



BlueCross BlueShield  
of Alabama

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**Name of Policy:**

**Anterior Eye Segment Optical Imaging**

Policy #: 311  
Category: Other

Latest Review Date: February 2014  
Policy Grade: C

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**Background/Definitions:**

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

## **Description of Procedure or Service:**

Optical coherence tomography (OCT) is a high resolution method of imaging the ocular structures. OCT for the anterior eye segment is being evaluated as a rapid and non-invasive diagnostic and screening tool for the detection of angle closure glaucoma, to assess corneal thickness and opacity, lens thickness, evaluate postsurgical anterior chamber anatomy, calculate intraocular lens power, guide laser-assisted cataract surgery, assess complications following surgical procedures and to image phakic intraocular lenses and intracorneal ring segments. It is also being studied in relation to pathologic processes such as dry eye syndrome, tumors, uveitis, and infections.

The classification of glaucoma (primary open angle or angle closure) relies heavily on knowledge of the anterior segment (AS) anatomy, particularly that of the AC angle. Angle closure glaucoma is characterized by obstruction of aqueous fluid drainage through the trabecular meshwork (the primary fluid egress site) from the eye's AC. The width of the angle is one factor affecting the drainage of aqueous humor. A wide unobstructed iridocorneal angle allows sufficient drainage of aqueous humor, whereas a narrow angle may impede the drainage system and leave the patient susceptible to angle closure glaucoma. The treatment for this condition is a peripheral iridotomy (laser) or peripheral iridectomy (surgery).

Slit lamp biomicroscopy is used to evaluate the anterior chamber; however, the chamber angle can only be examined with specialized lenses, the most common of these being the gonioscopic mirror. In this procedure a gonio lens is applied to the surface of the cornea under topical anesthesia and the image magnified with the slit lamp. Gonioscopy is the standard method for clinically assessing the anterior chamber angle. Other techniques for imaging the anterior eye segment include ultrasonography and optical coherence tomography (OCT).

Ultrasonography uses high-frequency mechanical pulses (10 to 20 MHz) to build up a picture of the front of the eye. An ultrasound scan along the optical axis assesses corneal thickness, AC depth, lens thickness, and axial length. Ultrasound scanning across the eye creates a 2-dimensional image of the ocular structures. It has a resolution of 100 microns but only moderately high intraobserver and low interobserver reproducibility. Ultrasound biomicroscopy (approximately 50 MHz) has a resolution of 30 to 50 microns. As with gonioscopy, this technique requires placement of a probe under topical anesthesia.

OCT is a non-invasive method that creates an image of light reflected from the ocular structures. In this technique, a reflected light beam interacts with a reference light beam. The coherent (positive) interference between the 2 beams (reflected and reference) is measured by an interferometer, allowing construction of an image of the ocular structures. This method allows cross-sectional imaging at a resolution of 6 to 25 microns. The Stratus OCT™ (Carl Zeiss Meditec), which uses a 0.8-micron wavelength light source, was designed for evaluating the optic nerve head, retinal nerve fiber layer, and retinal thickness (see policy #465-Ophthalmologic Technique for Evaluating Glaucoma). The Zeiss Visante OCT™ and AC Cornea OCT (Ophthalmic Technologies) use a 1.3-micron wavelength light source designed specifically for imaging the anterior eye segment. Light of this wavelength penetrates the sclera, allowing high-resolution cross-sectional imaging of the AC angle and ciliary body. The light is, however, typically blocked by pigment, preventing exploration behind the iris. Ultrahigh resolution OCT

can achieve a spatial resolution of 1.3 microns, allowing imaging and measurement of corneal layers.

An early application of OCT technology was the evaluation of the cornea before and after refractive surgery. Since this is a non-invasive procedure that can be conducted by a technician, it has been proposed that this device may provide a rapid diagnostic and screening tool for the detection of angle closure in glaucoma. In addition, the non-contact method eliminates patient discomfort and inadvertent compression of the globe. Also being investigated is the possibility that the 0.8 micron wavelength Stratus OCT, which is already available in a number of eye departments, may provide sufficient detail for routine clinical assessment of the anterior chamber angle in glaucoma patients. Add-on lens are also available for imaging the anterior segment with OCT devices designed for posterior segment imaging.

