Medical Department Procedure Manual

Section: Chapter 7A Prescription Medications Prior Authorization  Number: 07.042

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Approval: Robert Bonnell, M.D., Med. Dir.  DATES - Origination: 12/16/05
Responsible Party: CPM Director  Revised: 08/17/16  Effective:
Distribution: Medical Department  P&T Review: 08/24/16  Annual Review: 08/23/17

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that require 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 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, revised, or archived:

3.1 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.
Background Information, continued:

Medication Summary

- Humira (adalimumab) is a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor (TNF). Adalimumab binds specifically to TNF-alpha and blocks its interaction with the cell surface TNF receptors.

- Humira is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (RA) and in children (4 years of age or older) with Polyarticular Juvenile Rheumatoid Arthritis (JRA) who have an inadequate response to one or more disease modifying anti-Rheumatic drugs (DMARDs).

- Humira is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis (PsA).

- Humira is indicated for reducing signs and symptoms in patients with ankylosing spondylitis.

- Humira is indicated for the treatment of adult Members (18 years or older) with chronic, moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

- Humira is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn’s disease (CD) who have had an inadequate response to conventional therapy or have lost response to or are intolerant to Remicade (infliximab).

- Humira may be used alone or in combination with Methotrexate (MTX) or other DMARDs.

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

- Member less than four (4) years of age;
- Concurrent use of multiple biological response modifiers including, but not limited to: Kineret (anakinra), Humira (adalimumab), Cimzia (certolizumab), Amevive (alefacept), and Remicade (infliximab). Only one (1) agent at a time will be covered for the treatment of Rheumatoid Arthritis, Polyarticular Juvenile Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis, or Plaque Psoriasis;
- Guttate, erythrodermic, or pustular psoriasis;
- Member experiencing acute infection or significant chronic infection including, but not limited to, sepsis, tuberculosis, aplastic anemia, opportunistic infections.

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.

Procedure:

1.0 Request for initial therapy for Rheumatoid Arthritis (RA) with adalimumab (Humira) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying ALL of the following:

1.1 Provider must be a rheumatologist; AND

1.2 Member is at least 18 years of age; AND

1.3 Diagnosis of moderate to severely active RA of at least six (6) months duration as evidenced by at least one (1) of the following:
   1.3.1 Erythrocyte sedimentation rate (ESR) ≥ 28mm/hr;
   1.3.2 C-reactive protein (CRP) ≥ 2.0 mg/dL;
   1.3.3 Morning stiffness;
   1.3.4 Swollen and/or tender joints;
   1.3.5 Synovitis; AND
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Procedure, continued:

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

1.4 Member shows inadequate response to a three (3) to six (6) month minimum trial of 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;
   1.4.1 Leukopenia;
   1.4.1 Thrombocytopenia;
   1.4.1 Creatinine clearance less than 40mL/minute;
   1.4.1 Immunodeficiency; AND

1.5 Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of OR is not a candidate for any of the following DMARDs:
   1.5.1 Leflunomide (Arava);
   1.5.2 Hydroxychloroquine (Plaquenil);
   1.5.3 Sulfasalazine (Azulfidine);

1.6 If all criteria are met, Humira 40mg SQ every other week may be approved for up to three (3) months, or Humira 40mg SQ weekly may be approved for up to three (3) months if not on concurrent Methotrexate therapy.

2.0 Request for continuation of therapy beyond initial authorization period for rheumatoid arthritis (RA) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

2.1 Reduction in Member’s signs and symptoms (i.e., 20% improvement in painful joint count, ESR, CRP, or morning stiffness);

2.2 If all criteria are met, Humira 40mg SQ every other week may be approved for up to one (1) year of therapy, or Humira 40mg SQ weekly may be approved for up to one (1) year if not on concurrent Methotrexate therapy.
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Procedure, continued:

3.0 Request for initial therapy with adaplimab (Humira) for polyarticular juvenile idiopathic arthritis (pJIA) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

