

Maintenance/Custodial Care

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Policy Statement

Maintenance or custodial care is considered to be unproven and not medically necessary for the treatment of disorders typically managed by chiropractors, physical and occupational therapists.

The role of maintenance/custodial care has not been established in scientific literature. A beneficial impact on health outcomes, e.g., prevention of recurrences and/or the sustainability of optimal health status has not been established.

Purpose

This policy has been developed as the clinical criterion that describes the Optum* by OptumHealth Care Solutions, LLC position regarding the efficacy of maintenance or custodial care in the context of in-office services rendered by chiropractors, occupational and physical therapists.

Key Policy Question

Is there sufficient research evidence supporting the efficacy of maintenance (custodial) care for primary, secondary or tertiary prevention in a specific patient population?

Population: Adults with musculoskeletal disorders (acute/subacute/chronic/recurrent) that have been responsive to an initial phase of SMT and have achieved maximum improvement.

Intervention: Regularly scheduled manipulative therapy eg, every 2-4 weeks, or 1-3 months

Comparators: No treatment; home-based self-care eg, home exercise program; placebo or sham intervention

Outcomes: *Critical* outcomes include patient-reported measures of pain (eg, VAS) and function (eg, Oswestry Disability Questionnaire). *Important* outcome = recurrence rate.



Summary

- o Maintenance/custodial care is commonly recommended by chiropractors. The prevalence of application within the disciplines of physical and occupational therapy is unclear.
- Recently published studies suggest there is general agreement about patient selection criteria
 for secondary and tertiary preventive/maintenance care; however, the patients who tend to
 receive maintenance do not appear to meet the criteria described in consensus survey findings.
- o There appears to be no common convention on the frequency and duration of maintenance care programs
- Concerns about patients' risks and burdens have been articulated (eg, promotion of passive coping) but no definitive data were identified
- o The clinical evidence on maintenance care is sparse and generally of very low quality. There is uncertainty about making judgments based upon the estimates of treatment effect.
- Health care organizations appear to uniformly exclude maintenance (custodial) care from benefit coverage

Scope

This policy is limited to those services that take place within an in-office setting e.g., manual therapies, and is applicable to all in and out of network programs involving all provider types, where utilization review determinations about benefit coverage are rendered.

Out of Scope: Preventive screening measures as described by the U.S. Preventive Services Task Force¹ and Medicare Preventive Services.²

Definitions

See Table 1



Description

For the purposes of this policy services are defined as *Maintenance/Custodial Care* when any of the following are satisfied:

- Treatment that seeks to prevent disease, promote health, and prolong and enhance quality of life
- A specific regime (usually at regular intervals) designed to provide for the patient's wellbeing or maintaining the optimum state of health
- Services that can be carried out by nonskilled persons e.g., passive exercises to maintain range of motion, distribution of educational pamphlets, etc.
- Treatment following a course of care, where a condition is symptomatically and/or functionally stationary, that seeks to preserve the patient's present level of symptoms/function and prevents regression of those symptoms and/or function
- Treatment that is intended to maintain a gradual process of healing or to prevent deterioration or relapse
- Treatment solely to improve physical performance e.g., endurance, strength, distance, proprioception, etc.
- Treatment directed towards biomechanical goals e.g., saggital spinal curve correction in the absence of operant, and achievable therapeutic goals i.e., pain reduction, increased function
- A general exercise program to promote overall fitness
- Treatment that is intended to provide diversion or general motivation
- Services rendered solely for the comfort and convenience of the patient

Analogous Terminology:

- Wellness care
- o Elective care
- o Preventive care
- o Palliative care

- o Primary prevention
- Secondary prevention
- o Tertiary prevention
- Non-therapeutic care

Background

Introduction:

Chiropractors, physical and occupational therapists are regularly consulted for the treatment of chronic or recurrent disorders. It is understandable that, once improvement has been achieved, clinicians attempt to prevent new events or maintain patients at their optimal level. In the clinical domain of physical medicine and rehabilitation (inclusive of chiropractic), this type of care is typically termed maintenance or custodial care. In the context of public health, this type of care management is described as secondary or tertiary prevention. *Secondary prevention* is aimed at preventing subsequent events (episodes); whereas *tertiary prevention* means that improved patients, who have incurable conditions, are maintained at the best possible level. Additionally, individuals may elect to receive care that may mitigate the development of a disorder. This is termed *primary prevention*.

There does not seem to be consensus on a uniform definition of maintenance/custodial care.³ A search of electronic databases yielded a number of definitions of maintenance care reported in healthcare policies, guidelines, descriptive surveys, reviews, commentaries, and texts. [Table 1] The core elements from these definitions are incorporated into the operational description (above) of this policy.



Beliefs and Prevalence:

In spite of the general lack of consensus on a singular evidence-based definition for maintenance/custodial care, the concept seems to be firmly ensconced in the chiropractic profession. While the evidence is sparse, respondents to surveys appear to heavily favor maintenance or wellness care for at least some patients (93%), for the 'average' patient (98%), or for the asymptomatic patient (92%). The conclusions from these surveys, however, are suspect due to low response rates, a focus on the prevention of non-musculoskeletal disorders, and possible changes in professional beliefs over time (these data are ~20 years old). More recently, a survey of 129 members of the Swedish Chiropractors' Association indicated that 98% of respondents seem to support the concept of maintenance care.

Rupert and Jamison published data on the perceptions of maintenance care respectively from surveys of North American and Australian chiropractors. ^{8,9} Forty percent of respondents in North America and 22% of the Australian sampled believed there was adequate research supporting maintenance care.

A 2007 "practice analysis" compiled by the Federation of State Boards for Physical Therapy did not include maintenance/custodial care as a measurable component of clinical knowledge or practice characteristics. ¹⁰ An additional literature search failed to identify any empirical or observational data pertaining to the occupational and physical therapy professionals on their beliefs or prevalence of use, or factors associated with the use of maintenance/custodial care.

The prevalence of maintenance/custodial care has been sparsely reported in chiropractic literature. A retrospective records review of ~3,000 files in Great Britain concluded that maintenance care was associated with 36% of the cases. A survey of newly graduated chiropractors in Australia reported that 34% of patients were on maintenance care. These estimates again suffer from being based upon very old data (1976, 1987). A 2005 records audit conducted in the United States by the Office of the Inspector General, reported that 40% of Medicare-eligible patients' claims were representative of maintenance care. A subsequent audit published in 2009 found no appreciable change (36%). A 2007 survey published in a chiropractic professional trade journal reported that ~20% of respondents call their clinics "wellness centers". The description of wellness care was analogous to maintenance/custodial care (above). A direct observational study published in 2010 used pre-defined criteria for making judgments about maintenance care prevalence in private practice settings found that 22% of the patients in Denmark and 26% in Norway were on maintenance care. The prevalence of use may be higher in certain subgroups. Moller reported that a mean of 35% (median 42%) of patients seeing chiropractors known to have strong views favoring preventive care were on maintenance care.

