

Select Health Medical Policies Pediatric Policies

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CHIROPRACTIC SERVICES FOR CHILDREN

Policy # 584

Implementation Date: 5/9/16

Review Dates: 7/25/18, 7/8/19, 8/17/20, 8/16/21, 7/12/22, 8/24/23, 8/13/24 Revision Dates: 6/15/17, 3/6/20, 9/8/21, 11/19/21, 6/16/22, 7/21/22, 10/4/23

Disclaimer

1. Policies are subject to change without notice.

2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Chiropractic care is a healthcare profession that focuses on disorders of the musculoskeletal system and the nervous system, and the effects of these disorders on general health. Chiropractic care is used most often to treat neuromusculoskeletal complaints, including, but not limited to back pain, neck pain, pain in the joints of the arms or legs, and headaches.

The most common therapeutic procedure performed by chiropractic doctors is known as "spinal manipulation," also called "chiropractic adjustment." The purpose of spinal manipulation is to restore joint mobility by manually applying a controlled force into joints that have become hypomobile, or restricted in their movement, as a result of a tissue injury. Tissue injury can be caused by a single traumatic event, such as improper lifting of a heavy object, or through repetitive stresses, such as sitting in an awkward position with poor spinal posture for an extended period. In either case, injured tissues undergo physical and chemical changes that can cause inflammation, pain, and diminished function for the sufferer. Manipulation, or adjustment, of the affected joint and tissues restores mobility, thereby alleviating pain and muscle tightness, and allowing tissues to heal.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

A. Criteria for Utah/Idaho/Nevada Large Employer plans and Utah Small Employer plans

Select Health covers chiropractic care for children ages 13 to 18.

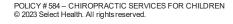
For children ages 9 to 12, chiropractic care is allowed when the following criteria are met:

- The child has a neuromusculoskeletal disorder causing significant and persistent disability; and
- 2. Other conservative therapies (e.g., stretching, heat or ice, over-the-counter pain relievers) have been tried and have failed to relieve the symptoms.

B. Exclusions

Select Health does not provide chiropractic benefits in the following circumstances:

1. Chiropractic appliances;





- 2. Services for treatment of non-neuromusculoskeletal disorders;
- 3. Professional radiology services (reading of an X-ray); and
- Services for children ages 8 and under*; there is a lack of evidence affirming efficacy or safety for this age group as established in medical literature; this meet's the plan's definition of experimental/investigational.

*This age restriction does not apply to Idaho/Nevada Small Employer and Idaho/Nevada Individual ACA plans [this also applies to corresponding Colorado plans, effective Jan. 1, 2024], which do not have age restrictions for chiropractic care. <u>All other coverage criteria apply to these plans</u>.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp8 or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Current evidence related to the safety and efficacy of chiropractic care in children and adolescents is limited and weak. This fact was acknowledged in the consensus guidelines published and funded by the Foundation for Chiropractic Education and Research, and authored by Hawk et al., in 2009. In this article which relates "best care," based on a Delphi approach of consensus, it is stated: "A 2008 systematic review on chiropractic manipulation for children's health problems concluded that "the evidence rests primarily with clinical experience, descriptive case studies, and very few observational and experimental studies." This guideline acknowledges the weakness of clinical evidence, in noting one of the limitations to their conclusions relates to the consensus process itself, which represents chiefly expert opinion, which is a less convincing level of evidence than that provided by large-scale experimental studies, and it goes on to state: "It is essential that rigorous observational and experimental studies be implemented to provide a more substantial body of evidence to inform future clinical guidelines."

