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

We would like to thank those who suggested changes to the draft Ophthalmology: Posterior Segment Imaging (Extended Ophthalmoscopy and Fundus Photography) LCD. The official notice period for the final LCD begins on October 1, 2007, and the final determination will become effective on December 1, 2007.

Comment: A representative of a medical device company submitted a power point presentation listing concerns about the LCD:

1. Retinal photography in diabetic patients should not be screening.
2. Services are limited to optometrists and ophthalmologists

Response: National Government Services has received determinations from CMS on several different occasions that retinal photography as a screening procedure is a non-covered service. Fundus photography is not a substitute for an annual dilated examination in diabetic patients by a qualified professional.

The LCD states that fundus photography performed by non-eye professionals and electronically transmitted to a qualified professional for interpretation would not be covered. We believe that the performance of this test requires expertise so that the test is of sufficient technical quality to provide the needed information. When the technical portion of the test is performed in this manner we believe that even the standard for general supervision is not met.

Comment: A neuro-ophthalmologist from the Indiana-Kentucky jurisdiction outlined his expertise in the diagnosis and treatment of neuro-ophthalmologic disease. He stated that he does not report ophthalmology examination codes, 92002, 92004, 92012 and 92014 with codes 92225 and 92226, but uses
E&M codes 99201-99215 and 99241-99245 to report his examinations, and would like these added to the LCD as payable with codes 92225 and 92226.

Response: The sentences that he objects to are in the supplemental information article: “Code 92225 is payable with ophthalmoscopic examination codes 92002, 92004, 92012 and 92014. Code 92226 is payable only with examination codes 92012 and 92014.” The purpose of these statements was to clarify the use of the initial and subsequent extended ophthalmoscopy codes when used with other visit codes. We did not intend that these services could not be billed with E&M codes. We will amend the LCD so that code 92225 may also be billed with the requested E&M codes, and that code 92226 may be billed with the 99211-99215 and 99241-99245.

Comment: An optometry representative had several comments:
1. He asks to add ICD codes 363.31-363.35, 363.41-363.43, 363.51-363.57, 363.61-363.63, and 363.71-363.72 to the LCD for Fundus photography that are in the current LCD for fundus photography.


Response: The ICD-9 codes that appear duplicated in these sections will be deleted from the “Additional ICD-9-CM codes for fundus photography” list.

3. Multiple Sclerosis is listed as a condition for use of intra-ocular photography, but the ICD-9 code for MS is not listed in the LCD. The commenter submitted two article links on MS.

Response: ICD-9 code 340 (multiple sclerosis) is listed under “Additional ICD-9 codes for fundus photography”.

4. Extended ophthalmoscopy and fundus photography sometimes need to be performed on the same day for the same eye. The commenter thinks this is still allowed but the policy is not clear.
Response: The commenter is correct that fundus photography and extended ophthalmoscopy may be performed during the same encounter. However, as stated in the LCD, there must a reasonable medical expectation that the multiple imaging services might provide additive (non-duplicative) information.

5. Commenter is not sure why fundus photography is referred to as “intra-ocular photography” in the policy.

Response: We will change this to “fundus photography.”

6. Payment for extended ophthalmoscopy when there is no drawing should be allowed in some circumstances, such as a trauma victim who requires a comprehensive extended ophthalmoscopy detailed retinal exam to make sure that the peripheral retinal is intact but no pathology is detected.

Response: The extended ophthalmoscopy service as described in CPT includes a retinal drawing as part of the service. The code should not be billed unless a drawing has been made. In order to bill this service, it would be necessary to create a properly labeled drawing, albeit of a normal fundus. Alternatively, it would be appropriate to document in the medical record that the fundus was normal, forego creating the drawing, and not bill this as a separate service.

7. Utilization guidelines are not specific about the definition of “normal” in the statement “Fundus photography of a normal retina is not considered medically necessary and will be denied for reimbursement”. This guideline severely limits the physician in making accurate inter-ocular comparisons. Additional judgments regarding the progression to a bilateral condition or final regression of pathology are hampered without immediate availability of simultaneous images.

Response: The contractor believes that the recognition of a “normal” retina is standard judgment for qualified professionals. In any instances in which the retina is thought not to be normal, the provider should document in the medical record those features that are not normal.