Patient Selection:

The literature search identified only sparse information on the general indications for maintenance care by chiropractors and no information by physical or occupational therapists. A survey of 658 North American chiropractors suggests that there is a common understanding about the purposes of maintenance care. Over 80% of respondents either agreed or strongly agreed that its purpose was to minimize recurrence or exacerbation, maintain or optimize health status, prevent conditions from developing, provide palliative care for "incurable" problems, and to determine and treat subluxation. A small majority (56.2%) of chiropractors surveyed also agreed the purpose of maintenance care was to prevent subluxation. Jamison subsequently conducted a survey of 138 Australian chiropractors. The results obtained parallel the levels of agreement found with chiropractors in North America.



There appears to be lesser concordance on the body systems/conditions that can be helped by maintenance/custodial care. Both Rupert and Jamison found surveyed respondents who agreed (>80%) that maintenance care was appropriate for musculoskeletal conditions and stress. There was less agreement on the value of maintenance care for conditions directly related to the respiratory, gastrointestinal, cardiovascular, and reproductive systems.^{8,9}

The concept of "maintenance physiotherapy" has been described. ¹⁸ The criteria list developed from a consensus definition, however, was analogous to the concept of "supportive care" (see policy # 84 – Determination of Maximum Therapeutic Benefit). The criteria emphasize consideration of other options, significant residuals (decreased function and quality of life) at maximum improvement, the application of standardized clinical outcomes measures, a self-care component, and consideration of eventual discharge.

More recently, work on defining and exploring the concept of maintenance care has been initiated in the Nordic countries. In a series of survey methods publications the *Nordic Maintenance Care Program* work group described the criteria used for patient selection by chiropractors in Sweden, Denmark, and Finland. Survey data were then compared to the use of maintenance care in a sampling of actual practices. 16

The results from these surveys suggest there is relative agreement among chiropractors practicing in different countries and sampled through different methods in relation to clinical decision making about recommendations for or against maintenance care. "Maintenance care for low back pain appears to be used in order to prevent further events, in particular with patients who react well to treatment and who have a long history of previous problems." Hansen, et al. summarized the results of a 413 (72% response rate) chiropractors practicing in Denmark. The non-indications for maintenance care were a good outcome combined with no previous events, or a past history of LBP associated with a gradual worsening with treatment. Indications in favor of maintenance care were a good outcome combined with a previous history of low back pain recurring between once a month and once a year. Most survey respondents indicated that tertiary preventive care should be recommended only in those circumstances where a patient shows at least 50% improvement during the 'active' phase of treatment. In contrast to survey reporting, a Norwegian multi-centered outcome study of patients with more persistent or chronic low back pain showed that maintenance care was, at the one-year follow-up, given mainly to patients who did *not* have a good short-term outcome. ²¹

Treatment Protocol:

There appears to be no common convention on the frequency of treatments and duration of the maintenance treatment program. Thus it is not known if patients on MC [maintenance care] are coerced to partake in a program of frequent treatments over a long period of time, or if they are actively involved in designing their own individualized treatment program.

Axen, et al have proposed a dual model, "symptom-guided" vs. "clinical findings-guided", as the fundamental means by which chiropractors determine treatment in terms of maintenance care. ¹⁹ The authors incorporated this model within a small survey. Nine case scenarios were presented to 100 Swedish chiropractors. The 59 respondents selected one of six clinical management strategies for each scenario. The "symptom-guided model was preferred for patients who presented with the following two vignettes: 1) An acute attack of LBP of 2 days' duration and no previous history of LBP. The pain is completely gone after 2 visits. The patient is very worried that the pain will come back again. The patient asks if he could come back regularly to make sure this will not happen; 2) An acute attack of LBP of 1 week's duration. The patient has had several similar attacks over the past 12 months. The pain is completely gone after 2 weeks of treatment. The "clinical-findings-guided" paradigm also received significant favour.



Sandnes, et al. ¹⁶ authored what appears to be the most comprehensive investigation of the patterns of intervals between treatments for patients receiving and not on maintenance care, as well as who decides on the next treatment. Data were collected on 868 patients from 28 Danish and Norwegian chiropractors using trained observers and standardized recording methods. For patients on maintenance care, the most common interval between the current and previous visit was 2-4 weeks. The most common interval for the next maintenance care appointment was between 2 weeks and 3 months. In contrast, active or acute care intervals between appointments were usually less than 1 week. The decision on the interval between maintenance care visits was mainly made by the chiropractor.

Beyond these broad conceptual approaches there does not appear to be a consensus on the clinical application of maintenance/custodial care. "The indications for maintenance care and clear descriptions of preventive treatment for specific types of conditions are not found in the literature." ¹⁹

Efficacy:

A comprehensive literature review of maintenance/custodial care was conducted by a work group. The minimum search strategy described in the current updated methods guide published by the Cochrane Back and Neck Group (CBNG) was followed [23]. Bibliographic databases searched included MEDLINE, EMBASE, Manual Alternative and Natural Therapy (MANTIS), Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Index to Chiropractic Literature (ICL) were updated to July 2011. All databases were originally searched from their beginning. In addition, references were screened, attempts were made to contact authors to obtain omitted data, and the grey literature was searched for relevant articles. Searches of databases containing evidence summaries and syntheses were assistive in elevating confidence that the primary search strategy was sufficiently comprehensive to capture all relevant literature.

Case studies, descriptive surveys, records audits, and opinion papers were not included in the formal quality appraisal. Additionally, trials that did not assess intermediate-term (~6 months) and/or long-term (\geq 9 months) outcomes of importance were excluded from the quality appraisal.

A total of six studies were extracted for quality appraisal [Table 2]. A single randomized clinical trial (RCT) was identified that investigated manipulative therapy for the prevention of chronic neck pain. ²⁴ Four studies that evaluated the preventive effects of manipulation for chronic/recurrent low back pain, disability, or recurrence of disability were subjected to formal appraisal. ²⁵⁻²⁸ A single RCT reporting on the preventive effect of manipulation for hamstring injuries was identified. ³⁰ Risk of bias (RoB) was assessed using the CBNG approach for RCTs and a modification of the Critical Appraisal Skills Programme (CASP) checklist was applied to observational designs. With the exception of the RCT conducted by Eklund, et al. (2018), all the appraised studies were judged to have a high RoB [Tables 3,4]. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was used to assess overall evidence quality. ³¹⁻⁴⁰ The overall quality of evidence was rated very low to low across outcomes for pain intensity, disability, and work status; most commonly due to study limitations (RoB) and imprecision [Tables 5-8]. Evidence quality was judged to be moderate for the outcome of LBP bothersomeness [Table 9].



Martel [24] investigated the effect of high velocity/low amplitude cervical and thoracic manipulation for the tertiary prevention of chronic neck pain. Following randomization, ninety eight adult subjects received 10-15 sessions of SMT over a five to six week time period. Subjects were then allocated into 3 groups. One group attended the clinic once/2 months for assessment but no treatment (attention-control). The second and third groups received monthly SMT. The third group received home exercise instruction in addition to SMT. Serial outcomes were assessed every 2 months for up to 10 months. Overall, SMT with or without exercise did not yield significant advantages when compared to the no treatment strategy. There were no significant between-group differences for the primary and secondary outcome variables [Table 5].

