CORNEAL HYSTERESIS AND INTRAOCULAR PRESSURE MEASUREMENT

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INSTRUCTIONS FOR USE

This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COMMERCIAL, MEDICARE & MEDICAID COVERAGE RATIONALE

Measurement of corneal hysteresis is not medically necessary for evaluating and managing of corneal disorders and glaucoma. There is insufficient evidence to evaluate corneal hysteresis measurement for the purpose of assessing corneal viscoelasticity. Studies do not demonstrate that the measurement of corneal hysteresis impacts health outcomes such as improving vision or increasing the detection of ocular disorders. Further investigation that demonstrates the clinical usefulness of this procedure is necessary before it can be considered medically necessary.

Measurement of ocular blood flow by intraocular pressure sampling using an ocular blood flow tonometer is not medically necessary for evaluating and managing glaucoma and other ocular disorders. There is insufficient evidence to evaluate ocular blood flow measurement. Studies do not demonstrate that the measurement of ocular blood flow improves health outcomes such as improving
vision or increasing the detection of glaucoma and other ocular disorders. Further clinical trials demonstrating the clinical usefulness of this procedure are necessary before it can be considered medically necessary.

Monitoring of intraocular pressure during vitrectomy is **not medically necessary**. There is insufficient evidence to indicate that intraocular pressure improves health outcomes such as visual acuity recovery in patients who undergo vitrectomy. Additional clinical trials are required to determine if monitoring of intraocular pressure during vitrectomy accurately measures intraocular pressure and if it improves visual acuity recovery after vitrectomy.

Continuous monitoring of intraocular pressure for 24 hours or longer in patients with glaucoma is **not medically necessary**. There is insufficient evidence to conclude that continuous monitoring of intraocular pressure improves health outcomes in patients with glaucoma. Further studies are needed to evaluate the long-term safety and tolerability of continuous monitoring of intraocular pressure before it can be implemented in clinical practice.

**Medicare** does not have a National Coverage Determination (NCD) or a Local Coverage Determination (LCD) for Nevada for Corneal Hysteresis and/or Intraocular Pressure Measurement (Accessed June 2016).

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**
Please review Local Coverage Determinations that apply to other states outside of Nevada.

**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

**DESCRIPTION OF SERVICES**

Corneal hysteresis (CH) measurement assesses corneal resistance to deformation. CH has been proposed as a possible indicator of the viscoelastic properties in the cornea. The Ocular Response Analyzer® is an instrument that measures corneal hysteresis by using a rapid air impulse to apply force to the cornea. An advanced electro-optical system then monitors the deformation. Two independent pressure values are derived from the inward and outward applanation events. The difference between these two pressure values is corneal hysteresis. Low CH demonstrates that the cornea is less capable of absorbing (damping) the energy of the air pulse. Abnormalities in corneal hysteresis have been detected in a variety of corneal diseases, including keratoconus, Fuchs’ dystrophy, and in post-LASIK patients. Glaucoma is another potential indication for corneal hysteresis measurement. The preferred method of measuring intraocular pressure (IOP) is using a contact applanation method such as a Goldmann tonometer. Corneal compensated IOP, derived from the CH measure has been suggested as a superior measurement of IOP compared to the Goldmann tonometer measurement.

The ocular blood flow (OBF) tonometer measures intraocular pressure (IOP) and pulsatile OBF. It has been proposed that the IOP and OBF test results taken together increase the detection rate for glaucoma when compared to traditional tonometry, which measures only average IOP. The ocular Blood Flow Analyzer (BFA) (Paradigm Medical Industries, Inc.) is an electronic pneumotonometer
that measures IOP 200 times per second over a period of 5-15 seconds and automatically measures OBF. The BFA is basically an OBF tonometer, using a pneumatic mode of operation.

IOP monitoring during vitrectomy may be accomplished indirectly by placing disposable blood pressure transducers into the line tubing utilized for vitrectomy infusion. It may also be monitored by inserting a catheter pressure transducer directly into the vitreous by an extra pars plana incision. In either approach, pressure measurements are obtained simultaneously during the various stages of the vitrectomy, including air-fluid exchange and gas-forced fusion. Monitoring IOP during vitrectomy surgery has been proposed to measure fluctuations in IOP that may have an adverse effect on retinal and optic nerve function and visual acuity recovery.

