ARPIL 2018

MICHIGAN MAC J – 8

LOCAL DETERMINATION COVERAGE (LCD)

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Covered- No ABN required if ICD-10 code(s) listed in the section specific for the test ordered.

Local Coverage Determination (LCD): Allergy Testing (L36402)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

Document Information

LCD ID
L36402

LCD Title
Allergy Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL36402

Original Effective Date
For services performed on or after 03/18/2016

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For services performed on or after 04/01/2018

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
02/01/2016

Notice Period End Date
03/17/2016

CMS National Coverage Policy
Italicized font – represents CMS national NCD language/wording copied directly from CMS Manuals or CMS Transmittals. Contractors are prohibited from changing national NCD language/wording.

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

Title XVIII of the Social Security Act, Section 1862 (a) (1) (A) allows coverage and payment of those items or services that are considered to be *medically 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, Section 1862 (a) (1) (D) excludes investigational or experimental from Medicare coverage.

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

42 CFR, Section 410.20 – Physicians' Services.

42 CFR Section, 410.32 tests not ordered by the physician or other qualified non-physician provider who is treating the patient are not reasonable and necessary. (See 42 CFR 411.15(k)(1).

42 CFR, Section 410.32(b) diagnostic tests must be furnished under the appropriate level of supervision by a physician. Services furnished without the required level of supervision are not reasonable and necessary.

CMS Pub 100-02 *Medicare Benefit Policy Manual*, Chapter 15 – Covered Medical and Other Health Services, Sections
20.2 – Physician Expense for Allergy Treatment,
80.1 – Clinical Laboratory Services, and
80.6 – Requirements for Ordering and Following Orders for Diagnostic Tests.

CMS Pub 100-03 *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1 – Coverage Determinations, Part 2, Sections
110.9 – Antigens Prepared for Sublingual Administration
110.11 – Food Allergy Testing and Treatment
110.12 – Challenge Ingestion Food Testing
110.13 – Cytotoxic Food Tests.

CMS Pub 100-03 *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1 – Coverage Determinations, Part 4, Section 230.10 – Incontinence Control Devices.

CMS Pub 100-04 *Medicare Claims Processing Manual*, Chapter 12 – Physicians/Nonphysician Practitioners, Section 200 - Allergy Testing and Immunotherapy.
Chapter 16 – Laboratory Services, Section
40.7 – Billing for Noncovered Clinical Laboratory Tests.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Overview:
Allergy testing is performed to determine a patient's immunologic sensitivity or reaction to particular allergens for the purpose of identifying the cause of the allergic state. It is based on findings during a complete medical and immunologic history, and appropriate physical exam obtained by face-to-face contact with the patient.

Indications:
Allergy skin testing is a clinical procedure that is used to evaluate an immunologic response to allergenic material. It would not be expected that all patients would receive the same tests or the same number of sensitivity tests. The number and type of antigens used for testing must be chosen judiciously given the patient's presentation, history, physical findings, and clinical judgment.

To be covered by Medicare, the antigens must meet all of the following criteria:

1. Skin testing must be performed based on a complete history and physical exam,
2. Proven efficacy as demonstrated through scientifically valid peer reviewed published medical studies, and
3. Exist in the patient's environment with a reasonable probability of exposure

Allergy testing can be broadly subdivided into two methodologies:

A. In vivo testing (skin tests): this testing correlates the performance and evaluation of selective cutaneous and mucous membrane tests with the patient's history, physician examination, and other observations.

1. Percutaneous Testing (scratch, puncture, prick) and is used to evaluate immunoglobulin E (IgE) mediated hypersensitivity. Percutaneous tests require medical supervision, since there is a small but significant risk of anaphylaxis. Overall, skin testing is quick, safe, and cost-effective. It remains the test of choice in most clinical situations where immediate hypersensitivity reactions are suspected.

Percutaneous testing is the usual preferred method for allergy testing. Medicare covers percutaneous (scratch, prick or puncture) testing when IgE-mediated reactions occur with **any** of the following:

a. Inhalants.
b. Foods. (Patients present with signs and symptoms such as urticarial, angioedema, esosinophilic esophagitis, or anaphylaxis after ingestion of specific foods. Testing for food allergies in patients who present with wheezing is occasionally required.)
c. Hymenoptera (stinging insects).
d. Specific drugs (penicillins, macromolecular agents, enzymes, and egg-containing vaccines). Skin testing is unreliable with other drugs.

2. Intracutaneous/Intradermal Tests are usually performed when increased sensitivity is the main goal such as when percutaneous tests are negative and there is a strong suspicion of allergen sensitivity. Intradermal tests are injections of small amounts of antigen into the superficial layers of the skin. The usual testing program may include 2 concentrations of an extract: a weaker concentration and a stronger concentration. It would not be expected that 3 or more concentrations of one extract would be medically necessary. Medicare covers intradermal (intracutaneous) testing when IgE-mediated reactions occur to **any** of the following:

a. Inhalants.
b. Hymenoptera (stinging insects).
c. Specific drugs (penicillins and macromolecular agents).
d. Vaccines.

3. Patch Testing is the gold standard method of identifying the cause of allergic contact dermatitis. This testing is indicated to evaluate a nonspecific dermatitis, pruritus, to differentiate allergic contact dermatitis (ACD) and irritant contact dermatitis (ICD) and determine the causative antigen. It is a diagnostic test reserved for patients with skin eruptions for which a contact allergy source is likely.

The patch test procedure can induce an eczematous reaction in miniature by applying suspect allergens to normal skin, allowing the physician to determine a specific patient allergy. Patch tests are applied to the skin on the patient's back and left in place for 48 hours. The test is interpreted after 48 hours, and typically once again at 72 or 96 hours, and the reactions are systematically scored and recorded. The patient is then informed and educated regarding specific allergies and avoidance of exposure. Avoidance of the identified allergen(s) is critical to patient improvement and resolution of the dermatitis.

Allergy patch testing is a covered procedure only when used to diagnose allergic contact dermatitis after the following exposures: dermatitis due to detergents, oils and greases, solvents, drugs and medicines in contact with skin, other chemical products, food in contact with skin, plants (except food), cosmetics, metals, rubber additives, other and unspecified. Patch tests may also be used and may be helpful when a distribution and persistence of dermatitis suggests a possible contact allergy, but the exact etiology of the dermatitis is unknown. These allergens are part of a useful, but limited series of 36 allergens. While this series of 36 allergens represents some of the most common contact allergies, there are a significant number of patients who suffer intractable

contact dermatitis for which the 36 allergens are inadequate to diagnose their problem. A supplemental series of allergens in this case can enhance accurate diagnosis, patient education, and treatment. This supplemental series is particularly critical in the diagnosis of occupationally induced dermatitis. If another supplemental series of allergens are clinically indicated for an accurate diagnosis, the documentation must support the medically reasonable and necessary use of the additional allergens.

The clinician should recognize that contact sensitization to metals or bone cement that is used in orthopedic, cardiac, dental, and gynecological implants has been associated with both dermatitis and noncutaneous complications. These complications may include
localized pain, swelling, erythema, warmth, implant loosening, decreased range of motion, stent stenosis, and pericardial effusions in the case of cardiac implants. Patch testing to implant or device components has been recommended to help determine the etiology of the adverse reaction.

4. Photo Patch Testing uses two patches, with one of them being irradiated with ultraviolet light half way through the occlusive period. It is indicated to evaluate unique allergies resulting from light exposure. Some chemicals or medications produce an allergic reaction only when exposed to light (usually ultraviolet type A, UVA). Patients who are over-sensitive to light and those with a rash that appears on parts of the body normally exposed to light but that does not appear in areas shielded from the light should have a photo-patch test.

5. Photo Tests is skin irradiation with a specific range of ultraviolet light. Photo tests are performed for the evaluation of photosensitivity disorders.

6. Skin Endpoint Titration (SET) Testing or Intradermal Dilutional Testing (IDT) analyzes the highest dilution of a substance that produces a reaction, and may be used to determine the starting dose(s) of allergen immunotherapy.

7. Delayed Hypersensitivity Skin Testing has been commonly used in three ways: anergy testing, testing for infection with intracellular pathogens, and testing for sensitivity to contact allergens. Accurate testing for contact allergy requires careful attention to technique, and limitation of testing to the specific allergens known to be associated with a contact reaction.

8. Ophthalmic Mucous Membrane Tests and Direct Nasal Mucous Membrane Tests are rarely indicated. They are allowed when skin testing cannot test allergens.

Ophthalmic mucous membrane tests and direct nasal mucous membrane tests are approved if levels of allergic mediators (such as histamine and tryptase) are measured and a placebo control is performed. This is usually performed in allergy research laboratories. It is also approved in the office setting if the physician is there to observe objective measurement of reactions which might include redness of the eyes, tearing and sneezing.

9. Inhalation Bronchial Challenge Testing involves the inhalation of agents that can trigger respiratory responses and are often used to evaluate new allergens and/or substantiate the role of allergens in patients with significant symptoms. Results of these tests are ordinarily evaluated by objective measures of pulmonary function and occasionally by characterization of bronchoalveolar lavage samples.

a. Inhalation bronchial challenge tests should be performed as dose-response assays where in provocation concentration thresholds can be determined on the basis of allergen concentration required to cause a significant decrease in measured pulmonary function.
b. Inhalation bronchial challenge tests with occupational allergens need to be carefully controlled with respect to dose and duration of exposure. When industrial small molecular weight agents are assessed, tests should be performed under conditions of continuous monitoring of the specific chemical being assessed so as not to exceed the threshold limit level permitted in the workplace.

10. Ingestion (Oral) Challenge Test involves the administration of sequentially or incrementally larger doses of the test item. The test items may include food or antibiotics. The service is allowed once per patient encounter, regardless of the number of items tested, and includes evaluation of the patient's response to the test items.

Challenge ingestion food testing is a safe and effective technique in the diagnosis of food allergies. This procedure is covered when it is used on an outpatient basis if it is reasonable and necessary for the individual patient. (CMS Pub. 100-03 Medicare National Coverage Determination (NCD)Manual, Chapter 1- Coverage Determinations, Part 2 Section 110.12- Challenge Ingestion Food Testing).

Challenge ingestion food testing is covered for the following indications:

- Food allergy, dermatitis

- Anaphylactic shock due to adverse food reaction
- Allergy to medicinal agents
- Allergy to foods

Challenge ingestion food testing has not been proven to be effective in the diagnosis of rheumatoid arthritis, depression, or respiratory disorders. Accordingly, its use in the diagnosis of these conditions is not reasonable and necessary within the meaning of section 1862(a) (1) of the Medicare law, and no program payment is made for this procedure when it is so used. (CMS Pub. 100-03 *Medicare National Coverage Determination (NCD)Manual,* Chapter 1- Coverage Determinations, Part 2 Section 110.12- Challenge Ingestion Food Testing).

11. Intracutaneous testing, delayed reaction - more than 6 tests, may be covered but requires additional justification and case-by-case review for the number of tests performed and the medical necessity except when the skin test is used:

Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4 week period. CMS Pub 100-03 *Medicare National Coverage Determinations (NCD) Manual, Chapter 1* – Coverage Determinations, Part 4, Section 230.10 – Incontinence Control Devices.

12. Organ challenge test materials may be applied to the mucosae of the conjunctivae, nares, GI tract, or bronchi. Considerable experience with these methods is required for proper interpretation and analysis. All organ challenge tests should be preceded by a control test with diluent and, if possible, the procedure should be performed on a double blind or at least single-blind basis.

B. In vitro testing (blood serum analysis): immediate hypersensitivity testing by measurement of allergen-specific serum IgE in the blood serum. They are useful when testing for inhalant allergens (pollens, molds, dust mites, animal danders), foods, insect stings, and other allergens such as drugs or latex, when direct skin testing is impossible due to extensive dermatitis, marked dermatographism, or in children younger than four years of age.

In vitro testing is covered when skin testing is not possible or would be unreliable; or in vitro testing is medically reasonable and necessary as determined by the physician. When in vitro testing is ordered or performed, the medical record must clearly document the indication and why it is being used instead of skin testing.

It is not covered when done in addition to a skin test for the same antigen, except in the case of suspected latex sensitivity, hymenoptera, or nut/peanut sensitivity where both the skin test and the in-vitro test may be performed. The number of tests done, choice of antigens, frequency of repetition and other coverages issues are the same as skin testing.

Testing must be based on a careful history/physical examination which suggests IgE medicated disease. Total Serum IgE is not appropriate in most general allergy testing. Instead, individual IgE tests are performed against a specific antigen.

Special clinical situations in which specific IgE immunoassays are performed against a specific antigen may be appropriate in the following situations:

1. Patients with extensive dermatitis, severe dermatographism, ichthyosis or generalized eczema that will not make direct skin testing possible.
2. Patients needing continued use of H-1 blockers (antihistamines), or in the rare patient with persistent unexplained negative histamine control.
3. Patients who cannot be safely withdrawn from medications that interfere with skin testing, such as long-acting antihistamines, tricyclic antidepressants, beta-blockers, or medications that may put the patient at undue risk if they are discontinued long enough to perform skin tests.
4. Uncooperative patients with mental or physical impairments.
5. For evaluation of cross-reactivity between insect venoms (e.g., fire ant, bee, wasp, yellow jacket, hornet).
6. As adjunctive laboratory testing for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic disease.
7. To diagnose atopy in small children.
8. Patients at increased risk for anaphylactic response from skin testing based on clinical history (e.g., when an unusual allergen is not available as a licensed skin test extract), or who have a history of a previous systemic reaction to skin testing.
9. Patients in who skin testing were equivocal/inconclusive and in vitro testing is required as a confirmatory test.

Total IgE is reasonable and necessary for follow-up of Allergic Bronchopulmonary Aspergillosis (ABPA) and to diagnosis atopy in children.

Retesting with the same antigen(s) should rarely be necessary within a three-year period. Exceptions include young children with negative skin tests, or older children and adults with negative skin tests in the face of persistent symptoms. Routine repetition of skin tests is not indicated (i.e., annually) and not covered.

Limitations:
The following tests are considered not medically reasonable and necessary:
1. Ingestion (Oral) Challenge Food Testing performed by the patient in the home, and not in the office setting, will not be covered.

2. Provocative Testing for which there is limited or no evidence of validity include the cytotoxic test, the provocation-neutralization procedure, electrodermal diagnosis, applied kinesiology, the "reaginic" pulse test, and chemical analysis of body tissues. Controlled studies for the cytotoxic and provocation-neutralization tests demonstrated that the results are not reproducible and do not correlate with clinical evidence of allergy. Electrodermal diagnosis and applied kinesiology have not been evaluated for efficacy. Similarly, the "reaginic" pulse test and chemical analysis of body tissues for various exogenous chemicals have not been substantiated as valid tests for allergy.

Provocative and neutralization testing and neutralization therapy (Rinkel test) of food allergies (sublingual, intracutaneous and subcutaneous) are excluded from Medicare coverage because available evidence does not show these tests and therapies are effective.

3. IgG and IgG Subclass Antibody Tests measure allergen-specific IgG and IgG subclasses by using immunoabsorption assays and IgG and IgG subclass antibody tests for food allergy/delayed food allergic symptoms or intolerance to specific foods. These tests are considered experimental and investigational since there is insufficient evidence in the published peer-reviewed scientific literature to support the diagnostic value of these tests.

4. Antigens for which no clinical efficacy is documented in peer reviewed literature include the following: newsprint, tobacco smoke and leaf, dandelion, orris root, phenol, alcohol, sugar, yeast, grain mill dust, soybean dust (except when the patient has a known exposure to soybean dust such as a food processing plant), honeysuckle, marigold, goldenrod, fiberglass, wool, green tea, or chalk.

5. Radioallergosorbent test (RAST), fluoroallergosorbent test (FAST), and multiple antigen simultaneous test (MAST) are in vitro techniques for determining whether a patient's serum contains IgE antibodies against specific allergens of clinical importance. As with any allergy testing, the need for such tests is based on the findings during a complete history and physical examination of the patient. These tests are not appropriate in most general allergy testing. Instead, individual IgE tests should be performed against a specific antigen.

6. ELISA (enzyme-linked immunoaorbent assay) test is another in vitro method of allergy testing for specific IgE antibodies against allergens. It is used to determine in vitro reaction to various foods and relies on lymphocyte blastogenesis in response to certain food antigens.

7. Quantitative multi-allergen screen is a non-specific screen that does not identify a specific antigen. It is does not have sufficient literature demonstrating clear cut clinical implication. It is a screening tool and therefore not covered by Medicare.

8. *Effective August 5, 1985,* ***cytotoxic leukocyte tests*** *for food allergies are excluded from Medicare coverage because available evidence does not show that these tests are safe and effective.* (CMS Pub. 100-03 *Medicare National Coverage Determination (NCD) Manual,* Chapter 1- Coverage Determinations, Part 2 Section 110.13-Cytotoxic Food Tests).

9. *Effective October 31, 1988,* ***sublingual intracutaneous and subcutaneous provocative and neutralization testing*** *and neutralization therapy for food allergies are excluded from Medicare coverage because available evidence does not show that these tests and therapies are effective.* (CMS Pub 100-03 *Medicare National Coverage Determinations Manual,* Chapter 1- Coverage Determinations, Part 2, Section 110.11 – Food Allergy Testing and Treatment).

10. The following tests are considered **experimental and investigational for allergy testing** as these have not been proven to be effective or appropriate for the evaluation and/or management of IgE-mediated allergic reactions. This list is not all inclusive:

a. Antigen leukocyte cellular antibody (ALCAT) automated food allergy testing
b. Applied kinesiology or Nambudripad's allergy elimination test (NAET (i.e., muscle strength testing or

measurement after allergen ingestion)
c. Anti-Fc epsilon receptor antibodies testing
d. Anti-IgE receptor antibody testing
e. Blood, urine, or stool micro-nutrient assessments
f. Candidiasis test
g. Chemical analysis of body tissues (e.g., hair)
h. Chlorinated pesticides (serum)
i. Chronic urticarial index testing
j. Clifford materials reactivity testing
k. Complement (total or components)
l. Complement antigen testing
m. C-reactive protein
n. Cytokine and cytokine receptor assay
o. Cytotoxic testing for environmental or clinical ecological allergy testing (Bryans Test, ACT)
p. Electrodermal testing or electro-acupuncture
q. Electromagnetic sensitivity syndrome/disorder (allergy to electricity, electro-sensitivity, electrohypersensitivity, and hypersensitivity to electricity).
r. Environmental cultures and chemicals
s. Eosinophil cationic protein (ECP) test
t. Food immune complex assay (FICA) or food allergenic extract immunotherapy
u. General immune system assessments
v. Immune complex assay
w. Immunoglobulin G (IgG) testing for allergy
x. Iridology
y. Leukocyte antibodies testing
z. Leukocyte histamine release test (LHRT)/basophil histamine release test
aa. Lymphocytes (B or T subsets)
ab. Lymphocyte function assay
ac. Mediator release test (MRT) or the LEAP program
ad. Metabolic assessments
ae. Multiple chemical sensitivity syndrome (a.k.a., idiopathic environmental intolerance (IEI), clinical ecological illness, clinical ecology, environmental illness, chemical AIDS, environmental/chemical hypersensitivity disease, total allergy syndrome, cerebral allergy, 20th century disease)
af. Prausnitz-Kustner or P-K testing - passive cutaneous transfer test
ag. Pulse response test
ah. Qualification of nutritional assessments
ai. Rebuck skin window test
aj. Secretory IgA (salvia)
ak. Sage Complement Antigen Test
al. Specific Immunoglobulin (IgG) (e.g., by Radioallergosorbent (RAST) or Enzyme-linked immunosorbent assay (ELISA)
am.Sublingual provocative neutralization testing and treatment with hormones.
an.Total serum IgG, immunoglobulin A (IgA) and immunoglobulin M (IgM
ao. Venom blocking antibodies
ap. Volatile chemical panels (blood testing for chemicals)
aq. Live Cell Analysis
ar. Passive Transfer
as. Cytotoxic Food Testing

Routine allergy re-testing does not meet the definition of medically necessity according to the practice parameters and recommendations from the American College of Allergy, Asthma, and Immunology (ACAAI), the American Academy of Allergy, Asthma, and Immunology (AAAAI), and the Joint Council of Allergy, Asthma, and Immunology (JCAAI).

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

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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.

N/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.

N/A

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

Allergy Testing - Covered

Group 1 Codes:

82785 Assay of ige
86003 Allg spec ige crude xtrc ea
86008 Allg spec ige recomb ea
95004 Percut allergy skin tests
95017 Perq & icut allg test venoms
95018 Perq&ic allg test drugs/biol
95024 Icut allergy test drug/bug
95027 Icut allergy titrate-airborn
95028 Icut allergy test-delayed
95044 Allergy patch tests
95052 Photo patch test
95056 Photosensitivity tests
95060 Eye allergy tests
95065 Nose allergy test
95070 Bronchial allergy tests
95071 Bronchial allergy tests
95076 Ingest challenge ini 120 min
95079 Ingest challenge addl 60 min

Group 2 Paragraph:

Allergy Testing Non-covered

Group 2 Codes:
86001 Allergen specific igg
86005 Allg spec ige multiallg scr

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph:
Note: Diagnosis codes must be coded to the highest level of specificity.

Allergy Testing **95004, 95017, 95018, 95024, 95027**

For codes in the table below that requires a 7th character: letter A initial encounter, D subsequent encounter or S sequela may be used.

Group 1 Codes:

ICD-10 Codes	Description
B44.81	Allergic bronchopulmonary aspergillosis
H10.11	Acute atopic conjunctivitis, right eye
H10.12	Acute atopic conjunctivitis, left eye
H10.13	Acute atopic conjunctivitis, bilateral
H10.31	Unspecified acute conjunctivitis, right eye
H10.32	Unspecified acute conjunctivitis, left eye
H10.33	Unspecified acute conjunctivitis, bilateral
H10.411	Chronic giant papillary conjunctivitis, right eye
H10.412	Chronic giant papillary conjunctivitis, left eye
H10.413	Chronic giant papillary conjunctivitis, bilateral
H10.44	Vernal conjunctivitis
H10.45	Other chronic allergic conjunctivitis
H16.261	Vernal keratoconjunctivitis, with limbar and corneal involvement, right eye
H16.262	Vernal keratoconjunctivitis, with limbar and corneal involvement, left eye
H16.263	Vernal keratoconjunctivitis, with limbar and corneal involvement, bilateral
H65.01	Acute serous otitis media, right ear
H65.02	Acute serous otitis media, left ear
H65.03	Acute serous otitis media, bilateral
H65.04	Acute serous otitis media, recurrent, right ear
H65.05	Acute serous otitis media, recurrent, left ear
H65.06	Acute serous otitis media, recurrent, bilateral
H65.21	Chronic serous otitis media, right ear
H65.22	Chronic serous otitis media, left ear
H65.23	Chronic serous otitis media, bilateral
H65.411	Chronic allergic otitis media, right ear
H65.412	Chronic allergic otitis media, left ear
H65.413	Chronic allergic otitis media, bilateral
H65.491	Other chronic nonsuppurative otitis media, right ear
H65.492	Other chronic nonsuppurative otitis media, left ear
H65.493	Other chronic nonsuppurative otitis media, bilateral
H66.91	Otitis media, unspecified, right ear
H66.92	Otitis media, unspecified, left ear
H66.93	Otitis media, unspecified, bilateral
J01.00	Acute maxillary sinusitis, unspecified
J01.01	Acute recurrent maxillary sinusitis
J01.10	Acute frontal sinusitis, unspecified
J01.11	Acute recurrent frontal sinusitis
J01.20	Acute ethmoidal sinusitis, unspecified
J01.21	Acute recurrent ethmoidal sinusitis
J01.30	Acute sphenoidal sinusitis, unspecified
J01.31	Acute recurrent sphenoidal sinusitis
J01.40	Acute pansinusitis, unspecified
J01.41	Acute recurrent pansinusitis

ICD-10 Codes	Description
J01.80	Other acute sinusitis
J01.81	Other acute recurrent sinusitis
J01.90	Acute sinusitis, unspecified
J01.91	Acute recurrent sinusitis, unspecified
J04.0	Acute laryngitis
J04.30	Supraglottitis, unspecified, without obstruction
J04.31	Supraglottitis, unspecified, with obstruction
J05.0	Acute obstructive laryngitis [croup]
J30.0	Vasomotor rhinitis
J30.1	Allergic rhinitis due to pollen
J30.2	Other seasonal allergic rhinitis
J30.5	Allergic rhinitis due to food
J30.81	Allergic rhinitis due to animal (cat) (dog) hair and dander
J30.89	Other allergic rhinitis
J31.0	Chronic rhinitis
J31.1	Chronic nasopharyngitis
J31.2	Chronic pharyngitis
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J33.0	Polyp of nasal cavity
J33.8	Other polyp of sinus
J34.3	Hypertrophy of nasal turbinates
J34.81	Nasal mucositis (ulcerative)
J34.89	Other specified disorders of nose and nasal sinuses
J35.01	Chronic tonsillitis
J35.02	Chronic adenoiditis
J35.03	Chronic tonsillitis and adenoiditis
J35.1	Hypertrophy of tonsils
J35.2	Hypertrophy of adenoids
J35.3	Hypertrophy of tonsils with hypertrophy of adenoids
J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma with status asthmaticus
J45.30	Mild persistent asthma, uncomplicated
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J45.909	Unspecified asthma, uncomplicated
J45.991	Cough variant asthma
J45.998	Other asthma
K20.0	Eosinophilic esophagitis
K29.30	Chronic superficial gastritis without bleeding
K29.60	Other gastritis without bleeding
L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L23.9	Allergic contact dermatitis, unspecified cause

ICD-10 Codes	Description
L24.9	Irritant contact dermatitis, unspecified cause
L25.9	Unspecified contact dermatitis, unspecified cause
L27.0	Generalized skin eruption due to drugs and medicaments taken internally
L27.1	Localized skin eruption due to drugs and medicaments taken internally
L27.2	Dermatitis due to ingested food
L27.8	Dermatitis due to other substances taken internally
L27.9	Dermatitis due to unspecified substance taken internally
L29.9	Pruritus, unspecified
L30.0	Nummular dermatitis
L30.2	Cutaneous autosensitization
L30.8	Other specified dermatitis
L50.0	Allergic urticaria
L50.1	Idiopathic urticaria
L50.3	Dermatographic urticaria
L50.6	Contact urticaria
L50.8	Other urticaria
R05	Cough
R06.02	Shortness of breath
R06.03	Acute respiratory distress
R06.09	Other forms of dyspnea
R06.2	Wheezing
R06.83	Snoring
R06.89	Other abnormalities of breathing
R09.81	Nasal congestion
R21	Rash and other nonspecific skin eruption
R43.0	Anosmia
R43.1	Parosmia
R43.2	Parageusia
R43.8	Other disturbances of smell and taste
T36.0X5A - T44.2X5S	Adverse effect of penicillins, initial encounter - Adverse effect of ganglionic blocking drugs, sequela
T44.3X5A - T50.Z95S	Adverse effect of other parasympatholytics [anticholinergics and antimuscarinics] and spasmolytics, initial encounter - Adverse effect of other vaccines and biological substances, sequela
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T63.421A	Toxic effect of venom of ants, accidental (unintentional), initial encounter
T63.422A	Toxic effect of venom of ants, intentional self-harm, initial encounter
T63.423A	Toxic effect of venom of ants, assault, initial encounter
T63.424A	Toxic effect of venom of ants, undetermined, initial encounter
T63.441A	Toxic effect of venom of bees, accidental (unintentional), initial encounter
T63.442A	Toxic effect of venom of bees, intentional self-harm, initial encounter
T63.443A	Toxic effect of venom of bees, assault, initial encounter
T63.444A	Toxic effect of venom of bees, undetermined, initial encounter
T63.451A	Toxic effect of venom of hornets, accidental (unintentional), initial encounter
T63.452A	Toxic effect of venom of hornets, intentional self-harm, initial encounter
T63.453A	Toxic effect of venom of hornets, assault, initial encounter
T63.454A	Toxic effect of venom of hornets, undetermined, initial encounter
T63.461A	Toxic effect of venom of wasps, accidental (unintentional), initial encounter
T63.462A	Toxic effect of venom of wasps, intentional self-harm, initial encounter
T63.463A	Toxic effect of venom of wasps, assault, initial encounter
T63.464A	Toxic effect of venom of wasps, undetermined, initial encounter
T65.811A	Toxic effect of latex, accidental (unintentional), initial encounter
T65.812A	Toxic effect of latex, intentional self-harm, initial encounter
T65.813A	Toxic effect of latex, assault, initial encounter
T65.814A	Toxic effect of latex, undetermined, initial encounter
T65.894A	Toxic effect of other specified substances, undetermined, initial encounter
T78.00XA	Anaphylactic reaction due to unspecified food, initial encounter
T78.01XA	Anaphylactic reaction due to peanuts, initial encounter

ICD-10 Codes	Description
T78.02XA	Anaphylactic reaction due to shellfish (crustaceans), initial encounter
T78.03XA	Anaphylactic reaction due to other fish, initial encounter
T78.04XA	Anaphylactic reaction due to fruits and vegetables, initial encounter
T78.05XA	Anaphylactic reaction due to tree nuts and seeds, initial encounter
T78.06XA	Anaphylactic reaction due to food additives, initial encounter
T78.07XA	Anaphylactic reaction due to milk and dairy products, initial encounter
T78.08XA	Anaphylactic reaction due to eggs, initial encounter
T78.09XA	Anaphylactic reaction due to other food products, initial encounter
T78.1XXA	Other adverse food reactions, not elsewhere classified, initial encounter
T78.2XXA	Anaphylactic shock, unspecified, initial encounter
T78.3XXA	Angioneurotic edema, initial encounter
T78.40XA	Allergy, unspecified, initial encounter
T78.49XA	Other allergy, initial encounter
T80.51XA	Anaphylactic reaction due to administration of blood and blood products, initial encounter
T80.52XA	Anaphylactic reaction due to vaccination, initial encounter
T80.59XA	Anaphylactic reaction due to other serum, initial encounter
T80.61XA	Other serum reaction due to administration of blood and blood products, initial encounter
T80.62XA	Other serum reaction due to vaccination, initial encounter
T80.69XA	Other serum reaction due to other serum, initial encounter
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, initial encounter
Z88.0	Allergy status to penicillin
Z88.1	Allergy status to other antibiotic agents status
Z88.2	Allergy status to sulfonamides status
Z88.3	Allergy status to other anti-infective agents status
Z88.4	Allergy status to anesthetic agent status
Z88.5	Allergy status to narcotic agent status
Z88.6	Allergy status to analgesic agent status
Z88.7	Allergy status to serum and vaccine status
Z88.8	Allergy status to other drugs, medicaments and biological substances status
Z91.010	Allergy to peanuts
Z91.011	Allergy to milk products
Z91.012	Allergy to eggs
Z91.013	Allergy to seafood
Z91.018	Allergy to other foods
Z91.02	Food additives allergy status
Z91.030	Bee allergy status
Z91.038	Other insect allergy status
Z91.040	Latex allergy status
Z91.041	Radiographic dye allergy status
Z91.048	Other nonmedicinal substance allergy status
Z91.09	Other allergy status, other than to drugs and biological substances

Group 2 Paragraph:
Specific IgE in Vitro Test **86003, 86008**

For codes in the table below that requires a 7th character: letter A initial encounter, D subsequent encounter or S sequela may be used.