Investigators conducted a pragmatic randomized controlled trial (RCT) to assess the efficacy of chiropractic maintenance care, as a prevention approach for individuals having recurrent or persistent low back pain (LBP). The authors sought to integrate the current state of the evidence with the clinical decision-making process and maintenance care approach typically employed by chiropractors. Thirty-five chiropractic clinics in Sweden identified patients, who met initial eligibility criteria and demonstrated an early (by the 4th visit) favorable response to treatment. A total of 328 patients were randomized to receive either symptom-guided/usual care (UC) or maintenance care (MC), with visits planned at 1-3 month intervals. Patients receiving scheduled chiropractic care at <1 month intervals were excluded from the study. MC visits typically included manipulative therapy (94%). The primary outcome for the trial was the number of days with bothersome LBP, which was reported via weekly text messages through the 52-week study period. Compared to those receiving UC, the MC group had 12.8 days fewer (95% CI 10.1 to 15.6 fewer) of bothersome LBP. The efficacy of MC was not supported; however, as the relative effect (13% difference favoring MC) did not meet the prespecified clinically meaningful difference between groups of 20% for acute LBP and 30% for chronic LBP. This study was judged to have a low RoB, representing moderate quality evidence [Table 9].

Two clinical trials that employed similar methodologies and obtained critical outcomes data investigated the effects of SMT for the tertiary prevention of chronic low back pain. ^{25,28} Both studies presented with a high risk of bias [Table 3] and serious imprecision, which resulted in downgrading the quality rating (very low) for answering the policy question. [Table 6] After a one month *therapeutic care phase*, subjects in the maintenance care group (N=40) received scheduled SMT every 2-3 weeks for 9-months. Subjects receiving maintenance SMT reported statistically significant lower pain and disability scores compared to the groups that did not attend maintenance care. Measures of pain intensity (relative and absolute) at both intermediate and long-term assessments, however, did not achieve the threshold of minimal clinically important change (MCIC). For the outcome of disability, the mean initial improvements achieved by the maintenance group were sustained at both intermediate and long-term follow-ups. During the same timeframes, the group not receiving maintenance manipulation gravitated toward baseline values that approximated but did not exceed the MCIC threshold. The relative effects (comparisons between groups) modestly exceeded MCIC values at both intermediate and long-term follow up assessments.

The effect of "health maintenance care" on the recurrence of work disability (secondary prevention) was investigated in a single retrospective claims data analysis.²⁹ This study was judged to have a high RoB [Table 4], and was rated as being of very low quality for answering the policy question due to design, indirectness, and imprecision [Table 7]. Workers' compensation claims data (894 cases), encompassing a single carrier in 6 states, were analyzed using an explicit methodology. Analysis was performed from the perspective of provider type (chiropractor, physical therapist, or physician). "Health Maintenance Care" was defined as the period after the initial disability episode had ended and the person had returned to work for >14 days. After controlling for demographics and severity indicators, only those receiving primarily physical therapy showed significantly greater recurrence rates (HR = hazard ratio) than chiropractic care. The recurrence rate between those individuals receiving chiropractic care during the health maintenance care period and those not receiving any services was essentially the same. Calculation of the number needed to treat (NNT) showed that 96 patients would need to be treated over the course of 1-year to prevent 1 recurrence.



A small RCT was conducted to investigate the primary and secondary preventive effects of spinal and/or extremity manipulation on the occurrence of disabling hamstring injuries. This study's quality was rated as very low (high RoB, indirectness, imprecision) for answering the policy question. [Table 8] Following randomization, 59 semi-elite Australian footballers were allocated to receive best practice multimodal medical and sports science management with or without HVLA manipulation. Subjects received weekly treatment during the initial phase of the trial (6 weeks). The second phase consisted of one session every 2 weeks for 3 months, followed by one session per month for 3 months. There was no statistical difference between groups in the prevention of hamstring injuries or weeks missed due to hamstring injury at the end of the trial (6 months). This trial also sought to investigate the preventive effect of manipulation for low back pain. Outcomes assessment was not sustained beyond 3 months, which was judged *a priori* to be insufficient for answering the policy question.

Risks and Burdens:

Information about the potential risks and burdens associated with maintenance care has largely been extracted from publications reflective of practices in Scandinavia (chiropractors) and Australia (physical therapists). While the applicability of these conclusions to other geographic areas should be questioned, it is notable that the use of maintenance care was highest in Nordic chiropractors who were educated in North America and tended to have more years of experience. Patient demographic variables did not show any associations with the application of maintenance care.

In a commentary, Leaver articulated concerns about the application of maintenance care to cases in which abnormal symptom-focus and illness behavior are being 'maintained' with ineffective treatment. ⁴¹ The Nordic Maintenance Care Program work group described a parallel theme associated with maintenance care, "…there seems to be a general management culture to continue treating patients with LBP past the initial treatment period." ⁷ The relevance of this conclusion is amplified, when observation in clinical practice settings suggests that maintenance care is given mainly to patients who did *not* have a good short-term outcome. ²¹

A shared-decision making approach between patient and clinician seems appropriate when considering secondary or tertiary prevention options such as maintenance care. Sandnes et al. $(2010)^{16}$, however, reported the decision on the interval between maintenance care visits was mainly made by the chiropractor. A long-term care program such as maintenance care, when imposed on patients, may become more of a passive ritual, removing responsibility for keeping well from the patient to the treatment program. A passive coping strategy may be detrimental to a patient's prognosis.⁴²

The burden for some patients to attend open-ended care maintenance care scheduled at intervals between 2 weeks and 3 months has not been investigated. "It might well be relevant to choose a long-term management strategy in order to prevent further problems or keep them under control. However, this is only relevant if the patient gains more than it costs in terms of time and money." ²²



| Eviden | nce Rating | |
|---------|-----------------------------------|---|
| Neck Pa | in: | |
| D | No Proven Benefit | Use of maintenance/custodial care for neck pain has not been shown to improve health outcomes |
| Low Ba | ck Pain: | |
| C | Potential but Unproven Benefit | Use of maintenance/custodial care is supported by some positive published data regarding safety and/or efficacy for chronic low back pain, but a beneficial impact on health outcomes has not been proven for the following reason: the clinical evidence is imprecise and the quality of evidence is very low. |
| Hamstri | ing Injury: | |
| D | No Proven Benefit | Use of maintenance/custodial care for hamstring injury prevention has not been shown to improve health outcomes |
| Other M | Iusculoskeletal Disorders: | |
| D | No Proven Benefit | The research regarding use of maintenance/custodial care for the prevention of other musculoskeletal disorders is so limited that an appraisal of safety and efficacy cannot be made. |

^{*}Optum is a brand used by OptumHealth Care Solutions, LLC and its affiliates



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Source Documents: Definition of Maintenance Care

