

<b>Case Number:</b>	CM13-0062822		
<b>Date Assigned:</b>	12/30/2013	<b>Date of Injury:</b>	09/05/2012
<b>Decision Date:</b>	01/23/2015	<b>UR Denial Date:</b>	11/13/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/09/2013

### 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 Physical Medicine Rehab and is licensed to practice in Wisconsin. 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:

The injured worker is a 45-year-old male who reported an injury due to cumulative trauma on 09/05/2012. On 10/29/2013, his diagnoses included bilateral wrist sprain/strain, rule out bilateral carpal tunnel syndrome, rule out bilateral de Quervain's tenosynovitis, and sleep disorder. His complaints included burning bilateral wrist pain with weakness and numbness and tingling radiating to his hands and 3 middle fingers with muscle spasms rated 3/10, and, difficulty sleeping. He stated that his symptoms persisted but the medications offered him temporary relief of pain and improved his ability to have restful sleep. The pain was also alleviated by activity restrictions. His medications included Fanatrex oral suspension 25 mg/ml, Synapryn oral suspension 10 mg/ml, and Tabradol oral suspension 1 mg/ml. There was no rationale included in this injured worker's chart. A request for authorization dated 10/29/2013 was included.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Synapryn 10mg/1ml oral suspension 500ml 5ml, three (3) times per day:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Dailymed.nlm.nih.gov

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Compound Drugs, Physician-dispensed drugs

**Decision rationale:** The request for Synapryn 10mg/1ml oral suspension 500ml 5ml, three (3) times per day is not medically necessary. The Official Disability Guidelines do not recommend compound drugs as a first line therapy. In general, commercially available, FDA approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA approved ingredients may be considered. They further note that physician dispensed drugs are not generally recommended over pharmacy dispensing due to higher costs and worse outcomes in Workers' Compensation cases. Physician dispensing is the process of distributing prepackaged medications directly to patients at the point of care and is generally recommended only for the initial visit to provide patients with medications for acute injuries. The patient may prefer physician dispensed drugs because of convenience. Physician dispensing may create financial incentives that affect the use of compound drugs and other medications, due primarily to fee schedule ambiguities. In addition, physician dispensed drugs typically do not go through the pharmacy benefit management companies but are submitted directly to the payer. Physician dispensing has been found to be associated with higher costs and more lost time than pharmacy dispensed medications. The guidelines do not support the use of compound, physician dispensed medications. Therefore, this request for Synapryn 10mg/1ml oral suspension 500ml 5ml, three (3) times per day is not medically necessary.

**Tabradol 10mg/1ml oral suspension, 250ml 5ml, 2-3 times a day:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Dailymed.nlm.nih.gov

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Compound Drugs, Physician-dispensed drugs

**Decision rationale:** The request for Tabradol 10mg/1ml oral suspension, 250ml 5ml, 2-3 times a day is not medically necessary. The Official Disability Guidelines do not recommend compound drugs as a first line therapy. In general, commercially available, FDA approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA approved ingredients may be considered. They further note that physician dispensed drugs are not generally recommended over pharmacy dispensing due to higher costs and worse outcomes in Workers' Compensation cases. Physician dispensing is the process of distributing prepackaged medications directly to patients at the point of care and is generally recommended only for the initial visit to provide patients with medications for acute injuries. The patient may prefer physician dispensed drugs because of convenience. Physician dispensing may create financial incentives that affect the use of compound drugs and other medications, due primarily to fee schedule ambiguities. In addition, physician dispensed drugs typically do not go through the pharmacy benefit management companies but are submitted directly to the payer. Physician dispensing has been found to be associated with higher costs and more lost time than pharmacy dispensed medications. The guidelines do not support the use of compound, physician dispensed medications. Therefore, this request for Tabradol 10mg/1ml oral suspension, 250ml 5ml, 2-3 times a day is not medically necessary.

**Fanatrex 25mg/ml oral suspension, 420ml/5ml, three (3) times per:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Dailymed.nih.gov

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Compound Drugs, Physician-dispensed drugs

**Decision rationale:** The request for Fanatrex 25mg/ml oral suspension, 420ml/5ml, three (3) times per day is not medically necessary. The Official Disability Guidelines do not recommend compound drugs as a first line therapy. In general, commercially available, FDA approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA approved ingredients may be considered. They further note that physician dispensed drugs are not generally recommended over pharmacy dispensing due to higher costs and worse outcomes in Workers' Compensation cases. Physician dispensing is the process of distributing prepackaged medications directly to patients at the point of care and is generally recommended only for the initial visit to provide patients with medications for acute injuries. The patient may prefer physician dispensed drugs because of convenience. Physician dispensing may create financial incentives that affect the use of compound drugs and other medications, due primarily to fee schedule ambiguities. In addition, physician dispensed drugs typically do not go through the pharmacy benefit management companies but are submitted directly to the payer. Physician dispensing has been found to be associated with higher costs and more lost time than pharmacy dispensed medications. The guidelines do not support the use of compound, physician dispensed medications. Therefore, this request Fanatrex 25mg/ml oral suspension, 420ml/5ml, three (3) times per day is not medically necessary.