Group 2 Codes:

ICD-10 Codes	Description
B44.81	Allergic bronchopulmonary aspergillosis
H10.11	Acute atopic conjunctivitis, right eye
H10.12	Acute atopic conjunctivitis, left eye
H10.13	Acute atopic conjunctivitis, bilateral
H10.31	Unspecified acute conjunctivitis, right eye

ICD-10 Codes	Description
H10.32	Unspecified acute conjunctivitis, left eye
H10.33	Unspecified acute conjunctivitis, bilateral
H10.411	Chronic giant papillary conjunctivitis, right eye
H10.412	Chronic giant papillary conjunctivitis, left eye
H10.413	Chronic giant papillary conjunctivitis, bilateral
H10.44	Vernal conjunctivitis
H10.45	Other chronic allergic conjunctivitis
H16.261	Vernal keratoconjunctivitis, with limbar and corneal involvement, right eye
H16.262	Vernal keratoconjunctivitis, with limbar and corneal involvement, left eye
H16.263	Vernal keratoconjunctivitis, with limbar and corneal involvement, bilateral
H65.01	Acute serous otitis media, right ear
H65.02	Acute serous otitis media, left ear
H65.03	Acute serous otitis media, bilateral
H65.04	Acute serous otitis media, recurrent, right ear
H65.05	Acute serous otitis media, recurrent, left ear
H65.06	Acute serous otitis media, recurrent, bilateral
H65.21	Chronic serous otitis media, right ear
H65.22	Chronic serous otitis media, left ear
H65.23	Chronic serous otitis media, bilateral
H65.411	Chronic allergic otitis media, right ear
H65.412	Chronic allergic otitis media, left ear
H65.413	Chronic allergic otitis media, bilateral
H65.491	Other chronic nonsuppurative otitis media, right ear
H65.492	Other chronic nonsuppurative otitis media, left ear
H65.493	Other chronic nonsuppurative otitis media, bilateral
H66.91	Otitis media, unspecified, right ear
H66.92	Otitis media, unspecified, left ear
H66.93	Otitis media, unspecified, bilateral
H68.011	Acute Eustachian salpingitis, right ear
H68.012	Acute Eustachian salpingitis, left ear
H68.013	Acute Eustachian salpingitis, bilateral
H68.021	Chronic Eustachian salpingitis, right ear
H68.022	Chronic Eustachian salpingitis, left ear
H68.023	Chronic Eustachian salpingitis, bilateral
J01.00	Acute maxillary sinusitis, unspecified
J01.01	Acute recurrent maxillary sinusitis
J01.10	Acute frontal sinusitis, unspecified
J01.11	Acute recurrent frontal sinusitis
J01.20	Acute ethmoidal sinusitis, unspecified
J01.21	Acute recurrent ethmoidal sinusitis
J01.30	Acute sphenoidal sinusitis, unspecified
J01.31	Acute recurrent sphenoidal sinusitis
J01.40	Acute pansinusitis, unspecified
J01.41	Acute recurrent pansinusitis
J01.80	Other acute sinusitis
J01.81	Other acute recurrent sinusitis
J01.90	Acute sinusitis, unspecified
J01.91	Acute recurrent sinusitis, unspecified
J04.0	Acute laryngitis
J04.30	Supraglottitis, unspecified, without obstruction
J04.31	Supraglottitis, unspecified, with obstruction
J05.0	Acute obstructive laryngitis [croup]
J30.0	Vasomotor rhinitis
J30.1	Allergic rhinitis due to pollen
J30.2	Other seasonal allergic rhinitis
J30.5	Allergic rhinitis due to food
J30.81	Allergic rhinitis due to animal (cat) (dog) hair and dander
J30.89	Other allergic rhinitis

ICD-10 Codes	Description
J31.0	Chronic rhinitis
J31.1	Chronic nasopharyngitis
J31.2	Chronic pharyngitis
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J33.0	Polyp of nasal cavity
J33.8	Other polyp of sinus
J34.3	Hypertrophy of nasal turbinates
J34.81	Nasal mucositis (ulcerative)
J34.89	Other specified disorders of nose and nasal sinuses
J35.01	Chronic tonsillitis
J35.02	Chronic adenoiditis
J35.03	Chronic tonsillitis and adenoiditis
J35.1	Hypertrophy of tonsils
J35.2	Hypertrophy of adenoids
J35.3	Hypertrophy of tonsils with hypertrophy of adenoids
J45.20	Mild intermittent asthma, uncomplicated
J45.21	Mild intermittent asthma with (acute) exacerbation
J45.22	Mild intermittent asthma with status asthmaticus
J45.30	Mild persistent asthma, uncomplicated
J45.31	Mild persistent asthma with (acute) exacerbation
J45.32	Mild persistent asthma with status asthmaticus
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J45.991	Cough variant asthma
J45.998	Other asthma
K29.30	Chronic superficial gastritis without bleeding
K29.60	Other gastritis without bleeding
L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L23.9	Allergic contact dermatitis, unspecified cause
L24.9	Irritant contact dermatitis, unspecified cause
L25.9	Unspecified contact dermatitis, unspecified cause
L27.0	Generalized skin eruption due to drugs and medicaments taken internally
L27.1	Localized skin eruption due to drugs and medicaments taken internally
L27.2	Dermatitis due to ingested food
L27.8	Dermatitis due to other substances taken internally
L27.9	Dermatitis due to unspecified substance taken internally
L29.9	Pruritus, unspecified
L30.0	Nummular dermatitis
L30.2	Cutaneous autosensitization
L30.8	Other specified dermatitis
L50.0	Allergic urticaria
L50.1	Idiopathic urticaria
L50.3	Dermatographic urticaria
L50.6	Contact urticaria
L50.8	Other urticaria

ICD-10 Codes	Description
R05	Cough
R06.02	Shortness of breath
R06.03	Acute respiratory distress
R06.09	Other forms of dyspnea
R06.2	Wheezing
R09.81	Nasal congestion
R21	Rash and other nonspecific skin eruption
R43.0	Anosmia
R43.1	Parosmia
R43.2	Parageusia
R43.8	Other disturbances of smell and taste
T36.0X5A - T44.2X5S	Adverse effect of penicillins, initial encounter - Adverse effect of ganglionic blocking drugs, sequela
T44.3X5A - T50.Z95S	Adverse effect of other parasympatholytics [anticholinergics and antimuscarinics] and spasmolytics, initial encounter - Adverse effect of other vaccines and biological substances, sequela
T50.905A	Adverse effect of unspecified drugs, medicaments and biological substances, initial encounter
T50.995A	Adverse effect of other drugs, medicaments and biological substances, initial encounter
T63.421A	Toxic effect of venom of ants, accidental (unintentional), initial encounter
T63.422A	Toxic effect of venom of ants, intentional self-harm, initial encounter
T63.423A	Toxic effect of venom of ants, assault, initial encounter
T63.424A	Toxic effect of venom of ants, undetermined, initial encounter
T63.441A	Toxic effect of venom of bees, accidental (unintentional), initial encounter
T63.442A	Toxic effect of venom of bees, intentional self-harm, initial encounter
T63.443A	Toxic effect of venom of bees, assault, initial encounter
T63.444A	Toxic effect of venom of bees, undetermined, initial encounter
T63.451A	Toxic effect of venom of hornets, accidental (unintentional), initial encounter
T63.452A	Toxic effect of venom of hornets, intentional self-harm, initial encounter
T63.453A	Toxic effect of venom of hornets, assault, initial encounter
T63.454A	Toxic effect of venom of hornets, undetermined, initial encounter
T63.461A	Toxic effect of venom of wasps, accidental (unintentional), initial encounter
T63.462A	Toxic effect of venom of wasps, intentional self-harm, initial encounter
T63.463A	Toxic effect of venom of wasps, assault, initial encounter
T63.464A	Toxic effect of venom of wasps, undetermined, initial encounter
T65.811A	Toxic effect of latex, accidental (unintentional), initial encounter
T65.812A	Toxic effect of latex, intentional self-harm, initial encounter
T65.813A	Toxic effect of latex, assault, initial encounter
T65.814A	Toxic effect of latex, undetermined, initial encounter
T65.894A	Toxic effect of other specified substances, undetermined, initial encounter
T78.00XA	Anaphylactic reaction due to unspecified food, initial encounter
T78.01XA	Anaphylactic reaction due to peanuts, initial encounter
T78.02XA	Anaphylactic reaction due to shellfish (crustaceans), initial encounter
T78.03XA	Anaphylactic reaction due to other fish, initial encounter
T78.04XA	Anaphylactic reaction due to fruits and vegetables, initial encounter
T78.05XA	Anaphylactic reaction due to tree nuts and seeds, initial encounter
T78.06XA	Anaphylactic reaction due to food additives, initial encounter
T78.07XA	Anaphylactic reaction due to milk and dairy products, initial encounter
T78.08XA	Anaphylactic reaction due to eggs, initial encounter
T78.09XA	Anaphylactic reaction due to other food products, initial encounter
T78.1XXA	Other adverse food reactions, not elsewhere classified, initial encounter
T78.2XXA	Anaphylactic shock, unspecified, initial encounter
T78.3XXA	Angioneurotic edema, initial encounter
T78.40XA	Allergy, unspecified, initial encounter
T78.49XA	Other allergy, initial encounter
T80.51XA	Anaphylactic reaction due to administration of blood and blood products, initial encounter
T80.52XA	Anaphylactic reaction due to vaccination, initial encounter
T80.59XA	Anaphylactic reaction due to other serum, initial encounter
T80.61XA	Other serum reaction due to administration of blood and blood products, initial encounter
T80.62XA	Other serum reaction due to vaccination, initial encounter

ICD-10 Codes	Description
T80.69XA	Other serum reaction due to other serum, initial encounter
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, initial encounter
Z88.0	Allergy status to penicillin
Z88.1	Allergy status to other antibiotic agents status
Z88.2	Allergy status to sulfonamides status
Z88.3	Allergy status to other anti-infective agents status
Z88.4	Allergy status to anesthetic agent status
Z88.5	Allergy status to narcotic agent status
Z88.6	Allergy status to analgesic agent status
Z88.7	Allergy status to serum and vaccine status
Z88.8	Allergy status to other drugs, medicaments and biological substances status
Z91.010	Allergy to peanuts
Z91.011	Allergy to milk products
Z91.012	Allergy to eggs
Z91.013	Allergy to seafood
Z91.018	Allergy to other foods
Z91.048	Other nonmedicinal substance allergy status
Z91.09	Other allergy status, other than to drugs and biological substances

Group 3 Paragraph:
Food allergy testing **95004**
Medicare is establishing the following limited coverage for food allergies.

For codes in the table below that requires a 7th character: letter A initial encounter, D subsequent encounter or S sequela may be used.

Group 3 Codes:

ICD-10 Codes	Description
K20.0	Eosinophilic esophagitis
K52.21	Food protein-induced enterocolitis syndrome
K52.22	Food protein-induced enteropathy
K52.29	Other allergic and dietetic gastroenteritis and colitis
K52.3	Indeterminate colitis
K52.831	Collagenous colitis
K52.832	Lymphocytic colitis
K52.838	Other microscopic colitis
K52.89	Other specified noninfective gastroenteritis and colitis
R05	Cough
R06.02	Shortness of breath
R06.03	Acute respiratory distress
R06.2	Wheezing
R11.0	Nausea
R11.10	Vomiting, unspecified
R11.11	Vomiting without nausea
R11.12	Projectile vomiting
R11.2	Nausea with vomiting, unspecified
R14.0	Abdominal distension (gaseous)
R14.1	Gas pain
R14.2	Eructation
R14.3	Flatulence
R19.7	Diarrhea, unspecified
T78.00XA	Anaphylactic reaction due to unspecified food, initial encounter
T78.00XD	Anaphylactic reaction due to unspecified food, subsequent encounter
T78.00XS	Anaphylactic reaction due to unspecified food, sequela
T78.01XA	Anaphylactic reaction due to peanuts, initial encounter

ICD-10 Codes	Description
T78.01XD	Anaphylactic reaction due to peanuts, subsequent encounter
T78.01XS	Anaphylactic reaction due to peanuts, sequela
T78.02XA	Anaphylactic reaction due to shellfish (crustaceans), initial encounter
T78.02XD	Anaphylactic reaction due to shellfish (crustaceans), subsequent encounter
T78.02XS	Anaphylactic reaction due to shellfish (crustaceans), sequela
T78.03XA	Anaphylactic reaction due to other fish, initial encounter
T78.03XD	Anaphylactic reaction due to other fish, subsequent encounter
T78.03XS	Anaphylactic reaction due to other fish, sequela
T78.04XA	Anaphylactic reaction due to fruits and vegetables, initial encounter
T78.04XD	Anaphylactic reaction due to fruits and vegetables, subsequent encounter
T78.04XS	Anaphylactic reaction due to fruits and vegetables, sequela
T78.05XA	Anaphylactic reaction due to tree nuts and seeds, initial encounter
T78.05XD	Anaphylactic reaction due to tree nuts and seeds, subsequent encounter
T78.05XS	Anaphylactic reaction due to tree nuts and seeds, sequela
T78.06XA	Anaphylactic reaction due to food additives, initial encounter
T78.06XD	Anaphylactic reaction due to food additives, subsequent encounter
T78.06XS	Anaphylactic reaction due to food additives, sequela
T78.07XA	Anaphylactic reaction due to milk and dairy products, initial encounter
T78.07XD	Anaphylactic reaction due to milk and dairy products, subsequent encounter
T78.07XS	Anaphylactic reaction due to milk and dairy products, sequela
T78.08XA	Anaphylactic reaction due to eggs, initial encounter
T78.08XD	Anaphylactic reaction due to eggs, subsequent encounter
T78.08XS	Anaphylactic reaction due to eggs, sequela
T78.09XA	Anaphylactic reaction due to other food products, initial encounter
T78.09XD	Anaphylactic reaction due to other food products, subsequent encounter
T78.09XS	Anaphylactic reaction due to other food products, sequela

Group 4 Paragraph:

Patch Tests **95044, 95052**

Group 4 Codes:

ICD-10 Codes	Description
L23.0	Allergic contact dermatitis due to metals
L23.1	Allergic contact dermatitis due to adhesives
L23.2	Allergic contact dermatitis due to cosmetics
L23.3	Allergic contact dermatitis due to drugs in contact with skin
L23.4	Allergic contact dermatitis due to dyes
L23.5	Allergic contact dermatitis due to other chemical products
L23.6	Allergic contact dermatitis due to food in contact with the skin
L23.7	Allergic contact dermatitis due to plants, except food
L23.81	Allergic contact dermatitis due to animal (cat) (dog) dander
L23.89	Allergic contact dermatitis due to other agents
L23.9	Allergic contact dermatitis, unspecified cause
L24.0	Irritant contact dermatitis due to detergents
L24.1	Irritant contact dermatitis due to oils and greases
L24.2	Irritant contact dermatitis due to solvents
L24.3	Irritant contact dermatitis due to cosmetics
L24.4	Irritant contact dermatitis due to drugs in contact with skin
L24.5	Irritant contact dermatitis due to other chemical products
L24.6	Irritant contact dermatitis due to food in contact with skin
L24.7	Irritant contact dermatitis due to plants, except food
L24.81	Irritant contact dermatitis due to metals
L24.89	Irritant contact dermatitis due to other agents
L24.9	Irritant contact dermatitis, unspecified cause
L25.0	Unspecified contact dermatitis due to cosmetics

ICD-10 Codes	Description
L25.1	Unspecified contact dermatitis due to drugs in contact with skin
L25.2	Unspecified contact dermatitis due to dyes
L25.3	Unspecified contact dermatitis due to other chemical products
L25.4	Unspecified contact dermatitis due to food in contact with skin
L25.5	Unspecified contact dermatitis due to plants, except food
L25.8	Unspecified contact dermatitis due to other agents
L30.0	Nummular dermatitis
L30.2	Cutaneous autosensitization
L30.8	Other specified dermatitis
T84.89XS	Other specified complication of internal orthopedic prosthetic devices, implants and grafts, sequela
Z91.09	Other allergy status, other than to drugs and biological substances

Group 5 Paragraph:
Ingestion Challenge Testing **95076, 95079**

For codes in the table below that requires a 7th character: letter A initial encounter, D subsequent encounter or S sequela may be used.

Group 5 Codes:

ICD-10 Codes	Description
L27.2	Dermatitis due to ingested food
T78.00XA	Anaphylactic reaction due to unspecified food, initial encounter
T78.00XD	Anaphylactic reaction due to unspecified food, subsequent encounter
T78.00XS	Anaphylactic reaction due to unspecified food, sequela
T78.01XA	Anaphylactic reaction due to peanuts, initial encounter
T78.01XD	Anaphylactic reaction due to peanuts, subsequent encounter
T78.01XS	Anaphylactic reaction due to peanuts, sequela
T78.02XA	Anaphylactic reaction due to shellfish (crustaceans), initial encounter
T78.02XD	Anaphylactic reaction due to shellfish (crustaceans), subsequent encounter
T78.02XS	Anaphylactic reaction due to shellfish (crustaceans), sequela
T78.03XA	Anaphylactic reaction due to other fish, initial encounter
T78.03XD	Anaphylactic reaction due to other fish, subsequent encounter
T78.03XS	Anaphylactic reaction due to other fish, sequela
T78.04XA	Anaphylactic reaction due to fruits and vegetables, initial encounter
T78.04XD	Anaphylactic reaction due to fruits and vegetables, subsequent encounter
T78.04XS	Anaphylactic reaction due to fruits and vegetables, sequela
T78.05XA	Anaphylactic reaction due to tree nuts and seeds, initial encounter
T78.05XD	Anaphylactic reaction due to tree nuts and seeds, subsequent encounter
T78.05XS	Anaphylactic reaction due to tree nuts and seeds, sequela
T78.06XA	Anaphylactic reaction due to food additives, initial encounter
T78.06XD	Anaphylactic reaction due to food additives, subsequent encounter
T78.06XS	Anaphylactic reaction due to food additives, sequela
T78.07XA	Anaphylactic reaction due to milk and dairy products, initial encounter
T78.07XD	Anaphylactic reaction due to milk and dairy products, subsequent encounter
T78.07XS	Anaphylactic reaction due to milk and dairy products, sequela
T78.08XA	Anaphylactic reaction due to eggs, initial encounter
T78.08XD	Anaphylactic reaction due to eggs, subsequent encounter
T78.08XS	Anaphylactic reaction due to eggs, sequela
T78.09XA	Anaphylactic reaction due to other food products, initial encounter
T78.09XD	Anaphylactic reaction due to other food products, subsequent encounter
T78.09XS	Anaphylactic reaction due to other food products, sequela
Z88.0	Allergy status to penicillin
Z88.1	Allergy status to other antibiotic agents status
Z88.2	Allergy status to sulfonamides status
Z88.3	Allergy status to other anti-infective agents status

ICD-10 Codes	Description
Z88.4	Allergy status to anesthetic agent status
Z88.5	Allergy status to narcotic agent status
Z88.6	Allergy status to analgesic agent status
Z88.7	Allergy status to serum and vaccine status
Z88.8	Allergy status to other drugs, medicaments and biological substances status
Z91.010	Allergy to peanuts
Z91.011	Allergy to milk products
Z91.012	Allergy to eggs
Z91.013	Allergy to seafood
Z91.018	Allergy to other foods
Z91.02	Food additives allergy status

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph:

N/A

Group 1 Codes: N/A

ICD-10 Additional Information Back to Top

General Information

Associated Information
Documentation Requirements
Adequate documentation is essential for high-quality patient care and to demonstrate the reasonableness and medical necessity of the testing. Documentation must support the criteria for coverage as described in the Coverage Indications, Limitations, and/or Medical Necessity section of this LCD. There should be a permanent record of the allergy test and its interpretation including the test methodology and either the measurement (in mm) of reaction size of both the wheal and erythema response or a standardized grading system for in vivo testing. If in vitro testing is used, instead of skin testing, the medical necessity must be documented. For the in vitro testing, the quantitative result(s) (in kIU/L) for specific IgE must be documented. All patient reaction(s) or complications should be recorded. The report should address or answer any specific clinical questions. If there are factors that prevent answering the clinical questions, this should be explained in the documentation. An official interpretation (final report) of the testing should be included in the patient's medical record. Retention of the allergy test(s) should be consistent both with clinical need and with relevant legal and local health care facility requirements.

The medical record must document the elements of the medical and immunologic history including but not limited to correlation of symptoms; occurrence of symptoms; exposure profile; documentation of allergic sensitization by accepted means and where attempts at avoidance have proven unsuccessful (or the impracticality of avoidance exists); and a copy of the sensitivity results; along with the physical examination. The history should support that attempts to narrow the area of investigation were taken so that the minimal number of necessary skin tests might deliver a diagnosis. Testing results need to justify the diagnosis and code on each claim form. The clinical condition that is claimed to justify this test must be clearly documented in the record. Note: A payable diagnosis alone does not support medical necessity of ANY service. The interpretation of the test results and how the results of the test will be used in the patient's plan of care for treatment and the management of the patient's medical condition (s) must be documented.

Claims submitted without such evidence will be denied as not medically necessary. 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 under Section 1862(a)(1) of the Social Security Act.

All documentation must be maintained in the patient's medical record and made available to Medicare upon request.

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

It would not be expected that all patients would receive the same tests or the same number of sensitivity tests. The number of tests performed must be judicious and related to the history, physical findings and clinical judgment specific to each individual patient. The selection of antigens should be individualized, based on the history and physical examination.

Retesting with the same antigen(s) should rarely be necessary within a three-year period. Exceptions include young children with negative skin tests or older children and adults with negative skin tests, but persistent symptoms suggestive of allergic disease where skin tests may be repeated one year later. Claims for retesting within a three-year period should be submitted with documentation of the medical necessity.

Testing done on separate days for different antigens is acceptable as long as the total number of tests done within any three-year period is not excessive.

In vitro testing is covered when medically reasonable and necessary as a substitute for skin testing; it is not usually necessary in addition to skin testing. If in vitro testing is inconclusive, and contraindications for skin testing have been resolved, then skin testing may be done and is covered. The medical record must document this rationale. In vitro IgE testing will be limited to 30 allergens/beneficiary over a 12-month period. If more tests are performed, medical records may be requested.

A maximum of 55 allergy patch tests for diagnose of allergic contact dermatitis per beneficiary per year is allowed without the submission of documentation with the claim to support medical necessity. Greater than 55 patch tests per patient per year may result in a request of medical records.

It would not be expected that more than forty (40) units be reported for intracutaneous (intradermal) testing per year for a patient. If more than 40 units are reported, medical records may be requested.

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Bibliography

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
04/01/2018	R8	04/01/2018 - For clarification, added the following bullet point "d. Vaccines" to A. In Vivo Testing under 2. Intracutaneous/Intradermal Tests. Usable codes for vaccines are already listed in Group 1 for intracutaneous/intradermal allergy testing.	• Other
01/01/2018	R7	01/01/2018 CPT/HCPCS code updates: description change to Group 1 code 86003, description change to Group 2 code 86005, and added code 86008 to Group 1 table of codes and to Group 2 Paragraph. Annual review done 12/06/2017	• Revisions Due To CPT/HCPCS Code Changes • Other (Annual Review)
10/01/2017	R6	10/01/2017 ICD-10 code updates: Added the following code to Groups 1, 2 and 3: R06.03. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Revisions Due To ICD-10-CM Code Changes
05/01/2017	R5	05/01/2017 Added diagnosis code K20.0 to Groups 1 and 3. Added verbiage "eosinophilic esophagitis" to indications for percutaneous testing A.1.b.	• Reconsideration Request
02/01/2017	R4	02/01/2017 Annual review done 01/03/2017. Added diagnosis codes T84.89XS and Z91.09 to Group 4 for Patch Tests 95044, 95052. Added a paragraph to clarify patch testing for joint replacement patients. Updated Sources of Information.	• Other (Annual Review)
10/01/2016	R3	10/01/2016 Per ICD-10 code updates: In Group 3: deleted code K52.2 and added codes K52.21, K52.22, K52.29, K52.3, K52.831, K52.832, and K52.838, effective 10/01/2016.	• Revisions Due To ICD-10-CM Code Changes
03/18/2016	R2	08/01/2016 Added codes Z88.0-Z88.8 to Group 5, effective 03/18/2016.	• Revisions Due To ICD-10-CM Code Changes
03/18/2016	R1	04/01/2016 Added initial annual review date into system.	• Other

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Associated Documents

Attachments Billing and Coding Guidelines (PDF - 40 KB)

Related Local Coverage Documents Article(s) A54842 - Response to Comments: Allergy Testing (L36402) LCD(s) DL36402 - (MCD Archive Site)

Related National Coverage Documents NCD(s) 110.12 - Challenge Ingestion Food Testing 110.13 - Cytotoxic Food Tests 110.11 - Food Allergy Testing and Treatment

Public Version(s) Updated on 03/20/2018 with effective dates 04/01/2018 - N/A Updated on 12/20/2017 with effective dates 01/01/2018 - 03/31/2018 Updated on 09/19/2017 with effective dates 10/01/2017 - 12/31/2017

Updated on 04/17/2017 with effective dates 05/01/2017 - 09/30/2017 Updated on 01/17/2017 with effective dates 02/01/2017 - 04/30/2017 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

Keywords

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Local Coverage Determination (LCD):
MolDX: Biomarkers in Cardiovascular Risk Assessment (L36523)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

B **Type Natriuretic Peptide**

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

Document Information

LCD ID
L36523

LCD Title
MolDX: Biomarkers in Cardiovascular Risk Assessment

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL36523

Original Effective Date
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N/A

Retirement Date
N/A

Notice Period Start Date
05/01/2016

Notice Period End Date
06/15/2016

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 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS Pub. 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 80-Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

CMS Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 16, Section 50.5-Jurisdiction of Laboratory Claims, 60.12: Independent Laboratory Specimen Drawing, 60.2: Travel Allowance.

CMS Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 23, Section 10-Reporting ICD Diagnosis and Procedure Codes

CMS Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 18, Section 100-Preventive and Screening Services, Cardiovascular Disease Screening

CMS Pub. 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Section 190.23-Lipid Testing.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Under preventative services, Medicare Part B covers the basic lipid panel (total cholesterol, high density lipoprotein-cholesterol (HDL-C), triglycerides, and low density lipoprotein-cholesterol (LDL-C) for cardiovascular (CV) disease screening, every 5 years when ordered by a doctor.

NCD 190.23 covers lipid panel testing for symptomatic patients for evaluating atherosclerotic CV disease, to monitor the progress of patients on anti-lipid dietary management and pharmacologic therapy for various lipid disorders.

This policy denies coverage for **all CV risk assessment panels,** except the basic lipid panel, for symptomatic (with signs and symptoms) patients with suspected or documented CV disease because panel testing is not specific to a given patient's lipid abnormality or disease. The policy indicates the medical indication(s) based on published scientific articles and consensus guidelines for individual lipid biomarkers that may be covered to characterize a given lipid abnormality or disease, to determine a treatment plan or to assist with intensification of therapy. Each individual lipid biomarkers must be specifically ordered and the reason for the test order documented in the patient's medical record. The policy denies coverage for all **non-lipid** biomarkers when used for CV risk assessment including but not limited to, biochemical, immunologic, hematologic, and genetic biomarkers for CV risk assessment regardless of whether ordered in a panel or individually.

The following biomarkers, when they are included in a CV risk assessment panel, are non-covered:

- Lipoprotein subclasses;
- LDL particles;
- Intermediate density lipoproteins;
- High density lipoprotein AI9LpAI and AI/AII;
- Lipoprotein(a);

- Apolipoprotein B (Apo B), apo A-I and apo E;
- Lipoprotein-associated phospholipase A2 (Lp-PLA2)
- BNP
- Cystatin C
- Thrombogenic/hematologic actors
- Interleukin-6 (IL-6), tissue necrosis factor- a (TNF- a) , plasminogen activator inhibitor-1 (PAI-1) and IL-6 promoter polymorphism
- Free fatty acids
- Visfatin, angiotensin-converting enzyme 1 (ACE2) and serum amyloid A
- Microalbumin
- Myeloperoxidase (MPO)
- Homocysteine and methylenetetrahydrofolate reductase (MTHFR) mutation testing
- Uric acid
- Vitamin D
- White blood cell count
- Long-chain omega-3 fatty acids in red blood cell membranes
- Gamma-glutamyltransferase (GGT)
- Genomic profiling including CardiaRisk angiotensin gene
- Leptin, ghrelin, adiponectin and adipokines including retinol binding protein 4 (RBP4) and resistin
- Inflammatory markers including VCAM-1, P-selectin (PSEL) and E-selectin (ESEL)
- Cardiovascular risk panels

Note #1: There is no Medicare benefit for screening CV risk assessment testing for asymptomatic (without signs or symptoms of disease) patients. Screening asymptomatic patients for cardiovascular risk is statutorily excluded by Medicare and will not be addressed in this policy.

Note #2: FDA approval/clearance means that a test/assay has analytical and clinical validity. The FDA does not review clinical utility (that the test/assay demonstrates improved patient outcomes). To meet Medicare's "reasonable and necessary" criteria for coverage, a test/assay must have proven clinical utility.

Traditional vs Non-traditional CV Risk Assessment
During the last two decades the interest in CV biomarkers as early screening tools has risen dramatically, largely fueled by the recognition that traditional CV risk factors (diabetes, smoking, hypertension and hyperlipidemia) do not fully explain individual variation in CV risk, and by advances in genetic and molecular research. Risk assessment for determining the 10-year risk for developing CHD is traditionally carried out using the Framingham risk score.