Comment: An ophthalmology representative had these comments:
1. The abstract and indication for extended ophthalmoscopy appear to be appropriate for both fundus photography and extended ophthalmoscopy.

Response: We appreciate his review.

2. The Limitations requires all testing must include a written interpretation and formal report. This represents a change from current policy (ASF).
Response: These services require an interpretation and report. This may be included in the other notes in the medical record, as long as it is separately addressed. The extended ophthalmoscopy requires that the drawing be labeled.

3. Telemedicine-based nonprofessionally taken fundus interpreted by a professional at distance is non-covered, but several government organizations including the VA use this as a screening for a large population of patients with diabetes and AMD. Consensus is needed regarding this policy and other national government organizations such as the VA.

Response: Responses to repeated inquiries of CMS have confirmed that telemedicine-based fundus photography is a screening service that it is not a substitute for an annual dilated examination in a diabetic patient by a qualified professional.

4. On limitations for extended ophthalmoscopy, denial of a fellow eye without signs and symptoms is of concern. From studies published between 1976 to 1990, it is known that asymptomatic eyes can have advanced diabetic retinopathy. For diabetic patients, both eyes are examined by the ophthalmologist to look for signs of extra-retinal neovascularization and clinically significant macular edema, both of which can occur in the absence of any visual symptoms. Also, early neovascular macular degeneration can also occur in the absence of any visual symptoms. Early recognition can prevent vision loss and can be a substantial long-term health benefit savings. The commenter disagrees with the statement regarding denial of this as not medically necessary if there are no symptoms. Repeated extended ophthalmoscopy exams at each visit are also required, sometimes as frequently as 3 or 4 times per year in patients with aggressive diabetic retinopathy.

Response: We agree that systemic diseases can affect a fellow eye. However, frequent repeat examinations of a fellow eye should not be necessary. Periodic examinations in diabetics could be appropriate.

5. Bundling extended ophthalmoscopy into the 90 global surgery period for ophthalmologic surgery for the same provider is inappropriate because the RVUs for surgical procedures, specifically those involving the posterior segment, do not include special ophthalmological testing (fluorescein angiography, fundus photography, optical coherence tomography, extended ophthalmoscopy). Coverage for extended ophthalmoscopy should begin one week following the posterior segment ophthalmologic procedure. The commenter is particularly concerned about pars plana vitrectomy, scleral buckling, or any combination of those posterior segment procedures. Patients following cataract surgery are at greater risk for developing retinal detachment, as documented in multiple studies. The dx. and treatment of retinal detachment in the post-operative period requires extended ophthalmoscopy.

Response: We do not disagree with the need to perform the service during the post-operative period. However, extended ophthalmology is a physician service (type of service = 1 on MPFSDB) and not a
test. It is therefore included in global period for surgery (see Medicare Claims Payment Manual (publication 100-4), Chapter 12, Section 40.1.A). This is comparable to a physical examination of other operated areas by performing surgeons. This has been discussed with the Regional Office who concurred with the Carrier determination, and has been upheld at ALJ hearings.

6. The commenter is also concerned about bundling other ophthalmologic tests such as fundus photography with fluorescein angiography, ultrasound, and optical coherence tomography (OCT) with extended ophthalmoscopy. This makes it much more likely that those who have no skills in extended ophthalmoscopy will be able to perform unnecessary and invalid testing and be reimbursed for the testing in full while those of us who perform extended ophthalmoscopy and careful examinations, and then subsequently order testing, will be not reimbursed for this additional work that is performed in due diligence and within the confines of the standard of care expected from all ophthalmologists. The extended ophthalmoscopy and the ophthalmic imaging are not interchangeable. Extended ophthalmoscopy is a physical evaluation by an examiner using stereoscopic binocular viewing. Fundus photography and fluorescein angiography as a routine are not stereoscopically performed, but do not yield the same kind of information that can be gleaned from an extended ophthalmoscopy examination. Anatomic detail can often be discerned, allowing us to make a recommendation to obtain fluorescein angiography or optical coherence tomography (OCT). In addition, changes that may be seen anatomically and visibly on evaluation of the retina often can be missed with optical coherence tomography and with fluorescein angiography. In addition, both changes that may appear normal on extended ophthalmoscopy may be found to be quite abnormal on optical coherence tomography, specifically, that of vitreomacular traction, development of early macular hole, or presence of occult subretinal fluid in multiple conditions. It is reasonable to expect that multiple imaging services will provide additive and nonduplicative information to manage patients with retinal diseases. Imaging studies qualitatively and quantitatively enhance those findings of extended ophthalmoscopy and are essential to be performed because of the findings of extended ophthalmoscopy. This will provide standard of care for retinal diseases. Thus, extended ophthalmoscopy should not be bundled with other imaging modalities.

