

Local Coverage Determination (LCD): Non-covered Services (L33629)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
National Government Services, Inc.	MAC - Part A	06101 - MAC A	J - 06	Illinois
National Government Services, Inc.	MAC - Part B	06102 - MAC B	J - 06	Illinois
National Government Services, Inc.	MAC - Part A	06201 - MAC A	J - 06	Minnesota
National Government Services, Inc.	MAC - Part B	06202 - MAC B	J - 06	Minnesota
National Government Services, Inc.	MAC - Part A	06301 - MAC A	J - 06	Wisconsin
National Government Services, Inc.	MAC - Part B	06302 - MAC B	J - 06	Wisconsin
National Government Services, Inc.	A and B and HHH MAC	13101 - MAC A	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13102 - MAC B	J - K	Connecticut
National Government Services, Inc.	A and B and HHH MAC	13201 - MAC A	J - K	New York - Entire State
National Government Services, Inc.	A and B and HHH MAC	13202 - MAC B	J - K	New York - Downstate
National Government Services, Inc.	A and B and HHH MAC	13282 - MAC B	J - K	New York - Upstate
National Government Services, Inc.	A and B and HHH MAC	13292 - MAC B	J - K	New York - Queens
National Government Services, Inc.	A and B and HHH MAC	14111 - MAC A	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14112 - MAC B	J - K	Maine
National Government Services, Inc.	A and B and HHH MAC	14211 - MAC A	J - K	Massachusetts
National Government Services, Inc.	A and B and HHH MAC	14212 - MAC B	J - K	Massachusetts

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Inc.	MAC			
National Government Services, Inc.	A and B and HHH MAC	14311 - MAC A	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14312 - MAC B	J - K	New Hampshire
National Government Services, Inc.	A and B and HHH MAC	14411 - MAC A	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14412 - MAC B	J - K	Rhode Island
National Government Services, Inc.	A and B and HHH MAC	14511 - MAC A	J - K	Vermont
National Government Services, Inc.	A and B and HHH MAC	14512 - MAC B	J - K	Vermont

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CMS National Coverage Policy

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

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

Title XVIII of the Social Security Act (SSA):

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.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Section 1862(a)(7) excludes routine physical examinations, unless otherwise covered by statute.

Code of Federal Regulations:

42 CFR, Section 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 Sec. 411.15(k)(1) of this chapter).

CMS Publications:

CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 16:
20 Services Not Reasonable and Necessary

CMS Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Part 1:
20.15 Electrocardiographic Services

CMS Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Part 1:
70.5 - Hospital and Skilled Nursing Facility Admission Diagnostic Procedures

CMS Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Part 3
190.23 NCD for Lipid Testing

CMS Publication 100-04, *Medicare Claims Processing Manual*, Chapter 2:
80–80.2 Required Hospital Notice to Beneficiaries

CMS Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 4:
10 Outpatient Prospective Payment System (OPPS)

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Abstract:

This LCD lists specific services which are considered not medically necessary and will be denied. Some of these services were previously included in National Government Services LCDs which are now retired. The non-coverage provisions have been transferred to this umbrella Non-covered Services LCD.

Indications and Limitations:

Pre-operative Testing

The use of diagnostic testing as part of a pre-operative examination, where there is an absence of signs or symptoms indicating a need for the test, is not covered under the Medicare benefit. Such studies will be considered not reasonable and medically necessary.

The coverage of services defined as “reasonable and necessary” applies to all diagnostic procedures, with the exception of Medicare covered preventative and screening services. The existence of policies or protocols in hospitals or other providers, requiring the routine use of these tests, in and of themselves, does not justify coverage.

Certain diagnostic tests which are often performed routinely prior to surgical procedures and do not meet the definition of reasonable and necessary include:

- Electrocardiograms performed pre-operatively, when there are no indications for this test;
- Radiologic examination of the chest performed pre-operatively, when there are no indications for this test;

Claims submitted for these tests performed solely as part of a preoperative examination, **without additional diagnoses indicating medical necessity**, will be denied as not reasonable and necessary.

