Medical Department Procedure Manual

Section:  Chapter 7A Prescription Medications Prior Authorization  Number:  07.067

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Approval:  Robert Bonnell, M.D., Med. Dir.  DATES - Origination:  08/26/09
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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:

   1.1  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.

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.

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

- Remicade (infliximab) is a chimeric monoclonal antibody that binds specifically to human tumor necrosis factor alpha (TNFα), thereby neutralizing its activity. TNFα activity is attributed to induction of inflammatory cytokines. Elevated levels of TNFα are found in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), plaque psoriasis, Crohn’s disease, and ulcerative colitis (UC).
- Remicade, in combination with methotrexate (MTX), is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical functioning in Members with moderately to severely active rheumatoid arthritis.
- Remicade is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric Members with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy.
- Remicade is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult Members with fistulizing Crohn’s disease.
- Remicade is indicated for reducing signs and symptoms in Members with active ankylosing spondylitis.
- Remicade is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical functioning in Members with psoriatic arthritis.
- Remicade is indicated for the treatment of Members with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.
- Remicade is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in Members with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- Remicade is administered as an intravenous (IV) infusion over at least a two (2) hour period given initially at week zero (0) then followed by a dose at week two (2) and week six (6), then maintenance infusions are given every four (4) to eight (8) weeks depending on response and diagnosis. Remicade is available as a single use 100mg vial.
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Background Information, continued:

Additional Information

- AvMed’s Clinical Pharmacists are PharmDs 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 Infliximab (Remicade - L29198)” – Refer to Attachment A or view on-line at: http://www.cms.hhs.gov/mcd/results_index.asp?from=%27lmrpcontractor%27&contractor=197&name=First+Coast+Service+Options%2CInc%2E+%2809102%2C+MAC+%2D+Part+B%29&letter_range=4&retired

Coverage Guidelines

- Member must be eligible and have applicable benefits.
- Remicade infusions will be directed towards in-office administration, or at an infusion center, or through home health care. All outpatient infusion requests will be required to transition future infusions to an alternate location site unless a Member has had a documented severe adverse reaction and/or infusion reaction that required hospital intervention.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criteria

- Members less than six (6) years of age.
- Doses greater than 5mg/kg in Members with a diagnosis of moderate to severe heart failure (NYHA class III/IV).
- Concurrent administration of multiple biological response modifiers including, but not limited to: Kineret (anakinra), Embrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), and Rituxan (rituximab). Only one (1) agent at a time will be covered for any indication.
- Member with a hypersensitivity to murine proteins, Remicade, or any of its ingredients.
- Members experiencing a clinically significant, active infection including, but not limited to, sepsis, tuberculosis without treatment, aplastic anemia, or opportunistic infections.
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Procedure:

1.0 Request for initial therapy with Remicade for rheumatoid arthritis (RA) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

1.1 Requesting practitioner is a rheumatologist; AND
1.2 Diagnosis of moderate to severe RA; AND
1.3 Member shows inadequate response to an adequate dose of OR is not a candidate for any of the following DMARDs:
   1.3.1 Oral or Injectable Gold;
   1.3.2 Leflunomide (Arava);
   1.3.3 Hydroxychloroquine (Plaquenil);
   1.3.4 Sulfasalazine (Azulfidine);
   1.3.5 Azathioprine (Imuran);
   1.3.6 D-Penicilamine;
   1.3.7 Cyclosporine; AND
1.4 Member shows inadequate response to an adequate dose of Methotrexate; OR
1.4 Member has contraindication to Methotrexate as evidenced by at least one (1) of the following:
   1.4.1 Chronic liver disease;
   1.4.2 Leukopenia;
   1.4.3 Thrombocytopenia;
   1.4.4 Creatinine clearance less than 40mL/minute;
   1.4.5 Immunodeficiency; AND
1.5 If criteria are met, initial therapy with Remicade may be approved at 3mg/kg weeks 0, 2 and 6 then every 8 weeks (may be increased to maximum 10mg/kg before shortening frequency interval to minimum four (4) weeks) for up to six (6) months.
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Procedure, continued:

2.0 Request for continuation of therapy beyond initial authorization period for RA requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a reduction in Member’s signs and symptoms of RA (i.e., 20% improvement in painful joint count, ESR, CRP, or morning stiffness) and/or an improvement in Member’s physical functioning:

2.1 If criteria are met, Remicade may be approved at a maximum dose of 10mg/kg every four (4) weeks for up to one (1) year.

3.0 Request for initial therapy with Remicade for psoriatic arthritis (PsA) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

3.1 Requesting practitioner is a rheumatologist or dermatologist; AND

3.2 Member shows inadequate response to an adequate dose of OR is not a candidate for any of the following DMARDs:

   3.2.1 Oral or Injectable Gold;
   3.2.2 Leflunomide (Arava);
   3.2.3 Hydroxychloroquine (Plaquenil);
   3.2.4 Sulfasalazine (Azulfidine);
   3.2.5 Azathioprine (Imuran);
   3.2.6 D-Penicillamine;
   3.2.7 Cyclosporine;
   3.2.8 Methotrexate;

3.3 If criteria are met, Remicade may be approved for induction at 5mg/kg at week 0, 2 and 6 and then every 8 weeks for up to six (6) months.
4.0 Request for *continuation of therapy* beyond initial authorization period for psoriatic arthritis (PsA) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a positive response to therapy as evidenced by a reduction in signs and symptoms:

4.1 If criterion is met, Remicade may be approved at a maximum dose of 5mg/kg every eight (8) weeks for up to one (1) year.

