

<b>Case Number:</b>	CM14-0210732		
<b>Date Assigned:</b>	12/23/2014	<b>Date of Injury:</b>	07/10/2007
<b>Decision Date:</b>	02/27/2015	<b>UR Denial Date:</b>	11/17/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/15/2014

### 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. 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & Gen Prev Med

### 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 patient is a 53 year old employee with date of injury of 7/10/07. Medical records indicate the patient is undergoing treatment for s/p L2-L3, L3-L4 and L4-L5 spinal decompression with laminectomy at L3 and foraminotomies at L2-:3 and L4-L5. S/P dural leak repair (no date). Her diagnoses include: pain in joint, lower left leg and knee; degeneration of lumbar disc; bursitis NOS and postlaminectomy lumbar syndrome. Subjective complaints include low back pain that is non-consistent. It is made worse with sitting, repetitive bending, twisting and lifting. The patient has numbness and tingling that radiates down the posterolateral portion of the left lower extremity. She reports pain in the right foot accompanied with cramping. She has numbness and tingling in the distal portion of the right foot. She complains of hip pain, left groin pain which is made worse with flexion of the hip and walking. Her left knee has a "jabbing" pain. The patient does "push through" with exercise on a bicycle and the pool. She says she can mountain bike for 20-25 minutes. She complains of depression. Objective findings include upon exam the patient is anxious and tearful. She has normal muscle tone without atrophy in all extremities; she has normal strength; she has an antalgic gait. Treatment has consisted of epidural injection, Sprix nasal spray 18.75, DOS: 2/12/14, 03/03/2014, 03/28/14, 4/16/14, 06/03/14, QTY: 1.00 PT, Ibuprofen and Hydrocodone. The utilization review determination was rendered on 11/17/14 recommending non-certification of Sprix nasal spray 15.75 DOS: 10/03/13, 10/22/13, 11/06/13, 12/03/13, 12/17/13, 1/08/14, 01/23/14, QTY: 1.00; Sprix nasal spray 18.75, DOS: 2/12/14, 03/03/2014, 03/28/14, 4/16/14, 06/03/14, QTY: 1.00.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Sprix nasal spray 15.75 DOS: 10/03/13, 10/22/13, 11/06/13, 12/03/13, 12/17/13, 1/08/14, 01/23/14, QTY: 1.00:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Sprix (ketorolac tromethamic nasal spray)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, NSAIDs and Spirix; <http://www.sprix.com/Home.aspx>.

**Decision rationale:** ODG states that Spirix is FDA approved as an intranasal formulation of Ketorolac. Ketorolac/Toradol is an NSAID. MTUS is silent on Ketorolac specifically, but MTUS has four recommendations regarding NSAID use in general:"1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain.2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP.3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics.4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat longterm neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain." ODG states the following: "Ketorolac (Toradol, generic available): The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose."The treating physician does not detail the intensity of pain after taking Sprix, pain relief, increased level of function, or improved quality of life. Therefore, the request for Sprix nasal spray 15.75 DOS: 10/03/13, 10/22/13, 11/06/13, 12/03/13, 12/17/13, 1/08/14, 01/23/14, QTY: 1.00 is not medically necessary.

**Sprix nasal spray 18.75, DOS: 2/12/14, 03/03/2014, 03/28/14, 4/16/14, 06/03/14, QTY: 1.00:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Sprix (ketorolac tromethamic nasal spray)

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, NSAIDs and Sprix;  
<http://www.sprix.com/Home.aspx>.

**Decision rationale:** ODG states that Sprix is FDA approved as an intranasal formulation of Ketorolac. Ketorolac/Toradol is an NSAID. MTUS is silent on Ketorolac specifically, but MTUS has four recommendations regarding NSAID use in general: "1) Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. 2) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. 3) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. 4) Neuropathic pain: There is inconsistent evidence for the use of these medications to treat longterm neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain." ODG states the following: "Ketorolac (Toradol, generic available): The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose." The treating physician does not detail the intensity of pain after taking Sprix, pain relief, increased level of function, or improved quality of life. Therefore, the request for Sprix nasal spray 18.75, DOS: 2/12/14, 03/03/2014, 03/28/14, 4/16/14, 06/03/14, QTY: 1.00 is not medically necessary.