Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization Number: 07.069

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Approval: Robert Bonnell, M.D., Med. Dir. DATES - Origination: 08/26/09
Responsible Party: CPM Director Revised: 11/08/13 Effective: 11/20/13
Distribution: Medical Department P&T Review: 08/24/16 Annual Review: 08/24/16

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

   3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.
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Background Information, continued:

Medication Summary

- Rituximab is indicated for adults with moderately-to-severely active rheumatoid arthritis (RA) who have failed methotrexate combination therapy or sequential administration of other DMARDs and one (1) or more tumor necrosis factor (TNF) antagonist therapies. It should only be used for Members who have high disease activity and poor prognostic features.

- Rituximab is a genetically engineered chimeric murine/human monoclonal antibody that binds to CD20 antigen on normal and malignant B-lymphocytes. As a result, rituximab triggers a host cytotoxic immune response against CD20-positive cells resulting in cell apoptosis. B-cells are believed to play a role in the development and progression of rheumatoid arthritis (RA) through production of rheumatoid factor (RF) and other autoantibodies, antigen presentation, T cell activation, and/or pro-inflammatory cytokine production. Treatment with rituximab causes near complete depletion of peripheral B lymphocytes within two (2) weeks of the first dose and continues for at least six (6) months until subsequent gradual recovery.

- Rituximab is dosed as two (2) 1000mg intravenous (IV) infusions given on days 1 and 15 (two weeks apart). Methylprednisolone (100mg IV or its equivalent) should be given 30 minutes prior to each infusion to reduce the incidence and severity of infusion reactions. Although the safety and efficacy of more than one (1) treatment course (two infusions) has not been established, prospective data of patients receiving multiple treatment courses (3 to 5 courses) has shown consistent and sustained efficacy relative to the original baseline with no additive adverse effects.

Coverage Guidelines

- Member must be eligible and have applicable benefits.

- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.
Background Information, continued:

Exclusion Criteria

- Members with a history of hypersensitivity to Rituximab or any of its ingredients.

- Concurrent administration of multiple biological response modifiers [including, but not limited to: Actemra (tocilizumab), Kineret (anakinra), Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept), Simponi (golimumab)]. Only one (1) agent at a time will be covered for the treatment of Rheumatoid Arthritis.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.

- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.

- Requests received for Medicare Members will be reviewed using Center for Medicare & Medicaid Services (CMS) “LCD for Rituximab (Rituxan)”
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Procedure:

1.0 Request for therapy (initiation and continuation) with Rituxan requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying one (1) of the following diagnoses:

1.1 Rheumatoid Arthritis:
   1.1.1 Diagnosis of moderate to severe RA; AND

   1.1.2 Combination therapy with methotrexate (MTX) unless Member has contraindication or intolerance to MTX; AND

   1.1.3 Previous failure with oral DMARDs; AND

   1.1.4 For Commercial Members (excludes Medicare or Miami Dade County) - Member shows inadequate response, or intolerance to, an adequate dose both Humira (adalimumab) AND Enbrel (etanercept);

   1.1.5 Age greater than 18 years old; AND

   1.1.6 Member has NOT received Rituxan in previous four (4) months;

   1.1.7 If criteria are met, Rituxan is approvable for two treatments of 1000mg on day 1 and day 15 every six (6) months for one (1) year;

1.2 Non-Hodgkin’s Lymphoma:
   1.2.1 Rituxan is approvable for six (6) months;

1.3 Primary CNS Cancers:
   1.3.1 Rituxan is approvable for six (6) months;

1.4 Hodgkin’s Lymphoma:
   1.4.1 Rituxan is approvable for six (6) months;

1.5 Multiple myeloma:
   1.5.1 Rituxan is approvable for six (6) months;
Procedure (continued):

1.0 Request for *therapy (initiation and continuation)* with Rituxan requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying one (1) of the following diagnoses, continued:

1.6 Chronic lymphocytic leukemia:
   1.6.1 Rituxan is approvable for six (6) months;

1.7 Relapsed or refractory waldenstrom macroglobulinemia:
   1.7.1 Rituxan is approvable for six (6) months;

1.8 Thrombocytopenic purpura:
   1.8.1 Rituxan is approvable for six (6) months;

1.9 Wegener’s Granulomatosis and Microscopic Polyangiitis (MPA) in combination with glucocorticoids:
   1.9.1 Rituxan is approvable for six (6) months.

References:


