LCD - Cataract Extraction (including Complex Cataract Surgery) (L35091)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania

Created on 09/10/2021. Page 1 of 13

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware District of Columbia Maryland New Jersey Pennsylvania

LCD Information

Document Information

LCD ID

L35091

LCD Title

Cataract Extraction (including Complex Cataract Surgery)

Proposed LCD in Comment Period N/A

Source Proposed LCD DL35091

Original Effective Date For services performed on or after 10/01/2015

Revision Effective Date For services performed on or after 07/11/2021

Revision Ending Date N/A

Retirement Date N/A

Notice Period Start Date 05/27/2021

Notice Period End Date 07/10/2021

CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2020 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Current Dental Terminology $\ensuremath{\mathbb{C}}$ 2020 American Dental Association. All rights reserved.

Copyright © 2013 - 2021, the American Hospital Association, Chicago, Illinois. Reproduced by CMS with permission. No portion of the American Hospital Association (AHA) copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816. You may also contact us at ub04@aha.org.

Determinations (NCDs) or payment policy rules and regulations for cataract extraction services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for cataract extraction services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, Medicare Benefit Policy Manual,
 - Chapter 15, Section 30.4 Optometrist's Services and Section 120 Prosthetic Devices
 - Chapter 16, Section 10 General Exclusions from Coverage and Section 90 Routine Services and Appliances
- CMS IOM Publication 100-03, Medicare National Coverage Determinations (NCD) Manual,
 - Chapter 1, Part 1, Section 10.1 Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery, Section 80.8 Endothelial Cell Photography, Section 80.10 Phaco-Emulsification Procedure -Cataract Extraction, and Section 80.12 Intraocular Lenses (IOLs)
- CMS IOM Publication 100-04, Medicare Claims Processing Manual,
 - Chapter 14, Section 40.3 Payment for Intraocular Lens (IOL)
 - Chapter 32, Section 120 Presbyopia-Correcting (P-C IOLS) and Astigmatism-Correcting Intraocular Lenses (A-C IOLs) (General Policy Information)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual,
 - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1832(a)(2)(F) defines ASC Surgical Services furnished in connection with surgical procedures.
- Title XVIII of the Social Security Act, Section 1833(t)(1)(B)(iii) states Implantable Items may be covered as defined in SSA Section 1861(s) in Hospital Outpatient Departments.
- Title XVIII of the Social Security Act, Section 1861(s)(1) describes Physicians' Services.
- Title XVIII of the Social Security Act, Section 1861(s)(2)(A) describes Incident To Physician's Professional Service.
- Title XVIII of the Social Security Act, Section 1861(s)(2)(B) describes Incident To Physician's Professional Service furnished to Hospital Outpatients.
- Title XVIII of the Social Security Act, Section 1861(s)(8) refers to Eyeglasses or Contact Lenses Furnished after Cataract Surgery With Insertion of IOL.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Cataracts occur frequently as a progressive, age-related disease that is the leading cause of blindness in the U.S. and accounts for 50% of visual impairment over the age of 40. Cataracts are the leading cause of treatable blindness among African Americans age 40 and older. As part of the aging process, the lens increases in thickness and weight causing hardening and compression on the nucleus eventually developing a yellow-brown color that changes the transparency of the lens. Cataracts have several different types that have their own anatomical location, pathology, and risk factors (e.g., nuclear, cortical, subcapsular [anterior and posterior], and mixed).

Cataracts can lead to blurred or distorted vision, glare problems, color vision defects, and a decline of contrast sensitivity and depth perception. These impairments lead to loss of balance, less independent mobility, falls, injuries, increased mortality risk, and decreased mental well-being. This raises more concern for the elderly population due to underlying systemic comorbidities. Visual function plays a major role in physical performance, mental well-being, and mobility for the elderly.¹ Risk factors for cataracts include diabetes mellitus, family history, hypertension, ionizing radiation, myopia, obesity, smoking, ultraviolet-B light exposure, long-term topical, systemic, or oral corticosteroid use, prior intraocular surgery, and lower level education.

