

<b>Case Number:</b>	CM15-0013911		
<b>Date Assigned:</b>	02/02/2015	<b>Date of Injury:</b>	05/09/2000
<b>Decision Date:</b>	03/23/2015	<b>UR Denial Date:</b>	01/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/23/2015

### 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: Illinois, California, Texas  
 Certification(s)/Specialty: Orthopedic Surgery

### 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 68-year-old male who sustained an industrial injury on 5/9/00. Past surgical history was positive for L4/5 X-Stop procedure in 2009, right total knee arthroplasty on 4/22/14, and left total knee arthroplasty in August 2014. The 11/12/14 lumbar spine MRI impression documented progressive degenerative changes at L1/2, L2/3, L4/5, and L5/S1 since 2008. There was an X-Stop device in place at L4/5 which appears appropriately positioned. There was moderate right neuroforaminal narrowing at L5/S1, moderate narrowing of both lateral recess and mild bilateral neuroforaminal narrowing at L4/5, and moderate narrowing of both lateral recesses at L3/4. The 12/16/14 CT scan findings documented the X-Stop device in the interspinous space at L4/5, and the hardware was intact and appropriately positioned. The 12/29/14 treating physician report cited constant grade 5-8/10 low back pain radiating to the left leg over the past 6 months in an L4/5 distribution with numbness, tingling, burning, and cramping in the calf area to the foot. He complained of left leg weakness. Pain was worse with walking and prolonged sitting, and better with medications. Physical exam documented normal range of motion, 2+ and symmetrical deep tendon reflexes, 4/5 left quadriceps weakness, and negative straight leg raise bilaterally. The patient was able to tandem walk and heel to toe walk. Diagnoses included spinal stenosis of lumbar region at multiple levels; lumbar stenosis with neurogenic claudication; low back pain with radiation to the left leg; lumbar degenerative disc disease; history of back surgery. On 1/5/15, removal of X-Stop and inserting a new one was requested because of persistent symptoms. On 1/9/15 Utilization review non-certified the request for surgery-spine-removal of ex-stop, insertion of new one at L4-5 and LOS-out patient citing

ODG: Interspinous decompression device (X-Stop) and since the surgery was not approved the LOS-outpatient was not certified.

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

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

#### **Spine Surgery removal of ex-stop insertion of new one at L4-L5: 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) Treatment Index, 12th Edition (web), 2014, Low Back- interspinous decompression device (X-Stop)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Low Back Lumbar & Thoracic: X-Stop® Interspinous Process Decompression (IPD®) System, Interspinous decompression device (X-Stop®)

**Decision rationale:** The California MTUS guidelines do not provide recommendations relative to this request. The Official Disability Guidelines do not recommend the use of the X-Stop over decompression surgery, because the failure rate of X-Stop is typically much higher. Given the absence of guideline support for the use of X-Stop, the removal of the X-stop device and replacement would not be supported. Additionally, there is no imaging evidence of hardware failure. Detailed evidence of a recent, reasonable, and/or comprehensive non-operative treatment protocol trial and failure has not been submitted. There is no compelling reason to support the medical necessity of X-Stop over standard decompression surgery. Therefore, this request is not medically necessary.

**LOS-out patient:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not cite any medical evidence for its decision.

**Decision rationale:** Since the primary procedure is not medically necessary, none of the associated services are medically necessary.