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

<table>
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<th>Plan: Aetna Better Health</th>
<th>Submission Date: 09/04/2018</th>
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<td>Effective Date:</td>
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<tr>
<td></td>
<td>Revision Date: 06/14/2018</td>
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<td>Policy Name: Fundus Photography</td>
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Type of Submission – Check all that apply:
- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0539 Fundus Photography**

Clinical content was last revised 06/14/2018. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

Revision and Update History since last PARP submission:
- 04/13/2018 - This CPB has been updated with additional coding.
- 06/14/2018 - This CPB has been revised to state that fundus photography is considered medically necessary for age-related macular degeneration and congenital glaucoma.
- 05/23/2019 – Tentative next scheduled review date by Corporate.

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

Signature of Authorized Individual: [Signature]

[www.aetnabetterhealth.com/pennsylvania](http://www.aetnabetterhealth.com/pennsylvania) Updated 04/13/2018
Fundus Photography

Number: 0539

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

Policy

I. Aetna considers fundus photography medically necessary for any of the following indications:

- Abnormal electro-oculogram (EOG)
- Abnormal oculomotor studies
- Abnormal retinal function studies
- Abnormal visually evoked potential
- Age-related macular degeneration
- Benign neoplasm of choroid, cranial nerves, eyeball, or retina
- Carcinoma in situ of eye
- Chorioretinal inflammation, scars, and other disorders of choroid
- Color vision deficiencies
- Congenital anomalies of posterior segment of eye
- Congenital glaucoma
- Congenital rubella
- Diabetes mellitus (diabetic retinopathy)
- Disorders of aromatic amino-acid metabolism affecting the fundus
- Disorders of globe
- Disorders of optic nerve and visual pathways
- Endophthalmitis
- Glaucoma and glaucoma suspects
- Hamartoses involving the eye
- Histoplasmosis
- Human immunodeficiency virus (HIV) disease
- Initial baseline evaluation and periodical follow-up of individuals being treated with ethambutol (Myambutol)
- Lupus erythematosus
- Malignant neoplasm of eye
- Monitoring of members for toxicity by anti-malarials such as chloroquine (Aralen), hydroxychloroquine (Plaquenil) and drugs acting on other blood protozoa
- Multiple sclerosis
- Penetration of eyeball with magnetic or non-magnetic foreign body
- Peters anomaly
- Pseudotumor cerebri
- Retinal detachment and defects
- Rheumatoid arthritis and other inflammatory polyarthropathies
- Sickle-cell anemia
- Syphilitic retrobulbar neuritis
- Systemic lupus erythematosus
- Toxoplasmosis
- Tuberous sclerosis
- Other retinal disorders where the results of fundus photography will change the treatment of the member.

II. Frequency of Testing:

Aetna considers fundus photography medically necessary no more than two times per year. Justification for more frequent testing must be documented in the medical record.

III. Aetna considers fundus photography experimental and investigational for screening in asymptomatic persons without signs or symptoms of disease and for all other indications (e.g., toxocariasis) because there is insufficient evidence that this test affects management for these other indications such that clinical outcomes are improved.
Note: Fundus photography of a normal retina is considered not medically necessary.

IV. Aetna considers computer-aided animation and analysis of time series retinal images (e.g., MatchedFlicker) experimental and investigational for monitoring disease progression and for all other indications.

**Background**

Fundus photography involves the use of a retinal camera to photograph the regions of the vitreous, retina, choroid, and optic nerve. The resultant images may be either photographic or digital and become part of the member's medical record. Fundus photographs are usually taken through a dilated pupil in order to enhance the quality of the photographic record, unless unnecessary for image acquisition or clinically contraindicated.

Fundus photography is indicated to document abnormalities related to disease processes affecting the eye or to follow the progress of the disease, and is considered medically necessary for such conditions as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, or to identify glaucoma, multiple sclerosis, and other central nervous system abnormalities.

Fundus photographs are only considered medically necessary where the results may influence the management of the patient. In general, fundus photography is performed to evaluate abnormalities in the fundus, follow the progress of a disease, plan the treatment for a disease, and assess the therapeutic effect of recent surgery (e.g., photocoagulation). Fundus photographs are not medically necessary simply to document the existence of a condition. However, photographs may be medically necessary to establish a baseline to judge later whether a disease is progressive.

