

# SPINAL ULTRASONOGRAPHY

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Table of Contents	Page	Related Policies:
<a href="#">BENEFIT CONSIDERATIONS</a> .....	1	<a href="#">Collagen Crosslinks and Biochemical Markers of Bone Turnover</a>
<a href="#">COVERAGE RATIONALE</a> .....	2	
<a href="#">APPLICABLE CODES</a> .....	2	
<a href="#">DESCRIPTION OF SERVICES</a> .....	2	
<a href="#">CLINICAL EVIDENCE</a> .....	3	
<a href="#">U.S. FOOD AND DRUG ADMINISTRATION CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)</a> .....	7	
<a href="#">REFERENCES</a> .....	8	
<a href="#">POLICY HISTORY/REVISION INFORMATION</a> .....	9	

## INSTRUCTIONS FOR USE

*This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.*

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## BENEFIT CONSIDERATIONS

### Essential Health Benefits for Individual and Small Group:

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

## COVERAGE RATIONALE

**Spinal and paraspinal ultrasonography is proven and medically necessary in newborns and infants for the evaluation of suspected spinal disorders (e.g., congenital cord anomalies, spinal cord tumors, vascular malformations and birth-related trauma).**

**Spinal and paraspinal ultrasonography (including extremities, pelvis, or soft tissues of the head and neck) are unproven and not medically necessary for the following uses:**

- to diagnose and manage spinal pain and radiculopathies
- to guide rehabilitation of neuromusculoskeletal disorders and spinal pain

There is insufficient evidence in the peer-reviewed medical literature to establish the efficacy or clinical value of spinal and paraspinal ultrasonography as a diagnostic tool in the management of back pain, radiculopathies or for monitoring of therapies. The use of ultrasound imaging to guide rehabilitation is under investigation. More research is needed to define the role of rehabilitative ultrasound imaging.

## APPLICABLE CODES

The Current Procedural Terminology (CPT<sup>®</sup>) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT <sup>®</sup> Code	Description
76536	Ultrasound, soft tissues of head and neck (eg, thyroid, parathyroid, parotid), real time with image documentation
76800	Ultrasound, spinal canal and contents
76856	Ultrasound, pelvic (nonobstetric), real time with image documentation; complete
76857	Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (eg, for follicles)
76881	Ultrasound, extremity, nonvascular, real-time with image documentation; complete
76882	Ultrasound, extremity, nonvascular, real-time with image documentation; limited, anatomic specific

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## DESCRIPTION OF SERVICES

Ultrasonography is a noninvasive imaging technique that relies on detection of the reflections or echos generated as high-frequency sound waves are passed into the body. This technique is commonly used for a number of imaging purposes such as investigation of abdominal and pelvic masses, cardiac echocardiography, and prenatal fetal imaging. Less commonly, it has also been applied to detection of spinal and paraspinal disorders.

Spinal ultrasonography has been used to investigate degenerative disc disease to determine whether back pain is a consequence of fissuring or herniation of the gelatinous discs that separate the vertebrae. Spinal ultrasound has also been used in the assessment of injuries to paraspinal ligaments after spinal fractures. Although ultrasonography has limited ability to reveal bone and tissues surrounding bone, it has been studied as a means to assess the posterior ligament complex that contributes to the maintenance of spinal stability

Spinal ultrasonography is also being studied to determine if it can be used to guide rehabilitation of neuromusculoskeletal disorders and back pain. In this application, rehabilitative ultrasound imaging (RUSI) has been used to evaluate motor morphology and function during physical tasks and exercise and to assist in determining which exercise treatment or rehabilitation programs can improve neuromuscular function.

In newborns and infants, various tumors and vascular disorders, especially vascular malformations, can be detected with spinal US. In newborns up to six months of age, spinal cord lesions can be detected with US because the posterior elements are membranous rather than bony. Beyond this age, these elements calcify, reserving magnetic resonance imaging (MRI) for cases where spinal ultrasound is equivocal or has revealed a definite abnormality.

