

<b>Case Number:</b>	CM15-0162230		
<b>Date Assigned:</b>	09/04/2015	<b>Date of Injury:</b>	03/29/2004
<b>Decision Date:</b>	10/23/2015	<b>UR Denial Date:</b>	08/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/18/2015

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:

State(s) of Licensure: New York

Certification(s)/Specialty: Internal Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is 47 year old male, who sustained an industrial injury on March 29, 2004. The injury occurred while the injured worker was removing heavy equipment from the trunk of a car and experienced low back pain with radiation to the both lower extremities. The injured worker was noted to be working. Current diagnoses include chronic back and leg pain, lumbar disc displacement, neuropathic pain condition of the bilateral lower extremities, thoracic-lumbosacral radiculitis, spasm of muscle, lumbar-lumbosacral intervertebral disc degeneration, lumbago, post-laminectomy syndrome of the lumbar region, gastroesophageal reflux disease and unspecified myalgia and myositis. Treatment and diagnostics to date include an MRI of the lumbar spine (8-22-2014), transforaminal epidural steroid injections, radiological studies, electrodiagnostic studies (10-15-2014), home exercise program, physical therapy and two lumbosacral surgeries. Current medications include Lidoderm, Lyrica, Nucynta, Pristiq, Cymbalta and Zanaflex. According to the primary treating physician's progress report dated August 10, 2015 the injured worker presented with continued low back pain and bilateral hip and leg pain, greater on the left. The injured worker also noted urinary incontinence and poor sleep. Documentation dated August 13, 2015 notes that the injured worker complained of increasing back and leg pain. The injured worker reported multiple injections done through pain management without significant improvement. The injured worker noted having more difficulty with activities of daily living. Exam of the spine revealed diffuse tenderness to palpation. Bilateral hip flexion was 5-5. Sensation was decreased in the bilateral lumbar-four, lumbar-five and sacral-one distributions. The treating physician's plan of care included requests for Nucynta

ER 100 mg # 30, Nuvigil 150 mg # 30, Nucynta 50 mg # 30, Klonopin 0.5 mg # 60, transforaminal epidural steroid injections at right lumbar-five, sacral-one, transforaminal epidural steroid injections left at lumbar-five, sacral-one, transforaminal epidural steroid injections right at sacral-one, sacral-two and transforaminal epidural steroid injections left at sacral-one and sacral-two.

### **IMR ISSUES, DECISIONS AND RATIONALES**

The Final Determination was based on decisions for the disputed items/services set forth below:

**Nucynta ER 100mg Quantity: 30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), 18th edition, 2013, Pain Chapter.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids, criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter(Chronic) Nucynta.

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that central acting analgesics such as Nucynta may be used to treat chronic pain. Central analgesics drugs are reported to be effective in managing neuropathic pain. The MTUS guidelines discourage long-term usage unless there is evidence of ongoing review and documentation of pain relief, functional status and appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain relief lasts. A satisfactory response to treatment may be indicated by the injured worker's decreased pain level, increased level of function or improved quality of life. The MTUS guideline indicate functional improvement is "evidenced by a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." The Official Disability Guidelines recommend Nucynta only as a second-line therapy for patients who develop intolerable adverse effects with first-line opioids. "Three large randomized controlled trials concluded that Nucynta was efficacious and provided efficacy that was similar to Oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations." In this case, the injured worker was noted to have chronic low back pain with radiation to the bilateral lower extremities. The injured worker has been prescribed Nucynta ER since October of 2014. The Official Disability Guidelines recommend Nucynta ER as a second-line therapy for patients who develop adverse effects with first-line opioids. Documentation dated August 10, 2015 notes that there were no tried or failed medications. Therefore, the request for Nucynta ER is not medically necessary.

**Nuvigil 150mg Quantity: 30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), 18th edition, 2013, Pain Chapter.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter (Chronic) - Nuvigil.

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines do not address Nuvigil. The Official Disability Guidelines do not recommend Nuvigil solely to counteract sedation effects of narcotics. Armodafinil is used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. In this case, there is documentation of a poor sleep pattern. However, there is lack of documentation of narcolepsy. The injured worker is on opioid therapy. There is no documentation of sedation related to opioid therapy or an attempt to reduce the injured workers opioid therapy. Therefore, the requested treatment: Nuvigil 150 mg # 30 is not medically necessary.

**Nucynta 50mg Quantity: 30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), 18th edition, 2013, Pain Chapter.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, California Controlled Substance Utilization Review and Evaluation System (CURES) [DWC], Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Nucynta.

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines state that central acting analgesics such as Nucynta may be used to treat chronic pain. Central analgesics drugs are reported to be effective in managing neuropathic pain. The MTUS guidelines discourage long-term usage unless there is evidence of ongoing review and documentation of pain relief, functional status and appropriate medication use and side effects. Pain assessment should include: current pain, the least reported pain over the period since last assessment, average pain, the intensity of pain after taking the opioid, how long it takes for pain relief and how long the pain relief lasts. A satisfactory response to treatment may be indicated by the injured worker's decreased pain level, increased level of function or improved quality of life. The MTUS guideline indicate functional improvement is "evidenced by a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." The Official Disability Guidelines recommend Nucynta only as a second-line therapy for patients who develop intolerable adverse effects with first-line opioids. "Three large randomized controlled trials concluded that Nucynta was efficacious and provided efficacy that was similar to Oxycodone for the management of chronic osteoarthritis knee and

low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations." In this case, the injured worker was noted to have chronic low back pain with radiation to the bilateral lower extremities. The Official Disability Guidelines recommend Nucynta as a second-line therapy for patients who develop adverse effects with first-line opioids. Documentation dated August 10, 2015 notes that there were no tried or failed medications. Therefore, the request for Nucynta 50 mg # 30 is not medically necessary.

