the physician should evidence of complications arise.

The plan also has responsibilities to the doctor/patient relationship: the responsibility to attempt to understand information regarding the disease and its treatment, and to authorize appropriate treatment for the best possible clinical outcome for the patient.

4.0 DIAGNOSIS AND PROGNOSIS

4.1 Diagnosis

In order for the patient to consider a decision regarding treatment options, full information must be given regarding the correct diagnosis of diabetic retinopathy and the prognosis following the anticipated treatment. Two broad categories of diabetic retinopathy are: non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR).

NPDR is further classified into mild, moderate, severe and very severe levels according to clinical manifestations.

PDR is classified into mild, moderate and high risk levels depending on clinical manifestations,

Diabetic macular edema, which can be present at any level of NPDR and PDR, should be considered, regardless of the level of retinopathy.

Every diabetic retinopathy patient requires a yearly dilated eye examination.

The purpose of the comprehensive baseline diabetic retinopathy evaluation is to confirm the diagnosis, establish baseline status and determine appropriate action.

Retinal telescreening for the detection of diabetic of diabetic retinopathy is justified when specific criteria are met. Retinal telescreening systems use a digital fundus camera to photograph the retina for the detection of diabetic retinopathy. The retinal images can be stored and transferred to a central imaging evaluation center for reading by a trained technician. The imaging can be performed in conjunction with a primary care physician office visit without referral to an ophthalmologist or optometrist. This technology is an alternative to conventional ophthalmologic examination of the retina.

Retinal telescreening systems are considered **medically necessary** for annual diabetic retinopathy screening as an alternative to retinopathy screening by an ophthalmologist or optometrist when **all** of the following criteria are met:

- The individual does not have prior known diabetic retinopathy; **and**
- The imaging technique covers a total retinal area which includes the Diabetic Retinopathy Study seven-standard fields (DRS7); **and**
- The final images are graded for diabetic retinopathy using a manual process.

All other uses of retinal telescreening systems are considered **not medically necessary,** including, but not limited to those listed below:

- To follow the progression of disease in individuals who have been diagnosed with diabetic retinopathy
- To screen or evaluate retinal conditions other than diabetic retinopathy, including, but not limited to macular degeneration
- When the final composite image captured does not include the entire DRS7 field area
- When the final retinal images are graded using an automatic process only (e.g., artificial neural networks)

4.2 Prognosis

Many patients with diabetic retinopathy will lose substantial vision despite being treated appropriately. Surgery is effective in reducing, but not eliminating the risk of visual loss related to many aspects of diabetic retinal disease. Diabetic retinopathy is a chronic condition that is often progressive, and surgery is usually only palliative.

5.0 TREATMENT OPTIONS

5.1 Goal of Treatment

The goal of treatment in diabetic retinopathy is to minimize visual loss and functional impairment in these patients through appropriate detection, treatment and follow-up recommendations. There is no pharmaceutical therapy available that stops the progression of diabetic retinopathy by treating the underlying cause of the disease, hyperglycemia-induced microvascular damage. Currently, drug companies are conducting research to develop new drugs for diabetic eye complications, including diabetic retinopathy and macular edema.

5.2 Medical Management

In mild NPDR, annual examinations are generally sufficient as long as neither macular edema nor a coincident medical condition is present.

In moderate NPDR, a repeat evaluation in 6-12 months is appropriate if no macular edema or complicating medical or risk factors are present.

In severe NPDR, a retinal consult with a retinal subspecialist is appropriate. Laser photocoagulation may be indicated.

PDR, the most severe form of diabetic retinopathy, requires prompt referral to a retinal subspecialist.

5.3 Laser Treatment

Laser photocoagulation is advised for patients with high risk proliferative disease and for patients with clinically significant macular edema. Iris and angle neovascularization also may be indications for laser photocoagulation. Argon laser photocoagulation is the standard, most widely used technique for treating diabetic retinopathy, although other laser wavelengths also are effective in selected situations.

Three different methods of laser photocoagulation are used, depending upon the pathology being treated. Panretinal, focal and grid photocoagulation are each utilized depending upon a specific diabetic retinopathy mechanism.

5.4 Intravitreal Injections

There are ongoing studies with the anti-cancer drugs Avastin and Lucentis, which are very promising. Avastin is currently only FDA approved as an anti-colon cancer drug, but, studies indicate that Avastin is a good treatment modality for diabetic retinopathy. Treatments are every 4-6 weeks. Physicians are using Avastin "off-label" for the treatment of diabetic retinopathy. The current protocol for Avastin is:

Day 1: Consult, F/A, OCT, extended ophthalmoscopy.

Treatment 1: Intravitreal Injection of Avastin

Treatment 2: Six weeks later. OCT and Intravitreal Injection of Avastin.

Treatment 3: Six weeks later. OCT, F/A, Intravitreal Injection of Avastin.

