Rheumatoid Arthritis (RA)

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Patient Safety

S-M

9000015 Patient(s) taking methotrexate, sulfasalazine, gold, or leflunomide that had a CBC in last 3 reported months.

Hematological toxicities have been reported with several disease modifying anti-rheumatic drugs (1-3). The pharmaceutical manufacturers recommend monitoring for hematological toxicities as follows: at least monthly for patients taking methotrexate, frequently for 6 months following initiation of sulfasalazine and then at least once every 3 months thereafter, at least monthly for patients taking oral gold, every 2 weeks for patients taking intramuscular gold, and monthly for 6 months following initiation of leflunomide and then every 6 to 8 weeks thereafter (2,3). The American College of Rheumatology recommends a CBC every 8 weeks for methotrexate, every 12 weeks for sulfasalazine, every 8 weeks for leflunomide, every 12 weeks for oral gold, and every 8 weeks for intramuscular gold (4). Based on this information, the consensus opinion of experts was the primary source of our recommendation for a CBC every 3 months at minimum since the frequency of assessment is dependent on the clinical status of the patient and is not clearly defined in the literature. This rule will identify patients taking methotrexate, sulfasalazine, gold, or leflunomide for longer than 90 days that had a CBC within the last 3 months of the report period.

- 1. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the Management of Rheumatoid Arthritis: 2002 Update. Arthritis Rheum 2002;46(2):328-346.
- 2. Antirheumatic agents. Drug Facts and Comparisons. eFacts [online]. 2007. Available from Wolters Kluwer Health, Inc. Accessed January 20, 2010.
- 3. Arava (leflunomide). http://www.fda.gov/medwatch/SAFETY/2003/safety03.htm#arava (Posted 11/20/03). Accessed January 20, 2010.
- 4. American College of Rheumatology's Starter Set of Measures for Quality in the Care for Rheumatic and Musculoskeletal Diseases, February 2006. Accessed January 20, 2010. URL: http://www.rheumatology.org/practice/qmc/starterset0206.asp

S-M 9000016

Patient(s) taking methotrexate or sulfasalazine that had a serum creatinine in last 6 reported months.

Renal toxicities have been reported with methotrexate and sulfasalazine. The pharmaceutical manufacturers recommend monitoring for renal toxicities as follows: at least every 1 to 2 months for patients taking methotrexate and periodically for patients taking sulfasalazine (1). The American College of Rheumatology recommends a serum creatinine every 8 weeks for methotrexate (2). Based on this information, the consensus opinion of experts was the primary source of our recommendation for a serum creatinine every 6 months at minimum since the frequency of assessment is dependent on the clinical status of the patient and is not clearly defined in the literature. This rule will identify patients taking methotrexate or sulfasalazine for longer than 270 days that had a serum creatinine within the last 6 months of the report period.

- 1. Antirheumatic agents. Drug Facts and Comparisons. eFacts [online]. 2007. Available from Wolters Kluwer Health, Inc. Accessed January 20, 2010.
- 2. American College of Rheumatology's Starter Set of Measures for Quality in the Care for Rheumatic and Musculoskeletal Diseases, February 2006. Accessed January 20, 2010. URL: http://www.rheumatology.org/practice/qmc/starterset0206.asp

S-M 9000018

Patient(s) taking methotrexate, sulfasalazine, or leflunomide that had serum ALT or AST test in last 3 reported months.

Liver toxicities have been reported with several disease modifying anti-rheumatic drugs (1-3). The pharmaceutical manufacturers recommend monitoring for liver toxicities as follows: at least every 1 to 2 months for patients taking methotrexate, frequently for 6 months following initiation of sulfasalazine and then at least once every 3 months thereafter, and monthly for 6 months following initiation of leflunomide and then every 6 to 8 weeks thereafter (2,3). The American College of Rheumatology recommends a serum

AST or ALT every 8 weeks for methotrexate and leflunomide (4). Based on this information, the consensus opinion of experts was the primary source of our recommendation for a serum ALT or AST every 3 months at minimum since the frequency of assessment is dependent on the clinical status of the patient and is not clearly defined in the literature. This rule will identify patients taking methotrexate, sulfasalazine, or leflunomide for longer than 90 days that had a serum ALT or AST within the last 3 months of the report period.

