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

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Please note: Future Effective Date.

Contractor Information

Contractor Name  National Government Services, Inc.
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LCD Information

Document Information

FUTURE

L33629

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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 15:

20 Services Not Reasonable and Necessary


20.15 Electrocardiographic Services


70.5 - Hospital and Skilled Nursing Facility Admission Diagnostic Procedures


190.16 Partial Thromboplastin Time (PTT)

190.17 Prothrombin Time (PT)

190.18 Serum Iron Studies

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:**

Printed on 9/21/2015. Page 2 of 17
Items and 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 are not covered. (CMS Publication 100-02, Chapter 15, Section 20).

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;
- Serum iron studies performed as a pre-operative test when there is no indication of anemia or recent autologous blood collections prior to surgery.

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.

**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 (83719) and lipoprotein (a) (82172) 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 (CPT code 84066) will be denied as not medically necessary for all diagnoses, including Gaucher’s disease and osteoporosis.
Prostatic Urethral Lift

On September 13, 2013, the FDA approved the marketing of the UroLift as a permanent implant to relieve low or blocked urine flow in men aged 50 and older with BPH. This procedure is a minimally invasive treatment for benign prostatic hyperplasia (BPH) that mechanically opens the prostatic urethra using tensioned sutures that compress prostate tissue between the urethra and prostate capsule, while maintaining normal prostate and sexual function.

National Government Services considers the PUL a potentially promising treatment for symptomatic prostatic hyperplasia. However, the evidence is of short duration and insufficient to allow the device to be considered “reasonable and necessary.”

Following is a summary of studies reviewed:

Chin et al. (2012) evaluated a prostatic urethral lift (PUL) device placed in 64 men, > 55 years old, with moderate to severe symptomatic benign prostatic hyperplasia treated in six (6) Australian facilities. Effectiveness was evaluated at 2 weeks and 3, 6, 12, and 24 months. The International Prostate Symptom Score (IPPS) decreased 42% in 2 weeks, 49% at 6 months, and 42% at two years. Patients treated early in the study had a 34% decrease at three years. The quality of life score (QOL) score improved from an average of 4.9 at baseline to 2.7 at 2 weeks, and 2.5 at one and two years. The BPH Impact Index (BPHII) decreased 39% at 2 weeks with a 60% reduction at 2 years; these results were statistically significant at each measurement period. Peak flow increased an average amount of ≥ 30% at all intervals. There were no findings of degraded erectile function. Numbers of evaluable patients were not clear although it was noted that the sample size was reduced at 24 months because not all of the patients had reached that point of follow-up. There was no active or sham control group. Twenty percent (20%) (13/64) of the initially treated patients required repeat treatment.

Roehrborn et al. (2013) reported the first randomized trial of a PUL device for treatment of lower urinary tract symptoms (LUTS) secondary to BPH. The patient and questionnaire administrator were blinded to the randomization. Men aged > 50 years with an American Urological Association Symptom Index (AUASI) of > 13, a maximum flow rate of 12 ml/second or less, and a prostate of 30 to 80 cc were randomized 2:1 to PUL or sham. The sham consisted of rigid cystoscopy with sounds mimicking those heard with the PUL placement. At three months, the AUASI reduction was assessed; the primary end point of the study was to have an AUASI reduction of 25% greater than the sham. The PUL subjects were also assessed at one year for LUTS, peak urinary flow rate, quality of life and sexual function. Altogether, 206 men were randomized (140 to PUL, 66 to sham). Patients were evaluated at 1, 3, 6, and 12 months. The PUL patients had an AUASI reduction of 11.1 ± 7.67 whereas the sham patients change was 5.9 ± 7.66 (P = 0.003) at three months. The PUL reduction remained at 12 months. Peak urinary flow was increased 4.4 ml at 3 months and remained at 4.0 ml/second at 12 months (p <0.001). There was no new ejaculatory or erectile dysfunction. Adverse events were described as mild and transient. There was a 5% retreatment rate at one year.

McVary et al. (2013) analyzed the sexual function of the men in the study immediately above. No evidence of degradation in erectile or ejaculatory function after PUL was found.

McNicholas et al. (2013) described the outcomes of 102 men with symptomatic BPH treated at seven centers in five countries. The study was had a single arm and was not blinded. Average age was 68 years, average prostate size was 48 cm3, and average IPPS was 23. Patients were followed at 2 and 6 weeks, and 3, 6, and 12 months postoperatively. The mean IPPS improved 36%, the mean QOL improved 39%, and the maximum flow rate (Qmax) improved by 38% by two weeks. At 12 months observation, these rates of improvement were 52%, 53% and 51% respectively. These results were statistically significant although the postvoid residual volume (PVR) did not show a statistically significant change. There were no reports of retrograde ejaculation. Transurethral resection of the prostate (TURP) occurred in four patients (6.5%). Adverse events were short duration of dysuria (25%), hematuria (16%), and urgency (10%).

