MEDICAL POLICY

POLICY TITLE	INTERVENTIONS FOR PROGRESSIVE SCOLIOSIS
POLICY NUMBER	MP 1.120

Effective Date:	10/1/2023

I. POLICY

A rigid cervical-thoracic-lumbar-sacral orthosis may be considered **medically necessary** for the treatment of scoliosis in juvenile and adolescent patients at high-risk of progression which meets the following criteria:

- Idiopathic spinal curve angle between 25° and 40°; **and**
- Spinal growth has not been completed (Risser grade 0-3; no more than 1 year post-menarche in females)**;**
  OR
- Idiopathic spinal curve angle greater than 20°; **and**
- There is documented increase in the curve angle; **and**
- At least 2 years growth remain (Risser grade 0 or 1; pre-menarche in females.)

Use of an orthosis for the treatment of scoliosis that does not meet the criteria above is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

Vertebral body stapling and vertebral body tethering for the treatment of scoliosis is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with these procedures.

POLICY GUIDELINES

This policy does not address conventional surgery for scoliosis in patients with curve angles measuring 45° or more. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25 and 40 degrees who have not completed spinal growth, with maturity defined as Risser 4,or 2 years post-menarche for girls. Bracing may also be recommended for curves greater than 20 degrees in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.

- A rigid cervical-thoracic-lumbar-sacral orthosis is primarily prescribed for patients with thoracic apices above T7 for control of upper thoracic sagittal deformities and for other spinal deformities not amenable to treatment with lower-profile designs.
- A low profile, rigid thoracic-lumbar-sacral orthosis worn full-time (18-23 hours per day) through skeletal maturity is used for most idiopathic curve patterns with a thoracic curve apex at or below T7 (the majority of idiopathic curves).
- Night time bracing systems are more effective in patients with isolated flexible thoracolumbar and lumbar curves than in double curves; they may also be indicated in patients who are noncompliant with a full-time wear program, patients in whom other

types of orthotic management had failed, and patients nearing skeletal maturity who may not require full-time wear.

Cross-reference:

MP 1.136 Vertical Expandable Prosthetic Titanium Rib
M2058 Genetic Testing for Adolescent Idiopathic Scoliosis

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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Scoliosis

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis (AIS) is the most common form of idiopathic scoliosis, defined by the U.S. Preventive Services Task Force as “a lateral curvature of the spine with onset at ≥10 years of age, no underlying etiology, and risk for progression during puberty.” Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications. Diagnosis is made clinically and radiographically. The curve is measured by the Cobb angle, which is the angle formed between intersecting lines drawn perpendicular to the top of the vertebrae of the curve and the bottom vertebrae of the curve. Patients with AIS are also assessed for skeletal maturity, using the Risser sign, which describes the level of ossification of the iliac apophysis.

The Risser sign measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Risser sign ranges from 0 (no ossification) to 5 (full bony fusion of the apophysis). Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief, eg, 2-year, period.

Males and females are equally affected by scoliosis, but curve progression is up to 10 times more common in females than males. Patients who are overweight or obese have a greater risk of presenting with larger Cobb angles and more advanced skeletal maturity, possibly due to delayed detection. A retrospective review of 341 patients with adolescent idiopathic scoliosis who underwent surgery at a single tertiary pediatric hospital between 2013 and 2018 found that the major curve magnitude at presentation was significantly higher in patients with public compared to private insurance (50.0° versus 45.1°; p=.0040 and in Black compared to White patients (51.8° versus 47.0°; p=.042). Additionally, the odds of having an initial major curve magnitude <40° within the range of nonoperative treatment were 67% lower among Black

patients with public insurance compared to Black patients with private insurance (odds ratio [OR], 0.33; 95% CI, 0.13 to 0.83; p=.019).

Treatment

Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of the curve), and the growth of the patient remaining at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high risk of curve progression. Genetic markers to evaluate the risk of progression are also being evaluated. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.

Bracing

Bracing is used to reduce the need for spinal fusion by slowing or preventing further progression of the curve during rapid growth. Commonly used brace designs include the Milwaukee, Wilmington, Boston, Charleston, and Providence orthoses. The longest clinical experience is with the Milwaukee cervical-thoracic-lumbar-sacral orthosis. Thoracic-lumbar-sacral orthoses, such as the Wilmington and Boston braces, are intended to improve tolerability and compliance for extended (>18-hour) wear and are composed of lighter weight plastics with a low profile (underarm) design. The design of the nighttime Charleston and Providence braces is based on the theory that increased corrective forces will reduce the needed wear time (i.e., daytime), thereby lessening social anxiety and improving compliance. The smart brace consists of a standard rigid brace with a microcomputer system, a force transducer, and an air-bladder control system to control the interface pressure. Braces that are more flexible than thoracic-lumbar-sacral orthoses or nighttime braces, such as the SpineCor, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Surgery