A CGS Administrators, LLC Medicare Local Coverage Determination (LCD) allows coverage of fundus photography (L34399) for diagnosis of conditions such as macular degeneration. Fundus photography is usually medically necessary no more than two times per year. Fundus photography of a normal retina will be considered not medically necessary.

A First Coast Service Options, Inc. Medicare Local Coverage Determination (LCD) also allows coverage of fundus photography (L33670) and states that "fundus photos may be of value in the documentation of rapidly evolving diabetic retinopathy."
In the absence of prior treatment, studies would not generally be performed for this indication more frequently than every 6 months."

A National Government Services, Inc. Medicare Local Coverage Determination (LCD) allows coverage of fundus photography (L33567) which states that “fundus photography may be used for the diagnosis of conditions such as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, glaucoma, multiple sclerosis or other central nervous system anomalies.” It is not covered if study is performed as a “screening” service. Fundus photography is usually medically necessary no more than two times per year. Fundus photography of a normal retina will be considered not medically necessary.

Sequential series of photographs are considered medically necessary only if they document a clinically relevant condition that is subject to change in extent, appearance or size, and where such change would directly affect the management. Repeat fundus photography may be medically necessary when an examination of the fundus reveals that the disease of condition of the fundus has progressed, such that prior fundus photographs no longer depict the pathology at the present time. Repeated fundus photographs of the same disease or condition, without any meaningful change, are not considered medically necessary. In addition to disease progression, repeat fundus photographs may be necessary if there is a new disease affecting the fundus, or for planning for additional surgical treatment. Routine images to embellish the record, but a succession of which would not influence treatment, are not considered medically necessary. When performed concurrently, the medical necessity of fundus photography and scanning computerized diagnostic imaging of the posterior segment should be documented in the medical record.

Documentation in the patient's medical record should include a current, pertinent history and physical examination, and progress notes describing and supporting the covered indication for fundus photography, and pertinent prior diagnostic testing and completed report(s), including, when appropriate, previous fundus photographs. Fundus photographs should be properly labeled as to which eye they represent, the date they were taken, and the date they were reviewed. The medical records should document the findings of the fundus photography, including a description of changes from prior fundus photographs (if any), and an interpretation of those findings, and the implications of the photographic evidence, including whether any changes in the treatment plan will be instituted as a result of the photographs. Fundus photographs without an interpretation are considered not medically necessary. All documentation
must be maintained in the member’s medical record. The record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)), as well as the physician or non-physician practitioner responsible for and providing the care of the patient.

When indicated for glaucoma, the interpretation of the fundus photographs should include a report of the vertical and horizontal cup/disc ratio based upon vessel pattern and/or coloration, the presence or absence of diffuse or focal pallor, the presence or absence of asymmetry, and the presence or absence of progression regarding any of the above parameters. If the fundus photographs include red-free images, commentary on the status of the retinal nerve fiber layer should accompany the images.

The American Academy of Ophthalmology (Marmor et al, 2011) does not recommend the use of fundus photography for screening of chloroquine and hydroxychloroquine retinopathy. It is not sensitive enough for screening because recognizable bull's-eye retinopathy signifies relatively advanced chloroquine or hydroxychloroquine toxicity.

Salcone et al (2010) stated that retinopathy of prematurity (ROP) is a vision-threatening vaso-proliferative condition of premature infants worldwide. As survival rates of younger and smaller infants improve, more babies are at risk for the development of ROP and blindness. Meanwhile, fewer ophthalmologists are available for bedside indirect ophthalmoscopy screening examinations. Remote digital imaging is a promising method with which to identify those infants with treatment-requiring or referral-warranted ROP quickly and accurately, and may help circumvent issues regarding the limited availability of ROP screening providers. The Retcam imaging system is the most common system for fundus photography, with which high-quality photographs can be obtained by trained non-physician personnel and evaluated by a remote expert. It has been shown to have high reliability and accuracy in detecting referral-warranted ROP, particularly at later post-menstrual ages. Additionally, the method is generally well-received by parents and is highly cost-effective.

An UpToDate review on "Retinopathy of prematurity" (Paysse, 2012) does not mention the use of digital imaging or fundus photography. It states that "screening evaluation consists of a comprehensive eye examination performed by an ophthalmologist with expertise in neonatal disorders".
An UpToDate review on “Toxocariasis: visceral and ocular larva migrans” (Weller and Leder, 2013) does NOT mention the use of fundus imaging/photography.

