



Notice of Independent Review Decision

DATE OF REVIEW:

09/27/2010

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Chronic Pain Management Program five times per week for two weeks.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

Board Certified Chiropractor

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: **Upheld**

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.

Chronic Pain Management Program five times per week for two weeks is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- referral form
- 09/16/10 letter from Network & Medical Operations, with attached list of disputed services
- 09/16/10 Medication History
- 09/14/10 MCMC Referral
- 09/14/10 Notice To MCMC, LLC Of Case Assignment,
- 09/13/10 Confirmation Of Receipt Of A Request For A Review,
- 08/27/10 Request For A Review By An Independent Review Organization
- 08/24/10 letter from Review Nurse,
- 08/12/10 Office Visit Followup, M.D., Pain Specialists
- 07/29/10, 06/10/10 SOAP notes, Medical Healthcare
- 07/20/10 letter from Review Nurse,
- 07/01/10 Initial Visit, M.D.,
- 06/25/10 Mental Health Initial Evaluation, Ph.D
- 05/05/10 Followup Evaluation, M.D./ M.D.,
- 03/24/10 Initial Consultation, M.D./ M.D.,
- 02/04/10, 11/19/09 letters from, M.D.,
- 01/28/10 Follow-Up Consultation Notes, , M.D.,
- 01/28/10 Test Results Record
- 12/22/09 FollowUp Consultation Notes, DO,
- 12/01/09 Rx Guardian Report, Ameritox
- 05/04/09 Followup Evaluation, M.D./, M.D.,
- 04/30/09 cervical spine radiographs, Hospital

- 01/19/09 electrodiagnostic study, M.D.
- 04/23/08 Operative Report,
- 12/07/06 Report of Medical Evaluation, D.O., Evaluations
- 11/30/06 (Date of Exam) Report of Medical Evaluation,
- 11/30/06 Review of Medical History & Physical Exam, D.O., Evaluations
- 11/30/06 Report of Medical Evaluation – Narrative Overview, Spine, Right Upper Extremity, D.O.
- 11/28/06 MRI right shoulder, MRI
- 11/28/06 MRI right wrist, MRI
- EDG Integrated Treatment/Disability Duration Guidelines – Pain (Chronic)

PATIENT CLINICAL HISTORY [SUMMARY]:

Records indicate that the above captioned individual is a female who was allegedly injured as a result of an occupational incident. The history reflects that she reported injuring her neck and arm on xx/xx/xx when she fell over a shelf and injured her neck and right arm. She underwent injections in 2007 with reported moderate relief. A shoulder MRI was performed on 11/28/2006 which was read as negative for significant pathologies. A cervical MRI was performed on 12/06/2006 which showed protrusions at C5-C7. In addition to the injection therapy, she has also undergone medication management as well as chiropractic care and physical therapy. A mental health evaluation was performed on 06/25/2010 which opined the need for chronic pain management. Electrodiagnostic testing dated 01/19/2009 was negative for radiculopathies or carpal tunnel syndrome.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

The records reveal that the above captioned individual was injured more than four years ago. The records reveal that she has been working at least part of the time during this four year period, however at a modified capacity at best. The Official Disability Guidelines (ODG) clearly suggests that this long period of disability is a poor predictor of the success of this program. From the ODG: *“There is little research as to the success of return to work with functional restoration programs in long-term disabled patients (> 24 months).*

The ODG also suggest that *“There are limited studies about the efficacy of chronic pain programs for neck, shoulder, or upper extremity musculoskeletal disorders.*

The records do not clearly identify the nature, frequency, duration or types of treatment rendered to date. The records also do not document and quantify past efficacy or failures with regards to past care. There is lack of documentation to determine whether all lower forms of care have been exhausted at this point. Lastly, a CPM program has a significant psychosocial component to address issues of depression, anxiety and other psychosocial issues. While the records suggest some tendencies toward pain avoidance behavior, the mental health exam also shows that the injured individual testing in the mild categories for both anxiety and depression.

