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# Medicare

## **Comments and Responses Regarding Draft Local Coverage Determination: Corneal Pachymetry**

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Corneal Pachymetry LCD. The official notice period for the final LCD begins on April 15, 2009, and the final determination will become effective on July 1, 2009.

### **Comment:**

The New York Ophthalmology representative has these comments:

Pachymetry had been used exclusively in the past to diagnose limited cornea pathologies related to increased corneal thickness. As a result of the Ocular Hypertension Treatment Trial, the usefulness of knowing the central corneal thickness plays a key factor in evaluating the intraocular pressure measurement. Individual measurements deviating from "average" central corneal thickness were found to be misleading. Thinner central cornea measurements result in falsely low IOP readings by applanation methods. Conversely, thicker central cornea measurements provide inaccurate elevated applanation readings. Pachymetry plays a key role in deciding if a patient needs to be treated as a glaucoma suspect with ocular hypertension or low tension. While the concept of one such test per patient lifetime can be understood, the reality of being able to access this valuable information, if performed by another eye care professional, delays treatment or causes unnecessary treatment, unless the test is performed by the subsequent provider. Under current policy, that test would not be reimbursed to the subsequent provider. Perhaps, this can be modified to allow one Patient/Provider team funding for the diagnoses surrounding glaucoma when medically necessary.

Also under "Indications and Limitations" there is mention that both pachymetry and endothelial cell count may be performed at the same time when there is a question of corneal disease. Frankly, no additional useful information would be gained by performing the two tests simultaneously for corneal pathology. The rare occurrence of a patient having both glaucoma and corneal disease could be a medically necessary use of pachymetry for the glaucoma diagnosis while specular endothelial cell count would be for the cornea pathology. Simply having a specular device that simultaneously produces both pieces of information does not deserve separate Medicare funding.

An important medically necessary ICD-9 code that was overlooked is 371.22 "secondary corneal edema." This would cover many other individual diagnoses all ultimately resulting in secondary corneal edema with visual complaints.

Several methods of determining the center corneal thickness involve direct contact with the cornea. This necessitates the use of a topical anesthetic. Only physicians or healthcare providers, working within the scope of practice, governed by State Law, would be able to perform corneal pachymetry by those devices.

**Response:**

We agree that the tracking of previous tests by a patient or obtaining copies of records by other providers may be problematic. However, it is also not appropriate that the Medicare Program bear the sole burden of unnecessary repeat testing. It is not anticipated that this would be an issue in patients under the continuous care of a single physician or group, where such information and records should be readily available. Certainly in such instances the physician should be held to this standard. In those instances in which a physician has documented a good faith effort to identify previous tests performed and to request copies of them from previous providers, if repeat tests were denied then NGS could reimburse such tests on appeal.

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**Comment:**

A New York ophthalmologist specializing in corneal disease submitted the following comments.

Optical pachymetry refers to a method of determining the thickness of the cornea or depth of corneal opacities, using an optical method. The cornea is best examined using a thin slit of light as is commonly employed in slit lamp bio-microscopy. For many decades, an adaptation to the Haag-Streit slit lamp has allowed the slit beam of light to be split by a prism. The movement of the prism allows a variable degree of offset of the now two beams of light. This has been calibrated so that the degree of offset correlates with the thickness of the cornea as measured in microns.

The Haag-Streit optical pachymeter has been classically employed for many decades both to assess the total corneal thickness as well as to assess the depth of corneal opacities. The use of optical pachymetry to measure total corneal thickness has largely been supplanted by the introduction of ultrasonic pachymetry in the 1980's. Compared to the Haag-Streit unit, the ultrasonic pachymeter showed greater reliability.<sup>1</sup> However, the ability to measure the depth or thickness of intracorneal pathologies is something that cannot be accomplished by ultrasonic pachymetry and as such, optical pachymetry has continued to play a role in management of a variety of corneal diseases. It is especially helpful when determining whether surgical intervention may be required as the depth of a particular lesion or opacity will determine whether the patient may be a suitable candidate for an excimer laser PTK procedure or perhaps would alternatively require a keratoplasty approach.