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as alternatives to bracing. Both procedures use orthopedic devices off-label. The goal of these procedures is to reduce the rate of spine growth unilaterally, thus allowing the other side of the spine to “catch up.” The mechanism of action is believed to be down-regulation of the growth plate on the convex (outer) side by compression and stimulation of growth on the endplate of the concave side by distraction. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex side of the curve. The shape memory allows the prongs to be straight when cooled and clamp down into the bone when the staple returns to body temperature. Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The optimum degree of tension is not known. The polyethylene ligaments are more flexible than staples and are predicted to allow more spinal mobility. The goal of a fusionless growth modulating procedure is to reduce the curve and prevent progression, maintain spine mobility following

correction, and provide an effective treatment option for patients who are noncompliant or who have a large curve but substantial growth is remaining. Observational data suggest that overweight patients may be at higher risk for scoliosis progression after surgery.

Research Recommendations

The Scoliosis Research Society (SRS) provided evidence-based recommendations in 2005. updated in 2015, for bracing studies to standardize inclusion criteria, methodologies, and outcome measures to facilitate comparison of brace trials. Janicki et al (2007) reported the first study to use the SRS criteria concluded that a brace should prevent progression in 70% of patients to be considered effective. The SRS evidence review and recommendations may also aid in the evaluation of fusionless surgical treatments for scoliosis progression in children.

The SRS review of the natural history of scoliosis indicated that skeletally immature patients and patients with larger curves (between 20° and 29°) are significantly more likely to have more than 5° curve progression. Brace treatment for idiopathic scoliosis is usually recommended for juveniles and adolescents with curves measuring between 25° and 40° who have not completed spinal growth, with maturity defined as Risser grade 4, or at least 2 years after menarche for girls. Bracing may also be recommended for curves greater than 20° in a patient who has a rapidly progressing curve with more than 2 years of growth remaining.

Success from brace treatment is most frequently defined as progression of less than 5° before skeletal maturity, although alternative definitions may include progression of less than 10° before skeletal maturity or preventing the curve from reaching the threshold for surgical intervention. Surgery is usually recommended when the curve magnitude exceeds 45° to 50° (before or at skeletal maturity), although many patients will not undergo surgery at this point. Based on this information, SRS provided the following recommendations for brace studies on AIS:

- "Optimal inclusion criteria for brace studies consist of: age is 10 years or older when the brace is prescribed, Risser [grade] 0-2, curve 25°-40°, and no prior treatment."
- Outcomes of brace effectiveness should include all of the following:
  - "The percentage of patients with 5° or less curve progression and the percentage of patients who have 6° or more progression at skeletal maturity."
    - The number of patients at the start and end of treatment exceeding 10°, 30°, and 50° Cobb angles, as these risk thresholds have potential health consequences in adulthood, such as back pain and curve progression.
    - "A minimum of 2-year follow-up beyond skeletal maturity for each patient who was 'successfully' treated with a brace to determine the percentage who subsequently required or had surgery recommended. The surgical indications must be documented."
  - Clinically significant outcomes such as aesthetics, deformity progression, disability, pain, and quality of life.
- "Skeletal maturity should be considered achieved when <1 cm change in standing height has occurred on measurements made on 2 consecutive visits 6 months apart…. when Risser 4 is present and, in females, when the patient is 2 years after menarche."

- "All patients, regardless of subjective reports of compliance, should be included in the results. This process makes 'intent to treat' analysis possible.... An 'efficacy analysis' … should also be considered."

Regulatory Status

Some braces used for the treatment of scoliosis are considered class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from 510(k) requirements (examples include the Boston scoliosis brace [Boston Orthotics & Prosthetics, Avon, MA] and the SpineCor® Scoliosis System).

Staples, using a shape memory nickel-titanium alloy, have been cleared for marketing by FDA through the 510(k) process for various bone fixation indications. For example, nitinol staples (Sofamor Danek, Memphis, TN) are indicated for fixation with spinal systems. Other memory shape staples cleared for marketing by FDA through the 510(k) process for bone fixation include the OSStapleTM (BioMedical Enterprises, San Antonio, TX) and the reVERTOTM Dynamic Compression Device. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use.

A new titanium clip-screw system (HemiBridge™ System; SpineForm) has been tested on 6 patients with AIS, and investigational approval has now been granted by the FDA for the next cohort of 30 patients.

A new vetebral body tethering device (The Tether™; Zimmer Biomet Spine) received an FDA Humanitarian Device Exemption (HDE) (H190005, product code QHP) on 6/4/2019. The FDA HDE states that this device is indicated for "skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear."

