Please note: This is a Draft policy.
Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Please note: This is a Future Draft LCD.

Contractor Information

Contractor Name
Palmetto GBA

Contractor Number
11501

Contractor Type
MAC - Part A

Back to Top

LCD Information

Document Information

Primary Geographic Jurisdiction
North Carolina

Oversight Region
Region IV

Original Determination Effective Date
For services performed on or after 01/24/2011

Original Determination Ending Date

Revision Effective Date
For services performed on or after 01/17/2013

Revision Ending Date

Printed on 9/17/2012. Page 1 of 19
CMS National Coverage Policy
Language quoted from Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

Title XVIII of the Social Security Act §1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act §1862(a) (7) excludes routine physical examination unless otherwise covered by statute.

42 CFR §410.32 indicates that diagnostic tests may only be ordered by the treating physician (or other treating practitioner acting within the scope of his or her license and Medicare requirements).

CMS Internet-Only Manual, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §280.1 Glaucoma Screening

CMS Internet-Only Manual, Pub 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 1, §80.6 Intraocular Photography

CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 12, §40.1.A. a component of a Global surgical package

CMS Internet-Only Manual Pub 100-04, Medicare Claims Processing Manual, Chapter 18, §70-70.5 Glaucoma Screening Services

CMS One Time Notification Pub 100-20, Transmittal 477, dated April 24, 2009, Change Request 6338.

Indications and Limitations of Coverage and/or Medical Necessity

Abstract:

Fundus photography
Fundus photography involves the use of a retinal camera to photograph the regions of the vitreous, retina, choroid and optic nerve.

Extended ophthalmoscopy
Extended ophthalmoscopy is the detailed examination of the retina with drawing. It is most frequently performed utilizing an indirect lens, although it may be performed using contact lens biomicroscopy. It may use scleral depression.
It is performed by the physician, when a more detailed examination (including that of the periphery) is needed following routine ophthalmoscopy. It is usually performed with the pupil dilated and always includes a true drawing of the retina (macula, fundus and periphery) with interpretation and report. The examination must be used for medical decision making.

2. Indications:

Fundus photography

Fundus photography may be indicated to document abnormalities of disease processes affecting the eye, or to follow the progress of such disease.

In order to document a disease process or follow the progress of a disease, photographs and an interpretation and report of the test may be necessary. Photographs and an interpretation and report of the test may also be necessary to plan treatment for a disease process.

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.

Extended ophthalmoscopy

Extended ophthalmoscopy is indicated when the level of examination requires a complete view of the posterior segment of the eye and documentation is greater than that required for general ophthalmoscopy.

An extended ophthalmoscopy may be considered medically reasonable and necessary for the following conditions:

a. Malignant neoplasm of the retina or choroid.

b. Retained (old) intraocular foreign body, either magnetic or signs and symptoms may include a statement by the patient that something has hit his/her eye (foreign body sensation), normal or blurred vision, pain or no discomfort, and tearing.

c. Retinal hemorrhage, edema, ischemia, exudates and deposits, hereditary retinal dystrophies or peripheral retinal degeneration.

d. Retinal detachment with or without retinal defect - the patient may complain of light flashes, dark floating specks, and blurred vision that becomes progressively worse. This may be described by the patient as "a curtain came down over my eyes."

e. Symptoms suggestive of retinal defect (ex: flashes and/or floaters)

f. Retinal defects without retinal detachment

g. Diabetic retinopathy (i.e., background retinopathy or proliferative retinopathy), retinal vascular occlusion, or separation of the retinal layers - this may be evidenced by microaneurysms, cotton wool spots, exudates, hemorrhages, or fibrous proliferation.

h. Experienced sudden visual loss or transient visual loss

i. Chorioretinitis, chorioretinal scars or choroidal degeneration, dystrophies, hemorrhage and rupture, or detachment

j. Sustained penetrating wound to the orbit resulting in the retention of a foreign body in the eye

k. Sustained a blunt injury to the eye or adnexa

l. Disorders of the vitreous body (i.e., vitreous hemorrhage or posterior vitreous detachment) - spots before the eyes (floaters) and flashing lights (photopsia) can be signs/symptoms of these disorders
m. Posterior scleritis—signs and symptoms may include severe pain and inflammation, proptosis, limited ocular movements, and a loss of a portion of the visual field

n. Vogt-Koyanagi-Harady syndrome—a condition characterized by bilateral uveitis, dysacusia, meningeal irritation, whitening of patches of hair (poliosis), vitiligo, and retinal detachment. The disease can be initiated by a severe headache, deep orbital pain, vertigo, and nausea

o. Degenerative disorders of the globe

p. Retinoschisis and retinal cysts. Patients may complain of light flashes and floaters

q. Signs and symptoms of endophthalmitis, which may include severe pain, redness, photophobia, and profound loss of vision

r. Glaucoma or is a glaucoma suspect—this may be evidenced by increased intraocular pressure or progressive cupping of the optic nerve

s. Systemic disorders which may be associated with retinal pathology

t. High axial length myopia

u. Retinal edema

v. Metamorphopsia

w. High-risk medication for retinopathy or optic neuropathy

x. Choroidal nevus being evaluated for malignant transformation

y. Macular degeneration

Fundus photography and Extended ophthalmoscopy

CPT code 92227 (remote imaging for detection of retinal disease, e.g. retinopathy in a patient with diabetes, with analysis and report under physician supervision, unilateral or bilateral) is not for routine screening, but is covered for evaluation of asymptomatic patients at risk with known disease (e.g. diabetes mellitus) that is likely to cause retinal disease.

CPT code 92228 (remote imaging for monitoring and management of active retinal disease, e.g. diabetic retinopathy, with physician review, interpretation and report, unilateral or bilateral) is a covered service.

Limitations:

If the study is performed as a screening service, it is not covered by Medicare.

Fundus photography

- 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.

- Fundus photography is a bilateral service on the Medicare Physician Fee Schedule Data Base. Services performed unilaterally are subject to a reduction in fee.
• Fundus photography is not a substitute for an annual dilated examination by a qualified professional (e.g., in diabetic patients). Fundus photographs taken by a non-eye professional and sent (transtelephonically, via internet, or by other means) to a qualified professional for interpretation will be considered without Medicare benefit category. Such tests will be denied as non-covered. Fundus photography of a normal retina will be denied as not medically necessary.

• Provision of fundus photography, by providers other than ophthalmologists or optometrists, as a screening test to facilitate referral to a specialist is contrary to requirements for testing as codified in 42CFR 410.32, and is therefore not covered. Furthermore, the ordering/performance of fundus photography by eye specialists prior to a face-to-face encounter is similarly not covered or reimbursable.

**Extended ophthalmoscopy**

• Extended ophthalmoscopy of a fellow eye without signs or symptoms or new abnormalities on general ophthalmoscopic exam will be denied as not medically necessary. Repeated extended ophthalmoscopy at each visit without change in signs, symptoms or condition may be denied as not medically necessary.

• General ophthalmoscopy and biomicroscopy are part of an ophthalmologic examination (92002-92004) and are not separately payable, but these should still be documented in the patient’s medical record.

• If indirect ophthalmoscopy is done without a drawing or does not meet indicated standards, the service is not separately payable and will be considered part of a general ophthalmologic exam (92002-92014) or E&M service.

• Extended ophthalmoscopy (codes 92225, 92226) performed during the global surgery period of an ophthalmologic surgery procedure, by the same provider performing the surgery, will not be separately payable unless unrelated to the condition for which the surgery was performed.

• If the medical record does not include the interpretation and report, the extended ophthalmoscopy will be denied as not medically necessary.

• Extended ophthalmoscopy will be denied as not medically necessary when it is done in lieu of routine ophthalmoscopy unless the indication for this more extensive examination is documented in the medical record.

• When other ophthalmological tests (e.g., fundus photography, fluorescein angiography, ultrasound, optical coherence tomography, etc.) have been performed, extended ophthalmoscopy will be denied as not medically necessary unless there was a reasonable medical expectation that the multiple imaging services might provide additive (non-duplicative) information.

**Coding Information**

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.
Revenue Codes:

 Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>92225</td>
<td>OPHTHALMOSCOPY, EXTENDED, WITH RETINAL DRAWING (EG, FOR RETINAL DETACHMENT, MELANOMA), WITH INTERPRETATION AND REPORT; INITIAL</td>
</tr>
<tr>
<td>92226</td>
<td>OPHTHALMOSCOPY, EXTENDED, WITH RETINAL DRAWING (EG, FOR RETINAL DETACHMENT, MELANOMA), WITH INTERPRETATION AND REPORT; SUBSEQUENT</td>
</tr>
<tr>
<td>92227</td>
<td>REMOTE IMAGING FOR DETECTION OF RETINAL DISEASE (EG, RETINOPATHY IN A PATIENT WITH DIABETES) WITH ANALYSIS AND REPORT UNDER PHYSICIAN SUPERVISION, UNILATERAL OR BILATERAL</td>
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<tr>
<td>92228</td>
<td>REMOTE IMAGING FOR MONITORING AND MANAGEMENT OF ACTIVE RETINAL DISEASE (EG, DIABETIC RETINOPATHY) WITH PHYSICIAN REVIEW, INTERPRETATION AND REPORT, UNILATERAL OR BILATERAL</td>
</tr>
<tr>
<td>92250</td>
<td>FUNDUS PHOTOGRAPHY WITH INTERPRETATION AND REPORT</td>
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ICD-9 Codes that Support Medical Necessity

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>115.02</td>
<td>HISTOPLASMA CAPSULATUM RETINITIS</td>
</tr>
<tr>
<td>115.12</td>
<td>HISTOPLASMA DUBOISII RETINITIS</td>
</tr>
<tr>
<td>115.92</td>
<td>HISTOPLASMOsis RETINITIS UNSPECIFIED</td>
</tr>
<tr>
<td>130.2</td>
<td>CHORIORETINITIS DUE TO TOXOPLASMOSIS</td>
</tr>
<tr>
<td>190.0</td>
<td>MALIGNANT NEOPLASM OF EYEBALL EXCEPT CONJUNCTIVA CORNEA RETINA AND CHOROID</td>
</tr>
<tr>
<td>190.5</td>
<td>MALIGNANT NEOPLASM OF RETINA</td>
</tr>
<tr>
<td>190.6</td>
<td>MALIGNANT NEOPLASM OF CHOROID</td>
</tr>
<tr>
<td>224.5</td>
<td>BENIGN NEOPLASM OF RETINA</td>
</tr>
<tr>
<td>224.6</td>
<td>BENIGN NEOPLASM OF CHOROID</td>
</tr>
<tr>
<td>225.1</td>
<td>BENIGN NEOPLASM OF CRANIAL NERVES</td>
</tr>
<tr>
<td>249.00</td>
<td>SECONDARY DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED</td>
</tr>
<tr>
<td>249.01</td>
<td>SECONDARY DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, UNCONTROLLED</td>
</tr>
<tr>
<td>249.10</td>
<td>SECONDARY DIABETES MELLITUS WITH KETOACIDOSIS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED</td>
</tr>
<tr>
<td>249.11</td>
<td>SECONDARY DIABETES MELLITUS WITH KETOACIDOSIS, UNCONTROLLED</td>
</tr>
<tr>
<td>249.20</td>
<td>SECONDARY DIABETES MELLITUS WITH HYPEROSMOLARITY, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED</td>
</tr>
<tr>
<td>249.21</td>
<td>SECONDARY DIABETES MELLITUS WITH HYPEROSMOLARITY, UNCONTROLLED</td>
</tr>
<tr>
<td>249.30</td>
<td>SECONDARY DIABETES MELLITUS WITH OTHER COMA, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED</td>
</tr>
<tr>
<td>249.31</td>
<td>SECONDARY DIABETES MELLITUS WITH OTHER COMA, UNCONTROLLED</td>
</tr>
</tbody>
</table>

Printed on 9/17/2012. Page 6 of 19
SECONDARY DIABETES MELLITUS WITH RENAL MANIFESTATIONS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED

249.41 SECONDARY DIABETES MELLITUS WITH RENAL MANIFESTATIONS, UNCONTROLLED

249.50 SECONDARY DIABETES MELLITUS WITH OPHTHALMIC MANIFESTATIONS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED

249.51 SECONDARY DIABETES MELLITUS WITH OPHTHALMIC MANIFESTATIONS, UNCONTROLLED

250.00 DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED

250.01 DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED

250.02 DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED

250.03 DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE I [JUVENILE TYPE], UNCONTROLLED

250.11 DIABETES WITH KETOACIDOSIS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED

250.50 DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED

250.51 DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED

250.52 DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED

250.53 DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED

360.00 PURULENT ENDOPHTHALMITIS UNSPECIFIED

360.01 ACUTE ENDOPHTHALMITIS

360.02 PANOPHTHALMITIS

360.03 CHRONIC ENDOPHTHALMITIS

360.04 VITREOUS ABSCESS

360.11 SYMPATHETIC UVEITIS

360.12 PANUVEITIS

360.13 PARASITIC ENDOPHTHALMITIS UNSPECIFIED

360.14 OPHTHALMIA NODOSA

360.19 OTHER ENDOPHTHALMITIS

360.20 DEGENERATIVE DISORDER OF GLOBE UNSPECIFIED

360.21 PROGRESSIVE HIGH (DEGENERATIVE) MYOPIA

360.23 SIDEROSIS OF GLOBE

360.24 OTHER METALLOSIS OF GLOBE

360.29 OTHER DEGENERATIVE DISORDERS OF GLOBE

360.30 HYPOTONY OF EYE UNSPECIFIED

360.31 PRIMARY HYPOTONY OF EYE

360.32 OCULAR FISTULA CAUSING HYPOTONY

360.33 HYPOTONY ASSOCIATED WITH OTHER OCULAR DISORDERS

360.34 FLAT ANTERIOR CHAMBER OF EYE

360.40 DEGENERATED GLOBE OR EYE UNSPECIFIED

360.41 BLIND HYPOTENSIVE EYE

360.42 BLIND HYPERTENSIVE EYE

360.43 HEMOPHTHALMOS EXCEPT CURRENT INJURY

360.44 LEUCOCORIA

360.50 FOREIGN BODY MAGNETIC INTRAOCULAR UNSPECIFIED

360.51 FOREIGN BODY MAGNETIC IN ANTERIOR CHAMBER OF EYE

360.52 FOREIGN BODY MAGNETIC IN IRIS OR CILIARY BODY

360.53 FOREIGN BODY MAGNETIC IN LENS

360.54 FOREIGN BODY MAGNETIC IN VITREOUS

360.55 FOREIGN BODY MAGNETIC IN POSTERIOR WALL

360.59 INTRAOCULAR FOREIGN BODY MAGNETIC IN OTHER OR MULTIPLE SITES

360.60 FOREIGN BODY INTRAOCULAR UNSPECIFIED

360.61 FOREIGN BODY IN ANTERIOR CHAMBER

360.62 FOREIGN BODY IN IRIS OR CILIARY BODY

360.63 FOREIGN BODY IN LENS

360.64 FOREIGN BODY IN VITREOUS

360.65 FOREIGN BODY IN POSTERIOR WALL OF EYE

360.69 INTRAOCULAR FOREIGN BODY IN OTHER OR MULTIPLE SITES

360.81 LUXATION OF GLOBE
360.89 OTHER DISORDERS OF GLOBE
361.00 RETINAL DETACH WITH RETINAL DEFECT UNSPECIFIED
361.01 RECENT RETINAL DETACH PARTIAL WITH SINGLE DEFECT
361.02 RECENT RETINAL DETACH PARTIAL WITH MULTIPLE DEFECTS
361.03 RECENT RETINAL DETACH PARTIAL WITH GIANT TEAR
361.04 RECENT RETINAL DETACH PARTIAL WITH RETINAL DIALYSIS
361.05 RECENT RETINAL DETACH TOTAL OR SUBTOTAL
361.06 OLD RETINAL DETACH PARTIAL
361.07 OLD RETINAL DETACH TOTAL OR SUBTOTAL
361.10 RETINOSCHISIS UNSPECIFIED
361.11 FLAT RETINOSCHISIS
361.12 BULLOUS RETINOSCHISIS
361.13 PRIMARY RETINAL CYSTS
361.14 SECONDARY RETINAL CYSTS
361.19 OTHER RETINOSCHISIS AND RETINAL CYSTS
361.2 SEROUS RETINAL DETACH
361.30 RETINAL DEFECT UNSPECIFIED
361.31 ROUND HOLE OF RETINA WITHOUT DETACH
361.32 HORSESHOE TEAR OF RETINA WITHOUT DETACH
361.33 MULTIPLE DEFECTS OF RETINA WITHOUT DETACH
361.81 TRACTION DETACH OF RETINA
361.89 OTHER FORMS OF RETINAL DETACH
361.9 UNSPECIFIED RETINAL DETACH
362.01 BACKGROUND DIABETIC RETINOPATHY
362.02 PROLIFERATIVE DIABETIC RETINOPATHY
362.03 NONPROLIFERATIVE DIABETIC RETINOPATHY NOS
362.04 MILD NONPROLIFERATIVE DIABETIC RETINOPATHY
362.05 MODERATE NONPROLIFERATIVE DIABETIC RETINOPATHY
362.06 SEVERE NONPROLIFERATIVE DIABETIC RETINOPATHY
362.07 DIABETIC MACULAR EDEMA
362.10 BACKGROUND RETINOPATHY UNSPECIFIED
362.11 HYPERTENSIVE RETINOPATHY
362.12 EXUDATIVE RETINOPATHY
362.13 CHANGES IN VASCULAR APPEARANCE OF RETINA
362.14 RETINAL MICROANEURYSMS NOS
362.15 RETINAL TELANGECTASIA
362.16 RETINAL NEOVASCULARIZATION NOS
362.17 OTHER INTRARETINAL MICROVASCULAR ABNORMALITIES
362.18 RETINAL VASCULITIS
362.20 RETINOPATHY OF PREMATURITY, UNSPECIFIED
362.21 RETROLENTAL FIBROPLASIA
362.22 RETINOPATHY OF PREMATURITY, STAGE 0
362.23 RETINOPATHY OF PREMATURITY, STAGE 1
362.24 RETINOPATHY OF PREMATURITY, STAGE 2
362.25 RETINOPATHY OF PREMATURITY, STAGE 3
362.26 RETINOPATHY OF PREMATURITY, STAGE 4
362.27 RETINOPATHY OF PREMATURITY, STAGE 5
362.29 OTHER NONDIABETIC PROLIFERATIVE RETINOPATHY
362.30 RETINAL VASCULAR OCCLUSION UNSPECIFIED
362.31 CENTRAL RETINAL ARTERY OCCLUSION
362.32 RETINAL ARTerial BRANCH OCCLUSION
362.33 PARTIAL RETINAL ARTERIAL OCCLUSION
362.34 TRANSIENT RETINAL ARTERIAL OCCLUSION
362.35 CENTRAL RETINAL VEIN OCCLUSION
362.36 VENOUS TRIBUTARY (BRANCH) OCCLUSION OF RETINA
362.37 VENOUS ENGORGEMENT OF RETINA
362.40 RETINAL LAYER SEPARATION UNSPECIFIED
362.41 CENTRAL SEROUS RETINOPATHY
362.42 SEROUS DETACH OF RETINAL PIGMENT EPITHELIUM
362.43 HEMORRHAGIC DETACH OF RETINAL PIGMENT EPITHELIUM
362.50 MACULAR DEGENERATION (SENILE) OF RETINA UNSPECIFIED
362.51 NONEXUDATIVE SENILE MACULAR DEGENERATION OF RETINA
362.52 EXUDATIVE SENILE MACULAR DEGENERATION OF RETINA
362.53 CYSTOID MACULAR DEGENERATION OF RETINA
362.54 MACULAR CYST HOLE OR PSEUDEHOLE OF RETINA
362.55 TOXIC MACULOPATHY OF RETINA
362.56 MACULAR PUCKERING OF RETINA
362.57 DRUSEN (DEGENERATIVE) OF RETINA
362.60 PERIPHERAL RETINAL DEGENERATION UNSPECIFIED
362.61 PAVING STONE DEGENERATION OF RETINA
362.62 MICROCYSTOID DEGENERATION OF RETINA
362.63 LATTICE DEGENERATION OF RETINA
362.64 SENILE RETICULAR DEGENERATION OF RETINA
362.65 SECONDARY PIGMENTARY DEGENERATION OF RETINA
362.66 SECONDARY VITREORETINAL DEGENERATIONS
362.70 HEREDITARY RETINAL DYSTROPHY UNSPECIFIED
362.71 RETINAL DYSTROPHY IN SYSTEMIC OR CEREBRORETINAL LIPIDOSES
362.72 RETINAL DYSTROPHY IN OTHER SYSTEMIC DISORDERS AND SYNDROMES
362.73 VITREORETINAL DYSTROPHIES
362.74 PIGMENTARY RETINAL DYSTROPHY
362.75 OTHER DYSTROPHIES PRIMARILY INVOLVING THE SENSORY RETINA
362.76 DYSTROPHIES PRIMARILY INVOLVING THE RETINAL PIGMENT EPITHELIUM
362.77 RETINAL DYSTROPHIES PRIMARILY INVOLVING BRUCH'S MEMBRANE
362.81 RETINAL HEMORRHAGE
362.82 RETINAL EXUDATES AND DEPOSITS
362.83 RETINAL EDEMA
362.84 RETINAL ISCHEMIA
362.85 RETINAL NERVE FIBER BUNDLE DEFECTS
362.89 OTHER RETINAL DISORDERS
363.00 FOCAL CHORIORETINITIS UNSPECIFIED
363.01 FOCAL CHOROIDITIS AND CHORIORETINITIS JUXTAPAPILLARY
363.03 FOCAL CHOROIDITIS AND CHORIORETINITIS OF OTHER POSTERIOR POLE
363.04 FOCAL CHOROIDITIS AND CHORIORETINITIS PERIPHERAL
363.05 FOCAL RETINITIS AND RETINOCHOROIDITIS JUXTAPAPILLARY
363.06 FOCAL RETINITIS AND RETINOCHOROIDITIS MACULAR OR PARAMACULAR
363.07 FOCAL RETINITIS AND RETINOCHOROIDITIS OF OTHER POSTERIOR POLE
363.08 FOCAL RETINITIS AND RETINOCHOROIDITIS PERIPHERAL
363.10 DISSEMINATED CHORIORETINITIS UNSPECIFIED
363.11 DISSEMINATED CHOROIDITIS AND CHORIORETINITIS POSTERIOR POLE
363.12 DISSEMINATED CHOROIDITIS AND CHORIORETINITIS PERIPHERAL
363.13 DISSEMINATED CHOROIDITIS AND CHORIORETINITIS GENERALIZED
363.14 DISSEMINATED RETINITIS AND RETINOCHOROIDITIS METASTATIC
363.15 DISSEMINATED RETINITIS AND RETINOCHOROIDITIS PIGMENT EPITHELIOPATHY
363.20 CHORIORETINITIS UNSPECIFIED
363.21 PARS PLANITIS
363.22 HARADA'S DISEASE
363.30 CHORIORETINAL SCAR UNSPECIFIED
363.31 SOLAR RETINOPATHY
363.32 OTHER MACULAR SCARS OF RETINA
363.33 OTHER SCARS OF POSTERIOR POLE OF RETINA
363.34 PERIPHERAL SCARS OF RETINA
363.35 DISSEMINATED SCARS OF RETINA
363.40 CHOROIDAL DEGENERATION UNSPECIFIED
363.41 SENILE ATROPHY OF CHOROID
363.42 DIFFUSE SECONDARY ATROPHY OF CHOROID
363.43 ANGIOD STREAKS OF CHOROID
363.50 HEREDITARY CHOROIDAL DYSTROPHY OR ATROPHY UNSPECIFIED
363.51 CIRCUMPAPILLARY DYSTROPHY OF CHOROID PARTIAL
363.52 CIRCUMPAPILLARY DYSTROPHY OF CHOROID TOTAL
363.53 CENTRAL DYSTROPHY OF CHOROID PARTIAL
363.54 CENTRAL CHOROIDAL ATROPHY TOTAL
363.55 CHOROIDEREMIA
363.56 OTHER DIFFUSE OR GENERALIZED DYSTROPHY OF CHOROID PARTIAL
363.57 OTHER DIFFUSE OR GENERALIZED DYSTROPHY OF CHOROID TOTAL
363.61 CHOROIDAL HEMORRHAGE UNSPECIFIED
363.62 EXPULSIVE CHOROIDAL HEMORRHAGE
363.63 CHOROIDAL RUPTURE
363.64 CHOROIDAL DETACH UNSPECIFIED
363.65 SEROUS CHOROIDAL DETACH
363.66 HEMORRHAGIC CHOROIDAL DETACH
363.67 OTHER DISORDERS OF CHOROID
363.70 CHOROIDAL DETACHMENT UNSPECIFIED
363.71 SEROUS CHOROIDAL DETACH
363.72 HEMORRHAGIC CHOROIDAL DETACH
363.73 OTHER DISORDERS OF CHOROID
363.80 OTHER DISORDERS OF CHOROID TOTAL
364.22 GLAUCOMATOCYCLITIC CRISIS
364.23 VOGT-KOYANAGI SYNDROME
364.3 UNSPECIFIED IRIDOCYCLITIS
365.00 PREGLAUCOMA UNSPECIFIED
365.01 OPEN ANGLE WITH BORDERLINE FINDINGS, LOW RISK
365.02 ANATOMICALLY NARROW ANGLE BORDERLINE GLAUCOMA
365.03 STEROID RESPONDERS BORDERLINE GLAUCOMA
365.04 OCULAR HYPERTENSION
365.05 OPEN ANGLE WITH BORDERLINE FINDINGS, HIGH RISK
365.06 PRIMARY ANGLE CLOSURE WITHOUT GLAUCOMA DAMAGE
365.07 OPEN-ANGLE GLAUCOMA UNSPECIFIED
365.11 PRIMARY OPEN ANGLE GLAUCOMA
365.12 LOW TENSION OPEN-ANGLE GLAUCOMA
365.13 PIGMENTARY OPEN-ANGLE GLAUCOMA
365.14 GLAUCOMA OF CHILDHOOD
365.15 RESIDUAL STAGE OF OPEN ANGLE GLAUCOMA
365.20 PRIMARY ANGLE-CLOSURE GLAUCOMA UNSPECIFIED
365.21 INTERMITTENT ANGLE-CLOSURE GLAUCOMA
365.22 ACUTE ANGLE-CLOSURE GLAUCOMA
365.23 CHRONIC ANGLE-CLOSURE GLAUCOMA
365.24 RESIDUAL STAGE OF ANGLE-CLOSURE GLAUCOMA
365.31 CORTICOSTEROID-INDUCED GLAUCOMA GLAUCOMATOUS STAGE
365.32 CORTICOSTEROID-INDUCED GLAUCOMA RESIDUAL STAGE
365.41 GLAUCOMA ASSOCIATED WITH CHAMBER ANGLE ANOMALIES
365.42 GLAUCOMA ASSOCIATED WITH ANOMALIES OF IRIS
365.43 GLAUCOMA ASSOCIATED WITH OTHER ANTERIOR SEGMENT ANOMALIES
365.44 GLAUCOMA ASSOCIATED WITH SYSTEMIC SYNDROMES
365.51 PHACOLYTIC GLAUCOMA
365.52 PSEUDOEXFOLIATION GLAUCOMA
365.59 GLAUCOMA ASSOCIATED WITH OTHER LENS DISORDERS
365.60 GLAUCOMA ASSOCIATED WITH UNSPECIFIED OCULAR DISORDER
365.61 GLAUCOMA ASSOCIATED WITH PUPILLARY BLOCK
365.62 GLAUCOMA ASSOCIATED WITH OCULAR INFLAMMATIONS
365.63 GLAUCOMA ASSOCIATED WITH VASCULAR DISORDERS OF EYE
365.64 GLAUCOMA ASSOCIATED WITH TUMORS OR CYSTS
365.65 GLAUCOMA ASSOCIATED WITH OCULAR TRAUMA
365.70 GLAUCOMA STAGE, UNSPECIFIED
365.71 MILD STAGE GLAUCOMA
365.72 MODERATE STAGE GLAUCOMA
365.73 SEVERE STAGE GLAUCOMA
365.74 INDETERMINATE STAGE GLAUCOMA
365.81 HYPERSECRETION GLAUCOMA
365.82 GLAUCOMA WITH INCREASED EPISCERAL VENOUS PRESSURE
365.83 AQUEOUS MISDIRECTION
365.89 OTHER SPECIFIED GLAUCOMA
368.11 SUDDEN VISUAL LOSS
368.12 TRANSIENT VISUAL LOSS
368.13 VISUAL DISCOMFORT
368.14 VISUAL DISTORTIONS OF SHAPE AND SIZE
368.15 OTHER VISUAL DISTORTIONS AND ENTOPTIC PHENOMENA
368.16 PSYCHOPHYSICAL VISUAL DISTURBANCES
368.40 VISUAL FIELD DEFECT UNSPECIFIED
368.41 SCOTOMA INVOLVING CENTRAL AREA
368.42 SCOTOMA OF BLIND SPOT AREA
368.43 SECTOR OR ARCUATE VISUAL FIELD DEFECTS
368.44 OTHER LOCALIZED VISUAL FIELD DEFECT
368.45 GENERALIZED VISUAL FIELD CONTRACTION OR CONSTRICTION
368.61 CONGENITAL NIGHT BLINDNESS
368.8 OTHER SPECIFIED VISUAL DISTURBANCES
377.00 PAPILLEDEMA UNSPECIFIED
377.01 PAPILLEDEMA ASSOCIATED WITH INCREASED INTRACRANIAL PRESSURE
377.02 PAPILLEDEMA ASSOCIATED WITH DECREASED OCULAR PRESSURE
377.03 PAPILLEDEMA ASSOCIATED WITH RETINAL DISORDER
377.04 FOSTER-KENNEDY SYNDROME
377.10 OPTIC ATROPHY UNSPECIFIED
377.11 PRIMARY OPTIC ATROPHY
377.12 POSTINFLAMMATORY OPTIC ATROPHY
377.13 OPTIC ATROPHY ASSOCIATED WITH RETINAL DYSTROPHIES
377.14 GLAUCOMATOUS ATROPHY (CUPPING) OF OPTIC DISC
377.15 PARTIAL OPTIC ATROPHY
377.16 HEREDITARY OPTIC ATROPHY
377.21 DRUSEN OF OPTIC DISC
377.22 CRATER-LIKE HOLES OF OPTIC DISC
377.23 COLOBOMA OF OPTIC DISC
377.24 PSEUDOPAPILLEDEMA
377.30 OPTIC NEURITIS UNSPECIFIED
377.31 OPTIC PAPILLITIS
377.32 RETROBULBAR NEURITIS (ACUTE)
377.33 NUTRITIONAL OPTIC NEUROPATHY
377.34 TOXIC OPTIC NEUROPATHY
377.39 OTHER OPTIC NEURITIS
377.41 ISCHEMIC OPTIC NEUROPATHY
377.42 HEMORRHAGE IN OPTIC NERVE SHEATHS
377.49 OTHER DISORDERS OF OPTIC NERVE
377.51 DISORDERS OF OPTIC CHIASM ASSOCIATED WITH PITUITARY NEOPLASMS AND DISORDERS
377.52 DISORDERS OF OPTIC CHIASM ASSOCIATED WITH OTHER NEOPLASMS
377.53 DISORDERS OF OPTIC CHIASM ASSOCIATED WITH VASCULAR DISORDERS
377.54 DISORDERS OF OPTIC CHIASM ASSOCIATED WITH INFLAMMATORY DISORDERS
379.07 POSTERIOR SCLERITIS
379.21 VITREOUS DEGENERATION
379.22 CRYSTALLINE DEPOSITS IN VITREOUS
379.23 VITREOUS HEMORRHAGE
379.24 OTHER VITREOUS OPACITIES
379.25 VITREOUS MEMBRANES AND STRANDS
379.26 VITREOUS PROLAPSE
379.27 VITREOMACULAR ADHESION
379.29 OTHER DISORDERS OF VITREOUS
379.32 SUBLUXATION OF LENS
379.34 POSTERIOR DISLOCATION OF LENS
714.0 RHEUMATOID ARTHRITIS
714.30 CHRONIC OR UNSPECIFIED POLYARTICULAR JUVENILE RHEUMATOID ARTHRITIS
714.31 ACUTE POLYARTICULAR JUVENILE RHEUMATOID ARTHRITIS
714.32 PAUCIARTICULAR JUVENILE RHEUMATOID ARTHRITIS
714.33 MONOARTICULAR JUVENILE RHEUMATOID ARTHRITIS
743.51 VITREOUS ANOMALIES CONGENITAL
743.52 FUNDUS COLOBOMA
743.53 CHORIORETINAL DEGENERATION CONGENITAL
743.54 CONGENITAL FOLDS AND CYSTS OF POSTERIOR SEGMENT
743.55 CONGENITAL MACULAR CHANGES
743.56 OTHER RETINAL CHANGES CONGENITAL
743.57 SPECIFIED CONGENITAL ANOMALIES OF OPTIC DISC
743.58 VASCULAR ANOMALIES CONGENITAL
743.59 OTHER CONGENITAL ANOMALIES OF POSTERIOR SEGMENT
759.5 TUBEROUS SCLEROSIS
759.6 OTHER CONGENITAL HAMARTOSES NOT ELSEWHERE CLASSIFIED
759.82 MARFAN SYNDROME
871.5 PENETRATION OF EYEBALL WITH MAGNETIC FOREIGN BODY
871.6 PENETRATION OF EYEBALL WITH (NONMAGNETIC) FOREIGN BODY
995.54 CHILD PHYSICAL ABUSE
995.55 SHAKEN BABY SYNDROME
995.59 OTHER CHILD ABUSE AND NEGLECT
V58.69 LONG-TERM (CURRENT) USE OF OTHER MEDICATIONS
V67.51 FOLLOW-UP EXAMINATION FOLLOWING COMPLETED TREATMENT WITH HIGH-RISK MEDICATION NOT ELSEWHERE CLASSIFIED