Despite the Framingham risk-scoring tool, clinicians have sought non-traditional lipid and other biomarker measurements to predict CV events. The most promising biomarkers are the ones that closely correlate with the pathophysiological process of the disease. In general, there is evidence that some of these biomarkers may alter risk categorization (higher or lower) compared to traditional risk prediction, but it has not been established that changes in categorization provides clinically actionable information beyond that of traditional lipid measures. In addition, no study has provided high-quality evidence that measurement of non-traditional lipid and other biomarkers leads to changes in management that improve health outcomes.

To provide clinically useful knowledge, a biomarker should meet the following criteria:

- Adds clinical knowledge that improves patient outcomes (criteria for Medicare "reasonable and necessary");
- Provides risk information that is independent of established predictors;
- Is easy to measure and interpret in the clinical setting; and
- Is accurate, reproducible and standardized.

High-sensitivity C-reactive protein (hs-CRP)
CRP is a protein produced in the liver during episodes of acute inflammation or infection. The hs-CRP test measures CRP that is in the normal range for healthy people, and is used to distinguish people with low normal levels from those with high normal levels. In recent years, prospective epidemiologic studies have demonstrated that inflammation is essential for CV disease pathogenesis and that high normal levels of hs-CRP correlate with an increased risk of CV events such as myocardial infarction (MI), stroke, sudden cardiac death and peripheral vascular disease (PVD) even when lipid levels are within acceptable ranges. The American Heart Association (AHA) and the US Centers for Disease Control and Prevent (CDC) recommend averaging two hs-CRP levels obtained two weeks apart. Based on hs-CRP test results, they recognize: low (3.0 mg/L) risk groups.

In 2009, the US Preventive Services Task Force (USPSTF) report on the use of non-traditional risk factors noted

there is insufficient evidence to recommend the use of non-traditional risk factors to screen asymptomatic individuals with no history of CHD to prevent CHD events. The non-traditional risk factors in their recommendation included: hs-CRP, ankle-brachial index (ABI), leukocyte count, fasting blood glucose level, periodontal disease, carotid intima-media thickness, coronary artery calcification (CAC) score on electron beam computerized tomography (EBCT), homocysteine level, and lipoprotein(a) level. The USPSTF stated there is insufficient evidence to determine the percentage of intermediate-risk individuals who would be reclassified by screening with non-traditional risk factors, other than hs-CRP or ABI. For individuals re-classified as high-risk by hs-CRP or ABI, data are not available to determine whether they benefit from additional treatment. They note the potential harms resulting from re-classification including the use of medications without proven benefit and psychological effects. The USPSTF stated that clinicians should continue to use the Framingham model to assess CHD risk and guide risk-based preventive therapy.

While data from the Physicians' Health Study and Framingham Heart Study have shown that hs-CRP measurements may result in reclassification of an individual's risk compared to standard risk prediction models, meta-analysis including data from the second Northwick Park Heart Study (NPHS II) and the Edinburgh Artery Study concluded that the ability of hs-CRP to reclassify risk correctly was modest and inconsistent.

The Jupiter trial, a randomized, double-blind, placebo-controlled trial of the use of rosuvastatin vs placebo in the primary prevention of CVD in patients without diabetes with LDL-C <130mg/dL and CRP =2 mg/dL, was associated with a significant reduction in the primary endpoint of CV events. These findings suggest that hs-CRP measurement in highly preselected patients may have important clinical implications. However, the Jupiter study was not a trial of hs-CRP because individuals with unknown or low hs-CRP concentrations were not studied. Despite evidence that elevated hs-CRP levels are associated with increased risk of CHD, it has not been determined whether hs-CRP is causally related to CHD.

In 2010, The American College of Cardiology Foundation and the American Heart Association (ACCF/AHA) published guidance as to when and in whom to measure blood levels of hs-CRP. The guidance states that hs-CRP levels may assist in the selection of patients for statin therapy according to the following criteria (Class IIa; Level of evidence (LOE): B):

- Men >50 years of age, or women >60 years of age or older
- LDL-C <130 mg/dL
- Patients not on lipid-lowering, hormone replacement, or immunosuppressant therapy
- Patients without clinical CHD, diabetes, chronic kidney disease, severe inflammatory conditions, or contraindications to statins

For example, a patient may appear to have a low or low-moderate elevated risk of CV events based on traditional risk factor scoring with cholesterol levels, weight, level of exercise, smoking history, diabetes and hypertension. However, an elevated hs-CRP level would indicate that the cardiac risk may be substantially greater than traditional risk factors suggest, and that treatment might be considered. For patients who are already known to have high risk, according to current recommendations, hs-CRP levels will not add any substantially new information, since the patient should already be receiving all available therapy including statins to reduce the risk.

The ACCF/AHA recommended measurement of hs-CRP for CV risk assessment in asymptomatic intermediate-risk men 50 years of age or younger, or women 60 years of age or younger (Class IIb; LOE B). Since screening (asymptomatic patient) is statutorily excluded from coverage, hs-CRP testing for these individuals is not a Medicare benefit. They found no benefit for hs-CRP testing in asymptomatic high-risk adults or men and women below the ages stated above. (Class III; LOE B).

The Canadian Cardiovascular Society guidelines recommend hs-CRP testing in men older than 50 and women older than 60 years of age who are at intermediate risk (10-19%) according to their Framingham risk score and who do not otherwise qualify for lipid-lowering therapy. They also state that subjects who meet Jupiter criteria can be considered for treatment based on the results of that study.

In the National Academy of Clinical Biochemistry's (NACB) practice guidelines on emerging CV risk factors, only hs-CRP met the stated criteria as a biomarker for risk assessment in primary prevention. They recommended:

- If the 10-year predicted risk, after standard global risk assessment, is <5%, hs-CRP should not be measured.
- If the 10-year risk is 5-10%, it is expected that 10% might be reclassified to a higher risk group with the test.
- If the risk is intermediate (10-20%), and uncertainty remains as to the use of preventive therapies such as statins or aspirin, then hs-CRP measurement might be useful for further stratification into a higher or lower risk category.

The NACB also recommended that:

- Therapies based on hs-CRP should be based on a clinician's clinical judgment because benefits of such treatment are uncertain;There is insufficient data that therapeutic monitoring using hs-CRP
- over time is useful to evaluate effects of treatment in primary prevention;
- The utility of hs-CRP levels to motivate patients to improve lifestyle behaviors has not been demonstrated;
- Evidence is inadequate to support concurrent measurement of other inflammatory markers in addition to hs-CRP for coronary risk assessment.

In 2012, the American Association of Clinical Endocrinologist gave a 2b recommendation for the use of hs-CRP to stratify borderline CV risk in patients with a standard risk assessment, or those with an LDL-C
The AHA's statement on non-traditional risk factors and biomarkers in CV disease in youth notes "There is currently no clinical role for measuring CRP routinely in children when assessing or considering therapy for CVD risk factors." The AHA also state that it is not clear whether high hs-CRP levels during childhood and adolescence lead to an increased risk of CVD in adult life. While lifestyle changes have been shown to decrease hs-CRP in children, and statins reduce CRP in adults, the AHA indicates there is minimal information available on the effect of statins on hs-CRP in children and whether lowering hs-CRP in children mitigates preclinical disease or CVD in adulthood. Similarly, the National Heart, Blood and Lung Institute (NHBLI) guideline on CV risk in children and adolescents found insufficient evidence to recommend hs-CRP testing in these patient groups.

In summary, this contractor expects testing to be limited to the following criteria:

1. Patient has intermediate CV risk (10-20% risk of CVD per 10 years using the Framingham point score);**and**
2. Patient has LDL-C between 100-130 mg/dL; **and**
3. Patient has two or more CHD major risk factors, including
    - Age (Men > 50 years; Women > 60 years)
    - Current cigarette smoking
    - Family history of premature CHD (CHD in male first degree relative <55; CHD in female fist degree relative <65 years of age)
    - Hypertension (Systolic > 140 mm Hg, or on anti-hypertensive medication)
    - Low HDL-C (<40 mg/dL)

The use of hs-CRP testing to evaluate the effects of treatment or to motivate patients to improve lifestyle behaviors are not considered medically reasonable and necessary, and therefore not covered by Medicare.

Lipoprotein subclasses
Lipoprotein subclass determination based on density, electric charge and other physical chemistry aspect of particles such as nuclear magnetic resonance allow more specific characterization of the major subclasses (VLDL, LDL, IDL and HDL). Studies showed that small, dense LDL particles were highly associated with the occurrence of CVD and diabetes.

LDL Particles (LDL-P) (aka LDL or Lipoprotein Particles or Particle Number, LDL or Lipid Subfractionation, Lipid Phenotyping, Nuclear Magnetic Resonance or NMR Profile)

Small dense LDL with elevated triglyceride levels and low HDL-cholesterol levels constitute the "atherogenic lipoprotein phenotype" form of dyslipidemia that is a feature of type II diabetes and the metabolic syndrome. Measurement of LDL particle density has been proposed as a technique to further risk stratification in patients with elevated LDL levels or for patients with normal LDL levels who have other high-risk factors for CAD, or to predict response to a particular therapy.

Although great progress has been made in the development of refined lipoprotein assessment and such measurements have helped in understanding the atherosclerotic process, it is not known whether measurements beyond traditional lipids can identify CV risk subgroups and how treatment would differ based on subgroup classification. Furthermore, it is not known whether this additional information helps the health care provider to identify with greater precision and accuracy the person who will develop clinical or subclinical CVD.

The NACB does not recommend testing as there is insufficient data that measurement of lipoprotein subclasses can identify CV risk subgroups, how treatment would differ based on subgroup classification and whether, over time, measurement is useful to evaluate the effects of treatments. In addition, the 2010 ACCF/AHA guidelines for assessment of lipoprotein, other lipoprotein parameters and modified lipids state that "measurement of lipid parameters, including lipoproteins, apolipoproteins, particle size, and density, beyond standard fasting lipid profile is not recommended for cardiovascular disease risk assessment in asymptomatic adults."

Unlike lipoprotein size or subclass measures, which seek to improve CV risk assessment beyond conventional lipid testing, LDL particle number tests (NMR LDL-P) and apoB are simply an alternate measure of LDL quantity. Current data supports the ability of LDL particle number to provide clinically actionable information beyond traditional lipid measures to adjudicate individual response to treatment and guide adjustment in therapy. In addition, recent data demonstrate that patients with established CHD, stroke, TIA, peripheral arterial or diabetes achieving NMR LDL-P < 1000 nmol/L during the course of their normal medical care experienced a significant 22-25% reduction in risk of CV events (myocardial infarction, revascularization, angina and stroke) versus patients managed to LDL-C < 100 mg/dL at 12, 24, and 36 months follow-up.

LDL particle number (NMR LDL-P), rather than LDL size or subclass, has been shown to be significantly associated with CV risk independent of traditional lipid and established risk factors. The American Association of Clinical Endocrinologists (AACE), the National Lipid Association (NLA), the American Diabetes Association (ADA) in conjunction with the American College of Cardiology (ACC), and the American Association of Clinical Chemistry (AACC) have developed consensus position statement on lipoprotein particle management in individuals at risk for CVD. Due to the prevalence of discordantly elevated LDL-P despite achieving low LDL-C and non-HDL-C values, each endorses use of LDL particle number to evaluate LDL response and aid decision making regarding potential adjustment of therapy. The 2013 AACE Comprehensive Diabetes Management Algorithm, as well as the 2015 joint AACE/American College of Endocrinology Clinical Practice Guidelines for Comprehensive Diabetes Mellitus Care, advocate specific LDL particle number goals for statin treated diabetic patients at high CV risk.

Intermediate Density Lipoproteins (Remnant Proteins)
Intermediate density lipoproteins (IDLs) have a density that falls between LDLs and VLDLs, and may be referred to as remnant lipoproteins because they vary in size and contain varying proportion of triglycerides and cholesterol. Although there is abundant evidence the remnant lipoproteins are atherogenic, and a risk factor for CAD, there is no evidence how testing improves patient outcomes.

High Density Lipoprotein (HDL) Subclass (Lipoprotein AI 9LpAI) and Lipoprotein AI/AII (LpAI/AII) and/or HDL3 and HDL2
HDL cholesterol (HDL-C) is the risk indicator most often used in associated with CHD risk. HDL subfractions have been used for risk prediction. However, data is lacking how the subfractions aid in the diagnosis and management of CHD. Neither the NCEP nor ACCF/AHA guidelines recommend the routine measurement of HDL subspecies in CHD risk assessment.

Lipoprotein(a) (Lp(a))
Lp(a) is a modified form of LDL in which a large glycoprotein, apolipoprotein(a) is bound to apolipoprotein B. It promotes foam cell formation and the deposition of cholesterol in atherosclerotic plaques, and, because it is structurally similar to plasminogen, Lp(a) may contribute to clot formation. However, the complete role of lipoprotein(a) is not fully understood.

There is no standardized scale for measuring Lp(a) because there is no level that is considered "normal". Because Lp(a) levels are controlled predominantly by genes, cholesterol-lowering drugs have little effect on lowering Lp(a) levels. Elevated Lp(a) is considered an independent risk factor for cardiovascular events, including myocardial infarction, stroke, CVD, vein graft restenosis, and retinal arterial occlusion and may be used to identify individuals who might benefit from more aggressive treatment of other risk factors. However, regardless of the association between Lp(a) and CV disease, there is no data to suggest that more aggressive risk factor modification improves patient health outcomes.

The NACB specifies that Lp(a) screening is not warranted for primary prevention and assessment of cardiovascular risk. They comment that Lp(a) measurement may be done at the physician's discretion if the risk is intermediate (10%–20%) and uncertainty remains as to the use of preventive therapies such as statins or aspirin (Recommendation – IIb; LOE – C). They further note there is insufficient evidence to support therapeutic monitoring of Lp(a) concentrations for evaluating the effects of treatment.

Similarly, the 2010 ACCF/AHA guidelines conclude that apolipoproteins are not recommended for CV disease risk assessment in asymptomatic adults. UpToDate notes that Lp(a) is a modest, independent risk factor for CVD, especially MI, but notes there are no clinical trials that have adequately tested the hypothesis that Lp(a) reduction reduces the incidence of first or recurrent CVD events.

Lp(a) testing may be indicated in select patients, particularly intermediate risk patient, to assist physicians with the use of preventive therapies. Routine testing is not covered by Medicare.

Apolipoprotein B (Apo B), Apolipoprotein A-I (Apo AI), and Apolipoprotein E (Apo E)
Apo B is a constituent of LDL particles, and serves as an indirect measurement of the number of LDL particles. Consequently, elevated levels of Apo B suggest increased levels of small dense LDL particles that are thought to be atherogenic.

Apo AI is the major protein constituent of HDL-C. However, its measurement has not been established as a clinically useful test in determining clinical therapy for patients with CAD or dyslipemia at the current time.

While Apo B and Apo A-I are thought to be the main structural proteins of atherogenic and anti-artherogenic lipoproteins and particles, testing for these compounds has not been validated as a tool for risk assessment. As such, the 2010 ACCF/AHA guidelines indicate that apolipoproteins testing is not recommended for CV risk assessment in asymptomatic adults. However, AACE recommends Apo B testing to assess residual risk in patients for CAD (even when LDL-C levels are controlled) in patient when the triglyceride concentration is >150 mg/dL or the HDL-C concentration is 150 mg/dL or HDL-C of
Apo E, the major constituent of VLDL and chylomicrons, acts as the primary binding protein for LDL receptors in the liver and is thought to play a role in lipid metabolism. Although some individuals hypothesize that Apo E genotypes may be useful in the selection of drug therapy, the value of Apo E testing in the diagnosis and management of CHD is insufficient and needs further evaluation.

The National Cholesterol Education Program (NCEP) expert panel concluded that Apo AI is carried in HDL and it is usually low when HDL is reduced. A low Apo AI thus is associated with increased risk of CHD, but not independently of low HDL. Whether it has independent predictive power beyond HDL-C is uncertain and its measurement is not recommended for routine risk assessment in Adult Treatment Panel (ATP III) Guidelines.

Testing for Lipoproteins

Apolipoproteins
Apolipoproteins are measured in routine clinical laboratories with the use of immunonephelometric or immunoturbidimetric assays. ApoB reflects the number of potentially atherogenic lipoprotein particles because each particle of VLDL, IDL, LDL and lipoprotein(a) particle carries on its surface 1 Apo B100 protein. Most of plasma Apo B is found in LDL particles. HDL particles do not carry Apo B. Instead they carry Apo AI, which does not correspond directly to the concentration of HDL particles in a 1-to-1 fashion.

LDL Gradient Gel Electrophoresis (GGE) (used by Berkeley Heart Lab, Berkeley, CA)
GGE is the most commonly used lab technique to measure LDL particle density. It has been promoted as an important criteria of CHD risk, and as a guide to drug and diet therapy in patients with CAD. While the measurement of LDL subclass patterns may be useful in elucidating possible atherogenic dyslipemia in patients without abnormal total cholesterol, HDL, LDL and triglycerides, there is inadequate evidence that LDL sub-classification by GGE improves outcomes in patients with CV disease.

Density Gradient Ultracentrifugation (DGU) (used by Atherotec Inc, Birmingham, AL)
The Vertical Auto Profile (VAP) test measures the relative distribution of cholesterol within various lipoprotein subfractions, quantifying the cholesterol content in the VLDL, IDL, LDL, lipoprotein(a) and HDL subclasses. It includes components (e.g., total cholesterol, direct measured LDL-C, HDL-C and triglycerides), LDL density (i.e. pattern A versus pattern B), IDL, HDL sub types, VLDL density and Lp(a), and non-lipid CV risk assessment biomarkers including hs-CRP, homocysteine, Lp-PLA2, Apo-E genotype, vitamin D, cystatin and NT-proBNP.

Nuclear Magnetic Resonance Spectroscopy
In this method (NMR LipoProfile® is FDA cleared and available from LipoScience Inc, Raleigh, NC) particle concentrations of lipoprotein subfractions of different size are obtained from the measured amplitudes of their lipid methyl group NMR signals. Lipoprotein particle sizes are then derived from the sum of the diameter of each subclass multiplied by its relative mass percentage based on the amplitude of its methyl NMR signal.

Note: FDA clearance does not mean the test has clinical utility.

Ion-Mobility Analysis
This method (available from Quest Diagnostics Inc., Madison, NJ) measures both the size and concentration of lipoprotein particle subclasses on the basis of gas-phase differential electric mobility.

Summary of Lipoprotein Testing
At the current time, none of the above tests for lipoproteins have better predictive strength than total/HDL-C ratio and there has been no clear benefit for measuring particle number in most studies to date. Additional research is needed to establish the utility of following changes in lipoproteins as a therapeutic target and determine if any subgroups of patients benefit.

Lipoprotein-Associated Phospholipase A2 (Lp-PLA2)
Lp-PLA2 is also known as platelet activating factor acetylhydrolase. This enzyme hydrolyzes phospholipids and is primarily associated with LDLs. It has been suggested that this enzyme has a proinflammatory role in the development of atherosclerosis. Studies show that Lp-PLA2 is an independent predictor of CV risk but fail to demonstrate improved health outcomes. To improve outcomes, studies must demonstrate how risk factors improve risk classification and change in physician practice to improve patient outcomes.

The NCEP ATP III panel concluded that routine measurement of inflammatory markers (including Lp-PLA2) for the purpose of modifying LDL-cholesterol goals in primary prevention is not warranted. In the 2010 ACCF/AHA guidelines for assessment of CV risk, the experts concluded "lipoprotein-associated phospholipase (Lp-PLA2) might be reasonable for cardiovascular risk assessment in intermediate risk asymptomatic adults". However, at the current time, it is not known whether Lp-PLA2 concentrations are clinically effective for motivating patients, guiding treatment, or improving outcomes.

B-type Natriuretic Peptide (BNP)
BNP and NT-proBNP, hormones produced by cardiocytes in response to hemodynamic stress, have emerged as preferred biomarkers for assessing heart-related stress. There is evidence that these hormones provide prognostic information of mortality and first CV events beyond traditional risk factors. However, there is currently no evidence that treatment or intervention based on the increased risk implied by these biomarkers improves patient outcomes.

These hormones do play a role in the acute setting for use in diagnosing decompensated heart failure.

Cystatin C
Cystatin C, encoded by the CST3 gene, is a small serine protease inhibitor protein secreted by all functional cells in the body. It is used as a biomarker for renal function, and in CV risk assessment although there is no evidence that this marker improves outcomes when used in clinical care. The NACB guidelines on Biomarkers of Renal Function and Cardiovascular Disease Risk do not recommend testing. The NCEP advocates clinical studies to characterize the utility of these markers in the global assessment of CV disease risk.

Thrombogenic/Hematologic Factors
Hematologic factors including coagulation factors and platelets play a role in acute coronary syndrome although the precise mechanism is not known. That platelets are involved in this process is supported by strong evidence that aspirin and other antiplatelet therapies reduce the risk of myocardial infarction.

Fibrinogen has also been associated with CHD risk. A high fibrinogen level is associated with increased risk for coronary events, independent of cholesterol levels, while a low fibrinogen indicates a reduced risk even with high cholesterol levels. Other hemostatic factors associated with increased coronary risk include, but are not limited to, activated factor VII (aFVII), tissue plasminogen activator (tPA), plasminogen activator inhibitor-1 (PAI-1), von Willebrand factor (vWF), Factor V Leiden (FVL), Factor II (F2), Protein C (PC) and antithrombin III.

In 2009, the NACB guidelines reported there was sufficient data that fibrinogen is an independent marker of CVD risk. In addition, measurement of fibrinogen was not recommended because they expressed analytical concerns regarding insufficient assay standardization and uncertainty in identifying treatment strategies. Additionally, the NCEP expert panel concluded "ATPIII does not recommend measurement of prothrombotic factors as part of routine assessment of CHD risk". They indicated that the strength of the association between thrombogenic/hemotologic factors and CHD risk has not been defined and recommended clinical trials that target specific prothrombotic factors.

D-dimer is associated with an increased risk of venous and arterial thrombotic events, irrespective of baseline vascular disease, even after adjusting for confounders such as age, smoking and diabetes. In CVD, an increased fibrin turnover represents not only a prothrombotic state, but also is a marker for the severity of atherosclerosis. Although D-dimer is a simple test that is widely available, it remains unclear whether D-dimer plays a causal role in the pathophysiology of CV adverse events, or whether D-dimer is simply a marker of the extent of disease.

Interleukin-6 (IL-6), Tissue Necrosis Factor- a (TNF-a), Plasminogen Activator Inhibitor-1 (PAI-1), and IL-6 Promoter Polymorphism
Adipose tissue is a prominent source of PAI-1. Recent data indicates there is continuous production of large amounts of active PAI-1 in platelets that may contribute to clot stabilization. PAI-1 is the primary physiological inhibitor of plasminogen activation. Increased PAI-1 expression acts as a CV risk factor and plasma levels of PAI-1 strongly correlate with body mass index (BMI). Similar associations have been reported between PAI-1 activity and plasma insulin and triglycercide levels in patients with CAD and diabetes. However, there is no data that PAI-1 testing changes physician management to improve patient outcomes.

IL-6, an inflammatory cytokine, is involved in metabolic regulation of CRP. IL-6 plays an important role in the process of rupture or erosion of atherosclerotic plaques, and its serum levels are elevated during these events. At the current time, there is no consensus on IL-6 assay methods or reference values, and no data that demonstrates IL-6 testing changes physician management to improve patient outcomes.

Early in atherosclerotic plaque formation, leukocytes adhere to and are entrapped in the endothelial wall, a process mediated by inflammatory adhesion molecules such as P-selectin and ICAM-1 that are modulated by TNF-a. However, to date, these biomarkers have not provided additional predictive power above that of traditional lipid markers.

Because a polymorphism in the promoter region of IL-6 (174 bp upstream from the start site) appears to influence the transcription of the IL-6 gene and plasma levels of IL-6, this functional polymorphism was considered a candidate gene in the development of CV disease. However, multiple studies have produced inconsistent findings. In a large population-based study, no significant relationship between IL-6 promoter polymorphism and risk of CHD was identified. The authors concluded that IL-6-174 promoter polymorphism is not a suitable genetic marker for increased risk of CHD in person aged 55 years or older.

Free Fatty Acids (FFA, Saturated and Unsaturated)
The role of plasma FFA in thrombogenesis in humans is poorly established and no strong direct evidence is available. Increasing plasma FFA concentration is known to induce endothelial activation, increase plasma MPO level and promote a prothrombotic state in non-diabetic healthy subjects. Studies are ongoing to demonstrate the role of FFA in the pathogenesis of atherosclerosis. However, at the current time, there is sparse data on its role in early atherosclerosis and no evidence how testing improves patient outcomes.

Visfatin, Angiotensin-Converting Enzyme 2 (ACE2) and Serum Amyloid A
Visfatin is an active player promoting vascular inflammation and associated with atherosclerosis-related disease. It is involved in cytokine and chemokine secretion, macrophage survival, leukocyte recruitment by endothelial cells, vascular smooth muscle inflammation and plaque destabilization. Although visfatin has emerged as a promising pharmacological target in the context of CV complications, there is no evidence how testing improves patient outcomes.

The renin-angiotensin system (RAS) plays a major role in the pathophysiology of CVD. The enzyme angiotensin-converting enzyme (ACE) converts angiotensin I into the vasoconstrictor, angiotensin II, the main effector of the renin-angiotension system. It has been suggested that circulating ACE2 may be a marker of CVD with low levels of ACE2 in healthy individuals and increased levels in those with CV risk factors or disease. However, larger clinical studies are needed to clarify the role of ACE2 as a biomarker of CVD, determine the prognostic significance of circulating ACE2 activity and assess whether the measurement of ACE2 will improve CVD risk prediction.

Serum amyloid A (SAA) is a sensitive marker of inflammation and its elevation has been implicated in obesity and in CVD. It is a highly conserved acute-phase protein, stimulated by proinflammatory cytokines such as IL-6, TNF, interferon-gamma and transforming growth factor-beta (TGF-B). SAA is also a kind of apolipoprotein that is involved in cholesterol metabolism. However, there is sparse data on its role in early atherosclerosis and no evidence how testing improves patient outcomes.

Microalbumin
Microalbuminuria is both a renal risk factor and a CV risk factor in patients with diabetes, and particularly a risk marker of CV mortality in the general population. Microalbuminuria also appears to be a sensitive marker for detecting new onset of hypertension and diabetes. However, for albuminuria to be a target for therapy, one needs to prove that lowering of albuminuria per se is cardioprotective. Albuminuria-lowering effect of antihypertensive agents, particularly those that interfere with RAS, and the use of statins and glucoseaminoglycans have been proved in randomized, controlled trial to be cardioprotective. However, few have been directed at albuminuria lowering per se to evaluate the effect on CV outcome. The question remains as to whether microalbuminuria is the consequence or the cause of organ damage, particularly whether high levels of albuminuria in young children reflect normal physiological variations in endothelial function associated with CV and renal risk in later age. While albumin excretion levels may represent a primary marker for success of intervention strategies aimed at repairing vascular function, there is no data how testing improves patient outcomes at the current time.

Myeloperoxidase (MPO)
Elevated levels of myeloperoxidase, secreted during acute inflammation, are thought by some to be associated with coronary disease and predictive of acute coronary syndrome in patients with chest pain. Many studies have implicated MPO in the pathogenesis of atherosclerosis, showing that it is enriched within atheromatous plaques. Inflammatory cells recruited into the vascular wall release MPO-derived reactive oxygen species that can promote endothelial dysfunction by reducing the bioavailability of nitric oxide, generate atherogenic oxidized-LDL, and modify HDL, impairing its function in cholesterol efflux. However, at the current time there is insufficient data to demonstrate that plasma MPO can predict CHD independent of other CVD risk factors and there is no data that demonstrates how plasma MPO levels affect management of individuals at risk for or patients with CHD.

PPAR-*y* is a key regulator of fatty acid metabolism, promoting its storage in adipose tissue and reducing circulating levels of free fatty acids. Activation of PPAR-*y* has favorable effects on surrogate measures of adipocyte function, insulin sensitivity, lipoprotein metabolism, and vascular structure and function. However clinical trials of thiazolidinedione PPAR-*y* activators have not provided conclusive evidence that they reduce CV morbidity and mortality.

At the current time, there is no clinical data that demonstrates the clinical utility of testing for lipid peroxidation, isoprostanes, malondialdehyde, nitrotyrosine, S-glutathionylation, oxidized LDL, or oxidized phospholipids.

Additionally, genetic testing for genes that regulate cellular and systemic oxidative stress, including but not limited to, nuclear factor-2 (Nrf-2), peroxisome proliferator-activated receptor gamma-co-activator 1alpha (PCG-1a), and the thioredoxin family or proteins have no clinical data that demonstrates utility.

Homocysteine and Methylenetetrahydrofolate Reductase (MTHFR) Mutation Testing
Homocysteine is an amino acid found in the blood. Observational evidence generally supports the association of homocysteine levels with CV risk, particularly observational data that patients with hereditary homocystinuria, an inborn error of metabolism associated with high plasma levels of homocysteine, have markedly increased risk of CV disease. Folic acid and the B vitamins are involved in the metabolism of homocysteine. Several studies found the higher levels of B vitamins are associated with lower homocysteine levels, while other evidence shows that low levels of folic acid are linked to a higher risk of CHD and stroke. However, large randomized controlled trials do not support a protective effect of folic acid supplementation (rectifying homocysteine levels) in cardiovascular disease.

MTHFR is a key enzyme in folate metabolism. Two variants of the MTHFR polymorphisms result in reduced enzyme activity, impaired methylation and increased risk of CVD, stroke, and hypertension. MTHFR mutation testing has been advocated to evaluate the cause of elevated homocysteine levels.

However, in 2009, the US Preventive Services Task Force (USPSTF) concluded that the evidence was insufficient to assess the benefits and harms of using non-traditional risk factors to screen asymptomatic adults with no history of CHD to prevent CHD events. Homocysteine was one of the non-traditional factors considered in the recommendation. In 2010, later updated in March 2014, the AHA stated that a causal link between homocysteine levels and atherosclerosis has not been established, and noted that high homocysteine levels is not a major risk factor for CV disease. The 2012 American Association of Clinical Endocrinologists (AACE) guidelines for management of dyslipidemia and prevention of atherosclerosis stated that testing for homocysteine, uric acid, PAI-1 or other inflammatory markers is not recommended.

Uric acid
A recent systemic review and meta-analysis suggests that elevated uric acid levels may modestly increase the risk of stroke and mortality. However, future studies are needed to determine whether lowering uric acid levels has any beneficial effects on stroke risk. Data is inadequate to show that uric acid testing changes physician management to improve patient outcomes.