Computer-aided animation and analysis of time series retinal images (e.g., MatchedFlicker) has been proposed for use in monitoring glaucoma and other retinal diseases. According to the manufacturer of the MatchedFlicker (EyeIC, Wayne, PA), the technology automatically aligns and registers two images of the same object taken at different points in time, and generates a superimposed view that is alternated back and forth (i.e., a flicker). In so doing, areas of change present between the two images appear as motion.

MatchedFlicker has been cleared by the FDA based upon 510(k) premarket notification as a class II device.

The manufacturer states that MatchedFlicker helps to improve both the speed and accuracy of image diagnostic evaluations, resulting in more efficient workflow, more accurate patient diagnosis, and ease of documentation (EyeIC, 2014).

Studies have compared computer-aided animation and analysis of time series retinal images to side-by-side comparison of photographic images in a number of retinal diseases, including detection of glaucoma and screening of premature infant eyes for retinopathy of prematurity. Clinical utility studies are ongoing.

Screening for Diabetic Retinopathy:

van Ballegooie and van Everdingen (2000) stated that early detection and adequate treatment of complications of diabetes mellitus (DM) are important for many patients in maintaining independence and ability to work. Diabetic retinopathy (DR) cannot be prevented. Limitation of damage is possible by aiming for normoglycemia and normotension. While exudative as well as proliferative retinopathy can occur without any visual symptom, regular ophthalmological examination is necessary for timely laser coagulation. Fundus photography for screening is applicable under certain conditions; fluorescence angiography can be useful in patients with understood deterioration of visual acuity or diabetic maculopathy. In many patients foot disease can be prevented by simple measures: examining the foot at least once-yearly, recognition of the foot with a high level of risk, education of patient and family, adapted shoes and preventive foot care. Treatment of a foot ulcer consists of relief of mechanical pressure, repair of disturbed skin circulation, treatment of infection
and edema, optimal metabolic control, frequent local wound care and education. Patients with a diabetic foot have to be thoroughly followed-up for the rest of their lives. For patients with diabetic nephropathy cardiovascular complications are the main causes of morbidity and mortality. Of all patient with DM older than 10 years, urine has to be examined for loss of albumin at least once-yearly. Treatment of nephropathy consists of non-smoking, sufficient physical exercise, reduction of over-weight, well-composed nutrition and particularly treatment of hypertension.

Diagnosing cardiovascular diseases in patients with DM is in principle the same as for other patients. Treatment of hyper-cholesterolemia has to be based on an absolute risk of 20 % for cardiovascular disease in the following 10 years. The limit for treatment will be reached earlier in the presence of micro-albuminuria, persistent high HbA1c greater than 8.5 %, triglyceride concentration greater than 2.0 mmol/L, or a positive family history with myocardial infarction less than 60 years. In proven cardiovascular disease one needs to strive for optimization of the glucose metabolism, non-smoking and if necessary drug therapy.