Treatment 4: Six weeks later. OCT, Intravitreal Injection of Avastin.

Average treatments per patient is 4-5. Some patients require as little as 2 treatments, some may require as many as 7. Second eye treatments sometimes performed same day as initial eye.

In addition , Lucentis and Eylea have been FDA approved and Medicare approved for the treatment of diabetic retinopathy. Treatments are also every 4-6 weeks. The treatment of diabetic retinopathy will certainly be in flux while new drugs are being developed for the aging population.

5.4.1 Second Opinion

Second opinion may be useful in unusual cases of questionable diagnosis or prognosis. However, a second opinion does not relieve the examining physician of the responsibility for a thorough history and examination and the determination of both diagnosis and prognosis.

6.0 GOALS

The goals in diabetic retinopathy management is to identify patients at risk of developing diabetic retinopathy, to treat patients at risk of visual loss from retinopathy, to minimize the side effects of treatment and their impact on the patient's vision and quality of life and to engage the patient in the management of the patient's ocular condition.

7.0 PATIENT TRIAGE

7.1 Patient Triage Management

Optometrists and Ophthalmologists are licensed and governed by their respective state departments of health and their respective state boards of medicine. Most of the provider practices on Ocular Benefits' panel have Optometrists and Ophthalmologists on staff. Initial consults of newly diagnosed diabetic patients may be triaged to optometric physicians or ophthalmologists. Patients previously diagnosed with diabetic retinopathy may be triaged to optometric physicians or ophthalmologists for evaluation, diagnosis and management. Patients with diabetic macular edema, or with a suspicion of diabetic macular edema, should be referred immediately to a retinal subspecialist. Patients with complicated diabetic retinopathy histories and/or post- laser diabetic retinopathy patients should be triaged to an ophthalmologist or retinal subspecialist.

1.0 OVERVIEW – Management of Primary Open Angle Glaucoma

1.1 Introduction

These guidelines are based on the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines. Papers reviewed for the development of these standards were *Primary Open Angle Glaucoma*, produced by the American Academy of Ophthalmology and *Care of the Patient with Primary Open Angle Glaucoma*, produced by the American Optometric Association.

The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have been diagnosed with glaucoma.

1.2 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with primary open angle glaucoma, they are organized into the following subjects:

a) The Definition of Primary Open Angle Glaucoma
b) Responsibilities and Obligations
c) Diagnosis and Prognosis
d) Available Treatment Options
e) Goals
f) Patient Triage

2.0 PRIMARY OPEN ANGLE GLAUCOMA

2.1 Definition of Glaucoma

Primary Open Angle Glaucoma (POAG) is generally bilateral, though not necessarily symmetrical, and is characterized by either or both of the following:

(a) the appearance of the disc or nerve fiber layer

(b) the presence of abnormalities in the visual field

POAG is generally of adult onset with open, normal appearing angles.

2.2 The Natural History of Glaucoma

In most instances, glaucomatous damage is generally progressive. The speed with which optic nerve damage progresses varies with the patient, but left untreated, a large proportion suffer total optic nerve atrophy and blindness. These GUIDELINES specifically deal with glaucoma present in the otherwise healthy adult patient.

3.0 RESPONSIBILITIES AND OBLIGATIONS

3.1 Responsibilities and Obligations

The physician team has well established and firm responsibilities to the patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis, and understanding in the evaluation of the patient's disability, needs and concerns. The physician team is also responsible for completeness in informing and educating the patient regarding their disease, its potential treatment and the ultimate challenge in providing appropriate and competent treatment. The obligation of the physician team is to preserve visual function by controlling intraocular pressure and thereby preventing further optic nerve damage..

The patient has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, and to follow instructions, comply with prescriptions, and notify the physician should evidence of complications arise.

The plan also has responsibilities to the doctor/patient relationship: the responsibility to attempt to understand information regarding the disease and its treatment, and to authorize appropriate treatment for the best possible clinical outcome for the patient.

4.0 DIAGNOSIS AND PROGNOSIS

4.1 Diagnosis

In order for the patient to consider a decision regarding treatment options, full information must be given regarding the correct diagnosis of glaucoma and the prognosis following the anticipated treatment.

The purpose of the comprehensive baseline glaucoma evaluation is to confirm the diagnosis, establish baseline status and determine appropriate action.

4.2 Prognosis

Glaucoma management is particularly difficult because POAG is a chronic, often asymptomatic, condition that commonly requires the use of multiple, often expensive, medications that need to be used on a frequent basis and commonly cause unwanted side effects. Establishing an effective regimen requires attention to its efficacy and the degree to which this is reduced by noncompliance. The physician must evaluate the individual patient, choosing a regimen of maximal effectiveness for that particular patient, at that particular point in the disease process. The prognosis and treatment plan, and likelihood that therapy will be lifelong should be discussed with the patient.