Improving visual function and quality of life have increased the demand for cataract surgery. Since there are no pharmacologic treatments to eliminate cataracts, cataract surgery is the primary management of significant visual impairment.¹ Due to the different types of cataracts, the decision-making process for cataract surgery can be complex in determining the appropriate treatment, technique, devices, and complications to consider. Symptomatic cataract is a surgical disease and the standard of care in cataract surgery in the U.S. is a small-incision phacoemulsification with foldable intraocular lens (IOL) implantation.¹

In consideration for cataract surgery, cataract patients must have an impairment of visual function due to cataract(s) resulting in the decreased ability to carry out activities of daily living such as reading, viewing television, driving or meeting occupational or vocational expectations. This LCD provides medically reasonable and necessary indications for both routine and complex cataract surgery. Coverage will be based upon documentation that supports medical necessity and therefore covered by Medicare when one or more of the covered indications are present.

Covered Indications

Cataract Surgery will be considered medically reasonable and necessary when one or more of the following indications are present:

- Visual function no longer meets the patient's needs based on visual acuity, visual impairment, and potential for functional benefits.²
- 2. Visual Impairment and function are not correctable by glasses or other non-surgical measures.³
- 3. The patient has undergone a preoperative examination that documents the following:
 - Inability to function satisfactorily due to visual impairment while performing various Activities of Daily Living.^{1,2}
 - Confirmation that cataract is causing the visual impairment or other ocular or systemic conditions.¹
 - Cataract is causing unacceptable glare, polyopia, or reduced quality of vision.¹⁻³
- 4. There is clinically significant anisometropia in the presence of a cataract. 1,2

Created on 09/10/2021. Page 4 of 13

- 5. The lens opacity interferes with optimal diagnosis or management of posterior segment conditions.^{1,2}
- 6. The lens causes inflammation or secondary glaucoma (phacolysis, phaco-anaphylaxis).^{1,2}
- 7. There is worsening angle closure (phacomorphic glaucoma) due to increase in size of the crystalline lens. 1,2
- 8. A significant cataract is present in a patient who will be undergoing concurrent surgery in the same eye, such as a trabeculectomy or a corneal transplant when the surgeon deems that the decreased morbidity of single stage surgery is of significant benefit over surgery on separate dates.^{1,2}

Please refer to NCD 10.1-Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery for information on pre surgery evaluations.

Complex cataract surgery:

Indications:

Complex cataract surgery will be considered medically reasonable and necessary when there is one of the following:

- A miotic pupil that will not dilate sufficiently⁴ requiring the use of a mechanical iris expansion device (Iris retractors through four additional incisions, Beehler expansion device, or Malyugin ring) to adequately visualize the lens in the posterior chamber of the eye.⁴
- 2. Pre-existing zonular weakness requiring use of capsular tension rings or segments or intraocular suturing of the intraocular lens. 5
- 3. Pediatric cataract surgery, intraoperatively difficult because of an anterior capsule that is more difficult to tear, cortex that is more difficult to remove needing a primary posterior capsulotomy or capsulorrhexis.
- 4. Mature cataract requiring dye for visualization of capsulorrhexis.

Refer to CMS IOM Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 32, Section 120, for CMS guidelines on IOL insertion benefit following cataract surgery.

Limitations

The following are considered contraindicators to surgery for visually impairing cataract and are not considered medically reasonable and necessary:

- 1. Tolerable refractive correction that provides vision and meets the patient's needs and desires.²
- The patient's lifestyle is not compromised by the cataract and they are able to perform activities of daily living. 1,2
- 3. The patient cannot safely undergo surgery because of coexisting medical or ocular conditions. 1,2
- 4. Surgery is not expected to improve visual function, or no other indication for lens removal exists.^{1,2}

Provider Qualifications

Services will be considered medically reasonable and necessary when all aspects of care are within the scope of practice of the provider's professional licensure, when performed according to the supervision requirements per state scope of practice laws, and when all procedures are performed by appropriately trained providers in the appropriate setting.

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing

CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

The content of this LCD is supported through an evidence-based literature search of articles and publications through PubMed. We identified articles based on a key word search for: indications for complex cataract surgery, miotic pupil or small pupil in complex cataract surgery, and pseudoexfoliation in complex cataract surgery. The literature search was filtered to find articles within 5-10 years, with one exception where an article dated back to 2001. Filters also included full text articles, clinical trials, randomized controlled trials, and systematic reviews. Below is a summary of evidence to support the medically reasonable and necessary indications for Cataract Extraction (Including Complex Cataract Surgery) and explanation of limitations.