Given the length of time from the original injury and the lack of documentation in relation to past lower levels of care, the medical necessity for the requested course of CPM is not established.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Chronic pain programs (functional restoration programs) Recommended where there is access to programs with proven successful outcomes (i.e., decreased pain and medication use, improved function and return to work, decreased utilization of the health care system), for patients with conditions that have resulted in “Delayed recovery.” There should be evidence that a complete diagnostic assessment has been made, with a detailed treatment plan of how to address physiologic, psychological and sociologic components that are considered components of the patient’s pain. Patients should show evidence of motivation to improve and return to work, and meet the patient selection criteria outlined below. While these programs are recommended (see criteria below), the research remains ongoing as to (1) what is considered the “gold-standard” content for treatment; (2) the group of patients that benefit most from this treatment; (3) the ideal timing of when to initiate treatment; (4) the intensity necessary for effective treatment; and (5) cost-effectiveness. It has been suggested that interdisciplinary/multidisciplinary care models for treatment of chronic pain may be the most effective way to treat this condition. (Flor, 1992) (Gallagher, 1999) (Guzman, 2001) (Gross, 2005) (Sullivan, 2005) (Dysvik, 2005) (Airaksinen, 2006) (Schonstein, 2003) (Sanders, 2005) (Patrick, 2004) (Buchner, 2006) These treatment modalities are based on the biopsychosocial model, one that views pain and disability in terms of the interaction between physiological, psychological and social factors. (Gatchel, 2005) See Biopsychosocial model of chronic pain.

Types of programs: There is no one universal definition of what comprises interdisciplinary/multidisciplinary treatment. These pain rehabilitation programs (as described below) combine multiple treatments, and at the least, include psychological care along with physical and/or occupational therapy (including an active exercise component as opposed to passive modalities). The most commonly referenced programs have been defined in the following general ways (Stanos, 2006):

(1) Multidisciplinary programs: Involves one or two specialists directing the services of a number of team members, with these specialists often having independent goals. These programs can be further subdivided into four levels of pain programs:

- (a) Multidisciplinary pain centers (generally associated with academic centers and include research as part of their focus)
- (b) Multidisciplinary pain clinics
- (c) Pain clinics
- (d) Modality-oriented clinics

(2) Interdisciplinary pain programs: Involves a team approach that is outcome focused and coordinated and offers goal-oriented interdisciplinary services. Communication on a minimum of a weekly basis is emphasized.

The most intensive of these programs is referred to as a Functional Restoration Program, with a major emphasis on maximizing function versus minimizing pain. See Functional restoration programs. Types of treatment: Components suggested for interdisciplinary care include the following services delivered in an integrated fashion: (a) physical treatment; (b) medical care and supervision; (c) psychological and behavioral care; (d) psychosocial care; (e) vocational rehabilitation and training; and (f) education. Outcomes measured: Studies have generally evaluated variables such as pain relief, function and return to work. More recent research has begun to investigate the role of comorbid psychiatric and substance abuse problems in relation to treatment with pain programs. Recent literature has begun to suggest that an outcome of chronic pain programs may be to “demedicalize” treatment of a patient, and encourage them to take a more active role in their recovery. These studies use outcomes such as use of the medical care system post-treatment. The role of the increasing use of opioids and other medications (using data collected over the past decade) on outcomes of functional restoration is in the early stages, and it is not clear how changes in medication management have affected outcomes, if at all. (See Opioids for chronic pain.)

Outcomes (in terms of body parts)

Neck and Shoulder: There are limited studies about the efficacy of chronic pain programs for neck, shoulder, or upper extremity musculoskeletal disorders. (Karjalainen, 2003) This may be because rates of cervical claims are only 20-25% of the rates of lumbar claims. In addition, little is known as to chronicity of outcomes.