5.0 TREATMENT OPTIONS

5.1 Goal of Treatment

The ability to lower IOP varies with the therapeutic agent, the compliance and responsiveness of the individual patient, the state of the disease and the presence of complicating factors. The goal of treatment is to achieve a stable range of pressures deemed unlikely to cause further optic nerve damage or loss of visual field, in that particular patient.

5.2 Medical Management

IOP can be lowered, by varying degrees and for varying duration, by medical treatment, alone or in combination. Medical agents include topical and oral agents. They include miotics and epinephrine compounds that increase aqueous outflow, and topical and oral carbonic anhydrase inhibitors and beta adrenergic blockers that decrease aqueous production.

5.3 Laser and Surgical Treatment

The patient will make the elective decision regarding glaucoma laser and/or surgical intervention. The decision will be based on full information regarding the correct diagnosis, the prognosis for improvement and a detailed discussion of the potential risks and benefits of the procedure. Laser trabecular surgery increases aqueous outflow. Filtering surgery provides an alternative path for the escape of aqueous fluid, while cyclodestructive procedures reduce the rate of aqueous production.

5.3.1 Second Opinion

Second opinion may be useful in unusual cases of questionable diagnosis or prognosis. However, a second opinion does not relieve the examining physician of the responsibility for

a thorough history and ocular examination and the determination of both diagnosis and prognosis. In the large majority of elective glaucoma surgery patients, routine second opinion is not beneficial and significantly increases the cost of appropriate care to the patient and to third party payers.

5.4 Indications for Surgery

Laser trabecular surgery as initial therapy remains controversial, because long term IOP control and glaucoma stability have not been demonstrated. However, it may be considered in selected cases, where compliance is poor, where access to follow up care is limited or whose systemic or ocular condition makes medical therapy inadvisable. Filtering surgery usually provides a dramatic, stable reduction in IOP. While long term control is often achieved, many patients will require re-operation or further therapy.

The patient should consider the decision to intervene with surgery on the basis of the physician's recommendation based on full subjective, objective and educational criteria.

6.0 GOALS

The generally accepted paradigm for glaucoma therapy is to use medical therapy before laser surgery before other surgery. The limited effectiveness of medical therapy for glaucoma and the need for especially low pressures in patients with advanced disease or normal tension glaucoma needs to be recognized. Obtaining pressures in the “normal range” on office visits in no guarantee of optic nerve stability, since half to three quarters of glaucoma patients will progress even while IOP is in this range. The detection of elevated pressures and/or further damage calls for meaningful alterations in therapy, either additional medical therapy to lower IOP further, or laser or surgical therapy to achieve this goal.

7.0 POSTOPERATIVE CARE

7.1 Postoperative Care

The operating surgeon is responsible to the patient for the coordination of postoperative care. The number of postoperative office visits scheduled for the ophthalmologic and optometric physician offices should be determined according to the type of surgery performed and the individual needs of the patient.

The postoperative patient is ordinarily examined on the first day following surgery, then again during the week following surgery. Additional visits are thereafter scheduled according to the patient's needs. However, through the entire convalescent period, immediate and appropriate care must be readily available to the patient at any time of day or night. The managing physicians continue to bear this ultimate responsibility.

7.2 Patient Postoperative Education

The operating surgeon has the obligation to provide education and instruction to the patient regarding the following: resumption of activities, protection of the eye, the use of normal medications, the timing and scheduling of normal postoperative visits, the identifying signs and symptoms of possible complications, and detailed instructions for gaining access to emergency care. The patient of course has an obligation to actively participate in his or her care by following the surgeon's advice and instructions, and immediately notifying the surgeon should any evidence of problems arise.

7.3 Postoperative Visits The frequency of the examination during the postoperative period is determined by the surgeon's and optometric physician's experience and the patient's needs. The office examinations provide the opportunity to:

- Provide routine postoperative care as healing progresses.
- Educate and support the patient during the postoperative period.
- Identify, diagnose and treat any complications that may arise.

The suggested guideline for normal follow up examinations of the patient without signs or symptoms of complication is:

- First visit, during the first day following surgery.

- Second visit, within two weeks after surgery.
- Additional visits, as necessary throughout the global period.

7.4 Postoperative Examination

The postoperative visits should include the evaluation of visual function, the condition of the postoperative eye with special emphasis on possible complications and screening for undiagnosed preoperative conditions and concurrent ocular diseases. These examinations would include external, slit lamp examination, intraocular pressure, and as necessary, ophthalmoscopy.

The suggested components of postoperative examination include the following:

- Visual function, each visit.
- Intraocular pressure measurement, each visit.
- External examination, each visit.
- Slit lamp examination, each visit.
- Patient counseling/education, as necessary.
- Ophthalmoscopy appropriate to the patient's clinical circumstances.