3.1 Provider is a rheumatologist; AND

3.2 Member is ≥ two (2) years of age; AND

3.3 Diagnosis of active pJIA as evidenced by:

   3.3.1 Swollen joints, typically large weight-bearing joints, such as the knees or ankles; AND

   3.3.2 Limitation of motion as well as pain and/or tenderness; AND

3.4 Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of methotrexate; OR

3.4 Member has a contraindication to methotrexate (as listed in section 1.4); AND

3.5 Member shows inadequate response to a three (3) to six (6) month minimum trial of adequate doses of OR is not a candidate for any DMARDs (as listed in section 1.5);

3.6 If all criteria are met, Humira may be approved for up to three (3) months using the following dosing:

<table>
<thead>
<tr>
<th>Weight</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>30kg or more (66 lbs)</td>
<td>40mg every other week</td>
</tr>
<tr>
<td>15kg to 29kg (33-65lbs)</td>
<td>20mg every other week</td>
</tr>
<tr>
<td>10kg to 15kg (22-33lbs)</td>
<td>10mg every other week</td>
</tr>
</tbody>
</table>
4.0 Request for *continuation of therapy* beyond initial authorization period for *polyarticular juvenile rheumatoid arthritis (pJIA)* requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying there is reduction in Member’s signs and symptoms of JRA:

4.1 If all criteria are met, Humira may be approved for up to one (1) year using the following dosing:

<table>
<thead>
<tr>
<th>Weight</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>30kg or more (66 lbs)</td>
<td>40mg every other week</td>
</tr>
<tr>
<td>15kg to 29kg (33-65lbs)</td>
<td>20mg every other week</td>
</tr>
<tr>
<td>10kg to 15kg (22-33lbs)</td>
<td>10mg every other week</td>
</tr>
</tbody>
</table>

5.0 Request for *initial therapy* with adalimumab (Humira) for *Psoriatic Arthritis (PsA)* requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

5.1 Provider must be a rheumatologist or dermatologist; **AND**

5.2 Member must be at least 18 years of age; **AND**

5.3 Diagnosis of moderate to severe psoriatic arthritis as evidenced by:

5.3.1 At least three (3) swollen and three (3) tender joints; **AND**

5.3.2 Erythrocyte sedimentation rate (ESR) ≥ 28mm/hr.; **AND**

5.4 Member shows inadequate response to a three (3) month trial of an adequate dose of, or is not a candidate for, at least one non-steroidal anti-inflammatory medication (NSAIDs) including, but not limited to, the following:

5.4.1 Diclofenac (with or without misoprostol);
5.4.2 Ibuprofen (Motrin);
5.4.3 Indomethacin (Indocin);
5.4.4 Meloxicam (Mobic);
5.4.5 Naproxen (Naprosyn);
5.4.6 Celecoxib (Celebrex); **AND**
5.0 Request for initial therapy with adalimumab (Humira) for Psoriatic Arthritis (PsA) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

5.5 Member shows inadequate response to a three (3) to six (6) month minimum trial of an adequate dose of or is not a candidate for at least one (1) of the following DMARDs (either alone or in combination):

   5.5.1 Sulfasalazine (Azulfidine);
   5.5.1 Leflunomide (Arava);
   5.5.1 Methotrexate;
   5.5.1 Cyclosporine;

5.6 If all criteria are met, Humira 40mg SQ every other week may be approved for up to three (3) months.

6.0 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 reduction in Member’s signs and symptoms of PsA (i.e., improvement in tender/swollen joint count or ESR level) and/or an improvement in Member’s physical functioning:

6.1 If all criteria are met, Humira 40mg SQ every other week may be approved for up to one (1) year.

7.0 Request for initial therapy with adalimumab (Humira) for plaque psoriasis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

7.1 Provider is a dermatologist; AND

7.2 Member is at least 18 years of age; AND
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Procedure, continued:

7.0 Request for initial therapy with adalimumab (Humira) for plaque psoriasis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

7.3 Diagnosis of moderate to severe plaque psoriasis as evidenced by at least one (1) of the following:

7.3.1 Involvement of at least 10% of the body surface area (BSA); OR
7.3.1 Psoriasis Area and Severity Index (PASI) Score of 10 or greater; OR
7.3.1 Psoriasis leading to incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia);