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Tables

Definitions of Maintenance Care Table 1

| Source | Type | Discipline | Definition |
|------------------|---------------------------|---|---|
| CMS | Policy | Chiropractic | A treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. |
| Boisvert | Text | Chiropractic | Appropriate treatment directed toward maintaining optimal body function. This is treatment of the symptomatic patient who has reached pre-clinical status or maximum medical improvement, where the condition is resolved or stable. |
| Haldeman | Professional Guideline | Chiropractic | Care given to reduce the incidence or prevalence of illness, impairment, and risk factors, and to promote optimal function. |
| Glenerin | Professional Guideline | Chiropractic | Any management plan that seeks to prevent disease, prolong life, promote health and enhance the quality of life. A specific regimen is designed to provide for the patient's well-being or for maintaining the optimum state of health. |
| 3.6% 1 11 | | CI: | A regime designed to provide for the patient's continued well-being or for maintaining |
| Mitchell | Commentary | Chiropractic | the optimum state of health while minimizing recurrences of the clinical status |
| Breen | Review | Chiropractic | Treatment either scheduled or elective, which occurred after optimum recorded benefit was reached, provided there was no evidence of relapse |
| Boline & Sawyer | Survey | Chiropractic | Regular chiropractic care |
| Bonne & Sawyer | Survey | Chiropractic | During the last visits for rehabilitative treatment, the clinician may develop a |
| CMS | Policy | Physical and Occupational Therapy | maintenance program. The goals of a maintenance program would be, for example, to maintain functional status or to prevent decline in function The services of a qualified professional are not necessary to carry out a maintenance program |
| Aetna | Policy | Chiropractic | Elective health care that is typically long-term, by definition not therapeutically necessary but is provided at preferably regular intervals to prevent disease, prolong life, promote health and enhance the quality of life. This care may be provided after maximum therapeutic improvement, without a trial of withdrawal of treatment, to prevent symptomatic deterioration or it may be initiated with patients without symptoms in order to promote health and to prevent future problems. |
| CIGNA | Policy | Chiropractic | Chiropractic services are considered not medically necessary if services are considered maintenance /preventive: |
| | | Physical | Services to improve or maintain general physical condition or for long-term |
| CIGNA | Policy | Therapy | rehabilitative services when significant therapeutic improvement is not expected. |
| Oxford | Policy | Chiropractic | A regimen designed to provide for the patient's continued well-being or for maintaining the optimum state of health while attempting to minimize recurrence of a preexisting condition. Treatment usually follows completion of therapeutic or supportive care, is directed at a symptomatically stationary condition with anticipation of maintaining optimal body function, and usually provided on some routine or regular basis. Treatment is discretionary and elective on the part of the patient. By definition, medical necessity is absent. |
| BCBS of TN | Policy | Chiropractic | treatment for a patient who has no present pain or symptoms above their normal baseline but seeks to prevent pain /disability, promote health, and enhance quality of life. A preventive / maintenance program consists of activities that preserve the patient's present level of function and prevent regression below their functional baseline. Maintenance begins when the therapeutic goals of a treatment plan have been achieved, or when no additional functional progress is apparent or expected to occur. Therapy / treatment used to delay or minimize deterioration for patients suffering from a chronic condition in the absence of exacerbation (e.g., osteoarthritis, fibromyalgia) is also considered to be maintenance therapy. Preventive / maintenance care is not therapeutically necessary. |
| UnitedHealthcare | Policy | All | CMS definitions |



Table 2: Clinical Studies Meeting Selection Criteria for Quality Appraisal

| Author | Study | Population | Interventions | Outcome | Follow-up | Results |
|--------------------------|--|--|--|--|--|---|
| Descarreaux (2004) [25] | Quasi- Randomized Controlled Trial (Pilot Study) | - 30 subjects - Age: average 42.1 years - Chronic or recurrent LBP (> 6 months) - Tertiary prevention - 2 private chiropractic clinics | Intervention group (LBP-2; n=15): SMT –side-posture technique applied to lumbar and pelvic regions at reatments per week for 4 weeks; total = 12 SMT sessions followed by SMT once every 3 weeks for 9 months Control group (LBP-1; n=15): SMT –side-posture technique applied to lumbar and pelvic regions at reatments per week for 4 weeks; total = 12 SMT sessions | Variables - VAS (daily diary scores averaged for reporting) - ODI - Self-care frequency (ice bag) – surrogate for high pain episodes - No. of external consultations - No. days of sick leave | - 1-month (end of initial 12-sessions) - 4-months - 7-months - 10 months | Both groups demonstrated clinically significant improvement in pain intensity after 4 weeks of treatment. There was no difference in pain-related outcomes at any of the follow-up periods (1, 4, 7, 10 months) Self-care ie, use of ice bag was significantly greater at 10-month follow up for LBP-1 compared to LBP-2 No significant differences between groups in No. of external consults and sick days Control Group (LBP-1) Did not achieve clinically meaningful improvement in disability score using a broadly accepted scale (10% point change) during the treatment phase of the trial. Follow-up measures showed a trend toward the baseline score Intervention Group (LBP-2) The Intervention Group (LBP-2) The Intervention Group (LBP-2) demonstrated minimal clinically important change after 1 month Follow-up measures at 4, 7 and 10 months did not demonstrate further meaningful clinical change Initial improvement in the disability measure was sustained at each follow-up interval |
| Martel (2011) [24] | Randomized Controlled Trial | N = 98 Ages 18-60 years Chronic non- specific neck pain Tertiary prevention University affiliated outpatient clinic | All Groups: 10-15 treatment sessions over a 5-6 week period HVLA manipulation (cervical and upper thoracic regions) Limited myofascial therapy Attention-control group: No treatment HVLA Attended clinic once every 2 months (20-30 minutes) Standardized short history, VAS, and passive palpation Spinal manipulation group: Cervical and upper thoracic manipulation once per month (10-15 minutes) Spinal manipulation & home exercise group: Cervical and upper thoracic manipulation once per month (10-15 minutes) Standardized low-tech exercises (advised to perform at least 3 times per week) | Primary: VAS Secondary: CROM (function) NDI (disability) BQ (disability) Exploratory: SF-12 (HRQOL) FABQ (fear and avoidance phenomena Exercise adherence & co-intervention (diary) Self-care frequency (ice bag) – surrogate for high pain episodes | Following initial (symptomatic) treatment phase: - 2-months - 4-months - 6-months - 8-months - 10 months | Overall, SMT with or without exercise did not yield significant advantages when compared to the no treatment strategy. There were no significant between-group differences for the primary and secondary outcome variables There were no between group differences for the exploratory variables – fear/avoidance behavior and HRQOL The attention-control group utilized more cointervention and self-care No serious adverse events were reported |