8.0 PATIENT TRIAGE

8.1 Patient Triage Management

Optometrists and Ophthalmologists are licensed and governed by their respective state departments of health and their respective state boards of medicine. Most of the provider practices on Ocular Benefits' panel have Optometrists and Ophthalmologists on staff. Initial consults of previously undiagnosed glaucoma patients may be triaged to an optometrist or ophthalmologist. Patients previously diagnosed with glaucoma may be triaged to an optometrist or ophthalmologist for evaluation, diagnosis and management. Patients with complicated glaucoma histories and/or post- laser or surgical glaucoma patients will be triaged to an ophthalmologist.

1.0 OVERVIEW – Management of Pediatric Cataracts

1.1 Introduction

These guidelines are based on the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines.

The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have been diagnosed with pediatric cataracts.

1.2 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with pediatric cataracts, they are organized into the following subjects:

a) Classification of Types of Cataracts
b) Responsibilities and Obligations
c) Diagnosis and Prognosis
d) Available Treatment Options
e) Postoperative Care
f) Patient Triage

2.0 PEDIATRIC CATARACTS

2.1 Classification of Types of Cataracts

2.1.3 Anterior

a. Anterior Polar

- Less than 3mm diameter
- Located on center of anterior capsule
- 1/3 bilateral
- non-progressive
- usually not visually significant

b. Anterior Pyrimidal

- White conical in shape
- Apex of cone projecting into anterior chamber
- Usually bilateral

c. Anterior Subcapsular

- Often idiopathic
- Possibly traumatic induced
- Usually acquired and developed after birth

2.14 Central

a. Nuclear

- Congenital onset
- Non-progressive
- Unilateral or bilateral

b. Sutural

- Opacity concentrated along the Y-sutures
- May be progressive
- Bilateral associated with Autosomal Dominant Inheritance

c. Lamellar (Zonular)

- Whitish cortical opacity that surrounds the lens nucleus
- Just outside the Y sutures
- Develops in layers like onionskin
- Clear zones alternating with white cortical lamella

2.15 Posterior

a. Posterior Lenticonus
b. Persistent Hyperplastic Vitreous
c. Mittendorf's Dot
d. Posterior Subcapsular Cataract
e. Oil Drop Cataract

2.16 Diffuse

a. Christmas Tree Cataract
b. Cerulean (Blue dot) Cataract
c. Total Cataract

3.0 RESPONSIBILITIES AND OBLIGATIONS

3.1 Responsibilities and Obligations

The physician team has well established and firm responsibilities to the patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis and understanding in the evaluation of the patient's disability, needs and concerns. The physician team is also responsible for completeness in informing and educating the patient regarding their disease, its potential treatment and the ultimate challenge in providing appropriate and competent treatment. The obligation of the physician team is to preserve visual function by the proper management of pediatric cataracts.

The patient has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, and to follow instructions, comply with prescriptions, and notify the physician should evidence of complications arise.

The plan also has responsibilities to the doctor/patient relationship: the responsibility to attempt to understand information regarding the disease and its treatment, and to authorize appropriate treatment for the best possible clinical outcome for the patient.

4.0 DIAGNOSIS AND PROGNOSIS

4.1 Diagnosis

In order for the patient to consider a decision regarding treatment options, full information must be given regarding the correct diagnosis of pediatric cataracts and the prognosis following the anticipated treatment.

The early detection of childhood cataracts is mainly done by pediatricians. Only anterior polar lens opacities and mature cataracts can be seen with diffuse external illumination. Virtually any visually significant cataract can be recognized with the direct ophthalmoscope as a shadow against the red reflex.

Nystagmus may occasionally be a secondary sign of bilateral cataracts. Strabismus may signal unilateral or asymmetrical lens opacities.

The purpose of the comprehensive pediatric cataract evaluation is to confirm the diagnosis, establish baseline status and determine appropriate action.

4.2 Prognosis

The treatment options for patients with pediatric cataracts include correction of refractive error with spectacles and surgery.

There is no harm in delaying cataract surgery until it can be determined that visual acuity lags significantly behind normal levels for the patient's age.

5.0 TREATMENT OPTIONS

5.1 Goal of Treatment

The goals of treatment for pediatric cataracts are to maximize the potential for visual development by removing the cataract and to develop and maintain binocular vision. The physician also wants to minimize the adverse effects of the disorder and its treatment, including relief from amblyopia that might develop as a result of unilateral cataracts and aphakia.

5.2 Corrective Lenses

The rationale for correcting the refractive anomaly with spectacles is to ensure that the retina of each eye receives a clear optical image. After cataract surgery has been performed, the optical correction of aphakia in infants requires special consideration. Eyes with congenital cataracts often have unusually high degrees of aphakic hyperopia.

Contact lenses are commonly used for the correction of pediatric aphakia.

Intraocular lenses have been used in infants by an increasing number of surgeons.

5.3 Surgery

Cataract extraction with or without intraocular lens implantation is recommended before the age of three months in cases of congenital cataracts, to optimize the visual outcome and reduce the possibility of amblyopia.