Massin et al (2003) compared the results of fundus photography using a new non-mydriatic digital camera with the results of reference standard of Early Treatment Diabetic Retinopathy Study (ETDRS) retinal photographs, for the detection of DR. Fundus color photographs were taken with a Topcon non-mydriatic camera of 147 eyes of 74 diabetic patients, without pupillary dilation (5 overlapping fields of 45 degrees; posterior pole, nasal, temporal, superior and inferior). Three retinal specialists classified the photographs in a masked fashion, as showing no DR or mild non-proliferative DR (NPDR) not requiring referral, moderate or more severe NPDR and/or macular edema, or as non-gradable image requiring referral; ETDRS 35-mm color slides served as reference images for DR detection. For moderately severe to severe DR, the sensitivities of detection reported by the 3 observers were 92, 100 and 92 %, respectively, and the specificities, 87, 85, and 88 %, respectively. For 4 levels of DR severity (none or mild NPDR, moderate NPDR, severe NPDR and proliferative DR), the percentages of exact agreement between the 3 observers on the retinopathy grades assigned to the non-mydriatic photographs and to the ETDRS reference slides were 94.6, 93 and 87.6 %, respectively (kappa 0.60 to 0.80); 16 eyes of 9 patients (11%) were judged un-gradable by at least 1 observer. In a second series of 110 patients, evaluated in the setting of a screening procedure, fewer photographs were un-gradable (less than 6 %). The authors concluded that these findings suggested that fundus photographs taken by the Topcon TRC-NW6S non-mydriatic camera, without pupillary dilation, are suitable for DR screening.
In a prospective study, Aptel et al (2008) evaluated the sensitivity and specificity of 1- and 3-field, non-mydriatic and mydriatic, and 45 degrees digital color photography compared with mydriatic indirect ophthalmoscopy for DR screening. A group of 79 patients (158 eyes) were included. Color fundus photographs were taken with a Topcon TRC-NW6S digital camera, using 4 different techniques: (i) single-field non-mydriatic; (ii) 3-field non-mydriatic; (iii) single-field mydriatic; and (iv) 3-field mydriatic; followed by dilated ophthalmoscopy. Two independent ophthalmologists classified blinded photographs according to the presence or absence of specific diabetic retinal findings. The sensitivity, specificity and agreement (kappa analyses) of the 4 methods were calculated for the presence or absence of DR and for all diabetic retinal findings. The sensitivity and specificity of digital photography compared with ophthalmoscopy for detection of DR were respectively: 77 and 99 % using single-field non-mydriatic; 92 and 97 % using 3-field non-mydriatic; 90 and 98 % using single-field mydriatic; and 97 and 98 % using 3-field mydriatic. The degrees of agreement for the 4 methods were 0.82, 0.90, 0.90 and 0.95, respectively. For specific retinal findings, sensitivity was greater for detection of hard exudates, nerve fiber layer hemorrhage and venous beading, and lower for detection of micro-aneurysms, dot-blot hemorrhage, cotton wool spots and intra-retinal microvascular anomalies. The authors concluded that the 3-field strategy without pupil dilation represents a good compromise, with reasonable sensitivity and good comfort (short examination duration, able to drive after photography) favoring patient compliance with the screening program.

Polak and colleagues (2008) noted that the revised evidence-based guideline "Diabetic retinopathy: Screening, diagnosis and treatment" contained important recommendations concerning screening, diagnosis and treatment of DR. Regular screening and the treatment of risk factors, such as hyperglycemia, hypertension, obesity and dyslipidemia, can prevent retinopathy and slow down its development. Fundus photography is recommended as a screening method. If necessary, diagnosis by biomicroscopy and a treatment consisting of photocoagulation and/or vitrectomy should be performed by the ophthalmologist. The re-assessment of responsibilities is a vital component of the implementation of the guideline bearing in mind that the screening in particular, can be performed by personnel other than ophthalmologists.

In a cross-sectional study, Germain and associates (2011) compared the efficiency of the DR screening with digital camera by endocrinologists with that by specialist and resident ophthalmologists in terms of sensitivity, specificity, and level of "loss of
A total of 500 adult diabetic patients (1,000 eyes) underwent 3-field retinal photography with a digital fundus camera following pupillary dilatation; 5 endocrinologists and 2 ophthalmology residents underwent 40 hours of training on screening and grading of DR and detection of associated retinal findings. A κ test compared the accuracy of endocrinologist and ophthalmology resident screening with that performed by experienced ophthalmologists. Screening efficiency of endocrinologists was evaluated in terms of "loss of chance", namely, missed diagnoses that required ophthalmologist referrals. The mean weighted κ of DR screening performed by endocrinologists was similar to that of ophthalmology residents (0.65 versus 0.73). Out of 456 DR eyes, both endocrinologists and ophthalmology residents mis-diagnosed only stage 1 DR (36 and 14, respectively), which did not require ophthalmologist referral. There were no significant differences between endocrinologists and ophthalmology residents in terms of diabetic maculopathy and incidental findings except for papillary cupping and choroidal lesions, which were not the main purpose of the study or of the training. The authors concluded that endocrinologist with specific training for DR detection using a 3-field digital fundus camera with pupillary dilatation could perform a reliable DR screening without any loss of chance for the patients when compared with identical evaluation performed by experienced ophthalmologists.

Guigui et al (2012) reviewed the current screening methods for DR, with a focus on non-mydriatic digital fundus photography. Articles from Medline were reviewed from 1976 to November 2011 for different combinations of the words "diabetic retinopathy", "screening", "fundus photography" and "nonmydriasis". Current research has proven that pupillary dilation is not a necessary step in the fundus examination, although it reduces the number of unnecessary referrals to ophthalmologists. Automated grading systems, while saving time and reducing human error, still need refinement before they can replace manual grading by trained ophthalmologists. The authors concluded that non-mydriatic digital fundus photography with manual grading by a trained technician is an acceptable method of screening for DR.