5.0 Request for *initial therapy* with Remicade for plaque psoriasis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

5.1 Member is at least 18 years of age; **AND**

5.2 Diagnosis of moderate to severe plaque psoriasis for at least one (1) year; **AND**

5.3 Involvement of at least 10% of the body surface area (BSA); **AND**

5.4 Member has failed previous treatment with at least one (1) of the following:

   5.4.1 Psoralens with UVA light (PUVA); **OR**
   5.4.1 UVB with coal tar; **OR**
   5.4.1 Dithranol; **OR**
   5.4.1 Retinoids (acitretin, Soriatane); **OR**
   5.4.1 Methtrexate; **OR**
   5.4.1 Cyclosporine;

5.5 If criteria are met, Remicade may be approved for induction at 5mg/kg at week 0, 2 and 6 and then every 8 weeks for up to six (6) months.
6.0 Request for continuation of therapy beyond the initial authorization period for plaque psoriasis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a positive response to therapy as evidenced by a reduction in signs and symptoms:

6.1 If criterion is met, Remicade may be approved at a maximum dose of 5mg/kg every eight (8) weeks for up to one (1) year.

7.0 Request for initial therapy with Remicade for ankylosing spondylitis (AS) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying that the Member has failed previous treatment with at least two (2) NSAIDs:

7.1 If criterion is met, Remicade may be approved for induction at 5mg/kg at week 0, 2 and 6 then every six (6) weeks for up to six (6) months.

8.0 Request for continuation of therapy beyond initial authorization period for ankylosing spondylitis (AS) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a positive response to therapy as evidenced by a reduction in signs and symptoms:

8.1 If criterion is met, Remicade may be approved at a maximum dose of 5mg/kg every six (6) weeks for up to one (1) year.

9.0 Request for initial therapy with Remicade for Crohn’s disease (CD) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

9.1 Member is at least (six) 6 years of age; AND

9.2 Diagnosis of moderate to severe Crohn’s Disease (CD); AND
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Procedure, continued:

9.0 Request for initial therapy with Remicade for Crohn’s disease (CD) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

9.3 Member shows an inadequate response to an adequate dose of OR is not a candidate for at least one (1) of the following medications:

   9.3.1 Mesalamine (Asacol, Lialda, Pentasa, Rowasa, Canasa);
   9.3.2 Sulfasalazine (Azulfidine);
   9.3.3 Corticosteroids ( prednisone, methylprednisolone, budesonide, Entocort);
   9.3.4 Azathioprine (Imuran);
   9.3.5 Mercaptopurine (6-MP);
   9.3.6 Methotrexate;

9.4 If criteria are met, initial therapy with Remicade may be approved at 5mg/kg weeks 0, 2 and 6 then every 8 weeks (may be increased to maximum 10mg/kg before shortening frequency interval) for up to six (6) months.

10.0 Request for continuation of therapy beyond the initial authorization period for Crohn’s disease requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a positive response to therapy as evidenced by a reduction in signs and symptoms:

10.1 If criterion is met, Remicade may be approved at a maximum dose of 10mg/kg for up to one (1) year.

11.0 Request for initial therapy with Remicade for fistulizing Crohn’s disease requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying that the Member is at least (six) 6 years of age:

11.1 If criterion is met, initial therapy with Remicade may be approved at 5mg/kg weeks 0, 2 and 6 then every 8 weeks (may be increased to maximum 10mg/kg before shortening frequency interval) for up to six (6) months.
Procedure, continued:

12.0 Request for *continuation of therapy* beyond the initial authorization period for **fistulizing Crohn’s disease** requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a positive response to therapy as evidenced by a reduction in signs and symptoms:

12.1 If criterion is met, Remicade may be approved at a maximum dose of 10mg/kg for up to one (1) year.

13.0 Request for *initial therapy* with Remicade for **Ulcerative Colitis** (UC) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

13.1 Diagnosis of moderate to severe ulcerative colitis (UC); **AND**

13.2 Member shows inadequate response to an adequate dose of **OR** is not a candidate for **at least one (1)** of the following medications:

   13.2.1 Mesalamine (Asacol, Lialda, Pentasa);
   13.2.2 Sulfasalazine (Azulfidine);
   13.2.3 Balsalazide (Colazal);
   13.2.4 Corticosteroids (prednisone, methylprednisolone, budesonide, Entocort);
   13.2.5 Azathioprine (Imuran);
   13.2.6 Mercaptopurine (6-MP);
   13.2.7 Methotrexate;
   13.2.8 Cyclosporine;

13.3 If criteria are met, Remicade may be approved for induction at 5mg/kg at week 0, 2 and 6 and then every 8 weeks for up to six (6) months.
14.0 Request for continuation of therapy beyond the initial authorization period for Ulcerative Colitis (UC) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a positive response to therapy as evidenced by a reduction in signs and symptoms:

14.1 If criterion is met, Remicade may be approved for induction at 5mg/kg at week 0, 2 and 6 and then every 8 weeks for up to one (1) year.

References: