

Scoliosis: Conservative Interventions

Optum Health Solutions Musculoskeletal (MSK)

Utilization Management Policy Policy Number: 95

Effective Date: 04/25/2024

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Policy Statement

Optum considers brace therapy that utilizes a rigid orthosis (e.g., Boston Brace) to be proven and medically necessary for the sustained reduction and/or stabilization of curve magnitude, when patient selection criteria have been satisfied. It is viewed as the only active nonsurgical intervention described as proven effective.

Optum considers manual therapy (including manipulation), exercise (including specific exercise approaches), soft bracing (e.g., SpineCor), whole body vibration, and non-operative traction therapies to be unproven and not medically necessary for the sustained reduction and/or stabilization of curve magnitude due to insufficient scientific evidence of efficacy for the treatment of idiopathic scoliosis.

The use of manual therapy, exercise and soft braces for the treatment of idiopathic scoliosis deformity is supported by some positive published information regarding safety and/or efficacy. However, a beneficial impact on health outcomes (e.g., durable curve reduction) has not been proven because the data are sparse, and the evidence is of very low-quality.

The research evidence regarding the use of whole-body vibration and non-operative traction therapy in the treatment of idiopathic scoliosis is so limited that an appraisal of safety and efficacy cannot be made.

Purpose

This policy has been developed as the clinical criterion that describes the position of Optum regarding the efficacy, effectiveness, risks, and burdens associated with the use of conservative interventions (manual therapy, exercise, bracing, whole body vibration and non-operative traction) for the treatment of idiopathic scoliosis.

Scope

This policy applies to all in and out of network programs, involving all provider types, where utilization review (UR) determinations are rendered. This policy serves as a resource for peer-to-peer interactions in describing the position of Optum on the clinical appropriateness and/or medical necessity of conservative interventions for the treatment of idiopathic scoliosis

The application of this policy is limited to the conservative (non-operative) treatment of idiopathic scoliosis for the purpose of any of the following goals: arresting curve progression, slowing curve progression, or reducing the magnitude of curvature. Conservative interventions included in this policy encompass manual therapy, exercise, bracing, whole body vibration, and non-operative traction.

Clinical Evidence

Idiopathic scoliosis is defined radiographically as a lateral curvature of the spine greater than or equal to 10° Cobb with rotation, of unknown etiology. Idiopathic scoliosis is most commonly identified (~90% of cases) during adolescence (ages 10 – 18 years). Idiopathic scoliosis progresses most often in adolescents who are growing and have curves which are above 20 degrees. This is the time conservative interventions including bracing are commonly considered. The efficacy of conservative treatment in adolescent idiopathic scoliosis (AIS) is, however, controversial due to variations in inclusion and assessment criteria, as well as sparse and low-quality evidence.

The primary aim of scoliosis management is to stop curvature progression. Guidance for intervention is broadly based on the risk for significant curvature progression in each time period. Rowe described decision-making about treatment strategies by assessing a combination of Risser Sign (skeletal immaturity) and Cobb angle (curve magnitude) measurements.

Risser Sign	Cobb Angle (degrees)	Action
0 – 1	0 - 20	Observation
0 - 1	20 - 40	Bracing
2 – 3	0 - 30	Observation
2 – 3	30 - 40	Bracing
0 – 3	40 - 50	Bracing

Indications for Treatment

0 - 4	<u>></u> 50	Surgery
Adapted from: Rowe DE. The Scoliosis Researc	h Societv brace manual: introduction.	Scoliosis Research Society 2003

The Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) has published guidelines on the indications for the conservative management of scoliosis. The guidelines are intended to apply to all idiopathic scoliosis patients regardless of age. The main clinical questions that they cover are:

- Which assessment of the patient should be performed?
- Which conservative treatment should be provided and how?
- How and when should bracing be applied?
- How and when should exercises be used?

The 2016 version of SOSORT guidelines include a strength of treatments scheme (STS), which stratifies recommendations by curve severity, age, Risser stage, and the presence of pain and/or trunk decompensation.

There were several limitations associated with the 2016 SOSORT guidelines, which mitigate their ability to inform policy. The guidelines employed a parsimonious strength of evidence scheme, based on study design and numbers of studies. The strength of recommendation reflected the relative importance of the recommendation and how broadly the recommendation applied, as opposed to the extent to which a recommendation is likely to be affected by new evidence. The literature review, while comprehensive, was reported in a narrative format. The quality of the evidence (ie, confidence in the estimates of effect) was not evaluated. Further, the review did not evaluate important considerations of the body of evidence such as precision, consistency, and risks as part of the evidence review.

Broadly, scoliosis-specific exercises are recommended as the first step to treat idiopathic scoliosis to prevent/limit progression of the deformity and bracing. The SOSORT recommendation for exercise to impact curve progression was described as, "...less important, it can be applied on a voluntary basis." This recommendation is based upon the findings of multiple randomized controlled trials (RCTs) or systematic reviews of RCTs.

