

<b>Case Number:</b>	CM14-0057602		
<b>Date Assigned:</b>	07/09/2014	<b>Date of Injury:</b>	11/13/2009
<b>Decision Date:</b>	08/21/2014	<b>UR Denial Date:</b>	04/23/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/28/2014

### 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 Occupational 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:

As per CA MTUS guidelines, physical medicine is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Official Disability Guidelines (ODG) allows 21 post-surgical physical therapy visits over 16 weeks for ankle foot fractures. In this case, there is no record of previous physical therapy progress notes. There is no documentation of any improvement in the objective measurements with prior therapy to demonstrate the effectiveness of physical therapy in this injured worker. Furthermore, additional 12 physical therapy sessions would probably exceed the guidelines recommendation. Therefore, the medical necessity of the requested service cannot be established at this time based on the guidelines and available medical records; is non-certified.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Xolair Injections 150 mg Vial 2 Vials Q 14 days refill 12:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation [www.xolair.com](http://www.xolair.com).

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Formulary, XolairPDR, 2014, Xolair.

**Decision rationale:** The history and documentation do not objectively support the request for continued use of Xolair. The Official Disability Guidelines (ODG) formulary states Xolair is under study as a first-line choice for asthma; recommend anti-immunoglobulin E therapy as second line. Recommended as adjunctive therapy for patients greater than 12 years of age to control allergic diseases such as allergic rhinitis and asthma. This is an anti-IgE monoclonal antibody that prevents binding of IgE to high-affinity receptors on basophils and mast cells and further states regarding asthma medications: Stepwise approach for managing asthma: Intermittent Asthma: SABA as needed. For Mild Persistent Asthma: - First-line: Low-dose ICS. - Second-line: LTRA or Theophylline. For moderate persistent asthma: - First-line: Low-dose ICS + LABA OR Medium-dose ICS - Second-line: Medium-dose ICS + LABA .Third-line: Low-dose ICS + either LTRA or Theophylline - Fourth-line: Medium-dose ICS + either LTRA or Theophylline. For severe persistent asthma: - First-line: High-dose ICS + LABA and Consider Anti-IgE for patients who have allergies - Second-line: High-dose ICS + LABA + Oral corticosteroids And Consider Anti-IgE. Key drug class & drug names:SABA = inhaled short-acting beta2-agonists: Albuterol (Ventolin); Levalbuterol (Xopenex); Pirbuterol (Maxair); ICS = inhaled corticosteroids: Budesonide (Pulmicort); Fluticasone (Flovent)- LABA = inhaled long-acting beta2-agonists: Formoterol (Foradil); Salmeterol (Serevent)- LTRA = leukotriene receptor antagonists: Montelukast (Singulair); Zafirlukast (Accolate)- Anti-IgE = anti- immunoglobulin E therapy: Omalizumab (Xolair); Theophyllines: Slo-Bid; Uniphyl; Oral corticosteroids: Prednisone (Deltasone); Prednisolone (Pediapred); Combinations LABA/ICS: Advair (Salmeterol/Fluticasone); Combivent (Albuterol/Ipratropium); Symbicort (Formoterol/Budesonide) (NHLBI, 2007). The PDR states Xolair is an anti-IgE antibody indicated for: Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids. The review states that ██████ told the previous reviewer that he wanted the claimant to stop the Xolair for a few months to see how he did without it. No other notes have been submitted that cover the period of time when the claimant was off the medication, if that is what was done. The claimant's current clinical status is unknown, including whether or not other medications have been tried since the Xolair was planned to be discontinued, or whether he failed a trial off Xolair. Based on the available information in the submitted records, therefore, the medical necessity of continued use of Xolair at this time has not been clearly demonstrated.