Devices, including contact lens sensors, are being developed to monitor eye pressure in glaucoma patients for 24 hours or longer. Currently, the Triggerfish® contact lens sensor (CLS) (Sensimed, Lausanne, Switzerland) is the only commercially available device that has been shown to be able to provide 24 hour IOP data. This device has received marketing clearance by the U.S. Food and Drug Administration (FDA). The Triggerfish CLS is a disposable silicone contact lens with an embedded micro-electromechanical system, which measures changes in corneal curvature induced by variations in IOP. An antenna, mounted around the eye, receives the data, which are then transmitted to a recorder for analysis. These devices are being studied to determine if they improve detection and allow earlier treatment of glaucoma patients.

**CLINICAL EVIDENCE**

**Corneal Hysteresis Measurement**

Observational cohort studies have been conducted by Medeiros et al. (2013) and Zhang et al. (2016) to investigate the relationship between corneal hysteresis (CH) and progressive retinal nerve fiber layer (RNFL) loss/visual progression in patients with glaucoma followed prospectively over time. Medeiros’ study group included 114 eyes of 68 patients with glaucoma who were followed for an average of 4 years. Zhang’s group followed 186 eyes of 133 patients with glaucoma for an average of 3.8 years. Using the Ocular Response Analyzer to obtain CH measurements in both a univariable and multivariable models, both studies concluded that the CH measurements to be significantly associated with risk of glaucoma progression and that eyes with lower CH had faster rates of RNFL/visual field loss over time than those with higher CH. While Zhang concludes this study provides further evidence that CH is an important factor to be considered in the assessment of the risk of progression in patients with glaucoma, there is no information that these findings will affect patient management.

Shin et al. (2014) conducted a prospective, cross-sectional, comparative study to evaluate the effects of corneal biomechanical properties on intraocular pressure (IOP) measured with the ICare, and to compare IOP readings obtained with ICare, Ocular Response Analyzer (ORA), and Goldmann applanation tonometry (GAT) in normal-tension glaucoma (NTG) and normal subjects. IOP was measured with ICare, ORA, and GAT. All subjects had corneal hysteresis (CH) and corneal resistance factor (CRF), which were measured with ORA; and central corneal thickness (CCT), axial length, spherical equivalent, and keratometry. This study enrolled 97 eyes of 97 NTG patients and 89 eyes of 89 normal subjects. CCT, CH, and CRF in NTG patients were significantly lower than those in normal subjects (P = .033, P = .006, and P = .003). The difference in IOP between techniques was highly significant in NTG patients (P < .001), while there was no significant difference in IOP values between
techniques in normal controls (P = .931). ICare readings were significantly lower than corneal-compensated IOP in NTG patients (P = .014). CH and CRF were significantly associated with IOP measurements with ICare in NTG and normal subjects (P < .001). The greater difference between IOPcc and ICare in NTG patients was significantly influenced by the lower CH (P < .001). The author concluded that ICare is a convenient way to measure IOP, ICare is a reasonable option as an alternative tonometer in NTG patients. However, the clinician must consider that the corneal biomechanical characteristics in NTG can cause ICare to underestimate IOP. The findings of this study are further limited by the small size of the study group.

In a systematic review and meta-analysis, Cook et al. (2012) assessed the agreement of tonometers available for clinical practice with the Goldmann applanation tonometer (GAT), the most commonly accepted reference device. A total of 102 studies, including 130 paired comparisons, were included, representing 8 tonometers: dynamic contour tonometer, noncontact tonometer (NCT), ocular response analyzer, Ocuton S, handheld applanation tonometer (HAT), rebound tonometer, transpalpebral tonometer, and Tono-Pen. The agreement (95% limits) varied across tonometers: 0.2 mmHg (-3.8 to 4.3 mmHg) for the NCT to 2.7 mmHg (-4.1 to 9.6 mmHg) for the Ocuton S. The estimated proportion within 2 mmHg of the GAT ranged from 33% (Ocuton S) to 66% and 59% (NCT and HAT, respectively). Substantial inter- and intraobserver variability were observed for all tonometers. The authors concluded that the NCT and HAT seem to achieve a measurement closest to the GAT. However, there was substantial variability in measurements both within and between studies.

Nessim et al. (2012) analyzed the relationship between measured intraocular pressure (IOP) and central corneal thickness (CCT), corneal hysteresis (CH) and corneal resistance factor (CRF) in ocular hypertension (OHT), primary open-angle (POAG) and normal tension glaucoma (NTG) eyes using multiple tonometry devices. Right eyes of patients diagnosed with OHT (n=47), normal tension glaucoma (n=17) and POAG (n=50) were assessed. IOP was measured in random order with four devices: Goldmann applanation tonometry (GAT); Pascal(®) dynamic contour tonometer (DCT); Reichert(®) ocular response analyser (ORA); and Tono-Pen(®) XL. CCT was then measured using a hand-held ultrasonic pachymeter. CH and CRF were derived from the air pressure to corneal reflectance relationship of the ORA data. Compared to the GAT, the Tonopen and ORA Goldmann equivalent (IOPg) and corneal compensated (IOPcc) measured higher IOP readings, particularly in NTG. DCT was closest to Goldmann IOP and had the lowest variance. CCT was significantly different between the 3 conditions as was CH and CRF. According to the authors, this study suggests that as the true pressure of the eye cannot be determined non-invasively, measurements from any tonometer should be interpreted with care, particularly when alterations in the corneal tissue are suspected.