Cantwell et al. (2014) conducted a prospective crossover trial of PUL in patients with LUTS due to BPH. Men ≥ 50 years old with an IPPS > 13, a Qmax of <12 ml/s, and a prostate of 30-80 mL were enrolled. The study was prospective, randomized, controlled, “blinded,” and conducted in 19 centers in the USA, Canada, and Australia. Patients underwent a sham procedure with rigid cystoscopy, inability to see the operator or endoscopy imaging, and hearing sounds associated with an operative procedure. Three to six months later the patients were reassessed and a PUL was placed. At entry, there were 66 men; 53 (80%) elected to have the PUL. There was a similar change in the IPPS for both sham and crossover PUL patients at two weeks, but the change continued to increase in the latter group and reached statistical significance at three months. In contrast, the urinary flow rate change was more durable three months after the sham rigid cystoscopy showing a 2.4 ml/s increase in Qmax at 3 months. There was further improvement at 3 months post-PUL which was maintained at 12 months. Improvements in IPPS 3 months post-PUL was 11.1 points or 122% greater than the 3 month post-sham improvement of 5.0 points (P < 0.001). Improvements were similar to those noted in the study by Roehrborn et al. (2013) described above. Clinically and statistically significant improvement in Health Related Quality of Life (HRQL) scores and BPHII post-PUL also occurred. Sexual function was maintained. Adverse events were primarily mild except for two patients who developed urinary retention. One patient progressed to TURP.
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 sST2.

Manzano-Ferandez et al. (2011) examined the risk of mortality associated with soluble ST2 levels in patients with acutely uncomplicated heart failure (HF) whose ejection fraction was preserved (HFP EF). 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 HFP EF whose ejection fraction was ≥ 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 (hsC TnT)]. 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.

Breidthardt 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.

Printed on 9/21/2015. Page 5 of 17
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 (CPT codes 01470, 28035, 64702, 64704, 64708, 64712, 64714, 64722, 64726, 64727) 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 (CPT codes 94014, 94015, and 94016) 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.,
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.

Guyot 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.

Coding Information

Bill Type Codes:

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

011x Hospital Inpatient (Including Medicare Part A)
012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
014x Hospital - Laboratory Services Provided to Non-patients
018x Hospital - Swing Beds
021x Skilled Nursing - Inpatient (Including Medicare Part A)
022x Skilled Nursing - Inpatient (Medicare Part B only)
023x Skilled Nursing - Outpatient
071x Clinic - Rural Health
073x Clinic - Freestanding
074x Clinic - Outpatient Rehabilitation Facility (ORF)
077x Clinic - Federally Qualified Health Center (FQHC)
083x Ambulatory Surgery Center
085x Critical Access Hospital

Revenue Codes:

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

Revenue codes only apply to providers who bill these services to the Part A MAC. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the Part B MAC.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

All revenue codes billed on the inpatient claim for the dates of service in question may be subject to review.

0300 Laboratory - General Classification
0301 Laboratory - Chemistry
0305 Laboratory - Hematology
0306 Laboratory - Bacteriology & Microbiology
0309 Laboratory - Other Laboratory
0321 Radiology - Diagnostic - Angiocardiography
0324 Radiology - Diagnostic - Chest X-Ray
0359 CT Scan - CT - Other
0360 Operating Room Services - General Classification

Printed on 9/21/2015. Page 8 of 17
CPT/HCPCS Codes

**Group 1 Paragraph:** Vestibular autorotation testing (VAT) should be reported with CPT code 92700. (CPT codes 92270, 92542, 92546 and 92547 are not appropriate codes for this procedure.)

For dates of service prior to 01/01/2015, Prostatic Urethral Lift should be reported with CPT code 55899 for Part B claims and C9739 or C9740 for Part A claims. Effective 01/01/2015, these services should be reported with CPT codes 52441 and 52442 for Part B claims.

**Group 1 Codes:**

01470 ANESTHESIA FOR PROCEDURES ON NERVES, MUSCLES, TENDONS, AND FASCIA OF LOWER LEG, ANKLE, AND FOOT; NOT OTHERWISE SPECIFIED