Vitamin D
Low levels of vitamin D are an independent risk factor for CV death in populations without pre-existing CV disease. However, systematic reviews on interventional vitamin D supplementation and CV disease risk reported that vitamin D supplementation had no effect on cardiovascular disease risk, indicating a lack of a causal relationship.

An additional concern regarding vitamin D testing is the considerable variation between results obtained with the various methods (competitive immunoassays, direct detection by high performance liquid chromatography or liquid chromatography combined with tandem mass spectrometry), as well as between laboratories. Immunoassay technologies are less sensitive and specific for vitamin D than liquid chromatography with or without mass spectrometry.

WBC
A large body of data from prospective studies has established an association of leukocyte count with increased risk for CVD events. Leukocytes are thought to play a role in the development and/or progression of atherosclerotic plaques and their rupture due to their proteolytic capacity and oxidative properties. WBC count is correlated with other coronary disease risk factors, including cigarette smoking, BMI, cholesterol level, HDL-C (inversely), triglycerides, diabetes and blood glucose level, physical activity (inversely) and blood pressure. However, the NACB does not recommend WBC testing because clinical utility in reclassifying risk level and identifying treatment strategies is not known.

Long-chain Omega-3 Fatty Acids in Red Blood Cell (RBC) Membranes
It has been proposed that the fatty acid composition of RBCs are an index of long-term intake of eicosapentaenoic (EPA) plus docosahexaenoic (DPA) acids. The omega-3 fatty acids are considered a new modifiable and clinically relevant risk factor for death from CHD. Most studies to date have focused on the association between fish consumption and risk of CHD. In the Rotterdam Study, analysis of EPA plus DHA and fish intake was assessed in relation of incident heart failure (HF). With nearly 5300 study individuals, the authors concluded that their findings did not support a major role for fish intake in the prevention of HF. Not only is there no association between fish intake and EPA+DHA levels regarding prevention of HF, there is no scientific evidence regarding how measurements of RBC omega-3 fatty acids composition would affect management of individuals at risk for or patients with CHD. A recent article (Marai, 2014) notes that the available data do not support testing for omega-3 polyunsaturated fatty acids (EPA + DHA) among healthy subjects and patients with specific cardiac diseases.

Gamma-glutamyltransferase (GGT)
GGT, a marker of excessive alcohol consumption or liver disturbance, is an enzyme catalyzing the first step in extracellular degradation of the anti-oxidant gluatathione and is thought to play a role in the atherosclerotic process. Coverage for GGT is limited to the indications and limitations specified in CMS NCD 190.32. Whether serum levels of GGT can aid in the detection of individuals at high risk for incident CV events is under investigation. Despite its potential role in stratifying patient risk, there is no evidence testing improves patient outcomes.

Gene Mutations (any methodology) and Genomic Profiling
Proponents of molecular CV profile testing argue that improvement in CVD risk classification leading to management changes that improve outcomes warrants coverage of these tests. However, the Evaluation of Genomic Applications in Practice and Prevention Working Group (EWG) found insufficient evidence to recommend testing for 9p21 genetic variant or 57 other variants in 28 genes to assess risk for CVD in the general population, specifically heart disease and stroke.

The following genes were included in the EWG's assessment: ACE, AGT, AGTR1, APOB, APOC3, APOE, CBS, CETP, CYBA, CYP11B2, F2, F5, GNB3, GPX1, IL1B, LPL, ITGB3, MTHFR, MTR, MTRR, NOS3, PAI-1, PON1, SELE, SOD2, SOD3, TNF, and 9p21. The EWG found that the magnitude of net health benefit from the use of any of these tests alone or in combination is negligible.

CardiaRisk™ (Myriad, Salt Lake UT) markets a genetic test to identify a mutation in the AGT genes. This test supposedly identifies specific hypertensive patients at increased risk of CV disease and identifies patients likely to respond to antihypertensive drug therapy. However, at the present time there is no literature that points to clinical utility for this test.

Leptin, Ghrelin, Adiponectin, and Adipokines including Retinol Binding Protein 4 (RBP4) and Resistin
Leptin, a satiety factor secreted by adipocytes that is instrumental in appetite regulation and metabolism, is elevated in heart disease. In a recent study, leptin levels and proinflammatory high-density lipoprotein (piHDL) when combined into a risk score (PREDICTS) confers 28-fold increased odds of the presence of any current, progressive, or acquired carotid plaque and significantly associated with higher rates of intima-media thickness. However, there is no data that demonstrates how measurement of leptin levels affects management of individuals at risk for or patients with CHD.

Ghrelin is a hormone produced in the stomach and pancreas that plays a role in hunger and weight gain. In a recent study, ghrelin when incorporated in the CV risk model improved the prediction of CVD events in hypertensive patients with reclassification of roughly 21%. However, there is no evidence how testing improves patient outcomes.

Adiponectin is an adipose-specific hormone that has anti-inflammatory properties and is protective against obesity. Particularly in children, measurement of total adiponectin or high-molecular-weight adiponection (HMW adiponectin) as a biomarker for insulin sensitivity and/or as a risk factor for CVD is gaining support. However, the additive value of adiponectin levels remains unclear and how it changes patient outcomes is not known. It is not recommended clinically in children or adults.

RBP4 is gaining recognition as an adipokine that may play an important role in obesity and insulin resistance. The relationship between RBP4 and other traditional and non-traditional risk factors for CVD, such as inflammatory factors and/or oxidative stress, have not been confirmed in larger populations, and causality has not been established.

Resistin is an adipokine expressed highly in visceral compared with subcutaneous adipose tissue. In the Study of Inherited Risk of Coronary Atherosclerosis (Reilly, 2003), resistin levels were positively correlated with higher coronary calcium scores and correlated with higher levels of soluble TNF-a, receptor-2, Lp(a), and IL-6. The resistin gene (RETN) polymorphism (bp -420 and +299) leads to increased concentrations of the resistin peptide in circulation, which is associated with cardiomyopathy and CAD. One study suggests that in addition to primary risk factors (total cholesterol, LDL, triglycerides and low concentrations of HDL), resistin cytokine may be a risk factor for CVD. However, there is no clinical role for measuring resistin as no data demonstrates how measurement of resistin levels affects management of individuals at risk for or patients with CHD.

Inflammatory Markers – VCAM-1, ICAM-1, P-selectin (PSEL) and E-selectin (ESEL)
Clinical studies have shown that elevated serum concentrations of cell adhesion molecules such as inter-cellular adhesion molecule-1 (ICAM-1), vascular adhesion molecule-1 (VCAM-1), E-selectin (ESEL) and P-selectin (PSEL) may contribute to CVD through their inflammatory effects on the vascular endothelium and be independent risk factors for atherosclerosis and cardiovascular disease (CVD). However, at the current time, testing for these inflammatory markers has not been confirmed in larger populations, causality has not been established and testing has not resulted in improved patient outcomes.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

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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.

N/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.

N/A
CPT/HCPCS Codes
Group 1 Paragraph: The following CPT codes are covered:

Group 1 Codes:
82172 APOLIPOPROTEIN, EACH
82610 CYSTATIN C
83090 HOMOCYSTEINE
83695 LIPOPROTEIN (A)
83698 LIPOPROTEIN-ASSOCIATED PHOSPHOLIPASE A2 (LP-PLA2)
83700 LIPOPROTEIN, BLOOD; ELECTROPHORETIC SEPARATION AND QUANTITATION
LIPOPROTEIN, BLOOD; HIGH RESOLUTION FRACTIONATION AND QUANTITATION OF LIPOPROTEINS
83701 INCLUDING LIPOPROTEIN SUBCLASSES WHEN PERFORMED (EG, ELECTROPHORESIS, ULTRACENTRIFUGATION)
LIPOPROTEIN, BLOOD; QUANTITATION OF LIPOPROTEIN PARTICLE NUMBER(S) (EG, BY NUCLEAR
83704 MAGNETIC RESONANCE SPECTROSCOPY), INCLUDES LIPOPROTEIN PARTICLE SUBCLASS(ES), WHEN PERFORMED
83719 LIPOPROTEIN, DIRECT MEASUREMENT; VLDL CHOLESTEROL
83721 LIPOPROTEIN, DIRECT MEASUREMENT; LDL CHOLESTEROL
83880 NATRIURETIC PEPTIDE
86141 C-REACTIVE PROTEIN; HIGH SENSITIVITY (HSCRP)

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph: The following ICD-10 codes are covered when used for cardiac risk assessment. Please note, **83880** and **86141** are used for other medically necessary services that are not addressed in this LCD.

Group 1 Codes:

ICD-10 Codes	Description
E71.30	Disorder of fatty-acid metabolism, unspecified
E75.21	Fabry (-Anderson) disease
E75.22	Gaucher disease
E75.240	Niemann-Pick disease type A
E75.241	Niemann-Pick disease type B
E75.242	Niemann-Pick disease type C
E75.243	Niemann-Pick disease type D
E75.248	Other Niemann-Pick disease
E75.249	Niemann-Pick disease, unspecified
E75.3	Sphingolipidosis, unspecified
E75.5	Other lipid storage disorders
E75.6	Lipid storage disorder, unspecified
E77.0	Defects in post-translational modification of lysosomal enzymes
E77.8	Other disorders of glycoprotein metabolism
E77.9	Disorder of glycoprotein metabolism, unspecified
E78.00	Pure hypercholesterolemia, unspecified
E78.01	Familial hypercholesterolemia
E78.1	Pure hyperglyceridemia
E78.2	Mixed hyperlipidemia
E78.3	Hyperchylomicronemia
E78.4	Other hyperlipidemia
E78.5	Hyperlipidemia, unspecified
E78.70	Disorder of bile acid and cholesterol metabolism, unspecified
E78.79	Other disorders of bile acid and cholesterol metabolism
E78.81	Lipoid dermatoarthritis
E78.89	Other lipoprotein metabolism disorders
E78.9	Disorder of lipoprotein metabolism, unspecified
E88.1	Lipodystrophy, not elsewhere classified
E88.2	Lipomatosis, not elsewhere classified
E88.89	Other specified metabolic disorders
I10	Essential (primary) hypertension
I25.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I42.0	Dilated cardiomyopathy
I48.2	Chronic atrial fibrillation
I48.91	Unspecified atrial fibrillation
I51.9	Heart disease, unspecified
I52	Other heart disorders in diseases classified elsewhere
I70.0	Atherosclerosis of aorta
I70.1	Atherosclerosis of renal artery
I70.201	Unspecified atherosclerosis of native arteries of extremities, right leg
I70.202	Unspecified atherosclerosis of native arteries of extremities, left leg
I70.203	Unspecified atherosclerosis of native arteries of extremities, bilateral legs
I70.208	Unspecified atherosclerosis of native arteries of extremities, other extremity
I70.209	Unspecified atherosclerosis of native arteries of extremities, unspecified extremity
I70.211	Atherosclerosis of native arteries of extremities with intermittent claudication, right leg
I70.212	Atherosclerosis of native arteries of extremities with intermittent claudication, left leg
I70.213	Atherosclerosis of native arteries of extremities with intermittent claudication, bilateral legs
I70.218	Atherosclerosis of native arteries of extremities with intermittent claudication, other extremity
I70.219	Atherosclerosis of native arteries of extremities with intermittent claudication, unspecified extremity
I70.221	Atherosclerosis of native arteries of extremities with rest pain, right leg
I70.222	Atherosclerosis of native arteries of extremities with rest pain, left leg
I70.223	Atherosclerosis of native arteries of extremities with rest pain, bilateral legs
I70.228	Atherosclerosis of native arteries of extremities with rest pain, other extremity

ICD-10 Codes	Description
I70.229	Atherosclerosis of native arteries of extremities with rest pain, unspecified extremity
I70.231	Atherosclerosis of native arteries of right leg with ulceration of thigh
I70.232	Atherosclerosis of native arteries of right leg with ulceration of calf
I70.233	Atherosclerosis of native arteries of right leg with ulceration of ankle
I70.234	Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot
I70.235	Atherosclerosis of native arteries of right leg with ulceration of other part of foot
I70.238	Atherosclerosis of native arteries of right leg with ulceration of other part of lower right leg
I70.239	Atherosclerosis of native arteries of right leg with ulceration of unspecified site
I70.241	Atherosclerosis of native arteries of left leg with ulceration of thigh
I70.242	Atherosclerosis of native arteries of left leg with ulceration of calf
I70.243	Atherosclerosis of native arteries of left leg with ulceration of ankle
I70.244	Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot
I70.245	Atherosclerosis of native arteries of left leg with ulceration of other part of foot
I70.248	Atherosclerosis of native arteries of left leg with ulceration of other part of lower left leg
I70.249	Atherosclerosis of native arteries of left leg with ulceration of unspecified site
I70.25	Atherosclerosis of native arteries of other extremities with ulceration
I70.261	Atherosclerosis of native arteries of extremities with gangrene, right leg
I70.262	Atherosclerosis of native arteries of extremities with gangrene, left leg
I70.263	Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
I70.268	Atherosclerosis of native arteries of extremities with gangrene, other extremity
I70.269	Atherosclerosis of native arteries of extremities with gangrene, unspecified extremity
I70.291	Other atherosclerosis of native arteries of extremities, right leg
I70.292	Other atherosclerosis of native arteries of extremities, left leg
I70.293	Other atherosclerosis of native arteries of extremities, bilateral legs
I70.298	Other atherosclerosis of native arteries of extremities, other extremity
I70.299	Other atherosclerosis of native arteries of extremities, unspecified extremity
I70.301	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, right leg
I70.302	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, left leg
I70.303	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, bilateral legs
I70.308	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, other extremity
I70.309	Unspecified atherosclerosis of unspecified type of bypass graft(s) of the extremities, unspecified extremity
I70.311	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, right leg
I70.312	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, left leg
I70.313	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, bilateral legs
I70.318	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, other extremity
I70.319	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with intermittent claudication, unspecified extremity
I70.321	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, right leg
I70.322	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, left leg
I70.323	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, bilateral legs
I70.328	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, other extremity
I70.329	Atherosclerosis of unspecified type of bypass graft(s) of the extremities with rest pain, unspecified extremity
I70.331	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of thigh
I70.332	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of calf
I70.333	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of ankle
I70.334	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.335	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.8	Atherosclerosis of other arteries
I70.90	Unspecified atherosclerosis

ICD-10 Codes	Description
I70.91	Generalized atherosclerosis
I70.92	Chronic total occlusion of artery of the extremities
R00.2	Palpitations
R07.1	Chest pain on breathing
R07.2	Precordial pain
R07.82	Intercostal pain
R07.89	Other chest pain
R07.9	Chest pain, unspecified
Z13.220	Encounter for screening for lipoid disorders
Z13.6	Encounter for screening for cardiovascular disorders
Z86.711	Personal history of pulmonary embolism
Z86.718	Personal history of other venous thrombosis and embolism
Z86.72	Personal history of thrombophlebitis
Z86.73	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits
Z86.74	Personal history of sudden cardiac arrest
Z86.79	Personal history of other diseases of the circulatory system

ICD-10 Codes that DO NOT Support Medical Necessity N/A
ICD-10 Additional Information Back to Top

General Information

Associated Information
The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Coverage Indications, Limitations, 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.

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

Sources of Information
American Heart Association. AHA Recommendation: Homocysteine, Folic Acid and Cardiovascular Risk.

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Bibliography

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
04/01/2018	R5	04/01/2018-Annual review completed 03/08/2018. At this time, 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (Annual Review)
05/01/2017	R4	05/01/2017-Annual Review completed 04/03/2017. Added Note #1: There is no Medicare benefit for screening CV risk assessment testing for asymptomatic (without signs or symptoms of disease) patients. Screening asymptomatic patients for cardiovascular risk is statutorily excluded by Medicare and will not be addressed in this policy. Renumbered previous note 1 to note 2. Updated source of Information section with American Heart Association. AHA Recommendation: Homocysteine, Folic Acid and Cardiovascular Risk &National Academy of Clinical Biochemistry: Laboratory Medicine Practice Guidelines, Emerging biomarkers for primary prevention of cardiovascular disease and stroke. April, 2009. Removed: Due to the level of evidence, there will be no coverage for intermediate risk because there is no data to suggest that more aggressive risk factor modification improves patient health outcomes & Consequently, lipoprotein testing is considered investigational and not covered. Contractor Determination Number: CV-050 is being changed to MolDX-003.	• Other (Annual Review)
01/01/2017	R3	01/01/2017-Code update-83704 code description change.	• Revisions Due To CPT/HCPCS Code Changes • Other (2017 CPT/HCPCs code update)
10/01/2016	R2	10/01/2016- Clarification; The following changes were made in the summary paragraph for High sensitivity C-reactive protein (hs-CRP): Removed first bullet point "1. Men must be > 50 years of age; women must be > 60 years of age; In the first bullet changed the age for Men from >45 to >50 and Women from >55 to >60, changed bullets to numbers for 1-3.Code update- removed deleted code E78.0 and added E78.00 & E78.01.	• Other • Revisions Due To ICD-10-CM Code Changes
06/16/2016	R1	04/27/2016 - Corrected HTML coding for italicized "y" in term PPAR-*y* to allow characters to display correctly. Policy was incorrectly displaying a "?" symbol in error. No other changes to policy.	• Typographical Error

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Associated Documents

Attachments N/A

Related Local Coverage Documents Article(s) A55003 - Response to Comments: MolDX: Biomarkers in Cardiovascular Risk Assessment (L36523) LCD(s) DL36523 - (MCD Archive Site)

Related National Coverage Documents N/A

Public Version(s) Updated on 03/20/2018 with effective dates 04/01/2018 - N/A Updated on 04/17/2017 with effective dates 05/01/2017 - 03/31/2018 Updated on 12/19/2016 with effective dates 01/01/2017 - 04/30/2017 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top

Local Coverage Determination (LCD): Vitamin D Assay Testing (L34658)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

Document Information

LCD ID
L34658

Original ICD-9 LCD ID
L31076

LCD Title
Vitamin D Assay Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

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N/A

Notice Period End Date
N/A

CMS National Coverage Policy
Title XVIII of Social Security Act, Section 1861 Act provides for payment of clinical laboratory services under Medicare Part B. Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition.

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

42 CFR part 493, laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth. Section 1862(a)(1)(A) provides that Medicare payment may not be made for services that are not reasonable and necessary.

42 CFR 410.32(a), clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary.

42 CFR 410.32(a) (3), or by a qualified nonphysician practitioner.

CMS Pub 100-02, *Medicare Benefit Policy Manual*, Chapter 15 - Covered Medical and Other Health Care Services, §80.1 – Clinical Laboratory Services and 80.6 – Requirements for Ordering and Following Orders for Diagnostic Tests.

CMS Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 1- General Billing Requirements, Sections 60 – Provider Billing of Non-covered Charges on Institutional Claims – 60.1.1 - Basic Payment Liability Conditions.

CMS Pub 100-04, *Medicare Claims Processing Manual*, Chapter 25 – Completing and Processing the Form CMS-1450 Data Set, Section 75.5 – From Locators 43-81, FL-67 Principal Diagnosis Codes.

Italicized font - represents CMS national language/wording copied directly from CMS Manuals or CMS Transmittals. Contractors are prohibited from changing national language/wording.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Vitamin D is a hormone, synthesized by the skin, the liver, and then metabolized by the kidney to an active hormone, calcitriol. An excess of vitamin D may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders. This LCD identifies the indications and limitations of Medicare coverage and reimbursement for these services.

Vitamin D is called a "vitamin" because of its availability from an exogenous source, predominately from oily fish in the form of cholecalciferol, vitamin D3. Plant-based vitamin D is in the form of ergocalciferol, Vitamin D2. It is really a hormone, as it is synthesized by the skin, metabolized by the liver and converted by the kidney to an active hormone, calcitriol. Calcitriol in its classical action, absorbs calcium from the intestine, and promotes bone mineralization.

In the skin, 7-dehydrocholesterol is converted to vitamin D3 in response to sunlight, a process that is inhibited by sunscreen with a skin protection factor (SPF) of 8 or greater. Once in the blood, vitamin D2 or D3 from diet, or

D3 from skin production are carried by an alpha-2-globulin, vitamin D binding protein, and are carried to the liver where they are hydroxylated to yield 25-hydroxyvitamin D (25OHD; calcidiol). 25OHD then is converted in the kidney to 1, 25(OH)2D (calcitriol) by the action of 25OHD-1-alpha hydroxylase (CYP27B1). The CYP27B1 in the kidney is regulated by nearly every hormone involved in calcium homeostasis, and its activity is stimulated by PTH, estrogen, calcitonin, prolactin, growth hormone, low calcium levels, and low phosphorus levels. Its activity is inhibited by calcitriol, thus providing the feedback loop that helps regulates its synthesis.

An excess of vitamin D is unusual, but may lead to hypercalcemia. Vitamin D deficiency may lead to a variety of disorders; the well-described is rickets in growing children or osteomalacia in adults. Evaluating the status of a patient's vitamin D sufficiency is accomplished by measuring the level of 25-hydroxyvitamin D. Measurement of other metabolites is generally not necessary outside of several unusual metabolic bone disorders or in chronic kidney disease-mineral bone disorder (CKD-MBD).

Indications:
Measurement of vitamin D levels is indicated for patients with:

- chronic kidney disease stage III or greater;
- osteoporosis;
- osteomalacia;
- osteopenia;
- osteogenesis imperfecta;
- osteosclerosis;
- hypocalcemia;
- hypercalcemia;
- hypoparathyroidism;
- hyperparathyroidism;
- rickets;
- vitamin D deficiency to monitor the efficacy of replacement therapy;
- fibromyalgia;
- granuloma forming diseases;
- hypovitaminosis D;
- hypervitaminosis D;
- long term use of anticonvulsants or glucocorticoids and other medications known to lower - vitamin D levels;
- malabsorption states;
- obstructive jaundice;
- cirrhosis;
- psoriasis;
- Paget's disease of bone;
- gastric bypass;
- obesity.

Limitations:
For Medicare beneficiaries, screening tests are governed by statute (Social Security Act 1861 {nn}). Vitamin D testing may not be used for routine screening.

Assays of calcitriol need not be performed for each of the above conditions. The most common type of vitamin D deficiency is that of 25 OH Vitamin D.

The 1,25-dihydroxy form of vitamin D is generally only required to assist in the diagnosis of certain cases of rare endocrine disorders (primary hyperparathyroidism, hypothyroidism, pseudohypoparathyroidism), or for diagnosing and treating renal osteodystrophy and vitamin D-dependent and vitamin D resistant rickets, or in cases of unknown causes of hypercalcemia, including sarcoidosis. Level of both 25OHD and calcitriol are not needed as a panel for determining a patient's vitamin D status or to monitor routine vitamin D replacement therapy for most diseases. It is expected that the medical record will justify the tests chosen for a particular disease entity, that all available components of 25 OH vitamin D and other metabolite levels will not be performed routinely on every patient and that supportive documentation for test choices will be available to the Contractor upon request.

This Contractor does not expect to receive billing for the various component sources of 25 OH vitamin D separately (such as stored D or diet derived D). Only one total 25 OH vitamin D assay (comprising the sum of both 25OHD2 and 25OHD3) will be considered for reimbursement on any particular day, if medically necessary, for the patient's condition.

Once a beneficiary has been shown to be vitamin D deficient, further testing may be medically necessary only to ensure adequate replacement has been accomplished for this vitamin deficiency, although, generally, other parameters are measured. Annual testing of the vitamin D status may be appropriate depending upon the indication and other mitigating factors. Because there can be variability in individual 25OHD responses to supplemental vitamin D in high-risk individuals, the serum 25OHD levels could be retested after about 3 months of supplementation to confirm that the target 25OHD level has been reached. If the follow up test shows they have not yet reached the target level, the test can it be repeated in another 3 months until the target level is achieved.

Testing Methods
Several methods are available for measuring circulating concentrations of 25-OH-D. Medicare will cover laboratory tests that give practitioners accurate and reliable information. The method used to perform this testing should be validated.

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

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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.

999x Not Applicable

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.

N/A
CPT/HCPCS Codes
Group 1 Paragraph:

N/A

Group 1 Codes:
82306 VITAMIN D; 25 HYDROXY, INCLUDES FRACTION(S), IF PERFORMED
82652 VITAMIN D; 1, 25 DIHYDROXY, INCLUDES FRACTION(S), IF PERFORMED

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph:

Note: ICD-10 codes must be coded to the highest level of specificity. For Codes in the table below that require a 7th character, letter A initial encounter, D subsequent encounter or S sequel may be used.

CPT code: 82306

Group 1 Codes:

ICD-10 Codes	Description
A15.0	Tuberculosis of lung
A15.4	Tuberculosis of intrathoracic lymph nodes
A15.5	Tuberculosis of larynx, trachea and bronchus
A15.6	Tuberculous pleurisy
A15.7	Primary respiratory tuberculosis
A15.8	Other respiratory tuberculosis
A17.0	Tuberculous meningitis
A17.1	Meningeal tuberculoma
A17.81	Tuberculoma of brain and spinal cord
A17.82	Tuberculous meningoencephalitis
A17.83	Tuberculous neuritis
A17.89	Other tuberculosis of nervous system
A17.9	Tuberculosis of nervous system, unspecified
A18.01	Tuberculosis of spine
A18.02	Tuberculous arthritis of other joints
A18.03	Tuberculosis of other bones
A18.09	Other musculoskeletal tuberculosis
A18.10	Tuberculosis of genitourinary system, unspecified
A18.11	Tuberculosis of kidney and ureter
A18.12	Tuberculosis of bladder
A18.13	Tuberculosis of other urinary organs
A18.14	Tuberculosis of prostate
A18.15	Tuberculosis of other male genital organs
A18.16	Tuberculosis of cervix
A18.17	Tuberculous female pelvic inflammatory disease
A18.18	Tuberculosis of other female genital organs
A18.2	Tuberculous peripheral lymphadenopathy
A18.31	Tuberculous peritonitis
A18.32	Tuberculous enteritis
A18.39	Retroperitoneal tuberculosis
A18.4	Tuberculosis of skin and subcutaneous tissue
A18.50	Tuberculosis of eye, unspecified
A18.51	Tuberculous episcleritis
A18.52	Tuberculous keratitis
A18.53	Tuberculous chorioretinitis
A18.54	Tuberculous iridocyclitis
A18.59	Other tuberculosis of eye
A18.6	Tuberculosis of (inner) (middle) ear
A18.7	Tuberculosis of adrenal glands
A18.81	Tuberculosis of thyroid gland
A18.82	Tuberculosis of other endocrine glands
A18.83	Tuberculosis of digestive tract organs, not elsewhere classified
A18.84	Tuberculosis of heart
A18.85	Tuberculosis of spleen

ICD-10 Codes	Description
A18.89	Tuberculosis of other sites
A19.0	Acute miliary tuberculosis of a single specified site
A19.1	Acute miliary tuberculosis of multiple sites
A19.8	Other miliary tuberculosis
B38.0 - B38.89	Acute pulmonary coccidioidomycosis - Other forms of coccidioidomycosis
B39.0 - B39.5	Acute pulmonary histoplasmosis capsulati - Histoplasmosis duboisii
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C26.0	Malignant neoplasm of intestinal tract, part unspecified
C26.1	Malignant neoplasm of spleen
C26.9	Malignant neoplasm of ill-defined sites within the digestive system
C82.00 - C82.99	Follicular lymphoma grade I, unspecified site - Follicular lymphoma, unspecified, extranodal and solid organ sites
D13.0	Benign neoplasm of esophagus
D13.1	Benign neoplasm of stomach
D13.2	Benign neoplasm of duodenum
D13.30	Benign neoplasm of unspecified part of small intestine
D13.39	Benign neoplasm of other parts of small intestine
D13.4	Benign neoplasm of liver
D13.5	Benign neoplasm of extrahepatic bile ducts
D13.6	Benign neoplasm of pancreas
D13.7	Benign neoplasm of endocrine pancreas
D13.9	Benign neoplasm of ill-defined sites within the digestive system
D86.0	Sarcoidosis of lung
D86.1	Sarcoidosis of lymph nodes
D86.2	Sarcoidosis of lung with sarcoidosis of lymph nodes
D86.3	Sarcoidosis of skin
D86.81	Sarcoid meningitis
D86.82	Multiple cranial nerve palsies in sarcoidosis
D86.83	Sarcoid iridocyclitis
D86.84	Sarcoid pyelonephritis
D86.85	Sarcoid myocarditis
D86.86	Sarcoid arthropathy
D86.87	Sarcoid myositis
D86.89	Sarcoidosis of other sites
E20.0	Idiopathic hypoparathyroidism
E20.8	Other hypoparathyroidism
E21.0	Primary hyperparathyroidism
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E21.2	Other hyperparathyroidism

ICD-10 Codes	Description
E21.4	Other specified disorders of parathyroid gland
E21.5	Disorder of parathyroid gland, unspecified
E55.0	Rickets, active
E55.9	Vitamin D deficiency, unspecified
E64.3	Sequelae of rickets
E67.2	Megavitamin-B6 syndrome
E67.3	Hypervitaminosis D
E67.8	Other specified hyperalimentation
E68	Sequelae of hyperalimentation
E83.30	Disorder of phosphorus metabolism, unspecified
E83.31	Familial hypophosphatemia
E83.32	Hereditary vitamin D-dependent rickets (type 1) (type 2)
E83.39	Other disorders of phosphorus metabolism
E83.51	Hypocalcemia
E83.52	Hypercalcemia
E84.0	Cystic fibrosis with pulmonary manifestations
E84.11	Meconium ileus in cystic fibrosis
E84.19	Cystic fibrosis with other intestinal manifestations
E84.8	Cystic fibrosis with other manifestations
E84.9	Cystic fibrosis, unspecified
E89.2	Postprocedural hypoparathyroidism
G73.7	Myopathy in diseases classified elsewhere
J63.2	Berylliosis
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications

ICD-10 Codes	Description
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.419	Inflammatory polyps of colon with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K70.2	Alcoholic fibrosis and sclerosis of liver
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites
K74.0	Hepatic fibrosis
K74.3	Primary biliary cirrhosis
K74.4	Secondary biliary cirrhosis
K74.5	Biliary cirrhosis, unspecified
K74.60	Unspecified cirrhosis of liver
K74.69	Other cirrhosis of liver
K75.81	Nonalcoholic steatohepatitis (NASH)
K76.0	Fatty (change of) liver, not elsewhere classified
K76.89	Other specified diseases of liver
K80.01	Calculus of gallbladder with acute cholecystitis with obstruction
K80.11	Calculus of gallbladder with chronic cholecystitis with obstruction
K80.13	Calculus of gallbladder with acute and chronic cholecystitis with obstruction
K80.19	Calculus of gallbladder with other cholecystitis with obstruction