Response: This LCD does not bundle external ophthalmoscopy into other services. It does indicate that duplicative services may be deemed to be medically not necessary if they are provided without reasonable expectation of obtaining additive medical information.

7. The commenter submitted an article from the American Academy of Ophthalmology, “Laser Scanning Imaging for Macular Disease”, comparing the use of laser scanning imaging with slit lamp biomicroscopy or fundus photography to detect macular disease.
A copy of a technology assessment from the American Academy of Ophthalmology on “Laser Scanning Imaging for Macular Disease” was submitted in support of this technique being performed in addition to extended ophthalmoscopy and fundus photography. The article supports the use of OCT to quantify retinal thickness in diabetic neuropathy and provide additional information in patients with macular holes. The article does note that additional studies are needed to develop testing strategies for macular edema.

Comment: The New Jersey ophthalmology CAC representative commented on the discussion about requiring a drawing for extended ophthalmoscopy and suggested it could be billed with modifier 52 if a drawing is not needed.

Response: Extended ophthalmoscopy, as described in CPT, includes a retinal drawing as part of the service. The code cannot be billed if the drawing is not included. We will forward the issue to CMS for consideration.

Comments: Comments from the New York Medical Society meeting included:
1. Subjective visual disturbance is an inappropriate diagnosis along with several other diagnoses that should be removed from the LCD. NGS would like to be informed of these diagnoses.

Response: We agree that this diagnosis (ICD-9 code 368.10) may be inappropriate because it is non-specific when a more specific symptomatology should be specified. We will delete the diagnosis code.

2. Question was asked whether a normal fundus exam would be covered. The fundus exam should provide information and doesn’t have to have an abnormal result.

Response: Photography of an otherwise normally appearing fundus would be denied as medically unnecessary unless there were a medically reasonable expectation that it could be anticipated to provide additional information that would not otherwise be discernible, for use in the management of the patient.

Comments: A commenter from Massachusetts asks to make these changes to the draft:
1. Limitations – define “non-eye professional”. Is a Certified Ophthalmic Technician considered a professional?

Response: For purposes of this LCD, an “eye-professional” is defined as an ophthalmologist or optometrist. However, a certified ophthalmic technician working under the supervision of an ophthalmologist or optometrist would be included under this designation.
2. Based on an article referenced, “A Web-based Telemedicine System for Diabetic Retinopathy Screen Using Digital Fundus Photography”, there does not appear to be a valid reason to deny an interpretation done by a professional off site from a procedure done by another eye professional. Does the carrier deny other radiographs, CT scans or MRIs interpreted off site when the images are sent electronically? Will we deny professional services to a beneficiary with diabetes because they don’t have access to an optometrist or ophthalmologist who can interpret photographs?

Response: National Government Services has received determinations from CMS on several different occasions that retinal photography as a screening procedure is a non-covered service. Fundus photography is not a substitute for an annual dilated examination in diabetic patients by a qualified professional.

3. In Coding Guidelines, places of service for fundus photography should include 31, 32, 13 for technical and professional components, since at least 2 portable digital fundus cameras exist and can be used away from an office. (The commenter has submitted manufacturer’s brochures on NM-2000, handheld non-mydriatic fundus camera, and Kowa Genesis-D, hand-held fundus camera.)

Response: We will expand the places of services to include 13 (assisted living) and 32 (nursing facility or SNF Part B stay). Under SNF Consolidated Billing, only the professional component (92250-26) of the service is reimbursable in place of service 31.

4. In Coding Guidelines, the statement, “initial extended ophthalmoscopy code 92225 may be billed if the patient has (not) had extended ophthalmoscopy (of the same eye) by the same physician/physician group within the last 3 years”. The statement needs to have “Not” inserted to correct the intended meaning.

Response: This error will be corrected.