Additional ICD-9-CM codes for extended ophthalmoscopy (CPT Codes 92225 and 92226)
115.92 HISTOPLASMOSIS RETINITIS UNSPECIFIED
198.89 SECONDARY MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES
237.70 NEUROFIBROMATOSIS UNSPECIFIED
237.71 NEUROFIBROMATOSIS TYPE 1 VON RECKLINGHAUSEN'S DISEASE
237.72 NEUROFIBROMATOSIS TYPE 2 ACOUSTIC NEUROFIBROMATOSIS
237.73 SCHWANNOMATOSIS
237.79 OTHER NEUROFIBROMATOSIS
250.10 DIABETES WITH KETOACIDOSIS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.11 DIABETES WITH KETOACIDOSIS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.12 DIABETES WITH KETOACIDOSIS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.13 DIABETES WITH KETOACIDOSIS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.20 DIABETES WITH HYPEROSMOLARITY, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.21 DIABETES WITH HYPEROSMOLARITY, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.22 DIABETES WITH HYPEROSMOLARITY, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.23 DIABETES WITH HYPEROSMOLARITY, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.30 DIABETES WITH OTHER COMA, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.31 DIABETES WITH OTHER COMA, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.32 DIABETES WITH OTHER COMA, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.33 DIABETES WITH OTHER COMA, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.40 DIABETES WITH RENAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.41 DIABETES WITH RENAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.42 DIABETES WITH RENAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.43 DIABETES WITH RENAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED
364.00 ACUTE AND SUBACUTE IRIDOCYCLITIS UNSPECIFIED
364.01 PRIMARY IRIDOCYCLITIS
364.02 RECURRENT IRIDOCYCLITIS
364.03 SECONDARY IRIDOCYCLITIS INFECTIOUS
364.04 SECONDARY IRIDOCYCLITIS NONINFECTIOUS
364.10 CHRONIC IRIDOCYCLITIS UNSPECIFIED
364.11 CHRONIC IRIDOCYCLITIS IN DISEASES CLASSIFIED ELSEWHERE
364.21 FUCHS' HETEROCHROMIC CYCLITIS
364.23 LENS-INDUCED IRIDOCYCLITIS
364.41 HYPHEMA OF IRIS AND CILIARY BODY
364.42 RUBEOSIS IRIDIS
364.51 ESSENTIAL OR PROGRESSIVE IRIS ATROPHY
364.52 IRIDOSCHISIS
364.53 PIGMENTARY IRIS DEGENERATION
364.54 DEGENERATION OF PUPILLARY MARGIN

Printed on 9/17/2012. Page 12 of 19
364.55 MIOTIC CYSTS OF PUPILLARY MARGIN
364.56 DEGENERATIVE CHANGES OF CHAMBER ANGLE
364.57 DEGENERATIVE CHANGES OF CILIARY BODY
364.59 OTHER IRIS ATROPHY
364.60 IDIOPATHIC CYSTS OF IRIS AND CILIARY BODY
364.61 IMPLANTATION CYSTS OF IRIS AND CILIARY BODY
364.62 EXUDATIVE CYSTS OF IRIS OR ANTERIOR CHAMBER
364.63 PRIMARY CYST OF PARS PLANA
364.64 EXUDATIVE CYST OF PARS PLANA
364.70 ADHESIONS OF IRIS UNSPECIFIED
364.71 POSTERIOR SYNECHIAE OF IRIS
364.72 ANTERIOR SYNECHIAE OF IRIS
364.73 GONIOSYNECHIAE
364.74 ADHESIONS AND DISRUPTIONS OF PUPILLARY MEMBRANES
364.75 PUPILLARY ABNORMALITIES
364.76 IRIDIODIALYSIS
364.77 RECESSION OF CHAMBER ANGLE OF EYE
364.81 FLOPPY Iris SYNDROME
364.82 PLATEAU Iris SYNDROME
364.89 OTHER DISORDERS OF IRIS AND CILIARY BODY
368.46 HOMONYMOUS BILATERAL FIELD DEFECTS
368.47 HETERONYMOUS BILATERAL FIELD DEFECTS
368.60 NIGHT BLINDNESS UNSPECIFIED
368.62 ACQUIRED NIGHT BLINDNESS
368.63 ABNORMAL DARK ADAPTATION CURVE
368.69 OTHER NIGHT BLINDNESS
376.40 DEFORMITY OF ORBIT UNSPECIFIED
376.41 HYPERTELORISM OF ORBIT
376.42 EXOSTOSIS OF ORBIT
376.43 LOCAL DEFORMITIES OF ORBIT DUE TO BONE DISEASE
376.44 ORBITAL DEFORMITIES ASSOCIATED WITH CRANIOFACIAL DEFORMITIES
376.45 ATROPHY OF ORBIT
376.46 ENLARGEMENT OF ORBIT
376.47 DEFORMITY OF ORBIT DUE TO TRAUMA OR SURGERY
376.50 ENOPHTHALMOS UNSPECIFIED AS TO CAUSE
376.51 ENOPHTHALMOS DUE TO ATROPHY OF ORBITAL TISSUE
376.52 ENOPHTHALMOS DUE TO TRAUMA OR SURGERY
376.6 RETAINED (OLD) FOREIGN BODY FOLLOWING PENETRATING WOUND OF ORBIT
921.3 CONTUSION OF EYEBALL
958.1 FAT EMBOLISM AS AN EARLY COMPLICATION OF TRAUMA
995.50 UNSPECIFIED CHILD ABUSE
995.51 CHILD EMOTIONAL/PSYCHOLOGICAL ABUSE
995.52 CHILD NEGLECT (NUTRITIONAL)
995.53 CHILD SEXUAL ABUSE

Additional ICD-9-CM codes for fundus photography (CPT Code 92250):
017.30 - TUBERCULOSIS OF EYE UNSPECIFIED EXAMINATION - TUBERCULOSIS OF EYE TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF ANIMALS)
042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
078.5 CYTOMEGALOVIRAL DISEASE
091.51 SYPHILITIC CHORIORETINITIS (SECONDARY)
094.83 SYPHILITIC DISSEMINATED RETINOCHOROIDITIS
094.85 SYPHILITIC RETROBULBAR NEURITIS
115.01 HISTOPLASMA CAPSULATUM MENINGITIS
130.0 MENINGOENCEPHALITIS DUE TO TOXOPLASMOSIS
130.1 CONJUNCTIVITIS DUE TO TOXOPLASMOSIS
190.1 MALIGNANT NEOPLASM OF ORBIT
190.2 MALIGNANT NEOPLASM OF LACRIMAL GLAND
190.3 MALIGNANT NEOPLASM OF CONJUNCTIVA
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<td>MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF EYE</td>
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<td>MALIGNANT NEOPLASM OF EYE PART UNSPECIFIED</td>
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<td>SECONDARY MALIGNANT NEOPLASM OF OTHER PARTS OF NERVOUS SYSTEM</td>
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<td>BENIGN NEOPLASM OF EYEBALL EXCEPT CONJUNCTIVA CORNEA RETINA AND CHOROID</td>
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<td>228.03</td>
<td>HEMANGIOMA OF RETINA</td>
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<td>234.0</td>
<td>CARCINOMA IN SITU OF EYE</td>
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<td>238.8</td>
<td>NEOPLASM OF UNCERTAIN BEHAVIOR OF OTHER SPECIFIED SITES</td>
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<td>239.81</td>
<td>NEOPLASMS OF UNSPECIFIED NATURE, RETINA AND CHOROID</td>
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<td>OTHER OCULAR MANIFESTATIONS OF VITAMIN A DEFICIENCY</td>
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<td>OTHER DISTURBANCES OF AROMATIC AMINO-ACID METABOLISM</td>
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<td>OTHER RHEUMATOID ARTHRITIS WITH VISCERAL OR SYSTEMIC INVOLVEMENT</td>
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<td>NONSPECIFIC ABNORMAL ELECTRO-OCULOGRAM (EOG)</td>
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<td>NONSPECIFIC ABNORMAL VISUALLY EVOKED POTENTIAL</td>
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<td>OPTIC NERVE INJURY</td>
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Printed on 9/17/2012. Page 14 of 19
950.1 INJURY TO OPTIC CHIASM
961.4 POISONING BY ANTIMALARIALS AND DRUGS ACTING ON OTHER BLOOD PROTOZOA
961.5 POISONING BY OTHER ANTIPROTOZOAL DRUGS
996.53 MECHANICAL COMPLICATION OF PROSTHETIC OCULAR LENS PROSTHESIS
998.82 CATARACT FRAGMENTS IN EYE FOLLOWING CATARACT SURGERY
V10.84 PERSONAL HISTORY OF MALIGNANT NEOPLASM OF EYE
V15.53 PERSONAL HISTORY OF RETAINED FOREIGN BODY FULLY REMOVED
V58.63 LONG-TERM (CURRENT) USE OF ANTIPLATELETS/ANTITHROMBOTICS
V58.64 LONG-TERM (CURRENT) USE OF NONSTEROIDAL ANTI-INFLAMMATORIES
V58.65 LONG-TERM (CURRENT) USE OF STEROIDS
V90.10 RETAINED METAL FRAGMENTS, UNSPECIFIED
V90.11 RETAINED MAGNETIC METAL FRAGMENTS
V90.12 RETAINED NONMAGNETIC METAL FRAGMENTS
V90.2 RETAINED PLASTIC FRAGMENTS
V90.31 RETAINED ANIMAL QUILLS OR SPINES
V90.33 RETAINED WOOD FRAGMENTS
V90.39 OTHER RETAINED ORGANIC FRAGMENTS
V90.81 RETAINED GLASS FRAGMENTS
V90.83 RETAINED STONE OR CRYSTALLINE FRAGMENTS
V90.89 OTHER SPECIFIED RETAINED FOREIGN BODY
V90.9 RETAINED FOREIGN BODY, UNSPECIFIED MATERIAL

Diagnoses that Support Medical Necessity
Not applicable

ICD-9 Codes that DO NOT Support Medical Necessity
Not applicable

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
Not applicable

General Information

Documentations Requirements

Fundus photography
The patient's medical record must contain documentation that fully supports the medical necessity for fundus photography as it is covered by Medicare. (See "Indications and Limitations of Coverage and/or Medical Necessity.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

A copy of the fundus photographs must be retained in the patient's medical records. An interpretation and report of the test must also be included, in addition to the photographs themselves.