ICD-10 Codes	Description
K80.21	Calculus of gallbladder without cholecystitis with obstruction
K80.31	Calculus of bile duct with cholangitis, unspecified, with obstruction
K80.33	Calculus of bile duct with acute cholangitis with obstruction
K80.35	Calculus of bile duct with chronic cholangitis with obstruction
K80.37	Calculus of bile duct with acute and chronic cholangitis with obstruction
K80.41	Calculus of bile duct with cholecystitis, unspecified, with obstruction
K80.43	Calculus of bile duct with acute cholecystitis with obstruction
K80.45	Calculus of bile duct with chronic cholecystitis with obstruction
K80.47	Calculus of bile duct with acute and chronic cholecystitis with obstruction
K80.51	Calculus of bile duct without cholangitis or cholecystitis with obstruction
K80.61	Calculus of gallbladder and bile duct with cholecystitis, unspecified, with obstruction
K80.63	Calculus of gallbladder and bile duct with acute cholecystitis with obstruction
K80.65	Calculus of gallbladder and bile duct with chronic cholecystitis with obstruction
K80.67	Calculus of gallbladder and bile duct with acute and chronic cholecystitis with obstruction
K80.71	Calculus of gallbladder and bile duct without cholecystitis with obstruction
K80.81	Other cholelithiasis with obstruction
K82.0	Obstruction of gallbladder
K82.8	Other specified diseases of gallbladder
K82.9	Disease of gallbladder, unspecified
K83.0	Cholangitis
K83.1	Obstruction of bile duct
K83.2	Perforation of bile duct
K83.3	Fistula of bile duct
K83.4	Spasm of sphincter of Oddi
K83.5	Biliary cyst
K83.8	Other specified diseases of biliary tract
K83.9	Disease of biliary tract, unspecified
K85.10	Biliary acute pancreatitis without necrosis or infection
K85.11	Biliary acute pancreatitis with uninfected necrosis
K85.12	Biliary acute pancreatitis with infected necrosis
K86.2	Cyst of pancreas
K86.3	Pseudocyst of pancreas
K86.81	Exocrine pancreatic insufficiency
K86.89	Other specified diseases of pancreas
K86.9	Disease of pancreas, unspecified
K87	Disorders of gallbladder, biliary tract and pancreas in diseases classified elsewhere
K90.0	Celiac disease
K90.1	Tropical sprue
K90.2	Blind loop syndrome, not elsewhere classified
K90.3	Pancreatic steatorrhea
K90.41	Non-celiac gluten sensitivity
K90.49	Malabsorption due to intolerance, not elsewhere classified
K90.89	Other intestinal malabsorption
K90.9	Intestinal malabsorption, unspecified
K91.2	Postsurgical malabsorption, not elsewhere classified
L40.0	Psoriasis vulgaris
L40.1	Generalized pustular psoriasis
L40.2	Acrodermatitis continua
L40.3	Pustulosis palmaris et plantaris
L40.4	Guttate psoriasis
L40.8	Other psoriasis
L40.9	Psoriasis, unspecified
L90.0	Lichen sclerosus et atrophicus
L94.0	Localized scleroderma [morphea]
L94.1	Linear scleroderma
L94.3	Sclerodactyly
M32.0	Drug-induced systemic lupus erythematosus
M32.10	Systemic lupus erythematosus, organ or system involvement unspecified

ICD-10 Codes	Description
M32.11	Endocarditis in systemic lupus erythematosus
M32.12	Pericarditis in systemic lupus erythematosus
M32.13	Lung involvement in systemic lupus erythematosus
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M32.19	Other organ or system involvement in systemic lupus erythematosus
M32.8	Other forms of systemic lupus erythematosus
M33.01	Juvenile dermatomyositis with respiratory involvement
M33.02	Juvenile dermatomyositis with myopathy
M33.03	Juvenile dermatomyositis without myopathy
M33.09	Juvenile dermatomyositis with other organ involvement
M33.11	Other dermatomyositis with respiratory involvement
M33.12	Other dermatomyositis with myopathy
M33.13	Other dermatomyositis without myopathy
M33.19	Other dermatomyositis with other organ involvement
M33.91	Dermatopolymyositis, unspecified with respiratory involvement
M33.92	Dermatopolymyositis, unspecified with myopathy
M33.93	Dermatopolymyositis, unspecified without myopathy
M33.99	Dermatopolymyositis, unspecified with other organ involvement
M36.0	Dermato(poly)myositis in neoplastic disease
M60.811	Other myositis, right shoulder
M60.812	Other myositis, left shoulder
M60.821	Other myositis, right upper arm
M60.822	Other myositis, left upper arm
M60.831	Other myositis, right forearm
M60.832	Other myositis, left forearm
M60.841	Other myositis, right hand
M60.842	Other myositis, left hand
M60.851	Other myositis, right thigh
M60.852	Other myositis, left thigh
M60.861	Other myositis, right lower leg
M60.862	Other myositis, left lower leg
M60.871	Other myositis, right ankle and foot
M60.872	Other myositis, left ankle and foot
M60.88	Other myositis, other site
M60.89	Other myositis, multiple sites
M79.1	Myalgia
M79.7	Fibromyalgia
M80.00XA - M80.88XS	Age-related osteoporosis with current pathological fracture, unspecified site, initial encounter for fracture - Other osteoporosis with current pathological fracture, vertebra(e), sequela
M81.0	Age-related osteoporosis without current pathological fracture
M81.6	Localized osteoporosis [Lequesne]
M81.8	Other osteoporosis without current pathological fracture
M83.0	Puerperal osteomalacia
M83.1	Senile osteomalacia
M83.2	Adult osteomalacia due to malabsorption
M83.3	Adult osteomalacia due to malnutrition
M83.4	Aluminum bone disease
M83.5	Other drug-induced osteomalacia in adults
M83.8	Other adult osteomalacia
M83.9	Adult osteomalacia, unspecified
M85.80	Other specified disorders of bone density and structure, unspecified site
M85.811	Other specified disorders of bone density and structure, right shoulder
M85.812	Other specified disorders of bone density and structure, left shoulder
M85.821	Other specified disorders of bone density and structure, right upper arm
M85.822	Other specified disorders of bone density and structure, left upper arm
M85.831	Other specified disorders of bone density and structure, right forearm
M85.832	Other specified disorders of bone density and structure, left forearm
M85.841	Other specified disorders of bone density and structure, right hand

ICD-10 Codes	Description
M85.842	Other specified disorders of bone density and structure, left hand
M85.851	Other specified disorders of bone density and structure, right thigh
M85.852	Other specified disorders of bone density and structure, left thigh
M85.861	Other specified disorders of bone density and structure, right lower leg
M85.862	Other specified disorders of bone density and structure, left lower leg
M85.871	Other specified disorders of bone density and structure, right ankle and foot
M85.872	Other specified disorders of bone density and structure, left ankle and foot
M85.88	Other specified disorders of bone density and structure, other site
M85.89	Other specified disorders of bone density and structure, multiple sites
M85.9	Disorder of bone density and structure, unspecified
M88.0	Osteitis deformans of skull
M88.1	Osteitis deformans of vertebrae
M88.811	Osteitis deformans of right shoulder
M88.812	Osteitis deformans of left shoulder
M88.821	Osteitis deformans of right upper arm
M88.822	Osteitis deformans of left upper arm
M88.831	Osteitis deformans of right forearm
M88.832	Osteitis deformans of left forearm
M88.841	Osteitis deformans of right hand
M88.842	Osteitis deformans of left hand
M88.851	Osteitis deformans of right thigh
M88.852	Osteitis deformans of left thigh
M88.861	Osteitis deformans of right lower leg
M88.862	Osteitis deformans of left lower leg
M88.871	Osteitis deformans of right ankle and foot
M88.872	Osteitis deformans of left ankle and foot
M88.88	Osteitis deformans of other bones
M88.89	Osteitis deformans of multiple sites
M88.9	Osteitis deformans of unspecified bone
M89.9	Disorder of bone, unspecified
M94.9	Disorder of cartilage, unspecified
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N25.81	Secondary hyperparathyroidism of renal origin
O99.841	Bariatric surgery status complicating pregnancy, first trimester
O99.842	Bariatric surgery status complicating pregnancy, second trimester
O99.843	Bariatric surgery status complicating pregnancy, third trimester
O99.844	Bariatric surgery status complicating childbirth
O99.845	Bariatric surgery status complicating the puerperium
Q78.0	Osteogenesis imperfecta
Q78.2	Osteopetrosis
T30.0	Burn of unspecified body region, unspecified degree
T30.4	Corrosion of unspecified body region, unspecified degree
Z68.30 - Z68.45	Body mass index (BMI) 30.0-30.9, adult - Body mass index (BMI) 70 or greater, adult
Z79.3	Long term (current) use of hormonal contraceptives
Z79.51	Long term (current) use of inhaled steroids
Z79.52	Long term (current) use of systemic steroids
Z79.891	Long term (current) use of opiate analgesic
Z79.899	Other long term (current) drug therapy
Z98.0	Intestinal bypass and anastomosis status
Z98.84	Bariatric surgery status

Group 2 Paragraph:

CPT code: 82652

Group 2 Codes:

ICD-10 Codes	Description
A15.0	Tuberculosis of lung
A15.4	Tuberculosis of intrathoracic lymph nodes
A15.5	Tuberculosis of larynx, trachea and bronchus
A15.6	Tuberculous pleurisy
A15.7	Primary respiratory tuberculosis
A15.8	Other respiratory tuberculosis
A17.0	Tuberculous meningitis
A17.1	Meningeal tuberculoma
A17.81	Tuberculoma of brain and spinal cord
A17.82	Tuberculous meningoencephalitis
A17.83	Tuberculous neuritis
A17.89	Other tuberculosis of nervous system
A17.9	Tuberculosis of nervous system, unspecified
A18.01	Tuberculosis of spine
A18.02	Tuberculous arthritis of other joints
A18.03	Tuberculosis of other bones
A18.09	Other musculoskeletal tuberculosis
A18.10	Tuberculosis of genitourinary system, unspecified
A18.11	Tuberculosis of kidney and ureter
A18.12	Tuberculosis of bladder
A18.13	Tuberculosis of other urinary organs
A18.14	Tuberculosis of prostate
A18.15	Tuberculosis of other male genital organs
A18.16	Tuberculosis of cervix
A18.17	Tuberculous female pelvic inflammatory disease
A18.18	Tuberculosis of other female genital organs
A18.2	Tuberculous peripheral lymphadenopathy
A18.31	Tuberculous peritonitis
A18.32	Tuberculous enteritis
A18.39	Retroperitoneal tuberculosis
A18.4	Tuberculosis of skin and subcutaneous tissue
A18.50	Tuberculosis of eye, unspecified
A18.51	Tuberculous episcleritis
A18.52	Tuberculous keratitis
A18.53	Tuberculous chorioretinitis
A18.54	Tuberculous iridocyclitis
A18.59	Other tuberculosis of eye
A18.6	Tuberculosis of (inner) (middle) ear
A18.7	Tuberculosis of adrenal glands
A18.81	Tuberculosis of thyroid gland
A18.82	Tuberculosis of other endocrine glands
A18.83	Tuberculosis of digestive tract organs, not elsewhere classified
A18.84	Tuberculosis of heart
A18.85	Tuberculosis of spleen
A18.89	Tuberculosis of other sites
A19.0	Acute miliary tuberculosis of a single specified site
A19.1	Acute miliary tuberculosis of multiple sites
A19.2	Acute miliary tuberculosis, unspecified
A19.8	Other miliary tuberculosis
A19.9	Miliary tuberculosis, unspecified
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face, and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes

ICD-10 Codes	Description
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sezary disease, unspecified site
C84.12	Sezary disease, intrathoracic lymph nodes
C84.13	Sezary disease, intra-abdominal lymph nodes
C84.14	Sezary disease, lymph nodes of axilla and upper limb
C84.15	Sezary disease, lymph nodes of inguinal region and lower limb
C84.16	Sezary disease, intrapelvic lymph nodes
C84.17	Sezary disease, spleen
C84.18	Sezary disease, lymph nodes of multiple sites
C84.19	Sezary disease, extranodal and solid organ sites
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
D86.0	Sarcoidosis of lung
D86.1	Sarcoidosis of lymph nodes
D86.2	Sarcoidosis of lung with sarcoidosis of lymph nodes
D86.3	Sarcoidosis of skin
D86.81	Sarcoid meningitis
D86.82	Multiple cranial nerve palsies in sarcoidosis
D86.83	Sarcoid iridocyclitis
D86.84	Sarcoid pyelonephritis
D86.85	Sarcoid myocarditis
D86.86	Sarcoid arthropathy
D86.87	Sarcoid myositis
D86.89	Sarcoidosis of other sites
E20.0	Idiopathic hypoparathyroidism
E20.8	Other hypoparathyroidism
E21.0	Primary hyperparathyroidism
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E21.2	Other hyperparathyroidism
E21.4	Other specified disorders of parathyroid gland
E21.5	Disorder of parathyroid gland, unspecified
E55.0	Rickets, active
E55.9	Vitamin D deficiency, unspecified
E64.3	Sequelae of rickets
E67.2	Megavitamin-B6 syndrome
E67.8	Other specified hyperalimentation
E68	Sequelae of hyperalimentation
E89.2	Postprocedural hypoparathyroidism
M83.0	Puerperal osteomalacia
M83.1	Senile osteomalacia
M83.2	Adult osteomalacia due to malabsorption
M83.3	Adult osteomalacia due to malnutrition

ICD-10 Codes	Description
M83.4	Aluminum bone disease
M83.5	Other drug-induced osteomalacia in adults
M83.8	Other adult osteomalacia
M83.9	Adult osteomalacia, unspecified
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N25.81	Secondary hyperparathyroidism of renal origin
Q78.0	Osteogenesis imperfecta
Q78.2	Osteopetrosis

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph:

N/A

Group 1 Codes: N/A

ICD-10 Additional Information Back to Top

General Information

Associated Information
Documentation Requirements
The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Coverage Indications, Limitations, 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.

Utilization Guidelines
In accordance with CMS Ruling 95-1 (V. Acceptable Standards of Practice - - Application), utilization of these services should be consistent with locally acceptable standards of practice.

1. Only one 25 OH vitamin D level will be reimbursed in any 24 hour period. Storage and supplement components will not be reimbursed separately.
2. Only one 1,25-OH vitamin D level will be reimbursed in a 24 hour period if medically necessary.
3. Assays of vitamin D levels for conditions other than ICD-10 codes E55.0, E55.9, E64.3, M83.0 - M83.5, and M83.8 - M83.9 will be limited to once a year.
4. Assays of the appropriate vitamin D levels for ICD-10 codes E55.0, E55.9, E64.3, M83.0 - M83.5, and M83.8 – M83.9 will be limited to 4 per year, for the previously identified deficient form of vitamin D.

   (Because there can be variability in individual 25OHD responses to supplemental vitamin D in high-risk individuals, the serum 25OHD levels could be retested after about 3 months of supplementation to confirm that the target 25OHD level has been reached. If the follow up test shows they have not yet reached the target level, the test can be repeated in another 3 months until the target level is achieved.)

Sources of Information
American Academy of Dermatology and AAD Association Position Statement on Vitamin D. (June 2009).

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Bibliography

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2017	R9	10/01/2017 Annual review done 09/02/2017. Per ICD-10 code updates: To Group 1 description changes to codes M33.01, M33.02, M33.09, M33.11, M33.12, and M33.19; and added codes M3303, M33.13, and M33.93.	• Revisions Due To ICD-10-CM Code Changes • Other (Annual Review)
09/01/2017	R8	09/01/2017: Added the following codes to Group 1 for 82306: B38.0-B38.89, B39.0-B39.5, C82.00-C82.99, J63.2, M80.00XA-M80.88XS, Z68.30-Z68.45, and Z98.0. Added "obesity" to the list of indications for the measurement of vitamin D levels in the narrative section. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Revisions Due To ICD-10-CM Code Changes
10/01/2016	R7	10/01/2016 Annual review done. Per ICD-10 Code Updates: in Group 1 deleted codes K85.1, K86.8, and K90.4 and added codes K85.10, K85.11, K85.12, K86.81, K86.89, K90.41, and K90.49, effective 10/01/2016.	• Other (Annual Review) • Revisions Due To ICD-10-CM Code Changes • Other (ICD -10 Code Update
10/01/2015	R6		) • Revisions Due To ICD-10-CM Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		12/01/2015 Added codes C22.0, C22.1, C22.2, C22.3, C22.4, C22.7, C22.8, C22.9, C23, C24.0, C24.1, C24.8, C24.9, C25.0, C25.1, C25.2, C25.3, C25.4, C25.7, C25.8, C25.9, C26.0, C26.1, C26.9, D13.0, D13.1, D13.2, D13.30, D13.39, D13.4, D13.5, D13.6, D13.7, D13.9, K80.01, K80.11, K80.13, K80.19, K80.21, K80.31, K80.33, K80.35, K80.37, K80.41, K80.43, K80.45, K80.47. K80.51, K80.61, K80.63, K80.65, K80.67, K80.71, K80.81, K82.0, K82.8, K82.9, K83.0, K83.1, K83.2, K83.3, K83.4, K83.5, K83.8, K83.9, K85.1, K86.2, K86.3, K86.8, K86.9, K87, M85.80, M85.811, M85.812, M85.821, M85.822, M85.831, M85.832, M85.841, M85.842, M85.851, M85.852, M85.861, M85.862, M85.871, M85.872, M85.88, and M85.89 to Group 1 table with an effective date of 10/01/2015. Removed CAC information. Formatting changes made.	
10/01/2015	R5	10/06/2015 - Due to CMS guidance, we have removed the Jurisdiction 8 Notice and corresponding table from the CMS National Coverage Policy section. No other changes to policy or coverage.	• Other
10/01/2015	R4	10/01/2015 Annual review done. Formatting changes made. Updated Sources of Information. No change in coverage.	• Other (Annual review)
10/01/2015	R3	10/01/2014: Annual review done 09/09/2014. Formatting and punctuation changes made. Sources of Information updated. No change in coverage.	• Other
10/01/2015	R2	07/01/2014 For clarity, added the ICD-10 codes for vitamin D deficiency E55.0, E55.9, E64.3, M83.0 – M83.5, and M83.8 – M83.9 under the utilization guidelines. Theses codes already appear in the chart of Group 2 codes. No change in coverage.	• Other
10/01/2015	R1	04/01/2014 Removed reference to ICD-9 and changed to ICD-10. No change in coverage.	• Typographical Error

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Associated Documents

Attachments Billing and Coding Guidellines (PDF - 22 KB)

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

Public Version(s) Updated on 09/20/2017 with effective dates 10/01/2017 - N/A Updated on 08/22/2017 with effective dates 09/01/2017 - 09/30/2017 Updated on 09/19/2016 with effective dates 10/01/2016 - 08/31/2017 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top

Local Coverage Determination (LCD): Flow Cytometry (L34651)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

Document Information

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Flow Cytometry

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CMS National Coverage Policy
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Title XVIII of the Social Security Act section 1833 (e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title XVIII of the Social Security Act section 1862 (a) (1) (A). This section excludes coverage and payment of those items or services that are not considered to be *medically 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 section 1862 (a) (1) (D). This section states that no Medicare payment may be made under part A or part B for any expenses incurred for items or services that are investigational or experimental.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services.

42 CFR, Section 410.32 (b) *Diagnostic x-ray and other diagnostic tests. (1) Basic rule. .. all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861® of the Act. Services furnished without the required level of supervision are not reasonable and necessary. (see 42 CFR 411.15(k)(1)).*

CMS Pub 100-02 *Medicare Coverage Policy Manual*, Chapter 6 – Hospital Services Covered Under Part B, Section 20.4 – Outpatient Diagnostic Services.

CMS Pub 100-04 *Medicare Claims Processing Manual*, Chapter 25 - Completing and Processing the form CMS – 1450 Data Set, Section 75 – General Instructions for Completion of Form CMS – 1450 for Billing, 75.5 – Form Locators 43-65, 75.5- Form Locators 66-81.

CMS Pub 100-08 *Medicare Program Integrity Manual*, Chapter 3 – Verifying Potential Errors and Taking Corrective Actions, Sections
3.4.1.3 – Diagnostic Code Requirements and
3.6.2.3 – Limitation of Liability Determinations.
Chapter 13 – Local Coverage Determinations, Sections
13.7.1 – Evidence Supporting LCDs and
13.11- LCD Reconsideration Process.

CMS Pub 100-09 *Medicare Contractor Beneficiary and Provider Communication Manual*, Chapter 5 – Correct Coding Initiative.

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

Overview:
Flow Cytometry (FCM) is a highly complex cell analysis process performed by allowing cells in liquid suspension to pass through a laser-produced beam of light for the actual analysis of the cell. Specimens are usually treated with reagents that are chosen to amplify certain signals, such as antigens on a cell surface or within the cytoplasm or nucleus, or DNA content within a cell. The light activates fluorescent molecules, resulting in light scatter, which forms a pattern that can be analyzed for cell characteristics such as cell size, internal structure, antigens, DNA, ploidy (the number of single sets of chromosomes in a cell or organism), and cell cycle analysis of single cells in a

moving fluid stream. FCM can be used to analyze blood, body fluids, cerebrospinal fluid, bone marrow, lymph node, tonsil, spleen, and other solid organs. This information may help to determine prognosis, aid in the analysis of effusions, urine, or other fluids in which cancer cells may be few or mixed with benign cells, detect metastases in lymph nodes or bone marrow, and/or to supplement fine needle aspiration. Clinical analysis and interpretations are performed by an experienced physician, usually a pathologist or hematopathologist.

The flow cytometer is made up of three main systems: fluidics, optics and electronics. The fluidic system transports particles in a stream to the laser beam. The optics system consists of lasers to illuminate the particles in the sample stream and optical filters to direct the resulting light signals to the appropriate detectors. The electronics system converts the detected light signals into electronic signals that can be processed by the computer. Some flow cytometers have a sorting feature which allows the electronic system to initiate sorting decisions to charge and deflect particles.

Immunophenotyping
The cells of the immune system bear on their surfaces and within their cytoplasm or nucleus hundreds of molecules specific for their particular developmental stage and functional state. There have been more than 260 types of molecules identified on the surface of human leukocytes but only around 30 of these are associated with a known structure or function.

The process of measuring the types of antigens expressed on and within a cell by flow cytometry is referred to as immunophenotyping. To detect these antigens, antigen-specific monoclonal antibodies are used which have been labeled with a fluorescent dye or fluorochrome. After washing away any unbound antibody, the cells are analyzed by flow cytometry which categorizes them by size, granularity and fluorochrome intensity. An international standard nomenclature is used to categorize most antibodies according to the antigens they detect. Each category is called a cluster of differentiation (CD) and is numbered. A few clinically useful antibodies have not yet been "clustered" and are referred to by names derived from site of origin or nomenclature used in other classification systems (e.g. histocompatibility and immunoglobulin antigens).

DNA content (ploidy) and cell proliferative activity (S-phase fraction or % S-phase)
Malignant cells sometimes show abnormalities in total chromosome number and the frequency of these abnormalities generally increases with progression to higher-grade tumors. Flow cytometric methods can be used to measure nuclear deoxyribonucleic acid (DNA) content (ploidy) as a prognostic indicator of solid tumors. Fluorescent dyes are used to stain nucleic acids. DNA diploid tumors are those where a single peak containing an amount of DNA similar to normal cells is generated by flow cytometry. DNA aneuploid tumors have additional peaks on the DNA histogram which may represent cells containing more or less nucleic acid found in 46 normal chromosomes. Aneuploidy tumors have a chromosome number that is not an exact multiple of the normal diploid number, with either fewer or more than the normal number of chromosomes in the cell. In humans, an aneuploidy cell would be considered abnormal. A triploid cell (having three times the haploid number of chromosomes in the cell nucleus) and would be an example of aneuploidy in humans.

A more quantitative method of expression is the DNA index (DI), which is the ratio of the mean tumor sample G0/G1 DNA content divided by the mean G0/G1 DNA content of normal diploid reference cells. The greater the deviation of the DI from 1, the more "aneuploid" the tumor.

The assessment of % S-phase or the S phase fraction (SPF) measures the percentage or proportion of cells preparing for mitosis by their active doubling of DNA. Tumor cells tend to replicate more readily than normal cells therefore increased SPF activity can raise the question of malignancy. Frequently a high SPF will correlate positively with poor differentiation, increasing tumor size and degree of aggressiveness.

The specimen analysis is dependent on the diagnosis of the patient

Indications

1. **Leukemia or Lymphoma**

Leukemias and lymphomas may be analyzed from any solid tissue, blood, bone marrow or other fluids (e.g. cerebrospinal fluid, bronchoalveolar lavage, pleural and peritoneal fluids). Flow cytometry may be performed on peripheral blood and fine needle aspirate material, thus avoiding more invasive procedures for diagnosis. The presence or absence of antigens is determined using an appropriate antibody panel for differential diagnosis. This process may be necessary at the initial diagnostic phase, for evaluation of separate hematologic malignancies, or when tumor is present in several anatomic sites. It may also be necessary where there is abnormal tissue, bone marrow or blood histology, where results are suspicious for lymphoma or leukemia, and where the physician must distinguish reactive from neoplastic conditions; and morphologic exam is not sufficiently sensitive to resolve the diagnosis (e.g. minimal disease, either de novo or residual, after therapy).

Once a specimen is received the pathologist assesses the clinical history, reviews the morphology of the specimen (i.e. blood smear, bone marrow smear, and lymph node) and determines if the lesion is amenable to analysis by flow cytometry. This is a key step, as the initial clinical and or morphologic examination of the specimen may distinguish among potential "mature" lymphoproliferative disorders, acute leukemias and other conditions that may or may not be appropriate for cytometric evaluation.

Where flow cytometry has previously established a diagnosis, and where the neoplastic cells have a characteristic phenotype, it may be unnecessary to extensively re-phenotype the lesion; instead, a limited analysis may be used that allows the pathologist to definitively identify the abnormal cell population while referring back to the original phenotype. However, this approach may not be appropriate for complex fluid samples (e.g. marrow) or for acute leukemia, where changes in antigen profiles at relapse or post chemotherapy are not uncommon.

2. **Leukemia**

Flow cytometric analysis of blood and marrow mononuclear cells can generally differentiate between polyclonal and monoclonal (monotypic) B- cell lymphoproliferative disorders or lymphoid neoplasms. It can also define certain atypical gains and losses of T- cell related antigens that are associated with clonal T-cell lymphoproliferations.

At a minimum, flow cytometric analysis for mature B- cell or T-cell lymphoproliferations should evaluate leukemic cells for expression of multiple pan B-cell or T-cell lymphoid differentiation antigens, intrinsic (non-Fc bound) surface immunoglobulins, light chains (kappa and lambda), and additional leukocyte antigens, that help to distinguish between the various T- or B- cell leukemias. Additional antigens, such as CD38 and ZAP70, may provide prognostic information.

In the situation of plasma cell neoplasms (e.g. myeloma, MGUS), a smaller panel directed at both cell surface and cytoplasmic immunoglobulin light chains would be appropriate. The acute leukemic panel is designed to distinguish whether leukemic blasts are of myeloid or lymphoid origin and if the latter, whether they are T- or B- cell lineage. For the B- cell lineage certain differentiation antigens are prognostically useful.

The acute leukemia panel may also be necessary for the detection of minimal residual disease in post-therapy bone marrow samples from leukemic patients. Because of the need to define the presence of a given atypical profile, both the initial and post therapy panels require additional antigens to fully characterize the neoplastic cells.

3. **Acute Myeloid or Lymphoid Leukemia**

The diagnosis and management of acute leukemia depend on the detection, identification and characterization of leukemic cells. Each acute leukemia subgroup has heterogeneous biologic characteristics, many of which are associated with a different response to therapy. As part of a routine diagnostic workup, most suspected acute leukemia cases undergo initial multiparameter immunophenotypic analysis, combined with morphology, cytochemistry, cytogenetics, and molecular biology. A standard acute leukemia flow cytometry panel is designed to determine whether leukemic blasts are of myeloid or lymphoid origin, and then to further classify the neoplastic cells (myeloid blasts, B lymphoblasts, abnormal promyelocytes, monoblasts, etc.). When the routine panel is insufficient to characterize the leukemic cells, additional antibodies including erythroid markers (CD71 and glycophorin A), megakaryocytic markers (CD41, CD61) or cytoplasmic markers may be indicated.

4. **Chronic Lymphocytic Leukemia (CLL) & Other Chronic Lymphoproliferative Diseases (CLPD)**

The history, physical exam (lymphadenopathy, splenomegaly and/or hepatomegaly) laboratory findings (lymphocytosis, granulocytopenia, anemia, thrombocytopenia), and lymphocyte morphology are suggestive of CLL. The diagnosis is established by paradoxical co-expression of CD5 on peripheral lymphocytes that express B cell markers (CD19, CD20, CD21 and CD23) with Kappa or lambda immunoglobulin light chain restriction. Additional markers such as CD38 and ZAP70 may provide important prognostic information. Flow cytometry can distinguish CLL, the peripheral counterpart of small lymphocytic lymphoma, often diagnosed in lymph node biopsies, from other indolent lymphocytic malignancies including prolymphocytic leukemia, Waldenstrom's macroglobulinemia, leukemic phase of lymphomas, hairy cell leukemia, T-cell CLL, adult T-cell leukemia, large granulocytic leukemia and cutaneous T-cell lymphoma and natural killer (NK) disorders including KIR (Killer cell Immunoglobulin-like receptors) expression.

5. **Myelodysplasia (MDS)**

Hematological (blood related) medical conditions with ineffective production of the myeloid class of blood cells. The blood production is disorderly and ineffective. Those with MDS can develop severe anemia and require blood transfusions. If the disease worsens, cytopenias can progress to bone marrow failure.

Flow cytometric immunophenotyping is also useful in immunophenotyping MDS, because it allows for the detection of an accurate percentage of myeloblasts; microblasts are characteristic of MDS and often difficult to morphologically differentiate from lymphocytes. Also of interest, the use of 4-color flow cytometry has allowed for the identification of abnormal myeloid populations in more than 90% of non–chronic myeloid leukemia myeloproliferative disorders (MPDs) and MDSs with a clonal cytogenetic abnormality, supporting the use of FCI in the diagnosis of these disorders. Flow cytometric immunophenotyping may also allow for the detection of an accurate percentage of monocytic cells, by analyzing CD14 and CD64, in establishing a diagnosis of chronic myelomonocytic leukemia (CMML). In addition, the morphologically mature monocytes of CMML may reveal abnormalities by FCI (partial loss of CD13, CD14, and CD15 and expression of CD56) that are not observed in normal monocytes. These abnormalities may indicate clues to a correct classification of CMML in these cases. (Dunphy)

6. **Lymphoma**

In the current World Health Organization (WHO) classification, all non-Hodgkin lymphomas (NHLs) are distinct clinicopathologic entities defined by their clinical features, morpholology, and immunophenotype plus, where appropriate, their genetic abnormalities. Immunophenotyping by flow cytometry allows multiparameter evaluation of single cells and the ability to work on very small samples.

