

Case Number:	CM13-0048219		
Date Assigned:	02/20/2014	Date of Injury:	06/11/2006
Decision Date:	03/06/2015	UR Denial Date:	10/25/2013
Priority:	Standard	Application Received:	11/05/2013

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. 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: Maryland, Texas, Virginia

Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 is a 43 year old male with a date of injury of 6/11/06. He is being treated for hypertension, gastrointestinal issues, diabetes type 2, hypertriglyceridemia with low HDL. Subjective findings on 9/11/13 include worsening eye sight, chronic fatigue, decreased libido, night sweats, difficulty sleeping, constipation and chest pain. Objective findings include morbid obesity, puffy eye lids, distant heart sounds, right upper quadrant tenderness, hepatomegaly and bilateral non-pitting edema. His blood pressure is 128/82 at this visit. Laboratory work reveals triglycerides 670, HDL 39 and a creatinine of 1.48. Treatment thus far has consisted of medications, Levemir 60 U BID, Humalog 75/25 20U 15-30 minutes prior to meals, gabapentin 300mg daily, pravastatin 40mg qhs, Lisinopril/hydrochlorothiazide 20/25mg daily, phenteramine 37.5 mg qam, Topiramate 100mg qhs. The Utilization Review on 10/25/13 found the request for Pravachol 10mg #180 to be modified to #90 due to ODG recommendations to not use first-line in diabetics and to allow for reassessment in the ability to improve triglycerides and adjust as needed. The request for Norvasc 10mg #180 to be modified to #90 to allow for recheck of blood pressure and allow for changes to medications if needed. The request for Benazepril 20mg #180 to be modified to #90 to allow for recheck of blood pressure on this medication and allow for adjustments in dosage.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norvasc 10mg, #180: 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), Diabetes, Statins

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Hypertension treatment 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) JAMA 311(5) 2014

Decision rationale: The MTUS is silent of blood pressure management. The ODG states that they "Recommend that blood pressure in DM be controlled to levels of 140/80, but 130 may be appropriate for younger patients if it can be achieved without undue treatment burden. Over 88% of patients with type 2 DM either have uncontrolled hypertension or are being treated for elevated blood pressure. Agents such as angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers are preferred given their renal and/or CVD benefits. Other agents such as vasodilating b-adrenergic blockers, calcium channel blockers, diuretics, and centrally-acting agents should be used as necessary. (Gerstein, 2011) (Handelsman, 2011)" The Eighth Joint National Committee (JNC 8) has released new guidelines on the management of adult hypertension, which contain two key departures from JNC 7. For one, they recommend relaxing the more aggressive JNC 7 target blood pressures and treatment-initiation thresholds in elderly patients and in patients under age 60 with diabetes and kidney disease. JNC 8 also backs away from the recommendation that thiazide-type diuretics should be initial therapy in most patients, suggesting an ACE inhibitor, angiotensin-receptor blocker (ARB), calcium-channel blocker (CCB), or thiazide-type diuretic are reasonable choices. They wanted to make the message very simple for physicians: treat to 150/90 mm Hg in patients over age 60 and 140/90 for everybody else. Among the recommendations: (1) In patients 60 years or over, start treatment in blood pressures >150 mm Hg systolic or >90 mm Hg diastolic and treat to under those thresholds; (2) In patients <60 years, treatment initiation and goals should be 140/90 mm Hg, the same threshold used in patients >18 years with either chronic kidney disease (CKD) or diabetes; (3) In nonblack patients with hypertension, initial treatment can be a thiazide-type diuretic, CCB, ACE inhibitor, or ARB, while in the general black population, initial therapy should be a thiazide-type diuretic or CCB; (4) In patients >18 years with CKD, initial or add-on therapy should be an ACE inhibitor or ARB, regardless of race or diabetes status. Their first line medications are Ace-inhibitors with a first line 2nd addition of a CCB if not controlled. They recommend early and frequent follow up. The main objective of hypertension treatment is to attain and maintain goal BP. If goal BP is not reached within a month of treatment, increase the dose of the initial drug or add a second drug from one of the classes in recommendation 6 (thiazide-type diuretic, CCB, ACEI, or ARB). The clinician should continue to assess BP and adjust the treatment regimen until goal BP is reached. If goal BP cannot be reached with 2 drugs, add and titrate a third drug from the list provided. In this case, the Norvasc is a new addition to medication regimen. As recommended by JNC 8, he would need early and regular follow up since his medications are being changed. The request here is for 6 months worth of medication which does not allow for reassessment and modifications if necessary. The patient is already

having side-effects due to blood pressure medications, low libido. This patient is also on a medication for weight loss, phenteramine, which is an amphetamine with the side effect of increasing blood pressure. He also has evidence of possible acute renal failure with an increase in his creatinine to 1.48. Given his multiple co-morbidities and medications, he is at high risk and should receive frequent follow ups. The UR had modified the request to #90 which is reasonable. As such, the request for Norvasc 10mg #180 is not medically necessary.