5.3.1 Second Opinion

Second opinion may be useful in unusual cases of questionable diagnosis or prognosis. However, a second opinion does not relieve the examining physician of the responsibility for a thorough history and ocular examination and the determination of both diagnosis and prognosis. In the large majority of elective strabismus surgery patients, routine second opinion is not beneficial and significantly increases the cost of appropriate care to the patient and to third party payers.

5.4 Indications for Surgery

The patient should consider the decision to intervene with surgery on the basis of the physician's recommendation based on full subjective, objective and educational criteria.

6.0 POSTOPERATIVE CARE

6.1 Postoperative Care

The operating surgeon is responsible to the patient for the coordination of postoperative care. The number of postoperative office visits scheduled for the ophthalmologic and optometric physician offices should be determined according to the type of surgery performed and the individual needs of the patient.

The postoperative patient is ordinarily examined on the first day following surgery, then again during the week following surgery. Additional visits are thereafter scheduled according to the patient's needs. However, through the entire convalescent period, immediate and appropriate care must be readily available to the patient at any time of day or night. The managing physicians continue to bear this ultimate responsibility.

6.2 Patient Postoperative Education

The operating surgeon has the obligation to provide education and instruction to the patient's family regarding the following: resumption of activities, protection of the eye, the use of normal medications, the timing and scheduling of normal postoperative visits, the identifying signs and symptoms of possible complications, and detailed instructions for gaining access to emergency care. The patient's family of course has an obligation to actively participate in his or her care by following the surgeon's advice and instructions, and immediately notifying the surgeon should any evidence of problems arise.

6.3 Postoperative Visits The frequency of the examination during the postoperative period is determined by the surgeon's experience and the patient's needs. The office examinations provide the opportunity to:

- Provide routine postoperative care as healing progresses.
- Educate and support the patient during the postoperative period.
- Identify, diagnose and treat any complications that may arise.
- Assess the response to therapy and to alter or adjust treatment as necessary.

6.4 Postoperative Examination

The postoperative visits should include the evaluation of visual function, the condition of the postoperative eye with special emphasis on possible complications and screening for undiagnosed preoperative conditions and concurrent ocular diseases.

The suggested components of the postoperative examination include the following:

- Visual function, each visit.
- Intraocular pressure measurement.
- External examination, each visit.
- Slit lamp examination, each visit.
- Patient counseling/education, as necessary.
- Ophthalmoscopy appropriate to the patient's clinical circumstances.

7.0 PATIENT TRIAGE

7.1 Patient Triage Management

Optometrists and Ophthalmologists are licensed and governed by their respective state departments of health and their respective state boards of medicine. Most of the provider practices on Ocular Benefits' panel have Optometrists and Ophthalmologists on staff. Initial consults of members five years and younger with cataracts will be triaged to ophthalmologists. Children over age five, who have not had an eye examination within 12 months, may be triaged to optometrists or ophthalmologists for evaluation, diagnosis and management. Patients with complex cataract histories and/or recent post-surgical cataract patients will be triaged to an ophthalmologist.

1.0 OVERVIEW – Management of Strabismus

1.1 Introduction

These guidelines are based on the American Academy of Ophthalmology Clinical Guidelines and the American Optometric Association Clinical Guidelines. Papers reviewed for the development of these standards were, *Esotropia,* produced by the American Academy of Ophthalmology and *Care of the Patient with Amblyopia*, produced by the American Optometric Association.

The GUIDELINES consist of recommendations for the provision of the highest quality of care for patients who have been diagnosed with strabismus.

1.2 Organization of the GUIDELINES

To facilitate the application of these GUIDELINES to the care of patients with strabismus, they are organized into the following subjects:

a) The Definition of Strabismus
b) Responsibilities and Obligations
c) Diagnosis and Prognosis
d) Available Treatment Options
f) Postoperative Care
f) Patient Triage

2.0 STRABISMUS

2.1 Definition of Strabismus

Strabismus is a misalignment of the visual axes. Binocular fixation is not present, i.e., one eye is turned in relation to the other.

2.2 The Natural History of Strabismus

Strabismus is most commonly associated with an early onset. Strabismus occurs in nearly 2% of American children ages 1-3 years and nearly 5% of school age children. Children with strabismus are more likely to have impaired visual acuity. Esotropia (turning in of an eye) is the most common strabismus of childhood. Amblyopia is commonly associated with strabismus.

3.0 RESPONSIBILITIES AND OBLIGATIONS

3.1 Responsibilities and Obligations

The physician team has well established and firm responsibilities to the patient, including the responsibility for correctness in diagnosis, thoroughness of prognosis and understanding in the evaluation of the patient's disability, needs and concerns. The physician team is also responsible for completeness in informing and educating the patient regarding their disease, its potential treatment and the ultimate challenge in providing appropriate and competent treatment. The obligation of the physician team is to preserve visual function by the proper management of strabismus.