Michalska-Malecka, et al³ conducted a study at University Hospital No. 5 of the Medical University of Silesia between 2008-2009. In this retrospective study, Michalaska-Malecka and his colleagues set out to investigate the effectiveness and safety of cataract surgery and IOL implantation for patients aged 90 years or older (43 men and 79 women). Patients considered for the study had significant bilateral cataracts causing visual impairment not correctable by glasses, best corrected visual acuity (BCVA) score worse than 0.7, an unacceptable glare, polyopia, or overall reduced vision quality due to cataracts. As this study focuses on the very elderly population, Michalska-Malecka noted that coexisting systemic disorders, patient cooperation during surgery, higher incidence of hard nucleus, smaller pupil size and high rate of pseudoexfoliation syndrome make it difficult to perform cataract surgery. Individuals that were excluded from the study were those that were under the age of 90, had a BCVA score of 0.7 or greater, a baseline endothelial cell density of less than 1,500 cells/mm, uncontrolled glaucoma, and physical or mental disability that would make it difficult to perform the surgery. According to Michalska-Malecka, cataracts are one of the most frequent reasons for visual impairment around the world. As cataracts and its visual impairment reduces quality of life, phacoemulsification surgery and extracapsular cataract extraction have proven to be effective with increasing visual acuity. In this study, phacoemulsification was performed on 113 of 122 eyes and extracapsular cataract extraction (ECCE) was performed on 9 of 122 eyes. Visual acuity was increased after the first postoperative day, 3 months, and 6 months after surgery. The BCVA scores improved in 100 out of the 122 patients (82%) with senile cataracts from this study. Visual acuity results remained the same in 20 of the patients and decreased in 2 of the patients because of co-existing age-related macular degeneration (AMD). The Intraocular pressure (IOP) in patients with or without glaucoma were shown to have little to no postoperative differences than preoperatively. Patients with glaucoma had a significant difference in IOP, postoperatively, while the patients without glaucoma had no difference. These results show that cataract surgery is safe and effective in the treatment of senile cataracts in the very elderly population. Michalaska-Malecka states, "Little evidence has been found to support the hypothesis that age alone is a risk factor for phaco-cataract surgery for intraoperative complications."¹¹

Bargoud et al⁴ and colleagues conducted a retrospective, observational cohort study with the aim to see whether complex cataract surgery using the phacoemulsification technique and a mechanical iris expansion device (iris hooks, Kuglen hooks, and Malyugin rings) will lower IOP for patients with glaucoma. Bargoud⁴ mentions the importance of this study in glaucoma patients with the modifiable risk factor of increased IOP. However, a significantly higher proportion of patients with glaucoma have been found to have smaller pupils compared with similar control groups, and on patients who underwent cataract surgery, they require iris manipulation and pupil expansion more frequently. This study was conducted at the University Hospital in Newark, New Jersey of surgeries from 2008-2016. The study was comprised of two groups: the primary open angle closure group and the control group that included patients without primary open-angle glaucoma (POAG) who underwent phacoemulsification with intraoperative mechanical pupillary expansion. Thirty-seven eyes from the 31 glaucoma patients (5 with mature cataracts) and 29 eyes from the 28 control patients (3 with mature cataracts) were included in the study and met the inclusion criteria. The other eyes in both groups had non-mature cataracts. Inclusion criteria focused on eyes that were diagnosed with POAG and had no prior incisional surgery for 1 year or 1 year after. Exclusion criteria included 1. eyes that had no confirmed glaucoma diagnosis, 2. had non-POAG types of glaucoma such as neovascular, uveitic, or chronic angle closure, 3. prior incisional glaucoma surgery, 4. eyes that had a phacoemulsification that was combined with another surgery and pupillary expansion devices was not confirmed from the operative report, and 5. had a vitrectomy, anterior