A single RCT investigated the effectiveness of exercise on curve progression and was included as part of a systematic review. (Monticone, 2014) A second reference was also a systematic review (Lenssinck, 2005) and a third study included as a reference in the SOSORT guideline was a preliminary cohort design (Stone, 1979) that investigated the effectiveness of exercise on curve progression over a 3-month period. None of the other studies cited by the SOSORT guidelines evaluated the effect of exercise on curve progression for individuals diagnosed with idiopathic scoliosis.

The 2016 SOSORT guidelines also recommend bracing to treat adolescent idiopathic scoliosis.

In a systematic review of RCTs and non-randomized studies of an intervention (NRSI), Fan et al (2020) evaluated the effect of scoliosis-specific exercise (SSE) on scoliotic deformity improvement. The review included 10 studies encompassing 494 participants. SSE was compared to traditional exercise, standard care (observation or bracing) or any other non-SSE. The results, based on moderate quality evidence, determined there was insufficient evidence to prove that SSE with or without other conservative treatments can reduce Cobb angle or the angle of trunk rotation (ATR). Thompson et al (2019) conducted a systematic review and meta-analysis of 9 RCTs (N=480) to assess the effectiveness of SSE on adolescent idiopathic scoliosis (AIS) compared with other non-surgical interventions. The reviewers found only very-low-quality evidence to support the use of SSE rather than standard care or other types of exercise for patients with AIS to reduce spinal curvature and trunk rotation, improve pain, function, satisfaction with management and overall quality of life, although it is unclear if the reported differences are clinically relevant.

Burger et al (2019) found that Schroth exercises had a statistically significant effect on reducing the Cobb angle in adolescents with idiopathic scoliosis; however, the clinical relevance was not reported. This review's findings should be considered with caution for physiotherapy practice because of the limited number of identified articles and their methodologic limitations.

Day et al (2019) concluded, "There is insufficient evidence to suggest that both Schroth and SEAS (scientific exercise approach to scoliosis) methods can effectively improve Cobb angles in patients with AIS compared to no intervention. There is limited evidence that the SEAS method is more effective at reducing Cobb angles compared to traditional exercises in treating AIS."

Farooqui et al (2018) suggested that therapeutic exercise regimes alone have a pivotal role in both decelerating the progression of the curve and reducing the already increased magnitude of the curve. However, the meta-analysis has

more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies.

Laita et al (2018) described the positive effects of therapeutic exercise based on the Schroth method or stabilization exercises. However, it was not possible to describe the ideal moment for the intervention or the number of weekly sessions and the duration of each session.

Gámiz-Bermúdez et al (2021) performed a systematic review and meta-analysis of 8 RCTs (N=279) that analyzed the efficacy of corrective exercise compared to other active and inert interventions in the improvement of deformity in AIS. Overall, the reviewers described moderate-quality evidence for a medium effect (SMD =-0.52, 95% CI -0.96 to -0.1), favoring corrective exercise-based therapy for spinal deformity reduction. A reappraisal of the primary studies found the results were based on very low- to low-quality evidence – due to study limitations (RoB), inconsistency and imprecision – indicating that any estimate of effects is very uncertain, and that further research is very likely to have an important impact on our confidence in the estimate of effects and is likely to change the estimate. Additionally, the clinical relevance of the results could not be ascertained due to the method employed to assess effect size.

Li et al (2021) systematically reviewed and meta-analyzed 9 studies (7 RCTs and 2 NRSI) involving 325 participants, assessing the effectiveness of core-based exercise for correcting a spinal deformity in individuals irrespective of age with scoliosis. Based on very low-quality evidence, the exercise group had significantly lower Cobb angles (MD = -2.08, 95% CI: -3.89 to -0.28, P = 0.02). The difference was not, however, clinically significant (change of \geq 5°). There was no significant difference observed regarding the angle of trunk rotation between groups (MD = -0.69, 95% CI: -2.61 to 1.22, P = 0.48).

Zhou et al (2022) found exercise therapy to have potential benefits to treat patients diagnosed with AIS. However, the findings were not conclusive; given that some reviews relied on data from the trials with potential risk of bias and significant heterogeneity. More high-quality research is still needed to verify these findings.

Two systematic reviews assessed bracing intervention (rigid and soft orthoses) for idiopathic scoliosis deformity and reached differing conclusions. The authors of the earlier publication (Lenssinck, 2005) concluded that the effectiveness of bracing is not yet established, but might be promising. In a subsequent systematic review (Negrini, 2015), the conclusions favored bracing, although the evidence was of very low-quality. This Cochrane review also concluded that a rigid brace was more successful than an elastic brace at curbing curve progression when measured in Cobb degrees in low degree curves (20° to 30°), with no significant differences in the subjective perception of daily difficulties associated with wearing the brace.