The patient has responsibilities within the doctor/patient relationship: the responsibility to take an active part in the treatment program, to attempt to understand information regarding the disease and its treatment, and to follow instructions, comply with prescriptions, and notify the physician should evidence of complications arise.

The plan also has responsibilities to the doctor/patient relationship: the responsibility to attempt to understand information regarding the disease and its treatment, and to authorize appropriate treatment for the best possible clinical outcome for the patient.

4.0 DIAGNOSIS AND PROGNOSIS

4.1 Diagnosis

In order for the patient to consider a decision regarding treatment options, full information must be given regarding the correct diagnosis of strabismus and the prognosis following the anticipated treatment.

The purpose of the comprehensive strabismus evaluation is to confirm the diagnosis, establish baseline status and determine appropriate action.

4.2 Prognosis

The treatment options for patients with strabismus include correction of refractive state with spectacles, prism therapy, miotics, orthoptic therapy and surgery. Realignment by glasses in accommodative esotropia is approximately 75% successful, with 25% of patients requiring surgery for alignment.

5.0 TREATMENT OPTIONS

5.1 Goal of Treatment

The goals of treatment for strabismus are to align the visual axes and to develop and maintain binocular vision. The physician also wants to minimize the adverse effects of the disorder and its treatment, including relief from diplopia.

5.2 Corrective Lenses

The rationale for correcting the refractive anomaly with spectacles is to ensure that the retina of each eye receives a clear optical image. Accommodative esotropes may be fully corrected and alignment achieved with spectacle correction.

5.3 Prism Therapy

Prisms are useful in some forms of strabismus to alleviate diplopia and promote binocular vision.

5.4 Miotic Therapy

Historically, the use of miotics (DPF and phospholine iodide) was popular to reduce the accommodative component of esotropia, by stimulating ciliary muscle contraction and reducing the accommodative convergence. Parents need to be advised of possible adverse systemic effects.

5.5 Orthoptic Therapy

Orthoptic or visual therapy is designed to improve visual performance by the patient's conscious involvement in a series of specific, controlled visual tasks that provide feedback about the patient's performance.

5.6 Surgery

Surgical alignment is commonly indicated only when more conservative methods are ineffective in eliminating the strabismus. Generally, deviations of less than 12 prism diopters do not require surgery. The choice of surgical technique varies with respect to method (method of suture placement or method of measurement of recession or resection). One method may be chosen over another on the basis of preoperative diagnosis, angle of deviation, technical ease, anatomical exposure, presence of scar tissue or other factors.

5.6.1 Second Opinion

Second opinion may be useful in unusual cases of questionable diagnosis or prognosis. However, a second opinion does not relieve the examining physician of the responsibility for a thorough history and ocular examination and the determination of both diagnosis and prognosis. In the large majority of elective strabismus surgery patients, routine second opinion is not beneficial and significantly increases the cost of appropriate care to the patient and to third party payers.

5.7 Indications for Surgery

The patient should consider the decision to intervene with surgery on the basis of the physician's recommendation based on full subjective, objective and educational criteria.

6.0 POSTOPERATIVE CARE

6.1 Postoperative Care

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1.0 OVERVIEW – Management of Conjunctivitis

Members complaining of red, itching, burning or tearing eyes, or members with a tentative diagnosis of conjunctivitis (bacterial, viral or allergic) may be appropriately triaged to an optometrist or ophthalmologist.

Members five years and under will be triaged to an ophthalmologist.

1.0 OVERVIEW – Management of Foreign Body

Non penetrating corneal and scleral foreign bodies in patients 5 years old and older may be appropriately triaged to an optometrist or ophthalmologist.

Non penetrating corneal and scleral foreign bodies in patients **under** 5 years old will be triaged to an ophthalmologist.

Penetrating corneal and scleral foreign body injuries will be triaged directly to an ophthalmologist.

1.0 OVERVIEW – Management of Refractive Surgery

Refractive eye surgery is typically considered a non-covered service by insurance plans. It is elective and generally considered cosmetic surgery to reduce the dependence on eyeglasses or contact lenses.

INTRODUCTION

Refractive surgery procedures include the following:

- RK
- AK
- PRK
- LASIK
- LTK
- ICL

Radial Keratotomy (RK), Astigmatic Keratotomy (AK), Photorefractive Keratectomy (PRK), and Laser Assisted In-situ Keratomileusis (LASIK) are FDA approved procedures.

RK involves the placement of incisions, usually from four to eight, in the outer perimeter of the cornea in order to reshape it to correct nearsightedness and/or astigmatism.

AK is a procedure where tangential incisions are placed on the cornea to reduce the amount of astigmatism present.

PRK employs the excimer laser technology and is utilized to correct mild to moderate cases of nearsightedness.