An adequate biopsy is key to diagnosis and staging of lymphomas, and is often diagnostic in and of itself. Flow cytometry is usually a secondary test. However, some lymphoid proliferations can be morphologically confused with lymphoma. Further the use of fine needle aspirate biopsy (FNA) results in the loss of the biopsy architecture, a key feature in distinguishing benign from neoplastic lymphoproliferations. Lastly, the biopsy and FNA are not always able to distinguish clinically significant forms of lymphoma (e.g. mantle cell NHL). All of these situations are indications for flow cytometry and assist with the diagnosis, the prognosis, and the treatment of patients with lymphoma.

The panels of antibodies to leukocyte antigens are designed to identify and characterize lymphoproliferative disorders, which are usually comprised of mature B, T or plasma cells. Flow cytometric testing on blood or bone marrow for anaplastic large cell lymphoma, lymphomatoid granulomatosis (LYG), thymic B cell lymphoma, diffuse large B-cell lymphoma, plasma cell neoplasms or large cell lymphoma must be cautiously interpreted because of false negative results due to tumor cell loss in this disease population.

For B cell malignancies, demonstration of the presence of monoclonal population by restricted kappa or lambda, immunoglobulin light chain expression is useful, particularly when augmented by other differentiation antigens. These combined with a pan B antigen can not only help support the diagnosis of neoplasia, but significantly assist in defining the specific type of B cell lymphoma.

For T cell proliferations, clonality can usually be assessed using two complementary approaches. The first and newest is to use well-defined panels of 20 antibodies to TCR V beta genes. The other, more indirect method looks for atypical absence of well-defined pan T antigens and /or atypical intensities of pan T antigens may serve as reasonably specific markers of clonality. Lastly, atypical coexpression of certain antigens is helpful in defining certain subsets of T cell lymphomas. To render a formal diagnosis of T cell lymphoma, such flow data needs to be correlated with morphology and in some instances TCR gene clonality, HTLV serologic and or cytogenetic studies.

In the situation of plasma cell neoplasm (e.g. plasmacytoma, multiple myeloma) a smaller panel directed at both cell surface immunoglobulins light chains and cytoplasmic immunoglobulin light chains would be appropriate. Plasma cells develop from B lymphocytes (B-cells), a type of white blood cell that is made in the bone marrow. Plasma cell neoplasms are diseases in which abnormal plasma cells or myeloma cells from tumors in the bones or soft tissues of the body. Plasma cell neoplasms can be benign or malignant.

Flow cytometry can help define Natural Killer (NK) cell lineage in rare neoplastic NK proliferations. NK cells, belonging to the group of innate lymphoid cells, are defined as large granular lymphocytes (LGL) and constitute the third kind of cells differentiated from the common lymphoid progenitor generating B and T lymphocytes. NK cells are known to differentiate and mature in the bone marrow, lymph node, spleen, tonsils, and thymus where they enter into the circulation. Expression of the KIR family of NK-cell receptors has been used as a surrogate marker for clonality in NK cell disorders. For example, in chronic lymphoproliferative disorders of NK cells, expression of the KIR family is abnormal—either restricted isoform expression or a complete lack of detectable expression. Evaluation of KIR expression by flow cytometry can thus be used as evidence of a chronic NK-cell lymphoproliferative disorder versus a reactive NK-cell proliferation.

However, there are no immunophenotypic markers for clonality. In these instances, careful correlation with clinical course or molecular or cytogenetic testing may assist. The panel would be performed in stages and may include up to 20 antibodies for lymphomas. A standard lymphoma panel is designed to identify abnormal populations of B cells, T cells and/or NK cells. A standard lymphoma panel might include a combination of markers from the following categories: T cells, B cells, Kappa and lambda surface immunoglobulins light chains, and plasma cells. The immunophenotypes of lymphomas are widely known and flow cytometry allows appropriate classification of most cases. However, atypical patterns occur and pose significant diagnostic difficulties where aberrant antigen expression patterns must be reconciled with morphology. Additional markers may be required to characterize the abnormal population of cells including markers of immature cells (HLA-DR), B cells and myeloid cells.

7. **Histiocytic and Mast Cells**

In the premier diagnostic text for hematopathology, *World Health Organization Classification of Tumours of Haematopoetic and Lymphoid Tissues*, the demonstration of an aberrant mast cell phenotype is listed as independent criteria for the diagnosis of mast cell disease. This diagnostic criterion is based upon immunohistochemistry or flow cytometry. However, within the literature, the advantage of flow cytometric analysis in the detection and evaluation of mast cells has been touted due to the high sensitivity and objectivity that multiparametric analysis of a high number of cells can afford. Flow cytometry in mast cell evaluation is also of utility because it can aid in the identification of coexisting hematological malignancies, such as lymphoma, acute myeloid leukemia, myelodysplasia, and chronic myeloproliferative disorders that can accompany systemic mastocytosis in roughly one third of cases. Mast cell neoplasms are uncommon disorders. They are part of the immune system.

8. **Lymphocytosis (symptomatic)**

Flow cytometry may be indicated when signs and symptoms may suggest the presence of hematolymphoid neoplasm, and where flow cytometry is a useful tool in establishing the primary diagnosis. Flow cytometry is indicated where the up front utilization have a reasonable likelihood of diagnostic yield. These diagnoses include absolute lymphocytosis, lymphadenopathy and splenomegaly. This does not mean that it is necessary to randomly check lymphoproliferative disorders in peripheral blood specimens. Multiple flow cytometric strategies are used to evaluate hematolymphoid populations, including identification of neoplastic populations with aberrant immunophenotypes, abnormal maturation patterns, monotypic kappa/lambda light chain expression, restricted V-beta expression, and abnormal light scatter properties. (Calvo)

9. **Enlargement of Lymph Nodes**

Because of its increased specificity and in some cases increased sensitivity, flow cytometry has emerged as a primary diagnostic modality in the diagnosis of non-Hodgkin lymphoma and lymphoproliferative neoplasms and is no longer considered an ancillary tool. There is significant consensus to show the effectiveness of flow cytometry in diagnosing hematolymphoid neoplasms in the absence of obvious morphologic abnormalities. Delaying the ordering of flow cytometry until there is a review of the histologic sections because flow cytometry requires fresh tissue and even within 24 hours, the viability of neoplastic cells is reduced. Cytomorphologic examination and multiparametric flow cytometry (C-FCM) has proven to be an indispensable diagnostic and classification tool for chronic lymphoproliferative disorders with peripheral blood and bone marrow involvement. But C-FCM is valid not only for chronic lymphoproliferative disorders but also for other hematologic malignancies, including acute myeloid leukemia and lymphoblastic leukemia, in which histopathologic study is of little value. Flow cytometry is proved to be a very efficient diagnostic technique and properly classifies low-grade B-cell non-Hodgkin lymphomas. (Colorado)

10. **Transplants**

a. **Organ Transplants**

Postoperative monitoring of organ transplants may be necessary to determine early rejection, immunosuppressive therapy toxicity, or differentiation of infection from allograft rejection.

The cell surface marker examined is CD3. This may require repeated analysis when symptoms are expressed for the above conditions by the transplant patient. Flow cytometry is also used in the evaluation for the presence of a post-transplant lymphoproliferative disorder. Since even low levels of antibodies have been associated with early rejection episodes and graft loss, antibody detection by flow cytometry has become a routine technique for the study of donor and recipient compatibility. Flow cytometry is a valuable tool to monitor allograft recipients both pre and post transplantation, with the detection and characterization of HLA-specific alloantibody being the principal application in organ transplantation. With the use of flow cytometry antibody detection, donors expressing any of these antigens would be avoided, increasing the likelihood that, when a donor is cross matched with the particular candidate recipient, the final result will be negative. Detection of antidonor antibodies can confirm a suspected diagnosis of rejection and the need for antirejection therapy, indicate bone marrow toxicity during immunosuppressive therapies, and help in the differentiation of infections from transplant rejection. (Kirmizis)

b. **Stem Cell Transplants**

To measure stem cell counts (e.g. CD34, CD45) in patients undergoing autologous transplantation, flow cytometry offers the ability to examine rapidly thousands of cells stained with monoclonal antibodies conjugated to fluorescent dyes. Each cell is individually assessed for a variety of characteristics such as size and biochemical and/or antigenic composition. High precision and sensitivity, combined with the large numbers of cells that can be examined permits resolution of even very minor subpopulations from complex mixtures with high levels of statistical validity. The capacity to physically separate these subpopulations by flow sorting allows further functional, morphological and molecular correlations to be determined. (Preffer)

11. **Primary Immunodeficiencies (PIDS)**

Primary immunodeficiencies (e.g., Lymphocyte disorders, Phagocyte disorders, Monocyte/macrophage disorders, Chronic Granulomatous Disease) are immune disorders that are present at birth. These conditions are quite rare. Diagnosis typically occurs at an early age due to recurrent infections with frequent treatment failures. Affected individuals are prone to repeated infections, allergies, autoimmune disorders, and malignancies. In 2009, more than 120 inherited immunodeficiency disorders were currently recognized and placed in eight classes of PIDs. Initial evaluation for suspected primary immunodeficiencies includes physical exam, laboratory evaluation (e.g., CBC which includes platelet count and WBC with differential, ESR), and may include skin testing. Flow cytometry is indicated for diagnostic purposes in the presence of established disease or when abnormal results are found in the initial evaluation. The immunophenotypic evaluation of selected PIDs provides diagnostic clues as well as information useful to classify patients and predict clinical outcome. Functional flow cytometry can now help to clarify possible sites of genetic defects associated with specific PIDs. (Oliveira)

12. **Paroxysmal Nocturnal Hemoglobinuria (PNH)**

Paroxysmal nocturnal hemoglobinuria is a disease in which blood cells are unusually sensitive to lysis by complement. This condition is caused by a genetic mutation that results in the absence of over a dozen surface antigens on red and white blood cells. It can be diagnosed very efficiently by assessing both the red and white blood cells by flow cytometry for the absence of these antigens. In general staining both the red and white blood cells with fluorescent inactivated aureolysin (FLAER) and/or with antibodies to some of the missing GPI-anchored-antigens (such as CD59, CD14 and CD55) will allow for a very rapid and accurate diagnosis. PNH is a rare clonal hematopoietic disorder of stem cells.

13. **HIV Infection**

The clinical status of an HIV-infected patient can be monitored by the analysis of the surface antigens CD4 (a T-cell receptor for HIV) and CD8. This information can contribute to a staging as well as medical management for that individual (e.g., the need for drug therapy or prophylaxis). Monitoring would be considered appropriate no greater in frequency than once every 3 months. When a patient is stable, especially during the long period of clinical latency, assays would be appropriate at a frequency less often. When the patient has an acute problem and/or therapy change, it may be necessary to perform the test at an increased frequency. Flow cytometry provides important clinical information that helps predict disease outcome and guide treatment decisions. The strongest predictors of disease progression and need for further therapeutic intervention are CD4+T-cell count and viral load. These predictors do not capture an individual's risk for disease progression.

Note: In addition to flow cytometry, other tests are used to evaluate and follow this disease such as: T cell total count and or T cell; absolute CD4 and CD8 count including ratio.

On initial evaluation, additional T cell markers may be indicated. Flow Cytometry has helped define many new T-cell subsets. HIV infection causes significant changes in number of CD4 and CD8 positive lymphocytes, CD4 count falls roughly 30 % while CD8 count increases within 6 months after seroconversion, causing a decrease in the CD4/CD8 ratio. Following HIV infection diagnosis, flow cytometry should include enumeration of mature T-cells (CD3), helper T cells (CD4), and suppressor T cells (CD8) to ensure all major T cell subsets are accounted for (the sum of helper CD4 and suppressor CD8 cells is roughly close to the total number of CD3 positive T cells). This ensures that the absolute CD4 is not artificially decreased due to sample degradation or other artifact. A WBC count with differential also needs to be performed to calculate the absolute CD4 count (absolute lymphocyte count times CD4%). (CDC)

14. **Drug Monitoring**

Drugs that react against specific monoclonal antibodies are being developed to treat certain diseases that impact the immune system. Conventional therapeutic drug monitoring based on measuring immunosuppressive drug concentrations in blood is important in the clinical management of immunosuppressive therapy in transplantation medicine. Since rejection or infection occurs at irregular drug concentrations immunosuppressive drug therapy is often empiric and prophylactic in nature. In addition, blood immunosuppressant levels are only indirect predictors of the pharmacologic effects on immune cells, because the genetic heterogeneity the immune systems of transplant recipients are not equally sensitive to drug effects. Therefore, therapeutic drug monitoring requires the application of reliable and effective methods to study the pharmacodynamics variability by direct measurements of drug effects on immune cell functions. Flow cytometry offers a multiplicity of quantitative analysis possibilities, from detection of phosphorylated molecules up to complex multicolor analysis of whole blood samples. A large spectrum of flow cytometry-based applications for pharmacodynamic monitoring is available and allows detection and analysis of diverse function of T cells and dendritic cell subsets. By combining several assays, it is possible to generate a broad picture of the immune status of every single transplanted recipient. Furthermore, it is even possible to differentiate between synergistic and antagonistic pharmacodynamic effects of immunosuppressive drug combination therapy in vitro and to predict the pharmacodynamic drug effects in transplanted recipients. Such a pharmacodynamic drug monitoring may offer the opportunity to complete conventional therapeutic drug monitoring and, therefore, to tailor immunosuppressive therapy more individually. (Dieterlien) Through phosphor-specific flow cytometry the efficacy of immunosuppressive medication can be assessed, novel targets identified, and differences in drug sensitivity between cells and patients can be clarified. By analyzing the activity of intracellular signaling pathways in large patient populations, patient-specific differences in immune reactivity, drug susceptibility, and drug related side effects will be able to be determined. (Baan)

15. **Hereditary Persistence of Fetal Hemoglobin (HPFH)**

Hereditary persistence of fetal hemoglobin (HPFH) is a group of disorders in which hemoglobin F (the dominant hemoglobin in the developing fetus) persists into adult life. By itself this disorder is usually clinically benign. However, HPFH is sometimes inherited together with thalassemias and other hemoglobinopathies such as hemoglobin S (sickle cell trait). In these latter conditions, the presence of high levels of hemoglobin F modifies the clinical severity of the thalassemia or the hemoglobin S disorder. Complicating matters though is the observation that some patients with sickle cell disease have an increase in hemoglobin F levels that is not due to HPFH. These patients can have a relatively severe clinical course. Thus, it is critical to separate patients with homozygous hemoglobin S and physiologic increases in hemoglobin F levels from patients with heterozygous hemoglobin S and HPFH. Flow cytometry is a very effective way to distinguish between these two conditions. In most cases of HPFH, every red blood cell has about the same amount of hemoglobin F (called a "homocellular distribution") whereas in physiologic increases in hemoglobin F, the concentration of hemoglobin F varies from one red blood cell to the next (called a "heterocellular distribution"). Using antibodies to hemoglobin F, flow cytometry can readily distinguish a homocellular from a heterocellular hemoglobin F distribution and therefore distinguish HPFH from physiologic increases in hemoglobin F. The test would be indicated in anyone with an unexplained increase in hemoglobin F.

16. **Red Blood Cell Disorders (Hereditary Spherocytosis)**

A recently developed fluorescent dye method has great utility in the diagnosis of hereditary spherocytosis. In the past, the diagnosis of hereditary spherocytosis was based on recognizing spherocytes on the peripheral blood smears and by performing a test called the osmotic fragility test. The osmotic fragility test is sensitive and picks up most patients with hereditary spherocytosis, but it lacks specificity, because patients with other causes of hemolytic anemia can have an abnormal osmotic fragility result. Using flow cytometry with a fluorescent dye (eosin-5-maleimide) one can distinguish hereditary spherocytosis (the red blood cells have weaker staining with the dye) from other causes of spherocytosis (the red blood cells have normal binding to the dye). When coupled with the traditional tests (osmotic fragility and review of blood cell morphology), this has proven to be a very useful test. Flow cytometry for hereditary spherocytosis would be indicated in patients who have Coombs' negative hemolytic anemia.

17. **White Blood Cell Disorders (HLA-B27)**

An increased incidence of the HLA-B27 antigen has been reported in patients with ankylosing spondylitis, Reiter's syndrome, anterior uveitis, psoriatic arthritis, and inflammatory bowel disease. As a result, tests for the HLA-B27 antigen are a valuable adjunct in the diagnosis of these diseases. Traditionally, it has been the lymphocytotoxicity assay that was used to determine HLA status. The development of monoclonal antibodies to HLA antigens has rendered flow cytometry an alternative procedure which is economical and relatively simple. HLA-B27 typing by flow cytometry is performed as a lysed whole blood technique using a single color, directly conjugated antibody and gated peripheral blood lymphocytes as the marker population.

18. **Platelets Cell Disorders**

The use of flow cytometry in the quantitative and qualitative analysis of platelets is becoming more evident and will likely be part of the work-up of coagulation defects of primary and secondary hemostasis in the near future. For example, flow cytometry has been utilized for analysis of platelets in quantitative and qualitative disorders such as Glanzmann Thrombasthenia (GT) and Bernard-Soulier Disease (B-S).

GT is a rare inherited or acquired platelet disorder that derives from a defective GPIIA/GPIIIb receptor. Normally, the GIIA/GPIIIb receptor is involved in platelet cross linking by serving as a receptor for fibrin, thereby creating the initial platelet plug at the site of endothelial injury. Absence of this receptor results in increased susceptibility to bleeding. As demonstrated by Jennings, platelets with decreased expression or absence of the GPIIa/GPIIIb receptor can be easily distinguished in patients with GT by flow cytometry. Demonstration of decreased surface expression provides evidence as to the presence of hereditary GT. Acquired GT is more of an autoimmune phenomenon with the presence of GPIIb/GPIIIa blocking antibodies. Giannini et al, recently reported the ability to use flow cytometry as a rapid test to determine both the functional effect and identity of the molecular targets of these antibodies.

Bernard-Soulier (B-S) Disease is another rare inherited disorder that prevents the initial binding of platelets at the site of endothelial injury by absence of or presence of abnormal surface GPIa/V/IX receptor. Abnormalities of this receptor thereby prevent attachment of platelets to subendothelial or free von Willebrand's factor with subsequent tendency to bleed. Flow cytometry can be used to measures antibodies directed at specific loci of the GPIa/V/IX receptor which include GPIb (CD42b), GPIX (CD42a), and GPV (CD42d). Another characteristic of B-S Disease that can be utilized in the initial evaluation of the flow cytometric data is the size of platelets. In B-S disease platelets are generally larger than normal and may demonstrate an increase spectrum of size that can be distinguished from fragmented RBCs and debris by specific binding of antibodies directed to the GPIb/IX/V receptor, as previously mentioned.

19. **Plasma Cell Disorders**

Plasma cell disorders are a condition in which there is an increase population of plasma cells, including malignant and nonmalignant disorders. Plasma Cell Disorders are identified through a combination of clinical, laboratory studies (urine or serum gamma globulins), morphologic, and radiologic findings. Flow cytometry immunophenotyping is useful to identify abnormal plasma cells, and the distinction between lymphoid and plasma cell neoplasms, and between reactive plasma cells and neoplastic cells. Flow cytometry is also help in the differential diagnosis of myeloma and lymphoma. Flow cytometry is particularly useful in those patients with low tumor burden, because it defines with precision the percentage of clonal plasma cells infiltrating the bone marrow. Moreover, in patients without paraproteins, flow cytometry can distinguish whether the plasma cells in the bone marrow can be polyclonal (= reactive plasmacytosis) instead of monoclonal (= MM or MGUS). For clonal PC disorders, MFC (multiparameter flow cytometry) is of clear and established clinical relevance in: (1) the differential diagnosis between MM and other PC-related disorders; (2) the identification of high-risk MGUS and smoldering MM; (3) minimal residual disease investigation after therapy; additionally, it may also be useful for (4) the definition of prognosis-associated antigenic profiles; and (5) the identification of new therapeutic targets. MM is Multiple Myeloma and MGUS is monoclonal gammopathy of undetermined significance. Other types of plasma cell disorders include M- component, Smoldering multiple myeloma, Plasma cell leukemia, Waldenstrom macroglobulinemia, HDT (high dose melphalan)/ASCT (autologous stem cell), and Immune paresis. (Paiva)

20. **Chronic Myeloproliferative Disorders (CMPD)**

CMPD are a group of slow growing blood cancers in which the bone marrow makes too many red blood cells, white blood cells, or platelets. In myeloproliferative disorders, too many blood stem cells become one or more types of blood cells. There are 6 types of chronic myeloproliferative disorders, including chronic myelogenous leukemia, Polycythemia vera, Primary myelofibrosis, Essential thrombocythemia, chronic neutrophilic leukemia, and chronic eosinophilic leukemia. Although genetic (Philadelphia chromosome and BDR/abl) and molecular studies (Jak2) are the accepted cornerstone for the identification and classification of CMPDs Flow cytometry may assist in the distinction from reactive hematopoietic proliferations and is important in the enumeration of blasts in the distinction from acute leukemia and an accelerated phase of CMPS. CMPS also has a definite risk and rate of progression to acute leukemia. Standard flow cytometry leukemia panels are indicated to evaluate the progression and onset of leukemia.

21. **Minimal Residual Disease (MRD)**

Flow cytometry analysis for MRD identifies phenotypic features characteristic of the disease of interest. The MRD flow analysis should not rely on an exact match between the phenotype of the residual disease and the original diagnostic specimen because phenotypes can change over time and with treatment. The antibody combinations should be chosen to maximize detection of disease, limit the impact of phenotypic variation, and permit detection of disease following antibody directed therapy. In patients with acute leukemia, studies of minimal residual disease (MRD) provide powerful and independent prognostic information. Multiparameter flow cytometry is a widely applicable and reliable approach for monitoring MRD. Using triple or quadruple marker combinations, aberrant or uncommon phenotypic profiles can be identified in about 80% of patients with acute myeloid leukemia (AML) and 95% of patients with acute lymphoblastic leukemia (ALL). (Vidruales)

Indications - DNA Analysis

1. **Molar Pregnancies (Hydatidiform Mole)**
Flow cytometry has also been proven to be useful in evaluating molar and partial molar pregnancies. Using a method to quantify DNA, similar to that used for evaluation of carcinomas, partial moles, which are triploid, can be readily distinguished from normal placenta and complete molar pregnancies (which are usually diploid). This is a very important clinical distinction and is a valid indication for flow cytometry.
2. **Carcinomas**

DNA analysis of tumor for ploidy and percent-S-phase cells may be necessary for selective patients with carcinomas. Information obtained from flow cytometry is useful when the obtained prognostic information will affect treatment decisions in patients with low stage (localized disease). This is usually performed only one time after a diagnosis has been made and before treatment is initiated. These tests are not indicated for prognostic and therapeutic purposes in the routine clinical management of cancers. Some of the reasons for this are: Ploidy status may have uncertain value in individual patients depending on a number of factors that can include specimen size, source, and preparation; and that aneuploidy has been detected in non-tumor cells.

Increased S-phase activity is a more accepted prognostic indicator but it is technically more difficult to measure accurately. Not all tumors with S-phase fraction are malignant; not all tumors with increased S-phase metastasize; and not all malignant tumors with relatively small S-phase fraction fail to metastasize. It has not been proven that this testing provides useful information in colorectal or breast cancers.It has not been proven that this testing provides useful information in colorectal or breast cancers.

This testing is indicated for selected patients (without metastatic disease) with the following conditions:
a. Prostatic adenocarcinoma
b. Urinary Bladder Carcinoma
c. Ovarian Carcinoma
d. Endometrial adenocarcinoma
e. Renal cell adenocarcinoma
f. Mediastinal neuroblastoma
g. Medulloblastoma

Summary of Evidence

N/A

Analysis of Evidence
(Rationale for Determination)

N/A

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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.

N/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.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

88184	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; FIRST MARKER
88185	FLOW CYTOMETRY, CELL SURFACE, CYTOPLASMIC, OR NUCLEAR MARKER, TECHNICAL COMPONENT ONLY; EACH ADDITIONAL MARKER (LIST SEPARATELY IN ADDITION TO CODE FOR FIRST MARKER)
88187	FLOW CYTOMETRY, INTERPRETATION; 2 TO 8 MARKERS
88188	FLOW CYTOMETRY, INTERPRETATION; 9 TO 15 MARKERS
88189	FLOW CYTOMETRY, INTERPRETATION; 16 OR MORE MARKERS

Group 2 Paragraph:

N/A

Group 2 Codes:

88182 FLOW CYTOMETRY, CELL CYCLE OR DNA ANALYSIS

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

Note: diagnosis codes must be coded to the highest level of specificity.

Covered for:

CPT codes 88184-88189 are indicated for the following conditions:

Group 1 Codes:

ICD-10 Codes	Description
B20	Human immunodeficiency virus [HIV] disease
B97.33	Human T-cell lymphotrophic virus, type I [HTLV-I] as the cause of diseases classified elsewhere

ICD-10 Codes	Description
B97.34	Human T-cell lymphotrophic virus, type II [HTLV-II] as the cause of diseases classified elsewhere
B97.35	Human immunodeficiency virus, type 2 [HIV 2] as the cause of diseases classified elsewhere
C77.0 - C77.9	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck - Secondary and unspecified malignant neoplasm of lymph node, unspecified
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C81.00	Nodular lymphocyte predominant Hodgkin lymphoma, unspecified site
C81.01 - C81.09	Nodular lymphocyte predominant Hodgkin lymphoma, lymph nodes of head, face, and neck - Nodular lymphocyte predominant Hodgkin lymphoma, extranodal and solid organ sites
C81.10 - C81.19	Nodular sclerosis Hodgkin lymphoma, unspecified site - Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20 - C81.29	Mixed cellularity Hodgkin lymphoma, unspecified site - Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30 - C81.39	Lymphocyte depleted Hodgkin lymphoma, unspecified site - Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40 - C81.49	Lymphocyte-rich Hodgkin lymphoma, unspecified site - Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70 - C81.79	Other Hodgkin lymphoma, unspecified site - Other Hodgkin lymphoma, extranodal and solid organ sites
C81.90 - C81.99	Hodgkin lymphoma, unspecified, unspecified site - Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C82.00 - C82.09	Follicular lymphoma grade I, unspecified site - Follicular lymphoma grade I, extranodal and solid organ sites
C82.10 - C82.19	Follicular lymphoma grade II, unspecified site - Follicular lymphoma grade II, extranodal and solid organ sites
C82.20 - C82.29	Follicular lymphoma grade III, unspecified, unspecified site - Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30 - C82.39	Follicular lymphoma grade IIIa, unspecified site - Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.40 - C82.49	Follicular lymphoma grade IIIb, unspecified site - Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50 - C82.59	Diffuse follicle center lymphoma, unspecified site - Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.60 - C82.69	Cutaneous follicle center lymphoma, unspecified site - Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.80 - C82.89	Other types of follicular lymphoma, unspecified site - Other types of follicular lymphoma, extranodal and solid organ sites
C82.90 - C82.99	Follicular lymphoma, unspecified, unspecified site - Follicular lymphoma, unspecified, extranodal and solid organ sites
C83.00 - C83.09	Small cell B-cell lymphoma, unspecified site - Small cell B-cell lymphoma, extranodal and solid organ sites
C83.10 - C83.19	Mantle cell lymphoma, unspecified site - Mantle cell lymphoma, extranodal and solid organ sites
C83.30 - C83.39	Diffuse large B-cell lymphoma, unspecified site - Diffuse large B-cell lymphoma, extranodal and solid organ sites
C83.50 - C83.59	Lymphoblastic (diffuse) lymphoma, unspecified site - Lymphoblastic (diffuse) lymphoma, extranodal and solid organ sites
C83.70 - C83.79	Burkitt lymphoma, unspecified site - Burkitt lymphoma, extranodal and solid organ sites
C83.80 - C83.89	Other non-follicular lymphoma, unspecified site - Other non-follicular lymphoma, extranodal and solid organ sites
C83.90 - C83.99	Non-follicular (diffuse) lymphoma, unspecified, unspecified site - Non-follicular (diffuse) lymphoma, unspecified, extranodal and solid organ sites
C84.00 - C84.09	Mycosis fungoides, unspecified site - Mycosis fungoides, extranodal and solid organ sites
C84.10 - C84.19	Sezary disease, unspecified site - Sezary disease, extranodal and solid organ sites
C84.40 - C84.49	Peripheral T-cell lymphoma, not classified, unspecified site - Peripheral T-cell lymphoma, not classified, extranodal and solid organ sites
C84.60 - C84.69	Anaplastic large cell lymphoma, ALK-positive, unspecified site - Anaplastic large cell lymphoma, ALK -positive, extranodal and solid organ sites

ICD-10 Codes	Description
C84.70 - C84.79	Anaplastic large cell lymphoma, ALK-negative, unspecified site - Anaplastic large cell lymphoma, ALK-negative, extranodal and solid organ sites
C84.A0 - C84.A9	Cutaneous T-cell lymphoma, unspecified, unspecified site - Cutaneous T-cell lymphoma, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C84.90 - C84.99	Mature T/NK-cell lymphomas, unspecified, unspecified site - Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C85.10 - C85.19	Unspecified B-cell lymphoma, unspecified site - Unspecified B-cell lymphoma, extranodal and solid organ sites
C85.20 - C85.29	Mediastinal (thymic) large B-cell lymphoma, unspecified site - Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.80 - C85.89	Other specified types of non-Hodgkin lymphoma, unspecified site - Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C85.90 - C85.99	Non-Hodgkin lymphoma, unspecified, unspecified site - Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites
C86.0	Extranodal NK/T-cell lymphoma, nasal type
C86.1	Hepatosplenic T-cell lymphoma
C86.2	Enteropathy-type (intestinal) T-cell lymphoma
C86.3	Subcutaneous panniculitis-like T-cell lymphoma
C86.4	Blastic NK-cell lymphoma
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C88.0	Waldenstrom macroglobulinemia
C88.2	Heavy chain disease
C88.3	Immunoproliferative small intestinal disease
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue [MALT-lymphoma]
C88.8	Other malignant immunoproliferative diseases
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having achieved remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having achieved remission
C90.21	Extramedullary plasmacytoma in remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having achieved remission
C90.31	Solitary plasmacytoma in remission
C90.32	Solitary plasmacytoma in relapse
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C91.30	Prolymphocytic leukemia of B-cell type not having achieved remission
C91.31	Prolymphocytic leukemia of B-cell type, in remission
C91.32	Prolymphocytic leukemia of B-cell type, in relapse