A 1998 study by Balon et al., is an example of the lack of good evidence to support chiropractic care in a pediatric population. This study compared active to simulated chiropractic manipulation in children with asthma who were also receiving concomitant pharmacologic intervention. The primary outcome variable was improvement in morning peak flow after 2 and 4 months of chiropractic treatment. Multiple secondary variables included FEV1, methacholine sensitivity (PC20), symptom diary scores, rescue medication use, and quality of life questionnaires; patients were randomized to receive sham versus active manipulation. The patients and data managers were blinded but the chiropractors were not. Children 7 to 16 years of age with physician-diagnosed asthma were recruited, and inclusion required vertebral subluxation as determined by chiropractic screening. Of 199 subjects screened, 91 were eligible completed the 4-month study period: 38 received active chiropractic treatments and 42 received simulated chiropractic treatments. Both groups experienced minimal increases in peak flow and decreases in symptom scores and rescue beta-agonist use. There was no difference between groups in peak flow, FEV1, PC20, symptoms, rescue beta agonist use, oral steroid use, or quality of life measures. The authors postulated that the observed improvements were due to increased compliance and frequent professional attention during the study. No adverse side effects were noted. This study failed to identify a benefit of chiropractic manipulation for childhood asthma.

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Finally, a systematic review published in 2009 by Gotlib and Rupert substantiated the lack of high-quality evidence to support pediatric chiropractic care. The authors noted the health claims made by chiropractors with respect to the application of manipulation as a healthcare intervention for pediatric health conditions continue to be supported by only low levels of scientific evidence. Chiropractors continue to treat a wide variety of pediatric health conditions. The evidence rests primarily with clinical experience, descriptive case studies, and very few observational and experimental studies. The health interests of pediatric patients would be advanced if more rigorous scientific inquiry was undertaken to examine the value of manipulative therapy in the treatment of pediatric conditions.

Billing/Coding Information

CPT CODES

98940 Chiropractic manipulative treatment (CMT); spinal, one or two regions

98941 ; spinal, three to four regions

98942 ; spinal, five regions

98943 ; extraspinal, one or more regions

Medicare limits chiropractic billing to the above chiropractic CPT codes only

97140 Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage,

manual traction), 1 or more regions, each 15 minutes

97161 Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of

body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes

are spent face-to-face with the patient and/or family.

97162 Physical therapy evaluation: moderate complexity, requiring these components: A history

of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the

patient and/or family.

97163 Physical therapy evaluation: high complexity, requiring these components: A history of

present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the

patient and/or family.

97164 Re-evaluation of physical therapy established plan of care, requiring these components:

An examination including a review of history and use of standardized tests and measures is required; and revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent

face-to-face with the patient and/or family.

97010 Application of a modality to 1 or more areas; hot or cold packs

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97012	Application of a modality to 1 or more areas; traction, mechanical			
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)			
97016	Application of a modality to 1 or more areas; vasopneumatic devices			
97018	Application of a modality to 1 or more areas; paraffin bath			
97022	Application of a modality to 1 or more areas; whirlpool			
97024	Application of a modality to 1 or more areas; diathermy (eg, microwave)			
97026	Application of a modality to 1 or more areas; infrared			
97028	Application of a modality to 1 or more areas; ultraviolet			
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes			
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes			
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes			
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes			
97036	Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes			
97039	Unlisted modality (specify type and time if constant attendance)			
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility			
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities			
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises			
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)			
97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)			
97139	Unlisted therapeutic procedure (specify)			
97140	Manual therapy techniques (eg, mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes			
97150	Therapeutic procedure(s), group (2 or more individuals)			
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes			

HCPCS CODES

G0151	Services performed by a qualified physical therapist in the home health or hospice setting, each 15 minutes
S3900	Surface electromyography (EMG)
S9131	Physical therapy; in the home, per diem

Key References

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- Balon J, Aker PD, Crowther ER, et al. A comparison of active and simulated chiropractic manipulation as adjunctive treatment for childhood asthma. N Engl J Med. 1998; 339:1013-1020.



- Cheryl Hawk, DC, PhD, Michael Schneider, DC, PhD, Randy J. Ferrance, DC, MD, Elise Hewitt, DC, Meghan Van Loon, DC, PT, and Lora Tanis, DC. Best Practices Recommendations for Chiropractic Care in Infants, children and Adolescents: Results of a Consensus Process. *Journal of Manipulative and Physiological Therapeutics*. Volume 32, Number 8. 639-647. October 2009
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- 7. Driehuis F, Hoogeboom TJ, Nijhuis-van der Sanden MWG, de Bie RA, Staal JB. Spinal manual therapy in infants, children and adolescents: A systematic review and meta35 analysis on treatment indication, technique and outcomes. PLoS One. 2019 Jun 25;14(6): e0218940.
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- Harrison DD, Siskin LA, Betz JW, editor(s). Best practices & practice guidelines. Arlington (VA): International Chiropractors Association (ICA); 2013 Nov 22, p. 856.
- Hestbaek, L. & Stochkendahl, M. J., The evidence base for chiropractic treatment of musculoskeletal conditions in children and adolescents: The emperor's new suit? *Chiropr Osteopat.* 2010; 18:15. Published online 2010 Jun 2. doi: 10.1186/1746-1340-18-15, PMCID: PMC2891802

Revision History

	Revision Date	Summary of Changes
10/4/23		For Commercial Plan Policy, updated criteria to align with requirements for these services outlined
		in plan documents.

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INHALED NITRIC OXIDE (INO) THERAPY

Policy # 663

Implementation Date: 6/8/23 Review Dates: 8/15/24 Revision Dates:

Disclaimer:

- 1. Policies are subject to change without notice
- Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Nitric oxide (NO) is a lipophilic gas that is readily absorbed across pulmonary membranes in the ventilated lung after inhalation. iNO therapy increases the partial pressure of arterial oxygen by dilating pulmonary vessels in better ventilated areas of the lung, redistributing pulmonary blood flow away from lung regions with low ventilation/perfusion ratios toward regions with normal ratios.

Respiratory distress syndrome (RDS) is one of the most common causes of preterm infant respiratory failure and mortality. RDS results from developmental immaturity of the lungs, which leads to insufficient surfactant production and function. Bronchopulmonary dysplasia (BPD) is a long-term pulmonary complication of RDS in preterm newborns and is associated with prolonged hospitalization and lasting pulmonary and neurodevelopmental problems.

A high-quality, consistent body of evidence indicates that early rescue use iNO within the first 3 days of life does not increase survival, decrease pulmonary morbidity, or improve neurodevelopmental outcomes in preterm infants < 35 weeks gestation who require respiratory support. Similarly, 2 moderate-quality, consistent bodies of evidence assessing later treatment (after 3 days of life) in preterm infants at increased risk of BPD and routine treatment in preterm infants requiring respiratory support suggest no benefit of iNO regimens for survival, pulmonary morbidity, or improved neurodevelopmental outcomes.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health considers inhaled nitric oxide (iNO) proven and medically necessary for the following clinical circumstances:

- A. Treating newborns with persistent pulmonary hypertension of the newborn (PPHN), with hypoxic respiratory failure or echocardiographic evidence, with the following:
 - 1. Failure of conventional treatments (e.g., mechanical ventilation) with severe hypoxic respiratory failure refractory to conventional therapies with clinical or echocardiographic evidence of pulmonary hypertension; or
- B. In the postoperative management of pulmonary hypertension associated with heart or lung surgery in infants, iNO is a clinically accepted option and will be covered as bridge therapy during the acute recovery phase; or
- C. The diagnostic use of INO is considered medically necessary as a method of assessing pulmonary

POLICY#663 - INHALED NITRIC OXIDE (INO) THERAPY



Inhaled Nitric Oxide (INO) Therapy, continued

vaso-reactivity in persons with pulmonary hypertension.

Note: INO therapy is considered medically necessary for no longer than 14 days if the oxygen desaturation has been resolved. Medical director review required for use beyond 14 days.

Select Health considers INO therapy experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information

CPT CODES

- **94002** Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day
- 94003 Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day
- 94004 Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day
- 94005 Home ventilator management care plan oversight of a patient (patient not present) in home, domiciliary or rest home (eg, assisted living) requiring review of status, review of laboratories and other studies and revision of orders and respiratory care plan (as appropriate), within a calendar month, 30 minutes or more
- 93463 Pharmacologic agent administration (eg, inhaled nitric oxide, intravenous infusion of nitroprusside, dobutamine, milrinone, or other agent) including assessing hemodynamic measurements before, during, after and repeat pharmacologic agent administration, when performed (List separately in addition to code for primary procedure)
- **99503** Home visit for respiratory therapy care (e.g., bronchodilator, oxygen therapy, respiratory assessment, apnea evaluation)

Key References

- Boly, T. J., et al. Response categorization and outcomes in extremely premature infants born at 22-26 weeks gestation that received inhaled nitric oxide for hypoxic respiratory failure. *J Perinatol.* 2023 March; 43(3): 324–331. doi:10.1038/s41372-022-01582-4
- Hayes, Inc. Health Technology Assessment. Inhaled Nitric Oxide for the Treatment of Respiratory Failure in Preterm Newborns. Dec. 14, 2021.
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Inhaled Nitric Oxide (INO) Therapy, continued

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INTRAUTERINE FETAL SURGERY

Policy # 696

Implementation Date: 6/26/25

Review Dates:

Revision Dates:

Disclaimer:

- 1. Policies are subject to change without notice.
- Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Intrauterine fetal surgery involves accessing the fetus through the uterine wall using either an open or a minimally invasive, endoscopic technique, surgically correcting the fetal abnormality and closing the uterus to permit completion of gestational development until delivery. The purpose of intrauterine fetal surgery is to correct fetal malformations that interfere with organ development and fetal survival. Fetal surgery in-utero has been attempted for various congenital anomalies including congenital diaphragmatic hernia (CDH), spina bifida and urinary tract abnormalities.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

- A. Select Health covers intrauterine fetal surgery at an approved facility that offers specialized services for the following conditions:
 - Congenital cystic adenomatoid malformation (CCAM)/congenital pulmonary airway malformation (CPAM) and extralobar pulmonary sequestration (EPS): Fetal lobectomy or thoracoamniotic shunt placement for CCAM and thoracoamniotic shunt placement for EPS
 - 2. Pleural effusion: Thoracoamniotic shunt placement
 - 3. Sacrococcygeal teratoma (SCT): SCT resection
 - 4. Urinary tract obstruction (UTO): Urinary decompression via vesicoamniotic shunt placement
 - 5. Twin-twin transfusion syndrome (TTTS): Fetoscopic laser surgery (stages II, III, IV in pregnancies at < 26 weeks of gestation)
 - 6. Twin reversed arterial perfusion (TRAP): Ablation or occlusion of anastomotic vessels (e.g., laser coagulation or radiofrequency ablation)
 - 7. Myelomeningocele (MMC) repair
- B. Fetoscopic endoluminal tracheal occlusion (FETO) is proven and medically necessary for the intrauterine treatment of congenital diaphragmatic hernia (CDH) when the following criteria are met:



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Intrauterine Fetal Surgery, continued

- 1. Diagnosis of CDH before 30 weeks of gestation; and
- 2. Severe pulmonary hypoplasia defined as a quotient of the observed-to-expected lung-to-head ratios of less than 25.0%; and
- 3. No other major structural or chromosomal defects are present

SELECT HEALTH ADVANTAGE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Billing/Coding Information

Covered for the indications above when criteria are met

CPT CODES

- 59072 Fetal umbilical cord occlusion, including ultrasound guidance
- **59074** Fetal fluid drainage (e.g., vesicocentesis, thoracocentesis, paracentesis), including ultrasound guidance
- 59076 Fetal shunt placement, including ultrasound guidance
- 59897 Unlisted fetal invasive procedure, including ultrasound guidance, when performed

HCPCS CODES

- **S2400** Repair, congenital diaphragmatic hernia in the fetus using temporary tracheal occlusion, procedure performed in utero
- \$2401 Repair, urinary tract obstruction in the fetus, procedure performed in utero
- **\$2402** Repair, congenital cystic adenomatoid malformation in the fetus, procedure performed in utero
- \$2403 Repair, extralobar pulmonary sequestration in the fetus, procedure performed in utero
- **\$2404** Repair, myelomeningocele in the fetus, procedure performed in utero
- \$2405 Repair of sacrococcygeal teratoma in the fetus, procedure performed in utero
- \$2409 Repair, congenital malformation of fetus, procedure performed in utero, not otherwise classified
- **S2411** Fetoscopic laser therapy for treatment of twin-to-twin transfusion syndrome



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Pediatric Policies, Continued

Intrauterine Fetal Surgery, continued

Key References1. Bowman, R, M. Myelomeningocele (spina bifida): Management and outcome. UpToDate. Last Review: Feb. 2025.

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PROGRESSIVE ADOLESCENT IDIOPATHIC SCOLIOSIS

Policy # 662

Implementation Date: 6/8/23 Review Dates: 9/18/24 Revision Dates:

Disclaimer

- 1. Policies are subject to change without notice.
- 2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Scoliosis is a musculoskeletal disorder characterized by abnormal lateral curvature of the spine measuring more than 10 degrees in the coronal plane. The spinal curve may develop as a single curve (shaped like the letter C) or as 2 curves (shaped like the letter S). Adolescent Idiopathic Scoliosis (AIS) is by far the most common type of scoliosis, affecting children between ages 10 to 18; it is found in as many as 4 in 100 adolescents. In general, AIS curves progress during the rapid growth period of the patient. While most curves slow their progression significantly at the time of skeletal maturity, some, especially curves greater than 60°, continue to progress during adulthood. Many theories exist with regards to the cause of AIS, including hormonal imbalance, asymmetric growth, and muscle imbalance.

AIS is usually confirmed through a physical examination, an x-ray, spinal radiograph, computed tomography (CT) scan, or magnetic resonance imaging (MRI). Imaging tests take a closer look at the spine to determine whether there are any problems with the bones and to measure the curvature of the spine. The curve is measured in degrees commonly referred to as the Cobb angle. A positive diagnosis of scoliosis is made based on a coronal curvature measured on a posterior-anterior radiograph of > 10°. In general, a curve is considered significant if it is greater than 25° to 30°. Curves exceeding 45° to 50° are considered severe and often require more aggressive treatment.

The goal of treatment in AIS is to correct the spinal deformity while allowing for thoracic growth for optimal cardiopulmonary function. Treatment options include observation, bracing or casting, or surgery. The type of treatment chosen depends on several factors, including etiology, severity of the spinal curve, curve pattern, and remaining growth of the patient. Spinal fusion surgery is often recommended for individuals with severe scoliosis. However, if performed too early, fusion surgery can lead to arrested development, thoracic insufficiency syndrome (TIS), and loss of mobility over the fused section.

The ApiFix System is indicated for AIS patients with deformity classified as Lenke type 1 and 5 and a Cobb angle up to 60 degrees. Both major and secondary curves must be flexible, confirmed using Lateral Bending X-rays, to allow gradual correction over time. For patients with these indications, the surgical procedure is less invasive, compared to the traditional standard of care. The unilateral implant system is attached to the spine on the concave side of the major curve using only two to three screws. There is an insufficient quantity of published peer-reviewed, human clinical data to evaluate the Minimally Invasive Deformity Correction (MID-C)/ApiFix System for adolescent idiopathic scoliosis in a health technology assessment

Vertebral body tethering (VBT) is a fusionless surgical technique to modulate spine growth, provide spinal curve correction, and preserve spine mobility in skeletally immature patients with severe, progressive, idiopathic scoliosis who have failed or are intolerant to bracing. Placement of The Tether VBT system can

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Pediatric Adolescent Idiopathic Scoliosis, continued

be performed thoracoscopically, which is less invasive than the open surgical technique used for posterior spinal fusion (PSF) and prompts faster recovery.