Circulating Tumor Cell (CTC) Assay

CTCs represent the point in the metastatic process of solid tumors when cells from a primary tumor invade, detach,

disseminate, colonize and proliferate in a distant site. Detection of elevated CTCs during therapy may be an accurate indication of subsequent rapid disease progression and mortality in breast, colorectal and prostate cancer, noting that FDA labeling includes each of these neoplasms. Although some comparative cohort designs have been conducted to express the clinical utility of such testing, the vast majority of studies have been uncontrolled one-arm studies. As an illustration of the most sophisticated available evidence, Cristofanilli et al. (2004) and Tol et al. (2010) have reported two-armed studies in the prognostic/predictive assessment of metastatic breast and colorectal cancers, respectively. Two-armed prostate cancer studies have been performed, but are not available for review at this time, given their abstract-only availability. Paoletti et al. (2012) help to articulate such a current clinical niche as follows:

At present, the most feasible use of CTCs is monitoring of patients with metastatic disease. Although technically "prognostic," elevated CTC levels over time in a patient receiving therapy are essentially predictive of resistance to that therapy and suggest that a new therapy, if available, is indicated.

The assay is reported as a numerical result where five or more cells per 7.5 ml of whole blood predicts worse prognosis in patients with known recurrent breast and prostate cancer, and three or more cells are predictive of shorter Progression Free Survival (PFS) and Overall Survival (OS) in metastatic colorectal cancer.

As a result of this above limited acceptable study data, National Government Services will consider CTCs not medically necessary, for all indications.

Rationale/Review of Literature:

National Government Services has reviewed the following published studies:

Beveridge Community Oncology (2007) This review of 50 metastatic breast cancer patients acknowledges some of the limitations of the use of CTCs. In this author's study, 54% of the patient population had circulating tumor cells, and that in five specific cases, the patients' demonstrated progressive disease in the absence of any CTC elevation. The study demonstrated a specificity of 89%, but a much lower sensitivity of 70% because of those cases of aggressive disease that failed to elaborate an increase in CTCs.

Budd (2006) 138 patients with metastatic breast cancer had imaging studies performed at the start of a new systemic treatment and 10 weeks later. The presence of 5 or greater circulating tumor cells in a 7.5 ml serum assay sample was compared to standard radiographic imaging of disease progression. Interreader variability for radiographic responses and CTC counts were 15.2% and 0.7% respectively. CTC elevation was demonstrated to be a more accurate predictor of overall mean survival than the presence of absence of radiographic disease progression. The patients were not categorized by ongoing treatment regimens or anatomic sites of disease progression, but improved accuracy in the projection of survival was suggested by the study.

Krebs (2011) reviews the findings of selected prognostic studies published to date in patients with metastatic breast, colon and prostate cancer. Reviews of the various employed technologies including immunomagnetic separation, centrifugation, filtration, and nucleic acid based assay are included. Potential application both small and non-small cell lung cancer is discussed. The review is a strong endorsement of continued research in these technologies, raising the possibility of stratifying populations of heterogeneous CTCs and identifying receptors such as human epidermal growth factor receptor (HER-2) and others predictive of treatment response. It is also cautionary regarding application to earlier stages of disease, maximization of predictive value regarding treatment, and the need for improved sensitivity.

NEJM Cristofanilli (2004) 177 patients with metastatic breast cancer assigned to new treatment regimens had CTCs obtained at baseline and at first follow-up (3-4 week interval). 145 control patients without disease and 200 control patients with benign breast disease also were assayed. The patients were stratified according to menopausal status, receptor status and treatment received.

OncologySTAT-Dr.Scher (2011) The director of GU Oncology at MSK discusses the use of this assay in the

management of prostate cancer with potential patients at his facility. He explains that it is being used in conjunction with standard measures of disease progression such as imaging. He also discussed the first trial at MSK where CTCs are being used as a biomarker during treatment with abiraterone, and is the type of clinical scenario where NGS envisions coverage of CTCs. He also compares CTCs to the established biomarker PSA in the management of patients with metastatic prostate cancer.

Saad-Patel (2012) This review of current literature and discussion of research at Canadian and German centers addresses the limited value of current biomarkers such as PSA in advanced prostate cancer patients with skeletal disease and suggests a role for CTCs in these patients. Particular attention is paid to the value of CTCs as a biomarker to time the initiation of therapies such as Zoledronic acid for skeletal related events. The authors temper this opinion with a discussion of immunomagnetic assays and the limitation of that technology in those patients whose tumor cells lack epithelial cell adhesion molecules, the necessary cellular structure to bind the ferrous nanoparticle tagged antibodies that are the mechanism of this assay.