Researchers using PRIDE Program (Progressive Rehabilitation Institute of Dallas for Ergonomics) data compared a cohort of patients with cervical spine disorders to those with lumbar spine disorders from 1990-1995 and found that they had similar outcomes. Cervical patients were statistically less likely to have undergone pre-rehabilitative surgery. (Wright, 1999)

Multidisciplinary back training: (involvement of psychologists, physiotherapists, occupational therapists, and/or medical specialists). The training program is partly based on physical training and partly on behavioral cognitive training. Physical training is performed according to the "graded activity" principle. The main goal is to restore daily function. A recent review of randomized controlled studies of at least a year's duration found that this treatment modality produced a positive effect on work participation and possibly on quality of life. There was no long-term effect on experienced pain or functional status (this result may be secondary to the instrument used for outcome measure). Intensity of training had no substantial influence on the effectiveness of the treatment. (van Geen, 2007) (Bendix, 1997) (Bendix, 1998) (Bendix2, 1998) (Bendix, 2000) (Frost, 1998) (Harkapaa, 1990) (Skouen, 2002) (Mellin, 1990) (Haldorsen, 2002)

Intensive multidisciplinary rehabilitation of chronic low back pain: The most recent Cochrane study was withdrawn from the Cochrane (3/06) as the last literature search was performed in 1998. Studies selected included a physical dimension treatment and at least one other treatment dimension (psychological, social, or occupational). Back schools were not included unless they included the above criteria. There was strong evidence that intensive multidisciplinary biopsychosocial rehabilitation with functional restoration improved function when compared to inpatient or outpatient nonmultidisciplinary rehabilitation. Intensive (> 100 hours), daily interdisciplinary rehabilitation was moderately superior to noninterdisciplinary rehabilitation or usual care for short- and long-term functional status (standardized mean differences, -0.40 to -0.90 at 3 to 4 months, and -0.56 to -1.07 at 60 months). There was moderate evidence of pain reduction. There was contradictory evidence regarding vocational outcome. Less intensive programs did not show improvements in pain, function, or vocational outcomes. It was suggested that patients should not be referred to multidisciplinary biopsychosocial rehabilitation without knowing the actual content of the program. (Guzman, 2001) (Guzman-Cochrane, 2002) (van Geen, 2007) (Bendix, 1997) (Bendix, 1998) (Bendix2, 1998) (Bendix, 2000) (Frost, 1998) (Harkapaa, 1990) (Skouen, 2002) (Mellin, 1990) (Haldorsen, 2002)

Multidisciplinary biopsychosocial rehabilitation for subacute low back pain among working age adults: The programs described had to include a physical component plus either a psychological, social and/or vocational intervention. There was moderate evidence of positive effectiveness for multidisciplinary rehabilitation for subacute low back pain and that a workplace visit increases effectiveness. The trials included had methodological shortcomings, and further research was suggested. (Karjalainen, 2003)

Role of opioid use: See Chronic pain programs, opioids.

Role of comorbid psych illness: Comorbid conditions, including psychopathology, should be recognized as they can affect the course of chronic pain treatment. In a recent analysis, patients with panic disorder, antisocial personality disorder and dependent personality disorder were > 2 times more likely to not complete an interdisciplinary program. Personality disorders in particular appear to hamper the ability to successfully complete treatment. Patients diagnosed with post-traumatic stress disorder were 4.2 times more likely to have additional surgeries to the original site of injury. (Dersh, 2007) The prevalence of depression and anxiety in patients with chronic pain is similar. Cohort studies indicate that the added morbidity of depression and anxiety with chronic pain is more strongly associated with severe pain and greater disability. (Poleshuck, 2009) (Bair, 2008)

