Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: Aetna Better Health

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Type of Submission – Check all that apply:

- ☑ New Policy
- ☑ Revised Policy*
- ☐ Annual Review – No Revisions
- ☐ Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

**CPB 0508 Cataract Removal Surgery**

This CPB has been revised to state that: (i) the following are considered medically necessary: ALcon MTA2UO, MTA3UO, MTA4UO, MTA5UO, MTA6UO, and MTA7UO IOLs; and Staar Model CC4204A; (ii) B-scan ultrasound is considered medically necessary for pre-operative work-up of individuals with Morgagnian cataract; (iii) femtosecond laser-assisted cataract surgery is considered an equally effective alternative to standard methods of cataract removal; (iv) Optiwave Refractive Analysis (ORA) is considered not medically necessary for cataract surgery.

Name of Authorized Individual (Please type or print): Dr. Bernard Lewin, M.D.

Signature of Authorized Individual: ____________________________

Revised July 22, 2019
Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

I. Aetna considers a comprehensive eye examination or a brief or intermediate examination, and an A-scan medically necessary as a diagnostic test prior to cataract surgery. Other pre-operative ophthalmologic tests may be considered medically necessary if there is another diagnosis in addition to cataracts.

II. Aetna considers the following specialized ophthalmologic services medically necessary for the routine pre-operative work-up for cataract surgery:

- Optical coherence biometry
- Ultrasound, A-scan, diagnostic
- Ultrasound, A-scan, ophthalmic biometry
- Ultrasound, with intra-ocular lens (IOL) power calculation.

In addition to a comprehensive or brief/intermediate eye examination, A-mode ultrasound (A-scan) may be considered medically necessary prior to cataract surgery to determine the appropriate pseudophakic power of the IOL.
Aetna considers the following specialized ophthalmologic services experimental and investigational for the pre-operative work-up for cataract surgery, unless there is another indication in addition to cataracts, because they are of no proven value in routine pre-operative evaluation of cataracts:

- Contrast sensitivity testing
- Corneal pachymetry
  (see [CPB 0681 - Corneal Pachymetry](../600_699/0681.html))
- Corneal topography
  (see [CPB 0130 - Computerized Corneal Topography](../100_199/0130.html))
- Electrophysiologic tests (including electroretinography)
- External photography
- Fluorescein angiography
- Formal visual fields
- Glare testing
- Potential vision testing
- Specialized color vision tests
- Specular photographic microscopy
- Ultrasound, contact B-scan, diagnostic *
- Ultrasound, immersion B-scan, diagnostic *
- Visual evoked potentials.

The pre-operative tests listed above are considered experimental and investigational in most cases before cataract surgery. There is inadequate evidence that other pre-operative tests are useful in determining the need for cataract surgery, nor predict the benefits or adverse outcomes from cataract surgery.

*B-scan ultrasound is considered medically necessary in place of A-scan ultrasound where direct visualization of the retina is difficult or impossible including lid problems (e.g., severe edema, partial or total tarsorrhaphy), keratoprosthesis, corneal opacities (e.g., scars, severe edema), hyphema, hypopyon, miosis, dense cataract, pupillary membranes, or vitreous opacities (e.g., hemorrhage, inflammatory debris).

Note: B-scan ultrasound is considered medically necessary for pre-operative work-up of individuals with Morgagnian cataract.
IV. Aetna considers cataract removal surgery medically necessary according to the member's level of visual impairment as follows:

A.† For members with visual disability with a Snellen Acuity of 20/50 or worse, cataract surgery is considered medically necessary when all of the following subjective, objective, and educational criteria are met:

1. Subjective - The member perceives that his or her ability to carry out needed or desired activities is impaired. The member's decision is based on (i) the member’s own assessment of visual disability (e.g., impact on driving, viewing television, and special occupational or avocational needs) and, in particular, disability at near sight (e.g., reading, occupational activities requiring near vision); and (ii) the member's perception of the impact of the visual disability on lifestyle (e.g., loss of independence, loss of income).

Note: In general, driving an automobile is the limiting life-style activity with visual acuity in the 20/50 to 20/60 range. Almost all states require 20/40 vision in 1 eye to get a driver's license. Household activities and reading are usually not limiting until the member reaches 20/70 vision.

2. Objective - The best correctable Snellen visual acuity in the affected eye is 20/50 or worse, the eye examination confirms that the cataract is the limiting factor for improving visual function when other factors do not preclude improvement following surgery, and the member's medical and mental health permits surgery to be performed safely.

3. Educational - The member has been educated about the risks and benefits of cataract surgery, including alternatives to treatment and the member determines if the expected reduction in the disability outweighs the potential risk, cost and inconvenience of surgery.

B.‡For members with visual disability with a Snellen Acuity of 20/40 or better, cataract surgery is considered medically necessary when all of the following subjective, objective, and educational criteria are met:
1. **Subjective** - The member perceives that his or her ability to carry out needed or desired activities is impaired. The member’s decision is based on: (i) the member’s own assessment of visual disability (e.g., impact on driving, viewing television, and special occupational or avocational needs) and, in particular, disability at near sight (e.g., reading, occupational activities requiring near vision); (ii) the member’s perception of the impact of the disability on lifestyle (e.g., loss of independence, loss of income); and (iii) the member’s complaints of glare disabling eyesight in daylight conditions is inconsistent with the visual acuity measured in a darkened room; however, it must be confirmed by the documented assessment of visual functions under conditions of bright ambient light.

The loss of vision mimicking the member’s complaints should be verified before the member is considered a candidate for cataract surgery.

Note: A drop in visual acuity in bright light is the quantitative element that allows one to correlate the “loss of vision” with the “member’s complaints”. The most common cataract that produces this type of light-related visual loss is a centrally located posterior subcapsular plaque (PSCP).

2. **Objective** - The member’s best correctable Snellen visual acuity is 20/40 Snellen or better in the affected eye, there is a significant loss of visual acuity in bright ambient light, the eye examination confirms that the cataract is the limiting factor for improving visual function when other factors do not preclude improvement following surgery, and the member’s medical and mental health should permit surgery to be performed safely.

3. **Educational** - The member has been educated about the risks and benefits of cataract surgery, including alternatives to treatment and the member determines if the expected reduction in the disability outweighs the potential risk, cost and inconvenience of surgery.
C. One-eyed members: Cataract removal surgery is considered medically necessary for one-eyed members with visual disability of 20/80 or worse due to a cataract; that is, a member with irreversible, untreatable legal blindness (20/200 or worse) in the other eye.

D. Cataract removal surgery involving removal of the lens is considered medically necessary without regard to visual disability when any of the following criteria is met:

1. Member has lens-induced disease (e.g., phakomorphic glaucoma, phakolytic glaucoma, phakoanaphylactic endophthalmitis, dislocated or subluxated lens), or

2. There is a need to visualize the fundus (retina) in an eye that has the potential for sight in any of the following conditions:
   - Diabetes with significant risk of reduced visual acuity (diabetic retinopathy) requiring photocoagulation management through clear media to monitor glaucoma;
   - To prepare for vitrectomy;
   - To prepare for surgical repair of retinal detachment; or
   - When other special investigations demonstrate intra-ocular pathology where further attention is important and requires clear media.

Notes: Aetna considers standard fixed monofocal posterior chamber IOLs medically necessary for aphakia (e.g., Akreos posterior fixed monofocal IOL (Bausch & Lomb, Rochester, NY), Akreos AO Micro Incision Lens (Model MI60L), AcrySof SA60AT monofocal IOL (Alcon Surgical, Fort Worth, TX), AcrySof MA60AC, AcrySof MA60MA, AcrySof SN60AT, Alcon MZ30BD, CeeOn Edge (Pharmacia Corp., Peepack, NJ), Tecnis monofocal IOL (Model PCB00), and the Hydroview hydrogel foldable posterior IOL (Bausch & Lomb, Rochester, NY)).

Standard posterior chamber IOL for hyperopia (e.g., Clariflex, Sensar AR40e, Advanced Medical Optics, Santa Ana, CA) is considered medically necessary.

Aetna considers aspheric monofocal posterior chamber IOLs medically necessary for aphakia (e.g., AcrySof IQ IOL (Alcon Surgical, Fort Worth, TX), Alcon CZ70BD, Alcon SA60WF, SN6CWS, Tecnis (Z9000, Z9001, Z9002,
ZA9003, Abbott Medical Optics, Santa Ana, CA), SofPort AO IOL (Bausch & Lomb, Rochester, NY), Sofport Li61AO, Staar Model CC4204A, Akreos AO Aspheric IOL (Bausch & Lomb, Rochester, NY), Akreos SA 060, Hoya PY-60AD (Hoya Surgical Optics GmbH, Frankfurt, Germany), Abbott ZCB00, Tecnis AMO Aspheric IOL ZCB00 (Abbott Medical Optics, Santa Ana, CA), and Acrysof IQ SN60WS (Alcon Surgical, Fort Worth, TX).

Standard fixed monofocal posterior chamber ultraviolet absorbing IOLs (e.g., AcrySof Natural blue-light filtering IOL including the AcrySof MN60MA (Alcon Surgical, Fort Worth, TX), AcrySof SN60WF, SofPort AO IOL with Violet Shield Technology (Bausch & Lomb, Rochester, NY), C-flex IOL model 570C (Rayner Surgical Inc., Los Angeles, CA), EC-3 PAL (Aaren Scientific, Ontario, CA), iSpheric Model YA-60BB IOL (Hoya Surgical Optics, Chino Hills, CA), Softec HD (Lenstec Inc., St. Petersburg, FL); and XACT Foldable Hydrophobic Acrylic Ultraviolet Light-Absorbing Posterior Chamber IOLs (Bausch & Lomb) are also considered medically necessary for aphakia.

Piggyback posterior chamber IOLs (i.e., placement of 2 IOLs in the same eye) are considered experimental and investigational).

Aetna considers standard anterior chamber IOLs (e.g., ALcon MTA2UO, MTA3UO, MTA4UO, MTA5UO, MTA6UO, and MTA7UO) medically necessary.

Aetna considers the following IOLs non-covered deluxe items: Accommodating posterior chamber IOLs (e.g., Crystalens (Eyeonics Inc., Aliso Viejo, CA); multi-focal posterior chamber IOLs (e.g., Array Model SA40 (Abbott Medical Optics, Santa Ana, CA), ReZoom (Abbott Medical Optics, Santa Ana, CA), Tecnis ZM900, Tecnis posterior chamber IOLs (Model ZKB00), and ZMAOO (Abbott Medical Optics, Santa Ana, CA), AcrySof ReSTOR, (Alcon Surgical, Fort Worth, TX), Acrysof ReSTOR SA60D3 multifocal, Acrysof Natural ReSTOR SN60D3, Acrysof ReSTOR Aspheric IOL model SN6AD1, AcrySof ReSTOR Aspheric IOL model SN6AD3); astigmatism-correcting (toric) posterior chamber IOLs (e.g., Staar Toric IOL (Star Surgical, Monrovia, CA), Staar Elastic Toric Lens Model AA4203TL, Abbott Medical Optics Tecnis Toric model ZCT150, AcrySof Toric IOL (Alcon Surgical, Fort Worth, TX)) AcrySof Aspheric Toric IOL SN6AT3, SN6AT4 and SN6AT5, AcrySof Toric Models SA60T3, SA60T4 and SA60T5, AcrySof Toric Model SA60T, and Acrysof IQ Toric Model SN6ATT, SN6AT6, SN6AT7 SN6AT8, and SN6AT9); multifocal astigmatism-
correcting (toric) IOLs (ReSTOR Multifocal Toric IOL); accommodating toric IOLs (Trulign Toric IOL (Bausch & Lomb, Inc., Rochester, NY); and extended depth of focus multifocal lens (Tecnis Symfony ZXR00).