In addition to the evaluation of AC angle, OCT is being evaluated to assess corneal thickness and opacity, evaluate presurgical and postsurgical AC anatomy, calculate intraocular lens power, guide laser-assisted cataract surgery, assess complications following surgical procedures (e.g., blockage of glaucoma tubes, detachment of Descemet membrane, disrupted keratoprosthesis-cornea interface), and to image intracorneal ring segments. It is also being studied in relation to pathologic processes such as dry eye syndrome, tumors, uveitis, and infections.

### **Policy:**

**Scanning computerized ophthalmic (e.g., OCT) imaging does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

### **Key Points:**

A search of the MEDLINE database was initially performed in December 2007, focusing on the use of anterior imaging with OCT to diagnose or manage closed angle glaucoma. The literature search identified a number of technical reviews; however, clinical research at the time this policy was created appeared to be at an early stage of development. The evidence for this policy has been periodically updated, with the most recent search of the MEDLINE database performed through January 23, 2014. Recent literature searches have found numerous studies that use OCT to evaluate the anatomy of the AS and report qualitative and quantitative imaging and detection capabilities. Although these studies provide evidence for the technical performance of OCT, assessment of a diagnostic technology typically focuses on 3 domains: 1) technical performance; 2) diagnostic performance (sensitivity, specificity, positive and negative predictive value) in appropriate populations of patients; and 3) demonstration that the diagnostic information can be

used to improve patient outcomes. This policy focuses specifically on evidence for diagnostic performance of the technology and the effect on health outcomes (clinical utility).

## **Diagnostic Performance**

### Optical Coherence Tomography versus Gonioscopy

Several studies have compared OCT with gonioscopy for the detection of primary angle closure. For example, Nolan et al assessed the ability of a prototype of the Visante OCT to detect primary angle closure in 203 Asian patients. The patients, recruited from glaucoma clinics, had been diagnosed with primary angle closure, primary open-angle glaucoma, ocular hypertension, and cataracts; some had previously been treated with iridotomy. Images were assessed by 2 glaucoma experts, and the results compared with an independently obtained reference standard (gonioscopy). Data were reported from 342 eyes of 200 individuals. A closed angle was identified in 152 eyes with gonioscopy and 228 eyes with OCT; agreement was obtained between the 2 methods in 143 eyes. Although these results suggest low specificity for OCT, it is noted that gonioscopy is not considered to be a criterion standard. The authors suggest 3 possible reasons for the increase in identification of closed angles with OCT: lighting is known to affect angle closure, and the lighting conditions were different for the 2 methods (gonioscopy requires some light); placement of the gonioscopy lens on the globe may have caused distortion of the AS; and landmarks are not the same with the 2 methods. The authors noted that longitudinal studies will be required to determine whether eyes classified as closed by OCT, but not by gonioscopy, are at risk of developing primary angle closure glaucoma.

Narayanaswamy et al conducted a community-based cross-sectional study of glaucoma screening. The study population consisted of individuals 50 years or older who underwent ASOCT by a single ophthalmologist and gonioscopy by an ophthalmologist who was masked to the OCT findings. Individuals were excluded if they had a history of intraocular surgery, any evidence of aphakia/pseudophakia, or penetrating trauma in the eye; previous AS laser treatment; a history of glaucoma; or corneal disorders such as corneal endothelial dystrophy, corneal opacity, or pterygium, all of which could influence the quality of angle imaging by OCT. The angle opening distance (AOD) was calculated at 250, 500, and 750 microns from the scleral spur. Of 2047 individuals examined, 28% were excluded due to inability to locate the scleral spur (n=515), poor image quality (n=28), or software delineation errors (n=39). Of the remaining 1465 participants, 315 (21.5%) had narrow angles on gonioscopy, defined as having a narrow angle if the posterior pigmented trabecular meshwork was not visible for at least 180 degrees on nonindentation gonioscopy with the eye in the primary position. Out of those who had an acceptable image, the area under the receiver operating characteristic curve was highest at 750 microns from the scleral spur in the nasal (0.90) and temporal (0.91) quadrants. A noted limitation of this quantitative technique for screening of angle closure glaucoma was the inability to define the scleral spur in 25% of the study population.

A 2009 publication also examined the sensitivity and specificity of the Visante OCT when using different cutoff values for the AOD measured at 250, 500, and 750 microns from the scleral spur. OCT and gonioscopy records were available for 303 eyes of 155 patients seen at a glaucoma clinic. The patients were asked to look at prepositioned targets to prevent image distortion with low- and high-resolution OCT. The parameters analyzed could not be measured by commercially available software at the time of the study, so the images were converted to a format that could

be analyzed by ultrasound biomicroscopy software. Blinded analysis showed sensitivity and specificity between 70% and 80% (in comparison with gonioscopy), depending on the AOD and the cutoff value. Correlation coefficients between the qualitative gonioscopy grade and quantitative OCT measurement ranged from 0.75 (AOD 250) to 0.88 (AOD 750). As noted by these investigators, “a truer measure of occludable angles is whether an eye develops angle-closure glaucoma in the future.” Long-term follow-up of patients examined with these 2 methods would be informative.

A prospective observational study (n=26) evaluated imaging of the anterior angle chamber with the Stratus OCT, which had been developed for retinal imaging. Ten eyes with normal open angles and 16 eyes with narrow or closed angles or plateau iris configuration, as determined by gonioscopy, were assessed. The OCT image was rated for quality, ability to demonstrate the AC angle, and for ability to visualize the iris configuration; patients were classified as having open angles, narrow angles, closed angles, or plateau iris configuration. Ultrasound biomicroscopy (UBM) was performed for comparison if plateau iris configuration was diagnosed. The investigators reported that the Stratus OCT provided high-resolution images of iris configuration and narrow or closed angles, and imaging of the angle was found to be adequate in cases of acute angle-closure glaucoma, in which the cornea was too cloudy to enable a clear gonioscopic view. Open angles and plateau iris configurations could not be visualized with the 0.8- micron wavelength Stratus OCT.

#### OCT versus Ultrasound

Garcia and Rosen evaluated the diagnostic performance of AC Cornea OCT (Ophthalmic Technologies Inc., Toronto, Ontario, Canada) by comparing image results with UBM in patients with conditions of the AS. The patients were recruited from various specialty clinics, and imaging with OCT and ultrasound was performed sequentially after obtaining informed consent. Eighty eyes with pathologic conditions involving the anterior ocular segment were included in the study; 6 cases were reported in detail to demonstrate the imaging capabilities of OCT and UBM. Comparison of OCT and UBM images shows that while the AC Cornea OCT has high resolution for the cornea, conjunctiva, iris, and anterior angle, UBM images are also clear for these areas. In addition, UBM was found to be superior at detecting cataracts, anterior tumors, ciliary bodies, haptics, and posterior chamber intraocular lenses. OCT was found to be superior at detecting a glaucoma tube and a metallic foreign body in the cornea when imaging was performed in the coronal plane.

Mansouri et al published a study that compared the accuracy in measurement of the AC angle by AS OCT and UBM in European patients with suspected primary angle closure (PACS), primary angle closure (PAC), or primary angle-closure glaucoma (PACG). In this study, 55 eyes of 33 consecutive patients presenting with PACS, PAC, or PACG were examined with OCT, followed by UBM. The trabecular-iris angle (TIA) was measured in all 4 quadrants. The AOD was measured at 500 microns from the scleral spur. In this comparative study, the authors concluded that OCT measurements were significantly correlated with UBM measurements but showed poor agreement with each other. The authors do not believe that AS OCT can replace UBM for the quantitative assessment of the AC angle.

Several retrospective studies have compared OCT with UBM for AS tumors. Bianciotto et al reported a retrospective analysis of 200 consecutive patients who underwent both AS OCT and UBM for AS tumors. When comparing the image resolution for the 2 techniques, UBM was found to have better overall tumor visualization.

#### OCT versus Slitlamp Biomicroscopy

Jiang et al reported a cross-sectional, observational study of the visualization of aqueous tube shunts by high-resolution OCT, slitlamp biomicroscopy, and gonioscopy in 18 consecutive patients (23 eyes). High resolution OCT demonstrated the shunt position and patency in all 23 eyes. Compared with slitlamp, 4 eyes had new findings identified by OCT. For all 16 eyes in which the tube entrance could be clearly visualized by OCT, growth of fibrous scar tissue could be seen between the tube and the corneal endothelium. This was not identified in the patient records (retrospectively analyzed) of the slitlamp examination.

#### **Clinical Utility (Effect on health outcomes)**

In addition to the evaluation of anterior chamber angle, OCT is being evaluated to assess corneal thickness and opacity, evaluate presurgical and postsurgical anterior chamber anatomy, calculate intraocular lens power, guide laser-assisted cataract surgery, assess complications following surgical procedures (eg, blockage of glaucoma tubes, detachment of Descemet membrane, disrupted keratoprosthesis-cornea interface), and to image intracorneal ring segments. It is also being studied in relation to pathologic processes such as dry eye syndrome, tumors, uveitis, and infections.

Cauduro et al provided a retrospective review of 26 eyes of 19 pediatric patients (range, 2 months to 12 years) who presented with a variety of AS pathologies. OCT was used to clarify the clinical diagnosis. No sedation was needed for this noncontact procedure, and only 1 eye of a 2-month-old patient required topical anesthesia. The impact of the procedure on patient care was not reported.

#### Angle-closure Glaucoma

There are no studies that provide direct evidence on the clinical utility of OCT for diagnosing narrow angle glaucoma. The clinical utility of OCT for diagnosing glaucoma is closely related to its ability to accurately diagnose glaucoma, because treatment is generally initiated upon confirmation of the diagnosis. Therefore, if OCT is more accurate in diagnosing glaucoma than alternatives, it can be considered to have clinical utility above that of the alternative tests. While the available evidence does suggest that OCT is more sensitive than ultrasound or gonioscopy, the specificity and predictive value cannot be determined

#### Cataract Surgery

As of 2013, studies that compare the risk-benefit of OCT-laser assisted cataract surgery versus traditional phacoemulsification are ongoing. AS OCT is also being reported for preoperative evaluation of intraocular lens power, postoperative assessment of intraocular stability of phakic lens and optic changes related to intraocular lens or ocular media opacities.

#### Endothelial Keratoplasty

Use of OCT is being reported for intraoperative and postoperative evaluation of graft apposition and detachment in endothelial keratoplasty procedures. In 2011, Moutsouris et al reported a prospective comparison of AS OCT, Scheimpflug imaging, and slit-lamp biomicroscopy in 120 eyes of 110 patients after Descemet membrane endothelial keratoplasty (DMEK). All slit-lamp biomicroscopy and OCT examinations were performed by the same experienced technician and all images were evaluated by 2 masked ophthalmologists. From a total of 120 DMEK eyes, 78 showed a normal corneal clearance by all of the imaging techniques. The remaining 42 eyes showed persistent stromal edema within the first month, suggesting (partial) graft detachment. Biomicroscopy was able to determine the presence or absence of a graft detachment in 35 eyes. Scheimpflug imaging did not give additional information over biomicroscopy. In 15 eyes, only OCT was able to discriminate between a “flat” graft detachment and delayed corneal clearance. Thus, out of the 42 eyes, OCT had an added diagnostic value in 36% of cases. This led to further treatment in some of the additional cases. Specifically, a secondary Descemet stripping automated endothelial keratoplasty (DSAEK) was performed for total graft detachment, while partial graft detachments were rebubbled or observed for corneal clearing. There were no false negatives (graft detachment unrecognized) or false positives (an attached graft recognized as a graft detachment).

Steven et al published a retrospective analysis of the use of intraoperative microscope mounted OCT to improve DMEK. Intraoperative OCT improved visualization of all steps of the procedure (graft preparation, localization of the endothelial side of the graft, graft unfolding, apposition of the graft to the stroma and detection of interface fluid) and reduced anterior chamber air-filling time from 60-90 minutes to 4 minutes. OCT has also been reported to predict primary failure in DSAEK.

Additional studies are needed to further evaluate these results and to demonstrate the clinical utility of using OCT in these situations.

### Uveitis of the AS

In a study from India, Agarwal et al evaluated the anterior chamber inflammatory reaction by AS high-speed OCT. This was a prospective, nonrandomized, observational case series of 62 eyes of 45 patients. Hyper-reflective spots suggesting the presence of cells in the anterior chamber from the OCT images were counted manually and by a custom-made automated software package and correlated with clinical grading using Standardization of Uveitis Nomenclature criteria. Of 62 eyes, grade 4 aqueous flare was detected by OCT imaging in 7 eyes and clinically in 5 eyes. The authors concluded that AS OCT can be used as an imaging modality in detecting inflammatory reaction in uveitis and also in eyes with decreased corneal clarity. Additional studies are needed to further evaluate these results and to demonstrate the clinical utility of using OCT in this situation.

### **Summary**

Ideally, a diagnostic test would be evaluated based on its technical performance, diagnostic performance (sensitivity, specificity, predictive value), and clinical utility (effect on health outcomes). Current literature consists primarily of assessments of qualitative and quantitative imaging and detection capabilities. Technically, the AS OCT has the ability to create high-resolution images of the AS. In addition, studies indicate that the AS OCT detects more eyes

with narrow or closed angles than gonioscopy, suggesting that the sensitivity of OCT is higher than gonioscopy. However, because of the lack of a true criterion standard, it is not clear to what degree these additional cases are true positives versus false positives, and therefore the specificity and predictive values cannot be determined. Evaluation of the diagnostic performance depends, therefore, on evidence that the additional eyes identified with narrow angle by OCT are more likely to progress to primary angle closure glaucoma. OCT imaging may be less sensitive in comparison with UBM for other pathologic conditions of the AS, such as cataracts, anterior tumors, ciliary bodies, haptics, and posterior chamber intraocular lenses.

Evaluation of the clinical utility of AS OCT depends on demonstration of an improvement in clinical outcomes. For example, outcomes will be improved if OCT detects additional cases of primary angle closure glaucoma, which represent true cases of glaucoma and not false positives, and if these cases are successfully treated for glaucoma. It is not currently possible to determine the frequency of false positive results with OCT; therefore it cannot be determined whether health outcomes are improved. For other potential indications (eg, cataract surgery, endothelial keratoplasty, anterior uveitis) evidence is currently limited.

Since the impact on health outcomes of AS OCT for angle closure glaucoma, as well as for other disorders of the anterior chamber, is not known, this procedure is considered investigational.

### **Key Words:**

Scanning computerized ophthalmic, optical coherence tomography, OCT, Stratus OCT™, Zeiss OCT™, Visante OCT non-contact, high resolution tomographic and biomicroscopic device, anterior imaging techniques, AC Cornea OCT

### **Approved by Governing Bodies:**

The Visante™ OCT received marketing clearance through the U.S Food and Drug Administration (FDA) 510(k) process in 2005, listing the Stratus OCT™ and Orbscan™ II as predicate devices. The 510(k) summary describes the Visante OCT as “a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging and measurement of ocular structures in the AS, such as corneal and LASIK flap thickness.”

The Slit-Lamp OCT (SL-OCT, Heidelberg Engineering) received marketing clearance through FDA’s 510(k) process in 2006. The SL-OCT is intended as an aid for the quantitative analysis of structures and the diagnosis and assessment of structural changes in the AS of the eye. “The SL-OCT examination system is not intended for the analysis of the cross-sectional images to obtain quantitative measured values. Neither the obtained measured values nor the qualitative evaluation of the images should be used as the sole basis for therapy-related decisions.”

The RTVue (Optovue) is a commercially available Fourier-domain OCT system with a resolution of 5 microns that received marketing clearance from the FDA in 2010. Although indicated for posterior segment imaging, a lens is available to allow imaging of the anterior segment.

Three commercially available laser systems, the LenSx<sup>®</sup> (Alcon), Catalys (Optimedica), and VICTUS (Technolas Perfect Vision), include OCT to provide image guidance for laser cataract surgery.

The AC Cornea OCT from Canada is not cleared for marketing in the United States.

### **Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

### **Current Coding:**

CPT Codes:

**92132** Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral. **(Effective 01/01/2011)**

### **Previous Coding:**

CPT Codes:

**0187T** Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral. **(Deleted 12/31/2010)**

### **References:**

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### **Policy History:**

Medical Policy Group, December 2007 (2)

Medical Policy Administration Committee, January 2008

Available for comment January 5-February 20, 2008

Medical Policy Group, December 2008 (1)

Medical Policy Group, December 2009 (1)

Medical Policy Group, December 2010 (1): Description, Key Points updated, Key word added and info to Approved by Governing Body added, no policy change

Medical Policy Group, December 2010; 2011 coding update

Medical Policy Group, January 2011: Key Points, References

Medical Policy Panel February 2011

Medical Policy Panel, July 2011 **(2)**: Key Points updated

Medical Policy Group, September 2012 **(1)**: Update to Description, Key Points and References related to MPP update; no change to policy statement

Medical Policy Panel, February 2013

Medical Policy Group, February 2013 **(2)**: Update to Description, Key Points, Governing bodies and References related to MPP update; no change to policy statement

Medical Policy Panel, February 2014

Medical Policy Group, February 2014 **(1)** Update to Key Points and References; no change to policy statement

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*