Predictors of success and failure: As noted, one of the criticisms of interdisciplinary/multidisciplinary rehabilitation programs is the lack of an appropriate screening tool to help to determine who will most benefit from this treatment. Retrospective research has examined decreased rates of completion of functional restoration programs, and there is ongoing research to evaluate screening tools prior to entry. (Gatchel, 2006) There is need for research in terms of necessity and/or effectiveness of counseling for patients considered to be “at-risk” for post-discharge problems. (Proctor, 2004) The following variables have been found to be negative predictors of efficacy of treatment with the programs as well as negative predictors of completion of the programs: (1) a negative relationship with the employer/supervisor; (2) poor work adjustment and satisfaction; (3) a negative outlook about future employment; (4) high levels of psychosocial distress (higher pretreatment levels of depression, pain and disability); (5) involvement in financial disability disputes; (6) greater rates of smoking; (7) increased duration of pre-referral disability time; (8) higher prevalence of opioid use; and (9) elevated pre-treatment levels of pain. (Linton, 2001) (Bendix, 1998) (McGeary, 2006) (McGeary, 2004) (Gatchel, 2005) (Dersh, 2007)

Role of duration of disability: There is little research as to the success of return to work with functional restoration programs in long-term disabled patients (> 24 months).

Studies supporting programs for patients with long-term disability: Long-term disabled patients (at least 18 months) vs. short-term disabled (4 to 8 months) were evaluated using Pride data (1990-1993). No control was given for patients that did not undergo a program. During the time studied program dropouts averaged 8% to 12%. (It does appear that at the time of this study, participants in the program were detoxified from opioids prior to beginning.) The long-term disabled group was more likely to have undergone spinal surgery, with this likelihood increasing with time. Return to work was statistically different between the short-term disabled (93%) and the long-term disabled-18 months (80%). The long-term disabled-24 months group had a 75% return to work. Long-term disabled-18 month patients were statistically more likely to visit new health providers than short-term disabled patients (34% and 25% respectively). Work retention at one year in groups up to 24 months duration of disability was 80%. This dropped to 66% in the group that had been disabled for > 24 months. The percentage of recurrent lost time injury claims increased from around 1% in the groups disabled for < 35 months to 8.3% in the groups disabled for > 36 months. A main criterion for success appeared to be the decision of the patient to actively participate in the program rehabilitation goals. (Jordan, 1998)

Studies suggesting limited results in patients with long-term disability: While early studies have suggested that time out-of-work is a predictor of success for occupational outcomes, these studies have flaws when an attempt is made to apply them to chronic pain programs. (Gallagher, 1989) (Beals, 1972) (Krause, 1994) Washington State studied the role of duration of work injury on outcome using a statistical model that allowed for a comparison of patients that participated in a multidisciplinary pain program (using data from 1991-1993) vs. those that were evaluated and not treated. This was not an actual study of time of disability, but of duration of injury (mean years from injury to evaluation of 2.6 years for the treated group and 4.0 years for the evaluated only group). The original statistical analysis allowed for a patient to be included in a “treated group” for those individuals that both completed and did not complete the program. Data was collected from 10 sites. Each of the centers was CARF approved and included Pysch/behavioral treatment, vocation counseling and physical therapy. A sub-study evaluated a comparison of patients that were treatment completers vs. those that did not participate (78.6%, N=963). No information was given in terms of surgical procedures or medications. The primary outcome was time loss status of subjects 2 years after they had undergone the index pain center evaluation. In the 2001 study, if chronicity of duration of injury was controlled for, there was no significant benefit produced in terms of patients that were receiving time-loss benefits at 2-years post treatment between the two groups. Approximately 60% of both groups were not receiving benefits at the two-year period. As noted, the “treated patient” was only guaranteed to have started a program. A repeat analysis of only the patients who completed the study did not significantly change the results of the study. In a 2004 survey follow-up no significant difference was found between treated and untreated groups, although the treated group had better response. The survey response was 50%, and the treatment responders were more likely to be disabled at the time of the survey. The authors suggest that the results indicated early intervention was a key to response of the programs, and that modest goals (improvement, not cure) be introduced. (Robinson, 2004) (Robinson, 2001) [The authors also concluded that there was no evidence that pain center treatment affects either disability status or clinical status of injured workers.]