Given that the intent of the multi-focal IOL, accommodating IOL and the toric IOL is to obviate the need for reading glasses post-surgery, these IOLs are considered not medically necessary. For members who elect non-covered new technology IOLs, cataract removal and lens implantation would be considered medically necessary if the criteria for cataract surgery outlined above are met. The new technology lens itself would be non-covered.

V. Aetna considers Nd:YAG laser capsulotomy medically necessary when performed 6 months or more following cataract extraction in members with visually significant clouding (opacification) of the posterior portion of the membrane that surrounds the lens (the posterior capsule). Requests for Nd:YAG laser capsulotomy performed within 6 months of cataract extraction should be forwarded for medical review.

VI. Aetna considers Nd:YAG laser capsulotomy experimental and investigational in any of the following situations because of insufficient evidence in the peer-reviewed literature:

A. If performed concurrently with cataract surgery; or
B. If performed prophylactically; or
C. If scheduled routinely after cataract surgery without regard to whether there is clinically significant opacification of the posterior capsule.

Criteria for Inpatient Cataract Surgery:

An inpatient setting for cataract removal surgery generally is not considered medically necessary. However, inpatient surgery may be considered medically necessary for any of the following members:

- Medical conditions are present that require prolonged post-operative observation by a nurse or skilled personnel and the member requires general medical and nursing care for a particularly complex ocular procedure(s); or
- The member has multiple ocular conditions (e.g., best correctable vision in the non-operated eye is 20/200 or worse); or
- The member will undergo multiple ocular procedures (e.g., extraordinary medical circumstances exist in which it may be dangerous or life-threatening for the member to undergo anesthesia twice, so dual cataract removal is performed); or
- The member is mentally debilitated, diagnosed as mentally ill, or functionally incapacitated so that a risk of injury exists in the immediate post-operative period. Physical disability prevents satisfactory immediate post-operative care.

VII. Aetna considers combined glaucoma and cataract surgery medically necessary for persons with a visually significant cataract with uncontrolled glaucoma despite maximal medical therapy and/or laser trabeculoplasty.

VIII. Aetna considers femtosecond laser-assisted cataract surgery an equally effective alternative to standard methods of cataract removal.

IX. Aetna considers Optiwave Refractive Analysis (ORA) not medically necessary for cataract surgery.

Background

This assessment of cataract surgery is supported by the Clinical Practice Guideline No. 4, Cataract in Adults: Management of Functional Impairment of the Cataract Management Guideline Panel of the Agency for Health Care Policy and Research (AHCPR, 1993). The Panel, composed of an inter-disciplinary group of experts, reviewed the medical literature and prepared the guideline based on that review. The guideline included findings concerning pre-operative testing, cataract removal surgery, and post-operative issues.

A cataract is a hardening and opacification (or clouding) of the normally transparent crystalline lens within the eye behind the pupil. This condition usually occurs as a part of the aging process, developing on a continuum extending from minimal changes in the crystalline lens to the extreme stage of total opacification. Rarely, a cataract may form within months when related to trauma, inflammation or use of some medications. The intra-ocular lens (IOL) is a permanent plastic lens.
implanted inside the eye to replace the crystalline lens. Dick (2005) stated that the potential clinical benefits of accommodative IOL technology for both cataract patients and refractive patients may place accommodative IOLs in a competitive position with multi-focal IOL technology.

Cataracts may result in progressive loss of vision. The degree of loss depends on the location of the cataract, its size, and its density.

Cataracts may be nuclear or posterior subcapsular. Nuclear cataracts are located in the central substance of the lens. Posterior subcapsular cataracts are located beneath the posterior lens capsule, and affect vision out of proportion to the degree of cloudiness that is seen, because the cataract is located at the crossing point of the light rays from the viewed object. These cataracts tend to cause glare in bright light.

Pre-Operative Testing

Cataracts may be diagnosed with procedures included in the comprehensive ophthalmologic examination. Cataracts may be seen on ophthalmoscopy as gray opacities in the lens. Cataracts obscure the normal "red reflex" that is elicited by examining the dilated pupil with the ophthalmoscope held about 1 foot away. Slit-lamp examination provides more details about the character, location, and extent of the opacity.

One specialized ophthalmologic service is frequently needed prior to cataract surgery in routine cases. A-mode ultrasonography (A-scan) can be used to determine the appropriate pseudophakic power of the IOL. For most cases involving a simple cataract, a diagnostic ultrasound A-scan is used. This scan is billed and paid for separately from the comprehensive eye examination. A B-scan is used in place of the A-scan when the patient has a dense cataract. Alternatively, optical coherence biometry can be used in place of A- or B-scan ultrasonography to determine the appropriate pseudophakic power of the IOL.

Frequent changes in eyeglass prescription help maintain vision during cataract development. When useful vision is lost, lens extraction is necessary. Cataract extraction can be accomplished by removing the lens or by emulsification followed
by irrigation and aspiration. After cataract extraction, refractive correction is accomplished by glasses, contact lenses, or implantation of an IOL. An A-scan ultrasound is not necessary unless an IOL is to be inserted.

The AHCPR Cataract Management Guideline Panel (the Panel, 1993) sought to determine what pre-operative tests are needed in most cases to determine the need for cataract surgery. They examined whether these tests would indicate the presence or severity of a cataract, or predict the benefits or negative outcomes a patient may experience from the surgery.

The Panel found inadequate scientific evidence to support the use of most pre-operative tests in deciding whether cataract surgery is medically appropriate. These pre-operative tests include contrast sensitivity testing, glare testing, potential vision testing, and specular photographic microscopy (endothelial cell photography).

Contrast sensitivity testing is a measure of the contrast level required for detection of a specified size of a test object. This test reveals and quantifies decreased perception of low-contrast objects. The Panel found inadequate evidence that contrast sensitivity testing provides information, beyond that obtained through a patient's history and eye examination that is useful for determining whether a patient would benefit from cataract surgery.

Glare testing measures the effect of simulated glare on vision function. Disabling glare is often an indication that a cataract has developed. The Panel found inadequate evidence that glare testing provides useful information beyond that obtained in a patient's history and eye examination. This testing, however, may be useful for corroborating glare symptoms in a small percentage of cataract patients who complain of glare, yet measure good Snellen visual acuity.

Potential vision testing is designed to determine whether patients with obviously impaired vision have the potential to see well following cataract surgery. The Panel found inadequate evidence that potential vision testing can help the ophthalmologist in predicting the outcome of cataract surgery.

Specular photographic microscopy may be done before an intra-ocular operation because the corneal endothelium is particularly sensitive to the trauma of the surgery. This test is used to measure and record the evaluation of corneal...
endothelial cells. Patients with a pre-operative reduction of their endothelial cell density are unusually sensitive to the trauma of surgery and may not maintain adequate visual functions following surgery. The Panel also found inadequate evidence to support the use of specular photographic microscopy on all cataract patients in order to predict the response of the cornea to cataract surgery. They found that many patients of low endothelial cell density can be identified through the patient's medical history and clinical examination.

The Panel also concluded that the following tests are not indicated as part of the pre-operative work-up for cataract surgery unless specific circumstances justify them:

- B-scan ultrasonography
- Corneal pachymetry
- Electrophysiologic tests
- External photography
- Fluorescein angiography
- Formal visual fields
- Specialized color vision tests
- Tonography.

The Panel found inadequate evidence that these tests can predict the benefits a patient may experience from cataract surgery or predict the negative outcomes of the surgery. They concluded that there is inadequate evidence to support the use of these tests in most cases to determine the need for cataract removal surgery; they recognized, however, that these preoperative tests are needed in special circumstances.

The Panel stated that, for patients with a dense or cataract mature that interferes with ophthalmoscopic examination, a diagnostic B-mode ultrasonography (B-scan) may be appropriate to rule out retinal detachments or vitreous hemorrhages, ocular pathology which may influence the decision to perform cataract surgery.

Corneal topography is not routinely indicated prior to cataract removal surgery; it may be useful when irregular astigmatism is suspected of contributing to visual impairment (American Academy of Ophthalmology [AAO], 2001).
Cataract Removal Surgery

Cataract removal surgery is an established surgical procedure with excellent outcomes in improving vision and removing visual impediments. Cataract surgery is usually performed under local anesthesia.

The Panel stated that cataract removal surgery should be performed on each eye separately and sufficient time be allowed for the first eye to heal before the second cataract removal is performed (an interval of 2 to 6 months is customary).

YAG Laser Capsulotomy

Posterior capsule opacification is a common complication after cataract surgery. It can develop months or years later and is due to a slow growth of epithelial cells remaining from the removed cataract.

The Panel found that posterior capsular opacification rarely occurs within the first 3 months of surgery, and that it is uncommon for posterior capsular opacification to occur within the first 6 months of surgery. The Panel concluded that posterior capsulotomy should never be scheduled at the time cataract surgery is performed because one can not predict whether a cataract surgery patient will develop posterior capsular opacification or predict the time at which opacification will occur. The Panel also concluded that neodymium:yttrium-aluminum-garnet (Nd:YAG) laser capsulotomy should not be performed prophylactically or scheduled routinely at particular times after cataract surgery. For similar reasons, manual removal of the posterior capsule, performed with a needle or hook (called corneoscleral section), should not be performed at the time of cataract surgery.

Intra-Ocular Lenses

Surgical treatment of cataract involves replacing the patient's opacified lens with an artificial lens, which is usually of fixed power (monofocal), requiring the use of reading glasses for near vision. More recently, IOLs have been developed that are designed to allow both distance and reading vision without glasses. These can be either multi-focal lenses, which enable both near and distance vision by virtue of the design of the lens itself, or accommodating lenses, which are intended to move within the eye in a manner similar to a natural human lens.
An intraocular lens (IOL) implant is a small, clear, plastic lens that is used to replace the natural (native) lens of the eye when it has been surgically removed (most often during cataract surgery). The IOL becomes a permanent part of the eye, not requiring any care and cannot be seen or felt. An IOL is used to improve vision after the native lens is removed by helping to focus light directly onto the retina.

IOLs can be classified as standard, premium or refractive and can be further identified according to type - monofocal, multifocal accommodating, and phakic. Most IOLs are made using special materials (chromophores) that absorb ultraviolet light. Some IOLs may be a combination of more than one type (eg, light absorbing monofocal) and most IOLs are available in multiple models (eg, TECNIS monofocal, TECNIS multifocal, TECNIS toric monofocal, TECNIS Symfony).

Standard IOLs meet an individual's basic functional needs by replacing the native lens.

- **Monofocal IOLs** have a fixed focal length and provide clear vision at a single, distance (near, intermediate or far) only. Following monofocal lens placement, glasses may be required to assist with near or distance vision.

Premium IOLs are intended to also correct astigmatism, preclude the need for reading glasses, preclude the need for contact lenses after surgery, or a combination of these.

- **Accommodating IOLs** are purported to mimic the accommodation of the natural lens, focusing both distant and near images onto the retina
- **Multifocal IOLs** focus both distant and near images onto the retina
- **Toric IOLs** correct astigmatism.

Standard IOLs meet the basic functional needs of the member’s physical condition. Since the intent of the multifocal and accommodating IOLs, is to preclude the need for reading glasses or contact lenses post-surgery, those types of IOLs are considered not medically necessary.

Refractive IOLs are solely intended to correct refractive errors.
- Phakic IOLs are used to achieve refractive correction when the native lens is not removed, similar to the effect of LASIK or laser eye surgery.

Refractive eye surgeries (eg, LASIK, laser eye surgery, etc.) are generally excluded by contract; therefore, any IOL implant done for refractive purposes or in conjunction with this type of procedure would not be covered if the surgery itself is not a covered benefit.