At the present time, National Government Services does not find CTC to be of proven efficacy in the diagnosis or treatment of breast cancer, colorectal cancer, prostate cancer or suspected leptomeningeal disease.

Combined Ovarian Cancer Biomarker Tests

OVA-1 is an ovarian cancer blood test that is reported to detect ovarian cancer in a pelvic mass. It is an aggregation of five biomarkers, beta 2-microglobulin, apolipoprotein A-1, CA-125, transferrin and transthyretin. The Risk of Ovarian Malignancy Algorithm (ROMA™), is another test which combines the same traditionally proven tumor marker, CA-125, with HE-4, human epididymus protein 4, a relatively new protein marker produced by the over-expression of the gene WFDC2, and associated with epithelial ovarian neoplasia. At the present time, National Government Services does not find either the OVA-1 or the ROMA™ test to be superior in clinical value to the use of CA-125, a mucin family glycoprotein encoded by the MUC 16 gene, and found in over 90% of women with ovarian neoplasia. CA-125 has limited specificity, its use in the evaluation of women with a pelvic mass is covered per the National Coverage Determination (NCD) Tumor Antigen by Immunoassay-CA 125 (CMS Publication 100-3, *National Coverage Determinations (NCD) Manual*, Section 190.28). Broader use as a diagnostic test for symptoms of abdominal and pelvic discomfort remains controversial and non-covered.

At the present time, National Government Services does not find either the OVA-1 or the ROMA™ test to be of proven efficacy in the diagnosis or treatment of ovarian cancer. National Government Services will only allow coverage of CA-125 as allowed by the national coverage decision.

Galectin-3

Galectin-3 is a circulating protein associated with the inflammatory response. Administration of exogenous galectin-3 in animal models is associated with an accelerated rate of cardiac fibrosis. In a presentation given in the Netherlands, the review of galectin-3 levels obtained from over 8000 patients suggested they were “a strong independent predictor of demise or early hospitalization.” The manufacturer has also filed for the expanded indication of a biomarker to identify those patients with diabetes, hypertension, previous myocardial infarction and family members with congestive heart failure who are at increased risk of developing congestive heart failure (CHF). Potential correlation with accelerated renal disease and eclampsia/pre-eclampsia is also reported to be under investigation.

The Galectin-3 assay is an in-vitro diagnostic device that quantitatively measures galectin-3 in serum or plasma via enzyme linked immunosorbent assay. The manual assay was FDA approved in November, 2010. An automated assay and applications for indications other than congestive heart failure are in various stages of the 501k approval process. The manufacturer has contracts with multiple commercial laboratories to provide this service.

Review of the literature suggests that at some point this assay may be found useful in the management of congestive heart failure. Presently, National Government Services considers this assay for CHF patients and similar

assays related to the elaboration of galectin-3 protein to be of an uncertain role in the clinical management of patients. Consequently, it is considered not covered for all indications.

Lipid Profile/Cholesterol Tests

Claims for VLDL and lipoprotein (a) will be denied as not medically necessary, since NCEP recommendations do not include monitoring of VLDL or apolipoprotein levels for treatment of elevated cholesterol as risk factors for coronary and vascular atherosclerosis.

Prostatic acid phosphatase

The clinical accuracy of prostatic acid phosphatase assay is problematic. The assay is not organ specific, and levels measured are influenced by diurnal fluctuations, prostate examinations prior to blood sampling, and enzyme instability (due to pH, temperature and time since blood-drawing) if not handled properly prior to testing. Furthermore, elevated values of radioimmunoassays may not be as interpretable as results when the test is performed by the Roy enzymatic test.

Prostatic acid phosphatase will be denied as not medically necessary for all diagnoses, including Gaucher's disease and osteoporosis.

Quantitative calcium scoring

Quantitative calcium scoring is not a covered service and will be denied as not medically necessary. Calcium scoring reported in isolation is considered a screening service. When performed in association with CT angiography, there is neither separate nor additional included reimbursement for the calcium scoring.