Ku and colleagues (2013) evaluated the accuracy of grading DR using single-field digital fundus photography compared with clinical grading from a dilated slit-lamp fundus examination in Indigenous Australians living in Central Australia. Main outcome measures included sensitivity and specificity of grading using digital photography compared with the clinical gold standard of slit-lamp fundus examination. Of the 1,884 participants recruited for the study, 1,040 had self-
reported DM and, of those, 360 had fundus photographs available (706 eyes) that were able to be graded. On clinical grading, 163 eyes had any DR and 51 eyes had vision-threatening DR (VTDR). The sensitivity and specificity for detecting any DR were 74 % (95 % confidence interval [CI]: 67 % to 80 %) and 92 % (95 % CI: 90 % to 94 %), respectively. The sensitivity and specificity for detecting VTDR were 86 % (95 % CI: 77 % to 96 %) and 95 % (95 % CI: 93 % to 97 %), respectively. The authors concluded that single-field digital fundus photography is a valid screening tool for DR in remote communities of central Australia and may be used to provide eye care services to this region with acceptable accuracy.

An UpToDate review on "Diabetic retinopathy: Screening" (McCulloch, 2016) states that "Ophthalmoscopy is a reasonable screening method when performed by well-trained personnel on dilated fundi. The accuracy of ophthalmoscopy is substantially lower when performed by primary care physicians. As an alternative, 7-field stereoscopic fundus photography is another acceptable method, but also requires both a trained photographer and a trained reader. Fundal photography compares favorably with ophthalmoscopy (performed by an experienced ophthalmologist, optometrist, and ophthalmic technician) .... In patients with diabetes, we recommend screening for diabetic retinopathy (DR) (Grade 1B). Screening must be performed by those with expertise and can be accomplished with dilated fundus examination or retinal photography".

**Diagnosis and Management of Diabetic Retinopathy:**

The Institute for Clinical Systems Improvement’s clinical practice guideline on "Diagnosis and management of type 2 diabetes mellitus in adults" (Redmon et al, 2014) stated that "A dilated eye examination for diabetic eye disease performed by an ophthalmologist or optometrist is recommended annually for patients with T2DM. Less frequent exams (every 2 to 3 years) may be considered in the setting of a normal eye exam. The role of fundus photography is still being considered but doesn't replace a comprehensive exam".

**Monitoring of Ethambutol-Induced Optic Neuropathy:**

Chung and associates (1989) reported the case of a 54-year old Chinese woman with miliary choroidal tuberculosis who was followed for more than 3 years. She had had tuberculous meningitis for about 1 month before an ophthalmologic examination for blurred vision OU (oculus uterque meaning both eyes). There were 50 to 60 choroidal tubercles OU which were located mostly at the posterior poles including
the macular areas. The meningitis and tubercular lesions resolved with anti-
tuberculous medications. In a series of fundus photographs and fluorescein
angiograms, a macular subretinal neovascularization was noted in association with
the tubercular lesions, which resulted in disciform maculopathy. The authors stated
that this case had the largest number of tubercles reported in this century, and the
association of macular subretinal neovascularization with choroidal tuberculosis has
never been reported.

In a prospective, longitudinal, cohort study, Han and colleagues (2015) evaluated
longitudinal analysis of peri-papillary retinal nerve fiber layer (RNFL) and peri-foveal
ganglion cell-inner plexiform layer (GCIPL) thickness in patients being treated with
ethambutol (EMB). This study enrolled 37 patients who were treated with EMB for
pulmonary tuberculosis. Best-corrected visual acuity (BCVA), color vision test,
automated perimetry, fundus photography, and RNFL and GCIPL thickness were
measured at baseline and at 4 and 6 months after the start of EMB treatment, using
Cirrus optical coherence tomography (OCT). Among 37 patients, EMB-induced
optic neuropathy occurred in 1 patient (2.7 %). In this patient, thickening of the
RNFL and thinning of the GCIPL were noted at the onset of symptoms. After
discontinuation of EMB, RNFL and GCIPL thickness progressively normalized.
Changes in RNFL and GCIPL thickness were not statistically significant in the 36
patients who did not exhibit EMB-induced optic neuropathy-related symptoms during
follow-up (all p > 0.05). The authors concluded that thickening of the peri-papillary
RNFL and thinning of the peri-foveal GCIPL is an effective quantitative and early
marker for diagnosis of EMB-induced optic neuropathy.