The medical record should document whether the pupil was dilated, and which drug was used.

Documentation supporting the medical necessity should be legible, maintained in the patient's record, and must be available to the A/B MAC upon request.

Extended ophthalmoscopy
The patient's medical record must contain documentation that fully supports the medical necessity for extended ophthalmoscopy for each eye, as it is covered by Medicare. (See "Indications and Limitations of Coverage and/or Medical Necessity.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Printed on 9/17/2012. Page 15 of 19
Retinal drawings meeting the specifications indicated must be maintained in the patient's record.

- There must be a separate detailed sketch, minimal size of 3-4 inches.
- All items noted must be identified and labeled.
- Drawings in four (4) - six (6) standard colors are preferred. However, non-colored drawings are also acceptable, if clearly labeled.
- Optic nerve abnormalities should be separately drawn.
- An extensive scaled drawing must accurately represent normal, abnormal and common findings such as: lattice degeneration, hypertensive vascular changes, proliferative diabetic retinopathy, as well as retinal detachments, holes, tears or tumors.

Documentation in the patient's medical record for a diagnosis of glaucoma (ICD-9-CM codes 365.00-365.9) must include all of the following:

- A separate detailed drawing of the optic nerve along with an interpretation that affects the plan of treatment,
- Documentation of cupping, disc rim, pallor, and slope,
- Documentation of any surrounding pathology around the optic nerve.

Documentation specific to the method of examination (e.g., lens, scleral depression, instrument used) should be maintained in the medical record.

The medical record should document whether the pupil was dilated, and which drug was used.

All findings and a plan of action should be documented in notes.

Although routine ophthalmoscopy and biomicroscopy are part of an ophthalmologic examination and are not separately payable, these should still be documented in the patient's medical record.

Documentation supporting the medical necessity should be legible, maintained in the patient's record, and must be available to the A/B MAC upon request.

Appendices N/A

Utilization Guidelines

Patients actively being treated with intravitreal injections of medication for exudative (AMD) (ICD-9-CM code 362.52) may require up to 12 extended ophthalmoscopies per eye, per year.

Conditions coded with other ICD-9-CM codes in the range 360.0-365.9, may require up to six (6) extended ophthalmoscopic examinations per eye, per year.

For ICD-9-CM codes 190.0, 190.5, 190.6, 198.89, 224.5 and 224.6, up to four (4) extended ophthalmoscopic examinations may be required per eye, per year.

Other conditions usually require no more than two (2) extended ophthalmoscopic examinations per eye, per year.

Extended ophthalmoscopy is a physician service (examination of the eye) commonly occurring during the global post-operative period of ophthalmic surgery. As a physician service, it is included in the aftercare of the patient and is not separately billable.

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 and will be denied for reimbursement.

Services billed in excess of these Utilization Guidelines will be denied.

Sources of Information and Basis for Decision

Fundus photography


Printed on 9/17/2012. Page 16 of 19


**Extended ophthalmoscopy**


Williams GA, Scott IU, Haller JA, et al. Single-field fundus photography for diabetic retinopathy screening. *Ophthalmology*. 2004;111:1055-1062. Advisory Committee Meeting Notes This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, including include representatives from the provider community.

Contractor Advisory Committee meeting dates:

South Carolina - 10/02/2012
North Carolina - 10/02/2012
Virginia – 10/02/2012
West Virginia – 10/02/2012

Start Date ofComment Period 10/02/2012
End Date of Comment Period 11/16/2012
Start Date of Notice Period

Revision History Number Revision #5 Out for comment
Revision History Explanation Revision #5 Out for comment 10/02/2012-11/16/2012
Under CMS National Coverage section added the following citations: CMS Internet-Only Manual Pub 100-04, Medicare Claims Processing Manual, Chapter 15, §70.5 Glaucoma Screening Services and CMS One Time Notification Pub 100-20, Transmittal 477, dated April 24, 2009, Change Request 6338. Under Indications and Limitations of Coverage and/or Medical Necessity section Abstract: Fundus Photography changed the first sentence to read, “Fundus photography involves the use of a retinal camera to photograph of the vitreous, retina, choroid, and optic nerve. Under External ophthalmoscopy changed the first sentence to read, "Extended ophthalmoscopy is the detailed examination of the retina with drawings.” Under Indications Fundus photography section the last paragraph was deleted. Under Extended ophthalmoscopy section removed the word “nonmagnetic” from #b. #k changed "pariorbital" to "adnexa" Aadded the very last statement in this section. Under Limitations Fundus photography the last paragraph was deleted. Under Extended ophthalmoscopy removed the reference to Appendix A. Under Other Comments the entire section was deleted. Under Revenue Codes section deleted code 0962 and added code 0521. Under CPT/HCPCS Codes deleted 92230 as it is not valid for this LCD. Under ICD-9 Codes That Support Medical Necessity under fundus photography and extended ophthalmoscopy the following ICD-9 Codes were added: 249.00, 249.01, 249.10, 249.20, 249.21, 249.30, 249.31, 249.40, 249.41, 250.00, 250.01, 250.02, 250.03, 362.25, 368.61, 995.54, 995.55 and 995.59. The following codes were deleted 363.9, 364.82, 365.9 and 368.9. Under Extended ophthalmoscopy the following ICD-9 codes were added: 115.92, 237.73, 237.79 and 364.82. The following ICD-9 codes and deleted: 249.00, 249.01, 249.10, 249.11, 249.20, 249.21, 249.30, 249.31, 249.40, 249.41, 249.42, 249.60, 249.61, 249.62, 249.70, 249.71, 249.80, 249.81, 249.90, 249.91, 250.00, 250.01, 250.02, 250.03, 360.9, 364.9, 368.61, 871.7, 971.9, 995.54, 995.55 and 995.59. Under Fundus photography the following ICD-9 codes: 017.30-017.36,078.5, 091.51, 094.83, 130.0, 228.03, 264.7, 348.2, 362.25, 368.61, 379.60, 379.61, 379.62, 379.63, 995.0, 950.1, 950.5, 996.53, 998.82, V10.84, V15.53, V58.63, V58.65, V90.10, V90.11, V90.12, V90.2, V90.31, V90.33, V90.39, V90.81, V90.83, V90.89 and V90.9. The following ICD-9 codes have been deleted: 115.12, 116.90, 115.91, 115.94, 115.95, 115.99, 282.40, 282.42, 282.44, 282.46, 282.47, 362.9, 377.9, 995.54, 995.55 and 995.59. Under Documentation Requirements section changed the word “carrier” to “A/B MAC”. Under Extended ophthalmoscopy removed the reference to Appendix A. Re-wrote the last two statements to indicate services rendered that are not medically necessary and those billed in excess of the stated utilization guidelines will be denied. Under Sources of Information and Basis for Decision all references to web sites have been deleted. Deleted all references to National Guidelines Clearinghouse have been deleted. Also all reference to Duane’s Clinic Ophthalmology and Essentials of Ophthalmology have been deleted. This LCD is going out for comment from 10/02/2012-11/16/2012.

Revision #4, 09/13/2012
Annual Review-No changes made. This revision becomes effective on 09/13/2012.

Revision #3, 04/26/2012
Under CMS National Coverage Policy the following citation were added:
CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 15, §280.1
CMS Manual System, Pub 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 1, §80.6
CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 12, §40.1.A. Global surgery period
Under Bill Type Code deleted bill type 073x as it is no longer valid. Under ICD-9 Codes That Support Medical Necessity, fundus photography and extended ophthalmoscopy added 365.73. Under extended ophthalmoscopy revision #2 the following codes were inadvertently added to this section in error 365.06, 365.70, 365.71, 365.72, 365.73, 365.74 and 379.27. This revision becomes effective on 04/26/2012.

Revision #2, 10/01/2011
Under CPT/HCPCS Codes added CPT code 92230 as it was listed in the LCD, but left off the list. Under ICD-9 Codes That Support Medical Necessity, fundus photography and extended ophthalmoscopy: 365.03, 365.05, 365.06, 365.70, 365.71, 365.72 and 379.27. This revision becomes effective on 10/01/2011.

Revision #1, 05/16/2011
Per scheduled J11 implementation, contractor numbers 11301 (Virginia) and 11401 (West Virginia) were added to this LCD. This revision becomes effective on 05/16/2011.

01/24/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, in compliance with the J11 AB MAC Statement of Work (SOW), C.S.1.8.2 – Consolidation of Local Coverage Determinations, this LCD has been selected for implementation within the Palmetto GBA J11 AB MAC territory. Effective date of this implementation is January 24, 2011.
Reason for Change Coverage Change (actual change in medical parameters)
HCPCS Addition/Deletion
ICD9 Addition/Deletion
Maintenance (annual review with new changes, formatting, etc.)
Narrative Change
Other

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

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Back to Top

All Versions
Updated on 09/07/2012 with effective dates 01/17/2013 - N/A
Read the LCD Disclaimer opens in new window
Back to Top
CMS National Coverage Policy

Title XVIII of the Social Security Act, §1861 (r)(3) indicates podiatrists may practice as physicians "only with respect to functions which he/she is legally authorized to perform as such by the State in which he/she performs them."

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1833 (e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 CFR §410.27(f) defines direct physician supervision in a hospital outpatient setting.

42 CFR §410.26(a)(2) defines direct supervision

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 6, §20.5.2 Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2010

CMS Manual System, Pub 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 1, §20.29


Indications and Limitations of Coverage and/or Medical Necessity

1. Abstract:

This LCD is a clarification of the NCD as found in CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations (Internet-Only Manual).

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. The patient is entirely enclosed in a pressure chamber breathing 100% oxygen (O_2) at greater than one atmosphere (atm) pressure. Either a monoplace chamber pressurized with pure O_2 or a larger multiplace chamber pressurized with compressed air where the patient receives pure O_2 by mask, head tent, or endotracheal tube may be used.

Hyperbaric oxygen therapy serves four primary functions:

• 1. It increases the concentration of dissolved oxygen in the blood, which enhances perfusion
• 2. It stimulates the formation of a collagen matrix so that new blood vessels may develop
• 3. It replaces inert gas in the bloodstream with oxygen, which is then metabolized by the body; and
• 4. It works as a bactericide
Developed as treatment for decompression illness, this modality is an established therapy for treating medical disorders such as carbon monoxide poisoning and gas gangrene. HBO is also considered acceptable in treating acute vascular compromise and as adjuvant therapy in the management of disorders that are refractory to standard medical and surgical care.

For outpatient settings other than Comprehensive Outpatient Rehabilitation Facilities (CORFs), references to "physicians" throughout this policy include non-physicians: nurse practitioners, clinical nurse specialists and physician assistants. Such non-physician practitioners may certify, order, and establish the plan of care for hyperbaric oxygen therapy services as authorized by State law. (See §§1861(s)(2)(K) and 1862(a)(14) of Title XVIII of the Social Security Act; 42 CFR, §§410.74, 410.75, 410.76 and 419.22; 58 FR 18543, April 7, 2000.)

Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

2. Indications:

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions: See the UTILIZATION GUIDELINES section of this LCD for condition specific limitations and coverage guidelines.

1. Acute carbon monoxide intoxication
2. Decompression illness
3. Gas embolism
4. Gas gangrene
5. Aute traumatic peripheral ischemia
6. Crush injuries and suturing of severed limbs
7. Progressive necrotizing infections (necrotizing fasciitis)
8. Acute peripheral arterial insufficiency
9. Preparation and preservation of compromised skin grafts
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management
11. Osteoradionecrosis as an adjunct to conventional treatment
12. Soft tissue radionecrosis as an adjunct to conventional treatment
13. Cyanide poisoning
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
   a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
   b. Patient has a wound classified as Wagner grade III or higher; and
   c. Patient has failed an adequate course of standard wound therapy.

3. Limitations:

All other indications not listed above are not covered under the Medicare program.
Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)
013x Hospital Outpatient
085x Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0413 Respiratory Services - Hyperbaric Oxygen Therapy
0940 Other Therapeutic Services - General Classification

CPT/HCPCS Codes

99183 PHYSICIAN ATTENDANCE AND SUPERVISION OF HYPERBARIC OXYGEN THERAPY, PER SESSION
C1300 HYPERBARIC OXYGEN UNDER PRESSURE, FULL BODY CHAMBER, PER 30 MINUTE INTERVAL

ICD-9 Codes that Support Medical Necessity
It is the responsibility of the provider to code to the highest level specified in the ICD-9-CM (e.g., to the fourth or fifth digit). The correct use of an ICD-9-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

Claims for HBO submitted with ICD-9-CM codes 040.0, 444.21, 444.22, 444.81, 728.86, or 999.1 are presumed to be HBO therapy provided to inpatients requiring acute/emergent treatment.

Claims for HBO for ICD-9-CM code 444.21, 444.22 or 444.81 (arterial embolism and thrombosis) require documentation of dual diagnoses when billed in the outpatient setting following hospitalization. Report ICD-9-CM code 444.21, 444.22 or 444.81 in conjunction with V58.73 (aftercare following surgery of the circulatory system, not elsewhere classified).

Claims for HBO for ICD-9-CM code 999.1 (air embolism as a complication of medical care, not elsewhere classified) require documentation of dual diagnoses when billed in the outpatient setting following hospitalization. Report ICD-9-CM code 999.1 in conjunction with V58.89 (other specified aftercare).