Radiofrequency Treatment for Urinary Incontinence

Radiofrequency energy has been investigated as a technique to shrink and stabilize the endopelvic fascia of the urethra, thus improving the support for the urethra and bladder neck in the treatment of urinary incontinence. Proponents of this service believe that unlike radiofrequency ablation which necroses tissue, radiofrequency micro-remodeling utilizes lower temperatures to denature collagen in microscopic sites, resulting in a change in luminal function (dynamic compliance), but not gross anatomic narrowing or thickening.

At present, the literature and scientific evidence supporting the use of radiofrequency micro-remodeling by a transurethral, transvaginal, or paraurethral approach, (Renessa™ and similar devices) especially for the Medicare population, is insufficient to warrant coverage. These procedures are considered investigational, and are not eligible for coverage for the treatment of urinary incontinence.

ST2 Assay

Soluble ST2 (sST2) (suppression of tumorigenicity 2) is a protein in blood thought to act as a decoy receptor of interleukin-33. Other terms are "growth stimulation expressed gene 2" and "interleukin 1 receptor like-1." Either ST2 or sST2 may be used to indicate the soluble form. ST2 has been found to be induced in cardiac myocytes that have been mechanically overloaded. Onset or worsening of heart failure and scars from myocardial infarction that reduce stretching of the heart are examples of conditions in which ST2 is elevated. (Ciccone et al., 2013) Clinical use as a prognostic indicator for individuals with acute dyspnea and acute or chronic heart failure has been proposed and studied. Shah et al. (2009) studied 134 of 599 dyspneic patients enrolled in the "Pro-BNP Investigation of Dyspnea in the Emergency Department" study. The 134 patients in this study had echocardiography (ECHO) requested by the treating physician. ST2 levels were drawn on admission and correlated with the ECHO findings four years later. Independent risk factors for death were also reviewed. The study population was elderly (69 ± 14 years), overweight (BMI 28 ± 7 kg/m²), evenly divided by gender with a history of hypertension (61%), coronary artery disease (31%), heart failure (37%), obstructive pulmonary disease (27%), and preserved renal function. Acute heart failure was considered the etiology of dyspnea in 66%. The ST2 concentration was significantly correlated with high level ventricular (LV) end-systolic area, LV volume, and end-systolic dimension but not with left-atrial dimension or volume. Patients with higher ST2 levels, stratified by quartile, had incrementally higher risks of death at four (4)

years. Patients who had died, compared to survivors were older, more likely to have a history of heart failure, have used loop diuretics or an angiotensin-converting enzyme inhibitor on presentation, and more likely to have evidence of volume overload on admission chest x-ray, worse renal function, lower hemoglobin concentration, and higher concentrations of NT-proBNP as well as ST2.

Manzano-Ferandez et al. (2011) examined the risk of mortality associated with soluble ST2 levels in patients with acutely decompensated heart failure (HF) whose ejection fraction was preserved (HFpEF). The patients were enrolled in the "Pro-BNP Investigation of Dyspnea in the Emergency Department" study and seen at one of three sites. Blood samples for ST2 measurements in 447 patients were collected at presentation to the emergency department. The ST2 levels were higher (0.55 versus 0.38 ng/ml) in the 250 patients with systolic heart failure than the 197 patients with HFpEF whose ejection fraction was $\geq 50\%$. Mortality at one year showed that ST2 levels were higher in either group for 117 (26%) non-survivors. Values were a median of 0.80 ng/ml with an interquartile range 0.42 – 1.83 for the survivors versus 0.38 ng/ml with an interquartile range of 0.24 – 0.72 for the nonsurvivors ($p < 0.001$).

Lupón et al. (2013) prospectively studied 876 consecutive outpatients followed up in a structured heart failure unit. Levels of ST2 ("high-sensitivity") considered a marker of myocardial fibrosis were obtained as well as those thought to reflect myocardial stretch [N-terminal pro-B-type natriuretic peptide (NT-proBNP)] and myocyte injury [high-sensitivity cardiac troponin T (hs-cTnT)]. Multiple established risk factors for mortality were collected. Median patient age was 70.3 years. During a median follow-up of 41.4 months, 311 (35%) patients died with 168 of the 311 (54%) dying from cardiovascular (CV) disease. Refractory heart failure was the cause for 91 (54.1%), sudden death in 30 (17.8%) and acute myocardial infarction in 15 (8.9%). In multivariate analysis, the three (3) biomarkers remained independent predictors of mortality together with age, NYHA functional class, β -blocker treatment, and hemoglobin level. Reviewing the CV deaths, only the hs-cTnT and the hs-ST2 remained independently associated with CV mortality. However, addition of the NT-proBNP to these levels when they were below cut-off points provided prognostic discrimination. The authors concluded that further studies are needed to confirm whether hs-cTnT and hs-ST2 together without natriuretic peptides can be used for HF risk stratification.