| Eklund (2018) [26] | Pragmatic Randomized Controlled Trial | N = 328 Ages 18-65 years Recurrent and persistent LBP Secondary/tertiary prevention 35 Swedish chiropractic clinics | Maintenance care (MC) group: Pre-scheduled visits @ 1-3 month intervals Mainpulative therapy was the most commonly-reported intervention (94%) No maintenance care group: Usual "symptom-guided" treatment | Primary: Total # of days with bothersome LBP Secondary: Pain trajectories Utilization (visits) Adverse events | - Weekly over 52-weeks | MC group reported 12.8 (95% CI 10.1, 15.6) fewer days of bothersome LBP (absolute effect) The relative effect was 13% difference favoring the MC group Crude analysis of the pain trajectories showed the difference between groups held throughout the study; however, the difference narrowed between groups towards the end of the study. The MC group used ~2 more visits [MC= 6.7 (95% CI 6.6, 6.8); No MC=4.8 (95% CI 4.7, 4.9)] over the 12-month study period. No serious adverse events reported |
|--------------------------|--|---|--|---|---|---|
| Senna (2011) [28] | Randomized Controlled Trial | N = 93 Ages 20-60 years Chronic non-specific LBP Tertiary prevention University affiliated outpatient clinic | All groups: Home exercise program Sham group: 12 sham SMT sessions over 1 month No treatment for following 9-months SMT group: 12 SMT (3x/wk) for 1 month No treatment for following 9 months SMT + Maintenance group: 12 SMT (3x/wk) for 1 month Maintenance treatment every 2 wks for 9 months | Primary: ODI (disability) Secondary: VAS (pain) SF-36 (general health) GRS (satisfaction with outcome) Objective measures: Modified Schober test & lateral bending measurement (mobility) | - 1- month (immediately after 12 sessions) - 4-months - 7-months - 10-months | Subjects in the second and third groups experienced significantly lower pain and disability scores compared to the control group after the initial 1-month treatment period. Subjects receiving maintenance SMT reported significantly lower pain and disability scores compared to the SMT group. Subjects receiving maintenance SMT achieved noticeable differences in secondary and objective outcomes compared to the SMT group. |
| Cifuentes (2011) [29] | Observational study (retrospective records review) | N = 894 Ages 17-65 years LBP Secondary prevention Workers' Compensation records (USA) Claims from 6 states | Interventions defined from the perspective of provider type: Chiropractic Physical therapy Physician services Health Maintenance Care = the period after the initial disability episode had ended and the person had returned to work for >14 days | Time to disability recurrence Recurrent Disability = a resumption of temporary total disability compensation after a period of health maintenance care | Cases followed for 1-year | 11% (N=98) experienced recurrent disability because of work-related LBP. Provider type was significantly associated with recurrent disability Unadjusted hazard ratios (HR) were calculated using chiropractic care as the referent (1.0); Physical therapy and physician patients' disability recurrence rates were 2.0 and 1.6 respectively; Non-treated individuals HR was 1.2 After controlling for demographics and severity indicators, only the physical therapy HR remained significantly greater than chiropractic The recurrence rate between those individuals receiving chiropractic care during the health maintenance care period and those not receiving any services was essentially the same |



| Hoskins (2010) [30] | Randomized Controlled Trial | N = 59 Ages 18-27 years Semi-elite Australian footballers Hamstring injuries LBP Primary and secondary prevention Private outpatient clinic | Phase 1 (1 session/week for 6 weeks) Control Group: Best practice multimodal medical and sports science management (pragmatic) Intervention Group: Same as control group plus sports chiropractic intervention (discretionary HVLA manipulation of spine and/or extremities) Phase 2 (1 session/2 wks for 3 months; 1 session/month for 3 months) Control group: Same as Phase 1 Intervention group: Same as Phase 2 | Primary: Injury-related athletic disability (missed match) Secondary: MPQ-SF (LBP pain) SF-39 (general health) Adverse events | LBP: - 3-months (following phase 1) Hamstring Injury: - 6-months (following phase 1) | There was no statistical difference between groups in the prevention of hamstring injuries or weeks missed due to hamstring injury There was a positive and statistically significant change for the intervention group for overall and current LBP No adverse events were reported |
|------------------------|-----------------------------------|---|---|---|---|---|
|------------------------|-----------------------------------|---|---|---|---|---|

Abbreviations:

- o SMT Spinal manipulative therapy
- o HRQL Health related quality of life
- o HVLA High velocity low amplitude
- o NDI Neck Disability Index
- o VAS Visual Analog Scale
- o GRS Global Rating Scale
- o MPQ-SF McGill Pain Questionnaire Short Form
- o ODI Oswestry Disability Index
- o BQ Bournemouth Questionnaire



Table 3. Risk of Bias (limitations in study design or implementation)

| Bias Domain | Sour | rce of Bias | Martel ²⁴ | Descarreaux ²⁵ | Eklund ²⁶ | Senna ²⁸ | Hoskir | าร ³⁰ |
|-------------|------|---|----------------------|---------------------------|----------------------|---------------------|--------|------------------|
| Selection | 1. | Was the method of randomization adequate? | Yes | Unclear | Yes | Yes | Yes | |
| Selection | 2. | Was the treatment allocation concealed? | Yes | Yes | Yes | Unclear | Uncle | ar |
| Performance | 3. | Was the patient blinded to the intervention? | No | No | No | Unclear | No | |
| Performance | 4. | Was the care provider blinded to the intervention? | No | No | No | No | No | |
| Detection | 5. | Was the outcome assessor blinded to the intervention? | No | No | Yes | No | Yes | No |
| Attrition | 6. | Was the drop-out rate described and acceptable? | Yes | Yes | Yes | No | Yes | |
| Attrition | 7. | Were all randomized participants analyzed in the group to which they were allocated? | Yes | Yes | Yes | No | Yes | |
| Reporting | 8. | Are reports of the study free of suggestion of selective outcome reporting? | No | Yes | Yes | Yes | Uncle | ar |
| Selection | 9. | Were the groups similar at baseline regarding the most important prognostic indicators? | Yes | Yes | Yes | Yes | Uncle | ar |
| Performance | 10. | Were co-interventions avoided or similar? | Yes | Unclear | Unclear | Unclear | Uncle | ar |
| Performance | 11. | Was the compliance acceptable in all groups? | Yes | Yes | Yes | Unclear | Uncle | ar |
| Detection | 12. | Was the timing of the outcome assessment in all groups similar? | Yes | Yes | Yes | Yes | Yes | |
| Judgment | | <u> </u> | High RoB | High RoB | Low RoB | High RoB | High F | RoB |

Key: RoB = risk of bias; Low RoB = sources of bias are unlikely to alter the results seriously; High RoB = bias may alter the results seriously

Source:

Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928

A study was considered to be at low risk of bias if it fulfilled three key criteria related to randomization, allocation concealment and outcome assessor blinding.

Sources:

Van Tulder M, Furlan A, Bombardier C, Bouter L; Editorial Board of the Cochrane Collaboration Back Review Group. Updated method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group. Spine 2003;28:1290–1299.

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^{*}Optum is a brand used by OptumHealth Care Solutions, LLC and its affiliates



Table 4. Risk of Bias (limitations in study design or implementation)

Title: Cifuentes M, Willets J, Wasiak R. Health maintenance care in work-related low back pain and its association with disability recurrence. *Journal of Occupational and Environmental Medicine* 2011; 53:396-404

| No. | Source | Assessment | Notes |
|------|---|------------|--|
| 1 | Did the study address a clearly focused issue? | Yes | |
| 2 | Did the authors use an appropriate method to answer their question? | Yes | |
| 3 | Was the cohort recruited (identified) in an acceptable way? | Yes | Representative of a defined population (Workers' Compensation cases) |
| 4 | Was the exposure accurately measured to minimize bias? | Yes | |
| 5 | Was the outcome accurately measured to minimize bias? | Yes | |
| 6(A) | Have all important confounding factors been considered? | No | Prior history of LBP, contextual work-related factors (psychosocial and physical demands) were not identified in the data analysis** |
| 6(B) | Were the identified confounders taken into account in the design and/or analysis? | Yes | |
| 7(A) | Was the follow-up of subjects complete enough? | Yes | |
| 7(B) | Was the follow up of subjects long enough? | Yes | |

Source: Critical Appraisal Skills Programme (CASP) [modified]. *Solutions for Public Health* 2010; NHS, UK: http://www.sph.nhs.uk/what-we-do/public-health-workforce/resources/critical-appraisals-skills-programme

^{**} Fayad F, Lefevre-Colau MM, Poiraudeau S, et al. Chronicity, recurrence, and return to work in low back pain: common prognostic factors. *Annales de réadaptation et de médecine physique* 2004; 47:179–189



Table 5: Quality Assessment & Summary of Findings by Critical Outcomes: Manipulation for Tertiary Prevention of Chronic Neck Pain

| | | | Quality As | sessment | | | | Summary | of Finding | gs | |
|---------------|-------------|-------------------------------------|------------------------------|-------------------------|-----------------------|---|--------------------------------|---|--|---|----------|
| No of studies | Design | Study Limitations | Inconsistency | Indirectness | Imprecision | Other Considerations | No. of | Patients | E | ffect | Quality |
| studies | | (RoB) | | | | (AE reporting, publication bias, dose-response) | Int'n: manip.; mobs | Control: placebo; sham; active | Relative Benefit (Effect Size) | Absolute Benefit (<u>+</u> SD) | |
| Pain inte | nsity – Lon | ıg-term follow-u | p (9-months after | randomization; | range of scores: | -; better indicated b | y less) N | ICIC = 2.0 cm | n | | |
| 1 | RCT | Serious limitations -1 [A] | No important inconsistencies | No serious indirectness | Imprecise data -2 [B] | Adverse events were monitored – no serious events | 36-SMT 33-SMT + exercise | 29 - control | SMT: -0.4 cm (0.15) SMT+Ex: -0.9 cm (0.24) | C: +0.4 cm (± 2.9) SMT: 0.0 (± 2.3) SMT+Ex: -0.5 (± 2.3) | Very Low |
| Disability | y – NDI – I | ong-term follow | v-up (9-months aft | er randomizatio | n; range of score | es: -; better indicate | d by less) 1 | MCIC = 10 pt | ts | | |
| 1 | RCT | Serious limitations [A] | No important inconsistencies | Some uncertainty | Imprecise data -1 [C] | Adverse events were monitored – no serious events | 36-SMT 33-SMT + exercise | 29 - control | SMT: +2.0 pts (-0.29) SMT+Ex: -0.9 pts (0.37) | C: -4.0 pts (± 14.0) SMT:-2.0 pts (± 12.1) SMT+Ex: -4.2 (± 11.8) | Low |
| Disability | y – BQ – Lo | ong-term follow | -up (9-months afte | r randomization | ; range of scores | :: -; better indicated | by less) M | ICIC = 34% | | | |
| 1 | RCT | Serious limitations [A] | No important inconsistencies | Some uncertainty | Imprecise data -1 [C] | Adverse events were monitored – no serious events | 36-SMT 33-SMT + exercise | 29 - control | SMT: -2.3 pts (0.24) SMT+Ex: -3.3 pts (0.39) | C: -3.5 pts 16% (± 12.7) SMT:-5.8 pts 31% (± 10.4) SMT+Ex:: -6.8 pts 44% (+ 11.0) | Low |

 $Key: AE-adverse \ events; RCT-randomized \ controlled \ trial; \ N/A-not \ applicable; \ nc-not \ calculated \ data \ not \ available; \ Int'n-intervention \ group; \ Quality-Cochrane \ GRADE \ of \ high, \ moderate, low, \ or \ very \ low; \ CI-confidence \ interval; \ SMT-spinal \ manipulative \ therapy$

A. High risk of performance, detection and reporting bias

B. There is only one study for the outcome; Optimal information size criterion not met; CI cross the threshold of minimal clinically important change (confidence in results decreased by 2)

C. There is only one study for the outcome; Optimal information size criterion not met (confidence in results decreased by 1)



Table 6. Quality Assessment & Summary of Findings by Critical Outcomes: Manipulation for Tertiary Prevention of Chronic Low Back Pain

| | | <u> </u> | | <u> </u> | • | _ | | • | | | |
|------------|---------------|--|------------------------------|---------------------|---|---|---|--|--------------------|--------------------------------|-------------|
| | | | Quality As | sessment | | | | Summary | of Finding | ĮS | |
| No of | Design | Study Limitations | Inconsistency | Indirectness | Imprecision | Other Considerations | No. of | Patients | | ffect | Quality |
| studies | | (RoB) | | | (publication bias, dose- response) | Int'n: SMT (main- tenance) | Control: No Tx (after initial SMT period) | Relative Effect (Effect Size) | Absolute Effect | | |
| Pain inte | ensity – Lor | ng-term follow-u | p (9-months; rang | ge of scores: bette | er indicated by l | ess) N | MCIC = 2.0 | cm | | | |
| 2 | RCT | Very serious limitations -2 [A] | no important inconsistencies | No indirectness | very serious imprecision -2 [B] | publication bias: undetected; no dose gradient reported | 40 | 41 | 1.5 (0.964) | No SMT: +0.96 SMT: -0.59 | Very Low |
| Pain inte | ensity – Inte | ermediate-term f | follow-up (6-mont | hs; range of scor | es: better indica | ted by less) MC | IC = 2.0 cm | | | | |
| 2 | RCT | Very serious limitations -2 [A] | no important inconsistencies | No indirectness | very serious imprecision -2 [B] | publication bias: undetected; no dose gradient reported | 40 | 41 | 1.15 (0.936) | No SMT: +0.64 SMT: -0.41 | Very Low |
| Disability | y – Long-te | rm follow-up (9- | -months; range of | scores: better in | dicated by less) | MCI | C = 10 pts | | | | |
| 2 | RCT | Very serious limitations -2 [A] | no important inconsistencies | No indirectness | very serious imprecision -2 [B] | publication bias: undetected; no dose gradient reported | 40 | 41 | 13.85 (0.96) | No SMT: +9.82 SMT: -4.03 | Very Low |
| Disability | y – Interme | diate-term follo | w-up (6-months; 1 | range of scores: l | etter indicated | by less) MCI | C = 10 point | ts | | | |
| 2 | RCT | Very serious limitations -2 [A] | no important inconsistencies | No indirectness | very serious imprecision -2 [B] | publication bias: undetected; no dose gradient reported | 40 | 41 | 9.8 (0.93) | No SMT: +8.01 SMT: -2.26 | Very Low |

Key: RCT – randomized controlled trial; N/A – not applicable; nc – not calculated data not available; Int'n – intervention group; Quality – Cochrane GRADE of high, moderate, low, or very low; RoB – risk of bias; SMT – spinal manipulative treatment; MCIC – minimal clinically important change

A. High risk of performance and detection bias for both trials. The larger trial (Senna; N=93) also had a high risk of attrition bias (~35% overall drop-out rate; ~25% in the SMT groups; these subjects were not included in the analysis) at 10-month follow-up. (confidence in study results decreased by 2)

B. The optimal sample size criterion was not met. The larger trial (Senna) did not provide confidence interval (CI) reporting. The CI for the maintenance care group crossed the minimal clinically important change threshold. Outcomes not reported in terms of risk (group means only). (confidence in results decreased by 2)



Table 7. Quality Assessment & Summary of Findings by Critical Outcomes: Manipulation for Secondary Prevention of Low Back Pain

| | | | Quality As | sessment | | | | Summar | y of Findin | gs | |
|------------------|-------------|----------------------------------|------------------------------|--------------------------------------|--|--|------------------------------------|--|----------------------------|------------------------|-------------|
| No of studies | Design | Study Limitations (RoB) | Inconsistency | Indirectness | Imprecision | Other Considerations (publication bias, dose- response) | No. of Int'n: Chiro. (maintenance) | Patients Control: No Tx (after initial disability period) | Relative Effect (RR) | Effect Absolute Effect | Quality |
| Work Di | sability Re | currence – Long | g-term follow-up (1 | 12-months; range | e of scores: bette | er indicated by less) | | | | | |
| 1 | Obs. | Some limitations -1 [A] | no important inconsistencies | serious indirectness -2 [B] | very serious imprecision -2 [C] | publication bias: undetected; no dose gradient reported | 184 | 146 | 0.989 | 0.01 NNT: 95.94 | Very Low |

Key: Obs. – observational study; N/A – not applicable; nc – not calculated data not available; Int'n – intervention group; Quality – Cochrane GRADE of high, moderate, low, or very low; SMT – spinal manipulative treatment; NNT – number needed to treat; RR – relative risk

A. Some important confounding factors were not considered in the study methodology

B. The study employed several surrogate measures. Indirectness was present: in the use of treatment following return to work as a proxy for health maintenance care (HMC); the use of provider-type as a proxy for management approach; and work-disability recurrence as a proxy for the number of clinically meaningful recurrences. (confidence in results decreased by 2)

C. The optimal sample size criterion was not met. There was only a single study for the critical outcome (confidence in results decreased by 2)



Table 8. Quality Assessment & Summary of Findings by Critical Outcomes: Manipulation for 1° & 2° Prevention of Hamstring Injury

| | Quality Assessment | | | | | | | | Summary of Findings | | | | |
|------------------|--------------------|----------------------------------|------------------------------|---|--|--|----------------------------|---------------------------|--------------------------------------|------------------------|-------------|--|--|
| No of studies | Design | Study Limitations (RoB) | Inconsistency | Indirectness | Imprecision | Other Considerations (publication bias, dose- response) | No. of Int'n: Chiro. (SMT) | Patients Control: No SMT | Relative Effect (OR) | Effect Absolute Effect | Quality | | |
| Incidence | e of Hamsti | ring Injury – Lo | ng-term follow-up | (6-months) | | | | | | | | | |
| 1 | RCT | Some limitations -1 [A] | No important inconsistencies | Very serious indirectness -2 [B] | Very serious imprecision -2 [C] | Publication bias: undetected; no dose gradient reported | 29 | 30 | 0.116 95% CI = 0.013- 1.019 | N/A | Very Low | | |

Key: 1° – primary; 2° – secondary; RCT – randomized controlled trial; N/A – not applicable; nc – not calculated data not available; Int'n – intervention group; Quality – Cochrane GRADE of high, moderate, low, or very low; SMT – spinal manipulative treatment; MCIC – minimal clinically important change; RR – relative risk; HVLA – high velocity / low amplitude; OR – odds ratio

A. High risk of selection and performance bias. Unclear risk of reporting bias. (confidence in results decreased by 1)

B. Manipulation (HVLA) was provided in only 56% of the treatment rendered to the intervention group. There was wide variation in the amount and location (region) of manipulation making replication in broader settings unlikely. (confidence in results decreased by 2)

C. The optimal sample size criterion was not met. The CI crossed the threshold of benefit/no benefit. There was only a single study for the critical outcome (confidence in results decreased by 2)



Table 9. Quality Assessment & Summary of Findings by Critical Outcomes: Manipulation for 2° & 3° Prevention of Bothersome LBP

| Quality Assessment | | | | | | Summary of Findings | | | | | |
|--------------------|---|--|--------------------------|--------------------------|----------------------------------|--|------------------|----------------|---|---|----------|
| No of studies | Design | Study Limitations (RoB) | Inconsistency | Indirectness | Imprecision | Other Considerations (publication bias, dose-response) | No. of | Patients No MC | Relative Effect (95% CI) | Absolute Effect (95% CI) | Quality |
| Fewer da | Fewer days with bothersome LBP – Long-term follow-up (12-months; range of scores: better indicated by less) | | | | | | | | | | |
| 1 | RCT | No serious limitations ^A | Not serious ^B | Not serious ^C | Some imprecision ^D | No dose gradient reported; No serious AE; Study was modestly underpowered ^E ; Few missing data (1.1%) ^F | 166 ^G | 161 | 13% favoring the MC group (N/C) ^H | 12.8 days fewer (10.1 to 15.6 fewer) ¹ | Moderate |

Key: 2° - secondary; 3° - tertiary; AE - adverse events; CI - confidence interval; MC - maintenance care; N/C - not calculated data not available; RCT - randomized controlled trial; RoB - risk of bias

- A. Low RoB for the critical criteria related to randomization, allocation concealment and outcome assessor blinding
- B. No significant variation in effect estimates among participants (95% of participants had between 10 and 15.5 days fewer days with bothersome LBP)
- C. Participants and intervention similar to typical application of MC; outcome relevant to participants; relatively narrow 95% CI, with lower and upper limits all showing fewer bothersome days
- D. Single study for the outcome measured (confidence in the results reduced by 1)
- E. Potential for 'power bias', where the study is less likely to distinguish a small effect from chance
- F. Data set included 16,505 data points recorded weekly over 52-weeks
- G. 94% of MC visits included manipulation
- H. The relative effect (13% difference favoring MC) did not meet the prespecified clinically meaningful difference of 20% for acute LBP and 30% for chronic LBP
- I. Approximately one day fewer of bothersomeness per month favoring MC



What are the Policies/Positions of Other Organizations? Table 10

| Organization | Policy Information | Position |
|-----------------------------------|--|--|
| | | During the last visits for rehabilitative treatment, the clinician may develop a maintenance program. The goals of a maintenance program would be, for example, to maintain functional status or to prevent decline in function. The specialized skill, knowledge and judgment of a therapist would be required, and services are covered, to design or establish the plan, assure patient safety, train the patient, family members and/or unskilled personnel and make infrequent but periodic reevaluations of the plan. |
| Medicare Benefit Policy Manual | Chapter 15 – 220.2. Reasonable and Necessary Outpatient Rehabilitation Therapy Services Rev. 251; 11/30/2018 | The services of a qualified professional are not necessary to carry out a maintenance program, and are not covered under ordinary circumstances. The patient may perform such a program independently or with the assistance of unskilled personnel or family members. |
| | | Where a maintenance program is not established until after the rehabilitative therapy program has been completed (and the skills of a therapist are not necessary) development of a maintenance program would not be considered reasonable and necessary for the treatment of the patient's condition. It would be excluded from coverage under §1862(a)(1) of the Act unless the patient's safety was at risk (see below). |
| Medicare Benefit Policy Manual | Chapter 15 –30.5. Chiropractor's Services Rev. 251; 11/30/2018 | Under the Medicare program, Chiropractic maintenance therapy is not considered to be medically reasonable or necessary, and is therefore not payable. Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. |
| CIGNA HealthCare | Chiropractic Care Policy # 0278 Revised: 2/15/2018 | Chiropractic manipulation and adjunct therapeutic procedures/modalities (e.g., mobilization, therapeutic exercise, traction) are not covered when services are not related to the patient's symptoms, not likely to result in long-term improvement, or do not have defined endpoints, including maintenance, preventive or supportive care or care provided to prevent recurrences or slow deterioration or services provided to reduce potential risk factors where significant improvement is not expected. |
| CIGNA HealthCare | Physical Therapy Policy # 135 Revised: 1/01/2018 Occupational Therapy Policy # 155 Revised: 1/01/2018 | Therapy services are not medically necessary when the individual's condition does not have the potential to improve or is not improving in response to therapy; or would be insignificant relative to the extent and duration of therapy required; and there is an expectation that further improvement is NOT attainable. |