Several of the cleared devices are described in Table 1.

Table 1. Scoliosis Bracing Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Coronet Soft Tissue Fixation System	CoNextions Medical	3/4/2020	K200028	Off Label Use for Scoliosis support
Superelastic Staple	Neosteo	2/28/2020	K192447	Off Label Use for Scoliosis support
Mactafix CI Fixation Button With Continuous Loop	Medacta International SA	2/10/2020	K193165	Off Label Use for Scoliosis support

Motoband Cp Implant System	CrossRoads Extemity Systems, LLC	1/10/2020	K193452	Off Label Use for Scoliosis support
Trimax Implant System	CrossRoads Extemity Systems, LLC	8/16/2019	K190772	Off Label Use for Scoliosis support
Colink Plating System, Fracture and Correction System, Rts Implant System, Neospan Compression Staple System	In2Bones USA, LLC	8/8/2019	K190385	Off Label Use for Scoliosis support
Trimed Nitinol Staple System	TriMed, Inc.	7/1/2019	K190166	Off Label Use for Scoliosis support
Vertex Nitinol Staple System	Nvision Biomedical Technologies, LLC	4/4/2019	K182943	Off Label Use for Scoliosis support
Geo Staple System	Gramercy Extremity Orthopedics LLC	1/11/2019	K182212	Off Label Use for Scoliosis support
DynaClipTM Bone Staple	MedShape Inc.	11/5/2018	K181781	Off Label Use for Scoliosis support
DynaBridge	Fusion Orthopedics LLC	10/15/2018	K181815	Off Label Use for Scoliosis support
MotoCLIP/HiMAX Step Staple Implant System	CrossRoads Extremity Systems LLC	8/9/2018	K181866	Off Label Use for Scoliosis support
DePuy Synthes Static Staples	Synthes (USA) Products LLC	7/24/2018	K180544	Off Label Use for Scoliosis support
MotoCLIP/HiMAX Implant System	CrossRoads Extremity Systems LLC	6/29/2018	K181410	Off Label Use for Scoliosis support
Clench Compression Staple	F & A Foundation LLC d.b.a. Reign Medical	4/6/2018	K173775	Off Label Use for Scoliosis support
Orbitum Bone Staple Implant X and VI	Orthovestments LLC	2/23/2018	K173693	Off Label Use for Scoliosis support
ExoToe Staple	ExoToe LLC	1/11/2018	K172205	Off Label Use for Scoliosis support
ToggleLoc System	Biomet Inc.	1/5/2018	K173278	Off Label Use for Scoliosis support

IV. RATIONALE

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Summary of Evidence

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a conventional rigid brace, the evidence includes a systematic review, a high-quality nonrandomized controlled trial, and 3 retrospective studies. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Bracing has been considered the only option to prevent curve progression in juvenile or adolescent idiopathic scoliosis. The highest quality study on bracing is a sizable 2013 National Institutes of Health-sponsored trial that, using both randomized and observational arms, compared bracing with watchful waiting. This trial was stopped after interim analysis because of a significant benefit of bracing for the prevention of spinal fusion. Two retrospective studies with long-term follow-up (mean, 13 to 15 years) has also shown that curvature corrections with bracing were maintained. Another retrospective study demonstrated that nighttime bracing was more effective than a 24-hour brace for avoiding surgery and preventing curve progression, but investigators attributed this finding to likely noncompliance with the 24-hour brace. A systematic review and meta-analysis reported higher success with full-time and nighttime rigid braces compared to soft bracing or observation only. Based on several factors (evidence of efficacy, lack of alternative treatment options, professional society recommendations, potential to prevent the need for a more invasive procedure), bracing with a conventional rigid brace is considered an option for the treatment of scoliosis in patients with a high-risk of curve progression. Curves have a high-risk of progression when they measure 25° or more, and spinal growth has not been completed, or when a 20° curve is progressively worsening and at least 2 years of growth remain. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high risk of progression who receive a microcomputer-controlled brace, the evidence includes a pilot RCT. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. A pilot randomized trial using a microcomputer-controlled brace reported improved outcomes compared with the use of a standard rigid brace; however, the low number of individuals included in the trial (N=12) ultimately limited the interpretation of these results. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive a flexible brace, the evidence includes a randomized and a nonrandomized comparative study. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. One RCT evaluating a flexible brace did not show equivalent outcomes compared with conventional brace designs. Another study has suggested the flexible brace might improve outcomes compared with no treatment, but this study had design flaws, which interfered with drawing significant conclusions from the study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body stapling, the evidence includes a comparative cohort study, a case-