Benzapril 20mg, #180: 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), Diabetes, Statins

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Hypertension treatment 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults Report From the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) JAMA 311(5) 2014

Decision rationale: The MTUS is silent on the treatment of hypertension. The ODG states that they Recommend that blood pressure in DM be controlled to levels of 140/80, but 130 may be appropriate for younger patients if it can be achieved without undue treatment burden. Over 88% of patients with type 2 DM either have uncontrolled hypertension or are being treated for elevated blood pressure. Agents such as angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers are preferred given their renal and/or CVD benefits. Other agents such as vasodilating b-adrenergic blockers, calcium channel blockers, diuretics, and centrally-acting agents should be used as necessary. (Gerstein, 2011) (Handelsman, 2011)The Eighth Joint National Committee (JNC 8) has released new guidelines on the management of adult hypertension, which contain two key departures from JNC 7. For one, they recommend relaxing the more aggressive JNC 7 target blood pressures and treatment-initiation thresholds in elderly patients and in patients under age 60 with diabetes and kidney disease. JNC 8 also backs away from the recommendation that thiazide-type diuretics should be initial therapy in most patients, suggesting an ACE inhibitor, angiotensin-receptor blocker (ARB), calcium-channel blocker (CCB), or thiazide-type diuretic are reasonable choices. They wanted to make the message very simple for physicians: treat to 150/90 mm Hg in patients over age 60 and 140/90 for everybody else. Among the recommendations: (1) In patients 60 years or over, start treatment in blood pressures >150 mm Hg systolic or >90 mm Hg diastolic and treat to under those thresholds; (2) In patients <60 years, treatment initiation and goals should be 140/90 mm Hg, the same threshold used in patients >18 years with either chronic kidney disease (CKD) or diabetes; (3) In nonblack patients with hypertension, initial treatment can be a thiazide-type diuretic, CCB, ACE inhibitor, or ARB, while in the general black population, initial therapy should be a thiazide-type diuretic or CCB; (4) In patients >18 years with CKD, initial or add-on therapy should be an ACE inhibitor or ARB, regardless of race or diabetes status. Their first line medications are Ace-inhibitors with a first line 2nd addition of a CCB if not controlled. They recommend early and frequent follow up. The main objective of hypertension treatment is to attain and maintain goal BP. If goal BP is not reached within a month of treatment, increase the dose of the initial drug or add a second drug from one of the classes in recommendation 6

(thiazide-type diuretic, CCB, ACEI, or ARB). The clinician should continue to assess BP and adjust the treatment regimen until goal BP is reached. If goal BP cannot be reached with 2 drugs, add and titrate a third drug from the list provided. In this case, the benazepril is a new addition to medication regimen. This is a switch from Lisinopril /HCTZ. As recommended by JNC 8, he would need early and regular follow up since his medications are being changed. The request here is for 6 months worth of medication which does not allow for reassessment and modifications if necessary. The patient is already having side-effects due to blood pressure medications, low libido. This patient is also on a medication for weight loss, phenteramine, which is an amphetamine with the side effect of increasing blood pressure. He also has evidence of possible acute renal failure with an increase in his creatinine to 1.48 and the fact that he is on an ace-inhibitor with a change in his medications is concerning. Given his multiple comorbidities and medications, he is at high risk and should receive frequent follow ups. The UR had modified the request to #90 which is reasonable. As such, the request for Benazepril 20mg #180 is not medically necessary.

Pravachol 10mg, #180: 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), Diabetes, Statins

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Diabetes (Type 1, 2, and Gestational), Statins 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults., Stone NJ et al, Circulation

Decision rationale: The MTUS is silent on Statins. The ODG states, "Not recommended as a first-line treatment for diabetics. Patients with DM should be screened for dyslipidemia, and therapeutic recommendations should include lifestyle changes and, as needed, consultation with a registered dietitian. Statins may be a treatment in the absence of contraindications, but recent studies have associated increased risk of DM with use of all types of statins." There is mention that the patient has begun a self-directed vegetarian diet with some recommendation by the provider but there is no discussion about other lifestyle changes or referral to a registered dietitian. New guidelines from the American College of Cardiology (ACC) and American Heart Association (AHA), developed in conjunction with the National Heart, Lung, and Blood Institute (NHLBI), eliminate the recommended LDL- and non-HDL "cholesterol targets, specifically those that treat patients with cardiovascular disease to less than 100 mg/dL or the optional goal of less than 70 mg/dL. Instead, the new guidelines identify four groups of primary- and secondary-prevention patients in whom physicians should focus their efforts to reduce cardiovascular disease events. (Stone, 2014)" The four groups are on the basis of this large and consistent body of evidence, 4 major statin benefit groups were identified for whom the ASCVD risk reduction clearly outweighs the risk of adverse events. Individuals 1) with clinical ASCVD, 2) primary elevations of LDL C >190 mg/dL, 3) diabetes aged 40 to 75 years with LDL C 70 to 189 mg/dL and without clinical ASCVD, or 4) without ASCVD or diabetes with LDL C 70 To 189 mg/dL and estimated 10-year ASCVD risk >7.5%. This patient has a history of DM2, elevated triglycerides and does appear to be at risk for ASCVD and he most likely has an

indication for a statin. However, the medical records fail to provide his LDL or his total cholesterol level in order to determine his 10-year risk. Therefore, one is unable to place him in any of the 4 categories recommended by the ACC and AHA for treatment with a statin. Also, the request is for a 6 months supply which does not allow for follow up to reassess if this medication is working and to allow for modifications if needed. The UR modified to #90 which is reasonable. As such, the request for Pravacol 10mg #180 is not medically necessary.