In a prospective, randomized controlled study, Marshall and associates (2005) verified the safety and effectiveness of the new AcrySof Natural blue-light filtering IOL, which was designed to achieve a light-transmission spectrum similar to that of the natural human crystalline lens. A total of 150 patients received the AcrySof Natural IOL and 147 patients received the AcrySof single-piece IOL as a control. Patients with bilateral age-related cataracts who were willing and able to wait at least 30 days between cataract procedures and had verified normal pre-operative color vision were eligible for the study. Standardized surgery included a 4.0 to 5.0 mm capsulorhexis and phacoemulsification. All lenses were inserted in the capsular bag, with verification of in-the-bag placement of both haptics. In all bilateral implantation cases, the same model IOL was used in each eye. Post-operatively, contrast sensitivity and color perception were measured up to 180 days and up to 1 year (for visual acuity) after implantation. No statistically significant differences were observed between the 2 groups in visual acuity, contrast sensitivity evaluated under mesopic and photopic conditions, or the number of subjects who passed the Farnsworth D-15 color perception test. There were no lens-related adverse events in either group. These investigators concluded that the blue-light filtering AcrySof Natural IOL was equivalent to the conventional AcrySof lens in terms of post-operative visual performance. They stated that additional long-term clinical studies should show whether the IOL actually provides the theoretical benefits to retinal health.

In a prospective, randomized controlled trial, Heatley and colleagues (2005) examined the near visual clinical performance of an accommodative IOL when compared with a standard monofocal IOL in a fellow eye comparison. A total of 30 patients (60 eyes) with bilateral cataracts but otherwise normal eyes were recruited from a single university hospital cataract waiting list. Patients were randomized to receive either the 1CU accommodative IOL in their first eye or the Acrysof MA30 monofocal IOL. The alternative lens was then implanted in the second eye 4 to 6 weeks later. At all follow-up visits, a full assessment was made of distance, near
and reading visual performance, and accommodative amplitude. Data were available for all patients at 6 months and 20 patients at 1 year. At 6 months, no difference was found in distance-corrected visual acuity between the 2 IOLs. Of the 1CU eyes, 9 patients (30%) could read J6 or better at a reading speed of 80 words/min or better. In these 9 patients, the mean difference in the amplitude of accommodation between the 2 eyes was 0.71 diopters. These researchers concluded that no measurable variable distinguished eyes that developed functional reading vision from those that did not. The accommodative IOL appears to produce improved near vision in some eyes, but it does not work in all eyes, and in eyes where there is apparent accommodation, there is a discrepancy between subjective reading performance and the modest measured increase of accommodative amplitude.

Macsai et al (2006) evaluated and compared the visual outcomes and accommodative amplitude in cataract patients after implantation of the CrystaLens versus standard monofocal IOLs. The authors concluded that additional studies are needed to assess the visual outcomes of the CrystaLens in a larger number of patients. They also noted that "[g]iven our study limitations, we found successful distance and near vision results with the implantation of CrystaLens IOL. Further studies to evaluate long-term results of the accommodative capacity of the CrystaLens IOL and to help sort out the effects of pseudoaccommodation are warranted".

The Canadian Agency for Drugs and Technologies in Health (CADTH)'s evaluation of accommodative IOLs for age-related cataracts (Scott, 2006) stated that limited evidence suggests that accommodative IOLs provide better near vision than monofocal IOLs, but not better than multi-focal IOLs. In addition, the CADTH assessment stated that long-term follow-up is needed to confirm patient outcomes, and ascertain if the benefits justify the additional cost.

A meta-analysis by Takakura et al (2010) found no clear evidence of near visual acuity improvement with accommodating IOLs compared to monofocal IOLs. The investigators conducted a meta-analysis to compare accommodating IOLs and monofocal IOLs in restoring accommodation in cataract surgery. Because of measurement-scale variations, outcomes were pooled for distance-corrected near visual acuity (DCNVA) as standardized mean differences with 95% confidence intervals [CIs] and anterior displacement of the lens as weighted mean differences (95% CI). The meta-analysis comprised 12 randomized controlled studies of 727
eyes. The authors reported that, based on 10 studies that compared DCNVA, accommodating IOLs were favored but failed the test of heterogeneity ($I(2) = 94\%$). However, pooling only the 6 homogeneous trials ($I(2) = 43\%$) showed no difference (standardized mean difference, $-0.16; 95\% \text{ CI}: -0.56$ to $0.25$). The authors stated that heterogeneity could not be explained by any characteristic of the study population or methodology. Based on 4 studies that evaluated pilocarpine-induced IOL shift, there was a significant anterior compared with the control (weighted mean difference, $95\% \text{ CI}: -0.36$ to $-0.24$), although the studies were heterogeneous ($I(2) = 58\%$). Three of 5 studies mentioning posterior capsule opacification reported increased rates in the accommodating IOL group postoperatively. The authors concluded that there was no clear evidence of near acuity improvement despite statistically significant pilocarpine-induced anterior lens displacement. The authors stated that further randomized controlled studies with standardized methods evaluating adverse effects (e.g., posterior capsular opacification) are needed to clarify the trade-offs.

Guidance on accommodating intraocular lenses from the National Institute for Health and Clinical Excellence (NICE, 2007) concluded: "Current evidence suggests that there are no major safety concerns associated with the implantation of accommodating lenses for cataract. There is evidence of short-term efficacy in correcting visual acuity but there is inadequate evidence that the procedure achieves accommodation. Therefore, the procedure should not be used without special arrangements for consent and for audit or research." The assessment stated that publication of long-term efficacy outcomes of the procedure will be useful, particularly on the effects on accommodation.

Guidance on multi-focal IOLs from the National Institute for Health and Clinical Excellence (NICE, 2008) concluded: "The evidence on the implantation of multifocal (non-accommodative) intraocular lenses (IOLs) during cataract surgery raises no major safety concerns. Current evidence on the procedure’s efficacy shows that it can provide good near and distance vision without the need for spectacles, but this is at the risk of a variety of potential visual disturbances."

In a prospective, randomized, controlled clinical trial, Martínez Palmer et al (2008) evaluated visual function of 3 types of multi-focal IOLs and 1 monofocal IOL (as the control group) after cataract surgery. A total of 114 patients were included in the study. Subjects received monofocal Tecnis Z9000 (AMO) ($n = 24$, $48$ eyes); symmetric diffractive multi-focal Tecnis ZM900 (AMO) ($n = 26$, $52$ eyes); zonal
refractive multi-focal ReZoom (AMO) (n = 32, 64 eyes); or asymmetric diffractive multi-focal TwinSet (Acri.Tec) (n = 32, 64 eyes) IOLs. Mean binocular distance best spectacle-corrected visual acuity (BSCVA) (logMAR) was 0.05 for controls, 0.08 for ZM900, 0.07 for ReZoom, and 0.11 for TwinSet, with mean binocular distance BSCVA at near of 0.49, 0.06, 0.22, and 0.11, respectively. Mean contrast sensitivity was better for the monofocal IOL group than for the multi-focal IOLs. Patients assigned to TwinSet had less favorable contrast sensitivity scores. Patients with monofocal IOLs had more frequently recommended near addition (74 %) than those with multi-focal IOLs. Patients with refractive ReZoom had also recommended near addition more frequently than the 2 diffractive groups. The percentage of dysphotopsia phenomena was 81 % in patients with diffractive multifocal ZM900 compared with 48 % in patients with monofocal IOLs, 53 % with refractive ReZoom, and 47 % with diffractive TwinSet. The authors concluded that the monofocal IOL showed better visual function and lesser photic phenomena than multi-focal IOLs; however patients were spectacle-dependent. ReZoom provided better distance BSCVA than the TwinSet diffractive model. Patients with Tecnis and TwinSet diffractive multi-focal IOLs were more spectacle-independent than patients with ReZoom. Patients with TwinSet had the worst visual function. Patients implanted with the Tecnis diffractive ZM900 were those reporting more photic phenomena.

A prospective, 6-month, multicenter, bilateral, randomized, evaluator- and subject-masked trial compared 148 cataract patients implanted with the Tecnis Symfony IOL to 151 cataract patients implanted with a monofocal IOL. The study evaluated visual acuity at near, intermediate and far ranges; contrast sensitivity (the ability to distinguish small differences between light and dark); and adverse events for six months after implantation. Of the patients implanted with the Tecnis Symfony IOL, 77 percent had good vision (20/25), without glasses at intermediate distances, compared to 34 percent of those with the monofocal IOL. For near distances, patients with the Tecnis Symfony IOL were able to read two additional, progressively smaller lines on a standard eye chart than those with the monofocal IOL. Both sets of patients had comparable results for good distance vision. Patients implanted with the Tecnis Symfony IOL may experience worsening of or blurred vision, bleeding or infection. The device may cause reduced contrast sensitivity that becomes worse under poor visibility conditions such as dim light or fog. Some patients may experience visual halos, glare or starbursts. The device is not intended for use on patients who have had previous trauma to their eye.

http://www.aetna.com/cpb/medical/data/500_599/0508.html
A 2005 CMS ruling on "Requirements for Determining Coverage of Presbyopia-Correcting Intraocular Lenses that Provide Two Distinct Services for the Patient: (i) Restoration of Distance Vision Following Cataract Surgery, and (ii) Refractive Correction of Near and Intermediate Vision with Less Dependency on Eyeglasses or Contact Lenses" concluded that 1 pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an IOL is covered. A single presbyopia-correcting IOL essentially provides what is otherwise achieved by 2 separate items: (i) an implantable conventional IOL (one that is not presbyopia-correcting), and (ii) eyeglasses or contact lenses. Although presbyopia-correcting IOLs may serve the same function as eyeglasses or contact lenses furnished following cataract surgery, IOLs are neither eyeglasses nor contact lenses. Therefore, the presbyopia-correcting functionality of an IOL does not fall into the benefit category and is not covered. Any additional provider or physician services required to insert or monitor a patient receiving a presbyopia-correcting IOL are also not covered. For example, eye examinations performed to determine the refractive state of the eyes following insertion of a presbyopia-correcting IOL are non-covered (McClellan, 2005).

The Alcon CZ70BD is a single-piece polycast polymethylmethacrylate (PMMA) intra-ocular lens (IOL; posterior chamber). Alcon® UV-absorbing single-piece PMMA, Monoflex™ PMMA posterior chamber lenses, and single-piece PMMA anterior chamber lenses are optical implants for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract removal. These lenses have biconvex, convexoplano, convexoplano with Hoffer™* ridge modification, or meniscus optics with supporting haptics.

Waldron (2012) stated that B-scan ultrasound is most useful when direct visualization of intra-ocular structures is difficult or impossible. Situations that prevent normal examination include lid problems (e.g., severe edema, partial or total tarsorrhaphy), keratoprosthesis, corneal opacities (e.g., scars, severe edema), hyphema, hypopyon, miosis, pupillary membranes, dense cataracts, or vitreous opacities (e.g., hemorrhage, inflammatory debris). In such cases, diagnostic B-scan ultrasound can accurately image intra-ocular structures and give valuable information on the status of the lens, vitreous, retina, choroid, and sclera. However, in many instances, ultrasound is used for diagnostic purposes even though pathology is clinically visible. Such instances include differentiating iris or ciliary...
body lesions; ruling out ciliary body detachments; and differentiating intra-ocular tumors, serous versus hemorrhagic choroidal detachments, rhegmatogenous versus exudative retinal detachments, and disc drusen versus papilledema.