control study, and case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. There is a small body of published evidence on surgical interventions for preventing curve progression in juvenile and adolescent idiopathic scoliosis. Vertebral body stapling with memory shape staples may control some thoracic curves between 20° and 35°, but it is less effective than bracing for larger curves. The evidence is composed primarily from a center that developed the technique, along with a few case series from other institutions. Additional studies with larger sample sizes and longer follow-up are needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body tethering, the evidence includes case series and a systematic review and meta-analysis of case series. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. Vertebral body tethering has been evaluated for thoracic curves at high-risk of progression. Currently, there is very limited evidence on this technique, with published case series on The Tether and on off-label use of the Dynesys system. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. A meta-analysis of vertebral body tethering studies with more than 36 months follow-up reported a 74% clinical success rate, a 52% complication rate, and a 16% unplanned reoperation rate. Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Although reported Cobb angle corrections are promising, serious adverse events occurred, data is lacking on other important health outcomes, and there are important study design limitations including lack of a control group. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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510 (K) refers to a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

RISSER SIGN is defined by the amount of calcification present in the iliac apophysis and measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief, e.g., 2-year, period.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of

benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered when used to report vertebral body stapling or tethering for the treatment of scoliosis:

Procedure Codes								
L1001	22899							

Covered when medically necessary:

Procedure Codes							
L0700	L0710	L1000	L1005	L1010	L1020	L1025	L1030
L1040	L1050	L1060	L1070	L1080	L1085	L1090	L1100
L1110	L1120	L1200	L1210	L1220	L1230	L1240	L1250
L1260	L1270	L1280	L1290	L1300	L1310	L1499	

ICD-10-CM Diagnosis Codes	Description
M41.112	Juvenile idiopathic scoliosis; Juvenile idiopathic scoliosis, cervical region
M41.113	Juvenile idiopathic scoliosis; cervicothoracic region

ICD-10-CM Diagnosis Codes	Description
M41.114	Juvenile idiopathic scoliosis; thoracic region
M41.115	Juvenile idiopathic scoliosis; thoracolumbar region
M41.116	Juvenile idiopathic scoliosis; lumbar region
M41.117	Juvenile idiopathic scoliosis; lumbosacral region
M41.119	Juvenile idiopathic scoliosis, site unspecified
M41.122	Adolescent idiopathic scoliosis, cervical region
M41.123	Adolescent idiopathic scoliosis, cervicothoracic region
M41.124	Adolescent idiopathic scoliosis, thoracic region
M41.125	Adolescent idiopathic scoliosis, thoracolumbar region
M41.126	Adolescent idiopathic scoliosis, lumbar region
M41.127	Adolescent idiopathic scoliosis, lumbosacral region
M41.129	Adolescent idiopathic scoliosis, site unspecified
Q67.5	Congenital deformity of spine

IX. REFERENCES

TOP

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X. POLICY HISTORY

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MP-1.120	**CAC 11/30/2010 New Policy**, Adopt BCBSA
	CAC 11/22/11 Consensus review.
	CAC 10/30/12 Minor revision. Statement regarding the use of the vertical expandable titanium rib was removed from the policy and is now found in MP-1.136 Vertical Expandable Prosthetic Titanium Rib. References updated. FEP variation revised. Codes reviewed 9/24/12
	CAC 11/26/13 Consensus review. No changes to the policy statements. References updated. Rationale added.
	CAC 11/25/14 Consensus review. References and rationale updated. No change to the policy statements. Updated the ICD 10 codes. Coding Reviewed and verifie CLBJ
	CAC 11/24/15 Minor revision. Vertebral body tethering added as investigational. Background, references, and rationale updated. Coding reviewed/updated.
	CAC 9/27/16 Consensus review. No change to the policy statement. References updated. Variations reformatted. Coding reviewed.
	CAC 11/28/17 Consensus review. No change to policy statement. References and rationale updated. Coding reviewed.
	7/23/18 Consensus review. No changes to the policy statements. Background and references updated. Rationale revised**.**
	10/26/18 Admin update. Coding review. Diagnosis updated.
	5/17/19 Consensus review. No changes to the policy statements. Removed FEP variation. References updated.
	5/12/2020 Consensus review. Policy statement unchanged. Product Variation, Background, and References updated. Coding Reviewed.
	3/29/2021 Consensus review. No change to policy statement. References updated. Coding reviewed.
	6/14/2021 Admin update. New code 0656T and 0657T added to the policy.

MEDICAL POLICY

POLICY TITLE	INTERVENTIONS FOR PROGRESSIVE SCOLIOSIS
POLICY NUMBER	MP 1.120

	6/3/2022 Consensus Review. 0656T and 0657T are managed by TP and removed from policy. References updated and coding reviewed.
	6/16/2023 Consensus review. No change to policy statement. References reviewed and updated. Background and rationale updated. Coding reviewed.

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