Spinal ultrasonography has also been used for investigation of neonatal spinal dysraphism, a disorder resulting from incomplete closure of the neural tube during gestation. This type of birth defect occurs in approximately 2 per 1000 live births, and the resulting spinal disorders include spinal agenesis, low cord, tethered cord, hydromyelia, diastematomyelia, myelocystocele, and myelomeningocele. Spinal ultrasonography may be used as the primary screening tool, reserving magnetic resonance imaging (MRI) for cases where spinal ultrasound is equivocal or has revealed a definite abnormality.

Compared with computed tomography (CT) and magnetic resonance imaging (MRI), ultrasonography provides less detailed images of bone and the structures within and near bone. However, ultrasonography has the advantages of being simpler, more widely available, requiring no exposure to ionizing radiation, and having less susceptibility to patient movement.

## CLINICAL EVIDENCE

### **Spinal and Paraspinal Ultrasonography**

Evliyao et al. (2003) reported that ultrasonography had 81% sensitivity and 94% specificity for the detection of spinal disorders that included disc disease in at least 70% of patients; however, the study population was poorly characterized and the number and types of disorders detected were not reported.

The largest study of spinal ultrasonography for detection of disc disease was conducted by Berth et al. (2003) who performed magnetic resonance imaging (MRI) and ultrasonography on 119 patients. The diagnostic capability of ultrasonography varied depending on the disc examined, with 46% sensitivity and 91% specificity at the L3/4 level, 83% sensitivity and 65% specificity at the L4/5 level, and 78% sensitivity and 67% specificity at the L5/S1 level. This study could not be evaluated fully since it was published in a German-language journal and only the abstract was available in English.

A study by Leung et al. (2005) evaluated 10 healthy volunteers who underwent ultrasound examination of the cervical spine. Ultrasound images were compared to MRI imaging in 3 subjects. The investigators found that the posterior cervical spine musculature was demonstrated well using ultrasound.

In a study of 12 patients, Moon et al. (2002) reported 77% sensitivity and 83% specificity of ultrasonography for detection of posterior ligament complex injury after traumatic thoracolumbar spinal fracture in adults. Ultrasonography did not reveal deep spinal muscles or facet joints.

Klauser et al. (2005) evaluated the use of contrast agents for color Doppler ultrasound (CDUS) and magnetic resonance imaging (MRI) in the detection of sacroiliitis in 103 consecutive patients with inflammatory low back pain and 30 controls without low back pain. All patients and controls underwent unenhanced and contrast-enhanced CDUS and MRI. The investigators concluded that

enhanced CDUS was significantly better than unenhanced CDUS for the diagnosis of sacroilitis verified by MRI.

### **Professional Societies**

**American Chiropractic Association (ACA):** The ACA ratified the following policy in May 1996, titled Diagnostic Ultrasound of the Adult Spine, and this position has not been updated: "Diagnostic Ultrasound has been shown to be a useful modality for evaluating certain musculoskeletal complaints. Fetal, pediatric and intraoperative applications have been published in the scientific literature. The quality of ultrasound images is extremely dependent on operator skill. The resolution abilities of the equipment may have an impact on diagnostic yield and accuracy. Consequently, the importance of training to establish technologic as well as interpretive competency cannot be understated. The application of diagnostic ultrasound in the adult spine in areas such as disc herniation, spinal stenosis and nerve root pathology is inadequately studied and its routine application for these purposes cannot be supported by the evidence at this time.

**American Institute of Ultrasound in Medicine (AIUM):** A 2007(**Updated 2012**) practice guideline states that the indications for sonography of the neonatal spinal canal and its contents include visible stigmata known to be associated with congenital cord anomalies that lead to dysraphic anomalies and tethering of the cord, such as midline masses, skin discolorations, skin tags, hair tufts, and hemangiomas and pinpoint midline or paramedian deep dimples often associated with hyperpigmentation or hypertrichosis indicative of a dorsal dermal sinus tract. The spectrum of caudal regression syndrome, including anal atresia and cloacal extrophy, may be associated with cord anomalies and constitutes an established indication for sonography.