28035 RELEASE, TARSAL TUNNEL (POSTERIOR TIBIAL NERVE DECOMPRESSION)

52441 CYSTOURETHROSCOPY, WITH INSERTION OF PERMANENT ADJUSTABLE TRANSPROSTATIC IMPLANT; SINGLE IMPLANT

52442 EACH ADDITIONAL PERMANENT ADJUSTABLE TRANSPROSTATIC IMPLANT (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

55899 UNLISTED PROCEDURE, MALE GENITAL SYSTEM

64702 NEUROPLASTY; DIGITAL, 1 OR BOTH, SAME DIGIT

64704 NEUROPLASTY; NERVE OF HAND OR FOOT

64708 NEUROPLASTY, MAJOR PERIPHERAL NERVE, ARM OR LEG, OPEN; OTHER THAN SPECIFIED

64712 NEUROPLASTY, MAJOR PERIPHERAL NERVE, ARM OR LEG, OPEN; SCIATIC NERVE

64714 NEUROPLASTY, MAJOR PERIPHERAL NERVE, ARM OR LEG, OPEN; LUMBAR PLEXUS

64722 DECOMPRESSION; UNSPECIFIED NERVE(S) (SPECIFY)

64726 DECOMPRESSION; PLANTAR DIGITAL NERVE

64727 INTERNAL NEUROLYSIS, REQUIRING USE OF OPERATING MICROSCOPE (LIST SEPARATELY IN ADDITION TO CODE FOR NEUROPLASTY) (NEUROPLASTY INCLUDES EXTERNAL NEUROLYSIS)

71010 RADIOLOGIC EXAMINATION, CHEST; SINGLE VIEW, FRONTAL

71015 RADIOLOGIC EXAMINATION, CHEST; STEREO, FRONTAL

71020 RADIOLOGIC EXAMINATION, CHEST, 2 VIEWS, FRONTAL AND LATERAL;

71021 RADIOLOGIC EXAMINATION, CHEST, 2 VIEWS, FRONTAL AND LATERAL; WITH APICAL LORDOTIC PROCEDURE

71022 RADIOLOGIC EXAMINATION, CHEST, 2 VIEWS, FRONTAL AND LATERAL; WITH OBLIQUE PROJECTIONS

71023 RADIOLOGIC EXAMINATION, CHEST, 2 VIEWS, FRONTAL AND LATERAL; WITH FLUOROSCOPY

71030 RADIOLOGIC EXAMINATION, CHEST, COMPLETE, MINIMUM OF 4 VIEWS;

71034 RADIOLOGIC EXAMINATION, CHEST, COMPLETE, MINIMUM OF 4 VIEWS; WITH FLUOROSCOPY
ICD-10 Codes that Support Medical Necessity

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z0000</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

ICD-10 Codes that DO NOT Support Medical Necessity

**Group 1 Paragraph: For pre-operative testing** (Chest X-ray, EKG, Serum Iron):

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z01.30</td>
<td>Encounter for examination of blood pressure without abnormal findings</td>
</tr>
<tr>
<td>Z01.31</td>
<td>Encounter for examination of blood pressure with abnormal findings</td>
</tr>
<tr>
<td>Z01.810</td>
<td>Encounter for preprocedural cardiovascular examination</td>
</tr>
<tr>
<td>Z01.811</td>
<td>Encounter for preprocedural respiratory examination</td>
</tr>
<tr>
<td>Z01.818</td>
<td>Encounter for other preprocedural examination</td>
</tr>
<tr>
<td>Z01.82</td>
<td>Encounter for allergy testing</td>
</tr>
<tr>
<td>Z01.89</td>
<td>Encounter for other specified special examinations</td>
</tr>
</tbody>
</table>

