Fundus photography

Clinical Policy ID: CCP.1380

Recent review date: 6/2024

Next review date: 10/2025

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

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' 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, on a case by case basis, by AmeriHealth Caritas 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' 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' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Fundus photography (of the retina) is clinically proven and, therefore, may be 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

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

Professional Guidelines:

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).

The American Society of Retina Specialists has stated that fundus photography is an integral part of quantitatively grading diabetic retinopathy severity and can be useful in documenting clinical findings in other retinal vascular conditions (Ramakrishnan, 2024). Ultra-widefield fundus photography can also help screen for predominantly peripheral diabetic retinopathy lesions which may be associated with a greater risk for disease progression (Ramakrishnan, 2024). The guidelines suggest that in conjunction with fundus photography, ultra-widefield fluorescein angiography is helpful in assessing retinal nonperfusion, neovascularization, and permeability to guide treatment decisions (Ramakrishnan, 2024). However, the guidelines do not provide a specific recommendation or strength of evidence for using fundus photography to monitor retinal disease progression (Ramakrishnan, 2024).

The American Diabetes Association notes that high-quality fundus photographs can detect most clinically significant diabetic retinopathy (American Diabetes Association Professional Practice Committee, 2024). However, retinal photos are not a substitute for dilated comprehensive eye exams, which should be performed at least initially and at yearly intervals thereafter or more frequently as recommended by an eye care professional (American Diabetes Association Professional Practice Committee, 2024). The guideline recommends that programs using retinal photography with remote reading or FDA-approved artificial intelligence algorithms to improve access to diabetic retinopathy screening are appropriate screening strategies for diabetic retinopathy (Grade B recommendation) (American Diabetes Association Professional Practice Committee, 2024).

Literature Review:

Fundus photography has been extensively studied as a diagnostic tool in various ocular conditions, demonstrating high sensitivity and specificity. A study on (n = 1,175) participants who underwent fundus photography showed a 95.1% rate of adequate images and revealed abnormal findings in 14.9% of participants, including prevalent conditions such as macular degeneration and hypertensive retinopathy (Tarabishy, 2011). Furthermore, in a comparison between fundus photography and direct ophthalmoscopy for detecting diabetic retinopathy in (n = 728) eyes, fundus photography was found to be superior, with sensitivity and specificity of 55.67% and 76.68% respectively (Ahsan, 2014). Additionally, advanced applications using smartphones for fundus imaging have shown promising results, with a study involving (n = 602) from (n = 301) participants demonstrating a sensitivity of 92.7% and specificity of 98.4% in detecting diabetic retinopathy (Rajalakshmi, 2015).

The use of different imaging modalities has been compared in various studies to evaluate their effectiveness in diagnosing ocular diseases. Optical coherence tomography and stereoscopic fundus photography were examined in a systematic review of 15 studies, indicating similar performance in diagnosing diabetic macular edema with sensitivity and specificity rates of 79% and 88%, respectively (Virgili, 2007). Another systematic review assessed the variability in sensitivity and specificity of fundus autofluorescence imaging across eight studies, with results ranging from 32% to 100% and 34% to 100%, respectively, highlighting the heterogeneity in study outcomes (Frampton, 2017).

Fundus photography has also been applied in screening for conditions beyond traditional ocular diseases. A review of ten studies provided tentative support for using fundus photography to measure dementia-associated changes, suggesting the need for further research to replicate findings (McGrory, 2016). On a global scale, fundus photography is increasingly used in economically developing nations for screening diabetic retinopathy, as evidenced by a Lebanese study over 11 months which found diabetic retinopathy in 12.55% of (n = 2,205) screened participants (Arej, 2019).

Overall, fundus photography continues to play a critical role in ophthalmic diagnosis and screening. A comprehensive study at the Wills Eye Hospital over six years with (n = 15,180) eyes of (n = 9,946) diabetic participants found a 16.6% prevalence of diabetic retinopathy, underscoring the importance of such imaging techniques in early detection and prevention of blindness (Gao, 2018). The continued advancement in imaging

technology, including the use of machine learning algorithms and mobile devices, suggests a promising future for extending these capabilities, thus improving diagnostic accuracy and accessibility in eye care.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, 2022). 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).

In January 2023, we eliminated the hard limits in the coverage section.

In June 2023, we eliminated all citations of and references to the Centers for Medicare & Medicaid Services. We added systematic reviews:

- In 105 studies (n = 213,213), the performance of machine learning in glaucoma diagnosis was high when using fundus images (sensitivity 92%, specificity 93%) or retinal optical coherence tomography images (90%/91%) (Wu, 2022).
- In 12 studies (n = 1,348), spectral-domain optical coherence technology showed high sensitivity (87%) and specificity (83%) in the diagnosis of polypoidal choroidal vasculopathy. Authors recommend combining this method with the more clinically available color fundus photography (Jiang, 2022).

In 2024, we added new guidelines from the The American Diabetes Association and the American Society of Retina Specialists and reorganized some of the findings section. No policy changes warranted.

References

On May 12, 2024, 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.

6/2023: Policy references updated.

6/2024: Policy references updated.