chamber intraocular lens, and/or sulcus placement or conversion to large incisional surgery. The POAG group was significantly older than the control group at the time of surgery (72.5 ± 10.2 versus 65.3 ± 11.5 years old; p = 0.01). However, there were no significant differences in the proportions of hypertension, diabetes, or hyperlipidemia between the control and the POAG group. The study shows an increase 15.0 ± 4.6 to 15.9 ± 3.5 in IOP in the POAG group while the control group shows a decrease 14.1 ± 3.6 to 11.9 ± 3.9 at 12 months postoperative. Throughout the follow up period the control group showed significant decrease in IOP while the POAG group, more specifically the control group. More complications were noted in the POAG group than the control group. Complex cataract surgery did not decrease the IOP in patients with primary open angle glaucoma. However, it did improve visual acuity and reduced medication burden in the POAG group. Complex cataract surgery did, however, decrease IOP in patients without POAG and improve visual acuity. This study shows that complex cataract surgery, such as phacoemulsification with intraoperative mechanical pupillary expansion is useful in improvements of cataracts and glaucoma.

Miyoshi⁵ and colleagues conducted a retrospective study to assess the effects of using the capsular tension ring (CTR) on the surgical outcomes of toric and multifocal IOLs in eyes with zonular instability. A total of 55 eyes from 43 patients (70.7 \pm 10.3 years old) were included who were high risk for zonular instability that included pseudoexfoliation, shallow anterior chamber, high myopia, phacodonesis, or unstable zonules. A total of 55 eyes from 43 patients (70.7 ± 10.3 years old) were included in this retrospective study undergoing phacoemulsification and IOL implantation using CTR on toric and multifocal IOLs. These eyes were at high risk for zonular instability that included pseudoexfoliation, shallow anterior chamber, high myopia, phacodonesis, or unstable zonules. The Toric IOL group had 9 eyes with CTR and 22 eyes without CTR while the multifocal IOL had 9 eyes with CTR and 15 eyes without CTR. No history of ocular surgery other than cataract removal was reported. The exclusion criteria included any eyes that experienced intraoperative complications affecting the IOL stability, except for zonular instability. One surgeon performed all cases using a standard technique of phacoemulsification through a 2.4-mm temporal clear corneal incision. Patients were followed up for 3 months. Manifest refraction, refractive astigmatism, visual acuity, and degree of IOL decentration and tilt were measured using swept-source anterior segment optical coherence tomography. Axis misalignment of Toric IOLs was also evaluated. Results show that the decentration and axis misalignment of the Toric group was smaller with the CTR than without (p = 0.037), better visual acuity with CTR than without, and a smaller axis misalignment with CTR (p = 0.037). Although the multifocal group prevented IOL tilt, manifested better visual acuity with CTR than without (p = 0.021), and had a smaller degree of tilt in CTR than without (p = 0.025), the follow up period was longer with CTR. There were a few limitations in this study to include a random assignment of eyes to CTR or non-CTR by the judgement of the surgeon, the follow-up period was significantly longer in the multifocal IOL without CTR group than the multifocal IOL with CTR group, measurements of wave-front aberration were not conducted in this study, and no evaluation was done on the multifocal Toric IOLs. Overall, the end results show that the outcome of Toric IOLs co-implantation of CTR significantly reduce decentration and toxic axis misalignment that improves uncorrected and corrected visual acuity postoperatively. In multifocal IOLs, the combined use of CTR significantly prevented IOL tilt and resulted in better uncorrected visual acuity. This study shows that CTR is a useful device to improve surgical outcomes of premium IOL in eyes at high risk of compromised zonular integrity.

Vazquez-Ferreiro⁶ and colleagues conducted a systematic review and meta-analysis to evaluate the association pseudoexfoliation syndrome has on IOL dislocation after having phacoemulsification cataract surgery. The aim was to identify pseudoexfoliation as a risk factor for IOL dislocation and explore other related factors from the surgery. Two reviewers performed a systematic search of several cohort studies, case–control studies and clinical trials to include in this analysis were PubMed MEDLINE, Embase, Web of Science, Cochrane, and Lilacs database. All resources were used for searches specific to IOL dislocation in patients with and without pseudoexfoliation syndrome who had undergone phacoemulsification. The meta-analysis of this review included 2 questions of interest: 1. Do patients with pseudoexfoliation syndrome have a clinically relevant increased risk of late IOL dislocation compared with patients without this syndrome? 2. Can the risk of late lens IOL dislocation in patients with pseudoexfoliation compared with patients without this syndrome? 2. Can the risk of late lens IOL dislocation in patients with pseudoexfoliation compared with patients without this syndrome? 2. Can the risk of late lens IOL dislocation in patients with pseudoexfoliation be reduced using hooks, retractors, rings, or other devices to reduce incision size? Inclusion criteria focused on articles that provided enough data with which to calculate odds ratios (ORs) and corresponding confidence intervals (CIs) for IOL