In a Cochrane review, Keay et al (2012) examined the evidence for reductions in adverse events through pre-operative medical testing, and estimated the average cost of performing routine medical testing. These investigators searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2011, Issue 12), MEDLINE (January 1950 to December 2011), EMBASE (January 1980 to December 2011), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to December 2011), the metaRegister of Controlled Trials (mRCT), ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). There were no date or language restrictions in the electronic searches for trials. The electronic databases were last searched on December 9, 2011. They used reference lists and the Science Citation Index to search for additional studies. These researchers included randomized clinical trials (RCTs) in which routine pre-operative medical testing was compared to no pre-operative or selective pre-operative testing prior to age-related cataract surgery. Two review authors independently assessed abstracts to identify possible trials for inclusion. For each included study, 2 review authors independently documented study characteristics, extracted data, and assessed methodological quality. The 3 RCTs included in this review reported results for 21,531 total cataract surgeries with 707 total surgery-associated medical adverse events, including 61 hospitalizations and 3 deaths. Of the 707 medical adverse events reported, 353 occurred in the pre-testing group and 354 occurred in the n-testing group. Most events were cardiovascular and occurred during the intra-operative period. Routine pre-operative medical testing did not reduce the risk of intra-operative (OR 1.02, 95 % CI: 0.85 to 1.22) or post-operative medical adverse events (OR 0.96, 95 % CI: 0.74 to 1.24) when compared to selective-testing or no-testing. Cost savings were evaluated in 1 study that estimated the costs to be 2.55 times higher in those with pre-operative medical testing compared to those without pre-operative medical testing. There was no difference in cancellation of surgery between those with pre-operative medical testing and those with no or limited pre-operative testing, reported by 2 studies. The authors concluded that this review has shown that routine pre-operative testing does not increase the safety of cataract surgery. Alternatives to routine pre-operative medical testing have been proposed, including self-administered health questionnaires, which could substitute for health provider histories and physical examinations. Such avenues may lead to...
cost-effective means of identifying those at increased risk of medical adverse events due to cataract surgery. However, despite the rare occurrence, adverse medical events precipitated by cataract surgery remain a concern because of the large number of elderly patients with multiple medical co-morbidities who have cataract surgery in various settings. The studies summarized in this review should assist recommendations for the standard of care of cataract surgery, at least in developed settings. Unfortunately, in developing country settings, medical history questionnaires would be useless to screen for risk since few people have ever been to a physician, let alone been diagnosed with any chronic disease.

In a Cochrane review, Casparis et al (2012) noted that cataract and age-related macular degeneration (ARMD) are common causes of decreased vision that often occur simultaneously in people over age 50. Although cataract surgery is an effective treatment for cataract-induced visual loss, some clinicians suspect that such an intervention may increase the risk of worsening of underlying ARMD and thus have deleterious effects on vision. These investigators evaluated the safety and effectiveness of cataract surgery in eyes with ARMD. They searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2012, Issue 4), MEDLINE (January 1950 to April 2012), EMBASE (January 1980 to April 2012), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to April 2012), the metaRegister of Controlled Trials (mRCT), ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). There were no date or language restrictions in the electronic searches for trials. The electronic databases were last searched on April 16, 2012. These researchers included RCTs and quasi-randomized trials of eyes affected by both cataract and ARMD in which cataract surgery would be compared to no surgery. Two authors independently evaluated the search results against the inclusion and exclusion criteria. Two authors independently extracted data and assessed risk of bias for included studies. They resolved discrepancies by discussion. One RCT with 60 participants with visually significant cataract and ARMD was included in this review. Participants were randomized to immediate cataract surgery (within 2 weeks of enrollment) (n = 29) or delayed cataract surgery (6 months after enrollment) (n = 31). At 6 months, 4 participants were lost to follow-up; 2 participants from each group. The immediate surgery group showed mean improvement in best-corrected visual acuity (BCVA) compared with the delayed surgery group at 6 months (mean difference (MD) 0.15 LogMAR, 95% CI: 0.28 to 0.02). There was no significant difference in the development of choroidal neovascularization between groups (1/27 eyes in the immediate surgery group versus...
0/29 eyes in the delayed surgery group). Results from Impact of Vision Impairment (IVI) questionnaires suggested that the immediate surgery group fared better with quality of life outcomes than the delayed surgery group (MD in IVI logit scores 1.60, 95 % CI: 0.61 to 2.59). No post-operative complication was reported. These researchers identified a second potentially relevant study of immediate versus delayed cataract surgery in 54 people with ARMD. Results for the study were not yet available, but may be eligible for future updates of this review. The authors concluded that at this time, it is not possible to draw reliable conclusions from the available data to determine whether cataract surgery is beneficial or harmful in people with ARMD. Physicians will have to make practice decisions based on best clinical judgment until controlled trials are conducted and their findings published. It would be valuable for future research to investigate prospective RCTs comparing cataract surgery to no surgery in patients with ARMD to better evaluate whether cataract surgery is beneficial or harmful in this group. However ethical considerations need to be addressed when delaying a potentially beneficial treatment and it may not be feasible to conduct a long-term study where surgery is withheld from the control group. Utilization of pre-existing, standardized systems for grading cataract and ARMD and measuring outcomes (visual acuity, change in visual acuity, worsening of AMD and quality of life measures) should be encouraged.

The Alcon AcrySof Natural UV and blue light filtering acrylic foldable multi-piece posterior chamber lenses are optical implants for the replacement of the human crystalline lens in the visual correction of aphakia in adult patients following cataract surgery.

The SN6AT7 appears to be a type of AcrySof IQ toric posterior chamber IOL. The other models are SN6AT6, SN6AT8, and SN6AT9.

Leung and colleagues (2014) noted that cataract formation often occurs in people with uveitis. It is unclear which IOL type is optimal for use in cataract surgery for eyes with uveitis. In a Cochrane review, these investigators summarized the effects of different IOLs on visual acuity, other visual outcomes, and quality of life in people with uveitis. They searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2013, Issue 7), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to August 2013), EMBASE (January 1980 to August 2013), Latin American and Caribbean Literature on Health
Sciences (LILACS) (January 1982 to August 2013), the metaRegister of Controlled Trials (mRCT), ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). They did not use any date or language restrictions in the electronic searches for trials. They last searched the electronic databases on August 14, 2013. These researchers also performed forward and backward searching using the Science Citation Index and the reference lists of the included studies, respectively, in August 2013. They included RCTs comparing hydrophobic or hydrophilic acrylic, silicone, or poly(methyl methacrylate) (PMMA) IOLs with or without heparin-surface modification (HSM), with each other, or with no treatment in adults with uveitis, for any indication, undergoing cataract surgery. They used standard methodological procedures expected by The Cochrane Collaboration.

Two review authors screened the search results and for included studies, assessed the risk of bias and extracted data independently. They contacted study investigators for additional information. They did not perform a meta-analysis due to variability in reporting and follow-up intervals for the primary and secondary outcomes of interest. These researchers included 4 RCTs involving 216 participants (range of 2 to 140 participants with uveitic cataract per trial) and comparing up to 4 types of IOLs. The largest study was an international study with centers in Brazil, Egypt, Finland, France, Japan, the Netherlands, Slovak Republic, Spain, and the USA; 2 studies were conducted in Germany and 1 in Saudi Arabia. There was substantial heterogeneity with respect to the ages of participants and etiologies of uveitis within and across studies. The length of follow-up among the studies ranged from 1 to 24 months after cataract surgery. The studies were at low risk of selection bias, but 2 of the 4 studies did not employ masking and only 1 study included all randomized participants in the final analyses. The funding source was disclosed by investigators of the largest study (professional society) and not reported by the other 3. Due to heterogeneity in lens types evaluated and outcomes reported among the trials, these investigators did not combine data in a meta-analysis. In the largest study (140 participants), the study eye of each participant was randomized to receive 1 of 4 types of IOLs: (i) hydrophobic acrylic, (ii) silicone, (iii) HSM PMMA, or (iv) unmodified PMMA. Proportions of participants with 1 or more Snellen lines of visual improvement were similar among the 4 treatment groups at 1 year follow-up: 45 of 48 (94%) in the hydrophobic acrylic IOL group, 39 of 44 (89%) in the silicone IOL group, 18 of 22 (82%) in the HSM PMMA IOL group, and 22 of 26 (85%) in the unmodified PMMA IOL group. When comparing hydrophobic acrylic IOLs with silicone IOLs, the risk ratio (RR) was 1.06 (95% CI: 0.93 to 1.20). At 1 year follow-up, fewer eyes randomized to hydrophobic acrylic IOLs developed posterior synechiae when compared with eyes...
receiving silicone IOLs (RR 0.18, 95 % CI: 0.04 to 0.79); the effects between these groups were less certain with respect to developing posterior capsule opacification (PCO) (RR 0.74, 95 % CI: 0.41 to 1.37), corneal edema (RR 0.49, 95 % CI: 0.22 to 1.12), cystoid macular edema (RR 0.10, 95 % CI: 0.01 to 1.84), or mild IOL de-centration (RR 0.92, 95 % CI: 0.06 to 14.22). Two intra-individual studies also compared HSM PMMA IOLs with unmodified PMMA IOLs at 3 or 6 months of follow-up. These studies, including a combined total of 16 participants with uveitis, were insufficiently powered to detect differences in outcomes among eyes of people with uveitis randomized to receive HSM PMMA IOLs when compared with fellow eyes receiving unmodified PMMA IOLs. In the 4th study (60 participants), the study eye of each participant was randomized to receive a hydrophobic or hydrophilic acrylic IOL. At 3 months, there were no statistical or clinical differences between hydrophobic and hydrophilic acrylic IOL types in the proportions of participants with 2 or more Snellen lines of visual improvement (RR 1.03, 95 % CI: 0.87 to 1.22). There were similar rates in the development of PCO between hydrophobic or hydrophilic acrylic IOLs at 6 months' follow-up (RR 1.00, 95 % CI: 0.80 to 1.25). The effect of the lenses on posterior synechiae was uncertain at 6 months' follow-up (RR 0.50, 95 % CI: 0.05 to 5.22). None of the included studies reported quality of life outcomes. The authors concluded that based on the trials identified in this review, there is uncertainty as to which type of IOL provides the best visual and clinical outcomes in people with uveitis undergoing cataract surgery. The studies were small, not all lens materials were compared in all studies, and not all lens materials were available in all study sites. Evidence of a superior effect of hydrophobic acrylic lenses over silicone lenses, specifically for posterior synechiae outcomes comes from a single study at a high risk of performance and detection bias. However, due to small sample sizes and heterogeneity in outcome reporting, the authors found insufficient information to assess these and other types of IOL materials for cataract surgery for eyes with uveitis.