The guideline lists the following indications for ultrasound examination of the neonatal spine:

- Detection of sequelae of injury (e.g., hematoma after spinal tap or birth injury; post-traumatic leakage of cerebrospinal fluid; and sequelae of prior instrumentation, infection, or hemorrhage).
- Evaluation of suspected defects such as cord tethering, diastematomyelia, hydromyelia, and syringomyelia.
- Guidance for lumbar puncture.
- Lumbosacral stigmata known to be associated with spinal dysraphism.
- Post-operative assessment for cord retethering.
- Spectrum of caudal regression syndrome (e.g., anal atresia or stenosis; sacral agenesis).
- Visualization of fluid with characteristics of blood products within the spinal canal in neonates and infants with intra-cranial hemorrhage.

Other than evaluation of spina bifida aperta, there are no contraindications to this examination. Infants with simple, low-lying sacrococcygeal dimples typically have normal spinal contents, and in this group of patients, the examination is of low yield.

**American College of Radiology (ACR):** The ACR Practice Guideline for the Performance of an Ultrasound Examination of the Neonatal Spine (Updated 2011) states that the following indications/contraindications for neonatal spinal ultrasound:

- indicated for visible stigmata known to be associated with congenital cord anomalies that lead to dysraphic anomalies and tethering of the cord, such as midline masses, skin discolorations, skin tags, hair tufts, or hemangiomas; or pinpoint midline or paramedian deep dimples often associated with hyperpigmentation or hypertrichosis indicative of dorsal dermal sinus tract. The spectrum of caudal regression syndrome, including anal atresia and cloacal extrophy, may be associated with cord anomalies, and constitutes an established indication for sonography. Ultrasonography is also used to detect sequelae of injury, such as hematoma following spinal tap or birth injury, or leakage of central spinal fluid (CSF). Ultrasound can also visualize blood products within the spinal canal in patients with intracranial hemorrhage

- ultrasound is not indicated to visualize the neural placode and meninges in patients with spina bifida aperta and meningocele or meningomyelocele due to the risk of injury and infection. However, it may be useful postoperatively in evaluation of cord retethering and associated defects, such as diastematomyelia, hydromyelia, and syringomyelia. Other than evaluation of spina bifida aperta, there are no contraindications to this examination. Infants with simple, low-lying sacrococcygeal dimples typically have normal spinal contents, and in this group of patients the examination is of low yield.
- The guideline states, “in experienced hands, ultrasound of the infant spine has been demonstrated to be an accurate and cost-effective examination that is comparable to MRI for evaluating congenital or acquired abnormalities in the neonate and young infant.”

### **Rehabilitative Ultrasound**

Interest in rehabilitative ultrasound imaging (RUSI) of the posterior paraspinal muscles is growing, along with the body of literature to support integration of this technique into routine physical therapy practice. This clinical commentary review (Hides, 2007), shows RUSI can be used as an evaluative and treatment tool and proposes guidelines for its use for the posterior muscles of the lumbar and cervical regions. Measurement of morphological characteristics of the muscles (morphometry) in healthy populations and people with spinal pathology are described. Further investigation of many of these observations is required using controlled studies to provide conclusive evidence that RUSI enhances clinical practice.

Rehabilitative ultrasound imaging has been used to explore the neurophysiologic mechanisms of interventions e.g., spinal manipulation used in the treatment of common spine-related disorders (Brenner, 2007; Raney, 2007). The associations between variances in muscle morphology and their role in the etiology and/or persistence of spinal complaints are largely unknown (Fernandez-de-las-Penas, 2008).

There are conflicting conclusions from systematic reviews about the reliability of ultrasound imaging. Hebert, et al (2009) determined that there is good reliability of ultrasound imaging within the majority of research studies that measured the abdominal and lumbar trunk muscles. The levels of reliability were influenced by several factors: operator experience; measurement targets (measures of muscle thickness were more reliable than cross-sectional area); and calculation methodology (a mean of measures was more reliable). In another recent systematic review Costa, et al (2009) concluded, “The current evidence of the reproducibility of RUSI [rehabilitative ultrasound imaging] for measuring abdominal muscle activity is based mainly on studies with suboptimal designs and the study of people who were healthy.” The authors highlighted a lack of studies investigating the reproducibility of muscle thickness changes and differences in thickness changes over time as a key limitation of existing research on the reliability of ultrasound imaging for assessing the abdominal wall muscles. In addition to systematic reviews on the reliability of rehabilitative ultrasound imaging, questions about the influence of gender, body mass index, posture, hand dominance, and different populations on muscle morphology remain unclear (Stokes, 2006; Teyhen, 2006).

