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**Date notice sent to all parties:**

April 5, 2016

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Reconsideration: functional restoration program for 10 days.

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

Board Certified PM&R; Board Certified Pain Medicine

**REVIEW OUTCOME:**

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

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The patient is a male whose date of injury is XX/XX/XX. Designated doctor evaluation dated XX/XX/XX indicates that the patient was kneeling down when a 640 lb metal grate fell from 8-10 feet above him and struck him on his head and then his left shoulder. The patient was wearing a hard hat at the time. He subsequently developed pain in his neck, left shoulder, upper back and lower back. The patient was treated conservatively with physical therapy and massage therapy, neither of which helped. Diagnoses are listed as head contusion, left arm contusion, thoracic, lumbar and cervical sprain/strain, post-concussion syndrome, TMJ subluxation/dislocation and C3-4 and C5-6 disc bulges with annular tearing. MMI/impairment rating dated XX/XX/XX indicates that the patient has had an incomplete workup for his left shoulder element, dislocated jaws, axial spine and the patient has not reached maximum medical improvement. Functional capacity evaluation dated XX/XX/XX indicates that current PDL is light and required PDL is heavy. Treatment progress report dated XX/XX/XX indicates that treatment to date includes physical therapy/aquatic therapy, medication management, steroid injections and individual psychotherapy. Current medications are ibuprofen, hydrocodone, Zanaflex, Ambien and Prozac. BDI is 14 and BAI is 16.

Initial request for functional restoration program for 10 days was non-certified on XX/XX/XX noting that specifics are not provided with respect to what lower levels of care have been provided. Additionally, the length of time that the claimant is removed from the date of injury would be considered a negative predictor for a positive response from such an extensive program. Response to denial letter dated XX/XX/XX indicates that treatment to date includes injection therapy, physical and aquatic therapy, individual psychotherapy and medication management. The denial was upheld on appeal dated XX/XX/XX noting that the worker's extended time since injury, low BDI and BAI scores, moderate pain reports as well as limited use of narcotic analgesics are all poor predictors of response to a functional restoration program. At best the data for functional restoration programs is limited in terms of their long-range efficacy.

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

Based on the clinical information provided, the request for functional restoration program for 10 days is not recommended as medically necessary. There is no comprehensive assessment of treatment completed to date or the patient's response thereto submitted for review to establish that the patient has exhausted lower levels of care and is an appropriate candidate for this tertiary level program. Although a list of treatment modalities was provided, there are no specifics provided regarding treatment completed to date. The

patient presents with Beck scores in the mild range. The patient's date of injury is over xxxx years old. The Official Disability Guidelines note that if 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. Therefore, medical necessity is not established in accordance with current evidence based guidelines.

**IRO REVIEWER REPORT TEMPLATE -WC**

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**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

**X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**

**X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

ODG Pain Chapter 2016

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)

Shoulder (and other upper extremity disorders): This large cohort study concluded that an interdisciplinary functional restoration program (FRP) is equally effective for patients with chronic upper extremity disorders, including the elbow, shoulder and wrist/hand, as for patients with lumbar spine disorders, regardless of the injury type, site in the upper extremity, or the disparity in injury-specific and psychosocial factors identified before treatment. (Howard, 2012)

Knee (and other lower extremity disorders): This cohort study demonstrated that FRP was equally efficacious for patients with chronic lower extremity (LE) injuries (involving the hip, knee, ankle, and foot) and low back pain (LBP) injuries. Both patient groups significantly improved on measures of pain, disability, and depression after the FRP, and patients in both groups displayed similarly high return-to-work and work-retention rates one year later. (Mayer, 2013)

Neck (and cervical spine): There are limited studies about the efficacy of chronic pain programs for neck 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 XXXX/XXXX and found that they had similar outcomes. Cervical patients were statistically less likely to have undergone pre-rehabilitative surgery. (Wright, 1999) Interdisciplinary functional restoration programs (FRPs) are equally efficacious for treating both chronic occupational cervical and lumbar disorders, and FRPs are equally effective, irrespective of the compensable body part(s). (Hartzell, 2014)

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 XXXX. 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 psychiatric 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) (Gatchel2, 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 Psych/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) The latest AHRQ Comparative Effectiveness Research supports the ODG recommendations. (AHRQ, 2011)

See also Chronic pain programs, intensity; Chronic pain programs, opioids; Functional restoration programs; Chronic pain programs, early intervention; Progressive goal attainment program (PGAP™).

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 4 weeks (20 full-days or 160 hours), or the equivalent in part-day sessions if required by part-time work, transportation, childcare, or comorbidities. (Sanders, 2005) If treatment duration in excess of 4 weeks is required, a clear rationale for the specified extension and reasonable goals to be achieved should be provided. 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.

Inpatient pain rehabilitation programs: These programs typically consist of more intensive functional rehabilitation and medical care than their outpatient counterparts. They may be appropriate for patients who: (1) don't have the minimal functional capacity to participate effectively in an outpatient program; (2) have medical conditions that require more intensive oversight; (3) are receiving large amounts of medications necessitating medication weaning or detoxification; or (4) have complex medical or psychological diagnosis that benefit from more intensive observation and/or additional consultation during the rehabilitation process. (Keel, 1998) (Kool, 2005) (Buchner, 2006) (Kool, 2007) As with outpatient pain rehabilitation programs, the most effective programs combine intensive, daily biopsychosocial rehabilitation with a functional restoration approach. If a primary focus is drug treatment, the initial evaluation should attempt to identify the most appropriate treatment plan (a drug treatment /detoxification approach vs. a multidisciplinary/interdisciplinary treatment program). See Chronic pain programs, opioids; Functional restoration programs.