

<b>Case Number:</b>	CM14-0093002		
<b>Date Assigned:</b>	09/12/2014	<b>Date of Injury:</b>	01/14/2013
<b>Decision Date:</b>	10/24/2014	<b>UR Denial Date:</b>	06/12/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/19/2014

### 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. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in California 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 a 58 year old male injured on 01/14/13 while utilizing a roto-hammer while standing on a ladder when the device kicked back, striking him on the right side of the head. The injured worker was evaluated in the emergency department where x-rays showed fractures of unspecified location. The qualified medical evaluation performed on 07/25/13 indicated the injured worker complained of headaches, right shoulder pain extending to the neck and shoulder blade, dizziness, decreased sense of smell, blurred vision, and difficulty with thinking and memory. The physical examination revealed ability to heel and toe walk, no ataxia, motor strength revealed no weakness, reflexes normal and symmetric, sensation well-maintained, no tremor, no alteration of temperature/trigger/vasomotor status of the extremities, and decreased range of motion of the right shoulder noted. The documentation indicated CT and MRI imaging of the head revealed cortical atrophy and small vessel white matter changes with a number of naturally occurring conditions; however, no evidence of post-traumatic type pathology. Additionally, MRI of the shoulder revealed full thickness rotator cuff tear. There was no documentation of medication management. No subsequent clinical documentation was submitted for review. The initial request was non-certified on 06/12/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Sentra PM Qty 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** As noted in the Pain chapter of the Official Disability Guidelines - Online version, the use of herbal medicines or medical foods is not recommended. Sentra PM is intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan. Current guidelines do not recommend the use of herbal or medical foods as a first-line treatment. There is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. As such, the request for Sentra PM Qty 60 cannot be recommended as medically necessary.

**Theracodophen-325 (Theramine 2 tablets q. 6h. #90 and Norco 10/325mg 1-2 tablets q. 6h. #60): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** As noted in the Pain Chapter of the Official Disability Guidelines, Theramine is not recommended for use in chronic pain management. Theramine is a medical food that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. There are no high quality studies that support the use of Theramine. The use of herbal medicines or medical foods is not recommended. Additionally, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. Further, guidelines indicate combinations of medications are not recommended if one or more of the components are recommended for use. As such, the request for Theracodophen-325 (Theramine 2 tablets q. 6h. #90 and Norco 10/325mg 1-2 tablets q. 6h. #60) cannot be recommended as medically necessary.

**Therapentin Pak -90 (Theramine 2 tablets q. 6h. #180 and Gabapentin 300mg 1 tablet p.o. t.i.d. #120): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** As noted in the Pain Chapter of the Official Disability Guidelines, Theramine is not recommended for use in chronic pain management. Theramine is a medical food that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. There are no high quality studies that support the use of Theramine. The use of herbal medicines or medical foods is not recommended. Additionally, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. Further, guidelines indicate combinations of medications are not recommended if one or more of the components are recommended for use. As such, the request for Therapentin Pak -90 (Theramine 2 tablets q. 6h. #180 and Gabapentin 300mg 1 tablet p.o. t.i.d. #120) cannot be recommended as medically necessary.

**Theraproxen Pak -90 (Theramine 1-2 tablets q.6h. #90 and Naproxen 250mg p.o. b.i.d. #60):** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

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

**Decision rationale:** As noted in the Pain Chapter of the Official Disability Guidelines, Theramine is not recommended for use in chronic pain management. Theramine is a medical food that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. There are no high quality studies that support the use of Theramine. The use of herbal medicines or medical foods is not recommended. Additionally, there is no indication the injured worker has failed previous prescription medications or has obvious contraindications that necessitate medical food/herbal use. Further, guidelines indicate combinations of medications are not recommended if one or more of the components are recommended for use. As such, the request for Theraproxen Pak -90; (Theramine 1-2 tablets q.6h. #90 and Naproxen 250mg p.o. b.i.d. #60) cannot be recommended as medically necessary.