The clinical utility of spinal ultrasound imaging has received preliminary investigation. Whittaker (2006) outlined challenges of accurate interpretation, hurdles with comparing imaging studies over time, and in generating reliable and meaningful measurements in a clinical environment. Hodges (2006) commented on the consideration of spinal ultrasound imaging from a patient-centered perspective, “...whether rehabilitative ultrasound imaging measures contribute to prediction of those who benefit from an intervention, and whether changes in rehabilitative ultrasound imaging measures with intervention are associated with positive clinical outcomes. An additional consideration is whether feedback provided using rehabilitative ultrasound imaging improves clinical outcomes. Although a number of studies have confirmed that treatments that include rehabilitative ultrasound imaging lead to better outcomes than control interventions, these studies have not compared the same exercise interventions with and without feedback from rehabilitative ultrasound imaging.” A cross-sectional study (Hebert, 2010) provided preliminary

evidence that supports the construct validity of factors predictive of successful clinical outcomes and muscular activation via a stabilization exercise program monitored with ultrasound imaging. This study was limited by the lack of longitudinal follow-up and small sample size.

### **Professional Societies**

Neither the American Academy of Neurology nor the American Chiropractic Association, in published position statements, advocates the use of spinal ultrasound to manage patients with back pain and radicular disorders.

**American Academy of Neurology (AAN):** The AAN's Therapeutics and Technology Assessment (TTA) Subcommittee developed a statement on spinal ultrasound based on a search of the published literature for any studies involving the use of ultrasound for diagnosis of back pain and radicular disorders. This search did not yield any studies, and therefore the AAN stated that ultrasound cannot be recommended for use in the clinical evaluation of patients with back pain or radicular symptoms. The AAN obtained a statement from the American College of Radiology that indicates that while ultrasound is appropriately used intra-operatively and in newborns and infants for the evaluation of the spinal cord and canal, there is currently no documented evidence of the effectiveness of this modality in the evaluation of the spine and paraspinal tissues in adults. (AAN, Updated 2010)

**The American Institute of Ultrasound in Medicine (AIUM):** In the AIUM's 2009 official statement, the AIUM states that, at this time, the use of non-operative spinal/paraspinal ultrasound in adults (for study of intervertebral discs, facet joints and capsules, central nerves and fascial edema, and other subtle paraspinal abnormalities) for diagnostic evaluation, for screening, diagnostic evaluation, including pain or radiculopathy syndromes, and for monitoring of therapy has no proven clinical utility.

Nonoperative spinal/paraspinal ultrasound in adults should be considered investigational. The AIUM urges investigators to perform properly designed research projects to evaluate the efficacy of these diagnostic spinal ultrasound examinations.

### **Ultrasonography of Other Sites to Diagnose Spinal Pain**

Evidence regarding the use of ultrasound to diagnose back pain or the underlying etiology/pathology of back pain based on ultrasound examination of musculoskeletal or soft tissues of the head, neck, or of an extremity is too limited to draw a conclusion regarding the efficacy or clinical utility of ultrasound for this application.

### **Head and Neck**

Shiri et al. (2007) explored the association between carotid intima-media thickness and low back pain, using high-resolution B-mode ultrasound to measure the intima of the right carotid artery in 1386 individuals. Patient interviews were conducted to gather historical data of known spinal conditions, and to acquire a severity rating of sciatica, prior to clinical examinations. The researchers found carotid intima-media thickness was associated with continuous radiating low back pain and with a positive unilateral clinical sign of sciatica in men only. Carotid intima thickness was not found to be associated with local low back pain. Results of this study suggest that sciatica may be a manifestation of atherosclerosis, or both conditions may share common risk factors. This study did not demonstrate that ultrasound can identify the underlying pathology for sciatica in these patients.

