Scoliosis: Conservative Interventions

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Related Policies

Experimental and Investigational Services and Devices
General Guidelines for use of Plain Film Radiography

Policy Number	**95**
Original Effective Date:	1/1997
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Next Review:	4/2021
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Policy Statement

Optum* by OptumHealth Care Solutions, LLC 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.

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.

The use of manual therapy, exercise and soft braces for the treatment of idiopathic scoliosis deformity is supported by some preliminary 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.

Key Questions

1. Is there sufficient research evidence of the efficacy and safety of manual therapies e.g., manipulation, mobilization, soft-tissue techniques, etc. in the treatment of idiopathic scoliosis for the sustained reduction and/or stabilization of curve magnitude to conclude this/these interventions are an appropriate therapeutic alternative for patients diagnosed as having idiopathic scoliosis?
2. Is there sufficient research evidence of the efficacy and safety of exercise therapy in the treatment of idiopathic scoliosis for the sustained reduction and/or stabilization of curve magnitude to conclude this/these interventions are an appropriate therapeutic alternative for patients diagnosed as having idiopathic scoliosis?
3. Is there sufficient research evidence of the efficacy and safety of rigid and/or soft brace therapy in the treatment of idiopathic scoliosis for the sustained reduction and/or stabilization of curve magnitude to conclude this/these interventions are an appropriate therapeutic alternative for patients diagnosed as having idiopathic scoliosis?
4. Is there sufficient research evidence of the efficacy and safety of whole body vibration in the treatment of idiopathic scoliosis for the sustained reduction and/or stabilization of curve magnitude to conclude this intervention is an appropriate therapeutic alternative for patients diagnosed as having idiopathic scoliosis?
5. Is there sufficient research evidence of the efficacy and safety of non-operative traction therapy in the treatment of idiopathic scoliosis for the sustained reduction and/or stabilization of curve magnitude to conclude this intervention is an appropriate therapeutic alternative for patients diagnosed as having idiopathic scoliosis?

Background

Overview:
Idiopathic scoliosis is defined radiographically as a lateral curvature of the spine greater than or equal to 10º Cobb with rotation, of unknown etiology.[1] Idiopathic scoliosis is most commonly identified (~90% of cases) during adolescence (ages 10 – 18 years).[2] 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.[3] The efficacy of conservative treatment in adolescent idiopathic scoliosis (AIS) is, however, controversial due to variations in inclusion and assessment criteria[4], as well as sparse and low quality evidence.[5]

Indications for Conservative Intervention:
The primary aim of scoliosis management is to stop curvature progression.[6-8] Guidance for intervention is broadly based on the risk for significant curvature progression in a given period of time.[3,6,7] Rowe described decision-making about treatment strategies by assessing a combination of Risser Sign (skeletal immaturity) and Cobb angle (curve magnitude) measurements. [Table 1]

Table 1: Indications for Treatment

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
0 – 4	≥ 50	Surgery

Adapted from: Rowe DE. The Scoliosis Research Society 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.[8,9] 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.[8]

There were a number of 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."[8] This recommendation is based upon the findings of multiple randomized controlled trials (RCTs) or systematic reviews of RCTs.

The nine references supporting this recommendation are listed in Table 11 of the SOSORT guideline.[8] An assessment of these sources showed there was single RCT that investigated effectiveness of exercise on curve progression.[10] This study was included as part of a systematic review[11], which has been incorporated into the policy's literature review. Another reference was a systematic review that is also as part of the policy literature review.[12] A third study reported as a reference in the SOSORT guideline was a preliminary cohort design (N=42) that investigated effectiveness of exercise on curve progression over a 3 month period.[13] None of the other studies cited by the SOSORT guidelines evaluated the effect of exercise on curve progression for individuals diagnosed with idiopathic scoliosis. [Table 2]

Table 2: Sources cited to support SOSORT (2016) recommendation for scoliosis-specific exercises as the first step to treat idiopathic scoliosis to prevent/limit progression of the deformity and bracing

Author (Date)	Study type	Investigated effectiveness of exercise on curve progression?	Notes
Monticone[10] (2014)	RCT	Yes	Included in appraised systematic review(s)
Wong[14] (2005)	Cohort	No	The study compared two methods of spinal cast/modelling.
Périé[15] (2004)	Laboratory study	No	The study analyzed patient-specific bracing biomechanics in the treatment of scoliosis
Weiss[16] (2006)	Consensus report	No	Report describes a baseline for developing a consensus for language and goals for proposed multicenter clinical studies regarding scoliosis.
Lenssinck[12] (2005)	Systematic review	Yes	Included in literature review
Stone[13] (1979)	Cohort	Yes	Preliminary study
Diab[17] (2012)	RCT	No	The study investigated the effectiveness of forward head correction on postural parameters and functional level in AIS patients.
Toledo[18] (2011)	RCT	Yes	Not idiopathic scoliosis. The study participants were diagnosed with nonstructural (functional) scoliosis.
McMaster[19] (1983)	Case series	No	This study reported on the incidence of idiopathic scoliosis.

The 2016 SOSORT guidelines recommended bracing to treat adolescent idiopathic scoliosis (important but does not have to be applied to all patients with a specific need; based on multiple RCTs or systematic reviews of RCTs).[8]

Literature Review

Search Strategy:
An updated literature search was conducted on February 3, 2020. This supplemented the previous search (February 11, 2018). A comprehensive literature search was conducted using guidance provided by the Cochrane Handbook for Systematic Reviews of Interventions.[20] Biomedical databases and consumer-oriented search engines were used to identify and retrieve relevant evidence. Hand-searches of bibliographies and non-indexed documents were included in the search strategy. Additionally, professional specialty society websites e.g., SOSORT (http://sosort2014.com/), Scoliosis Research Society (http://www.srs.org/) were searched for research evidence. Research in-progress and protocols were identified by searching www.clinicaltrials.gov and published protocols.

Inclusion/Exclusion Criteria
Studies were included if they were designed to report on the effectiveness of one or more conservative interventions for the treatment of persons having been diagnosed with idiopathic scoliosis, and the intervention goal was to reduce, arrest or slow down the progression of curvature as measured by Cobb angle. Studies not meeting these criteria were excluded. Additionally, studies were excluded from independent appraisal if they were already evaluated in at least one included systematic review. Evidence syntheses that did not employ qualitative methods (eg, narrative reviews) were not included in the evidence appraisal but may have provided background information.

Evidence Extraction:
In addition to the previously appraised systematic literature reviews[11,12,21-33], five recently published studies were identified. These included four evidence syntheses that evaluated scoliosis-specific exercise approaches. These were in addition to the seven systematic reviews that were previously identified for exercise as a treatment for idiopathic scoliosis curvature.[34-38] There were five relevant systematic reviews and two narrative reviews of manual therapy. Four systematic reviews for bracing that were included in the evidence appraisal. Previous versions of systematic reviews on the same topic by the same authors were not extracted for appraisal. Additionally, data were extracted from primary studies (observational and experimental designs) that were conducted after the publication of relevant systematic reviews. A descriptive study regarding a form of non-operative traction (axial spinal unloading) was located in the previous literature search.[34] The updated literature search identified a single laboratory study concerning the effects of vibration on scoliotic spines.[39] There were no clinical studies (observational or experimental) identified concerning the treatment of idiopathic scoliosis deformity with whole body vibration.

Evidence Appraisal:
The previously identified systematic reviews were critically appraised for quality using the AMSTAR (A MeaSurement Tool to Assess Reviews) instrument, which was developed to evaluate systematic reviews of randomized trials.[40,41] The AMSTAR tool is comprised of 11 items that question the methodological quality of systematic reviews. It has good face and content validity. Literature reviews were rated as being methodologically strong (i.e. high quality), if the AMSTAR score was $\geq$6. This interpretation is consistent with the approaches of other recent 'reviews of reviews'.[42-44] The AMSTAR 2 tool has been used to assess risk of bias and the overall quality of reviews that include randomized and/or non-randomized studies of healthcare interventions. The AMSTAR 2 has 16 items in total, which includes 10 of the original 11 AMSTAR domains. It is not designed to generate an overall 'score'. The overall rating scheme is based on weaknesses in critical domains that may greatly weaken the confidence that can be placed in a systematic review.[45]

Five systematic reviews reported on manual therapy including manipulation for the treatment of idiopathic scoliosis [Table 3]. Three of the reviews were appraised as "high quality".[23,27,30] All the reviews arrived at similar conclusions; there is a lack of evidence, which does not permit conclusions on the efficacy of manual therapy for the treatment of adolescent and adult idiopathic scoliosis. Two narrative reviews, not suitable for quality appraisal, critically evaluated the body of evidence concerning the efficacy of manual therapy for idiopathic scoliosis.[46,47] Both reviews concluded that the evidence is insufficient to make judgments about the usefulness of various manual therapies in the treatment of idiopathic scoliosis.

For exercise as an intervention for the treatment of idiopathic scoliosis deformity, three systematic literature reviews and one meta-analysis were identified with the most recent literature search. [Table 4]. There were mixed conclusions rendered by the different authors. Three of the studies reported on the favorable effects of scoliosis-specific exercises for reducing Cobb angle progression; however, the clinical relevance (change of $\geq$5°) was not described. Additionally, the body of evidence was sparse, with few studies/participants, and of low quality. All of the reviews were either rated low or critically low quality.

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.[34] 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."[35] 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.[36] 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.[37]

These results are similar to the findings of previously assessed higher quality systematic reviews that concluded the effectiveness of exercises (including specific exercise approaches e.g., Schroth method), while promising, has not been established due to poor quality evidence.[11,12,22,24,29,32,33]

Four of the appraised systematic reviews assessed bracing intervention (rigid and soft orthoses) for idiopathic scoliosis deformity [Table 5]. Two of the reviews were appraised as being of high quality.[12,26] The conclusions differed between these two reviews. The authors of the earlier publication (2005) concluded that the effectiveness of bracing is not yet established, but might be promising.[12] In a more current systematic review (2015), the conclusions favored bracing, although the evidence was of very low quality.[26] 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.[26] The two low quality literature reviews concurred that the strength of evidence favors bracing over observation.[25,31]

A small pilot case series (N=5) sought to evaluate the potential benefits of axial spinal unloading – a form of non-operative traction – over a 3-month period.[39] 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.[Table 6]

A modeling study found that scoliotic spines were more sensitive to whole body vibration.[38] These results suggest that vibration may exacerbate the degree of scoliosis and so such patients should reduce their exposure to vibration.

Research In-Progress:

A search for clinical trials in varying stage of progress (e.g., recruiting, active, complete but not published) identified 35 registered studies (www.clinicaltrials.gov) concerning conservative interventions, predominantly exercise, for idiopathic scoliosis.

Evidence-Informed Practice

Clinical decision support resources have described evidence-informed guidance for the conservative management of individuals diagnosed with idiopathic scoliosis in clinical care settings.[40,41] Bracing, using rigid orthoses, is viewed as the only active nonsurgical intervention described as proven effective.

UpToDate®, a point-of-care evidence synthesis resource, has concluded that rigid bracing is a valid option for the treatment of adolescent idiopathic scoliosis in patients meeting established selection criteria.[48] UpToDate® has also determined, "There is a lack of high-quality evidence from randomized trials that physical therapy (scoliosis-specific exercises), chiropractic [manipulative] treatment, electrical stimulation, or biofeedback is effective." DynaMed, another point-of-care evidence synthesis resource, has arrived at

similar conclusions. In patients with adolescent idiopathic scoliosis, bracing is the primary treatment and appears effective. Scoliosis-specific exercises have limited evidence for improving spine curvature or reducing progression of adolescent idiopathic scoliosis. [49]

Table 3: Quality Appraisal of Systematic Reviews for Manual Therapy (including manipulation)

Appraisal Methods		Quality Appraisal				
Item	Description	Everett (2007)	Romano (2008)	Gleberzon (2012)	Posadski (2013)	Theroux (2017)
Was an 'a priori' design provided?	The research question and inclusion criteria should be established before the conduct of the review.	Yes	Yes	Yes	Yes	Yes
Was there duplicate study selection and data extraction?	There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	Yes	No	Yes	Yes	Yes
Was a comprehensive literature search performed?	At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	Yes	Yes	Yes	Yes	Yes
Was the status of publication (e.g., grey literature) used as an inclusion criterion?	The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.	Yes	No	Yes	Yes	Yes
Was a list of studies (included and excluded) provided?	A list of included and excluded studies should be provided.	No	No	No	No	Included-only
Were the characteristics of the included studies provided?	In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	No	N/A (None of the studies met inclusion criteria)	Yes	Yes	Yes
Was the scientific quality of the included studies assessed and documented?	'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	No (level of evidence scale only)	N/A	Yes (Sackett score)	Yes (Cochrane Risk of Bias)	Yes (Cochrane Risk of Bias; Effective Practice and Organisation of Care's criteria for nonrandomized Trials)
Was the scientific quality of the included studies used appropriately in formulating conclusions?	The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	N/A	N/A	Yes	Yes	Yes
Were the methods used to combine the findings of studies appropriate?	For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	N/A	N/A	N/A	N/A (single study met inclusion criteria)	N/A
Was the likelihood of publication bias assessed?	An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	No	N/A	No	No	No
Was the conflict of interest stated?	Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.	Yes	N/A	No	Yes	Yes
	Score	5	2	7	8	9

Table 4: Quality Appraisal of Systematic Reviews for Exercises Using AMSTAR 2*

Quality Assessment Item	Burger (2019)	Day (2019)	Farooqui (2018)	Laita (2018)
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes	Yes	Yes	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No	No	No	No
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes	No	No	Yes
4. Did the review authors use a comprehensive literature search strategy?	Partial Yes	Partial Yes	Partial Yes[7]	Partial Yes
5. Did the review authors perform study selection in duplicate?	Yes	No	No	Yes
6. Did the review authors perform data extraction in duplicate?	Yes	No	No	Yes
7. Did the review authors provide a list of excluded studies and justify the exclusions?	No	Yes	No	Yes
8. Did the review authors describe the included studies in adequate detail?	Yes	Partial Yes	Partial Yes	Partial Yes
9. Did the review authors use a satisfactory technique for assessing the RoB in individual RCTs that were included in the review?	Yes[1]	Yes	Yes	Yes
10. Did the review authors use a satisfactory technique for assessing the RoB in individual NRSI that were included in the review?	N/A	No[5]	N/A	N/A
11. Did the review authors report on the sources of funding for the studies included in the review?	No[2]	No	No	No
12. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results for RCTs?	No[3]	No[6]	No[8]	N/A
13. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results for NRSI?	N/A	No[6]	N/A	N/A
14. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	N/A	N/A	No	N/A
15. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes	No	No	Yes[9]
16. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	No	No	No	No
17. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A[4]	No	No	N/A
18. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes	Yes	No	Yes
Rating overall confidence in the results of the review	**Low**	**Low**	**Critically Low**	**Low**[10]

* Source: Shea BJ, Reeves BC, Wells G, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008.

Legend: PICO = population, intervention, comparator, outcome; MD = mean difference; N/A = not applicable; NRSI = nonrandomized studies of an intervention; RoB = risk of bias; SMD = standardized mean difference

Rating overall confidence in the results of the review

High	Zero or one non-critical weakness: The systematic review provides an accurate and comprehensive summary of the results of the available studies that address the question of interest.
Moderate	More than one non-critical weakness: The systematic review has more than one weakness, but no critical flaws. It may provide an accurate summary of the results of the available studies that were included in the review.
Low	One critical flaw with or without non-critical weaknesses: The review has a critical flaw and may not provide an accurate and comprehensive summary of the available studies that address the question of interest.
Critically low	More than one critical flaw with or without non-critical weaknesses: The review has more than one critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies.

