

Cigna Medical Coverage Policy- Therapy Services Spinal Ultrasound

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GUIDELINES

Medically Necessary

Spinal ultrasound is considered medically necessary for ANY of the following indications:

- use during spinal or paraspinal surgery
- evaluation of lumbosacral stigmata known to be associated with spinal dysraphism (e.g., atypical deep sacral dimple > 5 mm in diameter within > 2.5 cm of the anus)
- diagnosis of suspected spinal cord tumors, vascular malformations and birth-related trauma in newborns and infants

Experimental, Investigational, Unproven

Diagnostic ultrasound of the spine and/or paraspinal tissues is considered experimental, investigational or unproven for ANY other indication, including but not limited to:

- evaluation of neuromusculoskeletal conditions (e.g., intervertebral discs, facet joints and capsules, central nerves and fascial edema, paraspinous abnormalities, pain or radiculopathy syndromes, monitoring of therapy)
- diagnosis and management of spinal pain and radiculopathy

- guidance of the rehabilitation of neuromusculoskeletal disorders and back pain
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DESCRIPTION

This guideline addresses the use of spinal ultrasound as a tool for increased visualization during surgery and for diagnosing certain spinal conditions.

GENERAL BACKGROUND

Ultrasound, or sonography, consists of the sending of sound waves through the body. No ionizing radiation (i.e., x-ray) is involved in ultrasound imaging. Spinal ultrasound is proposed for intraoperative use and use in newborns. The use of spinal ultrasound as a diagnostic tool in the diagnosis of neuromusculoskeletal conditions has not been adequately studied. There is insufficient evidence in the peer-reviewed medical literature establishing the value of nonoperative spinal/paraspinal ultrasound in adults.

Intraoperative Use

Reliable intraoperative display of spinal lesions began in the early 1980s with B-mode ultrasonography. Now, real-time method sonography allows dynamic examinations. Extended field of view is now obtained as algorithms combine several individual images into one panoramic image. The ease of use and transportability of ultrasound allows for intraoperative applications over conventional imaging machinery. Endotransducers fit into the working channel of an endoscope. Three-dimensional (3-D) reconstruction and display promotes better anatomical viewing. Intramedullar and extramedullar processes can be localized by sonography because of their echogenicity (e.g., astrocytomas, ependymomas, meningiomas, and cavernomas). Not only solid processes but also cysts or a syrinx are shown as anechoic structures in the B-image. The advantages of intraoperative sonography are its true real-time information and the addition of Doppler, which provides hemodynamic information, and power or color, which provides a display of vascularity/perfusion.

Use in Newborns and Infants

In newborns and infants, various tumors and vascular disorders, especially vascular malformations, can be detected with spinal US. Ultrasound provides an easier and safer imaging experience for newborn and parent than conventional imaging such as x-ray. 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. Early evaluation and differentiation of spinal dysraphism (i.e., neural tube defects) is possible. Spinal dysraphism may include myelocoele, meningocele, myelomeningocele, and spina bifida. Spina bifida may be associated with various cutaneous abnormalities, such as lipoma, hemangioma, cutis aplasia, dermal sinus, or hairy patch, and it is often associated with a low-lying conus and other spinal cord anomalies. Spinal US 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.

Spinal ultrasound is used in diagnosing occult and non-occult spinal dysraphism (SD), evaluating spinal cord tumors and vascular malformations and in cases of birth-related trauma. SD, the most common congenital abnormality of the central nervous system, covers a spectrum of congenital disorders. Spinal ultrasound can be used as a screening test to detect occult SD in neonates with either SD-associated syndromes, such as anorectal and urogenital malformations, including the VATER group (i.e., vertebral defects, anal atresia, tracheoesophageal fistula, radial defects and renal anomalies) or cutaneous markers (e.g., atypical dimples, skin tag or tail, hemangiomas, hairy patches). Simple single sacral midline dimples in the skin are those overlying the coccyx, which have a visible intact base and are < 5 millimeters (mm) in diameter. This type of dimple is usually benign with little or no clinical significance (McKee-Garrett, 2016). In contrast, sacral dimples that are deep and large (i.e., > 0.5 cm), are associated with a high risk of occult SD. These atypical dimples include those in which the base of the dimple is not seen, that are located > 2.5 centimeter (cm) above the anus, or those seen in combination with other cutaneous stigmata. Infants with simple midline dimples of < 5 mm in diameter within 2.5 cm of the anus do not need spinal ultrasound (McKee-Garrett, 2016; American College of Radiology [ACR], 2016).

Diagnostic Ultrasound for the Spine

Diagnostic ultrasound (DUS; also called sonography or ultrasonography) for the evaluation of neuromusculoskeletal conditions involves the use of a device in which sound waves create images of different bodily tissues. Recently, its use has expanded by some practitioners to include evaluating soft tissue injuries and their rate of healing (i.e., response to care). Proponents for using DUS to diagnose neuromusculoskeletal disorders claim it is an important adjunct to all practitioners treating musculoskeletal conditions. They recognize that DUS does not image pathology of the spinal canal or its contents. However, DUS capabilities are postulated to apply to all muscles, tendons, ligaments, and periarticular soft tissue within view of sonogram and not obscured by bony or other hard surfaces. Proponents believe this ability to accurately visualize, and more specifically identify trauma and pathology involving soft tissues, helps establish the etiology of pain or pain syndromes.

Diagnostic ultrasound is an operator-dependent imaging modality, requiring both detailed knowledge of three-dimensional anatomy, and considerable understanding of the appropriate transducer frequency and orientation for optimal and reliable evaluation of the structures in the anatomic region of interest. It is a very difficult modality to perform and requires highly-qualified doctors to interpret.

“Low-end” ultrasound machines are currently being marketed to health care practitioners. Much of the published data in the indexed literature on musculoskeletal ultrasonography uses “high-end” ultrasound equipment. The cost difference ranges from machines priced at approximately \$15,000-30,000 versus \$200,000-250,000 machines. It appears that the prime focus of these DUS machines is their claim to “image pain,” “diagnose nerve root and facet inflammation,” and diagnose virtually any other paraspinal and/or intraspinal abnormality. These claims are unproven at the current time. The mainstream scientific or clinical literature does not support the opinion that these structures can be reliably visualized with any (low-end or high-end) ultrasound equipment.

Applications of diagnostic ultrasound in the musculoskeletal system have expanded to include diagnosing nearly all soft tissue problems as well as some bone abnormalities. Ultrasound of the muscles and tendons of the extremities has received attention in the literature, and it appears that ultrasound might be useful as a noninvasive modality for the qualitative evaluation of these muscles and tendons.

Pate (2003) states that the limitations of ultrasound imaging are important considerations; as with any imaging modality, the limitations are due to the physics involved in acquiring the images.

- Because ultrasound is based on waves reflected by air or gas, it is not an imaging modality that can be used to examine the bowel.
- Ultrasound has difficulty penetrating bone; therefore, it can only demonstrate the very outer surface of the bony structures, not what lies within or beyond. Computerized tomography (CT) and magnetic resonance imaging (MRI) are far better modalities when it comes to evaluating osseous and soft-tissue structures around osseous structures (e.g., the spine).
- Ultrasound resolution is still limited, and there are many situations in which even x-rays produce a more diagnostic image.
- The interpretation of ultrasound images requires highly skilled specialists, especially for complicated procedures.

LITERATURE REVIEW

Intraoperative Use

Although consisting of small case series, evidence in the peer-reviewed scientific literature supports the use of intraoperative spinal ultrasound. Examples of applications include:

- provides well-defined B-mode sonographic images of the spinal cord and spinal lesions in real time during surgery (Hara, et al., 2001)
- gives reliable diagnosis of intraspinal tumors, allowing the distinction between intra- and extramedullary tumors through their respective signal characteristics (Regelsberger, et al., 2005)
- useful during surgery for spinal tumors in order to reduce the extent of the laminectomy, dural opening and myelotomy (Maiuri, et al., 2000)

- yields information that guides aggressive surgical treatment of intradural spinal arachnoid cysts (Wang, et al., 2003)
- provides immediate assessment of blood flow in surgical closure of spinal arteriovenous fistula (Iacopino, et al., 2003)
- useful when collecting biopsies or resecting intramedullary tumors not visible on the surface of the medulla (Unsgaard, et al., 2006)
- useful for evaluating spinal cord decompression status during laminoplasty (Mihara, et al., 2007)
- for guiding regional anesthesia in infants and children (Tsui, et al., 2010)

Use in Newborns and Infants

The evidence in peer-reviewed, scientific literature consists primarily of individual case studies. A retrospective study evaluated the role of spinal ultrasound in detecting occult spinal dysraphism (OSD) in neonates and infants, and the degree of agreement between US and MRI findings (Hughes, et al., 2003). Eighty-five consecutive infants had spinal US over 31 months. Of these, 15 patients (mean age 40 days) had follow-up MRI. Six out of 15 (40%) ultrasound examinations showed full agreement with MRI, 47% had partial agreement, and 13% had no agreement. US failed to visualize four of four dorsal dermal sinuses, three of four fatty filum terminales, one of one terminal lipoma, two of four partial sacral agenesis, three of four hydromyelia and one of 10 low-lying cords. The authors reported that agreement between US and MRI was good, particularly for the detection of low-lying cord (90%) and recommends US as a first-line screening test for OSD. Additionally, if the US is abnormal, equivocal or technically limited, MRI is advised for full assessment. The American College of Radiology (ACR) Practice Guideline for the Performance of an Ultrasound Examination of the Neonatal Spine (2007; 2016) was developed collaboratively by the ACR the American Institute of Ultrasound in Medicine (AIUM), the Society for Pediatric Radiology (SPR), and the Society of Radiologists in Ultrasound (SRU). 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." According to the ACR, indications for ultrasonography of the neonatal spinal canal and its contents include, but are not limited to the following:

- lumbosacral stigmata known to be associated with spinal dysraphism, including but not limited to: midline or paramedian masses, skin discolorations, skin tags, hair tufts, hemangiomas, pinpoint midline dimples, paramedian deep dimples
- the spectrum of caudal regression syndrome, including patients with sacral agenesis and patients with anal atresia or stenosis
- evaluation of suspected defects such as cord tethering, diastematomyelia, hydromyelia, syringomyelia
- detection of sequelae of injury, such as: hematoma following birth injury, infection or hemorrhage due to prior instrumentation, post-traumatic leakage of cerebrospinal fluid
- visualization of blood products within the spinal canal in patients with intracranial hemorrhage
- guidance for lumbar puncture
- postoperative assessment for cord re-tethering

"Contraindications include preoperative examination in patients with open spinal dysraphism and examination of the contents of a closed neural tube defect if the skin overlying the defect is thin or no longer intact" (ACR, 2007; 2016).

Diagnosis of Spinal Conditions

The use of spinal ultrasound as a diagnostic tool in the diagnosis of neuromusculoskeletal conditions has not been adequately studied, and its application for these purposes is not supported in the published, peer-reviewed scientific literature. A review of the literature found some evidence supporting the use of DUS to evaluate certain musculoskeletal conditions and little evidence supporting DUS for the evaluation of the spine and related structures. There is little evidence that DUS information improves clinical outcomes or changes treatment planning decisions made possible by currently established diagnostic procedures.

Howie et al. (1983) found ultrasonography to be unreliable in identifying spinal cord and nerve root compression when compared to surgical findings. Merx et al. (1989) found DUS was inconclusive in 18% of patients examined and revealed a sensitivity in identifying disc herniations that varied from 63-77%. The authors concluded that their sensitivity level was too low to support the use of DUS in the evaluation of lumbar disc disease. The

American Chiropractic Association (ACA) ratified a related policy in May 1996, titled “Diagnostic Ultrasound of the Adult Spine”, and this position has not been updated since. It states this: “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.”

No indexed literature was found by Barry et al. (1996) describing a paraspinal method (a technique that has been promoted by the equipment manufacturers to the chiropractic profession) for evaluating spinal canal stenosis or disc herniation, and only one article (Kamei et al., 1990) using paraspinal transducer placement for identifying the level of disc herniation. A study by Nazarian et al. (1998) evaluated the ability of paraspinal ultrasonography to identify abnormal echogenicity in patients with cervical or lumbar back pain, or both. They concluded that paraspinal ultrasonography is neither accurate nor reproducible in evaluating patients with cervical and lumbar back pain. The joint clinical practice guideline by the American College of Physicians (ACP) and the American Pain Society (APS) (Chou, et al., 2007; Chou, et al., 2008) states that for the diagnosis and treatment of low back pain, “clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain;” noting that “prompt work-up with MRI or CT is recommended in patients who have severe or progressive neurologic deficits or are suspected of having a serious underlying condition (e.g., vertebral infection, the cauda equina syndrome, or cancer with impending spinal cord compression) because delayed diagnosis and treatment are associated with poorer outcomes.”

The Official Statement of the American Institute of Ultrasound in Medicine (AIUM) as noted in a document titled “Nonoperative Spinal/Paraspinal Ultrasound in Adults” (2019) states that, “There is insufficient evidence in the peer-reviewed medical literature establishing the value of nonoperative spinal/paraspinal ultrasound in adults for diagnostic evaluations of conditions involving the intervertebral disks, facet joints and capsules, and central nerves. Therefore, the AIUM states that, at this time, the use of ultrasound in diagnostic evaluations, screening, or monitoring of therapy for these conditions has no proven clinical utility and should be considered investigational. Ultrasound may, however, be used as a guidance modality for certain spinal injections.” The AIUM urges investigators to perform properly designed research projects to evaluate the efficacy of these diagnostic spinal ultrasound examinations. Heidari et al. (2015) completed a study on the role of ultrasound in the diagnosis of low back pain. They note that while earlier research focuses on spinal canal diameter, most recent studies have investigated its role in the evaluation of the deep abdominals and spinal stabilizers on core stability (thickness and activation). Authors state that well-controlled, prospective studies demonstrated that although spinal canal size might be a risk factor for LBP, ultrasound measurement of spinal canal size has no practical role in prediction and/or estimation of the prognosis of LBP, neither in workers nor in general population. With regards to the paraspinal muscles, diagnostic US to evaluate thickness, quality and contraction quality isn’t consistently related to low back pain complaints. There is variability that exists within the healthy population that restricts utilization of findings to diagnose low back conditions. Authors feel that focusing more on transabdominal muscle thickness can be considered as a future approach in investigation; however in most research, this is considered rehabilitative ultrasound vs. diagnostic.

