Medical Assessments, Inc.

4833 Thistledown Dr.

Fort Worth, TX 76137

P: 817-751-0545

F: 817-632-9684

January 24, 2016

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Neuvova cream #480gm, (ketamine 15%, Gabapentin 5%, Baciofen 3%, Bupivacaine 3%, Dicofenac sod 3%, Cyclob 2%, Flurbiprofen 3%, Tramadol 5%, fluticasone prop, 0.2%) refills 3

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The Reviewer is Board Certified in the area of Neurological Surgery with over 16 years of experience.

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

☒ Partially Overturned (Agree in part/Disagree in part)

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 claimant is a male who reported injury on XX/XX/XX. The claimant was inspecting a X. His car was struck by an 18 wheeler when pulling onto the road. The claimant spent a total of four and a half months in the hospital and was diagnosed with a sprain of the neck and unspecified HMIPLGA NONDMNT SIDE.

XX/XX/XX: Progress notes. Claimant reported pain level 6/10. The average pain is rated 8/10. This is about a 50% improvement in pain. Pain reported as achy, burning, and dull numb, sharp and stabbing with a shooting and stiff component. The claimant complains of swelling, throbbing and tingling as well. The pain is made better with pain cream and being in his walk in tub. **Medications:** Avinza 45mg, Percocet 10/325, Pain cream for the left lower extremity, Occasional Avinaza 30mg.

XX/XX/XX: Progress notes. Claimant reported pain level 6/10. This is a 40 to 50% improvement in pain with medications. The pain is still in the shoulder, low back and left lower extremity particularly. The pain is constant and interferes with work, sleep and the claimant's daily routines as well as recreation. Pain is made better by heat, ice, tub and pain cream. **PE**: The lower extremities show marked sensitivity. There is 2+ edema of the left lower extremity and trace on the right. The claimant had wheezes which were present and large tube rhonchi which are indicative to the pulmonary disease he has. He also has sleep apnea. The claimant has problems with his pulmonary system and aspiration pneumonia because he has difficulty swallowing. This is all related to his head injury. The claimant receives Lasix for his lower extremities edema to try to help control the edema. He has highly refractory edema in the left lower extremity which I equate to the edema that accompanies a patient who had had a stroke. He has reflex sympathetic dystrophy with pain on that side. His nervous system is completely disrupted by the traumatic brain injury and other injuries that have accompanied this issues. The patient had a

neurogenic bladder after the injury. He also has had an end-on ileostomy because his lower bowel did not work appropriately. It should be noted this is a complete disruption of the spinal cord activity as well as the central nervous system activity. In any event, the left lower extremity edema is probably of multifactorial origin being present from the reflex sympathetic dystrophy as well as the injury itself.

XX/XX/XX: Chest X-ray 2 views. **Impression:** 1. No acute disease is seen within the chest.

XX/XX/XX: Office visit. **Current Medications:** aspirin 81mg, Klonopin 1mg, Synthroid 150mg, Xopenex 125mg, Furoscomide 40mg, Lor-Con M20 20 Meq, Percocet 10-650mg, Bactrim 400-80mg, Omeprazole 40mg, Nystatin 100000 unit/gm, Compounded cream, Lovaza 1gm caps, Zofran 4mg, Antivert 25mg, Cortisone cream, Vitamin D 2000, Avinza 45mg, Systane, Genteal mild to moderate, Lamictal Xr 1000 mg, Folic acid, Analpram, Zyrtec, Astepro, Singulair 10mg, Gnp Magnasium, Bactroban 2%, Seroquel 100mg, Pristiq 50mg, Flomax, Ferrous Gluconate.

XX/XX/XX: Progress notes. Claimant reported he is having issues with regards to his pain. He has been participating in PT and OT and is having increasing pain in his left lower extremity, right shoulder, right hip and right ankle. **Diagnoses:** Status post traumatic brain injury with multiple trauma. Cervical spine pre-medullary contusion and hematoma resulting in severe brainstem injury. Cervical spine ligamentous injury at the cervical cranial junction. Parietal subarachnoid hemorrhage. Status post pneumothorax requiring chest tubes bilaterally. Multiple rib fractures. Left clavicular fracture. Left scapular fracture. Left pelvic fracture. Bilateral cranial nerve VI palsy resulting in severe strabismus. Status post ventriculoperitoneal shunt for hydrocephalus. Dysphagia. Status post percutaneous endoscopic gastrostomy placement. Severe gastroesophageal reflux disease and gastroparesis. Left upper extremity monoplegia. Respiratory insufficiency. Status post tracheostomy. Recurrent urinary tract infections. Neurogenic bladder. Adhesive capsulitis, bilateral shoulders. Left brachial pan-plexopahty. Left vocal cord paralysis. Balance deficits and intermittent dizziness. Subarachnoid cysts. Sleep disorder related to injuries and disruption of routine schedule. Status post end-on ileostomy for relief of constipation induced inspissated stool with rectal bleeding, relieved with the end on ilestomy. Status post revision of ventricular peritoneal shunt. **Current complaints:** claimant reported 9/10 pain level.