- 1. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the Management of Rheumatoid Arthritis: 2002 Update. Arthritis Rheum 2002;46(2):328-346.
- 2. Antirheumatic agents. Drug Facts and Comparisons. eFacts [online]. 2007. Available from Wolters Kluwer Health, Inc. Accessed January 20, 2010.
- 3. Arava (leflunomide). http://www.fda.gov/medwatch/SAFETY/2003/safety03.htm#arava (Posted 11/20/03). Accessed January 20, 2010.
- 4. American College of Rheumatology's Starter Set of Measures for Quality in the Care for Rheumatic and Musculoskeletal Diseases, February 2006. Accessed January 20, 2010. URL: http://www.rheumatology.org/practice/qmc/starterset0206.asp

S-M 9000019

Patient(s) taking hydroxychloroquine (Plaquenil) that had an eye exam in last 12 reported months.

Retinopathy has been reported with hydroxychloroquine use (1). The pharmaceutical manufacturer recommends baseline and periodic ophthalmologic exams with prolonged therapy (1). The American College of Rheumatology recommends fundoscopic and visual field examination annually (2). The Academy of Ophthalmology has recommended a retinopathy screening regimen that depends on an individual's degree of risk for retinal toxicity from hydroxychloroquine (3). However, claims data alone does not clearly identify low versus high risk individuals. Based on this information, the consensus opinion of experts was the primary source of our recommendation for an annual eye examination at minimum for patients taking hydroxychloroquine longer than 270 days since the frequency of assessment is dependent on the clinical status of the patient and is not clearly defined in the literature.

- 1. 4-Aminoquinoline compounds. Drug Facts and Comparisons. eFacts [online]. 2007. Available from Wolters Kluwer Health, Inc. Accessed January 20, 2010.
- 2. American College of Rheumatology's Starter Set of Measures for Quality in the Care for Rheumatic and Musculoskeletal Diseases, February 2006. Accessed January 20, 2010. URL: http://www.rheumatology.org/practice/qmc/starterset0206.asp
- 3. Marmor MF, Carr RE, Easterbrook M, et al. Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy, A Report by the American Academy of Ophthalmology. Ophthalmology 2002;109(7):1377-1382.

Care Pattern

CP-I

9000023 Patient(s) with complex RA treatment regimens or complications that had rheumatology consultation in last 6 reported months.

The American College of Rheumatology guidelines state that the level of training and experience in managing a patient with rheumatoid arthritis varies among primary care physicians; monitoring RA activity and drug toxicity may be appropriately assigned to a rheumatologist. Given this guideline recommendation, this measure was developed using the EBM Connect consultant panel process. This measure identifies patients on complex RA regimens or RA related complications that had specialty consultation during the last 180 days of the report period through 90 days after the end of the report period.

Using the EBM Connect consultant panel process, a complex RA regimen was defined as presence of a claim for any of the following medications during the last 120 days of the report period: gold, leflunomide (Arava), tumor necrosis factor inhibitors, or anakinra (Kineret). An RA related complication was defined as evidence of any of the following diagnosis during the last 12 months of the report period: rheumatoid lung disease, post-inflammatory pulmonary fibrosis, Felty's syndrome, or evidence of visceral/systemic involvement from the rheumatoid arthritis. Given the limitation of claims data, it is otherwise difficult to identify patients would benefit from rheumatology consultation.

1. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. American College of Rheumatology. Arthritis Rheum. 2008 Jun 15;59(6):762-84.

CP-I 9000024

Patient(s) taking chronic corticosteroids that had rheumatology consultation in last 6 reported months.

Oral corticosteroid medications are not recommended for routine use, as there is no sustained clinical or functional benefit and there is a high risk of toxicity with long-term use (1). Given this guideline recommendation, this measure was developed using the EBM Connect consultant panel process. This measure identifes patients taking chronic corticosteroids that had rheumatology consultation during the last 180 days of the report period through 90 days after the end of the report period; these individuals might benefit from specialty care and consideration of various disease modifying anti-rheumatic drug (DMARD) treatment options.

Using the EBM Connect consultant panel process, chronic corticosteroid use was defined as follows: 1) more than 90 days of oral corticosteroid medications dispensed and 2) two or more prescriptions of oral corticosteroids dispensed in the past 6 months.

1. Scottish Intercollegiate Guidelines Network. Management of Early Rheumatoid Arthritis (Released December 2000, updated October 2004). Accessed January 20, 2010. URL:http://www.sign.ac.uk