To that point, research on size and composition of multifidi and paraspinal musculature has increased. Ranger et al. (2017) completed a systematic review on the size and composition of the paraspinal muscles associated with low back pain because evidence prior has been conflicting. Of the 119 studies identified, 25 met the inclusion criteria. Eight studies were reported as having low to moderate risk of bias. There was evidence for a negative association between cross-sectional area (CSA) of multifidus and LBP, but conflicting evidence for a relationship between erector spinae, psoas and quadratus lumborum CSA and LBP. Moreover, there was evidence to indicate multifidus CSA was predictive of LBP for up to 12 months in men, but insufficient evidence to indicate a relationship for longer time periods. While there was conflicting evidence for a relationship between multifidus fat infiltration and LBP, there was no or limited evidence for an association for the other paraspinal musculature. Authors concluded that there is evidence that multifidus CSA was negatively associated with and predictive of LBP, up to 12 months but conflicting evidence for an association between erector spinae, psoas and quadratus lumborum CSA, and LBP. There is a need for high quality cohort studies which extend over both the short and longer term.

The American Academy of Neurology's (AAN) Therapeutics and Technology Assessment Subcommittee developed a statement on spinal ultrasound (1998, reaffirmed July 2016) in response to numerous inquiries from neurologists questioning the utility of spinal ultrasound in evaluating back pain and radicular disorders. After conducting a literature search and collecting expert opinion, the AAN concluded that it could not recommend the procedure for use in the clinical evaluation of such patients. As part of the AAN's 1998 research and included in the AAN's 1998 document, the American College of Radiology (ACR) submitted the following adopted statement on spinal ultrasound:

“Over the past several years interest has developed in the use of ultrasound technology for the evaluation of the spine and paraspinal regions in adults. While diagnostic ultrasound is appropriately used:

1. intraoperatively;
2. in the newborn and infants for the evaluation of the spinal cord and canal; and
3. for multiple musculoskeletal applications in adults, there is currently no documented scientific evidence of the efficacy of this modality in the evaluation of the paraspinal tissues and the spine in adults.”

The AAN concluded “currently, no published peer reviewed literature supports the use of diagnostic ultrasound in the evaluation of patients with back pain or radicular symptoms. The procedure cannot be recommended for use in the clinical evaluation of such patients.”

Todorov et al. (2018) questioned the possible diagnostic application of US in LBP through a review of the literature on the diagnostic value of US in different conditions that could cause LBP. In summary, they conclude that the evidence for the diagnostic value of US is not equivocal, though promising for some of the causative conditions, and this area remains open to further research.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®*	Description
76800	Ultrasound, spinal canal and contents

ICD-10-CM Diagnosis Codes	Description
C41.2	Malignant neoplasm of vertebral column
C70.1	Malignant neoplasm of spinal meninges
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
D32.1	Benign neoplasm of spinal meninges
D33.4	Benign neoplasm of spinal cord
G90.1	Familial dysautonomia [Riley-Day]
P11.5	Birth injury to spine and spinal cord
Q05.0- Q05.9	Spina bifida
Q06.0- Q06.9	Other congenital malformations of spinal cord
Q07.00- Q07.03	Arnold-Chiari syndrome

Q07.8	Other specified congenital malformations of nervous system
Q27.9	Congenital malformation of peripheral vascular system, unspecified
Q67.5	Congenital deformity of spine
Q76.0	Spina bifida occulta
Q76.3	Congenital scoliosis due to congenital bony malformation
Q76.425	Congenital lordosis, thoracolumbar region
Q76.426	Congenital lordosis, lumbar region
Q76.427	Congenital lordosis, lumbosacral region
Q76.428	Congenital lordosis, sacral and sacrococcygeal region
Q76.429	Congenital lordosis, unspecified region
Q82.6	Congenital sacral dimple

Considered Experimental/Investigational/Unproven:

ICD-10-CM Diagnosis Codes	Description
	All other codes

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