Recently, several new modalities for performing optical pachymetry have been developed. Pachymetry measurements are obtained as part of a specular microscopy examination of the cornea in a variety of specular microscopes are capable of producing accurate corneal thickness measurements.<sup>2,3</sup> Additionally, the Orbscan scanning slit pachymeter and the Pentacam Scheimpflug which also employs scanning slits have been shown to compare very favorably in terms of accuracy and reproducibility to ultrasonic pachymetry.<sup>4, 5</sup> Yet another new class of optical pachymeters using optical coherence tomography has been developed. Optical coherence tomography or optical coherence pachymetry (OCT or OCP) have been studied extensively and compared to ultrasonic pachymetry. A number of publications have confirmed that the repeatability and validity of the OCT devices equals or exceeds that of the ultrasonic pachymeter.<sup>6,7,8,9,10</sup> additionally, the OCT unit is also capable of imaging intracorneal pathology and providing mapping the depths of lesions in a similar manner to the old Haag-Streit device. It, however, offers improved accuracy in this area.<sup>11</sup>

The existing CPT code for pachymetry relates only to ultrasonic pachymetry and would therefore exclude optical pachymetry techniques as described above. The literature referenced above has demonstrated that a variety of new optical pachymetry devices including specular microscopes, the Orbscan and Pentacam units and OCT units are capable of giving pachymetry measurements of equal or greater accuracy or reproducibility to ultrasonic pachymetry. Therefore, these instruments could be employed for the same indications as the ultrasonic pachymeter. Additionally, some units, in particular, OCT units, can give accurate information about intrastromal lesions, which could not be obtained by ultrasonic pachymetry.

Because ultrasonic pachymetry is able to give only a total corneal thickness measurement, an examination of the cornea with optical techniques does provide valuable information for monitoring pathology and determining suitable surgical intervention. The depth and or thickness information of intracorneal pathology can only be determined by optical pachymetry. Measurement of intracorneal pathology is a separate and distinct function that cannot be performed with routine slit lamp bio-microscopy but rather requires additional instrumentation, operator intervention and interpretation of results. Accordingly, optical pachymetry may be deserving of either its own CPT code or separate reimbursement under an unlisted code.

1 Evaluation and comparison of sources of variability in the measurement of corneal thickness with ultrasonic and optical pachymeters.

Salz JJ, Azen SP, Berstein J, Caroline P, Villasenor RA, Schanzlin DJ.  
Ophthalmic Surg. 1983 Sep;14(9):750-4

2 Comparison of central corneal thickness measurements by ultrasound pachymetry, konan noncontact optical pachymetry, and orbscan pachymetry.

Christensen A, Narváez J, Zimmerman G.  
Cornea. 2008 Sep;27(8):862-5

3 Corneal thickness measurement by confocal microscopy, ultrasound, and scanning slit methods.

McLaren JW, Nau CB, Erie JC, Bourne WM.  
Am J Ophthalmol. 2004 Jun;137(6):1011-20

4 Central corneal thickness measurements using Orbscan II, Visante, ultrasound, and Pentacam pachymetry after laser in situ keratomileusis for myopia.

Ho T, Cheng AC, Rao SK, Lau S, Leung CK, Lam DS.  
J Cataract Refract Surg. 2007 Jul;33(7):1177-82

5 Central corneal thickness measurement with the Pentacam Scheimpflug system, optical low-coherence reflectometry pachymeter, and ultrasound pachymetry.

Barkana Y, Gerber Y, Elbaz U, Schwartz S, Ken-Dror G, Avni I, Zadok D.  
J Cataract Refract Surg. 2005 Sep;31(9):1729-35

6 Intraoperative corneal thickness measurement using optical coherence pachymetry and corneo-gage plus ultrasound pachymetry.

Wang JC, Bunce C, Lee HM.  
J Refract Surg. 2008 Jun;24(6):610-4

7 Central corneal thickness measurements by ultrasound, Orbscan II, and Visante OCT after LASIK for myopia.

Cheng AC, Rao SK, Lau S, Leung CK, Lam DS.  
J Refract Surg. 2008 Apr;24(4):361-5

8 Comparison of central corneal thickness using anterior segment optical coherence tomography vs ultrasound pachymetry.

Kim HY, Budenz DL, Lee PS, Feuer WJ, Barton K.  
Am J Ophthalmol. 2008 Feb;145(2):228-232. Epub 2007 Dec 11

9 Comparison of optical low coherence reflectometry and ultrasound pachymetry in the measurement of central corneal thickness before and after photorefractive keratectomy.