039.0 - 039.9 opens in new window
040.0
249.70*
249.71*

Printed on 10/11/2012. Page 4 of 13
SECONDARY DIABETES MELLITUS WITH PERIPHERAL CIRCULATORY DISORDERS, UNCONTROLLED
249.80*
SECONDARY DIABETES MELLITUS WITH OTHER SPECIFIED MANIFESTATIONS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED
249.81*
SECONDARY DIABETES MELLITUS WITH OTHER SPECIFIED MANIFESTATIONS, UNCONTROLLED
250.70 - 250.73* opens in new window DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED - DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.80 - 250.83* opens in new window DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED - DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED
444.21 ARTERIAL EMBOLISM AND THROMBOSIS OF UPPER EXTREMITY
444.22 ARTERIAL EMBOLISM AND THROMBOSIS OF LOWER EXTREMITY
444.81 EMBOLISM AND THROMBOSIS OF ILIAC ARTERY
526.4 INFLAMMATORY CONDITIONS OF JAW
526.89 OTHER SPECIFIED DISEASES OF THE JAWS
595.82 IRRADIATION CYSTITIS
707.10* UNSPECIFIED ULCER OF LOWER LIMB
707.12* ULCER OF CALF
707.13* ULCER OF ANKLE
707.14* ULCER OF HEEL AND MIDFOOT
707.15* ULCER OF OTHER PART OF FOOT
707.19* ULCER OF OTHER PART OF LOWER LIMB
707.23 PRESSURE ULCER, STAGE III
707.24 PRESSURE ULCER, STAGE IV
728.86 NECROTIZING FASCIITIS
730.10 CHRONIC OSTEOMYELITIS SITE UNSPECIFIED
730.11 CHRONIC OSTEOMYELITIS INVOLVING SHOULDER REGION
730.12 CHRONIC OSTEOMYELITIS INVOLVING UPPER ARM
730.13 CHRONIC OSTEOMYELITIS INVOLVING FOREARM
730.14 CHRONIC OSTEOMYELITIS INVOLVING HAND
730.15 CHRONIC OSTEOMYELITIS INVOLVING PELVIC REGION AND THIGH
730.16 CHRONIC OSTEOMYELITIS INVOLVING LOWER LEG
730.17 CHRONIC OSTEOMYELITIS INVOLVING ANKLE AND FOOT
730.18 CHRONIC OSTEOMYELITIS INVOLVING OTHER SPECIFIED SITES
730.19 CHRONIC OSTEOMYELITIS INVOLVING MULTIPLE SITES
785.4 GANGRENE
902.53 INJURY TO ILIAC ARTERY
903.01 INJURY TO AXILLARY ARTERY
903.1 INJURY TO BRACHIAL BLOOD VESSELS
904.0 INJURY TO COMMON FEMORAL ARTERY
904.41 INJURY TO POPLITEAL ARTERY
909.2 LATE EFFECT OF RADIATION
927.00 - 927.09 opens in new window CRUSHING INJURY OF SHOULDER REGION - CRUSHING INJURY OF MULTIPLE SITES OF UPPER ARM
927.10 CRUSHING INJURY OF FOREARM
927.11 CRUSHING INJURY OF ELBOW
927.20 CRUSHING INJURY OF HAND(S)
927.21 CRUSHING INJURY OF WRIST
927.8 CRUSHING INJURY OF MULTIPLE SITES OF UPPER LIMB
927.9 CRUSHING INJURY OF UNSPECIFIED SITE OF UPPER LIMB
928.00 CRUSHING INJURY OF THIGH
928.01 CRUSHING INJURY OF HIP
928.10 CRUSHING INJURY OF LOWER LEG
928.11 CRUSHING INJURY OF KNEE
928.20 CRUSHING INJURY OF FOOT
928.21 CRUSHING INJURY OF ANKLE
928.3 CRUSHING INJURY OF TOE(S)
928.8 CRUSHING INJURY OF MULTIPLE SITES OF LOWER LIMB
CRUSHING INJURY OF UNSPECIFIED SITE OF LOWER LIMB

CRUSHING INJURY OF MULTIPLE SITES NOT ELSEWHERE CLASSIFIED - CRUSHING INJURY OF UNSPECIFIED SITE

AIR EMBOLISM AS AN EARLY COMPLICATION OF TRAUMA

TRAUMATIC COMPARTMENT SYNDROME OF UPPER EXTREMITY

TRAUMATIC COMPARTMENT SYNDROME OF LOWER EXTREMITY

TOXIC EFFECT OF CARBON MONOXIDE

TOXIC EFFECT OF HYDROCYANIC ACID GAS

TOXIC EFFECT OF HYDROCYANIC ACID AND CYANIDES

EFFECTS OF RADIATION UNSPECIFIED

OTHER AND UNSPECIFIED EFFECTS OF HIGH ALTITUDE

CAISSON DISEASE

MECHANICAL COMPLICATION OF PROSTHETIC GRAFT OF OTHER TISSUE NOT ELSEWHERE CLASSIFIED

COMPLICATIONS OF UNSPECIFIED REATTACHED EXTREMITY - COMPLICATION OF OTHER SPECIFIED REATTACHED BODY PART

AIR EMBOLISM AS A COMPLICATION OF MEDICAL CARE NOT ELSEWHERE CLASSIFIED

AFTERCARE FOLLOWING SURGERY OF THE CIRCULATORY SYSTEM NOT ELSEWHERE CLASSIFIED

OTHER SPECIFIED AFTERCARE

*Claims for HBO for the treatment of persistent arterial insufficiency ulcers following reconstructive surgery require documentation of dual diagnoses. Report ICD-9-CM code 707.10, 707.12, 707.13, 707.14, 707.15 or 707.19 in conjunction with V58.73 (aftercare following surgery of the circulatory system, NEC).

**Claims for HBO for the treatment of diabetic wounds of the lower extremities require documentation of dual diagnoses. An ICD-9-CM code from either the 249.70-249.71, 249.80-249.81, 250.70-250.73 or 250.80-250.83 range (representing a diabetes-related problem) and one of the following ICD-9-CM codes: 707.10, 707.12, 707.13, 707.14, 707.15, or 707.19 (representing a lower extremity wound) must be reported.

Diagnoses that Support Medical Necessity

N/A

ICD-9 Codes that DO NOT Support Medical Necessity

All other ICD-9-CM codes not specified above are not reimbursable under the Medicare program.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Refer to CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations, Chapter 1, Part 1, §20.29.

General Information

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services addressed by this LCD. (See "Indications and Limitations of Coverage and/or Medical Necessity.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

1. Documentation in the medical record should support the specific condition being treated with HBO therapy and the medical necessity of such treatment. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the J11 A/B MAC upon request. Documentation submitted should include:
a. An initial assessment and medical history detailing the condition requiring HBO therapy and a physical exam. The medical history should list prior treatments including antibiotic therapy and surgical interventions.

b. Documentation of current adjunctive treatment should include type of treatment and the effectiveness of same.

c. Physician progress notes and any communication between physicians detailing past or future (proposed) treatments.

d. Established goals for HBO therapy.

e. HBO therapy treatment records describing the physical findings and the treatment rendered (including ascent time, descent time, total compression time, dose of oxygen, pressurization level, documentation of attendance, and a recording of events).

f. The effect of treatment upon the established goals for HBO therapy.

g. Condition specific information such as:

- documentation of laboratory tests (positive gram-stain smear or culture) that confirm the diagnosis of gas gangrene is required

- radiographic tests that confirm the clinical diagnosis of gas gangrene

- documentation supporting a threatened loss of function, limb, or life

- surgical and pathology reports for treatment of necrotizing fasciitis

- definitive radiographic findings or positive bone culture with sensitivity studies to confirm the diagnosis of osteomyelitis, and documentation of failed antibiotic therapy and surgical management

- history of radiation therapy (including date and anatomical site of radiation therapy), with documentation of fracture or resorption of bone, and radiographic studies, if available, to confirm the diagnosis of osteoradionecrosis

- history of radiation therapy and clinical photographs of the necrotic site will help support the medical necessity of HBO services for soft tissue radionecrosis

- documentation that the patient has type I or type II diabetes and a lower extremity wound (due to diabetes) classified as Wagner grade III or higher that has failed to respond to an adequate course of standard therapy. For treatment of diabetic wounds of the lower extremities, documentation must also reflect that there have been no measurable signs of healing for at least 30 days of treatment with standard wound therapy and that the HBO therapy is used in addition to standard wound care with wound evaluation at least every 30 days during HBO therapy.

**NOTE:** the ‘Wagner Ulcer Classification System’ is defined in the “Decision Memo for Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities” (CAG-00060N) published by CMS.
Utilization Guidelines
Utilization guidelines are presented relative to specific treatment conditions:

1. Acute carbon monoxide intoxication induces hypoxic stress and may result in injury to the cardiac and central nervous systems. HBO produces a higher rate of dissociation of carbon monoxide from hemoglobin than occurs at sea level pressure. Chamber compressions should be between 2.5 and 3.0 atmospheres absolute (ATA). Patients with persistent neurological dysfunction may require subsequent treatments within six to eight hours, continuing once or twice daily until there is no further improvement in cognitive functioning.

2. Decompression illness (gas bubbles in tissue or blood in volumes sufficient enough to interfere with the function of an organ or to cause alteration in sensation) resulting from rapid decompression during ascent presents clinical manifestations ranging from skin eruptions to shock and death. Treatment of choice for decompression illness is HBO therapy with mixed gases. The result is immediate reduction in the volume of bubbles. The treatment prescription is highly variable and case specific. The depths could range between 60 to 165 feet of sea water for durations of 1.5 to over 14 hours. The patient may or may not require repeat dives.

Gas embolism occurs when gases enter the venous or arterial vasculature embolizing in a large enough volume to compromise the function of an organ or body part and results in ischemia to the affected areas. Air emboli may occur as a result of surgical procedures (e.g., cardiovascular surgery, intra-aortic balloons, arthroplasties, or endoscopies), use of monitoring devices (e.g., Swan-Ganz introducer, infusion pumps), in nonsurgical patients (e.g., diving, ruptured lung in respirator-dependent patient, injection of fluids into tissue space), or traumatic injuries (e.g., gunshot wounds, penetrating chest injuries). HBO therapy, the treatment of choice, is most effective when initiated early. Therapy is directed toward reducing the volume of gas bubbles and increasing the diffusion gradient of the embolized gas. Treatment modalities range from high pressure to low pressure mixed gas dives.

4. Clostridial myositis and myonecrosis (gas gangrene) is an acute, rapidly growing invasive infection of the muscle characterized by profound toxemia, extensive edema, massive death of tissue and variable degree of gas production. The most prevalent toxin is the alpha-toxin which in itself is hemolytic, tissue-necrotizing and lethal. The diagnosis of gas gangrene is based on clinical data supported by a positive gram-stained smear or culture obtained from tissue fluids. X-ray radiographs, if obtained, can visualize tissue gas. The onset of gangrene can occur one to six hours after injury and presents with severe and sudden pain at the infected area. The skin overlying the wound progresses from shiny and tense, to dusky, then bronze in color. The infection can progress as rapidly as six inches per hour. Hemorrhagic vesicles may be noted. A thin, sweet-odored exudate is present. Swelling and edema occur. The noncontractile muscles progress to dark red to black in color. The goal of HBO therapy is to stop alpha-toxin production thereby inhibiting further bacterial growth at which point the body can use its own host defense mechanisms. HBO treatment starts as soon as the clinical picture presents and is supported by a positive gram-stained smear. A treatment approach utilizing HBO, is adjunct to antibiotic therapy and surgery. Initial surgery may be limited to opening the wound. Debridement of necrotic tissue can be performed between HBO treatments when clear demarcation between dead and viable tissue is evident. The usual treatment consists of oxygen administered at 3.0 ATA pressure for 90 minutes three times in the first 24 hours. Over the next four to five days, treatment sessions twice a day are usual. The sooner HBO treatment is initiated, the better the outcome in terms of life, limb and tissue saving.

5. Crush injuries and suturing of severed limbs, acute traumatic peripheral ischemia (ATI), and acute peripheral arterial insufficiency associated with arterial embolism and thrombosis: Acute traumatic ischemia is the result of injury by external force or violence compromising circulation to an extremity. The extremity is then at risk for necrosis or amputation. Secondary complications are frequently seen: infection, non-healing wounds, and non-united fractures. The goal of HBO therapy is to enhance oxygen at the tissue level to support viability. When tissue oxygen tensions fall below 30mm Hg, the body’s ability to respond to infection and wound repair is compromised. Using HBO at 2-2.4 ATA, the tissue oxygen tension is raised to a level such that the body’s responses can become functional again. The benefits of HBO therapy for this indication are:

a. increased oxygen delivery per unit of blood flow or enhanced tissue oxygenation

c. edema reduction and
HBO is not covered to prepare the patient for dental extraction in order to prevent the development of osteoradionecrosis. Coverage for osteoradionecrosis of the jaw is limited to cases with evidence of overt fracture or bony resorption. Therapy for these patients is highly individualized.

Hyperbaric Oxygen Therapy (HBO) treatments are delivered at a pressure of 2.0 to 2.5 ATA for a duration of 90-120 minutes. It is not unusual to receive daily treatments following major debridement surgery. The number of treatments required vary on an individual basis. Medicare can cover the use of HBO therapy for chronic refractory osteomyelitis that has been shown to be unresponsive to conventional medical and surgical interventions. HBO therapy augments the efficacy of certain antibiotics (gentamicin, tobramycin, and amikacin). Finally, the HBO therapy enhances flap survival. Treatments are given at a pressure of 2.0 to 2.5 ATA lasting from 90-120 minutes. It is not unusual to receive treatments twice a day. When the graft or flap appears stable, treatments are reduced to daily. Should a graft or flap fail, HBO therapy may be used to prepare the already compromised recipient site for a new graft or flap. It does not apply to the initial preparation of the body site for a graft. HBO therapy is not necessary for normal, uncompromised skin grafts or flaps. Medicare coverage does not apply to artificial skin grafts.

Chronic refractory osteomyelitis persists or recurs following appropriate interventions. These interventions include the use of antibiotics, drainage of the abscess, immobilization of the affected extremity, and surgical debridements with removal of the sequestrum. HBO therapy is an adjunctive therapy used with the appropriate antibiotics and surgical debridement to eliminate the dead bone. Antibiotics are chosen on the basis of bone culture and sensitivity studies. HBO therapy can elevate the oxygen tensions found in infected bone to normal or above normal levels. This mechanism enhances healing and the body’s antimicrobial defenses. It is believed that HBO therapy augments the efficacy of certain antibiotics (gentamicin, tobramycin, and amikacin). Finally, the body’s osteoclast function of removing necrotic bone is dependent on a proper oxygen tension environment. HBO therapy provides this environment. HBO treatments are delivered at a pressure of 2.0 to 2.5 ATA for a duration of 90-120 minutes. It is not unusual to receive daily treatments following major debridement surgery. The number of treatments required vary on an individual basis. Medicare can cover the use of HBO therapy for chronic refractory osteomyelitis that has been shown to be unresponsive to conventional medical and surgical management.