Breidhardt et al. (2013) measured ST2 levels at presentation to the emergency department (ED) and after 48 hours in 207 patients presenting with acute heart failure. Patients were grouped by the decrease in the ST2 levels as responders ($> 25\%$) or non-responders ($< 25\%$). The potential to predict mortality based on the groupings was determined at hospital discharge, six and 12 months. ST2 levels were significantly associated with age, estimated glomerular filtration rate, C-reactive protein levels, serum troponin-T, and leukocyte count but not BNP or hemoglobin levels. Sixteen (8%) of the patients died during hospitalization; 69 (33%) died during the entire study period. Levels of ST2 at ED presentation were significantly associated with mortality (150.0 ng/mL in nonsurvivors vs 73.2 ng/mL in survivors, $p < .01$). Changes over the 48 hours were also different among survivors (median overall decrease of 33% with a median of -25% for nonsurvivors vs. 0.42% for survivors, $p < .01$). The percentage change in the first 48 hours also predicted one year survival. The authors discussed potential correlations between changes in ST2 levels and various drug treatments.

Further investigations may show that ST2 can be a useful prognostic indicator for patient outcomes in CV disease. However, its role in clinical decision making has not been studied and there is no evidence that use of ST2 to guide the management of an individual results in clinically significant improvements in relevant clinical outcomes (for example, mortality or CV event rate) when compared to the current standards of care. Therefore, ST2 assay measurement is not considered "reasonable and necessary" for Medicare beneficiaries.

Surgical Decompression for Peripheral Polyneuropathy

Surgical decompression of multiple lower extremity peripheral nerves such as the posterior tibial nerve at the ankle, deep peroneal nerve on the dorsum of the foot, and both the common peroneal and lateral cutaneous nerve of the calf is being utilized as an alternative approach for the treatment of symptomatic diabetic polyneuropathy by more than 240 surgeons in 41 states and 15 countries. The procedures have been extended to patients with other etiologies of peripheral neuropathy.

The American Academy of Neurology's Therapeutics and Technology Assessment Subcommittee recently issued a Practice Advisory on the Utility of Surgical Decompression for Treatment of Diabetic Neuropathy. (Chaudhry, 2006)

The summary follows:

Abstract: Surgical decompression at the site of anatomic narrowing has been promoted as an alternative treatment for patients with symptomatic diabetic neuropathy. Systematic review of the literature revealed only Class IV studies concerning the utility of this therapeutic approach. Given the current evidence available, this treatment alternative should be considered unproven (Level U). Prospective randomized controlled trials with standard definitions and outcome measures are necessary to determine the value of this therapeutic intervention.

The Subcommittee noted concerns that standard testing for peripheral neuropathy was not included in the studies. It could not be determined whether the positive reported results were due to release of "traditionally compromised nerves as would be determined by electrodiagnostic studies, or the result of treatment of a process that would be considered a symmetric diabetic sensorimotor neuropathy." (Chaudry, 2006)

The International Neuropathy Decompression Registry and the literature report "primary outcomes" of prevention of ulceration, prevention of amputation, prevention of hospitalization for infection, and prevention of falls with hip fracture, all in the decompressed extremity. "Secondary outcomes" are subjective and include relief of pain, restoration of sensation and decrease in medication use. Very few complications and adverse events are reported, although there was a reported 12% wound complication rate in one series of 58 patients. (Chafee, 2000) Any unnecessary surgical procedure on diabetic individuals with potential cardiovascular disease and other complications of diabetes presents an unnecessary risk.

There are currently no accepted indications for the surgical decompression of diabetic, other metabolic or toxic, or idiopathic polyneuropathy. Neither the procedure nor the anesthesia services for the procedure will be considered medically necessary.

Transtelephonic Spirometry

Spirometry is a non-invasive technique that measures the vital capacity, forced expired volume in one second, and rates airflow at various lung volumes. Measurement of the forced vital capacity and corresponding flow rates is the most commonly used test to detect the presence of lung disease and to monitor changes in severity and response to treatment.

