Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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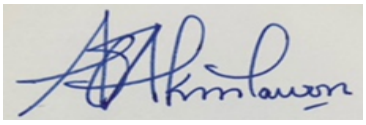
Plan: AmeriHealth Caritas Pennsylvania Community Health Choices	**Submission Date**: 6/28/2022
Policy Number: CCP.1380	**Effective Date:** 6/2018 **Revision Date:** June 1, 2022
Policy Name: Fundus photography	
Type of Submission – Check all that apply: ☑ **New Policy** **Revised Policy*** ☐ **Annual Review – No Revisions** ☐ **Statewide PDL**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** This is the first submission of this policy.	
Name of Authorized Individual (Please type or print): Akintayo Akinlawon, MD	**Signature of Authorized Individual:** 

Fundus photography

Clinical Policy ID: CCP.1380

Recent review date: 6/2022

Next review date: 10/2023

Policy contains: Diabetic retinopathy, fundus photography, glaucoma, ophthalmoscopy.

AmeriHealth Caritas Pennsylvania Community HealthChoices has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania Community HealthChoices will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Fundus photography (of the retina) is clinically proven and, therefore, medically necessary to monitor disease progression or provide guidance in evaluating need or response to treatment, when furnished by a qualified optometrist or ophthalmologist in the evaluation and management of a retinal disorder or another condition that has affected the retina (e.g., choroid disturbances and diabetic retinopathy, glaucoma, multiple sclerosis, and other central nervous system disorders) (American Academy of Ophthalmology, 2019a, 2019b).

Fundus photography is investigational/not clinically proven and, therefore, not medically necessary for the following indications:

- As the sole means of diagnosing a condition.
- Routine screening.
- Documentation for a condition at baseline that is reasonably expected to be static or not require future treatment.
- When the information would not affect care management.
- Photography of a normal retina, except in diabetic members who have symptoms of visual disturbances and a normal or unremarkable retinal examination.

See also clinical policy CCP.1230 Retinal telescreening for diabetic retinopathy.

Limitations

Fundus photography performed more than two times in a calendar year is not medically necessary. Additional testing will require clinical justification for medical necessity.

All tests must include a written interpretation. If an interpretation is not included in the same medical record with the photograph, then both the technical and professional components will be considered not medically necessary.

Alternative covered services

- Direct ophthalmoscopy.
- Slit-lamp examination.

Background

Fundus photography is the process of taking serial two-dimensional photographs through the pupil using a low-power microscope with an attached camera for imaging regions of the vitreous, retina, choroid, and optic nerve for diagnosis. These images are also used for therapeutic assessment of recently performed retinal laser surgery and to aid in the interpretation of fluorescein angiography.

Fundus photography is conducted by a qualified optometrist or ophthalmologist in the evaluation and management of various disorders, after a face-to-face encounter. It can be performed with colored filters or with specialized dyes, and both eyeballs can be photographed during the same encounter.

Fundus photography, along with laser ophthalmology, can be used for fundus autofluorescence, a non-invasive imaging technique that detects fluorophores, which are naturally occurring molecules that absorb and emit light of specified wavelengths. Fundus autofluorescence is a potential indicator for diagnosing and monitoring in the central retina and its periphery. Autofluorescence shows areas of fluorescence in certain conditions, such as macular degeneration, retinal detachment, inherited dystrophies, central serous chorioretinopathy, and vitelliform lesions (Stuart, 2012). For diabetic retinopathy evaluation, the Early Treatment Diabetic Retinopathy Study seven-field stereoscopic color fundus photography is the gold standard, but two- or three-fields fundus photography with or without mydriasis is available for screening (Goh, 2016).

Fundus cameras are nonportable, expensive, and operator dependent; as such, they are impractical for screening in primary care or mobile settings. Recently, fundus imaging has incorporated smart phone technology and a conventional handheld indirect ophthalmoscopy lens. The major advantage of this technology is that smart phones are much more readily available than fundus cameras, which often are not available in clinics or hospitals (Khanamiri, 2017).

Findings

Various professional guidelines for specific disorders mention fundus photography. For example, the American Academy of Ophthalmology guideline on age-related macular degeneration states that color fundus photos may be obtained when angiography is performed, to be used as a baseline and in follow-up of treated patients, as they are useful in identifying etiology and landmarks of the condition (American Academy of Ophthalmology, 2015). Another Academy guideline, on diabetic retinopathy, states funduscopy can be performed during the initial examination, as these photographs help detect the disorder and its severity (American Academy of Ophthalmology, 2017).

Building on a National Coverage Determination (Centers for Medicare & Medicaid Services, 1979),, current Medicare Local Coverage Determinations state that fundus photography is medically necessary when used to monitor potential disease progression or to guide clinical decisions in evaluating need for, or response to specific treatment. Other local coverage determinations specify that the technique is most helpful for conditions that include macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, glaucoma, multiple sclerosis, or other central nervous system disorders. Fundus photography by itself is not a reliable

means of diagnosing a disorder within the retina, and thus should not be used as a screening tool (Centers for Medicare & Medicaid Services, 2019, 2021a, 2021b). Ophthalmoscopy or slit-lamp examinations are used for initial screening.

Repeat fundus photography should only be performed at clinically appropriate intervals (i.e., consistent with a physical change on examination or after sufficient time has elapsed for progression or for a treatment to have reasonably had an impact) (Centers for Medicare & Medicaid Services, 2021a).

Early studies found a high level of sensitivity and specificity from fundus photography. A review of 1,175 participants who received fundus photography with a digital non-mydriatic camera (both eyes) as part of an executive health program revealed adequate photographs in 95.1% (1,117) eyes. Abnormal findings in either eye occurred in 14.9% (n = 166) of participants, with the most common abnormal findings to be macular degeneration (57%), optic nerve cupping (45%), hypertensive retinopathy (15%), and choroidal nevi (10%). Overall sensitivity was 87% (Tarabishy, 2011).

An assessment of sensitivity and specificity of direct ophthalmoscopy for detecting diabetic retinopathy, compared to fundus photographs, were 55.67% and 76.68%, based on 728 eyes tested; authors concluded that detection ability of fundus photography was superior to that of direct ophthalmoscopy (Ahsan, 2014).

A study of 16,670 subjects with diabetes who had not been diagnosed with diabetic retinopathy prior to the study compared two detection algorithms in fundus photography, including 1) that which won the 2009 Retinopathy Online Challenge Competition and 2) the one used in 2010 by EyeCheck, an early diabetic retinopathy detection project. The area under the receiver operating curve for the two algorithms, which measures sensitivity and specificity, was statistically similar (0.821 and 0.839) (Abramoff, 2010).

A systematic review of 15 studies, mostly of good quality, included a comparison of the ability of optical coherence tomography and stereoscopic fundus photography to diagnose diabetic macular edema (in six of 15studies). The sensitivity and specificity rates of 79% and 88% for optical coherence tomography suggested a good performance, comparable with fundus stereophotography (Virgili, 2007).

A systematic review of eight studies determined that fundus autofluorescence imaging sensitivity and specificity ranged from 32% to 100% and 34% to 100%, respectively. No meta-analysis was possible due to heterogeneity between studies (Frampton, 2017). This study updated initial findings in an earlier systematic review of the same data base (Frampton, 2016).

A systematic review of 10 studies indicated “tentative support” for using fundus photography for measuring dementia-associated changes, with more studies needed to duplicate results (McGrory, 2016).

A comparison of fundus photography using a smart phone and traditional fundus camera involved 301 participants with type 2 diabetes (602 eyes). The sensitivity and specificity for detecting any diabetic retinopathy using a smart phone were 92.7% and 98.4%, compared to a standard fundus camera (Rajalakshmi, 2015). A recent systematic review of nine studies (n = 4,219) of smart phone fundoscopy showed combined kappa agreement of 77.77% (“substantial”) of the gold standard of retinal camera images or clinical examinations (Vilela, 2018).

A study of 1,542 images using fundus photography included 786 normal controls, 467 advanced glaucoma, and 289 early glaucoma participants. Images were split into 754 training, 324 validation, and 464 test datasets. Accuracy of each dataset included 82.9% for training, 79.9% for validation, and 77.2% for test using a simple model, and higher for other models (Ahn, 2018).

A study of 15,180 eyes of 9,946 participants with diabetes tested with fundus photography at the Wills Eye Hospital in Philadelphia over six years showed 16.6% had diabetic retinopathy in at least one eye, and at risk for blindness. Other ocular pathologies were found in > 25% of participants (Gao, 2018).

Some economically developing nations have started to use fundus photography for screening for diabetic retinopathy, and thus, blindness. A sample of 2,205 participants in Lebanon screened over 11 months found 12.55% with type 2 diabetes had signs of di021abetic retinopathy. Only 6.28% of photos could not be interpreted accurately (Arej, 2019).

In 2020, we updated two American Academy of Ophthalmology guidelines (2019a, 2019b) that replaced the 2015 and 2017 versions; the findings are consistent with the current policy. We added limitations to testing based on four Centers for Medicare & Medicaid Services Local Coverage Determinations (2019, 2021a, 2021b).

In 2021, we deleted one retired local coverage determination and found no new relevant information to add to the policy. No policy changes are warranted.

In 2022, we added a meta-analysis of nine studies (n = 1430) of fundus photography to detect diabetic retinopathy using smart phones. Pooled sensitivity and specificifity were 87% and 94% (Tan, 2020). We also added a systematic review showing hand-held fundus cameras, versus a gold standard, had sensitivity and specificity rates of 87%/95% for diabetic retinopathy and 81%/83% for all other diagnoses (Palermo, 2021). A third systematic review found that applying artificial intelligence to color fundus photography had sensitivity and specificity of 88% and 90% for diagnosing age-related macular degeneration (Dong, 2021).

References

On April 21, 2022, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Retina” (MeSH), “Ophthalmoscopy” (MeSH), “fundus photography,” and “fundoscopy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

4/2018: initial review date and clinical policy effective date: 6/2018

6/2019: Policy references updated.

6/2020: Policy references updated. Limitations added.

6/2021: Policy references updated.

6/2022: Policy references updated.