Ong et al (2014) stated that following cataract surgery and IOL implantation, loss of accommodation or post-operative presbyopia occurs and remains a challenge. Standard mono-focal IOLs correct only distance vision; patients require spectacles for near vision. Accommodative IOLs have been designed to overcome loss of accommodation after cataract surgery. In a Cochrane review, these investigators defined (i) the extent to which accommodative IOLs improve unaided near visual function, in comparison with mono-focal IOLs; (ii) the extent of compromise to unaided distance visual acuity; and (iii) whether a higher rate of
additional complications is associated the use of accommodative IOLs. They searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2013, Issue 9), Ovid MEDLINE, Ovid MEDLINE in-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily Update, Ovid OLDMEDLINE (January 1946 to October 2013), EMBASE (January 1980 to October 2013), Latin American and Caribbean Health Sciences Literature Database (LILACS) (January 1982 to October 2013), the metaRegister of Controlled Trials (mRCT), ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). They did not use any date or language restrictions in the electronic searches for trials. They last searched the electronic databases on October 10, 2013. These researchers included RCTs that compared implantation of accommodative IOLs to implantation of mono-focal IOLs in cataract surgery. Two authors independently screened search results, assessed risk of bias and extracted data. All included trials used the 1CU accommodative IOL (HumanOptics, Erlangen, Germany) for their intervention group. One trial had an additional arm with the AT-45 Crystalens accommodative IOL (Eyeonics Vision). These investigators performed a separate analysis comparing 1CU and AT-45 IOL. They included 4 RCTs, including 229 participants (256 eyes), conducted in Germany, Italy and the UK. The age range of participants was 21 to 87 years. All studies included people who had bilateral cataracts with no pre-existing ocular pathologies. These researchers judged all studies to be at high risk of performance bias. They graded 2 studies with high risk of detection bias and 1 study with high risk of selection bias. Participants who received the accommodative IOLs achieved better distance-corrected near visual acuity (DCNVA) at 6 months (mean difference [MD] -3.10 Jaeger units; 95 % CI: -3.36 to -2.83, 2 studies, 106 people, 136 eyes, moderate quality evidence). Better DCNVA was seen in the accommodative lens group at 12 to 18 months in the 3 trials that reported this time-point but considerable heterogeneity of effect was seen, ranging from 1.3 (95 % CI: 0.98 to 1.68; 20 people, 40 eyes) to 6 (95 % CI: 4.15 to 7.85; 51 people, 51 eyes) Jaeger units and 0.12 (95 % CI: 0.05 to 0.19; 40 people, binocular) logMAR improvement (low quality evidence). The relative effect of the lenses on corrected distant visual acuity (CDVA) was less certain. At 6 months there was a standardized mean difference of -0.04 standard deviations (95 % CI: -0.37 to 0.30, 2 studies, 106 people, 136 eyes, low quality evidence). At long-term follow-up there was heterogeneity of effect with 18-month data in 2 studies showing that CDVA was better in the mono-focal group (MD 0.12 logMAR; 95 % CI: 0.07 to 0.16, 2 studies, 70 people, 100 eyes) and 1 study that reported data at 12 months finding similar CDVA in the 2 groups (-0.02 logMAR units, 95 % CI: -0.06 to 0.02, 51 people) (low
quality evidence). The relative effect of the lenses on reading speed and spectacle independence was uncertain. The average reading speed was 11.6 words per minute more in the accommodative lens group but the 95% CI ranged from 12.2 words less to 35.4 words more (1 study, 40 people, low quality evidence). People with accommodative lenses were more likely to be spectacle-independent but the estimate was very uncertain (RR 8.18; 95% CI: 0.47 to 142.62, 1 study, 40 people, very low quality evidence). More cases of PCO were seen in accommodative lenses but the effect of the lenses on PCO was uncertain (Peto odds ratio (OR) 2.12; 95% CI: 0.45 to 10.02, 91 people, 2 studies, low quality evidence). People in the accommodative lens group were more likely to require laser capsulotomy (Peto OR 7.96; 95% CI: 2.49 to 25.45, 2 studies, 60 people, 80 eyes, low quality evidence). Glare was reported less frequently with accommodative lenses but the relative effect of the lenses on glare was uncertain (RR any glare 0.78; 95% CI: 0.32 to 1.90, 1 study, 40 people, and RR moderate/severe glare 0.45; 95% CI: 0.04 to 4.60, low quality evidence). The authors concluded that there is moderate-quality evidence that study participants who received accommodative IOLs had a small gain in near visual acuity after 6 months. There is some evidence that distance visual acuity with accommodative lenses may be worse after 12 months but due to low quality of evidence and heterogeneity of effect, the evidence for this is not clear-cut. People receiving accommodative lenses had more PCO which may be associated with poorer distance vision. However, the effect of the lenses on PCO was uncertain. They stated that further research is needed to improve the understanding of how accommodative IOLs may affect near visual function, and whether they provide any durable gains. Additional trials, with longer follow-up, comparing different accommodative IOLs, multi-focal IOLs and mono-focal IOLs, would help map out their relative efficacy, and associated late complications. Research is needed on control over capsular fibrosis post-implantation. Risks of bias, heterogeneity of outcome measures and study designs used, and the dominance of one design of accommodative lens in existing trials (the HumanOptics 1CU) mean that these results should be interpreted with caution. They may not be applicable to other accommodative IOL designs.

Duman et al (2015) evaluated the impact of 4 different IOLs on PCO by comparing the Nd:YAG laser capsulotomy rates. This retrospective study included 4,970 eyes of 4,013 cataract patients who underwent phacoemulsification and IOL implantation between January 2000 and January 2008 by the same surgeon at 1 clinic; 4 different IOLs were assessed. The outcome parameter was the incidence of Nd:YAG laser posterior capsulotomies. An Nd:YAG laser posterior capsulotomy

http://www.aetna.com/cpb/medical/data/500_599/0508.html

07/29/2019
was performed in 153 (3.07 %) of the 4,970 eyes. The mean follow-up time was 84 months for all of the IOL groups. The percentage of eyes developing PCO was significantly greater for the acrylic hydrophilic IOLs than for the hydrophobic IOLs, although eyes with acrylic hydrophilic IOLs did not require Nd:YAG laser capsulotomy as soon as eyes with acrylic hydrophobic IOLs. There was no difference between the long-term PCO rates when 1- and 3-piece acrylic hydrophobic IOLs were compared or when IOLs made of the same material but with different haptic angles were compared. The authors concluded that in this study, eyes with acrylic hydrophilic IOLs were more likely to develop PCO than those with acrylic hydrophobic IOLs. The lens design (1-piece versus 3-piece and varying haptic angles) did not affect the PCO rate.

de Silva and colleagues (2016) stated that good unaided distance VA is now a realistic expectation following cataract surgery and (IOL implantation. Near vision, however, still requires additional refractive power, usually in the form of reading glasses. Multiple optic (multi-focal) IOLs are available which claim to allow good vision at a range of distances. It is unclear whether this benefit outweighs the optical compromises inherent in multi-focal IOLs. In a Cochrane review, these investigators evaluated the visual effects of multi-focal IOLs in comparison with the current standard treatment of mono-focal lens implantation. They searched CENTRAL (which contains the Cochrane Eyes and Vision Trials Register) (2016, Issue 5), Ovid Medline, Ovid Medline In-Process and other non-indexed citations, Ovid Medline Daily, Ovid OldMedline (January 1946 to June 2016), Embase (January 1980 to June 2016), the ISRCTN registry, ClinicalTrials.gov, and the WHO International Clinical Trials Registry Platform (ICTRP). These researchers did not use any date or language restrictions in the electronic searches for trials. They last searched the electronic databases on June 13, 2016. All RCTs comparing a multi-focal IOL of any type with a mono-focal IOL as control were included. Both unilateral and bilateral implantation trials were included. They also considered trials comparing multi-focal IOLs with "monovision" whereby 1 eye was corrected for distance vision and 1 eye corrected for near vision. These researchers used standard methodological procedures expected by Cochrane. They assessed the “certainty” of the evidence using GRADE. The authors concluded that multi-focal IOLs were effective at improving near vision relative to mono-focal IOLs although there was uncertainty as to the size of the effect. They also noted that whether that improvement outweighed the adverse effects of multi-focal IOLs, such as glare and haloes, would vary between people; and motivation to achieve spectacle independence was likely to be the deciding factor.
Combined Glaucoma and Cataract Surgery

Zhang and colleagues (2015) stated that cataract and glaucoma are leading causes of blindness worldwide, and their co-existence is common in elderly people. Glaucoma surgery can accelerate cataract progression, and performing both surgeries may increase the rate of post-operative complications and compromise the success of either surgery. However, cataract surgery may independently lower intra-ocular pressure (IOP), which may allow for greater IOP control among patients with co-existing cataract and glaucoma. The decision between undergoing combined glaucoma and cataract surgery versus cataract surgery alone is complex. Therefore, it is important to compare the effectiveness of these 2 interventions to aid clinicians and patients in choosing the better treatment approach. In a Cochrane review, these investigators evaluated the relative safety and effectiveness of combined surgery versus cataract surgery (phacoemulsification) alone for co-existing cataract and glaucoma. The secondary objectives included cost-analyses for different surgical techniques for co-existing cataract and glaucoma. These investigators searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (2014, Issue 10), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to October 2014), EMBASE (January 1980 to October 2014), PubMed (January 1948 to October 2014), Latin American and Caribbean Health Sciences Literature Database (LILACS) (January 1982 to October 2014), the metaRegister of Controlled Trials (mRCT), ClinicalTrials.gov, and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP). They did not use any date or language restrictions in the electronic searches for trials. They last searched the electronic databases on October 3, 2014. They checked the reference lists of the included trials to identify further relevant trials. These researchers used the Science Citation Index to search for references to publications that cited the studies included in the review. They also contacted investigators and experts in the field to identify additional trials. The authors included RCTs of participants who had open-angle, pseudoexfoliative, or pigmentary glaucoma and age-related cataract. The comparison of interest was combined cataract surgery (phacoemulsification) and any type of glaucoma surgery versus cataract surgery (phacoemulsification) alone. Two review authors independently assessed study eligibility, collected data, and judged risk of bias for included studies. They used standard methodological procedures expected by the Cochrane Collaboration. These investigators included 9 RCTs, with a total of 655 participants (657 eyes), and follow-up periods ranging from 12 to 30 months; 7 trials
were conducted in Europe, 1 in Canada and South Africa, and 1 in the United States. These researchers graded the overall quality of the evidence as low due to observed inconsistency in study results, imprecision in effect estimates, and risks of bias in the included studies. Glaucoma surgery type varied among the studies: 3 studies used trabeculectomy, 3 studies used iStent implants, 1 study used trabeculotomy, and 2 studies used trabecular aspiration. All of these studies found a statistically significant greater decrease in mean IOP post-operatively in the combined surgery group compared with cataract surgery alone; the MD was -1.62 mmHg (95 % CI: -2.61 to -0.64; 489 eyes) among 6 studies with data at 1 year follow-up. No study reported the proportion of participants with a reduction in the number of medications used after surgery, but 2 studies found the mean number of medications used post-operatively at 1 year was about 1 less in the combined surgery group than the cataract surgery alone group (MD -0.69, 95 % CI: -1.28 to -0.10; 301 eyes); 5 studies showed that participants in the combined surgery group were about 50 % less likely compared with the cataract surgery alone group to use 1 or more IOP-lowering medications 1 year post-operatively (RR 0.47, 95 % CI: 0.28 to 0.80; 453 eyes). None of the studies reported the mean change in visual acuity or visual fields. However, 6 studies reported no significant differences in visual acuity and 2 studies reported no significant differences in visual fields between the 2 intervention groups post-operatively (data not analyzable). The effect of combined surgery versus cataract surgery alone on the need for re-operation to control IOP at 1 year was uncertain (RR 1.13, 95 % CI: 0.15 to 8.25; 382 eyes). Also uncertain was whether eyes in the combined surgery group required more interventions for surgical complications than those in the cataract surgery alone group (RR 1.06, 95 % CI: 0.34 to 3.35; 382 eyes). No study reported any vision-related quality of life data or cost outcome. Complications were reported at 12 months (2 studies), 12 to 18 months (1 study), and 2 years (4 studies) after surgery. Due to the small number of events reported across studies and treatment groups, the difference between groups was uncertain for all reported adverse events. The authors concluded that there is low quality evidence that combined cataract and glaucoma surgery may result in better IOP control at 1 year compared with cataract surgery alone. The evidence was uncertain in terms of complications from the surgeries. Furthermore, this Cochrane review has highlighted the lack of data regarding important measures of the patient experience, such as visual field tests, quality of life measurements, and economic outcomes after surgery, and long-term outcomes (5 years or more). They stated that additional high-quality RCTs measuring clinically meaningful and patient-important outcomes are needed to provide evidence to support treatment recommendations.
Surgery for Post-Vitrectomy Cataract

