

December 16, 2008

George Waldman, MD  
Noridian Administrative Services, LLC  
P.O. Box 6402  
Fargo, ND 58108

Dear Dr. Waldman:

The American College of Rheumatology recently sent a letter objecting to the new reimbursement policy which has greatly impacted many medications, including abatacept (J0129). Although this change is not related to the medical necessity portion of an LCD, it is unduly burdensome to physicians and patients. The ACR respectfully requests that this reimbursement policy be reviewed and payment amounts remain at the original levels until the review is complete.

Abatacept is approved for use in rheumatoid arthritis patients who have had an inadequate response to an anti-TNF therapy. It delays the progression of structural damage and reduces signs and symptoms of rheumatoid arthritis. Abatacept is infused over 30 minutes; the first 3 doses are 2 weeks apart, then doses are given every 4 weeks. Patients should be infused in a safe environment where the physician can appropriately monitor the patient.

The ACR is concerned that this policy change is not in line with the current coding guidelines or in accordance with the national standards. Medicare is a national program and there is no justification for a regional administrator to cut reimbursement in their region, without warning or sufficient explanation, when there is a national infusion code that has been set by joint agreement between CMS and the physician community.

Noridian's summary of changes for the use of chemotherapy administration codes indicates that: "*the policy is being made in absence of proper clinical consideration.*"

The CPT ® defines that *chemotherapy services are typically highly complex and require direct physician supervision for any or all purposes of patient assessment, provision of consent, safety oversight and intra-service supervision of staff. Typically, such chemotherapy services require advanced practice training and competency for staff who provide these services; special considerations for preparation, dosage or disposal; and commonly, these services entail significant patient risk and frequent monitoring.*

The CPT code 96413 is allowed for biologic agents. The higher codes were allowed in recognition of the risks and overhead costs of administering these agents. These products are foreign proteins being given through IV route and there is always the potential risk of a reaction.

Abatacept is covered by this portion of the definition because administration requires direct physician supervision. There have been rare cases of anaphylaxis or anaphylactoid reactions in patients receiving abatacept as well as other events potentially associated with drug hypersensitivity such as hypotension, urticaria and dyspnea. Physicians need to exercise caution when prescribing abatacept for patients with recurrent infections or with underlying conditions that predispose them to infections. Trained infusion nurses should be on site to evaluate patients prior to the infusion and be prepared to treat with any drug reactions during the infusion.

Noridian did not offer physicians the opportunity to provide justification for biologic drug infusions under complex infusion codes. Rheumatologists had already obtained the medications, assuming that they would be paid at the previous payment rates. When the payment was dramatically decreased, rheumatologists took a significant and unprecedented financial loss, had to stop infusion therapy and scramble for other treatment options. Meanwhile, patient lives were disrupted with flares of their chronic arthritis, schedule changes, and concerns about their future treatments and access to a rheumatologist. None of this was necessary.

Physicians must be provided adequate time to review such drastic changes, make cogent comments, notify their patients, and identify other treatment options. This unprecedented change in the policy and reimbursement will affect the overhead cost of offering infusion services in physician offices and non-hospital infusion centers. The biologic DMARD therapies are reserved for our sickest patients. The restriction of access to these therapies is a major concern for the American College of Rheumatology.

The ACR requests that this policy and reimbursement change be reviewed and restored to the national Medicare rates. Rheumatologists who administered abatacept in good faith expecting the original payment must be reimbursed while the review is underway – it is not fair for them to wait until the entire issue is settled and apologies should be extended to those patients whose lives were affected.

I would be happy to discuss this issue with you further. Please feel free to contact me (805) 928-0881 or Tiffany Schmidt, VP of Socioeconomic Affairs at (404) 633-3777.

Sincerely,



Karen Kolba, MD  
Chair, Committee on Rheumatologic Care

cc: Mike Hamelik, President/CEO  
Noridian Administrative Services, LLC

Steve Phurrough, MD, MPA, Coverage and Analysis Group  
Centers for Medicare & Medicaid Services

Mark Levine, MD, Chief Medical Officer, Region VII  
Centers for Medicare & Medicaid Services

David Sayen, Regional Administrator, Region IX  
Centers for Medicare & Medicaid Services

Kim Kieu, MD, MPH, Medical Officer, Region X  
Centers for Medicare & Medicaid Services