A small pilot case series (N=5) sought to evaluate the potential benefits of axial spinal unloading – a form of nonoperative traction – over a 3-month period. The authors found reductions in curve magnitude suggesting this therapy may be a potential adjunct in the treatment of adolescent idiopathic scoliosis. The design and shortcomings in the inclusion criteria resulted in very low confidence in the results of this study. The inclusion criteria did not account for a minimum Cobb angle or Risser grade. Two of the five subjects had baseline Cobb angles of <10 degrees. Only one subject had a baseline Cobb angle of >20 degrees. (Chromy, 2006)

A modeling study found that scoliotic spines were more sensitive to whole body vibration. (Jia, 2019) These results suggest that vibration may exacerbate the degree of scoliosis and so such patients should reduce their exposure to vibration.

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Review and Approval History

Date	Description
1/1997	Original effective date
3/24/1998	Annual review completed
1/28/1999	Annual review completed
2/23/2000	Annual review completed
3/07/2001	Annual review completed
9/04/2001	Annual review completed
2/14/2002	Policy inactivated
4/17/2014	Policy revised: Scope changed to focus on conservative interventions; Methodology conducted in accordance with guidance recorded in policy 429
4/16/2015	Annual review completed
4/21/2016	Annual review completed
4/20/2017	Annual review completed; Legal entity name changed from "OptumHealth Care Solutions, Inc." to "OptumHealth Care Solutions, LLC."
4/26/2018	Annual review completed; Literature Review and References revised; Appendix deleted
4/25/2019	Annual review completed. Updated the literature review and references. Plain Language Summary added to the document.
4/23/2020	Annual review completed. Updated the literature review and references. Table 4 was revised using the AMSTAR 2 instrument
4/22/2021	Annual review and approval completed
5/3/2022	Annual review completed. Updated the literature review and evidence-informed practice sections, Table 4, and references
6/29/2022	Updated legal entity name "OptumHealth Care Solutions, LLC." to *Optum™ Physical Health ("Optum") includes OptumHealth Care Solutions, LLC; ACN Group IPA of New York, Inc.; ACN Group IPA of California, Inc. d/b/a OptumHealth Physical Health of California; Managed Physical Network, Inc.; and OrthoNet Holdings, Inc. which includes OrthoNet New York IPA, Inc., OrthoNet West, Inc., OrthoNet, LLC, OrthoNet of the South, Inc.
4/27/2023	Annual review and approval completed; no significant changes made to the document. Updated contact email from policy.inquiry@optumhealth.com to phpolicy_inquiry@optum.com.
1/31/2024	Annual review completed. Document content transitioned to new policy template. No substantive changes to clinical content. Approved by Optum Guideline Advisory Committee
4/25/2024	Annual review and approval completed. Document content transitioned to new policy template. No significant changes made to the document.

Plain Language Summary

Scoliosis: Conservative Interventions Utilization Management Policy # 95

Plain Language Summaries are a service provided by *Optum* by OptumHealth Care Solutions, LLC* to help patients better understand the complicated and often mystifying language of modern healthcare.

Plain Language Summaries are presented to supplement the associated clinical policy and/or guideline. These summaries are not a substitute for advice from your own healthcare provider.

What are conservative interventions for scoliosis and what is known about them so far?

Conservative interventions for scoliosis commonly include bracing, exercises, and manual therapy – a treatment that uses hands-on pressure to gently move your joints and tissues to correct any restrictions in your range of motion. There is evidence that rigid braces are helpful for preventing or slowing curve progression for adolescents diagnosed with idiopathic scoliosis.

How were conservative interventions for scoliosis evaluated?

A work group of clinicians was assigned to review the available research. The internet was searched for articles about conservative treatments for idiopathic scoliosis. The work group independently examined the selected research studies. A broadly accepted rating scale was used. Possible ratings were high or low quality. Before it was approved, the policy was presented to a series of committees that included independent health care practitioners.

What did the workgroup find?

The use of a rigid brace appears to be effective at curbing curve progression. Elastic braces are not as effective as rigid braces. There is some evidence showing exercises, including specialized scoliosis exercises, may help with scoliosis curvature. However, additional research is needed before making recommendations. There is too little evidence to make recommendations about the effectiveness of manual therapy for the treatment of curvature associated with scoliosis.

What were the limitations of the information?

The research supporting conservative interventions for idiopathic scoliosis is based upon low quality studies. For the most part, exercise and manual therapy have not been compared to surgery. Additional research will help in more accurately defining the benefit from these services.

What are the conclusions?

Optum considers rigid brace therapy to be proven and medically necessary for the prevention or stabilization of scoliosis curvature.

Soft braces, manual therapy, exercise and other forms of conservative interventions (e.g., traction) are viewed as unproven and not medically necessary.