ICD-10 Codes	Description
C91.40	Hairy cell leukemia not having achieved remission
C91.41	Hairy cell leukemia, in remission
C91.42	Hairy cell leukemia, in relapse
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.51	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated), in relapse
C91.60	Prolymphocytic leukemia of T-cell type not having achieved remission
C91.61	Prolymphocytic leukemia of T-cell type, in remission
C91.62	Prolymphocytic leukemia of T-cell type, in relapse
C91.A0	Mature B-cell leukemia Burkitt-type not having achieved remission
C91.A1	Mature B-cell leukemia Burkitt-type, in remission
C91.A2	Mature B-cell leukemia Burkitt-type, in relapse
C91.Z0	Other lymphoid leukemia not having achieved remission
C91.Z1	Other lymphoid leukemia, in remission
C91.Z2	Other lymphoid leukemia, in relapse
C91.90	Lymphoid leukemia, unspecified not having achieved remission
C91.91	Lymphoid leukemia, unspecified, in remission
C91.92	Lymphoid leukemia, unspecified, in relapse
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.01	Acute myeloblastic leukemia, in remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.30	Myeloid sarcoma, not having achieved remission
C92.31	Myeloid sarcoma, in remission
C92.32	Myeloid sarcoma, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.41	Acute promyelocytic leukemia, in remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.51	Acute myelomonocytic leukemia, in remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.61	Acute myeloid leukemia with 11q23-abnormality in remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A1	Acute myeloid leukemia with multilineage dysplasia, in remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z1	Other myeloid leukemia, in remission
C92.Z2	Other myeloid leukemia, in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.91	Myeloid leukemia, unspecified in remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.01	Acute monoblastic/monocytic leukemia, in remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.11	Chronic myelomonocytic leukemia, in remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.30	Juvenile myelomonocytic leukemia, not having achieved remission
C93.31	Juvenile myelomonocytic leukemia, in remission
C93.32	Juvenile myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission

ICD-10 Codes	Description
C93.Z1	Other monocytic leukemia, in remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.91	Monocytic leukemia, unspecified in remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.01	Acute erythroid leukemia, in remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.21	Acute megakaryoblastic leukemia, in remission
C94.22	Acute megakaryoblastic leukemia, in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not classified
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.01	Acute leukemia of unspecified cell type, in remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.91	Leukemia, unspecified, in remission
C95.92	Leukemia, unspecified, in relapse
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
C96.4	Sarcoma of dendritic cells (accessory cells)
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.A	Histiocytic sarcoma
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D45	Polycythemia vera
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D47.01	Cutaneous mastocytosis
D47.02	Systemic mastocytosis
D47.09	Other mast cell neoplasms of uncertain behavior
D47.1	Chronic myeloproliferative disease

ICD-10 Codes	Description
D47.2	Monoclonal gammopathy
D47.3	Essential (hemorrhagic) thrombocythemia
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D56.0	Alpha thalassemia
D56.1	Beta thalassemia
D56.2	Delta-beta thalassemia
D56.3	Thalassemia minor
D56.4	Hereditary persistence of fetal hemoglobin [HPFH]
D56.5	Hemoglobin E-beta thalassemia
D56.8	Other thalassemias
D57.01	Hb-SS disease with acute chest syndrome
D57.02	Hb-SS disease with splenic sequestration
D57.1	Sickle-cell disease without crisis
D57.20	Sickle-cell/Hb-C disease without crisis
D57.211	Sickle-cell/Hb-C disease with acute chest syndrome
D57.212	Sickle-cell/Hb-C disease with splenic sequestration
D57.219	Sickle-cell/Hb-C disease with crisis, unspecified
D57.3	Sickle-cell trait
D57.411	Sickle-cell thalassemia with acute chest syndrome
D57.412	Sickle-cell thalassemia with splenic sequestration
D57.80	Other sickle-cell disorders without crisis
D57.811	Other sickle-cell disorders with acute chest syndrome
D57.812	Other sickle-cell disorders with splenic sequestration
D57.819	Other sickle-cell disorders with crisis, unspecified
D58.0	Hereditary spherocytosis
D58.1	Hereditary elliptocytosis
D58.2	Other hemoglobinopathies
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
D59.6	Hemoglobinuria due to hemolysis from other external causes
D59.8	Other acquired hemolytic anemias
D59.9	Acquired hemolytic anemia, unspecified
D60.0	Chronic acquired pure red cell aplasia
D60.1	Transient acquired pure red cell aplasia
D60.8	Other acquired pure red cell aplasias
D61.01	Constitutional (pure) red blood cell aplasia
D61.09	Other constitutional aplastic anemia
D61.1	Drug-induced aplastic anemia
D61.2	Aplastic anemia due to other external agents
D61.3	Idiopathic aplastic anemia
D61.810	Antineoplastic chemotherapy induced pancytopenia
D61.811	Other drug-induced pancytopenia
D61.818	Other pancytopenia
D61.82	Myelophthisis
D61.89	Other specified aplastic anemias and other bone marrow failure syndromes
D61.9	Aplastic anemia, unspecified
D63.0	Anemia in neoplastic disease
D64.0	Hereditary sideroblastic anemia
D64.1	Secondary sideroblastic anemia due to disease
D64.2	Secondary sideroblastic anemia due to drugs and toxins
D64.3	Other sideroblastic anemias
D64.4	Congenital dyserythropoietic anemia
D64.89	Other specified anemias
D64.9	Anemia, unspecified
D69.1	Qualitative platelet defects
D69.3	Immune thrombocytopenic purpura
D69.41	Evans syndrome
D69.42	Congenital and hereditary thrombocytopenia purpura

ICD-10 Codes	Description
D69.49	Other primary thrombocytopenia
D69.51	Posttransfusion purpura
D69.59	Other secondary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D70.0	Congenital agranulocytosis
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
D70.3	Neutropenia due to infection
D70.4	Cyclic neutropenia
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D71	Functional disorders of polymorphonuclear neutrophils
D72.0	Genetic anomalies of leukocytes
D72.1	Eosinophilia
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D72.820	Lymphocytosis (symptomatic)
D72.821	Monocytosis (symptomatic)
D72.822	Plasmacytosis
D72.823	Leukemoid reaction
D72.824	Basophilia
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D73.1	Hypersplenism
D73.81	Neutropenic splenomegaly
D75.81	Myelofibrosis
D75.9	Disease of blood and blood-forming organs, unspecified
D76.1	Hemophagocytic lymphohistiocytosis
D76.2	Hemophagocytic syndrome, infection-associated
D76.3	Other histiocytosis syndromes
D80.0	Hereditary hypogammaglobulinemia
D80.1	Nonfamilial hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.4	Nezelof's syndrome
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells

ICD-10 Codes	Description
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
D84.0	Lymphocyte function antigen-1 [LFA-1] defect
D84.1	Defects in the complement system
D84.8	Other specified immunodeficiencies
D89.1	Cryoglobulinemia
D89.2	Hypergammaglobulinemia, unspecified
D89.3	Immune reconstitution syndrome
D89.810	Acute graft-versus-host disease
D89.811	Chronic graft-versus-host disease
D89.812	Acute on chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
D89.82	Autoimmune lymphoproliferative syndrome [ALPS]
D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified
D89.9	Disorder involving the immune mechanism, unspecified
E88.09	Other disorders of plasma-protein metabolism, not elsewhere classified
G11.3	Cerebellar ataxia with defective DNA repair
G11.8	Other hereditary ataxias
H20.9	Unspecified iridocyclitis
I81	Portal vein thrombosis
I82.91	Chronic embolism and thrombosis of unspecified vein
I88.0	Nonspecific mesenteric lymphadenitis
I88.1	Chronic lymphadenitis, except mesenteric
I88.8	Other nonspecific lymphadenitis
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula

ICD-10 Codes	Description
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.40	Inflammatory polyps of colon without complications
K51.411	Inflammatory polyps of colon with rectal bleeding
K51.412	Inflammatory polyps of colon with intestinal obstruction
K51.413	Inflammatory polyps of colon with fistula
K51.414	Inflammatory polyps of colon with abscess
K51.418	Inflammatory polyps of colon with other complication
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
M02.30	Reiter's disease, unspecified site
M02.311	Reiter's disease, right shoulder
M02.312	Reiter's disease, left shoulder
M02.321	Reiter's disease, right elbow
M02.322	Reiter's disease, left elbow
M02.331	Reiter's disease, right wrist
M02.332	Reiter's disease, left wrist
M02.341	Reiter's disease, right hand
M02.342	Reiter's disease, left hand
M02.351	Reiter's disease, right hip
M02.352	Reiter's disease, left hip
M02.361	Reiter's disease, right knee
M02.362	Reiter's disease, left knee
M02.371	Reiter's disease, right ankle and foot
M02.372	Reiter's disease, left ankle and foot
M02.38	Reiter's disease, vertebrae
M02.39	Reiter's disease, multiple sites
M08.00	Unspecified juvenile rheumatoid arthritis of unspecified site
M08.011	Unspecified juvenile rheumatoid arthritis, right shoulder

ICD-10 Codes	Description
M08.012	Unspecified juvenile rheumatoid arthritis, left shoulder
M08.021	Unspecified juvenile rheumatoid arthritis, right elbow
M08.022	Unspecified juvenile rheumatoid arthritis, left elbow
M08.031	Unspecified juvenile rheumatoid arthritis, right wrist
M08.032	Unspecified juvenile rheumatoid arthritis, left wrist
M08.041	Unspecified juvenile rheumatoid arthritis, right hand
M08.042	Unspecified juvenile rheumatoid arthritis, left hand
M08.051	Unspecified juvenile rheumatoid arthritis, right hip
M08.052	Unspecified juvenile rheumatoid arthritis, left hip
M08.061	Unspecified juvenile rheumatoid arthritis, right knee
M08.062	Unspecified juvenile rheumatoid arthritis, left knee
M08.071	Unspecified juvenile rheumatoid arthritis, right ankle and foot
M08.072	Unspecified juvenile rheumatoid arthritis, left ankle and foot
M08.08	Unspecified juvenile rheumatoid arthritis, vertebrae
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.1	Juvenile ankylosing spondylitis
M08.211	Juvenile rheumatoid arthritis with systemic onset, right shoulder
M08.212	Juvenile rheumatoid arthritis with systemic onset, left shoulder
M08.221	Juvenile rheumatoid arthritis with systemic onset, right elbow
M08.222	Juvenile rheumatoid arthritis with systemic onset, left elbow
M08.231	Juvenile rheumatoid arthritis with systemic onset, right wrist
M08.232	Juvenile rheumatoid arthritis with systemic onset, left wrist
M08.241	Juvenile rheumatoid arthritis with systemic onset, right hand
M08.242	Juvenile rheumatoid arthritis with systemic onset, left hand
M08.251	Juvenile rheumatoid arthritis with systemic onset, right hip
M08.252	Juvenile rheumatoid arthritis with systemic onset, left hip
M08.261	Juvenile rheumatoid arthritis with systemic onset, right knee
M08.262	Juvenile rheumatoid arthritis with systemic onset, left knee
M08.271	Juvenile rheumatoid arthritis with systemic onset, right ankle and foot
M08.272	Juvenile rheumatoid arthritis with systemic onset, left ankle and foot
M08.28	Juvenile rheumatoid arthritis with systemic onset, vertebrae
M08.29	Juvenile rheumatoid arthritis with systemic onset, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.88	Other juvenile arthritis, other specified site
M08.89	Other juvenile arthritis, multiple sites
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.951	Juvenile arthritis, unspecified, right hip

ICD-10 Codes	Description
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M35.9	Systemic involvement of connective tissue, unspecified
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine
M46.00	Spinal enthesopathy, site unspecified
M46.01	Spinal enthesopathy, occipito-atlanto-axial region
M46.02	Spinal enthesopathy, cervical region
M46.03	Spinal enthesopathy, cervicothoracic region
M46.04	Spinal enthesopathy, thoracic region
M46.05	Spinal enthesopathy, thoracolumbar region
M46.06	Spinal enthesopathy, lumbar region
M46.07	Spinal enthesopathy, lumbosacral region
M46.08	Spinal enthesopathy, sacral and sacrococcygeal region
M46.09	Spinal enthesopathy, multiple sites in spine
M46.1	Sacroiliitis, not elsewhere classified
M46.50	Other infective spondylopathies, site unspecified
M46.51	Other infective spondylopathies, occipito-atlanto-axial region
M46.52	Other infective spondylopathies, cervical region
M46.53	Other infective spondylopathies, cervicothoracic region
M46.54	Other infective spondylopathies, thoracic region
M46.55	Other infective spondylopathies, thoracolumbar region
M46.56	Other infective spondylopathies, lumbar region
M46.57	Other infective spondylopathies, lumbosacral region
M46.58	Other infective spondylopathies, sacral and sacrococcygeal region
M46.59	Other infective spondylopathies, multiple sites in spine
M46.80	Other specified inflammatory spondylopathies, site unspecified
M46.81	Other specified inflammatory spondylopathies, occipito-atlanto-axial region
M46.82	Other specified inflammatory spondylopathies, cervical region
M46.83	Other specified inflammatory spondylopathies, cervicothoracic region
M46.84	Other specified inflammatory spondylopathies, thoracic region
M46.85	Other specified inflammatory spondylopathies, thoracolumbar region
M46.86	Other specified inflammatory spondylopathies, lumbar region
M46.87	Other specified inflammatory spondylopathies, lumbosacral region
M46.88	Other specified inflammatory spondylopathies, sacral and sacrococcygeal region
M46.89	Other specified inflammatory spondylopathies, multiple sites in spine
M46.90	Unspecified inflammatory spondylopathy, site unspecified
M46.91	Unspecified inflammatory spondylopathy, occipito-atlanto-axial region
M46.92	Unspecified inflammatory spondylopathy, cervical region
M46.93	Unspecified inflammatory spondylopathy, cervicothoracic region
M46.94	Unspecified inflammatory spondylopathy, thoracic region
M46.95	Unspecified inflammatory spondylopathy, thoracolumbar region
M46.96	Unspecified inflammatory spondylopathy, lumbar region
M46.97	Unspecified inflammatory spondylopathy, lumbosacral region
M46.98	Unspecified inflammatory spondylopathy, sacral and sacrococcygeal region

ICD-10 Codes	Description
M46.99	Unspecified inflammatory spondylopathy, multiple sites in spine
M48.8X1	Other specified spondylopathies, occipito-atlanto-axial region
M48.8X2	Other specified spondylopathies, cervical region
M48.8X3	Other specified spondylopathies, cervicothoracic region
M48.8X4	Other specified spondylopathies, thoracic region
M48.8X5	Other specified spondylopathies, thoracolumbar region
M48.8X6	Other specified spondylopathies, lumbar region
M48.8X7	Other specified spondylopathies, lumbosacral region
M48.8X8	Other specified spondylopathies, sacral and sacrococcygeal region
M49.80	Spondylopathy in diseases classified elsewhere, site unspecified
M49.81	Spondylopathy in diseases classified elsewhere, occipito-atlanto-axial region
M49.82	Spondylopathy in diseases classified elsewhere, cervical region
M49.83	Spondylopathy in diseases classified elsewhere, cervicothoracic region
M49.84	Spondylopathy in diseases classified elsewhere, thoracic region
M49.85	Spondylopathy in diseases classified elsewhere, thoracolumbar region
M49.86	Spondylopathy in diseases classified elsewhere, lumbar region
M49.87	Spondylopathy in diseases classified elsewhere, lumbosacral region
M49.88	Spondylopathy in diseases classified elsewhere, sacral and sacrococcygeal region
M49.89	Spondylopathy in diseases classified elsewhere, multiple sites in spine
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified
R19.01	Right upper quadrant abdominal swelling, mass and lump
R19.02	Left upper quadrant abdominal swelling, mass and lump
R19.03	Right lower quadrant abdominal swelling, mass and lump
R19.04	Left lower quadrant abdominal swelling, mass and lump
R19.05	Periumbilic swelling, mass or lump
R19.06	Epigastric swelling, mass or lump
R19.07	Generalized intra-abdominal and pelvic swelling, mass and lump
R19.09	Other intra-abdominal and pelvic swelling, mass and lump
R59.0	Localized enlarged lymph nodes
R59.1	Generalized enlarged lymph nodes
R59.9	Enlarged lymph nodes, unspecified
R75	Inconclusive laboratory evidence of human immunodeficiency virus [HIV]
R80.0	Isolated proteinuria
R80.1	Persistent proteinuria, unspecified
R80.3	Bence Jones proteinuria
R80.8	Other proteinuria
R80.9	Proteinuria, unspecified
R89.7	Abnormal histological findings in specimens from other organs, systems and tissues
T86.01	Bone marrow transplant rejection
T86.02	Bone marrow transplant failure
T86.03	Bone marrow transplant infection
T86.09	Other complications of bone marrow transplant
T86.11	Kidney transplant rejection
T86.12	Kidney transplant failure
T86.13	Kidney transplant infection
T86.19	Other complication of kidney transplant
T86.21	Heart transplant rejection
T86.22	Heart transplant failure
T86.23	Heart transplant infection
T86.290	Cardiac allograft vasculopathy
T86.298	Other complications of heart transplant
T86.31	Heart-lung transplant rejection
T86.32	Heart-lung transplant failure
T86.33	Heart-lung transplant infection
T86.39	Other complications of heart-lung transplant
T86.41	Liver transplant rejection
T86.42	Liver transplant failure

ICD-10 Codes	Description
T86.43	Liver transplant infection
T86.49	Other complications of liver transplant
T86.5	Complications of stem cell transplant
T86.810	Lung transplant rejection
T86.811	Lung transplant failure
T86.812	Lung transplant infection
T86.818	Other complications of lung transplant
T86.850	Intestine transplant rejection
T86.851	Intestine transplant failure
T86.852	Intestine transplant infection
T86.858	Other complications of intestine transplant
T86.890	Other transplanted tissue rejection
T86.891	Other transplanted tissue failure
T86.892	Other transplanted tissue infection
T86.898	Other complications of other transplanted tissue
Z21	Asymptomatic human immunodeficiency virus [HIV] infection status
Z48.21	Encounter for aftercare following heart transplant
Z48.22	Encounter for aftercare following kidney transplant
Z48.23	Encounter for aftercare following liver transplant
Z48.24	Encounter for aftercare following lung transplant
Z48.280	Encounter for aftercare following heart-lung transplant
Z48.288	Encounter for aftercare following multiple organ transplant
Z48.290	Encounter for aftercare following bone marrow transplant
Z48.298	Encounter for aftercare following other organ transplant
Z79.899	Other long term (current) drug therapy
Z85.6	Personal history of leukemia
Z85.71	Personal history of Hodgkin lymphoma
Z85.72	Personal history of non-Hodgkin lymphomas
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic and related tissues
Z94.0	Kidney transplant status
Z94.1	Heart transplant status
Z94.2	Lung transplant status
Z94.3	Heart and lungs transplant status
Z94.4	Liver transplant status
Z94.5	Skin transplant status
Z94.6	Bone transplant status
Z94.7	Corneal transplant status
Z94.81	Bone marrow transplant status
Z94.82	Intestine transplant status
Z94.83	Pancreas transplant status
Z94.84	Stem cells transplant status
Z94.89	Other transplanted organ and tissue status

Group 2 Paragraph:

CPT code 88182 (Flow cytometry, cell cycle or DNA analysis) is indicated for selected patients (without metastatic disease) with the following conditions:

Group 2 Codes:

ICD-10 Codes	Description
C38.1	Malignant neoplasm of anterior mediastinum
C38.2	Malignant neoplasm of posterior mediastinum
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri

ICD-10 Codes	Description
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C61	Malignant neoplasm of prostate
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
O01.0	Classical hydatidiform mole
O01.1	Incomplete and partial hydatidiform mole

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph:

N/A

Group 1 Codes: N/A

ICD-10 Additional Information Back to Top

General Information

Associated Information
Documentation Requirements
Adequate documentation is essential for high-quality patient care and to demonstrate the reasonableness and medical necessity of the procedure(s). Documentation must support the criteria for coverage as described in the Coverage Indications, Limitations, and/or Medical Necessity section of this LCD. There should be a permanent record of the performed studies including clinical and morphologic findings, cell counts (quantitative values), and radiology and cytogenetic findings when available and interpretation. Comparison with prior relevant imaging studies needs to be addressed in the documentation along with both normal and abnormal findings. Variations from normal size should be documented along with measurements. The report should address or answer any specific clinical questions. If there are factors that prevent answering the clinical questions, this should be explained in the documentation. Retention of the flow cytometry testing should be consistent both with clinical need and with relevant legal and local health care facility requirements.

If the provider of the study is other than the ordering/referring physician/nonphysician practitioner, that provider must maintain a copy of the test results and interpretation, along with copies of the ordering/referring

physician/nonphysician practitioner's order for the studies. This order is required to provide adequate diagnostic information to the performing provider. The physician/nonphysician practitioner must state the clinical indication/medical necessity for the study in his/her order for the test. The provider is responsible for ensuring the medical necessity of procedures and maintaining the medical record, which must be available to Medicare upon request. Results of all testing must be shared with the referring physician. Flow cytometry studies are medically reasonable and medically necessary only if the outcomes will be utilized in the clinical management of the patient.

Utilization Guidelines
Routine use of flow cytometry absent clinical indication for its use will be considered screening and will not be covered.

Routinely performing more than 20 analyses per specimen is not expected. When more than the stated makers (cell surface, cytoplasmic, or nuclear) are required, the documentation should support the medical necessity for the excess markers.

Up to 20 antibodies may be required to adequately characterize acute leukemia, chronic lymphoproliferative disorder (CLD), or lymphoma.

Up to 8 antibodies may be required to adequately characterize plasma cell dyscrasia.

Rare cases are diagnostic problems and may require more antibodies to characterize the disease process. Such problems should be documented in the patient's medical record.

Performing duplicate testing on different sources (i.e. blood smear and bone marrow) from the same patient in the same time frame may sometimes be necessary and the documentation must reflect the medical necessity.

Examples:
The lymph node flow cytometry is performed in order to render the diagnosis of lymphoma as well as subtype the malignancy, in order to "grade" the tumor. The bone marrow flow is done to "stage" the tumor by identifying malignancy within the bone marrow compartment. Both the grade and stage are separate data that are required prior to initiating appropriate therapy.

Similarly, flow may be performed on a lymph node and a pleural effusion, or a bone marrow and pleural effusion on the same day of service when the possibility of a malignant effusion is also suspected.

Flow cytometry used as part of experimental protocols is not a covered service.

Sources of Information
This bibliography represents the sources use to development the policy and additional resources used during times of review and/or revisions.

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Bonilla, F.A., Bernstein, I. L., Khan, D. A., & et al. (2005, May). Practice parameter for the diagnosis and management of primary immunodeficiency. *Annals of Allergy, Asthma, and Immunology. 94*:S1-S63.

Borowitz, M.J., Bray, R., Gascoyne, R., & et al. (1997, Oct 15) U.S. – Canadian consensus recommendations on the immunophenotypic analysis of hematologic neoplasia by flow cytometry: Data analysis and interpretation. *Cytometry: Communications in Clinical Cytometry. 30*(5):236-244.

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Bibliography

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
10/01/2017	R9	10/01/2017 ICD-10 CM Code updates: Group 1 deleted: C96.2. Group 1 added: C96.20, C96.21, C96.22, C96.29, D47.01, D47.02, D47.09.	• Revisions Due To ICD-10-CM Code Changes
09/01/2017	R8	09/01/2017 Annual review completed 08/10/2017. Reformatting IOM titles/verbiage references to match CMS updates. No change in coverage. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (Annual Review)
10/01/2016	R7	10/01/2016- Code update-description changes to C81.10-C81.19, C81.20-C81.29, C81.30-C81.39, C81.40-C81.49, C81.70-C81.79; formatting changes-ranged dx codes and moved 88182 into Group 2 Paragraph: Group 2 Codes. Annual review completed 09/01/2016- removed reference to stem cell NCD from CMS Coverage section; no change in coverage.	• Other (Annual Review) • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R6	02/01/2016 Added C81.97, D59.9, D72.819, M46.91, M46.92, M46.93, M46.94, M46.95, M46.96, M46.97, M46.98, M46.99, R89.7, Z85.6, Z85.71, Z85.72, and Z85.79 to Group 1 and C67.9 to Group 2 effective 10/01/2015. Remove the CAC information.	• Revisions Due To ICD-10-CM Code Changes
10/01/2015	R5	11/01/2015 Added D83.9 to Group 1 Diagnostic codes. This code is effective 10/01/2015.	• Revisions Due To ICD-10-CM Code Changes
10/01/2015	R4	10/06/2015 - Due to CMS guidance, we have removed the Jurisdiction 8 Notice and corresponding table from the CMS National Coverage Policy section. No other changes to policy or coverage.	• Other
10/01/2015	R3	10/01/2015 - Corrected Typographical Error of the word Histiocytic and corrected numbering under Indications section.	• Typographical Error
10/01/2015	R2	10/01/2015 Annual review completed 09/02/2015. Added to Group 1 Diagnostic codes: C77.0-C77.5, C77.8, C77.9, C80.0, C80.1, C81.10, C81.20, C81.30, C81.40, C81.70, C81.90, C82.00, C82.10, C82.20-C82.30, C82.40, C82.50, C82.60, C82.80, C82.90-C82.97, C83.00, C83.10, C83.30, C83.50, C83.70, C83.80, C83.90, C83.92-C84.00. C84.10, C84.40, C84.60, C84.70, C84A0, C84.Z0, C84.90, C85.10-C85.13, C85.15-C85.18, C85.20, C85.80, C85.90, C93.90-C93.92, C96.5, C96.6, D46.4, D46.9, D56.0-D56.3, D56.5, D56.8, D57.219, D57.411, D57.412, D57.819, D58.1, D60.0, D60.1, D60.8, D61.810, D61.811, D61.9, D64.9, D69.6, D72.89, D73.1, D73.81, D75.81, D75.9, D80.0-D80.5, D80.7, D83.0, D83.2, D83.8, D89.1, D89.2, D89.813, E88.09, I88.0, I88.1, I88.8, M02.30, M08.00, M35.9, M45.9, M46.00, M46.50, M46.80, M46.90, R59.9, R80.0, R80.1, R80.3, R80.8, R80.9, and Z48.288. The following codes were removed from Group 1: A18.01, C88.9, D72.9, R19.00, R87.618, R89.7, T86.10, T86.30, T86.40, T86.830, T86.831, T86.832, T86.838, Z79.3, Z79.891, Z95.3, and Z95.4 because the condition is not addressed in the policy and the diagnosis was added in error. Updated and reformatted the CMS National Policy section. Documentation requirements were clarified. The sources of information had the web links removed.	• Other • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R1	12/01/2014: Annual review completed on 09/30/2014. Clarified the indications and documentation requirements which are effective 01/15/2015. Formatting and typos corrected throughout. Updates National Coverage Policy and sources of information.	• Typographical Error • Other

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Associated Documents

Attachments N/A

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

Public Version(s) Updated on 09/20/2017 with effective dates 10/01/2017 - N/A Updated on 08/22/2017 with effective dates 09/01/2017 - 09/30/2017 Updated on 09/19/2016 with effective dates 10/01/2016 - 08/31/2017 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top

Local Coverage Determination (LCD): Drug Testing (L34645)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05101 - MAC A	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05102 - MAC B	J - 05	Iowa
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05201 - MAC A	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05202 - MAC B	J - 05	Kansas
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05301 - MAC A	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05302 - MAC B	J - 05	Missouri - Entire State
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05401 - MAC A	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	05402 - MAC B	J - 05	Nebraska
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	05901 - MAC A	J - 05	Alaska Alabama Arkansas Arizona Connecticut Florida Georgia Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey Ohio Oregon Rhode Island South Carolina South Dakota Tennessee Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Virginia Virgin Islands Vermont Washington Wisconsin West Virginia Wyoming
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08101 - MAC A	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08102 - MAC B	J - 08	Indiana
Wisconsin Physicians Service Insurance Corporation	MAC - Part A	08201 - MAC A	J - 08	Michigan
Wisconsin Physicians Service Insurance Corporation	MAC - Part B	08202 - MAC B	J - 08	Michigan

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LCD Information

Document Information

LCD ID
L34645

Original ICD-9 LCD ID
L32450

LCD Title
Drug Testing

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

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Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy
Italicized font represents CMS national language/wording copied directly from CMS Manuals or CMS transmittals. Contractors are prohibited from changing national language.

Title XVIII of the Social Security Act section 1862 (a) (1) (A). This section excludes coverage and payment of those items or services that are not considered to be medically *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 section 1862 (a) (1) (D). This section states that no Medicare payment may be made under part A or part B for any expenses incurred for items or services that are investigational or experimental.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations and services.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Code of Federal Regulations (CFR) Title 42, Part 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) who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician (or other qualified non-physician provider) who is treating the beneficiary are not reasonable and necessary (see section 411.15 (k) (1) of this chapter).
Medicare regulations at 42 CFR 410.32(a) state in part, that "…diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." Thus, except where other uses have been authorized by statute, Medicare does not cover diagnostic testing used for routine screening or surveillance.

CMS Pub 100-03 *Medicare National Coverage Determination Manual*, Chapter 1 – Coverage Determinations, Part 2, Sections 130.5 – Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic and 130.6 – Treatment of Drug Abuse (Chemical Dependency).

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

A qualitative/presumptive drug screen is used to detect the presence of a drug in the body. A blood or urine sample may be used. However, urine is the best specimen for broad screening, as blood is relatively insensitive for many common drugs, including psychotropic agents, opioids, and stimulants.
Common methods of drug analysis include chromatography, immunoassay, chemical ("spot") tests, and spectrometry.

Analysis is comparative, matching the properties or behavior of a substance with that of a valid reference compound (a laboratory must possess a valid reference agent for every substance that it identifies). Drugs or classes of drugs are commonly assayed by qualitative/presumptive testing. A test may be followed by confirmation with a second method, only if there is a positive or negative inconsistent finding from the qualitative/presumptive test in the setting of a symptomatic patient, as described below.