AND

7.4 Member shows inadequate response to a three (3) to six (6) month minimum trial of OR is not a candidate for any one (1) of the following topical agents:

7.4.1 Anthralin;
7.4.2 Coal Tar Preparations;
7.4.3 Corticosteroids;
7.4.4 Emollients;
7.4.5 Immunosuppressives;
7.4.6 Keratolytics;
7.4.7 Retinoic Acid Derivatives;
7.4.8 Vitamin D Analogues;

AND

7.5 Member shows inadequate response to three (3) to six (6) month minimum trial of an adequate dose of OR is not a candidate for at least one (1) of the following systemic agents:

7.5.1 Immunosuppressives;
7.5.1 Retinoic Acid Derivatives;
7.5.1 Methotrexate; AND

7.6 Member shows inadequate response to three (3) month to six (6) month minimum trial of OR is not a candidate for treatment with phototherapy (PUVA);
Procedure, continued:

7.0 Request for initial therapy with adalimumab (Humira) for plaque psoriasis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

7.7 If all criteria are met, Humira Psoriasis Starter Package may be approved for one (1) month (4 syringes – 80mg given as 2 injections on day 1, then 40mg every other week starting at week 1), then 40mg SQ every other week for two (2) additional months (for a total of 3 months of therapy).

8.0 Request for continuation of therapy beyond initial authorization period for plaque psoriasis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a reduction in Member’s signs and symptoms (i.e., improvement in body surface area affected, skin lesions and/or PASI score):

8.1 If all criteria are met, Humira 40mg SQ every other week may be approved for up to one (1) year.

9.0 Request for initial therapy with adalimumab (Humira) for Ankylosing Spondylitis (AS) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

9.1 Provider must be a rheumatologist; AND

9.2 Member must be at least 18 years of age; AND

9.3 Diagnosis of active Ankylosing Spondylitis (AS) as evidenced by:

9.3.1 Inflammatory back pain (as defined as: stiffness and pain that worsens at rest, and improves with exercise); AND

9.3.2 Morning stiffness of 45 minutes or longer; AND
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Procedure, continued:

9.0 Request for initial therapy with adalimumab (Humira) for Ankylosing Spondylitis (AS) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

9.4 Member shows inadequate response to at least two different trials of NSAID therapy. Treatment should be three (3) to six (6) months at maximum recommended doses OR member is not a candidate for NSAIDs due to contraindications (i.e. GI bleed, anticoagulation intake). These include, but are not limited to, the following:

9.4.1 diclofenac (with or without misoprostol);
9.4.2 ibuprofen;
9.4.3 indomethacin;
9.4.4 meloxicam;
9.4.5 naproxen;
9.4.6 celecoxib; AND

9.5 Member shows an inadequate response to a three (3) to six (6) month trial of an adequate dose of sulfasalazine (Azulfidine) if the Member has a component of peripheral arthritis defined as pain/inflammation in arms, legs, elbows, wrist, knees, and/or ankles; (This step (5.5) is not required for axial arthritis);

OR

9.5 Member has a contraindication to sulfasalazine as evidenced by at least one (1) of the following:

9.5.1 GI tract obstruction;
9.5.2 Porphyria;
9.5.3 Urinary Tract Obstruction;
9.5.4 Sulfasalazine hypersensitivity;

9.6 If all criteria are met, Humira 40mg SQ every other week may be approved for up to three (3) months.
10.0 Request for continuation of therapy beyond initial authorization period for Ankylosing Spondylitis requires clinical documentation that there is reduction in Member’s signs and symptoms of AS (i.e., 20% improvement in morning stiffness and degree of nocturnal spinal pain):

10.1 If all criteria are met, Humira 40mg SQ every other week may be approved for up to one (1) year.

11.0 Request for initial therapy with adalimumab (Humira) for Crohn’s Disease (CD) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following:

11.1 Provider must be a gastroenterologist; AND

11.2 Member must be at least 18 years of age; AND

11.3 Diagnosis of moderate to severe active Crohn’s Disease (CD) as evidenced by:

11.3.1 Radiological or endoscopic evidence; AND

11.3.2 At least one (1) of the following more prominent symptoms:

11.3.2.1 Fevers;
11.3.2.1 Significant weight loss;
11.3.2.1 Abdominal pain or tenderness;
11.3.2.1 Intermittent nausea or vomiting (without obstructive findings);
11.3.2.1 Significant anemia;
11.3.2.1 Diarrhea; OR