In a prospective longitudinal observational study, Sullivan-Mee et al. (2012) examined the factors that influence intraocular pressure (IOP) measurement agreement between Goldmann applanation (GAT), Ocular Response Analyzer (ORA), and Pascal Dynamic Contour tonometers (DCT). The study included 243 eyes in 243 subjects. The authors identified 5 factors, including corneal hysteresis, by multivariate regression as being independently associated with disagreement in intraocular pressure results as measured by different types of instruments. The authors stated that further study is needed to explain the residual disagreements among these instruments.

Kaushik et al. (2012) evaluated corneal biomechanical properties across the glaucoma spectrum and studied the relationship between these measurements and intraocular pressure in a prospective cross-
sectional study that included 323 participants. Based on the results of the study, the investigators concluded that intraocular pressure measurements from the Ocular Response Analyzer are not interchangeable with, and are unlikely to replace, Goldmann applanation tonometry at the present time.

Touboul et al. (2011) estimated the ability of the Ocular Response Analyzer parameters to aid in the diagnosis of keratoconus in pre-laser in situ keratomileusis (LASIK) patients. The study group comprised 103 eyes and the control group, 97 eyes. Corneal hysteresis had a sensitivity of 66% with a specificity of 67%. The authors stated that despite low sensitivity and specificity, some parameters provided by the corneal analyzer offered high negative likelihood ratios and deserve more study with bigger samples.

Renier et al. (2010) compared the intra-ocular pressure (IOP) obtained by ocular response analyzer (ORA), dynamic contour tonometer (DCT), and Goldmann applanation tonometer (GAT) in 102 patients (47 with primary open-angle glaucoma and 55 healthy controls). According to the investigators, the results of the study showed a low degree of agreement between IOP measured by ORA, DCT and GAT. DCT and corneal compensated ORA (ORAcc) over-estimated the IOP compared to GAT.

Carbonaro et al. (2010) compared the reliability of the gold standard Goldmann applanation tonometer (GAT), with that of the ocular response analyzer (ORA), and the dynamic contour tonometer (DCT). A total of 694 subjects were included in the study. The agreement between the three methods was assessed using the Bland-Altman method. The study found similar reliability in all three tonometers. Bland-Altman plots showed the three instruments to have 95% limits of agreement outside the generally accepted limits, which means they are not interchangeable. GAT measurements were found to be significantly lower than the two newer instruments.

Schweitzer et al. (2010) evaluated the performance of the Ocular Response Analyzer (ORA) in the screening of forme fruste keratoconus (FFKc) in a retrospective comparative study that included 180 eyes. ORA preoperative data were analyzed for 125 normal control eyes (64 patients) undergoing laser in situ keratomileusis (LASIK) without corneal ectasia after 24 months of follow-up and 55 case eyes with unilateral keratoconus from a database. All eyes were matched in four groups of central corneal thickness (CCT). Corneal hysteresis (CH), the corneal resistance factor (CRF), the air pressure curve, and the infrared signal were compared between FFKc and normal eyes in each group. Based on the results of the study, the investigators concluded that the ORA provides additional information in the screening of FFKc, with an accurate analysis of the corneal biomechanical properties according to CCT, air pressure, and infrared curves. According to the investigators, further studies are required to confirm these results and to follow the corneal topography and the ORA parameters over time for both groups.

Fontes et al. (2011) compared corneal hysteresis (CH) and corneal resistance factor (CRF) in eyes with keratoconus with CH and CRF in matched controls, and estimated the sensitivity and specificity of these parameters for discriminating between the two groups. This prospective, comparative case series included 19 eyes of 19 patients with keratoconus and 19 eyes of 19 healthy sex-, age-, and central corneal thickness (CCT)-matched patients who underwent a complete clinical eye examination, corneal topography, tomography, and biomechanical evaluation. The investigators concluded that corneal hysteresis and CRF were statistically lower in the keratoconus group compared with the control group.
Given the large overlap, both CH and CRF had low sensitivity and specificity for discriminating between groups.