Furthermore, the American Optometric Association recommends fundus
photography for initial baseline evaluation and periodical follow-up of individuals
being treated with ethambutol.

**Age-Related Macular Degeneration:**

Holz and colleagues (2017) summarized the results of 2 consensus meetings
(Classification of Atrophy Meeting [CAM]) on conventional and advanced imaging
modalities used to detect and quantify atrophy due to late-stage non-neovascular
and neovascular age-related macular degeneration (ARMD) and to provide
recommendations on the use of these modalities in natural history studies and
interventional clinical trials. A panel of retina specialists participated in a systematic
debate on the relevance of distinct imaging modalities held in 2 consensus
meetings. During the CAM, a consortium of international experts evaluated the advantages and disadvantages of various imaging modalities on the basis of the collective analysis of a large series of clinical cases. A systematic discussion on the role of each modality in future studies in non-neovascular and neovascular ARMD was held. Main outcome measures were advantages and disadvantages of current retinal imaging technologies and recommendations for their use in advanced ARMD trials. Imaging protocols to detect, quantify, and monitor progression of atrophy should include color fundus photography (CFP), confocal fundus auto-fluorescence (FAF), confocal near-infrared reflectance (NiR), and high-resolution OCT volume scans. These images should be acquired at regular intervals throughout the study.

In studies of non-neovascular ARMD (without evident signs of active or regressed neovascularization [NV] at baseline), CFP may be sufficient at baseline and end-of-study visit. Fluorescein angiography (FA) may become necessary to evaluate for NV at any visit during the study. Indo-cyanine green angiography (ICG-A) may be considered at baseline under certain conditions. For studies in patients with neovascular ARMD, increased need for visualization of the vasculature must be taken into account. Accordingly, these studies should include FA (recommended at baseline and selected follow-up visits) and ICG-A under certain conditions. The authors concluded that a multi-modal imaging approach is recommended in clinical studies for the optimal detection and measurement of atrophy and its associated features. Specific validation studies will be necessary to determine the best combination of imaging modalities, and these recommendations will need to be updated as new imaging technologies become available in the future.

Fleckenstein and associates (2018) noted that geographic atrophy (GA) is an advanced form of ARMD that leads to progressive and irreversible loss of visual function. Geographic atrophy is defined by the presence of sharply demarcated atrophic lesions of the outer retina, resulting from loss of photoreceptors, retinal pigment epithelium (RPE), and underlying choriocapillaris. These lesions typically appear first in the peri-foveal macula, initially sparing the foveal center, and over time often expand and coalesce to include the fovea. Although the kinetics of GA progression are highly variable among individual patients, a growing body of evidence suggested that specific characteristics may be important in predicting disease progression and outcomes. This review synthesized current understanding of GA progression in ARMD and the factors known or postulated to be relevant to GA lesion enlargement, including both affected and fellow eye characteristics. In addition, the roles of genetic, environmental, and demographic factors in GA lesion enlargement were discussed. Overall, GA progression rates reported in the
literature for total study populations ranged from 0.53 to 2.6 mm²/year (median of approximately 1.78 mm²/year), assessed primarily by color fundus photography or FAF imaging. Several factors that could inform an individual's disease prognosis have been replicated in multiple cohorts: baseline lesion size, lesion location, multifocality, FAF patterns, and fellow eye status. Because BCVA does not correspond directly to GA lesion enlargement due to possible foveal sparing, alternative assessments are being explored to capture the relationship between anatomic progression and visual function decline, including micro-perimetry, low-luminance VA, reading speed assessments, and patient-reported outcomes. The authors concluded that understanding GA progression and its individual variability is critical in the design of clinical studies, in the interpretation and application of clinical trial results, and for counseling patients on how disease progression may affect their individual prognosis.

Appendix

**Note on Optomap coding:** The Optos Optomap is image-assisted ophthalmoscopy for evaluation of ocular health. Optomap meets the criteria for the CPT code for fundus photography (92250).