Note: Multiple non-critical weaknesses may diminish confidence in the review and it may be appropriate to move the overall appraisal down from moderate to low confidence

Rationale:

1. Only the RoB summary assessment scores were provided. A table showing the individually assessed items was not included in the study or as supplemental material. The narrative did add information about lack of blinding (participants, clinicians, assessors). [non-critical weakness]
2. Fixed effects meta-analytic model was used when a random effects analysis was the appropriate choice (Figure 2). This likely resulted in overestimating the pooled the effect size (that is, to a more substantial benefit). [critical flaw]
3. Only two studies per meta-analysis
4. Too few studies to assess for publication bias
5. The PEDro checklist for RCTs was used for NRSI
6. Forest plots calculated effect sizes (Hedge's d), when calculations using direct measurement (degrees) would have been more informative e.g., interpreting clinical relevance [critical flaw]. Meta-analysis not performed due to significant heterogeneity.
7. The search strategy included 3 data bases, only 1 of which was a standardized bibliographic platform. [critical flaw]
8. The Q test and I^2 test were reportedly calculated to identify the level of heterogeneity; however, the results were not described. Further, there was no exploration of the causes of heterogeneity. The authors reported both fixed and random pooled effects (which showed different results). Without knowing the significance of heterogeneity, it was not possible to determine the most appropriate analytic model. The meta-analysis used SMD when MD (degrees) would have been more informative. [critical flaw]
9. The analysis included studies deemed to have a low or moderate risk of bias
10. The analysis reported on statistical significance (p values) but did not provide information about clinically meaningful change (>5°) with intervention [critical flaw]

Table 5: Quality Appraisal of Systematic Reviews for Bracing Intervention

Appraisal Methods		Quality Appraisal			
Item	Description	Lenssinck (2005)	Maruyama (2011)	Weiss (2012)	Negrini (2015)
Was an 'a priori' design provided?	The research question and inclusion criteria should be established before the conduct of the review.	Yes	Yes	Yes	Yes
Was there duplicate study selection and data extraction?	There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	Yes	?	?	Yes
Was a comprehensive literature search performed?	At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	Yes	No (only a single data base was queried)	No (only a single data base was queried)	Yes
Was the status of publication (e.g., grey literature) used as an inclusion criterion?	The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.	Yes	No	No	Yes
Was a list of studies (included and excluded) provided?	A list of included and excluded studies should be provided.	No	No	No	Yes
Were the characteristics of the included studies provided?	In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	Yes	Yes	No	Yes
Was the scientific quality of the included studies assessed and documented?	'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	Yes	Yes (Cochrane Risk of Bias)	No	Yes (Cochrane Risk of Bias; Newcastle-Ottawa Scale)
Was the scientific quality of the included studies used appropriately in formulating conclusions?	The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	Yes	Yes	N/A	Yes
Were the methods used to combine the findings of studies appropriate?	For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	N/A	N/A	N/A	N/A
Was the likelihood of publication bias assessed?	An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	No	No	No	No
Was the conflict of interest stated?	Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.	No	Yes	Yes	Yes
	Score	7	5	2	9

Table 6. Risk of Bias (limitations in study design or implementation)

Title: Chromy CA, Carey MT, Balgaard KG, Iaizzo PA. The potential use of axial spinal unloading in the treatment of adolescent idiopathic scoliosis: A case series. *Arch Phys Med Rehabil*. 2006;87:1447–1453.

Clear study objective/question	Yes	To evaluate the potential benefits of axial spinal unloading over a 3-month period
Well-defined study protocol	Yes	Protocol included a training session and a pre-formatted "compliance" journal
Explicit inclusion and exclusion criteria for study participants	Yes	Criteria did not account for a minimum Cobb angle or Risser sign. Two of the five subjects had baseline Cobb angles of <10 degrees. Only one subject had a baseline Cobb angle of >20 degrees.*
Specified time interval for patient recruitment	Yes	6-months
Consecutive patient enrollment	Unsure*	Not reported
Clinically relevant outcomes	Yes	
Prospective outcome data collection	Yes	
High follow-up rate	Yes	100%

* = High risk of selection bias

Source: Chan K, Bhandari M. Three-minute critical appraisal of a case series article. *Indian Journal of Orthopaedics* 2011; 45:103–104

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Policy History/Revision Information

Date	Action/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

Contact Information

Please forward any commentary or feedback on OptumHealth Care Solutions, LLC (OptumHealth) Utilization Management policies to: policy.inquiry@optumhealth.com with the word "Policy" in the subject line.

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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 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 work group 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.