The LASIK procedure is now the most commonly used refractive surgical procedure for nearsightedness and farsightedness.

Laser Thermal Keratoplasty (LTK) and Implantable Contact Lenses (ICL) are still investigative procedures and are not FDA approved.

LTK is for the treatment of farsightedness and astigmatism and ICLs are utilized for the correction of nearsightedness and farsightedness.

GOALS AND EXPECTATIONS

Scientific studies of RK, PRK and LASIK procedures indicate that at least 90-95% of qualified patients might expect to achieve uncorrected visual acuity of 20/40 or better. If patients are expecting too much in the way of uncorrected visual acuity from the procedure, they might be disappointed in the results and therefore not an acceptable candidate for the surgery.

RISKS

There are risks involved in any eye surgery. This is true for refractive eye surgery procedures as well. Potential postoperative complications that might be experienced - such as glare, halos, and possible problems with night vision – are usually of a temporary nature. A certain percentage of patients will need a second procedure to achieve anticipated results. Any of the procedures could be associated with risks such as infection, irregular healing or corneal scarring. Typically the risks can be managed with medications or further surgery to prevent loss of vision.

POSTOPERATIVE RECOVERY

With RK there is little postoperative pain and vision improvement is achieved almost immediately. Results from the earlier RK procedures that were researched over a ten year period showed that about 43% of the patients studied experienced an earlier than normal shift toward farsightedness, a condition that required reading glasses sooner than expected.

It is estimated that 25-50% of RK patients will require a second procedure to achieve desired results.

PRK patients do experience more postoperative discomfort than RK patients. This can usually be remedied with analgesic eye drops. It may take a month or more before the desired vision correction is achieved, although there is some vision improvement within days of the procedure.

The LASIK procedure is associated with minimal postoperative discomfort. Visual recovery is usually rapid with up to 90% of patients achieving 20/40 or better vision on the first postoperative day. Some fluctuation of vision and disturbances of night vision such as glare and halo can occur early on after LASIK but theses usually correct themselves over time. Only 3-5% of LASIK patients are expected to need further surgical correction compared with up to 10% of PRK and up to 50% of RK patients.

LTK patients experience very little postoperative discomfort and see a gradual improvement in their vision over a two month period. LTK is still involved in FDA investigational studies and more data over a longer period of time needs to be collected.

ICL patients see an immediate improvement in their vision and also experience very little postoperative pain.

These refractive procedures are offered by many Ocular Benefits Eye Care Providers and may be available to members as a non-covered benefit.

1.0 – OVERVIEW - Coverage Criteria for Blepharoplasty, Blepharoptosis Repair, and Brow Lift

1,1 Introduction

Blepharoplasty is a surgical procedure performed on the upper and/or lower eyelids in which redundant tissues (skin, muscle, or fat) are excised. Levator resection is performed to repair blepharoptosis (ptosis). Blepharoptosis occurs when the eyelid itself droops below its normal position. Brow lift surgery is designed to restore the eyebrow to its normal anatomic position. These procedures are performed for both cosmetic and functional purposes. This document addresses blepharoplasty, blepharoptosis repair, and brow lift procedures performed for functional indications. The treatment of functional superior visual field restriction generally requires either a blepharoplasty and/or blepharoptosis repair OR a brow lift procedure depending upon the cause of the field loss. Those cases where combined procedures are requested must meet the individual criteria for each procedure.

Medically Necessary: procedures are considered medically necessary if there is a significant physical functional impairment AND the procedure can be reasonably expected to improve the physical functional impairment.

Reconstructive: procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or congenital defect.

Note: Not all benefit contracts include benefits for reconstructive services as defined by this document. Benefit language supersedes this document.

Cosmetic: procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those which are primarily intended to preserve or improve appearance.

1.2 Clinical Indications

Medically Necessary:

Upper eyelid blepharoplasty or blepharoptosis repair is considered **medically necessary** when BOTH of the following criteria are met:

a. Individual is less than or equal to nine (9) years of age; and

b. Intervention is intended to relieve obstruction of central vision which, in the judgment of the treating physician, is severe enough to produce occlusion amblyopia.

(Note: Children older than nine (9) are not at risk for occlusion amblyopia.)

Upper eyelid blepharoplasty or blepharoptosis repair is considered **medically necessary** for ANY of the following conditions:

1. Difficulty tolerating a prosthesis in an anophthalmic socket; or
2. Repair of a functional defect caused by trauma, tumor or surgery; or
3. Periorbital sequelae of thyroid disease; or
4. Nerve palsy.

Note: For cases where combined procedures (for example, blepharoplasty and brow lift) are requested, the individual must meet the criteria for each procedure.