XX/XX/XX: Progress notes. Claimant reported pain level 7/10. **Medications:** Embeda 60/2.4mg, Embeda 30/1.2mg, Percocet 10/325, Pain cream. The claimant is not working and has an impairment rating of 95%.

XX/XX/XX: Office visit. **New Medications:** Opioid medication, Bactrim, Lamictal 400mg, Lovaza, Nexium, Pain cream, Percocet, Seroquel 100, Seroquel XR 50, Synthoid, Xopenex, Augmentin.

XX/XX/XX: Note. Claimant reported very anxious about finding a new pain medicine. He has been fairly controlled for the last several months on his pain regimen. Pain has been tolerable with PT Lessing a bit and pain cream. He is not overusing his medications, takes as prescribed and very closely monitored by his wife.

XX/XX/XX: UR. Rationale for denial: The claimant is a male who reported injury on XX/XX/XX. He was struck by an 18 wheeler when pulling onto the road. Prior treatment included an unknown number of PT sessions, medications, activity modifications, respiratory therapy, and surgery. The clinical documentation submitted for review indicated the claimant had left lower extremity and right shoulder pain. The claimant rated the pain as a 7/10 on VAS. The claimant reported the pain cream helps; however, there was no documentation of the knowledge of the specific analgesic effect of each agent and how it will be useful for this specific therapeutic goal required. Gabapentin and baclofen are not recommended by guidelines. Peer to peer discussion has not been achieved despite calls to MD's office. Given the above, the request for Neuvova cream #480gm, (ketamine 15%, Gabapentin 5%, Baciofen 3%, Bupivacaine 3%, Dicofenac sod 3%, Cyclob 2%, Flurbiprofen 3%, Tramadol 5%, fluticasone prop, 0.2%) refills 3 is non-certified.

XX/XX/XX: UR. The claimant is a male who reported an injury on XX/XX/XX. The mechanism of injury was the patient was struck by an 18 wheeler when pulling on to the road. The patient was diagnosed with a sprain of the neck and unspecified hemiplegia of the no dominant side. Prior treatment included healthcare, an unknown

number of PT, medications, activity modification, respiratory therapy, and surgery**.** Neuvova cream #480gm, (ketamine 15%, Gabapentin 5%, Baciofen 3%, Bupivacaine 3%, Dicofenac sod 3%, Cyclob 2%, Flurbiprofen 3%, Tramadol 5%, fluticasone prop, 0.2%) refills 3 is not supported. Guidelines state any compounded product that contains at least 1 drug that is not recommended is not recommended. There was no documentation of the compounded agent's specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Peer to peer was not successful. Given the above, the request for Neuvova cream #480gm, (ketamine 15%, Gabapentin 5%, Baciofen 3%, Bupivacaine 3%, Dicofenac sod 3%, Cyclob 2%, Flurbiprofen 3%, Tramadol 5%, fluticasone prop, 0.2%) refills 3 is non-certified. **Addendum:** Spoke with XX, who stated that the patient was able to decrease medication with the use of the cream, but he does not have the records available to provide evidence at that time. Therefore, after peer to peer conversation, the request remained non-certified.

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

The previous determination has been partially overturned. This patient has history of head injury, multisystem trauma as well as reflex sympathetic dystrophy in lower extremity. His head injury history makes the use of Ketamine and Tramadol in the compound cream problematic with increased risk of seizure with Tramadol. Ketamine is not generally recommended after head injury. He should have those medications removed from the compounded cream as the other ingredients are not likely to cause him problems. His pulmonary medical problems make more oral medications risky for him. Therefore, the topical cream with the right medications is a reasonable option.

ODG Guidelines:

Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (**Namaka, 2004**) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (**Colombo, 2006**) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α-adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (**Argoff, 2006**) There is little to no research to support the use of many these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. For example, see **Duragesic®** (fentanyl transdermal system).]

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

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**