

<b>Case Number:</b>	CM15-0054623		
<b>Date Assigned:</b>	05/11/2015	<b>Date of Injury:</b>	08/16/1996
<b>Decision Date:</b>	06/08/2015	<b>UR Denial Date:</b>	02/16/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/23/2015

### 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: New York  
 Certification(s)/Specialty: Internal Medicine

### 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 50 year old male who sustained an industrial injury on August 16, 1996. He has reported right ankle pain and has been diagnosed with ankle pain right and status post ORIF right trimalleolar fracture. Treatment has included therapy and medication. He was working moving equipment when he fell and fractured his right ankle. The right ankle pain was noted as mild and moderate that is relieved by therapy and medications. The treatment request included Actos.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Actos 45mg #30 with 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Diabetes (Type 1, 2, and Gestational), Pioglitazone (Actos), Thiazolidinedione (TZD).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation UpToDate.

**Decision rationale:** Pioglitazone (brand name Actos) is a prescription drug of the class thiazolidinedione (TZD) with hypoglycemic (antihyperglycemic, antidiabetic) action to treat diabetes. While pioglitazone does decrease blood sugar levels, studies on the main cardiovascular outcomes has not yielded statistically significant results. Its cardiovascular safety profile compares favorably with rosiglitazone (Avandia), which was withdrawn after concerns about an increased risk of cardiac events. Pioglitazone has been found to be associated with bladder tumors and has been withdrawn in some countries. Actos can be used in combination with Metformin for glycemic control. In this case, there is no documentation of the patient's HbA1c levels to determine his level of glycemic control. There is no specific indication for the use of Actos especially given his history of obesity, as the TZD class can cause edema and weight gain. Medical necessity for the requested medication is not established. The requested medication is not medically necessary.