Spadea L, Giammaria D, Di Genova L, Fiasca A.  
J Refract Surg. 2007 Sep;23(7):661-6

10 Agreement among 3 methods to measure corneal thickness: ultrasound pachymetry, Orbscan II, and Visante anterior segment optical coherence tomography.

Li EY, Mohamed S, Leung CK, Rao SK, Cheng AC, Cheung CY, Lam DS.  
Ophthalmology. 2007 Oct;114(10):1842-7. Epub 2007 May 15

11 High-speed optical coherence tomography of corneal opacities.

Khurana RN, Li Y, Tang M, Lai MM, Huang D.  
Ophthalmology. 2007 Jul;114(7):1278-85. Epub 2007 Feb 20

**Response:**

Prior to the CAC meetings, the question of coverage of optical pachymetry was entertained. Consequently, at each CAC meeting a specific request for provider feedback on this issue was made. We appreciate the detailed and lucid discussion of each of the commenters on this issue, and their assistance in enabling this contractor to reach an appropriate coverage determination. Based upon all of the responses reviewed, we will revise this LCD to include optical pachymetry as a covered service equivalent to that performed ultrasonically. The CPT code 76514 describes ultrasonic pachymetry only. Optical pachymetry should be coded using the unlisted ophthalmological procedure code, 92499, and will be valued equal to the ultrasonic code.

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**Comment:**

An optometrist from Massachusetts had these comments:

1. Clinical requirement of documented worsening of glaucoma

The Indications and Limitation section of the draft LCD states:

“Effective for dates of service on or after 6/21/2006, Medicare will pay for ocular corneal pachymetry performed on patients who have been diagnosed and under treatment for glaucoma when there is documented worsening of glaucoma and the corneal thickness is unknown. The test must be integral to the medical management decision-making of the patient. Medicare will not pay for ocular corneal pachymetry when performed on patients who have been diagnosed and are under treatment for glaucoma that is stable and shows no evidence of progression/worsening of symptoms.”

Since the landmark Ocular Hypertension Study (OHTS), the optometric and ophthalmologic community has adopted the paradigm that performing pachymetry is the medical standard of care for patients identified as glaucoma suspects, as well as those who have glaucoma who have never had this procedure performed. These standards have been accepted nationally by physicians and payers alike.

We believe the policy limitation is out of step with the standard of care for glaucoma diagnosis and treatment, and the remainder of the entire Medicare carrier community.

Open angle glaucoma is a disease with virtually no symptoms, but is only diagnosed and treated based upon signs. As such, the language “worsening of symptoms” is not a medically sound criterion vis-à-vis open angle glaucoma.

Glaucoma is presumed to be an unstable condition and must demonstrate that it is stable over a period of months to years. The fact that a patient converts from a glaucoma suspect to de facto glaucoma represents a chronic unstable condition. Stability can only be measured by a lack of change to the optic

nerve or lack of visual field loss, a process that takes months to years. As such, documentation of glaucoma progression cannot be compared until the patient has been monitored for an extended period of time. The policy language excludes pachymetry at an initial evaluation where evidence of worsening is impossible to determine.

The treatment of glaucoma requires pachymetry for appropriate medical management decision making. Clinical literature abounds. In their peer-reviewed study entitled "Central Corneal Thickness as a Risk Factor for Advanced Glaucoma Damage," Herndon, et al. conclude that "central corneal thickness is a powerful clinical factor in determining glaucoma severity at the initial examination..." Furthermore, "Measuring CCT may aid the ophthalmologist in identification of glaucoma patients at high risk of progression."<sup>1</sup> In addition, Dr. Paul Palmberg indicates that the investigators in the Ocular Hypertension Treatment Study "recommend that CCT be measured in all patients with ocular hypertension so that those patients who in reality do not have elevated IOP may be excluded from unnecessary surveillance."

The Ocular Hypertension Treatment Study (OHTS) identified corneal thickness as a risk factor for glaucoma and was the impetus for the implementation of pachymetry as a payable service. Dr. Joshua Stein comments:

"The Ocular Hypertension Treatment Study (OHTS) demonstrated that patients with thinner CCT were at increased risk of developing primary open-angle glaucoma. Since that landmark study, researchers have tried to establish definitively whether thin CCT is associated not only with development of glaucoma but also with progression of glaucoma.

