Clinical Practice Guideline: **Spinal Ultrasound**

Date of Implementation: **February 9, 2006**

Product: **Specialty**

GUIDELINES

Diagnostic Ultrasound Spinal/Paraspinal Conditions

Spinal and/or paraspinal ultrasound is considered medically necessary in newborns and infants for the following indications:

- Detection of sequelae of injury (e.g., hematoma after birth injury, infection or hemorrhage, post-traumatic leakage of cerebral spinal fluid)
- Guidance for lumbar puncture
- Evaluation of suspected defects such as cord tethering, diastematomyelia, hydromyelia, and syringomyelia.
- 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)
- Evaluation and diagnosis of suspected spinal cord tumors, vascular malformations and birth-related trauma
- Post-operative assessment for cord retethering.
- Evaluation 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.

Spinal and/or paraspinal ultrasound is considered medically necessary when performed intraoperatively.

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

- Diagnose and manage spinal pain and radiculopathies
- Evaluate neuromusculoskeletal conditions (e.g., intervertebral discs, facet joints and capsules, central nerves and fascial edema, paraspinous abnormalities, pain or radiculopathy syndromes, monitoring of therapy)
- Guide the rehabilitation of neuromusculoskeletal disorders and back pain

Diagnostic Ultrasound Musculoskeletal Conditions

ASH considers diagnostic ultrasound medically necessary for the evaluation of specific musculoskeletal conditions (e.g., muscle/tendon tears, bursitis), excluding

To CQT for review 08/14/2023
CQT reviewed 08/14/2023
To QIC for review and approval 09/12/2023
QIC reviewed and approved 09/12/2023
To QOC for review and approval 09/21/2023
QOC reviewed and approved 09/21/2023

spinal/paraspinal (see above). See the *Non-Vascular Extremity Ultrasound (CPG 188-S)* guideline for medical necessity criteria and more information**.**

CPT Code and Description

CPT® Code	CPT® Code Description
76800	Ultrasound, spinal canal and contents

DESCRIPTION

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

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 myelocele, 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 should 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, 2021; American College of Radiology [ACR], 2021).

<u>Diagnostic Ultrasound for the Spine</u>

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. 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.

EVIDENCEREVIEW

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)

Nojiri et al. (2019) evaluated the usefulness of intraoperative ultrasound in improving the safety of lateral lumbar spine surgery. A transvaginal ultrasound probe was inserted into the operative field, and the intestinal tract, kidney, psoas muscle, and vertebral body were identified using B-mode ultrasound. The aorta, vena cava, common iliac vessels, and lumbar arteries and their associated branches were identified using the color Doppler mode. The study cohort comprised 100 patients who underwent lateral lumbar spine surgery, 92 via a left-sided approach. The intestinal tract and kidney lateral to the psoas muscle on the anatomical approach pathway were visualized in 36 and 26 patients, respectively. A detachment maneuver displaced the intestinal tract and kidneys in an anteroinferior direction, enabling confirmation of the absence of organ tissues above the psoas. In all patients, the major vessels anterior to the vertebral bodies and the lumbar arteries and associated branches in the psoas on the approach path were clearly visualized in the Doppler mode, and their orientation, location, and positional relationship with regard to the vertebral bodies, intervertebral discs, and psoas were determined. Authors concluded that when approaching the lateral side of the lumbar spine in the retroperitoneal space, intraoperative ultrasound allows real-time identification of the blood vessels surrounding the lumbar spine, intestinal tract, and kidney in the approach path and improves the safety of surgery without increasing invasiveness. Tat et al. (2022) reviewed the current spine surgery literature to establish a definition for adequate spine decompression using intraoperative ultrasound (IOUS) imaging. IOUS remains one of the few imaging modalities that allows spine surgeons to continuously monitor the spinal cord in real-time, while also allowing visualization of surrounding soft tissue anatomy during an operation. Although this has valuable applications for decompression surgery in spinal canal stenosis, it remains unclear how to best characterize adequacy of spinal decompression using IOUS. Authors search strategy yielded 985 of potentially relevant publications, 776 underwent title and abstract screening, and 31 full-text articles were reviewed. They found IOUS to be useful in spine surgery for decompression of degenerative cases in all regions of the spine. The thoracic spine was unique for IOUS-guided decompression of fractures, and the lumbar spine for decompressing nerve roots. Authors identified a common qualitative definition for adequate decompression involving a "free floating" spinal cord within the cerebrospinal fluid which indicates that the spinal cord is free from contact of the anterior elements.

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, 2022) 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 and tethered cord, including but not limited to: midline or paramedian masses, skin discolorations, skin tags, hair tufts, hemangiomas, atypical sacral dimples, paramedian deep dimples
- The spectrum of caudal regression syndrome, including patients with sacral agenesis and patients with anorectal malformations such as Currarino Triad, VACTERL association, Cloaca, and OEIS complex
- Evaluation of suspected defects such as cord tethering, diastematomyelia, hydromyelia, syringomyelia
- Detection of acquired abnormalities and complications, such as: hematoma following injury, infection, or hemorrhage secondary to prior instrumentation such as lumbar puncture, post-traumatic leakage of cerebrospinal fluid (CSF)

To CQT for review 08/14/2023
CQT reviewed 08/14/2023
To QIC for review and approval 09/12/2023
QIC reviewed and approved 09/12/2023
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QOC reviewed and approved 09/21/2023

- Visualization of blood products within the spinal canal in patients with intracranial hemorrhage
- Guidance for lumbar puncture
- Postoperative assessment for cord tethering
- Evaluation for congenital spine tumors, for example, sacrococcygeal teratoma

"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).

Rees et al. (2021) reviewed the diagnostic imaging approach to infant spine US, including technique and indications, normal anatomy and variants with a focus on embryological origins, and classification and diagnosis of congenital spine malformations. They report that US is the first-line imaging modality for screening neonates and young infants with suspected spinal abnormalities. Whether performed for a suspicious congenital skin lesion, such as a lumbosacral tract or lipomatous mass, or abnormal neurological findings, US can help define spinal anatomy, characterize congenital spine malformations, and direct further work-up and management.

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: "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."

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, 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 with 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. Ahmed et al. (2018) assessed ultrasound efficacy in diagnosis and therapeutic interventions for spine pathology. This systematic review identified 3,630 papers with eventual inclusion of 73 papers with an additional 21 papers supplemental papers subsequently added. Findings highlighted ultrasound utilization for different structural elements of the spine such as muscle, bone, disc, ligament, canal, and joints are presented and compared with radiographs, CT, and MRI imaging where relevant. In the body of evidence researched, nearly all the structures of the spine were shown to be clearly visible via ultrasound imaging, (however less than 10% of the reviewed articles addressed US as a spinal diagnostic modality) with the most common use being an aid for procedures involving injections and the use of needles near the spine. There was also preliminary evidence that US has comparable accuracy to CT for planning the placement of pedicle screws, thoracolumbar burst fracture repositioning and evaluating posterior ligament injuries, however it cannot replace CT and MRI in general trauma evaluation. Standardized and reproducible education training is needed for performance and interpretation, and high-quality studies comparing diagnostic accuracy to CT and MRI are needed before broad implementation of US for spinal diagnostics.

In the ACR Appropriateness Criteria for inflammatory back pain and suspected axial spondyloarthropathy, an expert panel on musculoskeletal imaging concluded that ultrasound (US) is not suggested as a routine diagnostic modality, or for the assessment of treatment response or disease progression due to a lack of diagnostic utility (2021).

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services.

It is best practice for the practitioner to appropriately render services to a patient only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and expert training, it would be best practice to refer the patient to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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