

January 6, 2016

Part B Policy  
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Dear Palmetto Medical Directors:

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of more than 35 State and regional professional Rheumatology societies whose mission is to advocate for excellence in the field of Rheumatology, ensuring access to the highest quality care for the management of Rheumatologic and musculoskeletal disease.

With access & quality of care always in mind, the CSRO would like to express its disappointment over the MolDx proposal not to cover Vectra DA for Medicare patients based on data from the recently published AMPLE study. The CSRO disagrees with the study conclusions which have serious limitations described by Dr. Jeff Curtis in his academic review of their paper.

According to Dr. Curtis, the AMPLE publication was based on an unusual method of statistical analysis for radiographic progression. When the data are analyzed using the more common method of analysis, the findings show the Vectra DA detects disease severity and accurately predicts radiographic progression in patients with Rheumatoid Arthritis (RA).

Contrary to the MolDx publication, the Vectra DA test has shown effectiveness in more than 20 peer-reviewed studies involving over 3,000 patients. This clinical evidence validates Vectra DA's usage and why 3 out of 4 rheumatologists have used this test in approximately 300,000 patients in the United States alone. This test is also validated and used by our colleagues in Europe as well.

The Vectra-DA test allows rheumatologists to personalize treatment for their RA patients and it has become an accepted marker of active disease by both physicians and insurers who often request measures of disease activity to evaluate drug efficacy. If its availability were to be limited, rheumatologists across the country would lose a valuable tool to measure the effectiveness of their prescribed therapies. This would argue against the effort to develop future innovative tests for diseases and more immediately hinder our management of Medicare patients struggling with RA.

At a time when the United States government will be undergoing changes and looking to affect new policies for a more progressive and innovative American healthcare system, the CSRO believes it would be irresponsible and harmful to our Medicare patients to take away their access to this testing.

On behalf of rheumatologists and our Medicare population, we would like to express serious doubts regarding the conclusions of the AMPLE study. We will continue to advocate for access to this important molecular diagnostic test for all Medicare patients with RA and, on behalf of our Medicare patients, we ask that you rescind the implementation of this proposal.

Sincerely,



Michael Stevens, MD  
President  
Coalition of State Rheumatology Organizations



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