Timing of use: Intervention as early as 3 to 6 months post-injury may be recommended depending on identification of patients that may benefit from a multidisciplinary approach (from programs with documented positive outcomes). See Chronic pain programs, early intervention.

Role of post-treatment care (as an outcome): Three variables are usually examined; (1) New surgery at the involved anatomic site or area; (2) Percentage of patients seeking care from a new provider; (3) Number of visits to the new provider over and above visits with the health-care professional overseeing treatment. It is suggested that a “new provider” is more likely to reorder diagnostic tests, provide invasive procedures, and start long-term analgesics. In a study to determine the relationship between post-treatment healthcare-seeking behaviors and poorer outcomes (using prospectively analyzed PRIDE data on patients with work-related musculoskeletal injuries), patients were compared that accessed healthcare with a new provider following functional restoration program completion (approximately 25%) to those that did not. The former group was significantly more likely to have an attorney involved with their case (22.7% vs. 17.1%, respectively), and to have had pre-rehabilitation surgery (20.7% vs. 12.1%, respectively). Return to work was higher in the group that did not access a new provider (90% vs. 77.6% in the group that did access). The group that did not access new providers also was more likely to be working at one year (88% vs. 62.2% in the group that accessed new providers). It should be noted that 18% of the patients that entered the program dropped out or were asked to leave. The authors suggested monitoring of additional access of healthcare over and above that suggested at the end of the program, with intervention if needed. (Proctor, 2004)

See also Chronic pain programs, intensity; Chronic pain programs, opioids; Functional restoration programs; & Chronic pain programs, early intervention.

Criteria for the general use of multidisciplinary pain management programs:

Outpatient pain rehabilitation programs may be considered medically necessary in the following circumstances:

- (1) The patient has a chronic pain syndrome, with evidence of loss of function that persists beyond three months and has evidence of three or more of the following: (a) Excessive dependence on health-care providers, spouse, or family; (b) Secondary physical deconditioning due to disuse and/or fear-avoidance of physical activity due to pain; (c) Withdrawal from social activities or normal contact with others, including work, recreation, or other social contacts; (d) Failure to restore preinjury function after a period of disability such that the physical capacity is insufficient to pursue work, family, or recreational needs; (e) Development of psychosocial sequelae that limits function or recovery after the initial incident, including anxiety, fear-avoidance, depression, sleep disorders, or nonorganic illness behaviors (with a reasonable probability to respond to treatment intervention); (f) The diagnosis is not primarily a personality disorder or psychological condition without a physical component; (g) There is evidence of continued use of prescription pain medications (particularly those that may result in tolerance, dependence or abuse) without evidence of improvement in pain or function.
- (2) Previous methods of treating chronic pain have been unsuccessful and there is an absence of other options likely to result in significant clinical improvement.
- (3) An adequate and thorough multidisciplinary evaluation has been made. This should include pertinent validated diagnostic testing that addresses the following: (a) A physical exam that rules out conditions that require treatment prior to initiating the program. All diagnostic procedures necessary to rule out treatable pathology, including imaging studies and invasive injections (used for diagnosis), should be completed prior to considering a patient a candidate for a program. The exception is diagnostic procedures that were repeatedly requested and not authorized. Although the primary emphasis is on the work-related injury, underlying non-work related pathology that contributes to pain and decreased function may need to be addressed and treated by a primary care physician prior to or coincident to starting treatment; (b) Evidence of a screening evaluation should be provided when addiction is present or strongly suspected; (c) Psychological testing using a validated instrument to identify pertinent areas that need to be addressed in the program (including but not limited to mood disorder, sleep disorder, relationship dysfunction, distorted beliefs about pain and disability, coping skills and/or locus of control regarding pain and medical care) or diagnoses that would better be addressed using other treatment should be performed; (d) An evaluation of social and vocational issues that require assessment.
- (4) If a goal of treatment is to prevent or avoid controversial or optional surgery, a trial of 10 visits (80 hours) may be implemented to assess whether surgery may be avoided.
- (5) If a primary reason for treatment in the program is addressing possible substance use issues, an evaluation with an addiction clinician may be indicated upon entering the program to establish the most appropriate treatment approach (pain program vs. substance dependence program). This must address evaluation of drug abuse or diversion (and prescribing drugs in a non-therapeutic manner). In this particular case, once drug abuse or diversion issues are addressed, a 10-day trial may help to establish a diagnosis, and determine if the patient is not better suited for treatment in a substance dependence program. Addiction consultation can be incorporated into a pain program. If there is indication that substance dependence may be a problem, there should be evidence that the program has the capability to address this type of pathology prior to approval.
- (6) Once the evaluation is completed, a treatment plan should be presented with specifics for treatment of identified problems, and outcomes that will be followed.
- (7) There should be documentation that the patient has motivation to change, and is willing to change their medication regimen (including decreasing or actually weaning substances known for dependence). There should also be some documentation that the patient is aware that successful treatment may change compensation and/or other secondary gains. In questionable cases, an opportunity for a brief treatment trial may improve assessment of patient motivation and/or willingness to decrease habituating medications.
- (8) Negative predictors of success (as outlined above) should be identified, and if present, the pre-program goals should indicate how these will be addressed.