HBO’s use in the treatment of osteoradionecrosis and soft tissue radionecrosis is one part of an overall plan of care that also includes debridement or resection of nonviable tissue in conjunction with antibiotic therapy. Soft tissue flap reconstruction and bone grafting may also be indicated. HBO treatment can be indicated in the preoperative and postoperative management of existing osteoradionecrosis or soft tissue radionecrosis. HBO therapy must be utilized as an adjunct to conventional therapy. The patients who suffer from soft tissue damage or bone necrosis present with disabling, progressive, painful tissue breakdown such as wound dehiscence, infection, tissue loss and graft or flap loss. The goal of HBO treatment is to increase the oxygen tension in both hypoxic bone and tissue to stimulate growth in functioning capillaries, fibroblastic proliferation and collagen synthesis. The recommended daily treatments last 90-120 minutes at 2.0 to 2.5 ATA. The duration of HBO therapy for these patients is highly individualized.

Coverage for osteoradionecrosis of the jaw is limited to cases with evidence of overt fracture or bony resorption. HBO is not covered to prepare the patient for dental extraction in order to prevent the development of osteoradionecrosis.
10. Cyanide poisoning carries a high risk of mortality. Victims of smoke inhalation frequently suffer from both carbon monoxide and cyanide poisoning. The traditional antidote for cyanide poisoning is the infusion of sodium nitrite. This treatment can potentially impair the oxygen carrying capacity of hemoglobin. Using HBO therapy as an adjunct therapy adds the benefit of increased plasma dissolved oxygen. HBO’s benefit for the pulmonary injury related to smoke inhalation remains experimental. The HBO treatment protocol is to administer oxygen at 2.5 to 3.0 ATA for up to 120 minutes during the initial treatment. Most patients with combination cyanide and carbon monoxide poisoning will receive only one treatment.

11. Actinomycosis is a bacterial infection caused by Actinomyces israelii. Its symptoms include slow growing granulomas that later break down, discharging viscid pus containing minute yellowish granules. The treatment includes prolonged administration of antibiotics (penicillin and tetracycline). Surgical incision and draining of accessible lesions is also helpful. Only after the disease process has been shown refractory to antibiotics and surgery, could HBO therapy be covered by Medicare. HBO therapy must be utilized as an adjunct to conventional therapy.

12. **Treatment of diabetic wounds of the lower extremities** in patients who meet all three (3) of the following criteria:

   a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes; and

   b. Patient has a wound classified as Wagner grade III or higher (Grade 2 – ulcer penetrates to tendon, bone or joint; Grade 3 – lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths; Grade 4 – wet or dry gangrene in the toes or forefoot; Grade 5 – gangrene involves the whole foot); and

   c. **Patient has failed an adequate course of standard wound therapy.** The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes:

      i. Assessment of a patient’s vascular status and correction of any vascular problems in the affected limb if possible
      ii. Optimization of nutritional status
      iii. Optimization of glucose control
      iv. Debridement by any means to remove devitalized tissue
      v. Maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings
      vi. Appropriate off-loading, and
      vii. Necessary treatment to resolve any infection that might be present

Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

**NOTE:** As with #8 above, standard therapy for osteomyelitis includes surgical debridement/excision of the infected nidus of bone.

**Utilization guidelines that are applicable to all of the above conditions:**

The diagnosis should be established by the referring or treating physician prior to the initiation of HBO therapy.

Continued HBO therapy without documented evidence of effectiveness does not meet the Medicare definition of medically necessary treatment.

HBO therapy should not be a replacement for other standard successful therapeutic measures. Depending on the response of the individual patient and the severity of the original problem, treatment may range from less than 1 week to several months duration, the average being 2 to 4 weeks. The use of hyperbaric oxygen for more than 2 months, (30 days for the treatment of diabetic wounds) regardless of the condition of the patient, may be subject to review for medical necessity before further reimbursement is made.

Appropriate direct physician supervision is a requirement for Medicare coverage.
In a hospital outpatient department, "direct supervision" means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. ... the physician is not required to be present in the room where the procedure is performed or within any other physical boundary as long as he or she is immediately available.

It is recommended that the physician be present during the ascent and descent portions of each treatment.

Podiatrists may practice as physicians "only with respect to functions which he is legally authorized to perform as such by the State in which he performs them" according to §1861(r)(3) of the Act. Therefore, podiatrists who practice HBO should have the same HBO training requirements as any other physician.

Qualified nonphysician practitioners (NPPs) may supervise hyperbaric oxygen therapy services, if such service is included within their State scope of practice, if their required supervision or collaborative agreement is with a physician qualified to provide HBOT services, and if the NPP meets the educational requirements identified herein.

...for services furnished on-campus, the supervisory physician or nonphysician practitioner may not be so physically distant on-campus from the location where hospital/CAH outpatient services are being furnished that he or she could not intervene right away. The hospital or supervisory practitioner must judge the supervisory practitioner’s relative location to ensure that he or she is immediately available.

For services furnished in CY 2011 and following, a supervisory practitioner may furnish direct supervision from a physician office or other nonhospital space that is not officially part of the hospital or CAH campus where the services are being furnished as long as he or she remains immediately available. Similarly, as of CY 2011, an allowed practitioner can furnish direct supervision from any location in or near an off-campus hospital or CAH building that houses multiple hospital provider-based departments where the services are being furnished as long as the supervisory practitioner is immediately available.


Sources of Information and Basis for Decision


Hampson NB, ed. Hyperbaric Oxygen Therapy: 1999 Committee Report. Kensington, MD: Undersea and Hyperbaric Medical Society 1999. This publication was used as a reference, especially concerning the Cierny-Mader classification of chronic refractory osteomyelitis.


NOTE: Some of the websites used to create this policy may no longer be available. Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, including include representatives from the provider community.

Contractor Advisory Committee meeting dates:

South Carolina - 08/01/2011
North Carolina - 08/01/2011
Virginia - 08/01/2011
West Virginia - 08/01/2011

Start Date of Comment Period 10/02/2012

End Date of Comment Period 11/16/2012

Start Date of Notice Period

Revision History Number Revision #4, 01/17/2013

Revision History Explanation Revision #4, 01/17/2013

Under CMS National Coverage Policy corrected Section 8161 to 1861 and corrected the spelling of podiatrists. Under ICD-9 Codes That Support Medical Necessity for codes 444.21, 444.22, 444.81 and 999.1 that are billed after hospitalization (outpatient services) they must be billed with V58.89. Under the asterisk (*)added ICD-9 codes 707.12, 707.13, 707.14, 707.15 or 707.19 are to be billed in conjunction with V58.73 for persistent arterial insufficiency ulcers. Under Documentation Requirements changed the word contractor to A/B MAC. This LCD is going out for comment 10/02/2012-11/16/2012.

Revision #3, 05/15/2012

The comment period ended 09/14/2011, and the comments have been reviewed. The notice period begins on 03/29/2012 and the LCD becomes final on 05/15/2012. Under CMS National Coverage added Title XVII of the Social Security Act, §1861 (r)(3)and CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 6, §20.5.2. Deleted the following cited reference: CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 6, §20.5.3. This section is no longer found in the CMS Manual System. Under Indications and Limitations of Coverage and/or Medical Necessity added (K) to the cited section of Title XVIII of the Social Security Act 1861 (s). Under ICD-9 Codes That Support Medical Necessity deleted ICD-9 code 707.22 as it is for staging of a stage II pressure ulcer which is not covered by Medicare for diabetic wounds of the lower extremities. V59.73 was a typographical error and should have been V58.73. Under Utilization Guidelines-Utilization guidelines that are applicable to all of the above conditions the definition of “direct supervision” was updated to reflect requirements indicated in Change Request 7672 and included in the updated CMS Manual System, Pub 100-02, Medicare Benefit Policy Manual, Chapter 6, §20.5.2. Multiple verbiage changes were made throughout this entire section of the LCD as relate to physician supervision requirements. The physician supervision requirements became effective 01/01/2012. The revision becomes effective on 05/15/2012.

Revision #2,

Under CMS National Coverage Policy the following citations were deleted:

Title XVIII of the Social Security Act, §1862(a)(7) excludes routine physical examinations.

Federal Register, Vol 74, No. 223, November 20, 2009, is the physician supervision Final Rule (p. 60586).


Printed on 10/11/2012. Page 12 of 13
Indications and Limitations of Coverage and/or Medical Necessity, Documentation Requirements, Utilization Guideline and Sources of Information sections have all been completely revised. Under ICD-9 Codes That Support Medical Necessity 707.25 has been deleted and V58.73 has been added.

Due to the complexity of this revision the LCD will be sent out for comment from 08/01/2011 - 09/14/2011. This revision becomes effective on 10/31/2011.

Revision #1, 05/16/2011
Per scheduled J11 implementation, contractor numbers 11301 (Virginia) and 11401 (West Virginia) were added to this LCD. This revision becomes effective on 05/16/2011.

01/24/2011 - In accordance with Section 911 of the Medicare Modernization Act of 2003, in compliance with the J11 AB MAC Statement of Work (SOW), C.5.1.8.2 – Consolidation of Local Coverage Determinations, this LCD has been selected for implementation within the Palmetto GBA J11 AB MAC territory. Effective date of this implementation is January 24, 2011.

Reason for Change Maintenance (annual review with new changes, formatting, etc.)
Typographical Correction

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

Draft Contact
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All Versions
Updated on 09/14/2012 with effective dates 01/17/2013 - N/A
Updated on 09/07/2012 with effective dates 01/17/2013 - N/A
Read the LCD Disclaimer opens in new window

Printed on 10/11/2012. Page 13 of 13
Please note: This is a Draft policy.
Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Please note: This is a Future Draft LCD.

Contractor Information

Contractor Name: Palmetto GBA
Contractor Number: 11501
Contractor Type: MAC - Part A

LCD Information

Primary Geographic Jurisdiction: North Carolina
Oversight Region: Region IV

Original Determination Effective Date: For services performed on or after 01/17/2013
Original Determination Ending Date:

Revision Effective Date: For services performed on or after 01/17/2013
Revision Ending Date:

AMA CPT/ADA CDT Copyright Statement
CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determination(s) or payment policy rules and regulations for cardiac and intensive cardiac rehabilitation services. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for cardiac and intensive cardiac rehabilitation services and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies regarding cardiac and intensive cardiac rehabilitation services are found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

Title XVIII of the Social Security Act, §1862 (a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1862(a)(1)(D) items and services related to research and experimentation

Title XVIII of the Social Security Act, §1862 (a)(D) Personal Comfort items

Title XVIII of the Social Security Act, §1862(a)(7) excludes routine physical examinations

Title XVIII of the Social Security Act, §1833 (e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

42 CFR 410.26 Services incident to a physican's professional services

42 CFR 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or non-physician practitioner's service

42 CFR 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: conditions of coverage.


CMS Internet-only Manual, Pub 100-04, Medicare Claims Processing Manual, Chapter 32, §140.1-140.3.

CMS Internet-only Manual, Pub 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.1.

Indications and Limitations of Coverage and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier (see “Coding Guidelines” section in the attached article for instructions).
Cardiac Rehabilitation (CR) is a comprehensive program of medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling (psychosocial assessment) designed to restore certain patients with coronary or valvular heart disease to active and productive lives (outcomes assessment). CR as described in the medical literature is divided into three phases: Phase I is the immediate in-hospital post-cardiac event phase; Phase II is the outpatient immediate post-hospitalization recuperation phase; and Phases III and IV are the long-term maintenance phases and are not payable under Medicare. This LCD encompasses Phase II or outpatient post-hospital CR. Phase II programs are typically initiated one to three weeks after hospital discharge and consist of a series of medically supervised exercise sessions with Continuous Electrocardiograph Monitoring (CEM). Clinically optimal results are obtained if these sessions are conducted two to three times per week over a 12–18-week period, generally for a total of 36 sessions.

**Phases of Cardiac Rehabilitation**

- **Phase I:** Acute in-hospital phase of CR. This is included in the hospital care for the acute illness and is not included under the CR benefit.
- **Phase II:** For the purposes of this LCD, Phase II is divided into
  - Phase IIA and Phase IIB.
  - Phase IIA is the initial outpatient CR, consisting of 36 or fewer sessions, occurring up to two sessions per day.
  - Phase IIB consists of up to an additional 36 sessions and will only be allowed if determined medically necessary. Phase IIB benefits must meet additional medical necessity criteria. Specifically, there must be clear demonstration that the patient is benefiting from CR and that the exit criteria below from phase IIA have not been met. The maximum total of allowable sessions under Phase IIA and IIB is 72.
- **Phase III:** CR programs that are self-directed or self-controlled/monitored exercise programs.
- **Phase IV:** CR programs or maintenance therapy that may be safely carried out without medical supervision.

**NOTE:** Only Phase II CR programs meet the supervisory requirements of the benefit and are covered under Medicare.

Individualized treatment plan is a written plan tailored to each individual patient that includes all of the following:

- A description of the individual’s diagnosis.
- The type, amount, frequency and duration of the items and services furnished under the plan.
- Must be reviewed and signed by a physician every 30 days.
- The goals set for the individual under the plan.

Intensive Cardiac Rehabilitation (ICR) services must include the comprehensive program components of a CR program, but must also demonstrate that it improves patients’ cardiovascular disease through specific outcome measurements. (See CMS National Coverage Policy section of this LCD)

**Standards for an ICR program:**

- To be approved as an ICR program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients:
  - Positively affected the progression of coronary heart disease.
  - Reduced the need for coronary bypass surgery.
  - Reduced the need for percutaneous coronary interventions.
- An ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before CR services to after CR services:
- Low-density lipoprotein.
- Triglycerides.
- Body mass index.
- Systolic blood pressure.
- Diastolic blood pressure.
- The need for cholesterol, blood pressure and diabetes medications.

Indications for CR and ICR

CR and ICR are covered for the following patients:

- Patients who begin the program within 12 months of an acute Myocardial Infarction (MI).
- Patients who have had Coronary Artery Bypass Graft (CABG) surgery.
- Patients with stable angina pectoris.
- Patients who have had heart valve repair/replacement.
- Patients who have had Percutaneous Transluminal Coronary Angioplasty (PTCA) or coronary stenting.
- Patients who have had a heart or heart-lung transplant.

Limitations

ICR services must be provided in a program approved through the NCD process:

- ICR programs must be approved by CMS.
- ICR programs that are approved by CMS, sites wishing to furnish ICR services via an approved ICR program may begin to enroll as ICR program suppliers using the CMS-855A for the fiscal intermediary or Part A Medicare Administrative Contractor (MAC).
- Contractors and MACs will ensure that claims submitted from individual ICR sites are submitted by enrolled ICR program sites.

A. Facilities for Both CR and ICR

For CR programs provided in the outpatient department of a hospital, coverage is subject to the following conditions:

- The facility is a hospital outpatient department or a physicians office.
- The facility has available for immediate use all the necessary cardiopulmonary emergency diagnostic and therapeutic life-saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment or defibrillator.
- The program is staffed by personnel necessary to conduct the program safely and effectively and who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. An identified supervising physician must be immediately available at all times while cardiac rehabilitation services are being rendered. This does not require that a physician be physically present in the exercise room itself but must be immediately available and accessible at all times in case of an emergency. It should also be noted that non-Physician practitioners may not serve in the supervisory role for Cardiac rehabilitation.