Do and colleagues (2018) stated that cataract formation or acceleration can occur after intra-ocular surgery, especially following vitrectomy, a surgical technique for removing the vitreous that is used in the treatment of many disorders that affect the posterior segment of the eye. The underlying problem that led to vitrectomy may limit the benefit from removal of the cataractous lens. In a Cochrane review, these investigators evaluated the safety and effectiveness of surgery versus no surgery for post-vitrectomy cataract with respect to VA, quality of life (QOL), and other outcomes. They searched the Cochrane Central Register of Controlled Trials (CENTRAL) (which contains the Cochrane Eyes and Vision Trials Register) (2017, Issue 5), Medline Ovid (1946 to May 17, 2017), Embase.com (1947 to May 17, 2017), PubMed (1946 to May 17, 2017), Latin American and Caribbean Health Sciences Literature database (LILACS) (January 1982 to May 17, 2017), the metaRegister of Controlled Trials (mRCT) (www.controlled-trials.com); last searched May 2013, ClinicalTrials.gov (www.clinicaltrials.gov); searched May 17, 2017, and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en); searched May 17, 2017. These researchers did not use any date or language restrictions in the electronic searches for trials. They planned to include RCTs and quasi-RCTs that had compared surgery versus no surgery to remove the lens from eyes of adults in which cataracts had developed following vitrectomy. Two review authors independently screened the search results according to the standard methodological procedures expected by Cochrane. They found no RCTs or quasi-RCTs that had compared surgery versus no surgery to remove the lens from eyes of adults in which cataracts had developed following vitrectomy. The authors concluded that there is no evidence from RCTs or quasi-RCTs on which to base clinical recommendations for surgery for post-vitrectomy cataract. There is a clear need for RCTs to address this evidence gap. Such trials should stratify participants by their age, the retinal disorder leading to vitrectomy, and the status of the underlying disease process in the contralateral eye. Outcomes assessed in such trials may include changes (both gains and losses) of VA, QOL, and adverse events (AEs) such as posterior capsular rupture and retinal detachment. Both short-term (6-month) and long-term (1- or 2-year) outcomes should be examined.

B-Scan Ultrasound for Pre-Operative Work-Up of Individuals with Morgagnian Cataract

http://www.aetna.com/cpb/medical/data/500_599/0508.html
American Academy of Ophthalmology’s EyeWiki (Patel and Sahu, 2019) lists B-scan ultrasound study for posterior segment evaluation to rule out complicated co-existing intra-ocular diseases for pre-operative work-up of patients with Morgagnian cataract.

Furthermore, an UpToDate review on “Cataract in children” (McCreery, 2019) states that “A complete eye examination by the ophthalmologist may require the use of sedation or general anesthesia and is often performed at the time of surgical intervention. Ancillary testing such as ocular ultrasound may be necessary in total cataracts where the posterior segment of the eye cannot be visualized. Electrophysiologic testing in the form of visual evoked potential (VEP) is helpful in total cataracts to assess the function of the visual pathway”.

**Femtosecond Laser-Assisted Cataract Surgery**

In a prospective, consecutive cohort study, Bali and colleagues (2012) described the intra-operative complications and evaluated the learning curve with femtosecond laser-assisted cataract surgery (FLACS). The initial 200 eyes undergoing cataract surgery between April 2011 and June 2011 by 6 surgeons were included in the study. The cases underwent anterior capsulotomy, lens fragmentation, and corneal incisions with the femtosecond laser. The procedure was completed by phacoemulsification and insertion of an IOL. Data were collected about patient demographics, pre-operative investigations and intra-operative complications. The cases were divided into 4 groups -- group 1 included the first 50 cases, group 2 included cases 51 through 100, group 3 included cases 101 through 150, and group 4 included cases 151 through 200 -- and were analyzed. Main outcome measure was intra-operative complication rates. The mean age of patients included was 69.2 ± 9.8 years. Of the 200 eyes, 74.5 % underwent a complete procedure of laser capsulotomy, lens fragmentation, and corneal incisions; 5 eyes had suction breaks during the laser procedure that led to the remainder of the laser procedure being aborted; 21 (10.5 %) eyes showed the presence of small anterior capsular tags. The number of eyes with free-floating capsulotomies was 35 (17.5 %). The other complications during the study were anterior radial tears (n = 8; 4 %), posterior capsular ruptures (n = 7; 3.5 %), and dropped nucleus (n = 4; 2 %). A significant difference was noted among the sequential groups with respect to the number of docking attempts (p < 0.001), miosis after the laser procedure (p < 0.001), and free-floating capsulotomies (p < 0.001), suggesting an improving learning curve. The surgeons with prior
experience with femtosecond lasers had fewer complications in the first 100 cases (p < 0.001). No difference in complications was observed after the initial 100 cases. The authors concluded that in this case-series study, there was a clear learning curve associated with the use of FLACS. Adjustment to surgical technique and prior experience with a femtosecond laser appeared to flatten the learning curve.

Filkorn and associates (2012) compared IOL power calculation and refractive outcome between patients who underwent laser refractive cataract surgery with a femtosecond laser and those with conventional cataract surgery. In this prospective study, 77 eyes from 77 patients underwent laser refractive cataract surgery (laser group; Alcon LenSx femtosecond laser), and conventional cataract surgery with phacoemulsification was performed in 57 eyes from 57 patients (conventional group). Biometry was done with optical low coherence reflectometry (Lenstar LS900, Haag-Streit AG), and IOL calculation was performed with 3rd-generation IOL formulas (SRK/T, Hoffer Q, and Holladay). The refractive outcome was analyzed using the mean absolute error (MAE; difference between predicted and achieved post-operative spherical equivalent refraction), and multi-variable regression analysis was performed to compare the 2 groups. No significant differences were found between age, axial length, keratometry, and pre-operative corrected VA in the laser and conventional groups (p > 0.05; Mann-Whitney U test). At least 6 weeks after surgery, MAE was significantly lower in the laser group (0.38 ± 0.28 diopters [D]) than in the conventional group (0.50 ± 0.38 D) (p = 0.04). The difference was the greatest in short (axial length less than 22.0 mm, 0.43 ± 0.41 versus 0.63 ± 0.48) and long (axial length greater than 26.0 mm, 0.33 ± 0.24 versus 0.63 ± 0.42) eyes. The authors concluded that laser refractive cataract surgery with a femtosecond laser resulted in a significantly better predictability of IOL power calculation than conventional phacoemulsification surgery. This difference was possibly due to a more precise capsulorrhexis, resulting in a more stable IOL position.

In a prospective, interventional case-series study, Roberts and co-workers (2013) reported the surgical outcomes and safety of FLACS with greater surgeon experience, modified techniques, and improved technology. A total of 1,500 consecutive eyes undergoing FS laser cataract and refractive lens exchange surgery in a single group private practice were included in this analysis. All eyes undergoing LCS between April 2011 and March 2012 were included in the study. Cases underwent anterior capsulotomy, lens fragmentation, and corneal incisions
with the Alcon/LenSx FS laser (Alcon/LenSx, Aliso Viejo, CA). The procedure was completed by phacoemulsification and insertion of an IOL. The cases were divided into 2 groups: Group 1, initial experience consisting of the first 200 cases; and group 2, the subsequent 1,300 cases performed by the same surgeons. Main outcome measures included intra-operative complication rates and comparison between groups. Both groups were comparable for baseline demographic parameters. Anterior capsule tears occurred in 4 % and 0.31 % of eyes, posterior capsule tears in 3.5 % and 0.31 % of eyes, and posterior lens dislocation in 2 % and 0 % of eyes in groups 1 group 2, respectively (p < 0.001 for all comparisons). Number of docking attempts per case (1.5 versus 1.05), incidence of post-laser pupillary constriction (9.5 % versus 1.23 %), and anterior capsular tags (10.5 % versus 1.61 %) were significantly lower in group 2 (p < 0.001 for all comparisons). The authors concluded that in the authors’ experience, the surgical outcomes and safety of LCS improved significantly with greater surgeon experience, development of modified techniques, and improved technology.

In a prospective, consecutive, single-surgeon, case-control study, Abell and colleagues (2013) compared effective phacoemulsification time after femtosecond laser pre-treatment with conventional phacoemulsification and the associated effect on visual outcomes and endothelial cell loss. Controls underwent phacoemulsification cataract extraction plus insertion of an IOL. Cases underwent pre-treatment with the femtosecond laser followed by phacoemulsification cataract extraction and IOL insertion. A total of 201 eyes underwent cataract surgery between April 2012 and July 2012. Data collected included patient demographics, pre-operative characteristics, femtosecond lens fragmentation method, effective phacoemulsification time (EPT), intra-operative complications, and post-operative outcomes. Main outcome measures included EPT, intra-operative complications, corneal endothelial cell loss, as well as post-operative BCVA, IOP, and refractive outcomes. Patient demographics were similar between groups. There was no difference between baseline cataract grades (2.59 ± 0.71 versus 2.52 ± 0.72, not significant); 100 % of cases pre-treated with the femtosecond laser had complete capsulotomy. Mean EPT was reduced by 83.6 % in the femtosecond pre-treatment group (p < 0.0001) when compared with controls, with 30 % having 0 EPT (p < 0.0001). Effective phacoemulsification time was reduced 28.6 % within the femtosecond group using improved lens fragmentation algorithms, and a further 72.8 % reduction was achieved with a 20-gauge phacoemulsification tip. Overall, there was a 96.2 % reduction in EPT between controls and the optimized femtosecond pre-treatment group. This was associated with a 36.1 % reduction in
endothelial cell loss in the femtosecond group. Visual and refractive outcomes were similar to those of conventional cataract surgery. The authors concluded that femtosecond laser pre-treatment results in a significant reduction in EPT, including the possibility of 0 EPT. These researchers stated that further reductions may be achieved using optimization of lens fragmentation patterns and surgical technique.

Dick and associates (2013) described a technique for performing FLACS without the use of ophthalmic viscosurgical devices (OVDs). After laser pre-treatment, the anterior chamber was stabilized with balanced salt solution during lens and cortex aspiration. A pre-loaded IOL was implanted under irrigation. In 23 eyes undergoing surgery without the use of OVDs, no complications were observed within a 1-month follow-up period. The time for surgery and the amount of fluid that went into the eye were similar to those of a standard procedure. There was no remarkable increase in IOP or corneal thickness. All patients achieved a significant increase in corrected distance VA after surgery. The authors concluded that the significant reduction of phacoemulsification use after femtosecond laser application might render the use of OVDs obsolete in many cases.

Menapace and Dick (2014) noted that the use of femto-second lasers (FSL) surgery improves the precision and reproducibility of corneal incisions and the capsular opening and reduces the amount of ultrasound (US) energy needed for lens nucleus work-up. However, the clinical benefits must be put into perspective due to the subsequent surgical manipulation of the incisions (during lens emulsification, aspiration and IOL injection), the lacking possibility to visualize the crystalline lens equator as the reference for correct capsulotomy centration and the relativity of US energy consumption on the corneal endothelial trauma. This was of particular relevance against the background of the significantly higher costs. Conversely, tears of the anterior capsule edge which, apart from interfering with correct IOL positioning, may entail serious complications presently occur more frequently with all FSL instruments.

