



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 11/15/2010
Next Review Date 11/15/2012
Coverage Policy Number 0246

Subject **Spinal Ultrasound**

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	4
References	6
Policy History	8

Hyperlink to Related Coverage Policies

Chiropractic Care
Minimally Invasive Treatment of Back Pain

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA covers spinal ultrasound as medically necessary when EITHER of the following indications is met:

- for use during spinal or paraspinal surgery
- for diagnosis of suspected spinal dysraphism, spinal cord tumors, vascular malformations and birth-related trauma in newborns and infants

CIGNA does not cover diagnostic ultrasound of the spine and/or paraspinal tissues for ANY other indication, including but not limited to the 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), because it is considered experimental, investigational or unproven.

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.

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. Intramedullary and extramedullary 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.

Literature Review: 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

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.

Literature Review: The evidence in peer-reviewed, scientific literature consists primarily of individual case studies. 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). Infants with simple midline dimples of < 5 mm in diameter within 2.5 centimeter (cm) of the anus do not need spinal ultrasound.

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 stated 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. They stated that if US is abnormal, equivocal or technically limited, MRI is advised for full assessment.

American College of Radiology (ACR): The ACR Practice Guideline for the Performance of an Ultrasound Examination of the Neonatal Spine (2007) 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.” The ACR states the following under Indications/Contraindications:

“The indications for ultrasonography 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, 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.”

American Institute of Ultrasound in Medicine (AIUM): The AIUM Practice Guideline for the Performance of an Ultrasound Examination of the Neonatal Spine (October 2007) 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. Sonography is also used to detect sequelae of injury, such as hematoma following a spinal tap or birth injury and cerebrospinal fluid leaks. 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 because of 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.”

Diagnosis of Neuromuscular 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.

American Academy of Neurology (AAN): The AAN's Therapeutics and Technology Assessment Subcommittee developed a statement on spinal ultrasound (1998, reaffirmed July 2010) 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.”

American College of Physicians (ACP) and the American Pain Society (APS): The ‘Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society’ (Chou, et al., 2007; Chou, et al., 2008) states that “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.”

American Chiropractic College of Radiology (ACCR): The ACCR Guideline for the use of diagnostic spinal ultrasound (1995, readopted 2005) notes that the application of diagnostic ultrasound in the adult spine is inadequately studied and “its routine application for these purposes cannot be supported by the evidence at this time”.

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): The Official Statement titled “Nonoperative Spinal/Paraspinal Ultrasound in Adults” (2009) states: “There is insufficient evidence in the peer-reviewed medical literature establishing the value of non-operative spinal/paraspinal ultrasound in adults. Therefore, 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 evaluation of pain or radiculopathy syndromes, and for monitoring of therapy has no proven clinical utility. Nonoperative spinal/paraspinal ultrasound in adults should be considered investigational.”

Summary

There is some evidence in the published, peer-reviewed scientific literature to support the use of spinal ultrasound for two specific indications. Intraoperative spinal ultrasound is a useful modality, aiding in diagnosis and treatment planning of several spinal conditions. Use on newborns and infants is effective in diagnosing suspected occult and non-occult spinal dysraphism, spinal cord tumors, vascular malformations and birth-related trauma. There is insufficient evidence in the peer-reviewed medical literature establishing the value of nonoperative spinal/paraspinal diagnostic ultrasound in adults (Chou, et al., 2007; American Academy of Neurology, reaffirmed 2010; American Chiropractic College of Radiology, readopted 2005; American Institute of Ultrasound in Medicine, 2009; American Chiropractic Association, 1996).

Coding/Billing Information

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

Covered when medically necessary:

CPT®* Codes	Description
76800	Ultrasound, spinal canal and contents

ICD-9-CM Diagnosis Codes	Description
170.2	Malignant neoplasm of vertebral column, excluding sacrum and coccyx
192.2	Malignant neoplasm of spinal cord
192.3	Malignant neoplasm of spinal meninges
225.3	Benign neoplasm of spinal cord
225.4	Benign neoplasm of spinal meninges
741.00 – 741.93	Spina bifida
742.51 – 742.59	Other specified congenital anomalies of spinal cord
742.8	Other specified congenital anomalies of nervous system
747.82	Spinal vessel anomaly
754.2	Congenital musculoskeletal deformity of spine
756.17	Spina bifida occulta
767.4	Injury to spine and spinal cord, birth trauma

Experimental/Investigational/Unproven/Not Covered:

CPT®* Codes	Description
76999†	Unlisted ultrasound procedure (eg, diagnostic, interventional)

†**Note:** Experimental, investigational or unproven and not covered when used to report diagnostic ultrasound of the spine or paraspinal tissues for indications not listed as covered in this policy, including but not limited to neuromusculoskeletal conditions.

ICD-9-CM Diagnosis Codes	Description
336.1	Other diseases of spinal cord, Vascular myelopathies
336.9	Other diseases of spinal cord, Unspecified disease of spinal cord
720.0-720.2	Ankylosing spondylitis and other inflammatory spondylopathies
720.9	Unspecified inflammatory spondylopathy
721.0-721.91	Spondylosis and allied disorders
722.0 - 722.93	Intervertebral disc disorders
723.1	Cervicalgia
723.9	Unspecified musculoskeletal disorders and symptoms referable to neck
724.1	Pain in thoracic spine
724.2	Lumbago
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache, unspecified
724.8	Other symptoms referable to back
724.9	Other unspecified back disorders

754.2	Certain congenital musculoskeletal deformities, Of spine
	All other codes

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	11/15/07	0246	Spinal Ultrasound

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