The Tether (Zimmer Biomet Spine Inc.) is one of several spinal tethering systems currently available or in clinical trials and is the only anterior VBT system allowed for in use in the United State outside a clinical trial setting (H190005). The Tether is indicated for treatment of idiopathic scoliosis* in skeletally immature patients who have failed or are intolerant to bracing, have a major Cobb angle of 30° to 65°, and have adequate vertebral bone structure to support necessary screws.

VBT, a nonfusion technique first published in 2010 by Crawford and Lenke (in human patients; animal model studies published earlier), modulates spinal growth by using an internal mechanical restraint in the form of a flexible cord that is anchored by screws placed into several adjacent vertebrae. The cord applies a compressive force to the convex side of the anterior aspect of the spine, which slows growth of the concave side of the spine, allowing it to grow relatively more than the convex side, thus creating conditions for a straighter spine to develop over time. Procedures are performed under general anesthesia using a thoracoscopic or mini-open approach. There is a known learning curve for surgeons new to this surgical technique that may affect operative time (including time patient spends intubated and under anesthesia), estimated blood loss for the patient, and hospital length of stay. VBT may also be referred to as dynamic spinal stabilization, soft stabilization, dynamic growth modulation, fusionless anterior scoliosis correction, or spine ligamentoplasty. VBT is not the same procedure as vertebral body stapling.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does not cover posterior dynamic deformity correction devices (e.g., MID-C/ApiFix System) for the treatment of progressive adolescent idiopathic scoliosis. There is insufficient clinical data available to support improved outcomes or long-term safety; therefore, this meets the plan's definition of experimental/investigational.

Select Health does not cover anterior vertebral body tethering (e.g., Zimmer Biomet/The Tether) for the treatment of progressive adolescent idiopathic scoliosis. There is insufficient clinical data available to support improved outcomes or long-term safety; therefore, this meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For this policy, specifically, there are no CMS criteria available; therefore, the Select Health Commercial policy or InterQual criteria apply. Select Health applies these requirements after careful review of the evidence that supports the clinical benefits outweigh the clinical risks. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

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Pediatric Adolescent Idiopathic Scoliosis, continued

Billing/Coding Information

Not covered for the indications listed above

CPT CODES

- **0656T** Vertebral body tethering, anterior; up to 7 vertebral segments
- 0657T Vertebral body tethering, anterior; 8 or more vertebral segments
- 20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only
- 20931 Allograft, structural, for spine surgery only
- 20936 Autograft for spine surgery only; local
- 20937 Autograft for spine surgery only; morselized (through separate skin or fascial incision)
- 20938 Autograft for spine surgery only; structural bicortical or tricortical (through separate skin or fascial incision)
- **22612** Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
- **22800** Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments (levels)
- +22840 Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)
- +22842 Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments
- +22843 Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments
- **22899** Unlisted procedure, spine [when specified as vertebral body stapling or implantation of a posterior (dynamic) distraction device]

Key References

- Hayes, Inc. Minimally Invasive Deformity Correction System (ApiFix) for Adolescent Idiopathic Scoliosis. Evidence Analysis Research Brief. Nov. 20, 2020.
- Hayes, Inc. The Tether (Zimmer Biomet) for Skeletally Immature Patients With Progressive Idiopathic Scoliosis. Evolving Evidence Review. Apr. 7, 2022.
- Hayes, Inc. Evidence Analysis Research Brief. ApiFix (ApiFix Ltd.) for Treatment of Adolescent Idiopathic Scoliosis. Dec. 11, 2023.

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