Abell and Vote (2014) performed a comparative cost-effectiveness analysis (CEA) of FLACS and conventional phacoemulsification cataract surgery (PCS). Participants were hypothetical cohort of patients undergoing cataract surgery in the better eye based on a review of the current literature and the authors’ direct experience using FLACS. A cost-effectiveness decision tree model was constructed to analyze the cost-effectiveness of FLACS compared with PCS. Complication rates of cataract surgery were obtained from a review of the current
literature to complete the cohort of patients and outcomes. These data were incorporated with time trade-off utility values converted from visual acuity outcomes. Improvements in BCVA obtained from the literature were used to calculate the increase in quality-adjusted life-years (QALYs) in a hypothetical cohort between 6 months and 1 year after cataract surgery. This was combined with approximate costs in a cost-utility analysis model to determine the incremental cost-effectiveness ratios (ICERs). Based on the simulated complication rates of PCS and FLACS and assuming resultant VA outcome improvement of 5% in uncomplicated cases of LCS, the cost-effectiveness (dollars spent per QALY) gained from LCS was not cost-effective at $92,862 Australian Dollars. The total QALY gain for LCS over PCS was 0.06 units. Multi-variate sensitivity analyses revealed that FLACS would need to significantly improve visual outcomes and complications rates over PCS, along with a reduction in cost to patient, to improve cost effectiveness. Modeling a best-case scenario of FLACS with excellent visual outcomes (100%), a significant reduction in complications (0%) and a significantly reduced cost to patient (of $300) resulted in an ICER of $20,000. The authors concluded that laser cataract surgery, irrespective of potential improvements in VA outcomes and complication rates, was not cost-effective at its current cost to patient when compared with cost-effectiveness benchmarks and other medical interventions, including PCS. A significant reduction in the cost to patient (via reduced consumable/click cost) would increase the likelihood of FLACS being considered cost-effective.

Dick and Schultz (2014) stated that employing a femtosecond laser as an initial step in cataract surgery has the clear potential to provide more precise capsulotomies and full lens fragmentation in cases of pre-existing astigmatism in conjunction with relaxing corneal incisions. In the long run FLACS might replace phacoemulsification which has been the standard in cataract surgery over the last 20 years. Besides precision and predictability, the low rate of complications impresses surgeons working with the technology, particularly those employing a laser with a fluid-filled interface which appeared to prevent major complications including increases in IOP.

Schultz and co-workers (2015) compared histologically the size and appearance of capsule disks after FLACS and conventional cataract surgery. In 100 eyes of 100 patients with visually significant cataracts, a femtosecond laser capsulotomy or a capsulorhexis with an aimed diameter of 5.0 mm was performed by 1 experienced surgeon. The diameter, area, circularity, and cut quality was histologically
examined with light microscopy and scanning electron microscopy. The mean diameter of the manual and the femtosecond laser capsule disk group were not statistically significantly different (manual 4.91 ± 0.34; femtosecond: 4.93 ± 0.03; p = 0.58). The mean area of the capsule disks was 18.85 ± 2.69 mm² in the manual and 19.03 ± 0.26 mm² in the femtosecond group (p = 0.64). The capsules of the femtosecond group (0.95 ± 0.02) were significantly more circular than the ones of the manual group (0.81 ± 0.07; p < 0.0001). The femtosecond laser capsule disks displayed a more saw blade-like structure created through the single laser spots. The histologic examination combined with prospective video analysis revealed respiratory movement of the eye during the capsulotomy as a potential risk factor for radial tears. The authors concluded that femtosecond laser could perform a capsulotomy with high reliability. In comparison to a highly experienced cataract surgeon, the achieved results in size were similar. In terms of circularity, the femtosecond laser was superior the manual procedure. Better refractive outcomes based on a 360°-degree optic overlap appeared to be possible, especially for less experienced surgeons.

The American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) (Stodola, 2013) stated that “According to the ASCRS/ASOA policy, the allowable Medicare reimbursement for cataract surgery does not change according to the surgical methods used. Therefore, reimbursement for a cataract procedure would be the same whether a femtosecond laser or another method is used. The only way a patient can be billed extra is if he or she is receiving an additional service, such as a premium refractive IOL, and in this case, a doctor must first discuss the extra out-of-pocket costs with the patient and gain consent in advance”.

Furthermore, the AAO Preferred Practice Pattern on cataract surgery (2016) stated that “Femtosecond laser-assisted cataract surgery (FLACS) increases the circularity and centration of the capsulorrhexis and reduces the amount of ultrasonic energy required to remove a cataract. However, the technology may not yet be cost-effective, and the overall risk profile has not yet been shown to be superior to that of standard phacoemulsification”.

**Optiwave Refractive Analysis (ORA)**
The Optiwave Refractive Analysis System, or ORA System, is an intra-operative wavefront aberrometer for use in the operating room (OR) during refractive cataract surgery. This system captures wavefront images of the patient’s eye during surgery. These images are used to calculate the patient’s total refractive error, from all aberrations due to the eye’s optical imperfections, at any point during the surgical procedure: phakic, aphakic or pseudophakic.

In a retrospective, consecutive, cases-series study, Ianchulev and colleagues (2014) evaluated a new method of intra-operative refractive biometry (IRB) for intraocular lens (IOL) power calculation in eyes undergoing cataract surgery after prior myopic LASIK or photorefractive keratectomy. These researchers included 215 patients undergoing cataract surgery with a history of myopic LASIK or photorefractive keratectomy. Patients underwent IRB for IOL power estimation. The Optiwave Refractive Analysis (ORA) System wavefront aberrometer was used to obtain aphakic refractive measurements intra-operatively and then calculate the IOL power with a modified vergence formula obtained before refractive surgery. Comparative effectiveness analysis was done for IRB predictive accuracy of IOL power determination against 3 conventional clinical practice methods: (i) surgeon best pre-operative choice (determined by the surgeon using all available clinical data), (ii) the Haigis L, and (iii) the Shammas IOL formulas. Main outcome measures were median absolute error of prediction and percentage of eyes within ±0.50 diopters (D) and ±1.00 D of refractive prediction error. In 246 eyes (215 first eyes and 31 second eyes) IRB using ORA achieved the greatest predictive accuracy (p < 0.0001), with a median absolute error of 0.35 D and mean absolute error of 0.42 D. Sixty-seven percent of eyes were within ±0.5 D and 94 % were within ±1.0 D of the IRB's predicted outcome. This was significantly more accurate than the other pre-operative methods: Median absolute error was 0.6, 0.53, and 0.51 D for surgeon best choice, Haigis L method, and Shammas method, respectively. The authors concluded that the IOL power estimation in challenging eyes with prior LASIK/photorefractive keratectomy was most accurately predicted by IRB/ORA. This was a retrospective, cases-series study; its findings need to be validated by well-designed studies.

Sheard (2014) stated that biometry has become one of the most important steps in modern cataract surgery and, according to the Royal College of Ophthalmologists Cataract Surgery Guidelines, what matters most is achieving excellent results. This paper is aimed at the NHS cataract surgeon and intends to be a critical review of the recent literature on biometry for cataract surgery, summarizing the evidence for
current best practice standards and available practical strategies for improving outcomes for patients. With modern optical biometry for the majority of patients, informed formula choice and IOL constant optimization outcomes of more than 90% within ± 1 D and more than 60% within ± 0.5 D of target are achievable. There are a number of strategies available to surgeons wishing to exceed these outcomes, the most promising of which are the use of strict-tolerance IOLs and second eye prediction refinement. This review does not mention the Optiwave refractive analysis system/intra-operative refractive biometry.

In a retrospective consecutive case-series study, Fram and colleagues (2015) compared the accuracy of intra-operative aberrometry technology and the Fourier-domain optical coherence tomography (OCT)-based intra-ocular lens (IOL) formula for IOL power calculation in eyes undergoing cataract surgery after previous laser vision correction (LVC) compared with established methods. Participants were patients undergoing cataract surgery with a history of LASIK or photorefractive keratectomy. The IOL power was estimated pre-operatively using the IOLMaster 500 (Carl Zeiss Meditec, Dublin, CA) to calculate the Haigis-L and Masket regression formulae (when prior data were available), and the Optovue RTVue (Optovue Inc., Fremont, CA) spectral domain OCT was used to obtain the Fourier-domain OCT-based IOL formula. The Optiwave Refractive Analysis (ORA) System (WaveTec Vision Systems Inc., Aliso Viejo, CA) wavefront aberrometer measured aphakic refractive measurements intra-operatively and calculated the IOL power with a modified vergence formula. Comparative analysis was done for predictive accuracy of IOL power determination using 2 conventional methods and 2 new technologies: the Haigis-L formula, Masket regression formula, ORA intra-operative aberrometry, and Optovue RTVue Fourier-domain OCT-based IOL formula.

Patients without historical data (n = 39) were compared using 3 methods (Haigis-L, ORA, and Optovue), and patients with historical data (n = 20) were compared using all methods (Masket regression formula, Haigis-L, ORA, and Optovue). Main outcome measures included median absolute error (MedAE), mean absolute error (MAE), and percentage of eyes within ±0.25, ±0.50, ±0.75, and ±1.00 diopters (D) of refractive prediction error. A total of 39 eyes of 29 patients without historical data were analyzed separately from 20 eyes of 20 patients with historical data. In the group without historical data (n = 39), 49% of eyes were within ±0.25 D, 69% to 74% of eyes were within ±0.50 D, 87% to 97% of eyes were within ±0.75 D, and 92% to 97% of eyes were within ±1.00 D of targeted refractive IOL power prediction error. The MedAE was 0.26 D for Haigis-L, 0.29 D for ORA, and 0.28 D for Optovue. The MAE was 0.37 D for Haigis-L, 0.34 D for ORA, and 0.39 D for...
Optovue. In the group with historical data (n = 20), 35 % to 70 % of eyes were within ±0.25 D, 60 % to 85 % of eyes were within ±0.50 D, 80 % to 95 % of eyes were within ±0.75 D, and 90 % to 95 % of eyes were within ±1.00 D of targeted refractive IOL power prediction error. The MedAE was 0.21 D for the Masket regression formula, 0.22 D for the Haigis-L formula, 0.25 D for ORA, and 0.39 for Optovue. The MAE was 0.28 D for the Masket regression formula, 0.31 D for the Haigis-L formula, 0.37 D for ORA, and 0.44 D for Optovue. There was no statistically significant difference among the methods. The authors concluded that newer technology to estimate IOL power calculations in eyes after LVC showed promising results when compared with established methods.

An UpToDate review on “Laser refractive surgery” (Bower, 2016) states that “Wavefront Testing -- In a standard eye examination, the refractive surgeon will test for myopia, hyperopia, and astigmatism. However, patients may have irregular astigmatism defined as higher order aberrations (e.g., coma or spherical aberrations). These higher order optical aberrations can have significant impact on vision. In the past, the ophthalmologist had no way to correct a patient's irregular astigmatism. Spectacles only correct lower order aberrations such as sphere and cylinder. Presently, objective techniques exist for a comprehensive measurement of the optics of the eye. The science of wavefront aberrometry is based upon the shape of the wavefront of light reflected from the eye. A beam of light is refracted from the eye and goes through a micro-lens array producing a spot image array of reflected light. A computer analysis determines the relative displacement of each spot image. The images are then computed to give the local slope and character of the wavefront of light. The analyzed wavefront is then used to derive a correction profile to remove the correct amount of corneal stroma in micron intervals using a guided laser. The information obtained from wavefront technology will enable the refractive surgeon to reduce the natural and surgically induced higher order aberrations. The refractive surgery patient may benefit from the correction of higher order aberrations by improving best spectacle corrected visual acuity (BSCVA), night vision, contrast sensitivity, and reducing glare and halos”.