... Kim and Chen found an association between thinner CCT and progression of glaucoma, as measured by automated achromatic perimetry. In their study, CCT was significantly lower in patients who progressed than in patients who did not (mean, 529  $\mu\text{m}$  versus 547  $\mu\text{m}$ ;  $P = 0.02$ ). This finding supports results of two earlier studies showing that thin CCT is a risk factor for glaucoma progression... , Visual field progression in patients with open-angle glaucoma appears to be significantly associated with a thinner central cornea. Such eyes progressing based on the optic nerve appearance or perimetry should be considered for aggressive treatment."<sup>3</sup>

In summary, the limitation cited above cannot be supported by the medical literature, nor is it relevant to how glaucoma is managed in contemporary times. I can state without reservation, that Ocular Pachymetry is the standard of care both for patients with existing glaucoma, as well as glaucoma suspects. I urge the Carrier to include de-facto diagnoses of glaucoma as payable ICD-9CM codes for Ocular Pachymetry and suggest the following revised language:

"Medicare will also pay for ocular corneal pachymetry performed on patients who have been diagnosed and under treatment for glaucoma when the corneal thickness is unknown. The test must be integral to the medical management decision-making of the patient."

This is consistent with current medical literature and standards of practice. As such, the Utilization Guidelines should also be revised to indicate, "It is expected that services performed for glaucoma that is diagnosed and under treatment will be performed once in a lifetime, unless....."

## 2. Payable Place of Service

The Coding Guidelines do not allow for payment the global, technical or professional components performed in places of service 31, skilled nursing facility, 32, nursing facility or 13, assisted living facility.

There is no medical contraindication or technical barrier to performing pachymetry these settings. I specialize in geriatrics and have performed thousands of examinations in nursing homes since 1990. I published a peer-reviewed article in 1994 , describing the multiple aspects of performing a nursing home comprehensive eye examination. Pachymetry of the cornea is virtually analogous to performing tonometry, in which I utilize a Tono-Pen XL portable tonometer (see enclosure). A similar portable instrument is used to perform pachymetry (see enclosure). In fact, I can state from extensive experience that performing pachymetry is faster and easier than performing tonometry.

Other part B carrier policies, including National Heritage Insurance Corporation (Pachymetry of the Cornea L12803), Wisconsin Physician Services (OPHTH-025 Corneal Pachymetry), and Trailblazer Health Enterprises (Pachymetry -4O-62AB (L26788) allow for pachymetry in these places of service.

I respectfully request their addition as payable places of service for all components of ocular corneal pachymetry.

### **Response:**

1. We appreciate the commenter's detailed discussion and citations from the literature. The literature clearly identifies the importance of pachymetry in the initial diagnosis and treatment of glaucoma patients. The commenter takes the position that the diagnosis of glaucoma and initiation of treatment may be protective in many patients, there is also a significant group of patients for whom progression of disease may be otherwise unpredictable and that pachymetry may help to identify those at greater risk of doing so. Furthermore, it may help to more accurately guide the therapy by quantitating the corneal thickness and adjusting the intraocular pressure goals accordingly. We believe that the universal testing of patients with known glaucoma, stable on treatment, will undoubtedly result in over-testing based upon individual patient need. However, we also recognize that in a universe of patients in which glaucoma may progress with age, that for those patients in whom such testing would alter the treatment and therefore outcomes, this testing is beneficial. In the absence of methods for stratifying these groups we believe that the commenter's suggestion of once-in-a-lifetime testing is currently in the best interest of patients with this condition. Consequently we will revise the LCD to extend coverage of pachymetry to all glaucoma patients and suspects to once-in-a-lifetime.
2. Based upon the commenter's information that the appropriate equipment for pachymetry testing is commercially available and technically reliable we will revise the LCD and accompanying article to indicate that pachymetry may be a covered service when performed in nursing and assisted living facilities.