Patient-initiated spirometric recording per 30-day period of time includes reinforced education, transmission of spirometric tracing, data capture, analysis of transmitted data, periodic recalibration and physician review and interpretation.

The use of peak flow meters by patients, and their recording and reporting of the results to their physician, has been a standard means of monitoring patients with pulmonary dysfunction at home.

Computerized capture of data and electronic transmission of the results has not been demonstrated to offer additional new benefits to patients in the management of their pulmonary dysfunction.

Transtelephonic spirometry has also been investigated in lung heart-lung transplant recipients who underwent monitoring of lung rejection with home spirometry. The small number of patients studied to date does not permit scientific conclusions regarding the utility of home monitoring in this clinical setting.

Transtelephonic spirometry is considered to be of unproven benefit as there is inadequate evidence that its use will significantly affect the care of lung transplant recipients, asthmatics, and persons with other chronic pulmonary disorders/diseases (e.g., emphysema). These services will be denied as not reasonable and necessary.

Vestibular Autorotation Testing (VAT)

The vestibulo-ocular reflex (VOR) generates eye movements that compensate for head rotations to preserve clear

vision during walking. The VOR is considered the most assessable measurement of vestibular function. Eye movements are measured after applying a vestibular stimulus. Active head rotational testing (AHR) is performed by having the patient rotate the head from side to side horizontally and vertically cued by an auditory stimulus at frequencies from 2 – 6 Hz. Electro-oculography (EOG) is used to record eye movements and a velocity rate sensor attached to the head is used to record head movements. The term “vestibular autorotation test” (VAT) is often used to describe the testing and also serves as the trade name of the Western Systems Research Inc., Pasadena, CA device. Examples of other devices are the Vorteq and another made by Watson Industries using software developed by University of Pittsburg staff. Portable devices allow testing in the non-specialist’s office and in the home.

National Government Services considers vestibular autorotation testing/ active head rotation testing not reasonable and necessary for the diagnosis or treatment of individuals with vestibular or other disorders because the testing has not been shown to be reliable or efficacious.

Following is a summary of studies reviewed:

O’Leary et al (1990) tested 46 volunteers 65 years of age and older using the VAT (Western Systems Research Inc., Pasadena, CA). The goal was to test subjects without vestibular pathology, so only 14 met the selection criteria for final data analyses. The authors stated all subjects easily performed both the horizontal and vertical 18-second tests and results were similar for both older and younger subjects.

Cheung et al. (1996) evaluated 10 subjects aged 25 to 59 years of age using the VAT (Western Systems Research Inc., Pasadena, CA). They were not able to obtain consistent vertical VOR responses. From previous experience they noted that training, up to 12 trials, was necessary before collection of data. Although the horizontal VOR responses were described for frequencies between 2.0 and 4.7 Hz, they concluded that extensive normative data using asymptomatic subjects and data from subjects known to be labyrinthine defective were required to determine the usefulness of this testing.

Furman et al. (1995) reported on 10 asymptomatic healthy adults, using the Watson device. They concluded additional studies were needed to define optimal test parameters and the efficacy of head-only rotation as a clinical tool.

Furman et al. (1998) studied 13 healthy symptomatic elderly subjects, aged 63 to 78, using the Watson device and found responses could not be distinguished from those in younger subjects except that the young had a slightly higher gain at 1 Hz. However, they also noted that the clinical utility of head-only rotation testing had not been firmly established.

Guyot et al. (1997) tested 12 healthy adults, aged 22 to 42 years, using the VAT (Western Systems Research Inc., Pasadena, CA). No subject was able to achieve four or five out of five reproducible results. Statistical analysis showed that the test-retest reliability was poor. The authors concluded the method could not be used routinely to evaluate vestibulo-ocular reflex anomalies. O’Leary (1998) protested that the study was flawed and that use of the device algorithms was sufficiently accurate to detect subtle differences in the VOR from tests performed over a five-week period. Guyot (1998) responded and noted that O’Leary had not provided references for the reliability of the VAT algorithms tested in multiple studies and multiple centers. Furthermore, he wrote that cited references included O’Leary on all but one.

Hirovonen et al. (1999) compared the VOR of 100 healthy subjects measured using the Vorteq and the VAT (Western Systems Research Inc., Pasadena, CA). The results showed intersubject variation which was larger in the higher frequency bands. Both tests produced similar gain results but there were systematic differences in the phase results. Thus, it was concluded the results of the two tests may not be directly comparable.

The American Academy of Neurology (Fife et al, 2000) performed a therapeutics and technology assessment of vestibular testing techniques. It concluded that data was limited for active head rotational testing (AHR) and was not

yet accepted by the authors as an established technique.

Tirelli et al. (2004) tested 16 subjects using the Vorteq. The test-retest results were found not to be sufficiently reliable and thus, not useful for clinical practice.

Ozgirgin et al. (2008) tested 20 patients with posterior semicircular canal benign paroxysmal positional vertigo (BPPV) before and after the Epley maneuver. There were no statistically significant differences before and after treatment.

Blatt et al. (2008) studied 98 patients chosen as a convenience sample from a pool of 280 with reports of dizziness who were referred for vestibular function testing. Forty-nine repeated the test for a second rater. The authors noted the peer-reviewed published literature had not ascertained reliability of head-only rotation testing using the VAT (Western Systems Research Inc., Pasadena, CA) in a patient population when referenced against an established vestibular function test such as the electronystagmographic examination. Subjects were asked to perform six consecutive VAT trials with a full range of head movement frequencies. The manufacturer of the device recommended the trials be repeated until three (3) tests demonstrate repeatability through a relatively small standard deviation. Sixty-six percent (66%) were unable to produce data that met the VAT algorithm criteria to be included in an assessment of reliability which required data at frequencies greater than or equal to 3.9 Hz with coherence values held constant trial to trial. Intra-rater reliability was good for gain independent of the effects of practice but a significant difference was found when the first three trials were compared to the last three. Inter-rater reliability was good for all variables at frequencies less than or equal to 3.9 Hz. The authors noted that many patients had trouble performing the VAT and that stability of results over time is yet to be demonstrated.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

General Information

Associated Information

N/A

Sources of Information

Other Medicare Contractor's Local Coverage Determinations.

National Coverage Determination, CMS Publication 100-3, *National Coverage Determinations (NCD) Manual*, Section 190.28 - Tumor Antigen by Immunoassay-CA 125.

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/28/2019	R14	This LCD was converted to the new "no-codes" format. There has been no change in coverage with this LCD revision.	<ul style="list-style-type: none">• Revisions Due To Code Removal