dislocation. A few specific data that were extracted for this analysis to mention are sample size, study setting, study population, use of hooks or retractors, type of cataract, study design, etc. A total of 859 articles were retrieved and only 14 articles met the inclusion criteria. All were cohort studies, excluding one that was a case-control study. Only 2 studies were from the United States. The overall OR for IOL dislocation was 6.02 (95% CI: 3.70; 9.79), with a p < 0.0001 suggest that patients with pseudoexfoliation are very prone to IOL dislocation. A reduction in IOL dislocation in patients with pseudoexfoliation syndrome was not noticeable, however there was no significant increase in the ORs throughout the different quarters. The odds of IOL dislocation in patients with pseudoexfoliation sizes have reduced the risk of IOL dislocation. The findings suggest that there is a high risk for late IOL dislocation in patients with pseudoexfoliation in patients with pseudoexfoliation cataract surgery. Suggestions point to larger incision sizes and the use of hooks and retractors during surgery as a contributing factor to the increased high risk of IOL dislocation. More studies are suggested to assess the long-term effects and if improvements to techniques will change the variables.

Society Evidence

According to the American Academy of Ophthalmology (AAO) 2011 et al,² cataract surgery is primarily recommended for visual function that no longer meets the patient's needs and should be considered based on visual acuity, visual impairment, and potential for functional benefits. The preoperative evaluation should not be solely based on a visual Snellen exam, but to include an ophthalmic evaluation, patient-centered visual function exams and questionnaires, and patient education about treatment options prior to consent. The AAO has set characterizations to ensure that improved visual function, physical function, and mental health is restored after cataract surgery. Cataract surgery is also known to decrease IOP after phacoemulsification cataract surgery in patients with or without glaucoma. Alternatives to cataract surgery and management of cataract are very few. Chang (2011), displays outcomes from studies that prove cataract surgery to be effective when considered in the AAO's practice patterns for cataract surgery guidelines. Across the studies mentioned, patients have improved BCVA scores, increased visual acuity, and were overall satisfied with the results of their surgery and improvement in quality of life. The AAO mentions, "the ASCRS National Cataract Database reported that at 3 months postoperatively 85.5% of all patients had a 20/40 or better BCVA, 57.2% of patients had 20/25 or better postoperative BCVA, and 74.6% of patients were within \pm D of target spherical equivalent. In studies of phacoemulsification cataract surgery performed by ophthalmology residents, the reported range of patients with postoperative BCVA of 20/40 or better was 80% to 91%." The only major potentially eye-threatening complications of cataract surgery are infectious endophthalmitis, toxic anterior segment syndrome (TASS), intraoperative suprachoroidal hemorrhage, cystoid macular edema (CME), retinal detachment, persistent corneal edema, and IOL dislocation. Comparing studies have shown that patients who receive cataract surgery in both eyes have greater functional improvement than those that had surgery in one eye. Although bilateral cataract surgery is beneficial, if both eyes show significant indications for it, determining the appropriate time interval between the first eye surgery and the second eye surgery is complex and influenced by several factors. Same-day bilateral cataract surgery is pending more evidence for safety and other concerns.

According to the AAO 2016 et al,¹ symptomatic cataract is a surgical disease and the standard of care in cataract surgery in the U.S. is a small-incision phacoemulsification with foldable IOL implantation. Cataracts are the leading cause of treatable blindness among African Americans age 40 and older. Lower level education has been added as one of the risk factors of cataracts. As part of the aging process, the lens increases in thickness and weight causing hardening and compression on the nucleus. The lens eventually develops a yellow-brown color that changes the transparency. In order to confirm that a cataract is causing the visual impairment rather than another ocular or systemic condition, a comprehensive evaluation should be conducted. Cataract surgery is the primary management of significant visual impairment. The complexity of cataract surgery requires special training, clinical experience, and judgment that are necessary to evaluate the medical, ocular, and psychosocial factors used to determine the appropriateness and timing of surgery. There are no pharmacologic treatments to eliminate cataracts. Visual function plays a major role in physical performance, mental well-being, and mobility for the elderly. Visual impairment increases the risk for falls and hip fractures in the elderly. Improved vision can reduce the fear of falling, which is one of the listed outcomes for characterized improvement in mental health and emotional well-being in the elderly. The

indications, contraindications, and complications for cataract surgery are the same. Multiple studies that were used for the AAO's preferred practice pattern show that BCVA scores improved, over 90% of patients, postoperatively, had improved visual acuity and improvement in VF-14 scores, and that the strongest preoperative indicator for visual function improvement is the glare disability test at low and medium spatial frequencies. Overall, cataract surgery is safe and effective for young adults and the elderly population. It reaches its goal of improving visual function and enhancing quality of life. The preferred practice patterns set by AAO, have clear guidelines that are suited to promote optimal health and a clear path of treating adult cataract patients.

The American College of Surgeons National Surgical Quality Improvement Program, the Geriatrics Healthcare Professionals, the American Geriatrics Society, and the John A. Hartford Foundation, have partnered to develop a geriatric assessment and guidelines for preoperative management. In a 2010 study, seventy percent of the patients over 60 years old lacked the decision-making capacity and over half of that population were required to make decisions about their treatment and final days of life. Preoperative treatment can sometimes require fasting, antibiotic prophylaxis, venous thromboembolism prophylaxis, and medication management, in which, proper planning and coordinating are required. Risk for falls are prevalent in the elderly population. Fall prevention was significantly reduced and found to include supervised exercises, environmental elements, assistive technology, and knowledge interventions according to a 2010 Cochrane review. In addition to preventing some of these age-related complications discussed above, reduction of cost and length of hospital stay, reduced risk of mortality, increased likelihood of discharge to home, improved care transitions, and improved patient satisfaction and functional status at discharge are some of the key components addressed in the guidelines for the geriatrics models of care.⁷

Analysis of Evidence (Rationale for Determination)

The evidence of literature supports that cataract surgery, including complex surgery, is a safe and effective procedure improving visual acuity and enhancing quality of life in adults and the elderly population with few intraoperative and postoperative complications.¹⁻³ The most frequent complication following cataract surgery in the very elderly population is posterior capsule tear without vitreous loss and corneal decompression according to Michalska.³ Olson and Chang, mention the only major potentially eye-threatening complications of cataract surgery are infectious endophthalmitis, TASS, intraoperative suprachoroidal hemorrhage, CME, retinal detachment, persistent corneal edema, and IOL dislocation.^{1,2}

Across the studies, patients have shown postoperative improvements in visual acuity, intraocular pressure, and function abilities. In a small prospective study conducted by Dunman et al⁸ Berg Balance Scale scores, Tinetti Gait test scores, and Tinetti Balance test scores, for functional balance all increased postoperatively after 1 month. In a retrospective study conducted by Michalska-Malecka,³ the BCVA scores improved in 100 out of the 122 patients (82%) with senile cataracts postoperative and at follow up. Lastly, in a retrospective, observational cohort study, complex cataract surgery did not decrease the intraocular pressure in patients with POAG. However, it did improve visual acuity and reduced medication burden in the POAG group. Complex Cataract surgery did, however, decrease IOP in patients without primary open angle glaucoma and improved visual acuity.⁴

Societies such as the AAO, the Ophthalmology Variation Analysis Committee: Optimum Physician Alliance, the American Society of Cataract and Refractive Surgery, and the European Society of Cataract & Refractive Surgeons are all in support of cataract surgery, including complex cataract surgery for its safe and effective methods of treatment for cataract and other ocular diseases.

More studies are needed to determine the safety between simultaneous or sequential bilateral cataract surgery.⁹ Based on the literature, limited coverage will be provided for cataract surgery, including complex cataract surgery as outlined in the LCD.

General Information

Created on 09/10/2021. Page 9 of 13

Please refer to the related Local Coverage Article: Billing and Coding: Cataract Extraction (including Complex Cataract Surgery) A56615 for documentation requirements, utilization parameters and all coding information as applicable.

Sources of Information

N/A

Bibliography

- 1. Olson R, Braga-Mele R, Chen S, et al. Cataract in the adult eye preferred practice pattern. *American Academy of Ophthalmology*. http://dx.doi.org/10.1016/j.ophtha.2016.09.027. Published 2016. Accessed October 22, 2020.
- 2. Chang DF, Henderson BA, Lee RH, et al. Preferred practice pattern: Cataract in the adult eye. *American Academy of Ophthalmology*. http://bdoc.info/dl/informationen/Cataract-in-the-Adult-Eye-2011-AAO-komplett.pdf. Published 2011. Accessed October 22, 2020.
- 3. Michalska-Malecka K, Nowak M, Gosciniewicz P, et al. Results of cataract surgery in the very elderly population. *Dove Press Journal.* 2013;8:1041-1046.
- 4. Bargoud A, Parikh H, Kalbag N, Greenberg P, Khouri A. Outcomes of Complex Cataract Surgery in Patients with Primary Open-angle Glaucoma. *Journal of Current Glaucoma Practice*. 2019;13(2):62-67.
- Miyoshi T, Fujie S, Yoshida H, Iwamoto H, Tsukamoto H, Oshika T. Effects of capsular tension ring on surgical outcomes of premium intraocular lens in patients with suspected zonular weakness. *PLOS ONE*. 2020;15(2):1-8.
- Vazquez-Ferreiro P, Carrera-Hueso F, Fikri-Benbrahim N, Barreiro-Rodriguez L, Diaz-Rey M, Barrios M. Intraocular lens dislocation in pseudoexfoliation: a systematic review and meta-analysis. *Acta Ophthalmologica* . 2017;95(3):e164-e169.
- Mohanty S, Rosenthal R, Russel M, Neuman M, Ko C, Esnaola N. Optimal perioperative management of the geriatric patient: Best practices guideline from ACS NSQIP/American Geriatrics Society. *J Am Coll Surg.* 2016:222(5):930-947.
- 8. Duman F, Kilic Z, Ozcan-Eksi E. Impact of cataract surgery on functional balance skills of adults. *Turk J Ophthalmol*. 2019;49:243-249.
- 9. Zuo L, Zou H, Fei X, Xu W, Zhang J. The impact of unilateral or bilateral cataract surgery on visual acuity and life quality of elderly patients. *Journal of Ophthalmology*. 2015;509049.
- 10. Jhanji, V,Chan, E, Das, S, Zhang, H, Vajpayee, RB. Trypan blue dye for anterior segment surgeries. *Eye*. 2011;25:1113-1120.
- 11. Craven ER, Katz J, Wells J, Giamporcaro JE. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: Two-year follow-up. *J Cataract Refract Surg*. 2012;38(8):1339-1345. doi.org/10.1016/j.jcrs.2012.03.025.
- 12. Perioperative Guideline. Institute for Clinical Systems Improvement Web site. www.icsi.org. Accessed October 22, 2020.
- 13. Li E, Margo C, Greenberg P. A primary care provider's guide to cataract surgery in the very elderly. *Federal Practitioner.* 2019;36(4):176-180.
- 14. Tabatabaei SA, Rajabi M, Tabatabaei SM, Soleimani M, Rahimi F, Yaseri M. Early versus late traumatic cataract surgery and intraocular lens implantation. *Eye*. 2017;31:1199-1204.
- Lundstrom M, Goh P, Henry Y, et al. The changing pattern of cataract surgery indications: A 5-year study of 2 cataract surgery databases. *American Academy of Ophthalmology*. 2015;122:31-38. doi:10.1016/j.ophtha.2014.07.047.
- 16. Grzybowski A, Kanclerz P, Huerva V, Ascaso F, Tuuminen R. Diabetes and phacoemulsification Cataract Surgery: Difficulties, risks and potential complications. *J. Clin. Med.* 2019;8(5):716. doi:10.3390/jcm8050716.

- 17. Papaconstantinou D, Kalantzis G, Brouzas D. Safety and efficacy of phacoemulsification and intraocular lens implantation through a small pupil using minimal iris manipulation. *Clinical Interventions in Aging*. 2016;11:651-657.
- Jensen E, Myers D. Preoperative guidelines for cataract surgery in the ambulatory surgery setting. *Optimum Physician Alliance*. https://opawny.com/files/preoperativeguidelinesforcataractsurgery_v3.pdf. Published 2020. Accessed October 23, 2020.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
07/11/2021	R11	LCD revised and published 09/09/2021 effective for dates of service on and after 07/11/2021 in response to an inquiry. The 'Covered Indications' section for 'Complex Cataract Surgery' was revised to add a covered indication for 'mature cataract requiring dye for visualization of capsulorrhexis'. Minor formatting changes were also made throughout.	• Other (In response to an inquiry)
07/11/2021	R10	LCD revised and published 7/8/2021 to reflect a typographical correction to LCD becoming effective 07/11/2021.	Typographical Error
07/11/2021	R9	LCD posted for notice on 05/27/2021 to become effective 07/11/2021. Proposed LCD posted for comment on 01/14/2021. 2020PITLAB015	 Request for Coverage by a Practitioner (Part B) Creation of Uniform LCDs With Other MAC Jurisdiction
11/07/2019	R8	LCD revised and published 11/7/2019 to completely remove the Coding Information Section from this LCD per CMS Change Request 10901. Please see the related Billing and Coding Article, A56615 for all codes and information related to coding and billing.	 Other (CMS Change Request 10901)
06/13/2019	R7	Article revised and published on 06/20/2019 to correct a typographical error in Revision History Number 6 (R6) below. The incorrect publication date was listed in the R6 Revision History Explanation. The correct publication date for R6 is 06/13/2019. There has been no change in content to the LCD.	• Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
06/13/2019	R6	LCD revised and published on 05/30/2019. Consistent with Change Request (CR) 10901 all CPT and ICD-10 codes have been removed from the LCD and placed in the related Billing and Coding Article, A56615. A link to A56615 has been added as a related document. There has been no change in coverage with this LCD revision.	 Other (Change in LCD process per CMS CR 10901)
03/28/2019	R5	LCD revised and published on 03/28/2019. The IOM Citation section was revised to add applicable manual reference for IOM language removed per CMS Change Request (CR) 10901 and to remove the reference to NCCI as it is a coding directive and not reasonable and necessary direction. Standard LCD format changes made for consistency. References listed in the Sources section of the LCD have been moved to the Bibliography section. Links have been added to the relevant NCDs. There has been no change in content to the LCD.	 Other (Change in LCD process per CMS CR 10901)
08/10/2017	R4	LCD revised and published on 08/10/2017 to update IOM Citations and Social Security Act (Title XVIII) Standard References per LCD Annual review. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy	 Other (Update to IOM Citations and Social Security Act Standard References)
10/01/2015	R3	LCD revised and published on 05/12/2016 to remove language requiring the beneficiary to sign a form pertaining to documented impairment.	 Reconsideration Request Other (Inquiry)
10/01/2015	R2	LCD revised and published on 09/11/2014, effective for dates of service on or after 10/01/2015 to remove the language that Medicare would not expect to see bilateral cataract extractions routinely performed on the same day. Utilization guideline limitations language removed from the LCD.	 Provider Education/Guidance
10/01/2015	R1	LCD revised effective 10/01/2014 to modify requirements on pre-operative visual function testing, as well as to help clarify one of the documentation requirements. Asterisk notes reformatted. (LCD updated on 06/06/2014)	 Creation of Uniform LCDs With Other MAC Jurisdiction Other (06/06/2014

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
			update in response to Reconsideration Request)

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A56615 - Billing and Coding: Cataract Extraction (including Complex Cataract Surgery)

A58764 - Response to Comments: Cataract Extraction (including Complex Cataract Surgery)

LCDs

DL35091 - Cataract Extraction (including Complex Cataract Surgery)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS	
09/03/2021	07/11/2021 - N/A	Currently in Effect (This Version)	
07/01/2021	07/11/2021 - N/A	Superseded	
05/21/2021	07/11/2021 - N/A	Superseded	
11/01/2019	11/07/2019 - 07/10/2021	Superseded	
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.			

Keywords

N/A