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**Comments:**

The Ophthalmology representative to the Indiana CAC commented:

This policy and SIA were reviewed and felt to be appropriate. I would indicate that within the abstract of corneal pachymetry in the first sentence is the ultrasonic or optical measurement of corneal thickness instead of just ultrasonic. Corneal thickness measurement, in the second sentence, can be performed using ultrasound and two different optical methods, specifically using optical images of reflective light or optical coherence tomography using a coherent laser light source. These are all acceptable methods of corneal thickness measurement.

Reference 1: Amano S, Honda N, Amano Y, et al., Comparison of central corneal thickness measurements by rotating Scheimpflug camera ultrasonic pachymetry and scanning-slit corneal topography. Ophthalmology. 2006. 113: 937-941.

The remainder of the draft appeared appropriate and did not require any other additional corrections.

**Response:**

We appreciate the representative's review and support of the LCD. As indicated previously, this contractor will revise this LCD to include optical pachymetry as a covered service equivalent to that performed ultrasonically. The CPT code 76514 describes ultrasonic pachymetry only. Optical pachymetry should be coded using the unlisted ophthalmological procedure code, 92499, and will be valued equal to the ultrasonic code.

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**Comment:**

A New York provider commented:

I think corneal pachymetry is also indicated post keratoplasty if beginning graft failure is suspected as thickening of the cornea may be the first sign. Also, most grafts are thicker than normal corneas so interpreting the true intra ocular pressure can be mistaken without the measurement. In the indication and limitation paragraph, suspected glaucoma of any sort should be added since you don't have to have a classical elevated pressure to have glaucoma.[low tension glaucoma].

**Response:**

We agree with the commenter that repeat testing may be indicated in patients who have undergone corneal surgery or sustained corneal trauma. The LCD already includes this in the indications section of the LCD, and includes 996.51 MECHANICAL COMPLICATION OF PROSTHETIC CORNEAL GRAFT among the diagnoses support medical necessity. We will revise the LCD to clarify coverage for suspect glaucoma patients.

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**Comment:**

The Connecticut optometry representative commented:

Add the following diagnosis codes: 371.48 Peripheral Degeneration of Cornea; 371.60 Keratoconus, unspecified; 371.61 Keratoconus, stable condition; 371.62 Keratoconus, acute hydrops.

**Response:**

We will revise the LCD to include these diagnoses.

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**Comment:**

The Optometric representative to the Kentucky CAC commented:

Pages 3 & 4 refer to "specialized training in ocular corneal pachymetry". It was discussed at the CAC that this language only applies if the provider is NOT an Optometrist or Ophthalmologist. The draft LCD does not read well to this regard. This is a fairly simple diagnostic test which is typically delegated to staff and does not carry a high RVU value. I question why other provider types would ever use the service/code. Requirements for specialized training are not applicable to ODs or EyeMDs as it is part of our regular didactic program. For others, Category 1 AMA Credit may apply, but Optometric CE is certified differently and would certainly be applicable. Again, I am not sure what other providers would ever need or obtain this specialized training. I suggest all reference to said training be struck from the policy.

Re: Optical pachymetry:

Much like with A-scans, the traditional/historical way to perform pachymetry has been with ultrasound. Now there are ways to do it optically with optical coherence types of technology. To my knowledge, these are currently wrapped up in a larger test, such as Orbscan which also provides topography information. So I don't know if anyone would use this just for the pachymetry. And I am not sure if a stand-alone pachymeter is around that uses this technology.

Further, there is an optical pachymeter that attaches to the slit lamp biomicroscope. It is a very subjective test dependent on the observer and I do not feel is accurate enough for this indication of use and should probably be excluded from the policy.

**Response:**

We agree with the commenter, and will delete the references to other providers. The LCD would limit the service to trained ophthalmologists and optometrists.

Multiple comments regarding optical pachymetry have been received. Other commenters have provided more positive information regarding the optical modalities, including references from the literature comparing the techniques. The commenter raises an issue not specific to the modality as to the commercial equipment with which to perform the test. As we have already indicated the coverage of pachymetry, by any means, does not imply coverage of other tests performed during the same encounter employing complex, multi-use equipment. Based upon the review of all responses, NGS will revise this LCD to include optical pachymetry as a covered service equivalent to that performed ultrasonically. The CPT code 76514 describes ultrasonic pachymetry only. Optical pachymetry should

be coded using the unlisted ophthalmological procedure code, 92499, and will be valued equal to the ultrasonic code.

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