11.3.2 Crohn’s Disease Activity Index (CDAI) score of 220-450 points; AND
11.0 Request for initial therapy with adalimumab (Humira) for Crohn’s Disease (CD) requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

11.4 Member shows an inadequate response to a three (3) to six (6) month trial of an adequate dose of OR is not a candidate for at least two (2) of the following medications:

   11.4.1 Mesalamine (Asacol, Lialda, Pentasa, Rowasa, Canasa);
   11.4.2 Sulfasalazine (Azulfidine);
   11.4.3 Corticosteroids (prednisone, methylprednisolone, budesonide, Entocort);
   11.4.4 Azathioprine (Imuran);
   11.4.5 Mercaptopurine (6-MP);
   11.4.6 Methotrexate;

11.5 If all criteria are met, Humira Crohn’s Disease Starter Package may be approved for one (1) month (6 syringes - 160mg given as 4 injections on day 1, then 80mg at week 2), then 40mg SQ every other week for 2 additional months (for a total of 3 months of therapy).

12.0 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 reduction in Member’s signs and symptoms (i.e., decrease in pain, fever, weight loss, diarrhea, anemia):

12.1 If all criteria are met, Humira 40mg SQ every other week may be approved for up to one (1) year of therapy.
Procedure, continued:

13.0 Request for initial therapy with Humira 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 must be TNF naïve; AND

13.3 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;

13.4 If criteria are met, Humira may be approved for induction at 160mg initially then 80mg two (2) weeks later then 40mg every other week for up to two (2) months.

14.0 Request for continuation of therapy with Humira 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 the signs and symptoms:

14.1 If criteria are met, Humira may be approved for 40mg every other week for up to three (3) months.
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15.0 Request for initial therapy with adalimumab (Humira) for hidradenitis suppurativa requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

15.1 Prescriber is a board-certified dermatologist or infectious disease specialist; AND

15.2 Member has a diagnosis of moderate to severe hidradenitis suppurativa; AND

15.3 Member has previously failed and/or has contraindication to at least one of the following treatments.

15.3.1 Oral anti-infective agents including, but not limited to, clindamycin, dapsone, doxycycline, and minocycline

15.3.2 Anti-androgenic agents including, but not limited to, dutasteride, finasteride, spironolactone, and oral contraceptives containing an estrogen plus non-androgenic progestin (i.e., desogestrel, dienogest, drospirenone, or norgestimate).

15.3.3 Intraleisional injection of a topical corticosteroid such as triamcinolone or systemic corticosteroid such as prednisone.

15.3.4 Acitretin (Soriatane)

15.4 If all criteria are met, Humira may be approved for three (3) months

15.4.1 Six (6) syringes for the first month, then four (4) syringes each month.
160 mg given as 4 injections on day 1, then 80 mg on day 15, then 40 mg weekly at week 4 for 2 additional months.

16.0 Request for continuation of therapy beyond initial authorization period for hidradenitis suppurativa requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a reduction in Member’s signs and symptoms and/or an improvement in Member’s physical functioning:

16.1 If all criteria are met, Humira 40mg SQ every week may be approved for up to one (1) year.
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17.0 Request for initial therapy with adalimumab (Humira) for non-infectious, intermediate, posterior or pan-uveitis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying the following, continued:

17.1 Prescriber is a board-certified ophthalmologist; AND

15.2 Member has a diagnosis non-infectious, intermediate, posterior and panuveitis (Documentation required);

15.3 If criteria are met, Humira may be approved for induction at 80mg initially, then 40mg every week for up to two (2) months.

18.0 Request for continuation with adalimumab (Humira) for non-infectious, intermediate, posterior or pan-uveitis requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying a reduction in Member’s signs and symptoms and/or an improvement in Member’s physical functioning:

18.1 If all criteria are met, Humira 40mg SQ every week may be approved for up to one (1) year.

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