### CPT Codes / HCPCS Codes / ICD-10 Codes

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

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<th>Code Description</th>
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<tr>
<td><strong>92250</strong></td>
<td>Fundus photography with interpretation and report [includes Optomap]</td>
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<th>Code Description</th>
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<td>Computer-aided animation and analysis of time series retinal images for the monitoring of disease progression, unilateral or bilateral, with interpretation and report</td>
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Other HCPCS code related to the CPB:

**Ethambutol - no specific code:**

**ICD-10 codes covered if selection criteria are met:**

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<th>Code Description</th>
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<td>Neoplasm of unspecified behavior of retina and choroid</td>
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<tr>
<td>H31.00 - H31.9</td>
<td>Other diseases of choroid</td>
</tr>
<tr>
<td>H32</td>
<td>Chorioretinal disorders in diseases classified elsewhere</td>
</tr>
<tr>
<td>H33.001 - H33.8</td>
<td>Retinal detachment and breaks</td>
</tr>
<tr>
<td>H34.00 - H34.9</td>
<td>Retinal vascular occlusions</td>
</tr>
<tr>
<td>H35.00 - H35.9</td>
<td>Other retinal disorders</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>H36</td>
<td>Retinal disorders in diseases classified elsewhere</td>
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<tr>
<td>H40.001 - H40.9</td>
<td>Glaucoma</td>
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<tr>
<td>H42</td>
<td>Glaucoma in diseases classified elsewhere</td>
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<td>H43.00 - H43.9</td>
<td>Disorders of vitreous body</td>
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<tr>
<td>H44.001 - H44.9</td>
<td>Disorders of the globe</td>
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<tr>
<td>H44.511 - H44.519</td>
<td>Absolute glaucoma</td>
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<tr>
<td>H46.00 - H47.9</td>
<td>Disorders of optic nerve and visual pathways</td>
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<tr>
<td>H53.50 - H53.59</td>
<td>Color vision deficiencies</td>
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<tr>
<td>H59.031 - H59.039</td>
<td>Cystoid macular edema following cataract surgery</td>
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<tr>
<td>L93.0 - L93.2</td>
<td>Lupus erythematosus</td>
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<tr>
<td>M05.00 - M14.89</td>
<td>Inflammatory polyarthropathies</td>
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<tr>
<td>M32.0 - M32.9</td>
<td>Systemic lupus erythematosus (SLE)</td>
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<td>P35.0</td>
<td>Congenital rubella syndrome</td>
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<tr>
<td>Q13.4</td>
<td>Other congenital corneal malformations [Peter's anomaly]</td>
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<tr>
<td>Q14.0 - Q14.9</td>
<td>Congenital anomalies of posterior segment of eye</td>
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<tr>
<td>Q15.0</td>
<td>Congenital glaucoma</td>
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<tr>
<td>Q85.1</td>
<td>Tuberous sclerosis</td>
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<tr>
<td>Q85.8 - Q85.9</td>
<td>Other and unspecified phakomatoses, not elsewhere classified</td>
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<tr>
<td>Q87.1 - Q87.89</td>
<td>Other specified congenital malformation syndromes affecting multiple systems</td>
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<td>Q89.8</td>
<td>Other specified congenital malformations</td>
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<tr>
<td>Q99.2</td>
<td>Fragile X chromosome</td>
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<td>R94.110</td>
<td>Abnormal electro-oculogram (EOG)</td>
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<td>R94.111</td>
<td>Abnormal electroretinogram [ERG]</td>
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<td>R94.112</td>
<td>Abnormal visually evoked potential [VEP]</td>
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<td>R94.113</td>
<td>Abnormal oculomotor study</td>
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The above policy is based on the following references:


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<tr>
<th>Code</th>
<th>Code Description</th>
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<tr>
<td>S05.50x+</td>
<td>Penetrating wound with foreign body of eyeball</td>
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<td>S05.52x+</td>
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<tr>
<td>T37.2x1+</td>
<td>Poisoning by antimalarials and drugs acting on other blood protozoa</td>
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<tr>
<td>T37.2x4+</td>
<td>[hydroxychloroquine toxicity]</td>
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<tr>
<td>T37.3x1+</td>
<td>Poisoning by other antiprotozoal drugs</td>
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<td>T37.3x4+</td>
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ICD-10 codes not covered for indications listed in the CPB: (not all inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>B83.0</td>
<td>Visceral larva migrans</td>
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</table>


24. Paysse EA. Retinopathy of prematurity. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2012.
34. Radcliffe NM, Sehi M, Wallace IB, et al. Comparison of stereo disc photographs and alternation flicker using a novel matching technology for
46. McCulloch DK. Diabetic retinopathy: Screening. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2016.


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Amendment to
Aetna Clinical Policy Bulletin Number:
0539 Fundus Photography

There are no amendments for Medicaid.

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Updated 04/13/2018