Examples of drugs or classes of drugs that are commonly assayed by qualitative/presumptive tests, followed by confirmation with a second method, are: alcohols, amphetamines, barbiturates/sedatives, benzodiazepines, cocaine and metabolites, methadone, antihistamines, stimulants, opioid analgesics, salicylates, cardiovascular

drugs, antipsychotics, cyclic antidepressants, and others. Focused drug screens, most commonly for illicit drug use, may be more useful clinically.

Indications:

A. Although technology has provided the ability to measure many toxins, most toxicological diagnoses and therapeutic decisions are made based on historical or clinical considerations:
   1. Laboratory turnaround time can often be longer than the critical intervention time course of an overdose.
   2. The cost and support of maintaining the instruments, staff training, and specialized labor involved in some analyses are prohibitive.
   3. For many toxins there are no established cutoff levels of .toxicity, making interpretation of the results difficult.

   Although comprehensive screening is unlikely to affect emergency management, the results may assist the admitting physicians in evaluating the patient if the diagnosis remains unclear. Screening panels should be used when the results will alter patient management or disposition.

B. A qualitative/presumptive drug test may be indicated for a variety of reasons including the following:
   1. A symptomatic patient when the history is unreliable, when there has been a suspected multiple-drug ingestion, to determine the cause of delirium or coma, or for the identification of specific drugs that may indicate when antagonists may be used.
   2. For monitoring patient compliance during active treatment for substance abuse or dependence.
   3. To monitor for compliance/adherence to the treatment plan or illicit drug use in patients under treatment or seeking treatment for a chronic pain condition. The clinical utility of drug tests in the emergency setting may be limited because patient management decisions are unaffected, since most therapy for drug poisonings is symptom directed and supportive.

C. Medicare will consider performance of a qualitative/presumptive drug test reasonable and necessary when a patient presents with suspected drug overdose and one or more of the following conditions:
   1. Unexplained coma
   2. Unexplained altered mental status in the absence of a clinically defined toxic syndrome or toxidrome
   3. Severe or unexplained cardiovascular instability (cardiotoxicity)
   4. Unexplained metabolic or respiratory acidosis in the absence of a clinically defined toxic syndrome or toxidrome
   5. Testing on neonates suspected of prenatal drug exposure
   6. Seizures with an undetermined history

D. Medicare will consider performance of a qualitative/presumptive drug test reasonable and necessary when a patient presents with one or more of the following conditions:
   1. For monitoring patient compliance during active treatment for substance abuse or dependence.
   2. A drug screen is considered medically reasonable and necessary in patients on chronic opioid therapy:
      - In whom illicit drug use, non-compliance or a significant pre-test probability of non-adherence to the prescribed drug regimen is suspected and documented in the medical record; and/or
      - In those who are at high risk for medication abuse due to psychiatric issues, who have engaged in aberrant drug-related behaviors, or who have a history of substance abuse.
   3. Medicare will consider performance of a drug test reasonable and necessary in patients with chronic pain to:
      - determine the presence of other substances prior to initiating pharmacologic treatment
      - detect the presence of illicit drugs
      - monitor adherence to the plan of care

Drugs, or drug classes for which testing is performed, should reflect only those likely to be present, based on the patient's medical history, current clinical presentation, and illicit drugs that are in common use. Drugs for which specimens are being tested must be indicated by the referring provider in a written order.

A drug test may be reasonable and necessary for patients with known substance abuse or dependence, only when the clinical presentation has changed unexpectedly and one of the above indications is met.

A drug test may be reasonable and necessary for patients with symptoms of schizophrenia suspected to be secondary to drug or substance intoxication.

Definitive drug testing is indicated when:

1. The results of the screen are presumptively positive.
2. Results of the screen are negative and this negative finding is inconsistent with the patient's medical history.
3. This test may also be used, when the coverage criteria of the policy are met AND there is no presumptive test available, locally and/or commercially, as may be the case for certain synthetic or semi-synthetic opioids.

A positive screen often results in an inadequate result upon which to make a proper determination. A more specific method, such as gas or liquid chromatography coupled with mass spectrometry, may be needed in order to obtain a confirmed analytical result. In particular, screens are frequently inadequate for interpretation of opiate and benzodiazepine results and therefore; quantitative testing may be needed in these instances. Confirmation testing is usually not required for drugs like methadone, wherein false positive results are rare. However, factors such as cross-reactivity with other similar compounds or interfering substances in the specimen may affect test results. Confirmatory testing eliminates the risk of false positives. Also, eliminated by confirmation, is the risk of a "pill scraper" slipping through. Patients diverting their drug, attempt to cheat the test by scraping a bit of drug from a pill into their urine sample. It would screen positive, but there would be no metabolite upon confirmation. Frequent use of this code will be monitored for appropriateness.

Limitations:
It is considered not reasonable or necessary to test for the same drug with both a blood and a urine specimen simultaneously.

Drug screening for medico-legal purposes (e.g., court-ordered drug screening) or for employment purposes (e.g., as a pre-requisite for employment or as a requirement for continuation of employment) are not covered.

Summary of Evidence

NA

Analysis of Evidence
(Rationale for Determination)

NA

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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.

N/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.

N/A
CPT/HCPCS Codes
Group 1 Paragraph:

N/A

Group 1 Codes:
80305 Drug test prsmv dir opt obs
80306 Drug test prsmv instrmnt
80307 Drug test prsmv chem anlyzr
G0480 Drug test def 1-7 classes
G0481 Drug test def 8-14 classes
G0482 Drug test def 15-21 classes
G0483 Drug test def 22+ classes
G0659 Drug test def simple all cl

Group 2 Paragraph:

The following CPT codes are Non-Covered by Medicare

Group 2 Codes:
80320 - 80377 Drug screen quantalcohols - Drug/substance nos 7/more

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph:
For monitoring of patient compliance in a drug treatment program, use diagnosis code Z03.89 as the primary diagnosis and the specific drug dependence diagnosis as the secondary diagnosis.
For the monitoring of patients on methadone maintenance and chronic pain patients with opioid dependence use diagnosis code Z79.891, suspected of abusing other illicit drugs, use diagnosis code Z79.899.

G0480, G0481, G0482, G0483, G0659, 80305, 80306, 80307.
Diagnosis codes must be coded to the highest level of specificity.
For codes in the table below that require a 7th character, letter A initial encounter, D subsequent encounter or S sequela may be used.

Group 1 Codes:

ICD-10 Codes	Description
E87.2	Acidosis
F11.20	Opioid dependence, uncomplicated
F11.23	Opioid dependence with withdrawal
F18.10	Inhalant abuse, uncomplicated
F18.120	Inhalant abuse with intoxication, uncomplicated
F18.90	Inhalant use, unspecified, uncomplicated
F19.20	Other psychoactive substance dependence, uncomplicated
F20.0	Paranoid schizophrenia
F20.1	Disorganized schizophrenia
F20.2	Catatonic schizophrenia
F20.89	Other schizophrenia
F55.3	Abuse of steroids or hormones
F55.8	Abuse of other non-psychoactive substances
I45.81	Long QT syndrome
I47.2	Ventricular tachycardia
R40.0	Somnolence
R40.1	Stupor

ICD-10 Codes	Description
R40.20	Unspecified coma
R40.2110	Coma scale, eyes open, never, unspecified time
R40.2111	Coma scale, eyes open, never, in the field [EMT or ambulance]
R40.2112	Coma scale, eyes open, never, at arrival to emergency department
R40.2113	Coma scale, eyes open, never, at hospital admission
R40.2114	Coma scale, eyes open, never, 24 hours or more after hospital admission
R40.2120	Coma scale, eyes open, to pain, unspecified time
R40.2121	Coma scale, eyes open, to pain, in the field [EMT or ambulance]
R40.2122	Coma scale, eyes open, to pain, at arrival to emergency department
R40.2123	Coma scale, eyes open, to pain, at hospital admission
R40.2124	Coma scale, eyes open, to pain, 24 hours or more after hospital admission
R40.2210	Coma scale, best verbal response, none, unspecified time
R40.2211	Coma scale, best verbal response, none, in the field [EMT or ambulance]
R40.2212	Coma scale, best verbal response, none, at arrival to emergency department
R40.2213	Coma scale, best verbal response, none, at hospital admission
R40.2214	Coma scale, best verbal response, none, 24 hours or more after hospital admission
R40.2220	Coma scale, best verbal response, incomprehensible words, unspecified time
R40.2221	Coma scale, best verbal response, incomprehensible words, in the field [EMT or ambulance]
R40.2222	Coma scale, best verbal response, incomprehensible words, at arrival to emergency department
R40.2223	Coma scale, best verbal response, incomprehensible words, at hospital admission
R40.2224	Coma scale, best verbal response, incomprehensible words, 24 hours or more after hospital admission
R40.2310	Coma scale, best motor response, none, unspecified time
R40.2311	Coma scale, best motor response, none, in the field [EMT or ambulance]
R40.2312	Coma scale, best motor response, none, at arrival to emergency department
R40.2313	Coma scale, best motor response, none, at hospital admission
R40.2314	Coma scale, best motor response, none, 24 hours or more after hospital admission
R40.2320	Coma scale, best motor response, extension, unspecified time
R40.2321	Coma scale, best motor response, extension, in the field [EMT or ambulance]
R40.2322	Coma scale, best motor response, extension, at arrival to emergency department
R40.2323	Coma scale, best motor response, extension, at hospital admission
R40.2324	Coma scale, best motor response, extension, 24 hours or more after hospital admission
R40.2340	Coma scale, best motor response, flexion withdrawal, unspecified time
R40.2341	Coma scale, best motor response, flexion withdrawal, in the field [EMT or ambulance]
R40.2342	Coma scale, best motor response, flexion withdrawal, at arrival to emergency department
R40.2343	Coma scale, best motor response, flexion withdrawal, at hospital admission
R40.2344	Coma scale, best motor response, flexion withdrawal, 24 hours or more after hospital admission
R41.0	Disorientation, unspecified
R41.82	Altered mental status, unspecified
R44.0	Auditory hallucinations
R44.2	Other hallucinations
R56.9	Unspecified convulsions
T39.011A	Poisoning by aspirin, accidental (unintentional), initial encounter
T39.012A	Poisoning by aspirin, intentional self-harm, initial encounter
T39.013A	Poisoning by aspirin, assault, initial encounter
T39.014A	Poisoning by aspirin, undetermined, initial encounter
T39.091A	Poisoning by salicylates, accidental (unintentional), initial encounter
T39.092A	Poisoning by salicylates, intentional self-harm, initial encounter
T39.093A	Poisoning by salicylates, assault, initial encounter
T39.094A	Poisoning by salicylates, undetermined, initial encounter
T39.1X1A	Poisoning by 4-Aminophenol derivatives, accidental (unintentional), initial encounter
T39.1X2A	Poisoning by 4-Aminophenol derivatives, intentional self-harm, initial encounter
T39.1X3A	Poisoning by 4-Aminophenol derivatives, assault, initial encounter
T39.1X4A	Poisoning by 4-Aminophenol derivatives, undetermined, initial encounter
T39.2X1A	Poisoning by pyrazolone derivatives, accidental (unintentional), initial encounter
T39.2X2A	Poisoning by pyrazolone derivatives, intentional self-harm, initial encounter
T39.2X3A	Poisoning by pyrazolone derivatives, assault, initial encounter
T39.2X4A	Poisoning by pyrazolone derivatives, undetermined, initial encounter

ICD-10 Codes	Description
T39.311A	Poisoning by propionic acid derivatives, accidental (unintentional), initial encounter
T39.312A	Poisoning by propionic acid derivatives, intentional self-harm, initial encounter
T39.313A	Poisoning by propionic acid derivatives, assault, initial encounter
T39.314A	Poisoning by propionic acid derivatives, undetermined, initial encounter
T39.391A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], accidental (unintentional), initial encounter
T39.392A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], intentional self-harm, initial encounter
T39.393A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], assault, initial encounter
T39.394A	Poisoning by other nonsteroidal anti-inflammatory drugs [NSAID], undetermined, initial encounter
T40.0X1A	Poisoning by opium, accidental (unintentional), initial encounter
T40.0X2A	Poisoning by opium, intentional self-harm, initial encounter
T40.0X3A	Poisoning by opium, assault, initial encounter
T40.0X4A	Poisoning by opium, undetermined, initial encounter
T40.1X1A	Poisoning by heroin, accidental (unintentional), initial encounter
T40.1X2A	Poisoning by heroin, intentional self-harm, initial encounter
T40.1X3A	Poisoning by heroin, assault, initial encounter
T40.1X4A	Poisoning by heroin, undetermined, initial encounter
T40.2X1A	Poisoning by other opioids, accidental (unintentional), initial encounter
T40.2X2A	Poisoning by other opioids, intentional self-harm, initial encounter
T40.2X3A	Poisoning by other opioids, assault, initial encounter
T40.2X4A	Poisoning by other opioids, undetermined, initial encounter
T40.3X1A	Poisoning by methadone, accidental (unintentional), initial encounter
T40.3X2A	Poisoning by methadone, intentional self-harm, initial encounter
T40.3X3A	Poisoning by methadone, assault, initial encounter
T40.3X4A	Poisoning by methadone, undetermined, initial encounter
T40.4X1A	Poisoning by other synthetic narcotics, accidental (unintentional), initial encounter
T40.4X2A	Poisoning by other synthetic narcotics, intentional self-harm, initial encounter
T40.4X3A	Poisoning by other synthetic narcotics, assault, initial encounter
T40.4X4A	Poisoning by other synthetic narcotics, undetermined, initial encounter
T40.5X1A	Poisoning by cocaine, accidental (unintentional), initial encounter
T40.5X2A	Poisoning by cocaine, intentional self-harm, initial encounter
T40.5X3A	Poisoning by cocaine, assault, initial encounter
T40.5X4A	Poisoning by cocaine, undetermined, initial encounter
T40.601A	Poisoning by unspecified narcotics, accidental (unintentional), initial encounter
T40.602A	Poisoning by unspecified narcotics, intentional self-harm, initial encounter
T40.603A	Poisoning by unspecified narcotics, assault, initial encounter
T40.604A	Poisoning by unspecified narcotics, undetermined, initial encounter
T40.691A	Poisoning by other narcotics, accidental (unintentional), initial encounter
T40.692A	Poisoning by other narcotics, intentional self-harm, initial encounter
T40.693A	Poisoning by other narcotics, assault, initial encounter
T40.694A	Poisoning by other narcotics, undetermined, initial encounter
T40.7X1A	Poisoning by cannabis (derivatives), accidental (unintentional), initial encounter
T40.7X2A	Poisoning by cannabis (derivatives), intentional self-harm, initial encounter
T40.7X3A	Poisoning by cannabis (derivatives), assault, initial encounter
T40.7X4A	Poisoning by cannabis (derivatives), undetermined, initial encounter
T40.8X1A	Poisoning by lysergide [LSD], accidental (unintentional), initial encounter
T40.8X2A	Poisoning by lysergide [LSD], intentional self-harm, initial encounter
T40.8X3A	Poisoning by lysergide [LSD], assault, initial encounter
T40.8X4A	Poisoning by lysergide [LSD], undetermined, initial encounter
T40.901A	Poisoning by unspecified psychodysleptics [hallucinogens], accidental (unintentional), initial encounter
T40.902A	Poisoning by unspecified psychodysleptics [hallucinogens], intentional self-harm, initial encounter
T40.903A	Poisoning by unspecified psychodysleptics [hallucinogens], assault, initial encounter
T40.904A	Poisoning by unspecified psychodysleptics [hallucinogens], undetermined, initial encounter
T40.991A	Poisoning by other psychodysleptics [hallucinogens], accidental (unintentional), initial encounter
T40.992A	Poisoning by other psychodysleptics [hallucinogens], intentional self-harm, initial encounter
T40.993A	Poisoning by other psychodysleptics [hallucinogens], assault, initial encounter

ICD-10 Codes	Description
T40.994A	Poisoning by other psychodysleptics [hallucinogens], undetermined, initial encounter
T42.0X1A	Poisoning by hydantoin derivatives, accidental (unintentional), initial encounter
T42.0X2A	Poisoning by hydantoin derivatives, intentional self-harm, initial encounter
T42.0X3A	Poisoning by hydantoin derivatives, assault, initial encounter
T42.0X4A	Poisoning by hydantoin derivatives, undetermined, initial encounter
T42.3X1A	Poisoning by barbiturates, accidental (unintentional), initial encounter
T42.3X2A	Poisoning by barbiturates, intentional self-harm, initial encounter
T42.3X3A	Poisoning by barbiturates, assault, initial encounter
T42.3X4A	Poisoning by barbiturates, undetermined, initial encounter
T42.4X1A	Poisoning by benzodiazepines, accidental (unintentional), initial encounter
T42.4X2A	Poisoning by benzodiazepines, intentional self-harm, initial encounter
T42.4X3A	Poisoning by benzodiazepines, assault, initial encounter
T42.4X4A	Poisoning by benzodiazepines, undetermined, initial encounter
T42.6X1A	Poisoning by other antiepileptic and sedative-hypnotic drugs, accidental (unintentional), initial encounter
T42.6X2A	Poisoning by other antiepileptic and sedative-hypnotic drugs, intentional self-harm, initial encounter
T42.6X3A	Poisoning by other antiepileptic and sedative-hypnotic drugs, assault, initial encounter
T42.6X4A	Poisoning by other antiepileptic and sedative-hypnotic drugs, undetermined, initial encounter
T42.71XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, accidental (unintentional), initial encounter
T42.72XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, intentional self-harm, initial encounter
T42.73XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, assault, initial encounter
T42.74XA	Poisoning by unspecified antiepileptic and sedative-hypnotic drugs, undetermined, initial encounter
T43.011A	Poisoning by tricyclic antidepressants, accidental (unintentional), initial encounter
T43.012A	Poisoning by tricyclic antidepressants, intentional self-harm, initial encounter
T43.013A	Poisoning by tricyclic antidepressants, assault, initial encounter
T43.014A	Poisoning by tricyclic antidepressants, undetermined, initial encounter
T43.021A	Poisoning by tetracyclic antidepressants, accidental (unintentional), initial encounter
T43.022A	Poisoning by tetracyclic antidepressants, intentional self-harm, initial encounter
T43.023A	Poisoning by tetracyclic antidepressants, assault, initial encounter
T43.024A	Poisoning by tetracyclic antidepressants, undetermined, initial encounter
T43.1X1A	Poisoning by monoamine-oxidase-inhibitor antidepressants, accidental (unintentional), initial encounter
T43.1X2A	Poisoning by monoamine-oxidase-inhibitor antidepressants, intentional self-harm, initial encounter
T43.1X3A	Poisoning by monoamine-oxidase-inhibitor antidepressants, assault, initial encounter
T43.1X4A	Poisoning by monoamine-oxidase-inhibitor antidepressants, undetermined, initial encounter
T43.201A	Poisoning by unspecified antidepressants, accidental (unintentional), initial encounter
T43.202A	Poisoning by unspecified antidepressants, intentional self-harm, initial encounter
T43.203A	Poisoning by unspecified antidepressants, assault, initial encounter
T43.204A	Poisoning by unspecified antidepressants, undetermined, initial encounter
T43.211A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, accidental (unintentional), initial encounter
T43.212A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, intentional self-harm, initial encounter
T43.213A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, assault, initial encounter
T43.214A	Poisoning by selective serotonin and norepinephrine reuptake inhibitors, undetermined, initial encounter
T43.221A	Poisoning by selective serotonin reuptake inhibitors, accidental (unintentional), initial encounter
T43.222A	Poisoning by selective serotonin reuptake inhibitors, intentional self-harm, initial encounter
T43.223A	Poisoning by selective serotonin reuptake inhibitors, assault, initial encounter
T43.224A	Poisoning by selective serotonin reuptake inhibitors, undetermined, initial encounter
T43.291A	Poisoning by other antidepressants, accidental (unintentional), initial encounter
T43.292A	Poisoning by other antidepressants, intentional self-harm, initial encounter
T43.293A	Poisoning by other antidepressants, assault, initial encounter
T43.294A	Poisoning by other antidepressants, undetermined, initial encounter
T43.3X1A	Poisoning by phenothiazine antipsychotics and neuroleptics, accidental (unintentional), initial encounter

ICD-10 Codes	Description
T43.3X2A	Poisoning by phenothiazine antipsychotics and neuroleptics, intentional self-harm, initial encounter
T43.3X3A	Poisoning by phenothiazine antipsychotics and neuroleptics, assault, initial encounter
T43.3X4A	Poisoning by phenothiazine antipsychotics and neuroleptics, undetermined, initial encounter
T43.4X1A	Poisoning by butyrophenone and thiothixene neuroleptics, accidental (unintentional), initial encounter
T43.4X2A	Poisoning by butyrophenone and thiothixene neuroleptics, intentional self-harm, initial encounter
T43.4X3A	Poisoning by butyrophenone and thiothixene neuroleptics, assault, initial encounter
T43.4X4A	Poisoning by butyrophenone and thiothixene neuroleptics, undetermined, initial encounter
T43.501A	Poisoning by unspecified antipsychotics and neuroleptics, accidental (unintentional), initial encounter
T43.502A	Poisoning by unspecified antipsychotics and neuroleptics, intentional self-harm, initial encounter
T43.503A	Poisoning by unspecified antipsychotics and neuroleptics, assault, initial encounter
T43.504A	Poisoning by unspecified antipsychotics and neuroleptics, undetermined, initial encounter
T43.591A	Poisoning by other antipsychotics and neuroleptics, accidental (unintentional), initial encounter
T43.592A	Poisoning by other antipsychotics and neuroleptics, intentional self-harm, initial encounter
T43.593A	Poisoning by other antipsychotics and neuroleptics, assault, initial encounter
T43.594A	Poisoning by other antipsychotics and neuroleptics, undetermined, initial encounter
T43.601A	Poisoning by unspecified psychostimulants, accidental (unintentional), initial encounter
T43.602A	Poisoning by unspecified psychostimulants, intentional self-harm, initial encounter
T43.603A	Poisoning by unspecified psychostimulants, assault, initial encounter
T43.604A	Poisoning by unspecified psychostimulants, undetermined, initial encounter
T43.611A	Poisoning by caffeine, accidental (unintentional), initial encounter
T43.612A	Poisoning by caffeine, intentional self-harm, initial encounter
T43.613A	Poisoning by caffeine, assault, initial encounter
T43.614A	Poisoning by caffeine, undetermined, initial encounter
T43.621A	Poisoning by amphetamines, accidental (unintentional), initial encounter
T43.622A	Poisoning by amphetamines, intentional self-harm, initial encounter
T43.623A	Poisoning by amphetamines, assault, initial encounter
T43.624A	Poisoning by amphetamines, undetermined, initial encounter
T43.631A	Poisoning by methylphenidate, accidental (unintentional), initial encounter
T43.632A	Poisoning by methylphenidate, intentional self-harm, initial encounter
T43.633A	Poisoning by methylphenidate, assault, initial encounter
T43.634A	Poisoning by methylphenidate, undetermined, initial encounter
T43.691A	Poisoning by other psychostimulants, accidental (unintentional), initial encounter
T43.692A	Poisoning by other psychostimulants, intentional self-harm, initial encounter
T43.693A	Poisoning by other psychostimulants, assault, initial encounter
T43.694A	Poisoning by other psychostimulants, undetermined, initial encounter
T43.8X1A	Poisoning by other psychotropic drugs, accidental (unintentional), initial encounter
T43.8X2A	Poisoning by other psychotropic drugs, intentional self-harm, initial encounter
T43.8X3A	Poisoning by other psychotropic drugs, assault, initial encounter
T43.8X4A	Poisoning by other psychotropic drugs, undetermined, initial encounter
T43.91XA	Poisoning by unspecified psychotropic drug, accidental (unintentional), initial encounter
T43.92XA	Poisoning by unspecified psychotropic drug, intentional self-harm, initial encounter
T43.93XA	Poisoning by unspecified psychotropic drug, assault, initial encounter
T43.94XA	Poisoning by unspecified psychotropic drug, undetermined, initial encounter
T45.0X1A	Poisoning by antiallergic and antiemetic drugs, accidental (unintentional), initial encounter
T45.0X2A	Poisoning by antiallergic and antiemetic drugs, intentional self-harm, initial encounter
T45.0X3A	Poisoning by antiallergic and antiemetic drugs, assault, initial encounter
T45.0X4A	Poisoning by antiallergic and antiemetic drugs, undetermined, initial encounter
T46.0X1A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, accidental (unintentional), initial encounter
T46.0X2A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, intentional self-harm, initial encounter
T46.0X3A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, assault, initial encounter
T46.0X4A	Poisoning by cardiac-stimulant glycosides and drugs of similar action, undetermined, initial encounter
T50.901A	Poisoning by unspecified drugs, medicaments and biological substances, accidental (unintentional), initial encounter

ICD-10 Codes	Description
T50.902A	Poisoning by unspecified drugs, medicaments and biological substances, intentional self-harm, initial encounter
T50.903A	Poisoning by unspecified drugs, medicaments and biological substances, assault, initial encounter
T50.904A	Poisoning by unspecified drugs, medicaments and biological substances, undetermined, initial encounter
Z03.89	Encounter for observation for other suspected diseases and conditions ruled out
Z79.891	Long term (current) use of opiate analgesic
Z79.899	Other long term (current) drug therapy
Z91.120	Patient's intentional underdosing of medication regimen due to financial hardship
Z91.128	Patient's intentional underdosing of medication regimen for other reason
Z91.130	Patient's unintentional underdosing of medication regimen due to age-related debility
Z91.138	Patient's unintentional underdosing of medication regimen for other reason
Z91.14	Patient's other noncompliance with medication regimen
Z91.19	Patient's noncompliance with other medical treatment and regimen

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph:

N/A

Group 1 Codes: N/A

ICD-10 Additional Information

N/A

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General Information

Associated Information

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The record must include the identity of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record should support the use of the selected diagnosis code(s). The submitted CPT/HCPCS code should describe the service performed.
4. Medical record documentation (e.g., history and physical, progress notes) maintained by the ordering physician/treating physician must indicate the medical necessity for performing a drug test. All tests must be ordered in writing by the treating provider and all drugs/drug classes to be tested must be indicated in the order.
5. If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the lab results, along with copies of the ordering/referring physician's order for the drug test. The physician must include the clinical indication/medical necessity in the order for the drug test.

Sources of Information

Christo, P.J., & et. al. (2011). Urine drug testing in chronic pain. *Pain Physician*, 14: 123-143.

Chou, R., & et. al. (2009). Opioid treatment guidelines: Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *The Journal of Pain, 10* (2): 113-130.

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Jackman, R.P. and Purvis, J.M. (2008). Chronic nonmalignant pain in primary care. *American Family Physician, 78* (10): 1155-1162.

Melanson, S., & et. al. (2010) Interpretation and utility of drug of abuse immunoassays: Lessons from laboratory drug testing surveys. *Archives of Pathology and Laboratory Medicine, 134*: 736-739.

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Other Contractor(s)' Policies

Bibliography

NA

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
01/01/2018	R13	01/01/2018 CPT/HCPCS code updates; description changes for Group 1 codes 80305, 80306, and 80307.	• Revisions Due To CPT/HCPCS Code Changes
12/01/2017	R12	12/01/2017 Annual review completed on 11/07/2017 with no changes in coverage. Typographical error corrected.	• Typographical Error • Other (Annual)
08/01/2017	R11	08/01/2017 Added F11.23 to Group 1 Codes effective 08/01/2017. Corrected typographical errors. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Typographical Error • Other (Added ICD-10-CM Code)
01/01/2017	R10	03/01/2017 Moved G0659 from the Group 1 Paragraph to the Group 1 Table. Long description change for Group 1 codes: G0480, G0481, G0482, and G0483 effective 01/01/2017.	• Revisions Due To CPT/HCPCS Code Changes
01/01/2017	R9	02/01/2017 HCPCS code G0659 added effective 01/01/2017.	

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
			• Revisions Due To CPT/HCPCS Code Changes
01/01/2017	R8	01/01/2017 CPT code changes added codes 80305, 80306 and 80307. Deleted codes 80300, 80301, 80302, 80303, 80304, G0477, G0478 and G0479. Annual review 12/02/2016.	• Revisions Due To CPT/HCPCS Code Changes
08/01/2016	R7	08/01/2016- changed CPT descriptions to short description no change in coverage.	• Other
01/01/2016	R6	02/01/2016: Added G0477, G0478, G0479, G0480, G0481, G0482, and G0483 to Group 1 codes section as technically unable to do so last month.	• Other
01/01/2016	R5	01/01/2016 Annual review 12/04/2015. CPT/HCPCS code updates for 2016: G0431, G0434, and G6058 are deleted and added G0477, G0478, G0479, G0480, G0481, G0482, and G0483 to Group 1 codes. Added code range 80320-80377 to Group 2 non-covered codes. Added Z03.89 to Group 1 Paragraph codes. CAC information removed.	• Revisions Due To CPT/HCPCS Code Changes • Other (CPT/HCPCS code changes ICD 10 code additions Other) • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R4	10/06/2015 - Due to CMS guidance, we have removed the Jurisdiction 8 Notice and corresponding table from the CMS National Coverage Policy section. No other changes to policy or coverage.	• Other
10/01/2015	R3	04/01/2015 Annual review 03/02/2015, added codes T40.5X1A, T40.5X2A, T40.5X3A, and T40.5X4A. "qualitative" was removed from Indications D 3. Updated sources of information.	• Other (Revisions due to ICD 10 addition Annual Review) • Revisions Due To ICD-10-CM Code Changes
10/01/2015	R2	01/01/2015 CPT/HCPCS code updates 2015, added codes G6058, 80300,80301, 80302, 80303 and 80304 Deleted codes 80100, 80101 and 80102. Removed Qualitative from title and Changed references from qualitative to qualitative/ presumptive to reflect new reporting mechanisms in CPT for 2015.	• Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R1	05/01/2014 Annual review 03/26/2014, no change to policy coverage.	• Other (Maintenance)

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Associated Documents

Attachments Billing and Coding Guidelines (PDF - 19 KB)

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

Public Version(s) Updated on 12/18/2017 with effective dates 01/01/2018 - N/A Updated on 11/20/2017 with effective dates 12/01/2017 - 12/31/2017 Updated on 07/18/2017 with effective dates 08/01/2017 - 11/30/2017 Updated on 03/02/2017 with effective dates 01/01/2017 - 07/31/2017 Updated on 01/19/2017 with effective dates 01/01/2017 - N/A Updated on 12/19/2016 with effective dates 01/01/2017 - N/A Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

Keywords

- N/A

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