There is insufficient evidence available from the peer-reviewed literature to validate the clinical role for measurement of corneal hysteresis.

**Professional Societies**
The AAO Preferred Practice Pattern (PPP) for Primary Open-Angle Glaucoma (2015) states that determination of true IOP may be better by methods less influenced by corneal thickness or hysteresis such as by pneumatonometry, dynamic contour tonometry, or with noncontact differential tonometry (such as the Ocular Response Analyzer®). The PPP also states that decreased corneal hysteresis has been shown to be associated with the risk of glaucoma progression.

The AAO PPPs for both Primary Open-Angle Glaucoma and for Primary Open-Angle Glaucoma Suspect (2015) state that low corneal hysteresis is associated with glaucoma progression.

**Measurement of Ocular Blood Flow by Intraocular Pressure Sampling**
In a cross-sectional study, Resch et al. (2011) correlated ocular blood flow parameters with parameters of optic nerve head (ONH) morphology and visual field performance. A total of 103 patients with primary open angle glaucoma were included. Choroidal and ONH blood flow was assessed using laser Doppler flowmetry. Retinal blood velocities and retinal vessel diameters were measured with laser Doppler velocimetry and a Retinal Vessel Analyzer, respectively. Among all measured ocular hemodynamic parameters, the ONH blood flow was most strongly correlated to structural parameters of ONH damage and visual field loss. Reduced retinal vessel diameters were only slightly correlated with the degree of glaucomatous damage. The authors concluded that reduced blood flow in the ONH was associated with an increasing amount of visual field defect and morphological changes of the ONH. Retinal vessel diameters were only marginally associated with glaucomatous optic nerve damage. According to the authors, based on retinal vessel diameter determination alone, it is not possible to assess whether reduced retinal blood flow is causative or secondary in glaucoma.

Janulevičiene et al. (2011) evaluated hemodynamic parameters as possible predictors for glaucoma progression in an 18-month randomized double-masked cohort study including 30 open-angle glaucoma patients. Intraocular pressure (IOP), arterial blood pressure (BP), ocular and diastolic perfusion pressures (OPP, DPP), color Doppler imaging, pulsatile ocular blood flow analysis, scanning laser polarimetry, and Humphrey visual field evaluations were included. The authors concluded that structural changes consistent with glaucoma progression correlate with non-IOP-dependent risk factors. The authors stated that larger group studies with longer followup, standardization of measurement techniques for glaucoma progression, and ocular blood flow parameters are required to elicit a clear understanding of vascular risk factors in glaucoma progression.

In a prospective observational clinical study, Deokule et al. (2009) evaluated one randomly selected eye from 21 normal subjects, 30 glaucoma suspects based on optic disc appearance, and 22 open-angle glaucoma (OAG) patients. The pulsatile ocular blood flow (POBF), a measure of choroidal blood flow, was assessed using ocular blood flow analyzer whereas parapapillary blood flow and blood velocity of retrobulbar blood vessels were measured using scanning laser Doppler flowmetry and color Doppler imaging, respectively. POBF was significantly associated with parapapillary blood flow and temporal
short posterior ciliary artery resistive index in normal subjects. Results were consistent when corrected for age, intraocular pressure, and blood pressure parameters. POBF values did not correlate with parapapillary blood flow values or temporal short posterior ciliary artery resistive index in glaucoma suspects or OAG patients. The investigators concluded that the relationships of POBF with parapapillary blood flow and calculated retrobulbar vascular resistance differs among normal subjects, glaucoma suspects, and OAG patients and this provides further evidence of vascular dysregulation in OAG.

Erickson et al. (2010) evaluated intraocular blood flow using ocular pulse amplitude (OPA). Refractive error, corneal curvature, Goldmann applanation tonometry (GAT), dynamic contour tonometry (DCT), OPA, axial length, and central corneal thickness (CCT) measurements were obtained on 104 healthy subjects. OPA ranged from 0.7 to 4.7 mmHg and showed a significant correlation with refractive error, axial length, GAT, and DCT. Mean intraocular pressure with GAT was 15.6 mmHg. The investigators concluded that OPA provides information regarding ocular blood flow; however, more studies are needed to determine its significance in glaucoma treatment.

There is inadequate evidence that measurement of ocular blood flow with ocular blood flow tonometry is effective for evaluating ocular disorders. Further investigation is needed to demonstrate that ocular blood flow tonometer can provide clinically useful and accurate measurements.

The clinical evidence was reviewed on March 16, 2016 with no additional information identified that would change the not medically necessary conclusion for the measurement of ocular blood flow by intraocular pressure sampling and its use in the treatment of glaucoma and other ocular disorders.