**Group 2 Paragraph: For Surgical Decompression:**

**Group 2 Codes:**

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A52.15</td>
<td>Late syphilitic neuropathy</td>
</tr>
</tbody>
</table>
ICD-10 Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E09.49</td>
<td>Drug or chemical induced diabetes mellitus with neurological complications with other diabetic neurological complication</td>
</tr>
<tr>
<td>E10.49</td>
<td>Type 1 diabetes mellitus with other diabetic neurological complication</td>
</tr>
<tr>
<td>E11.49</td>
<td>Type 2 diabetes mellitus with other diabetic neurological complication</td>
</tr>
<tr>
<td>E13.49</td>
<td>Other specified diabetes mellitus with other diabetic neurological complication</td>
</tr>
<tr>
<td>G13.0</td>
<td>Paraneoplastic neuromyopathy and neuropathy</td>
</tr>
<tr>
<td>G13.1</td>
<td>Other systemic atrophy primarily affecting central nervous system in neoplastic disease</td>
</tr>
<tr>
<td>G60.3</td>
<td>Idiopathic progressive neuropathy</td>
</tr>
<tr>
<td>G60.8</td>
<td>Other hereditary and idiopathic neuropathies</td>
</tr>
<tr>
<td>G61.1</td>
<td>Serum neuropathy</td>
</tr>
<tr>
<td>G61.81</td>
<td>Chronic inflammatory demyelinating polyneuritis</td>
</tr>
<tr>
<td>G62.0</td>
<td>Drug-induced polyneuropathy</td>
</tr>
<tr>
<td>G62.1</td>
<td>Alcoholic polyneuropathy</td>
</tr>
<tr>
<td>G62.2</td>
<td>Polyneuropathy due to other toxic agents</td>
</tr>
<tr>
<td>G62.82</td>
<td>Radiation-induced polyneuropathy</td>
</tr>
<tr>
<td>G63</td>
<td>Polyneuropathy in diseases classified elsewhere</td>
</tr>
<tr>
<td>G65.0</td>
<td>Sequelae of Guillain-Barre syndrome</td>
</tr>
<tr>
<td>G65.1</td>
<td>Sequelae of other inflammatory polyneuropathy</td>
</tr>
<tr>
<td>G65.2</td>
<td>Sequelae of toxic polyneuropathy</td>
</tr>
<tr>
<td>M05.511</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of right shoulder</td>
</tr>
<tr>
<td>M05.512</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of left shoulder</td>
</tr>
<tr>
<td>M05.521</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of right elbow</td>
</tr>
<tr>
<td>M05.522</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of left elbow</td>
</tr>
<tr>
<td>M05.531</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of right wrist</td>
</tr>
<tr>
<td>M05.532</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of left wrist</td>
</tr>
<tr>
<td>M05.541</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of right hand</td>
</tr>
<tr>
<td>M05.542</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of left hand</td>
</tr>
<tr>
<td>M05.551</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of right hip</td>
</tr>
<tr>
<td>M05.552</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of left hip</td>
</tr>
<tr>
<td>M05.561</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of right knee</td>
</tr>
<tr>
<td>M05.562</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of left knee</td>
</tr>
<tr>
<td>M05.571</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of right ankle and foot</td>
</tr>
<tr>
<td>M05.572</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of left ankle and foot</td>
</tr>
<tr>
<td>M05.59</td>
<td>Rheumatoid polyneuropathy with rheumatoid arthritis of multiple sites</td>
</tr>
<tr>
<td>M34.83</td>
<td>Systemic sclerosis with polyneuropathy</td>
</tr>
</tbody>
</table>

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 "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Sources of Information and Basis for Decision

This bibliography presents those sources that were obtained during the development of this policy. National Government Services is not responsible for the continuing viability of Web site addresses listed below.

Printed on 9/21/2015. Page 11 of 17
Sources reviewed as the basis for non-coverage of the prostatic urethral lift


McNicholas T. Editorial: Going with the flow! Relieving lower urinary tract symptoms and preserving ejaculation. BJUI. 2014;518-519.


Sources reviewed for reconsideration request received in December 2014 for prostatic urethral lift:


Hakim LS, Sharlip ID. Letter from Sexual Medicine Society of North America, Inc. dated February 2015


Printed on 9/21/2015. Page 12 of 17
Additional resources reviewed for prostatic urethral lift


Additional sources reviewed for reconsideration request received in May 2015 for prostatic urethral lift:


Sources reviewed as the basis for non-coverage of ST2 Assay:


Sources reviewed as the basis for non-coverage of Vestibular Autorotation Test.


Blue Cross Blue Shield of Alabama policy #329: Vestibular Autorotation Test (VAT). Last reviewed October 2010.


Printed on 9/21/2015. Page 14 of 17


O'Leary DP. Diagnostic Screening with the Vestibular Autorotation Test (VAT). Presented on AudiologyOnline October 2002.


National Government Services LCD for Acid Phosphatase (L25879).

National Government Services LCD for Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA) (L25907).

National Government Services LCD for Lipid Profile/Cholesterol Testing (L27352).

National Government Services LCD for Surgical Decompression for Peripheral Polyneuropathy (L25271).

National Government Services LCD for Transtelephonic Spirometry (L26874).


Sources reviewed as the basis for non-coverage of Galectin-3:


Printed on 9/21/2015. Page 15 of 17


**Revision History Information**

Please note: Most Revision History entries effective on or before 01/24/2013 display with a Revision History Number of "R1" at the bottom of this table. However, there may be LCDs where these entries will display as a separate and distinct row.

<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/2015</td>
<td>R2</td>
<td>Sources updated for Reconsideration request for Prostatic urethral lift, received May 2015. 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.</td>
<td>• Reconsideration Request</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>R1</td>
<td>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. 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 is considered non-covered by Medicare. 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.</td>
<td>• New/Updated Technology • Reconsideration Request</td>
</tr>
</tbody>
</table>

**Associated Documents**

Attachments N/A

Related Local Coverage Documents N/A

Related National Coverage Documents N/A

Public Version(s) Updated on 08/19/2015 with effective dates 10/01/2015 - N/A Updated on 06/08/2015 with effective dates 10/01/2015 - N/A Updated on 04/02/2014 with effective dates 10/01/2015 - N/A