**Klonopin 0.5mg Quantity: 60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Benzodiazepines.

**Decision rationale:** In regards to the request for Klonopin (benzodiazepine), the California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines do not recommend benzodiazepines for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an anti-depressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. The CA MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional restoration rather than the elimination of pain. In this case, the injured worker has been prescribed Klonopin since at least January of 2015. Klonopin is recommended for short-term use of 4 weeks. There is lack of documentation of ongoing functional benefit or an indicated need for the chronic use of Klonopin. The request for Klonopin 0.5 mg # 60 is not medically necessary.

**TFE Right at L5-S1:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines recommend epidural steroid injections (ESI) for treatment of radicular pain when the injured worker has been unresponsive to initial conservative care, which includes exercises, physical therapy, non-steroidal anti-inflammatory drugs and muscle

relaxants. Most current guidelines recommend no more than 2 ESI injections. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehabilitative efforts, including continuing a home exercise program. Repeat blocks should be based on findings of continued objective pain and functional improvement, including at least fifty percent pain relief, with associated reduction of medication use for six to eight weeks. The California MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional restoration rather than the elimination of pain. In this case, the injured worker had prior epidural steroid injections on November 26, 2014 and February 5, 2014. Documentation dated August 13, 2015 notes that the injured worker complained of increasing back and leg pain. The injured worker reported multiple injections done through pain management without significant improvement. The injured worker noted having more difficulty with activities of daily living. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in activities of daily living and dependency on continued medical care. Therefore, the requests for transforaminal epidural steroid injections at right lumbar-five, sacral-one is not medically necessary.

**TFE Left at L5-S1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines recommend epidural steroid injections (ESI) for treatment of radicular pain when the injured worker has been unresponsive to initial conservative care, which includes exercises, physical therapy, non-steroidal anti-inflammatory drugs and muscle relaxants. Most current guidelines recommend no more than 2 ESI injections. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehabilitative efforts, including continuing a home exercise program. Repeat blocks should be based on findings of continued objective pain and functional improvement, including at least fifty percent pain relief, with associated reduction of medication use for six to eight weeks. The California MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional restoration rather than the elimination of pain. In this case, the injured worker had prior epidural steroid injections on November 26, 2014 and February 5, 2014. Documentation dated August 13, 2015 notes that the injured worker complained of

increasing back and leg pain. The injured worker reported multiple injections done through pain management without significant improvement. The injured worker noted having more difficulty with activities of daily living. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in activities of daily living and dependency on continued medical care. Therefore, the requests for transforaminal epidural steroid injections left at lumbar-five, sacral-one is not medically necessary.

**TFE Right at S1-S2: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines recommend epidural steroid injections (ESI) for treatment of radicular pain when the injured worker has been unresponsive to initial conservative care, which includes exercises, physical therapy, non-steroidal anti-inflammatory drugs and muscle relaxants. Most current guidelines recommend no more than 2 ESI injections. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Epidural steroid injection can offer short-term pain relief and use should be in conjunction with other rehabilitative efforts, including continuing a home exercise program. Repeat blocks should be based on findings of continued objective pain and functional improvement, including at least fifty percent pain relief, with associated reduction of medication use for six to eight weeks. The California MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional restoration rather than the elimination of pain. In this case, the injured worker had prior epidural steroid injections on November 26, 2014 and February 5, 2014. Documentation dated August 13, 2015 notes that the injured worker complained of increasing back and leg pain. The injured worker reported multiple injections done through pain management without significant improvement. The injured worker noted having more difficulty with activities of daily living. There is a lack of functional improvement with the treatment already provided. The treating physician did not provide sufficient evidence of improvement in activities of daily living and dependency on continued medical care. Therefore, the requests for transforaminal epidural steroid injections right at sacral-one, sacral-two is not medically necessary.

**TFE Left at S1-S2: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Epidural steroid injections (ESIs).

**Decision rationale:** The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Medical Treatment Guidelines recommend epidural steroid injections (ESI) for treatment of radicular pain when the injured worker has been unresponsive to initial conservative care, which includes exercises, physical therapy, non-steroidal anti-inflammatory drugs and muscle relaxants. Most current guidelines recommend no more than 2 ESI injections. Research has now shown that, on average, less than two injections are required for a successful ESI outcome. Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehabilitative efforts, including continuing a home exercise program. Repeat blocks should be based on findings of continued objective pain and functional improvement, including at least fifty percent pain relief, with associated reduction of medication use for six to eight weeks. The California MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional restoration rather than the elimination of pain. In this case, the injured worker had prior epidural steroid injections on November 26, 2014 and February 5, 2014. Documentation dated August 13, 2015 notes that the injured worker complained of increasing back and leg pain. The injured worker reported multiple injections done through pain management without significant improvement. The injured worker noted having more difficulty with activities of daily living. There is a lack of functional improvement with such treatment previously provided. The treating physician did not provide sufficient evidence of improvement in activities of daily living and dependency on continued medical care. Therefore, the requests for transforaminal epidural steroid injections left at sacral-one and sacral-two is not medically necessary.