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| Highmark Highmark Blue Cross & Blue Shield - NC | Physical Medicine Policy Y-1-055 Issued: 1/01/2018 Manipulative Services Policy Y-9-032 Issued: 1/29/18 Chiropractic Services Accessed: 2/22/2018 | Physical medicine services performed repetitively to maintain a level of function is not eligible for payment unless the member has Habilitative Services benefits. Physical medicine services performed repetitively to maintain a level of function is not eligible for payment unless the member has Habilitative Services benefits. Maintenance programs are not covered |
|---|--|--|
| UnitedHealthcare / Oxford | Manipulative TherapyPolicy # 011.12 T2Approved: 11/01/2018 | Manipulative therapy is unproven for: • Prevention/maintenance/custodial care |
| Aetna | Policy # 0107Approved: 6/06/2018 | Once maximum therapeutic benefit has been achieved, continuing chiropractic care is considered not medically necessary Chiropractic manipulation in asymptomatic persons or in persons without an identifiable clinical condition is considered not medically necessary Chiropractic care in persons, whose condition is neither regressing nor improving, is considered not medically necessary |
| Blue Cross & Blue Shield of Tennessee | Rehabilitation Therapy Outpatient Services Revised: 12/2018 | Therapy services normally not covered include, but are not limited to treatment beyond what can reasonably be expected to significantly improve health, including therapeutic treatments for ongoing maintenance or palliative care. |



PLAIN LANGUAGE SUMMARY

Maintenance/Custodial Care

Utilization Management Policy # 449

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 is maintenance/custodial care and what is known about it so far?

Musculoskeletal pain is a common experience for most people. Traditional nonsurgical treatments that are helpful for some patients with musculoskeletal pain include physical therapy, manipulation (chiropractic), exercise, and drugs (pain killers, anti-inflammatory drugs, and muscle relaxants). Most treatments reach a point where either patient complaints have resolved or no further improvement can be expected. It is understandable that, once improvement has been achieved, some patients choose to continue with periodic in-office care with an expectation of preventing recurrences or to keep a chronic condition from worsening. This type of care is termed *Maintenance or Custodial Care*.

Most healthcare benefit certificates do not include coverage for maintenance (custodial) care, when rendered in a chiropractic, physical therapy or occupational therapy office.

How was the maintenance/custodial care benefit evaluated?

A work group of clinicians was assigned to review the available research. The internet and journals were searched for policies and articles that provided information about 1) current descriptions and uses of maintenance/custodial care; 2) are there types of patients or conditions likely to benefit from maintenance (custodial) care; 3) what is/are the recommended treatment schedules for patients who elect to receive maintenance care; and 4) is there scientific literature confirming that either new episodes can be prevented or chronic symptoms can be kept from worsening?

After gathering and analyzing this information, a policy was presented to a series of committees that included independent health care practitioners.



What did the work group find?

- The value of maintenance/custodial care is unclear
- The research regarding the use of maintenance/custodial care is limited and of very low quality that conclusions about the types of patients and/or conditions likely to benefit from regular maintenance/custodial care cannot be made
- Other health care organizations and governmental agencies have reached the same conclusions
- There is a need for additional research studies

What were the limitations of the information?

The majority of research related to maintenance/custodial care was performed by chiropractors. Much of this research is based upon opinion. There is little to no information about how this type of care is actually provided by physical and occupational therapists.

What are the conclusions?

Maintenance/custodial care is considered to be *unproven and not medically necessary* due to insufficient scientific evidence of benefit in the treatment of disorders typically managed by chiropractors, physical therapists and occupational therapists.

What are the options?

Once complaints have either resolved or no further improvement can be expected, the patient and treating provider may consider:

- a) Discharge from scheduled in-office care with home-care recommendations
- b) Discharge from scheduled in-office care; return for treatment only when complaints noticeably worsen in spite of self-care measures
- c) Elect to pursue maintenance/custodial care, which is not a covered benefit.
 - The patient may be required to sign a "Billing Acknowledgement Form" prior to receiving maintenance/custodial care.* (*not required in NJ)
 - By signing this form, a patient assumes financial responsibility for maintenance (custodial) care.



Policy History/Revision Information

| Date | Action/Description | | | |
|------------|---|--|--|--|
| 3/07/2001 | Original effective date | | | |
| 9/20/2002 | Annual review and approval completed | | | |
| 11/11/2003 | Annual review and approval completed | | | |
| 10/18/2004 | Annual review and approval completed | | | |
| 2/14/2006 | Annual review and approval completed | | | |
| 4/10/2008 | Annual review and approval completed | | | |
| 10/09/2009 | Policy revised. Added were: an updated and detailed literature review and Plain Language Summary | | | |
| 1/15/2009 | Policy retitled (from Preventive/Maintenance Care to Maintenance/Custodial Care); Policy reformatted | | | |
| 4/30/2009 | Annual review and approval completed | | | |
| 4/08/2010 | Annual review and approval completed | | | |
| 10/26/2010 | Policy rebranded to "OptumHealth Care Solutions, Inc. (OptumHealth)" | | | |
| 4/07/2011 | Annual review and approval completed | | | |
| 10/13/2011 | Policy revised to include recently published clinical trials and data produced by the Nordic Maintenance Care Program | | | |
| 4/19/2012 | Annual review and approval completed | | | |
| 4/18/2013 | Annual review and approval completed | | | |
| 4/17/2014 | Annual review and approval completed; Policy rebranded "Optum* by OptumHealth Care Solutions, Inc." | | | |
| 4/16/2015 | Annual review and approval completed | | | |
| 4/21/2016 | Annual review and approval completed | | | |
| 4/20/2017 | Annual review and approval completed. Legal entity name changed from "OptumHealth Care | | | |
| | Solutions, Inc." to "OptumHealth Care Solutions, LLC." | | | |
| 4/26/2018 | Annual review and approval completed: Updated Table 7 and associated references | | | |
| 4/25/2019 | Annual review and approval completed; Revised Efficacy section and Tables 2, and 10. Added | | | |
| | Tables 3 and 9; Updated associated references | | | |
| 4/23/2020 | Annual review and approval completed | | | |

Contact Information

Please forward any commentary or feedback on Optum utilization management policies to: policy.inquiry@optumhealth.com with the word "Policy" in the subject line.

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