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/28/2019	R13	<p>Consistent with Change Request 10901, all coding information, National coverage provisions, and Associated Information (Documentation Requirements, Utilization Guidelines) have been removed from the LCD and placed in the related Billing and Coding Article, A57812. There has been no change in coverage with this LCD revision.</p>	<ul style="list-style-type: none"> • Revisions Due To Code Removal
05/01/2019	R12	<p>Correction to IOM chapter in Abstract section: (CMS Publication 100- 02, Chapter <u>16</u>, Section 20)</p> <p>Deleted reference to Serum Iron in ICD-10 section for Pre-operative Testing.</p>	<ul style="list-style-type: none"> • Typographical Error
10/01/2018	R11	<p>Based on a reconsideration request for OVA1/MIA(Multi-Variate Index Assay) testing, sources reviewed have been added to the Sources of Information section of the LCD. No change was made to coverage.</p> <p><i>DATE 10/01/2018: At this time, the 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which require comment and notice.</i></p> <p><i>This revision is not a restriction to the coverage determination; and therefore, not all the fields included are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> • Reconsideration Request
01/01/2018	R10	<p>LCD revised for 2018 HCPCS updates. CPT codes 71010, 71015, 71020-71023, 71030, 71034 and 71035 have been deleted and replaced by CPT codes 71045-71048.</p> <p>CPT code 0003U was added to the CPT/HCPCS code list.</p> <p><i>DATE 01/01/2018: At this time, the 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which require comment and notice.</i></p> <p><i>This revision is not a restriction to the coverage determination; and therefore, not all the fields included are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
03/16/2017	R9	<p>LCD revised to add sources reviewed for a reconsideration request for coverage of apolipoprotein B (apo B). No change in coverage was made.</p> <p>Under CMS National Coverage, the IOM reference for Services Not Reasonable and Necessary was corrected to Chapter 16.</p> <p><i>DATE (10/01/2017): At this time, the 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.</i></p>	<ul style="list-style-type: none"> • Reconsideration Request
03/16/2017	R8	<p>Correction to previous revision history: Under ICD-10 codes that DO NOT support medical necessity for Surgical Decompression, ICD-10 code G60.9 has been added effective 4/1/2017.</p>	<ul style="list-style-type: none"> • Typographical Error
03/16/2017	R7	<p>Under ICD-10 codes that DO NOT support medical necessity for Surgical Decompression, ICD-10 code M60.9 has been added effective 4/1/2017.</p> <p>HCPCS code 0003U has been added to the codes for Combined Ovarian Cancer Biomarker Tests. Sources of Information has been updated to include sources reviewed for a reconsideration request for Combined Ovarian Cancer Biomarker Tests. No change in coverage was made.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Reconsideration Request
11/01/2016	R6	<p>Non-coverage provisions have been added to the LCD under Indications and Limitations, CPT/HCPCS Codes (81500, 81503 and 84999), and Sources of Information and Basis for Decision, for Combined Ovarian Cancer Biomarker Tests. The LCD for these tests has been retired, effective 11/01/2016.</p> <p>Under ICD-10 codes that DO NOT support medical necessity for Surgical Decompression, ICD-10 codes M05.519, M05.529, M05.539, M05.549, M05.559,</p>	<ul style="list-style-type: none"> • Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>M05.569, and M05.579 have been added.</p> <p>References to Serum Iron studies have been removed from the pre-operative testing section in Indications and CMS National Coverage Policy.</p>	
07/01/2016	R5	<p>References to Prostatic Urethral Lift (PUL) have been removed from this LCD under: Indications and Limitations of Coverage, CPT/HCPCS codes, and Sources of Information, and moved to LCD L36601 - Prostatic Urethral Lift (PUL), effective 7/01/2016.</p> <p>Duplicate Revenue codes have been deleted.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
03/01/2016	R4	<p>Non-coverage provisions have been added under Indications and Limitations, CPT/HCPCS Codes, and Sources of Information and Basis for Decision for CPT codes 86152 and 86153 (Circulating Tumor Cell (CTC) Assay) and CPT code 53860 (Radiofrequency Treatment for Urinary Incontinence). The additional provisions for these procedures replace the same provisions in LCDs L33587 and L35054, respectively, that are retired effective 03/01/2016.</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
10/01/2015	R3	<p>08/20/2015 - For the following Revenue Codes the description changed: 0321 descriptor was changed</p>	<ul style="list-style-type: none"> • Provider Education/Guidance
10/01/2015	R2	<p>Sources updated for Reconsideration request for Prostatic urethral lift, received May 2015.</p>	<ul style="list-style-type: none"> • Reconsideration Request
10/01/2015	R1	<p>June 2015: Non-coverage provisions have been added under Indications and Limitations, CPT/HCPCS Codes, and Sources of Information and Basis for Decision for CPT code 82777 (Galectin-3). The additional provisions for Galectin-3 replace the same provisions in the Galectin-3 LCD - L32977 that is retired effective 06/01/2015. No comment and notice periods required and none given.</p> <p>May 2015: Based on a reconsideration request for prostatic urethral lift (PUL), reviewed sources were added to the LCD. No change was made to coverage.</p> <p>Carotid Intima-Media Thickness (CIMT) criteria that were included in the Draft LCD presented in Oct. 2014, have been deleted since, effective January 1, 2015, this service</p>	<ul style="list-style-type: none"> • New/Updated Technology • Reconsideration Request

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>is considered non-covered by Medicare.</p> <p>April 2015: The LCD was returned for comment in the JK and J6 MAC jurisdictions, from October 30, 2014 to December 13, 2014. Non-coverage provisions and CPT codes were added for Carotid Intima Media Thickness (CIMT) and ST2 Assay. Sources reviewed as the basis for non-coverage were added to the LCD including those received during the comment period.</p>	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A57812 - Billing and Coding: Non-Covered Services

Related National Coverage Documents

N/A

Public Version(s)

Updated on 11/21/2019 with effective dates 11/28/2019 - N/A

Updated on 11/21/2019 with effective dates 11/28/2019 - N/A

Updated on 04/18/2019 with effective dates 05/01/2019 - 11/27/2019

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Keywords

N/A