B. Diagnoses for Both CR and ICR
For MI, the date of entry into the program must be within 12 months of the date of infarction. (ICD-9-CM diagnosis codes: 410.XX (see “ICD-9-CM Codes That Support Medical Necessity” section below for complete list); or 412 if the Acute Myocardial Infarction (AMI) occurred more than eight weeks and less than 12 months before the first CR or ICR session).

For CABG, the initiation of the program should be early enough to have a restorative effect on the recuperative process. Optimal results are generally expected when the program is started within three months of the CABG procedure (ICD-9-CM diagnosis code V45.81).

For patients with current stable angina, the diagnosis of angina must be based on a detailed symptom history, focused physical examination, directed risk factor assessment, and appropriate confirmatory testing such as a stress test (ICD-9-CM diagnosis codes 413.9 or 414.8).

For patients with heart valve repair or replacement, the program should be early enough to provide a restorative benefit. Therefore, the date of entry must be within three months of surgery. Exceptions to this (rationale for a later start) must be documented in the medical record and made available to Medicare upon request. (ICD-9-CM diagnosis codes: V42.2 or V43.3).

For patients who have had a PTCA or stent replacement, the program should be early enough to provide a restorative benefit. Therefore, the date of entry must be within three months of surgery (ICD-9-CM diagnosis code: V45.82).

Patients who have had a heart or heart-lung transplant may present special and complex post-transplant management problems. The date of entry is extended to within one year of the surgery (ICD-9-CM diagnosis codes: V42.1 or V42.89).

C. Frequency and Duration for CR and ICR

Once a beneficiary begins CR, he may not switch to ICR, and once a beneficiary begins ICR, he may not switch to CR. Upon completion of a CR or ICR program, beneficiaries must experience another indication in order to be eligible for additional coverage for CR or ICR. Should a beneficiary experience more than one indication simultaneously, he may participate in a single series of CR or ICR sessions (e.g., a patient who had a myocardial infarction within 12 months and currently experiences stable angina is entitled to one series of CR sessions).

• CR Program:
  - The frequency and duration of the program is generally a total of 36 sessions over a maximum of 36 weeks.
  - A single session must last at least 31 minutes in order to be billable. If two sessions are billed for a single day, then the total combined time must be at least 91 minutes (60 minutes for the first session and at least 31 minutes for the second session) in duration.
  - No more than two one-hour sessions, utilizing any combination of the CPT codes (93798) will be allowed per day for up to 36 sessions over a maximum of 36 weeks (Phase IIA).
  - An additional 36 sessions may be allowed if a significant intercurrent illness or comorbidity occurred during the first 36 sessions and the exit criteria have not been met (Phase IIB). Inclusion of the KX modifier on the claim line(s) will be accepted as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond 36 sessions of CR up to a total of 72 sessions meets the CR coverage requirements.
  - An additional series of 36 sessions may be allowed as a new series of CR initiated after an intervening event described as an indication for CR in this LCD. Inclusion of the KX modifier on the claim line(s) will be accepted as an attestation by the provider of the service that documentation is on file verifying that an additional series of CR meets the CR coverage requirements.

• ICR Program:
  - The frequency and duration of the program are generally a total of 72 sessions over a maximum of 18 weeks (126 days).
  - A single session must last at least 31 minutes in order to be billable. If two or more sessions are billed for a single day, then the total combined time must be at least 91 minutes for two sessions or at least 181 minutes for three sessions, etc. in duration.
  - Six sessions may be allowed per day, not to exceed a total of 72 sessions over a period of up to 18 weeks (126 days).
  - Additional sessions may be allowed if a significant intercurrent illness or comorbidity occurred beyond 126 days from the date of the first session and the exit criteria have not been met. Inclusion of the KX modifier on the claim line(s) will be accepted as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond the 126 days meets the ICR coverage requirements.
  - An additional series of 72 sessions may be allowed as a new series of ICR initiated after an intervening event described as an indication for ICR in this LCD. Inclusion of the KX modifier on the claim line(s) will be accepted as an attestation by the provider of the service that documentation is on file verifying that an additional series of ICR meets the ICR coverage requirements.

D. Exit Criteria for Both CR and ICR

Outcome assessments should include:
• Minimally, assessments from the commencement and conclusion of CR/ICR, based on patient-centered outcomes, which must be measured by the physician immediately at the beginning and end of the program.
• Objective clinical measures of the effectiveness of the CR/ICR program for the individual patient, including exercise performance and self-reported measures of exertion and behavior.

Once a patient has reached the following, further CR may not be considered reasonable and necessary unless medical record documentation clearly indicates otherwise:
• Ischemic heart disease: Patient’s status following MI, CABG, PTCA or stent, and patients with angina undergoing stress testing without demonstrating significant ischemia or dysrhythmia after completion of six minutes of a Bruce protocol, or equivalent, achieving a stable level of exercise tolerance (7 METS). (See the American Heart Association’s functional classification: Class I, or normal function status, begins at 7 metabolic equivalent units (METS).)
• Following valve repair/replacement: Patients achieving a stable level of exercise tolerance (7 METS).
• Heart and heart-lung transplant patients: Issues such as deconditioning and cachexic deterioration may complicate the definition of reasonable exit criteria. Based on the study of long term cardiopulmonary exercise performed after heart transplant (Osada et al), a peak oxygen consumption (VO2) of greater than 90 percent of predicted will be used as the exit criterion for phase IIA. Patients whose peak VO2 is less than 90 percent of predicted may qualify for phase IIB.

E. Non-Covered Diagnoses for Both CR and ICR

• Use of any ICD-9-CM diagnosis code not in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this LCD will be cause for denial of claims.
• A patient with unstable angina or a patient status post-non-cardiac surgery will not qualify for CR services.
• Congestive heart failure in the absence of other covered conditions is not included as a covered condition of CR. (See CMS National Coverage Policy section of this LCD)

F. Other Services

• Evaluation and Management (E/M) services, Electrocardiograms (ECGs) and other diagnostic services may be covered on the day of CR if these services are separate and distinct from the CR program and are reasonable and necessary, but would not be covered if provided routinely as part of the CR program.
• Forms of counseling, such as dietary counseling, psychosocial intervention, lipid management and stress management, are components of the CR program and are not separately reimbursed.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

013x Hospital Outpatient
085x Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Note: Palmetto GBA J11 Part A MAC has identified the Bill Types and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes.

0943 Other Therapeutic Services - Cardiac Rehabilitation

CPT/HCPCS Codes
93797 Cardiac rehab
93798 Cardiac rehab/monitor
G0422 Intens cardiac rehab w/exerc
G0423 Intens cardiac rehab no exer

ICD-9 Codes that Support Medical Necessity
The CPT/HCPCS codes included in this LCD will be subjected to "procedure to diagnosis" editing. The following lists include only those diagnoses for which the identified CPT/HCPCS procedures are covered. If a covered diagnosis is not on the claim, the edit will automatically deny the service as not medically necessary.

Medicare is establishing the following limited coverage for CPT/HCPCS codes 93798, G0422 and G0423:

410.00 - 410.02 opens in new window
ACUTE MYOCARDIAL INFARCTION OF ANTEROLATERAL WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF ANTEROLATERAL WALL SUBSEQUENT EPISODE OF CARE

410.10 - 410.12 opens in new window
ACUTE MYOCARDIAL INFARCTION OF OTHER ANTERIOR WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER ANTERIOR WALL SUBSEQUENT EPISODE OF CARE

410.20 - 410.22 opens in new window
ACUTE MYOCARDIAL INFARCTION OF INFEROLATERAL WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF INFEROLATERAL WALL SUBSEQUENT EPISODE OF CARE

410.30 - 410.32 opens in new window
ACUTE MYOCARDIAL INFARCTION OF INFEROPOSTERIOR WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF INFEROPOSTERIOR WALL SUBSEQUENT EPISODE OF CARE

410.40 - 410.42 opens in new window
ACUTE MYOCARDIAL INFARCTION OF OTHER INFERIOR WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER INFERIOR WALL SUBSEQUENT EPISODE OF CARE

410.50 - 410.52 opens in new window
ACUTE MYOCARDIAL INFARCTION OF OTHER LATERAL WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER LATERAL WALL SUBSEQUENT EPISODE OF CARE

410.60 - 410.62 opens in new window
TRUE POSTERIOR WALL INFARCTION EPISODE OF CARE UNSPECIFIED - TRUE POSTERIOR WALL INFARCTION SUBSEQUENT EPISODE OF CARE

410.70 - 410.72 opens in new window
SUBENDOCARDIAL INFARCTION EPISODE OF CARE UNSPECIFIED - SUBENDOCARDIAL INFARCTION SUBSEQUENT EPISODE OF CARE

410.80 - 410.82 opens in new window
ACUTE MYOCARDIAL INFARCTION OF OTHER SPECIFIED SITES EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF OTHER SPECIFIED SITES SUBSEQUENT EPISODE OF CARE

410.90 - 410.92 opens in new window
ACUTE MYOCARDIAL INFARCTION OF UNSPECIFIED SITE EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF UNSPECIFIED SITE SUBSEQUENT EPISODE OF CARE

412*
OLD MYOCARDIAL INFARCTION

413.0 - 413.9 opens in new window
ANGINA DECUBITUS - OTHER AND UNSPECIFIED ANGINA PECTORIS

414.01 - 414.07 opens in new window
CORONARY ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY - CORONARY ATHEROSCLEROSIS OF BYPASS GRAFT (ARTERY) (VEIN) OF TRANSPLANTED HEART

414.8
OTHER SPECIFIED FORMS OF CHRONIC ISCHEMIC HEART DISEASE

V15.1
PERSONAL HISTORY OF SURGERY TO HEART AND GREAT VESSELS PRESENTING HAZARDS TO HEALTH

Printed on 9/20/2012. Page 7 of 11
V42.1  HEART REPLACED BY TRANSPLANT
V42.2  HEART VALVE REPLACED BY TRANSPLANT
V42.89*  OTHER SPECIFIED ORGAN OR TISSUE REPLACED BY TRANSPLANT
V43.3  HEART VALVE REPLACED BY OTHER MEANS
V45.81  POSTSURGICAL AORTOCORONARY BYPASS STATUS
V45.82  PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY STATUS
Note: ICD-9-CM code 412* (old myocardial infarction) refers to an MI that has occurred more than eight weeks prior to cardiac rehabilitation services.

Note: Use V42.89* for heart-lung transplant.

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
All diagnoses not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this LCD.

A patient with unstable angina or a patient status post-non-cardiac surgery does not qualify for CR services.

Congestive heart failure in the absence of other covered conditions is not included as a covered condition of CR. (see CMS National Coverage Policy section of this LCD)

Back to Top

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General Information

Documentation Requirements
Documentation supporting medical necessity should be legible, maintained in the patient’s medical record and made available to the A/B MAC upon request.

ICD-9-CM diagnosis codes supporting medical necessity must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.

Any diagnosis submitted must have documentation in the patient’s record to support coverage and medical necessity.

All CR providers must have documentation of the qualifying event in the patient’s medical record. This information may include copies of the referring physician's records or reports. A prescription for CR from the referring physician must be maintained in the patient’s medical record by the provider of the CR service.

When billing HCPCS/CPT codes 93798, G0422 or G0423, the documentation must clearly indicate the patient is receiving continuous ECG monitoring.

For CABG, the initiation of the program should be early enough to have a restorative effect on the recuperative process. Optimal results are generally expected when the program is started within three months of the CABG procedure (ICD-9-CM diagnosis code V45.81). Exceptions to this (rationale for a later start) must be documented in the medical record and made available to the A/B MAC upon request.

A CR record must be maintained. All components, including ECG strips, must be maintained. All components of the service (medical assessment, ECG monitoring, smoking cessation, dietary counseling and psychological counseling) must be assessed and provided, where appropriate. It is not expected that every component is provided at each session, but the total Phase II Part A record must reflect those benefits.

Printed on 9/20/2012. Page 8 of 11
A record must be kept indicating the identity of the supervising physician and the identity of the physician who will respond immediately should an adverse consequence develop. This record must be made available to the A/B MAC upon request.

Appendices N/A

Utilization Guidelines Refer to “Indications and Limitations of Coverage and/or Medical Necessity,” Section C – “Frequency and Duration,” above.

Notice: This LCD imposes utilization guideline limitations. Although Medicare allows up to these maximums, each patient’s condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient’s medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

Notice: This LCD imposes diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

For services to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary. Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD, are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member.
  - Furnished in a setting appropriate to the patient’s medical needs and condition.
  - Ordered and furnished by qualified personnel.
  - One that meets, but does not exceed, the patient’s medical needs.
  - At least as beneficial as an existing and available medically appropriate alternative.

Sources of Information and Basis for Decision


Printed on 9/20/2012. Page 9 of 11
Leon et al. Cardiac Rehabilitation and Secondary Prevention of Coronary Heart Disease: An American Heart Association Scientific Statement From the Council on Clinical Cardiology (Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention) and the Council on Nutrition, Physical Activity, and Metabolism (Subcommittee on Physical Activity), in Collaboration With the American Association of Cardiovascular and Pulmonary Rehabilitation. Circulation 2005; 111; 369-376.

King et al. Medical Director Responsibilities for Outpatient Cardiac Rehabilitation/Secondary Prevention Programs: A Scientific Statement From the American Heart Association/American Association for Cardiovascular and Pulmonary Rehabilitation. Circulation 2005; 112; 3354-3360.


Trailblazers "Cardiac Rehabilitation and Intensive Cardiac Rehabilitation" LCD

Advisory Committee Meeting Notes This LCD does not reflect the sole opinion of the contractor or contractor medical director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which include representatives from various specialists consulted.

Contractor Advisory Committee meeting dates:
North Carolina-10/2/2012
South Carolina-10/2/2012
Virginia-10/2/2012
West Virginia-10/2/2012

Start Date of Comment Period 10/02/2012
End Date of Comment Period 11/16/2012

Revision History Number Revision #1

Revision History Explanation Revision #1
Added CPT code 93797 for physician supervision during cardiac rehabilitation exercise without continuous EKG monitoring, this LCD is out for comment 10/02/2012-11/16/2012.

Reason for Change Coverage Change (actual change in medical parameters)

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

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Back to Top
Please note: This is a Draft policy. Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Please note: This is a Future Draft LCD.