Professional Societies
The AAO Preferred Practice Pattern for Primary Open-Angle Glaucoma does not address measurement of ocular blood flow for the evaluation and management of this condition (2015).

Monitoring of Intraocular Pressure during Vitrectomy:
In a prospective, interventional, consecutive case series, Sugiura et al. (2011) measured ophthalmodynamometric pressure (ODP) during vitrectomy in 75 patients with proliferative diabetic retinopathy (PDR). Multiple regression analysis revealed that ODP had a significant correlation with diastolic blood pressure (DBP), presence of rubeosis iridis, and severity of PDR. There is no evidence from this study that this information will affect patient management.

Moorhead et al. (2005) conducted a clinical study of 10 patients to directly measure dynamic intraocular pressure (IOP) during vitrectomy and to determine whether disposable pressure transducers placed in the infusion line can indirectly measure with accuracy the dynamic IOP during vitrectomy. The directly measured IOP varied between 0 and 120 mm Hg during vitrectomy. During fluid flow, the indirectly measured IOP, calculated from the infusion line pressures, accurately corresponded with the directly measured IOP. The investigators concluded that closed vitrectomy causes wide fluctuations in IOP. The IOP can be accurately measured during fluid flow with inline sensors. According to the authors, the physiologic significance of these findings requires further study.

There is insufficient evidence that monitoring of intraocular pressure during vitrectomy has clinical benefit. Additional clinical trials are required to determine if monitoring of intraocular pressure during
vitrectomy accurately measures intraocular pressure and if it improves outcomes such as visual acuity recovery after vitrectomy.

The clinical evidence was reviewed on March 21, 2016 with no additional information identified that would change the unproven conclusion for the monitoring of intraocular pressure during vitrectomy.

**Monitoring of Intraocular Pressure for 24 Hours or Longer**

Mansouri et al. (2012) examined the safety, tolerability, and reproducibility of intraocular pressure (IOP) patterns during repeated continuous 24-hour IOP monitoring with a contact lens sensor (Sensimed Triggerfish CLS). Forty patients suspected of having glaucoma (n = 21) or with established glaucoma (n = 19) were included in the study. Correlation between the 2 sessions was moderate, suggesting good reproducibility of the IOP recordings. There was also no difference in adverse events or survey scores for tolerability between those with established glaucoma compared with those with suspected glaucoma. Main adverse events were blurred vision (82%), conjunctival hyperemia (80%), and superficial punctate keratitis (15%). The authors concluded that repeated use of the contact lens sensor demonstrated good safety and tolerability. According to the authors, the recorded IOP patterns showed fair to good reproducibility, suggesting that data from continuous 24-hour IOP monitoring may be useful in the management of patients with glaucoma. Limitations of this study included the lack of a patient group without glaucoma within the cohort. Thus, the study did not address reproducibility and accuracy of IOP measurements in populations with IOP close to or within normal range.

In a prospective, observational cohort of 15 patients, Mansouri and Shaarawy (2011) reported their initial clinical results with a wireless ocular telemetry sensor (OTS) (Sensimed AG, Switzerland) for continuous intraocular pressure (IOP) monitoring in patients with open angle glaucoma. A signal was recorded in all patients. Thirteen (87%) patients completed 24 hour IOP monitoring: one patient discontinued IOP monitoring due to device intolerance, and incomplete recordings were obtained in a second patient due to technical device malfunction. In 9/13 (69%) patients, the highest signals were recorded during the nocturnal period. No serious adverse events were recorded. According to the authors, the OTS shows good safety and functionality to monitor IOP fluctuations in patients over 24 hours. The significance of this study is limited by small sample size.

The clinical evidence was reviewed on March 17, 2016 with no additional information identified that would change the unproven conclusion of monitoring of intraocular pressure for 24 hours or longer in patients with glaucoma.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**


On October 21, 2002 the Blood Flow Analyzer (BFA) received FDA marketing clearance. See the For more information, please go to: [http://www.accessdata.fda.gov/cdrh_docs/pdf2/k023245.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf2/k023245.pdf) (Accessed June 2016).
On March 4, 2016, the Triggerfish® contact lens sensor (CLS) received FDA marketing clearance. For more information, please go to: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm489308.htm (Accessed June 2015).

### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply. This list of codes may not be all inclusive.

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<td>Measurement of ocular blood flow by repetitive intraocular pressure sampling, with interpretation and report</td>
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<td>0329T</td>
<td>Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report</td>
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<td>92145</td>
<td>Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report</td>
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### REFERENCES


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The foregoing Health Plan of Nevada/Sierra Health & Life Healthcare Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.