

Case Number:	CM15-0011970		
Date Assigned:	01/29/2015	Date of Injury:	10/29/1995
Decision Date:	04/07/2015	UR Denial Date:	12/30/2014
Priority:	Standard	Application Received:	01/21/2015

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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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:

This 65-year-old woman sustained an industrial injury on 10/29/1995. The mechanism of injury was not detailed. Current diagnoses include chronic pain syndrome, chronic discogenic pain syndrome, and myofascial syndrome. Treatment has included oral medications and trigger point injections. Physician notes dated 11/17/2014 show a flare up of neck pain rated 9/10.

Recommendations include maintaining the Ultram tablets and adding KCGI topical to help avoid class II or III opioids. It is unclear whether the worker received trigger point injections and/or Toradol injection at this visit. On 12/30/2014, Utilization Review evaluated prescriptions for Gabapentin powder 12 grams and Cyclobenzaprine 12 grams, that were submitted on 1/9/2015. The UR physician noted there is no clear evidence whether compounded medications are more efficacious than single medications. The MTUS, ACOEM Guidelines, (or ODG) was cited. The request was denied and subsequently appealed to Independent Medical Review.

IMR ISSUES, DECISIONS AND RATIONALES

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

Gabapentin powder 12 grams, provided on November 20, 2014: 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).

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.

Decision rationale: ODG states "Not recommended 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." ODG Criteria for Compound drugs: (1) Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. (2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code. (3) Is not a drug that was withdrawn or removed from the market for safety reasons. (4) Is not a copy of a commercially available FDA-approved drug product. (5) Include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence. (6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011) The treating physician has not detailed a trial and failure of first line therapies. In addition the treating physician has not met the above ODG criteria. As such, the request for Gabapentin powder 12 grams, provided on November 20, 2014 is not medically necessary.

Cyclobenzaprine 12 grams, provided on November 20, 2014: 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).

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.

Decision rationale: ODG states "Not recommended 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." ODG Criteria for Compound drugs: (1) Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. (2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code. (3) Is not a drug that was withdrawn or removed from the market for safety reasons. (4) Is not a copy of a commercially available FDA-approved drug product. (5) Include

only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence. (6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011) The treating physician has not detailed a trial and failure of first line therapies. In addition the treating physician has not met the above ODG criteria. As such, the request for Cyclobenzaprine 12 grams, provided on November 20, 2014 is not medically necessary.