Contractor Information

Contractor Name: Palmetto GBA
Contractor Number: 11501
Contractor Type: MAC - Part A

LCD Information

Document Information

Primary Geographic Jurisdiction: North Carolina
Oversight Region: Region IV

Original Determination Effective Date: For services performed on or after 01/17/2013
Original Determination Ending Date

Revision Effective Date
Revision Ending Date

AMA CPT/ADA CDT Copyright Statement
CMS National Coverage Policy
Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

42 Code of Federal Regulations (CFR) §410.32 indicates that diagnostic tests are payable only when ordered by the physician who is treating the beneficiary for a specific medical problem and who uses the results in such treatment.

CMS Manual System, Publication 100-03, National Coverage Determinations Manual, Chapter 1, Part 3, §190.21 - Glycated Hemoglobin/Glycated Protein

CMS Manual System, Publication 100-08, Medicare Program Integrity Manual, Chapter 3, §3.4.1.3, Diagnosis Code Requirement

Indications and Limitations of Coverage and/or Medical Necessity
Hemoglobin A1c (HbA1c) refers to the major component of hemoglobin A1, usually determined by ion-exchange affinity chromatography, immunoassay or agar gel electrophoresis. HbA1c assesses glycemic control over a period of 4-8 weeks and appears to be the more appropriate test for monitoring a diabetic patient who is capable of maintaining long term, stable control. Measurement may be medically necessary every 3 months to determine whether a patient’s metabolic control has been. on average, within the target range. More frequent assessments, every 1-2 months, may be appropriate in the patient whose diabetes regimen has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery, severe hypoglycemia or ketoacidosis, or as a result of glucocorticoid or other therapy).

HbA1c is widely accepted as medically necessary for the management and control of patients with diabetes. It is also valuable to assess hyperglycemia, a history of hyperglycemia or dangerous hypoglycemia. It is not considered reasonable and necessary to perform HbA1c tests more often than once every three months on a controlled diabetic patient to determine whether the patient’s metabolic control has been, on average, within the target range. It is not considered reasonable and necessary for these tests to be performed more frequently than once a month for diabetic pregnant women.

Testing for uncontrolled type one or type two diabetes mellitus (or other causes of severe hyper or hypoglycemia) may require testing more than four times a year. We will allow one additional HbA1c test every three months for a total of 8 tests per year in patients with uncontrolled blood glucose levels. Additional tests beyond that frequency may be reimbursed on appeal with appropriate documentation of medical necessity.

HbA1c may be inaccurate in certain situations including anemia, transfusions, hemoglobinopathies and conditions of rapid red cell turnover. Other tests to assess diabetes, including glucose, glycated protein, or fructosamine levels, may be used and are described in the Lab National Coverage Decision 190.21 (NCD for Glycated Hemoglobin / Glycated Protein). This NCD lists the ICD-9 codes for HbA-1-C for frequencies up to once every three months. The ICD-9-CM codes for test frequencies exceeding one every 90 days are listed below.
Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)
012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
014x Hospital - Laboratory Services Provided to Non-patients
018x Hospital - Swing Beds
021x Skilled Nursing - Inpatient (Including Medicare Part A)
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
071x Clinic - Rural Health
085x Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0300 Laboratory - General Classification
0301 Laboratory - Chemistry

CPT/HCPCS Codes
83036 HEMOGLOBIN; GLYCOXYLATED (A1C)

ICD-9 Codes that Support Medical Necessity

**ICD-9-CM codes for performing tests at frequencies more than every 90 days.**

249.01 SECONDARY DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, UNCONTROLLED
249.11 SECONDARY DIABETES MELLITUS WITH KETOACIDOSIS, UNCONTROLLED
249.21 SECONDARY DIABETES MELLITUS WITH HYPEROSMOLARITY, UNCONTROLLED
249.31 SECONDARY DIABETES MELLITUS WITH OTHER COMA, UNCONTROLLED
249.41 SECONDARY DIABETES MELLITUS WITH RENAL MANIFESTATIONS, UNCONTROLLED
249.51 SECONDARY DIABETES MELLITUS WITH OPHTHALMIC MANIFESTATIONS, UNCONTROLLED
249.61 SECONDARY DIABETES MELLITUS WITH NEUROLOGICAL MANIFESTATIONS, UNCONTROLLED
249.71 SECONDARY DIABETES MELLITUS WITH PERIPHERAL CIRCULATORY DISORDERS, UNCONTROLLED
249.81 SECONDARY DIABETES MELLITUS WITH OTHER SPECIFIED MANIFESTATIONS, UNCONTROLLED
250.02 DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.03 DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.12 DIABETES WITH KETOACIDOSIS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.13 DIABETES WITH KETOACIDOSIS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.22 DIABETES WITH HYPEROSMOLARITY, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.23 DIABETES WITH HYPEROSMOLARITY, TYPE I [JUVENILE TYPE], UNCONTROLLED

Printed on 9/17/2012. Page 3 of 5
Diabetes with Other Coma, Type II or Unspecified Type, Uncontrolled

Diabetes with Renal Manifestations, Type II or Unspecified Type, Uncontrolled

Diabetes with Renal Manifestations, Type I [Juvenile Type], Uncontrolled

Diabetes with Ophthalmic Manifestations, Type II or Unspecified Type, Uncontrolled

Diabetes with Ophthalmic Manifestations, Type I [Juvenile Type], Uncontrolled

Diabetes with Neurological Manifestations, Type II or Unspecified Type, Uncontrolled

Diabetes with Neurological Manifestations, Type I [Juvenile Type], Uncontrolled

Diabetes with Peripheral Circulatory Disorders, Type II or Unspecified Type, Uncontrolled

Diabetes with Peripheral Circulatory Disorders, Type I [Juvenile Type], Uncontrolled

Diabetes with Other Specified Manifestations, Type II or Unspecified Type, Uncontrolled

Diabetes with Other Specified Manifestations, Type I [Juvenile Type], Uncontrolled

Diabetes with Unspecified Complication, Type II or Unspecified Type, Uncontrolled

Diabetes with Unspecified Complication, Type I [Juvenile Type], Uncontrolled

Hypoglycemic Coma

Other Specified Hypoglycemia

Postsurgical Hypoinsulinemia

ICD-9-CM related to pregnancy and can be covered no more frequently than once per month.

Diabetes Mellitus of Mother Complicating Pregnancy Childbirth or the Puerperium Unspecified as to Episode of Care - Abnormal Glucose Tolerance of Mother Postpartum

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed in this policy under ICD-9-CM Codes That Support Medical Necessity above.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed in this policy under ICD-9-CM Codes That Support Medical Necessity above.

Back to Top

General Information

Documentations Requirements

Documentation supporting medical necessity should be legible, maintained in the patient's medical record, and must be made available to the A/B MAC upon request.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Appendices N/A

Utilization Guidelines A. One additional test for Diabetes Mellitus out of control (Group 2).
B. Up to one monthly test for pregnant Type I diabetic patients (Group 3).

Printed on 9/17/2012. Page 4 of 5
Sources of Information and Basis for Decision

National Coverage Determination for Glycated Hemoglobin/Glycated Protein (190.21) CR2130, Transmittal 17


Advisory Committee Meeting Notes This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community.

Contractor Advisory Committee meeting dates:
North Carolina - 10/02/2012
South Carolina - 10/02/2012
Virginia - 10/02/2012
West Virginia - 10/02/2012

Start Date of Comment Period 10/02/2012
End Date of Comment Period 11/16/2012
Start Date of Notice Period
Revision History Number
Revision History Explanation
Reason for Change Other

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

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All Versions
Updated on 09/05/2012 with effective dates 01/17/2013 - N/A
Read the LCD Disclaimer opens in new window

Printed on 9/17/2012. Page 5 of 5
Please note: This is a Draft policy.
Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Contractor Information

Contractor Name | Contractor Number | Contractor Type
--- | --- | ---
Palmetto GBA | 11501 | MAC - Part A

Back to Top
CMS National Coverage Policy

Title XVIII of the Social Security Act, 1862(a)(1)(A) allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act, 1833(e) prohibits Medicare payment for any claim, which lacks the necessary information to process the claim.

CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 1, §40.5- Treatment of Obesity


CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations
Manual, Chapter 1, Part 2, §100.14 - Surgery for Diabetes describes coverage of bariatric surgery for persons with type 2 diabetes mellitus and a body mass index \( \geq 35 \).

CMS Manual System, Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, §§150, 150.1, 150.2, 150.3, 150.4, 150.5, 150.6, and 150.7 - Billing Requirements for Bariatric Surgery for Treatment of Morbid Obesity. Although Pub. 100-04 sets claims processing standards rather than coverage, explicit guidance to payable CPT and ICD-9-CM codes are provided here.

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 3, §3.4.1.3 - Diagnosis Code Requirements

Decision Memo (CAG-00250R2) for Laparoscopic Sleeve Gastrectomy Treatment of Morbid Obesity, June 27, 2012 Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions A-C are satisfied.

A. The beneficiary has a body-mass index (BMI) \( \geq 35 \) kg/m²,
B. The beneficiary has at least one co-morbidity related to obesity, and
C. The beneficiary has been previously unsuccessful with medical treatment for obesity.

Indications and Limitations of Coverage and/or Medical Necessity

The sleeve gastrectomy (SG) is a surgical procedure performed in either open or laparoscopic manner. The surgery involves excision of the lateral aspect of the stomach, leaving a much reduced, lesser-curve based, tubular stomach. When performed laparoscopically, the term laparoscopic sleeve gastrectomy (LSG) is used. Presently, LSG is being used as a stand-alone approach to bariatric surgery. By reducing gastric capacity, there is both short and longer term weight loss. A stand-alone sleeve gastrectomy is sometimes referred to as an isolated sleeve gastrectomy. There are variations in the detail and technique for the sleeve gastrectomy procedure itself. LSG has been gaining popularity over the last few years with increased experience among surgeons and the procedure is taking its place among other bariatric surgical procedures for extreme obesity. Unlike some bariatric surgical procedures, this technique is irreversible.

Obesity is recognized as an important risk factor for morbidity and mortality when associated with a number of chronic diseases such as heart disease and diabetes (Flegal, 2010). The Centers for Disease Control and Prevention (CDC) reported that obesity rates in the U.S. have increased dramatically over the last 30 years, and obesity is now epidemic in the United States (Kahn, 2009). For adults 60 years and older, the prevalence of obesity is about 37% among men and 34% among women (NHANES - National Health and Nutrition Examination Survey). Obesity may be further classified according to the National Institutes of Health (NIH):

- Class I Obesity = BMI 30.0-34.9 kg/m²
- Class II Obesity = BMI 35.0-39.9 kg/m²
- Class III (Extreme) Obesity = BMI \( \geq 40.0 \) kg/m²

CMS has recognized the importance of screening and treating obesity and recently
provided Medicare coverage for intensive behavioral therapy for obesity. CMS also has allowed national coverage for some bariatric surgical procedures for Class II and Class III obesity:

- Open and laparoscopic Roux-en-Y gastric bypass (RYGBP);
- Laparoscopic adjustable gastric banding (LAGB); and
- Open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS).

Laparoscopic sleeve gastrectomy was specifically not approved under past NCDs. Recently, under a national coverage analysis (Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity CAG-00250R2) CMS has made the decision for stand-alone LGS coverage to be at the local Medicare contractor level. Open sleeve gastrectomy is specifically not covered in the CMS NCD.

Palmetto GBA is concerned that there are no randomized controlled trials (RCTs) that evaluated adults ≥ 65 years, few large scale trials on stand alone LGS and few, if any, long term trials. Palmetto GBA medical directors have also discussed the surgery with subject matter experts in our jurisdiction. Given the above lack of a large body of peer reviewed data, Palmetto GBA will cover laparoscopic sleeve gastrectomy only when all of the following criteria are met:

- Patient is under 65 years of age.
- Patients has a BMI ≥ 35.0 kg/m² (Class II or Class III obesity)
- Patient has at least one co-morbidity related to obesity
- Active participation within the last 12 months prior to bariatric surgery in a weight-management program that is supervised by a physician for a minimum of four consecutive months. The weight-management program must include monthly documentation of ALL of the following components:
  - weight
  - current dietary
  - physical activity (e.g., exercise program)

Physician-supervised programs consisting exclusively of pharmacological management are not sufficient to meet this requirement.

- A thorough multidisciplinary evaluation within the previous six months which includes ALL of the following:
  - an evaluation by a bariatric surgeon recommending surgical treatment, including a description of the proposed procedure(s)
  - a separate medical evaluation from a physician other than the requesting surgeon that includes both a recommendation for bariatric surgery as well as a medical clearance for surgery
  - clearance for bariatric surgery by a mental health provider including a statement regarding motivation and ability to follow post-surgical requirements
  - a nutritional evaluation by a physician or registered dietician

- LSG is furnished in a CMS approved bariatric facility.
The information above must be documented in the patient's medical record and available on request.

### Coding Information

**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

| 011x | Hospital Inpatient (Including Medicare Part A) |

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

| 0360 |

**CPT/HCPCS Codes**

| 43775 | LAPAROSCOPY, SURGICAL, GASTRIC RESTRICTIVE PROCEDURE; LONGITUDINAL GASTRECTOMY (IE, SLEEVE GASTRECTOMY) |

**ICD-9 Codes that Support Medical Necessity**

Claims payment requires the coding of at least three diagnoses: the primary diagnosis (278.01 morbid obesity), the appropriate V-code for the degree of morbid obesity, and the co-morbid condition(s) necessitating the procedure.

**Primary Diagnosis**
ICD-9 Diagnosis Codes for BMI ≥ 35 are:

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<tr>
<th>Code</th>
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Co-morbid condition

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Diagnoses that Support Medical Necessity
All ICD-9-CM codes listed in this policy under ICD-9-CM Codes that Support Medical Necessity above.

ICD-9 Codes that DO NOT Support Medical Necessity
All ICD-9-CM codes not listed in this policy under ICD-9-CM Codes that Support Medical Necessity above.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
All ICD-9-CM codes not listed in this policy under ICD-9-CM Codes that Support Medical Necessity above.

Appendices
Utilization Guidelines
Sources of Information and Basis for Decision


Other Contractor Policy - Draft LCD Laparoscopic Sleeve Gastrectomy DL32866, Noridian Administrative Services.
Advisory Committee Meeting Notes
This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community.

Contractor Advisory Committee meeting dates:
South Carolina-10/02/2012
North Carolina-10/02/2012
Virginia-10/02/2012
West Virginia-10/02/2012

Start Date of Comment Period
10/02/2012

End Date of Comment Period
11/16/2012

Start Date of Notice Period

Revision History Number

Revision History Explanation

Reason for Change
Other

Related Documents
This LCD has no Related Documents.

LCD Attachments
There are no attachments for this LCD.

Draft Contact
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All Versions

Updated on 09/14/2012 with effective dates N/A

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