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| <b>Case Number:</b>   | CM14-0103304 |                              |            |
| <b>Date Assigned:</b> | 09/24/2014   | <b>Date of Injury:</b>       | 06/12/1998 |
| <b>Decision Date:</b> | 10/24/2014   | <b>UR Denial Date:</b>       | 07/03/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 07/03/2014 |

### 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 Orthopedic Surgery 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:

This 53-year-old female sustained an industrial injury on 6/12/98 relative to cumulative trauma. Past surgical history was positive for partial medial meniscectomy, synovectomy, and chondroplasty in 2000, 2004, and 2010. Conservative treatment had included corticosteroid injections, activity modifications, TENS unit, and viscosupplementation. The patient had discontinued the use of ibuprofen due to gastritis and H. pylori. The 4/22/14 treating physician report cited increasing knee pain over the last 6 months. Pain was reported grade 7/10 with walking tolerance limited to 15 minutes. She performed a daily home exercise program, used a TENS unit, and rode a stationary bike. She used a compressive brace that was effective in decreasing pain. Physical exam documented significant right quadriceps atrophy, exquisite patellar tenderness, tight hamstrings, range of motion 0-130 degrees, pain no valgus stress, 3+ crepitation, and medial joint line tenderness. A right total knee arthroplasty consult was recommended. The 7/3/14 utilization review denied the request for Proteolin as there was no evidence of a dietary deficiency to support the medical necessity of this medical food. The request for Motrin was denied as the patient had been advised to stop this medication previously due to gastritis and H. pylori and there was no documentation that she was medically cleared to resume use. The request for Exoten pain lotion was denied as guideline criteria had not been met for the use of this topical medication relative to intolerance of other treatments. The 7/22/14 treating physician report appealed the denial of Proteolin. The patient reported that Proteolin decreased pain from 8/10 to 6/10 without gastrointestinal distress.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Proteolin:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

**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), Medical food

**Decision rationale:** Proteolin is a proprietary formulation of anti-inflammatory and immunomodulatory peptides (Hyperimmune Milk Protein Concentrate), Curcuminoids (Turmeric), Proteolytic Enzymes (Bromelain), and Piperin. It is intended for use in nutritional management of certain inflammatory processes and related pain symptoms. The California MTUS do not provide recommendations for medical foods. The Official Disability Guidelines stat that medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain. The treating physician has reported a pain reduction associated with the use of this product without gastrointestinal side effects. No functional benefit has been reported. There is no evidence of a dietary deficiency. Given the absence of guideline support and lack of clinical studies documenting efficacy, this request is not medically necessary.

**Motrin 800mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-72.

**Decision rationale:** The California MTUS recommend the use of NSAIDs (non-steroidal anti-inflammatory drugs) like Motrin for the treatment of knee osteoarthritis in patients with moderate to severe pain. It is generally recommended that the lowest effective dose be used for the shortest duration of time consistent with the individual patient treatment goals. Guidelines recommend identifying patients at risk for gastrointestinal events. Guideline criteria have not been met. This patient presents with significant risk factors for gastrointestinal events with prior discontinuation of this medication advised due to gastritis and H. pylori. There is no current indication that the patient has been cleared to resume use of this medication. Therefore, this request is not medically necessary.

**Exoten Pain Lotion:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** Exoten pain lotion contains methyl salicylate, menthol, and capsaicin. The California MTUS state that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin is recommended only as an option for patients who have not responded or are intolerant to other treatments. Guidelines recommend the short term use of non-steroidal anti-inflammatory agents (NSAIDs), such as methyl salicylate, for osteoarthritis and tendinitis, particularly of the knee and elbow or other joints that are amenable to topical treatment. Short term use is defined as 4-12 weeks. Menthol is a topical cooling agent that guidelines support as an optional form of cryotherapy. Guideline criteria have not been met. There is no evidence that the patient has failed to respond or is intolerant to other treatments, besides Motrin, to support the medical necessity of Capsaicin consistent with guidelines. Given the failure to meet guideline indications for Capsaicin, the request for Exoten is not considered medically necessary. Therefore, this request is not medically necessary.