(9) If a program is planned for a patient that has been continuously disabled for greater than 24 months, the outcomes for the necessity of use should be clearly identified, as there is conflicting evidence that chronic pain programs provide return-to-work beyond this period. These other desirable types of outcomes include decreasing post-treatment care including medications, injections and surgery. This cautionary statement should not preclude patients off work for over two years from being admitted to a multidisciplinary pain management program with demonstrated positive outcomes in this population.

(10) Treatment is not suggested for longer than 2 weeks without evidence of compliance and significant demonstrated efficacy as documented by subjective and objective gains. (Note: Patients may get worse before they get better. For example, objective gains may be moving joints that are stiff from lack of use, resulting in increased subjective pain.) However, it is also not suggested that a continuous course of treatment be interrupted at two weeks solely to document these gains, if there are preliminary indications that they are being made on a concurrent basis.

(11) Integrative summary reports that include treatment goals, compliance, progress assessment with objective measures and stage of treatment, must be made available upon request at least on a bi-weekly basis during the course of the treatment program.

(12) Total treatment duration should generally not exceed 20 full-day (160 hours) sessions (or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities). (Sanders, 2005) Treatment duration in excess of 160 hours requires a clear rationale for the specified extension and reasonable goals to be achieved. Longer durations require individualized care plans explaining why improvements cannot be achieved without an extension as well as evidence of documented improved outcomes from the facility (particularly in terms of the specific outcomes that are to be addressed).

(13) At the conclusion and subsequently, neither re-enrollment in repetition of the same or similar rehabilitation program (e.g. work hardening, work conditioning, out-patient medical rehabilitation) is medically warranted for the same condition or injury (with possible exception for a medically necessary organized detox program). Prior to entry into a program the evaluation should clearly indicate the necessity for the type of program required, and providers should determine upfront which program their patients would benefit more from. A chronic pain program should not be considered a "stepping stone" after less intensive programs, but prior participation in a work conditioning or work hardening program does not preclude an opportunity for entering a chronic pain program if otherwise indicated.

(14) Suggestions for treatment post-program should be well documented and provided to the referral physician. The patient may require time-limited, less intensive post-treatment with the program itself. Defined goals for these interventions and planned duration should be specified.

(15) Post-treatment medication management is particularly important. Patients that have been identified as having substance abuse issues generally require some sort of continued addiction follow-up to avoid relapse.