Blepharoplasty

Unilateral or bilateral **upper eyelid** blepharoplasty is considered **medically necessary** to relieve obstruction of central vision when **ALL** of the following criteria are met:

1. Documented complaints of interference with vision or visual field-related activities such as difficulty reading or driving due to upper eyelid skin drooping, looking through the eyelashes or seeing the upper eyelid skin; and
2. There is either redundant skin overhanging the upper eyelid margin and resting on the eyelashes or significant dermatitis on the upper eyelid caused by redundant tissue. This must be confirmed by photographs from the front and side (or sides) on which operation planned with the camera at eye level and the individual looking straight ahead (primary gaze); and
3. Prior to manual elevation of redundant upper eyelid skin (taping), the superior visual field is a) less than or equal to 20 degrees or b) there is a 30 percent loss of upper field of vision compared to normal; and
4. Manual elevation (taping) of the redundant upper eyelid skin results in restoration of upper visual field measurements to within normal limits.

Blepharoptosis Repair

Blepharoptosis repair is considered **medically necessary** to relieve obstruction of central vision when **ALL** of the following criteria are met:

1. Documented complaints of interference with vision or visual field-related activities such as difficulty reading or driving due to eyelid position; and
2. Photographs taken with the camera at eye level and the individual looking straight ahead, document the abnormal lid position (photos should be submitted for review); and
3. Prior to manual elevation of the upper eyelid and redundant upper eyelid skin (taping), the superior visual field is a) less than or equal to 20 degrees or b) there is a 30 percent loss of upper field of vision compared to normal, or c) the margin reflex distance between the pupillary light reflex and the upper eyelid skin edge is less than or equal to 2.0 mm; and
4. Manual elevation (taping) of the upper eyelid and redundant upper eyelid skin results in restoration of upper visual field measurements to within normal limits.

Brow Lift

Brow lift (i.e., repair of brow ptosis due to laxity of the forehead muscles) is considered **medically necessary** when **ALL** of the following criteria are met:

1. Brow ptosis is causing a functional impairment of upper/outer visual fields with documented complaints of interference with vision or visual field related activities such as difficulty reading due to upper eyelid drooping, looking through the eyelashes or seeing the upper eyelid skin; and
2. Photographs show the eyebrow below the supraorbital rim;

NOTE: Conjunctival irritation or eye disease related to ectropion, entropion, metabolic disease, trauma or other conditions may require surgical intervention using a variety of ophthalmologic procedures. These conditions are not discussed in this document. The medical necessity of the surgical correction of these problems should be determined by considering the specific underlying medical and ophthalmologic issues.

Not Medically Necessary:

Blepharoplasty, blepharoptosis repair, or brow lift for visual field defects is considered **not medically necessary** when the criteria noted above are not met.

Cosmetic and Not Medically Necessary:

Blepharoplasty, blepharoptosis repair, or brow lift is considered **cosmetic and not medically necessary** when performed to improve an individual's appearance in the absence of any signs or symptoms of functional abnormalities.

Lower lid blepharoplasty is considered **cosmetic and not medically necessary.**

Reconstructive:

Blepharoplasty, blepharoptosis repair or brow lift procedures which are intended to correct a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or congenital defect are considered **reconstructive** in nature.

Program History and Revisions

This section is used to keep track of all changes and revisions to the Clinical Guidelines

June 9th 2006: Policy was reviewed and the policy was reformatted. Introduction added.

The Macular Degeneration Guidelines were reviewed and revised to include the treatment of wet macular degeneration with Intravitreal Injection of Macugen and other Anti-VEGF drugs.

May 11th 2007: Macular Degeneration guidelines have been updated to reflect the new types of procedures available to treat it.

December 11th, 2007: Introduction updated to include compliance with Florida law requiring an ophthalmological visit upon request from a provider.

July 17th, 2008: Policy reviewed.

July 23rd, 2009: Annual policy review done by UM Committee.

January 4th, 2010: Policy reviewed, amended to include quarterly review and updates as necessary.

January 10th, 2011: Policy reviewed and approved.

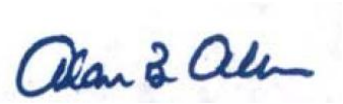
March 3, 2012 Policy reviewed and updated to include Avastin and Lucentis as treatment options for diabetic retinopathy. Revised post op global period for YAG laser from 2 weeks to 90 days.

December 31, 2012: References to "Florida" law and "Florida state Department of Health" modified to "state law" and "state departments of health".

March 7, 2013: Annual review: Eylea added to page 39, s.5.4, last paragraph, opening sentence: "In addition , Lucentis and Eylea have been FDA approved and Medicare approved for the treatment of diabetic retinopathy."

April 23, 2013: Added coverage guidelines for use of retinal telescreening systems (fundus photos) to diagnose diabetic retinopathy; added coverage criteria for Blepharoplasty, Blepharoptosis Repair, and Brow Lift

Signature Page



Alan B. Aker, M.D., Medical Director

April 24, 2013

Date

Michael Hecht, O.D., Medical Director

April 23, 2013

Date