The Work Loss Data Institute's clinical practice guideline on "Neck and upper back (acute & chronic)" (2011) listed diagnostic ultrasound as one of the interventions that was considered, but was not recommended.



## **Extremities**

A comparative, cross-sectional study evaluated quantitative ultrasound (QUS) of the calcaneus for predicting degenerative changes in the lumbar spine in 117 patients with low back pain or pain in the lower extremity. Ultrasound parameters (i.e., speed of sound, broadband ultrasound attenuation, stiffness) of the calcaneus were compared with evidence of degenerative changes and stenosis that was found on magnetic resonance scans of the spine. Lumbar spine stenosis was associated with elevated calcaneus QUS "speed of sound." Narrowing of the lumbar spine dural sac was detected by QUS (89% sensitivity and 75% specificity) in males aged > 60 years. Significant correlation was also found between QUS (speed of sound and stiffness) and intervertebral disc degeneration. These findings suggest that in some patients, ultrasound examination of the calcaneus may indicate the presence of lumbar spine stenosis and/or disc degeneration. (Mariconda, 2004)

## **Additional Search Terms**

dorsal dermal sinus, laminectomy, lipoma, lipomyelocele, myelography, neoplasm, pseudoarthrosis, scar tissue, spondylolisthesis, syrinx

The clinical evidence was reviewed in June 2014 with no additional information identified that would change the conclusion.

## **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

The use of musculoskeletal ultrasound to diagnose low back pain is a procedure and, as such, is not regulated by the FDA. However, the devices used to perform this procedure are regulated by the FDA and a number of ultrasound devices and probes have received FDA approval for marketing. Examples for which "musculoskeletal" is listed as an intended use include:

- MyLab30™ System (K071996) approved on August 3, 2007
- SONOLINE G20™ Diagnostic Ultrasound System (K071314) approved on May 22, 2007
- SonoSite Maxx™ Series Ultrasound Systems (K071134) approved on May 8, 2007
- DP-9900 Digital Ultrasonic Diagnostic Imaging System (K070526) approved on March 23, 2007
- Ultrasound Scanner Pro Focus, Model 2202 (K070077) approved on March 5, 2007

Additional information, under product code IYO (subsequent product codes IXT and IYN), is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnmn.cfm> Accessed June 16, 2014.

## **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) which specifically addresses spinal and paraspinal ultrasonography as a diagnostic tool in the management of back pain, radiculopathies; or for guiding the rehabilitation of neuromusculoskeletal disorders and spinal pain. Medicare covers specific medically appropriate ultrasound diagnostic procedures. For the list of covered ultrasound procedures and coverage guidelines, refer to the NCD for [Ultrasound Diagnostic Procedures \(220.5\)](#).

Local Coverage Determinations (LCDs) exist. Refer to the LCDs for [Dysphagia/Swallowing Diagnosis and Therapy](#), [Nerve Blocks for Peripheral Neuropathy](#), [Nonvascular Extremity Ultrasound](#), [Non-Vascular Extremity Ultrasound](#), [Post-Void Residual Urine and/or Bladder Capacity by Ultrasound](#), [Radiology: Nonobstetric Pelvic Ultrasound](#), [Ultrasound of the Spine](#) and [Ultrasound, Soft Tissues of Head and Neck](#).

(Accessed June 18, 2014)

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**POLICY HISTORY/REVISION INFORMATION**

Date	Action/Description
09/01/2014	<ul style="list-style-type: none"> <li>• Reorganized policy content</li> <li>• Added benefit considerations language for <i>Essential Health Benefits for Individual and Small Group plans</i> to indicate:                             <ul style="list-style-type: none"> <li>○ For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)</li> <li>○ Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-</li> </ul> </li> </ul>

Date	Action/Description
	<p>Grandfathered plans</p> <ul style="list-style-type: none"> <li>○ The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage</li> <li>● Updated coverage rationale; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement</li> <li>● Updated supporting information to reflect the most current CMS information and references</li> <li>● Archived previous version 2013T0462I</li> </ul>