In a retrospective study, Zhang et al (2017) compared the outcomes of intra-operative wavefront aberrometry (e.g., optiwave refractive analysis (ORA)) versus optical biometry alone for intra-ocular lens (IOL) power calculation in eyes undergoing cataract surgery with mono-focal IOL implantation. Pre-operative data were obtained with the IOLMaster. Intra-operative aphakic measurements and IOL power calculations were obtained in some patients with the ORA system. Analysis
was performed to determine the accuracy of mono-focal IOL power prediction and post-operative manifest refraction at 1 month of the ORA versus IOLMaster. A total of 295 eyes were reviewed, 61 had only pre-operative IOLMaster measurements and 234 had both IOLMaster and ORA measurements. Of these 234 eyes, 6 were excluded, 107 had the same recommended IOL power by ORA and IOLMaster; 64% of these eyes were within ± 0.5D; 95 eyes had IOL power implantation based on ORA instead of IOLMaster; 70% of these eyes were within ± 0.5D of target refraction; 26 eyes had IOL power chosen based on IOLMaster predictions instead of ORA; 65% were within ± 0.5D. In the group with IOLMaster without ORA measurements, 80% of eyes were within ± 0.5D of target refraction. The absolute error was statistically smaller in those eyes where the ORA and IOLMaster recommended the same IOL power based on pre-operative target refraction compared to instances in which IOL selection was based on ORA or IOLMaster alone. Neither prediction errors were statistically different between the ORA and IOLMaster alone. The authors concluded that intra-operative wavefront aberrometry with the ORA system provided post-operative refractive results comparable to conventional biometry with the IOLMaster for mono-focal IOL selection.

The authors stated that a drawback of the study was that there was no standardized pre-operative IOL calculation method, instead relying on surgeon's best choice. Most cases relied on the Holladay 1 formula, with some preference to SRK/T for eyes with longer axial length, and Hoffer Q for eyes with shorter axial length. This study did not compare the predictive errors of each individual prediction formula (i.e., Haigis versus Holladay 1 versus Hoffer Q, etc.), and this may prove beneficial in the future research by providing additional data to aid in comparison between groups. In general, the surgeon looked for agreement in various formulas when choosing an IOL. Regarding the few instances where ORA gave several different IOL powers during aphakic measurements, the IOL was selected to closely match that of the initial prediction by the IOL master. This may influence the data by introducing confounding and bias. However, these cases comprised a small portion of this study, and the IOL powers provided by ORA were also chosen with the patients’ post-operative goals in mind. In addition, in this study, several different types of IOLs were used although the majority consisted of ZCB00 or ZA9003 (Abbott Medical Optics, Santa Ana, CA), or SN60WF (Alcon, Fort Worth, TX). The use of different IOL types and A-constant modification may have influenced the pre-operative or intra-operative predictions. Other factors, such as patient fixation, intra-ocular pressure (IOP), external pressure from the
eyelid speculum, and viscoelastic versus balanced saline solution in the anterior chamber may also affect the accuracy of the ORA measurements. In this study, Healon was used in the anterior chamber for all ORA measurements, which very well may impact the predictions by ORA. In the future, additional studies to optimize these variables may be needed to determine the best conditions for intra-operative biometry.

Another drawback of this study centered arounds the cases when ORA recommended several different IOL powers during aphakic measurements. ORA depends on several variables (e.g., IOP, hydration, and external pressure), and these data were not recorded in this retrospective study. It may be useful in the future studies to focus on this issue as a possible limitation of ORA. Another drawback was only 121 patients out of 289 patients had recorded anterior chamber lengths in chart review. Other uses for intra-operative wavefront aberrometry included the measurement of cylindrical power and axes to determine the placement of limbal relaxing incisions (LRI) for astigmatism and as well as orientation and power of toric IOL implants. This study examined the accuracy of ORA in standard mono-focal non-toric IOLs only. While some surgeons already use this technology for LRIs, further studies to elucidate the value of intra-operative aberrometry specifically for toric IOL implantation, rotation, and residual post-operative cylinder would be useful.

Zhang (2018) reported a case of significant hyperopic outcome (both eyes) following ORA IOL power recommendation in a cataract patient with history of 8 cut radial keratotomy (RK) in each eye. It was hypothesized that increased IOP from phacoemulsification could make the RK cuts swell, and change cornea shape intra-operatively. In this unique scenario, the corneal curvature readings from ORA could be quite different from pre-operative readings or from stabilized post-operative corneal measurements. The change in corneal curvature could also affect the anterior chamber depth and axial length readings, skewing multiple parameters on which ORA bases recommendations for IOL power. The authors concluded that ORA has been widely used among cataract surgeons on patients with history of RK, but its validation, unlike for laser-assisted in-situ keratomileusis (LASIK) and photorefractive keratectomy (PRK), has yet to be established by peer reviewed studies. Surgeons should be cautious when using ORA on RK patients, especially for those patients who have more than 6 cuts.
CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td></td>
<td>CPT codes covered if selection criteria are met:</td>
</tr>
<tr>
<td>66820</td>
<td>Discussion of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); stab incision technique</td>
</tr>
<tr>
<td></td>
<td>(Ziegler or Wheeler knife)</td>
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<tr>
<td>66821</td>
<td>Laser surgery (e.g., YAG laser) (one or more stages)</td>
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<tr>
<td>66830 - 66986</td>
<td>Removal of cataract</td>
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<tr>
<td>76511</td>
<td>Ophthalmic ultrasound, diagnostic; quantitative A-scan only</td>
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<td>76516</td>
<td>Ophthalmic biometry by ultrasound echography, A-scan</td>
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<tr>
<td>76519</td>
<td>with intraocular lens power calculation</td>
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<td>92002 - 92004</td>
<td>Ophthalmologic services: medical examination and evaluation with initiation of diagnostic and treatment program, new patient</td>
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<tr>
<td>92012 - 92014</td>
<td>Ophthalmologic services: medical examination and evaluation with initiation of diagnostic and treatment program, established patient</td>
</tr>
<tr>
<td>92136</td>
<td>Ophthalmic biometry by partial coherence interferometry with intraocular lens power calculation</td>
</tr>
<tr>
<td></td>
<td>CPT codes not covered for indications listed in the CPB:</td>
</tr>
<tr>
<td>0333T</td>
<td>Visual evoked potential, screening of visual acuity, automated</td>
</tr>
<tr>
<td>0509T</td>
<td>Electoretinography (ERG) with interpretation and report, pattern (PERG)</td>
</tr>
<tr>
<td>76514</td>
<td>Ophthalmic ultrasound, diagnostic; corneal pachymetry, unilateral or bilateral (determination of corneal thickness)</td>
</tr>
<tr>
<td>92025</td>
<td>Computerized corneal topography, unilateral or bilateral, with interpretation and report</td>
</tr>
<tr>
<td>92081 - 92083</td>
<td>Visual field examination</td>
</tr>
<tr>
<td>92133</td>
<td>Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve</td>
</tr>
<tr>
<td>92134</td>
<td>retina</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>92265</td>
<td>Needle oculo electromyography, one or more extraocular muscles, one or both eyes, with interpretation and report</td>
</tr>
<tr>
<td>92270</td>
<td>Electro-oculography with interpretation and report</td>
</tr>
<tr>
<td>92273</td>
<td>Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG</td>
</tr>
<tr>
<td>92283</td>
<td>Color vision examination, extended, e.g., anomaloscope or equivalent</td>
</tr>
<tr>
<td>92285</td>
<td>External ocular photography with interpretation and report for documentation of medical progress (e.g., close-up photography, slit lamp photography, goniophotography, stereo-photography)</td>
</tr>
<tr>
<td>92286</td>
<td>Special anterior segment photography with interpretation and report; with specular endothelial microscopy and cell count</td>
</tr>
<tr>
<td>92287</td>
<td>with fluorescein angiography</td>
</tr>
<tr>
<td>95930</td>
<td>Visual evoked potentials (VEP) testing central nervous system, checkerboard or flash</td>
</tr>
</tbody>
</table>

Other CPT codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>65770</td>
<td>Keratoprosthesis</td>
</tr>
<tr>
<td>67005-67043</td>
<td>Vitreous procedures</td>
</tr>
<tr>
<td>67101-67113</td>
<td>Repair of retinal detachment</td>
</tr>
<tr>
<td>67880-67882</td>
<td>Tarsorrhaphy</td>
</tr>
<tr>
<td>76510</td>
<td>Ophthalmic ultrasound, diagnostic; B-scan and quantitative A-scan performed during the same patient encounter</td>
</tr>
<tr>
<td>76513</td>
<td>anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy</td>
</tr>
<tr>
<td>92100</td>
<td>Serial tonometry (separate procedure) with multiple measurements of intraocular pressure over an extended time period with interpretation and report, same day (e.g., diurnal curve or medical treatment of acute elevation of intraocular pressure)</td>
</tr>
</tbody>
</table>

HCPCS codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1780</td>
<td>Lens, intraocular (new technology) [standard fixed monofocal posterior chamber intraocular lenses (IOL) for aphakia only]</td>
</tr>
<tr>
<td>V2630</td>
<td>Anterior chamber intraocular lens</td>
</tr>
<tr>
<td>V2631</td>
<td>Iris supported intraocular lens</td>
</tr>
</tbody>
</table>

http://www.aetna.com/cpb/medical/data/500_599/0508.html

07/29/2019
<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V2632</td>
<td>Posterior chamber intraocular lens</td>
</tr>
</tbody>
</table>

HCPCS codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1004</td>
<td>New technology intraocular lens category 4 as defined in Federal</td>
</tr>
<tr>
<td></td>
<td>Register notice</td>
</tr>
<tr>
<td>Q1005</td>
<td>New technology intraocular lens category 5 as defined in Federal</td>
</tr>
<tr>
<td></td>
<td>Register notice</td>
</tr>
<tr>
<td>V2702</td>
<td>Deluxe lens feature</td>
</tr>
<tr>
<td>V2755</td>
<td>U-V lens, per lens</td>
</tr>
<tr>
<td>V2787</td>
<td>Astigmatism correcting function of intraocular lens</td>
</tr>
<tr>
<td>V2788</td>
<td>Presbyopia correcting function of intraocular lens</td>
</tr>
</tbody>
</table>

Other HCPCS codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>V2797</td>
<td>Vision supply, accessory, and/or service component of another HCPCS</td>
</tr>
<tr>
<td></td>
<td>vision code</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H25.011- H26.9</td>
<td>Cataract</td>
</tr>
<tr>
<td>H27.00 - H27.03</td>
<td>Aphakia</td>
</tr>
<tr>
<td>Q12.0</td>
<td>Congenital cataract</td>
</tr>
<tr>
<td>Q12.3</td>
<td>Congenital aphakia</td>
</tr>
</tbody>
</table>

B-scan Ultrasound:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B-scan (with or without superimposed non-quantitative A-scan)</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B94.0</td>
<td>Sequelae of trachoma</td>
</tr>
<tr>
<td>E50.6</td>
<td>Vitamin A deficiency with xerophthalmic scars of cornea</td>
</tr>
<tr>
<td>H02.841 - H02849</td>
<td>Edema of eyelid</td>
</tr>
<tr>
<td>H16.031 - H16.039</td>
<td>Corneal ulcer with hypopyon</td>
</tr>
<tr>
<td>H16.9</td>
<td>Unspecified keratitis</td>
</tr>
<tr>
<td>H17.00 - H17.9</td>
<td>Corneal scars and opacities</td>
</tr>
<tr>
<td>H18.20 - H18.239</td>
<td>Corneal edema</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


47. Centers for Medicare and Medicaid Services (CMS). Requirements for determining coverage of presbyopia-correcting intraocular lenses that provide two distinct services for the patient: (1) Restoration of distance vision following cataract surgery, and (2) Refractive correction of near and intermediate vision with less dependency on eyeglasses or contact lenses. CMS Rulings. Ruling No. 05-01. Baltimore, MD: CMS; May 3, 2005.


86. McCreery KM. Cataract in children. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2019.
91. Bower KS. Laser refractive surgery. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed May 2016.
AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0508 Cataract Removal Surgery

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania