ADALIMUMAB

<table>
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<td>HUMIRA</td>
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GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

   If yes, approve for 4 months for #1 kit (2 syringes/pens) per month.
   **APPROVAL TEXT:** Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, continue to #2.

2. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 2 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)
   - documentation of patient's current weight

   If yes, approve for 5 months for #1 kit (2 syringes/pens) per month. Use the following:
   - 10mg/0.2mL syringes: If 10kg to <15kg in weight
   - 20mg/0.4mL syringes: If 15-30kg in weight
   - 40mg/0.8mL syringes: If 30kg or heavier
   **APPROVAL TEXT:** Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, continue to #3.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of psoriatic arthritis (PsA) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist or dermatologist
   - previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)
   
   If yes, approve for 4 months for #1 kit (2 syringes/pens) per month.

   APPROVAL TEXT: Renewal requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy. If no, continue to #4.

4. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meets all of the following criteria?
   - therapy initiated by or in consultation with a rheumatologist
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)
   
   If yes, approve for 4 months for #1 kit (2 syringes/pens) per month.

   APPROVAL TEXT: Renewal requires that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). If no, continue to #5.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meets all of the following criteria?
   - therapy initiated by or in consultation with a dermatologist
   - plaque psoriasis involve at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, or genital area
   - previous trial with one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

If yes, **approve for a total of 3 months. Please enter two authorizations as follows:**
   - **Approve for 1 fill for #1 Psoriasis Starter Package (containing four 40mg syringes),**
   - **Approve for 2 months for #1 kit (2 syringes/pens) per month.**

**APPROVAL TEXT:** Renewal requires that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more.

If no, continue to #6.

6. Does the patient have a diagnosis of moderate to severe Crohn's disease and meets all of the following criteria?
   - therapy initiated by or in consultation with a gastroenterologist
   - previous trial with at least one of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - 6 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

If yes, **approve for a total of 3 months. Please enter two authorizations as follows:**
   - **Approve for 1 fill for #1 Crohn's Disease Starter Package (containing either six or three 40mg syringes/pens),**
   - **Approve for 2 months for #1 kit (2 syringes/pens) per month.**

If no, continue to #7.

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ADALIMUMAB

INITIAL CRITERIA (CONTINUED)

7. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC) and meets all of the following criteria?
   - therapy initiated by or in consultation with a gastroenterologist
   - previous trial with one or more of the following conventional agents such as corticosteroids (i.e., budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Oencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

   If yes, approve for a total of 3 months. Please enter two authorizations as follows:
   - Approve for 1 fill for #1 Humira Pen Starter Package for Ulcerative Colitis (UC) (containing six single-use pens),
   - Approve for 2 months for #1 kit (2 syringes/pens) per month.
   If no, do not approve.

   DENIAL TEXT: See the initial denial text at the end of the guideline.

8. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS) and meets all of the following criteria?
   - 18 years of age or older
   - patient will not be on concurrent therapy with Kineret (anakinra), Oencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

   If yes, approve for a total of 3 months. Please enter two authorizations as follows:
   - Approve for 1 fill for #1 Humira Pen Starter Package for Hidradenitis Suppurativa (HS) (containing six single-use pens),
   - Approve for 2 months for #2 kits (4 syringes/pens) per month.
   If no, do not approve.

   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ADALIMUMAB

GUIDELINES FOR USE (CONTINUED)

INITIAL DENIAL TEXT: Our guideline for ADALIMUMAB requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, or moderate to severe hidradenitis suppurativa. Additional guideline requirements apply.

For patients with moderate to severe rheumatoid arthritis, approval requires all of the following:

- therapy initiated by or in consultation with a rheumatologist
- previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- patient age of at least 18 years
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

For patients with moderate to severe polyarticular juvenile idiopathic arthritis, approval requires all of the following:

- therapy initiated by or in consultation with a rheumatologist
- previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- patient age of at least 2 years
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)
- documentation of patient's current weight

For patients with psoriatic arthritis, approval requires all of the following:

- therapy initiated by or in consultation with a rheumatologist or dermatologist
- previous trial with at least one of the following DMARD (disease-modifying antirheumatic drug) agents: methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
- patient age of at least 18 years
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

For patients with ankylosing spondylitis, approval requires all of the following:

- therapy initiated by or in consultation with a rheumatologist
- 18 years of age or older
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituxan (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

Initial denial text continued on next page

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ADALIMUMAB

GUIDELINES FOR USE (CONTINUED)

For patients with moderate to severe plaque psoriasis, approval requires all of the following:

- therapy initiated by or in consultation with a dermatologist
- plaque psoriasis involve at least 10% body surface area (BSA) or psoriatic lesions affecting the hands, feet, or genital area
- previous trial with one of the following conventional therapies such as PUVA (Phototherapy Ultraviolet Light A), UVB (Ultraviolet Light B), topical corticosteroids, calcipotriene, acitretin, methotrexate, or cyclosporine
- 18 years of age or older
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituam (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

For patients with moderate to severe Crohn's disease, approval requires all of the following:

- therapy initiated by or in consultation with a gastroenterologist
- previous trial with one or more of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- patient age of at least 6 years
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituam (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

For patients with moderate to severe ulcerative colitis, approval requires:

- therapy initiated by or in consultation with a gastroenterologist
- previous trial with one or more of the following conventional agents such as corticosteroids (i.e. budesonide, methylprednisolone), azathioprine, mercaptopurine, methotrexate, or mesalamine
- patient age of at least 18 years
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituam (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

For patients with moderate to severe hidradenitis suppurativa, approval requires:

- patient age of at least 18 years
- patient will not be on concurrent therapy with Kineret (anakinra), Orencia (abatacept), Rituam (rituximab), or a TNF inhibitor (Enbrel, Cimzia, Remicade, Simponi, or Simponi Aria)

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ADALIMUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA)?
   
   If yes, continue to #2.
   If no, continue to #4.

2. Is the request for Humira 40mg dosed every other week for the treatment of moderate to severe rheumatoid arthritis (RA) and meets the following criteria?
   
   • Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy
   
   If yes, approve for 12 months for #1 kit (2 syringes/pens) per month.
   If no, continue to #3.

3. Is the request for Humira 40mg dosed every week for the treatment of moderate to severe rheumatoid arthritis (RA) and meets ALL of the following criteria?
   
   • Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy
   • Trial of at least a 3-month regimen of Humira 40mg every other week
   • Concurrent methotrexate use or contraindication to methotrexate
   
   If yes, approve for 12 months for #2 kits (4 syringes/pens) per month.
   If no, do not approve. If the request is for rheumatoid arthritis, please enter a proactive authorization for 12 months for #1 kit (2 syringes/pens) per month.
   NOTE: If a proactive PA is entered then please add FREE TEXT (a proactive Prior Authorization has been entered).
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA) and meets the following criteria?
   
   • Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy
   
   If yes, approve for 12 months for #1 kit (2 syringes/pens) per month.
   If no, continue to #5.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

5. Does the patient a diagnosis of psoriatic arthritis (PsA) and meets the following criteria?
   - Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

     If yes, approve for 12 months for #1 kit (2 syringes/pens) per month.
     If no, continue to #6.

6. Does the patient have a diagnosis of ankylosing spondylitis (AS) and meets the following criteria?
   - Documentation that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

     If yes, approve for 12 months for #1 kit (2 syringes/pens) per month.
     If no, continue to #7.

7. Does the patient have a diagnosis of moderate to severe plaque psoriasis (PsO) and meets the following?
   - Documentation that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

     If yes, approve for 12 months for #1 kit (2 syringes/pens) per month.
     If no, continue to #8.

8. Does the patient have a diagnosis of moderate to severe Crohn's disease (CD)?

     If yes, approve for 12 months for #1 kit (2 syringes/pens) per month.
     If no, continue to #9.

9. Does the patient have a diagnosis of moderate to severe ulcerative colitis (UC)?

     If yes, approve for 12 months for #1 kit (2 syringes/pens) per month.
     If no, continue to #10.

10. Does the patient have a diagnosis of moderate to severe hidradenitis suppurativa (HS)?

     If yes, approve for 12 months for #2 kits (4 syringes/pens) per month.
     If no, do not approve.

DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ADALIMUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: Our guideline for ADALIMUMAB renewal requires a diagnosis of moderate to severe rheumatoid arthritis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis, ankylosing spondylitis, moderate to severe plaque psoriasis, moderate to severe Crohn's disease, moderate to severe ulcerative colitis, or moderate to severe hidradenitis suppurativa. Additional guideline requirements apply.

Renewal for the diagnosis of moderate to severe rheumatoid arthritis requires:

- Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

For Humira weekly dosing requests for the diagnosis of moderate to severe rheumatoid arthritis requires all of the following:

- Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy
- Trial of at least a 3-month trial of Humira 40mg every other week
- Concurrent methotrexate use or contraindication to methotrexate

Renewal for the diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis requires:

- Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

Renewal for the diagnosis of psoriatic arthritis requires:

- Documentation that the patient has experienced or maintained a 20% or greater improvement in tender or swollen joint count while on therapy

Renewal for the diagnosis of ankylosing spondylitis requires:

- Documentation that the patient has experienced or maintained an improvement of at least 50% or 2 units (scale of 1-10) in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)

Renewal for the diagnosis of moderate to severe plaque psoriasis requires:

- Documentation that the patient has achieved or maintained clear or minimal disease or a decrease in PASI (Psoriasis Area and Severity Index) of at least 50% or more

RATIONALE

Ensure appropriate diagnostic, utilization and safety criteria are used for the management of requests for adalimumab.

FDA APPROVED INDICATIONS

HUMIRA is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. HUMIRA can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

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FDA APPROVED INDICATIONS (CONTINUED)
HUMIRA is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. HUMIRA can be used alone or in combination with methotrexate.

HUMIRA is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. HUMIRA can be used alone or in combination with non-biologic (DMARDs).

HUMIRA is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

HUMIRA is indicated for reducing signs and symptoms, inducing, and maintaining clinical remission in adults with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy. HUMIRA is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn’s disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

HUMIRA is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressant’s such as corticosteroids, azathioprine, or 6-mercaptopurine (6-MP). The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers.

HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa.

DOSING
Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis
40 mg every other week. Some patients with RA not receiving methotrexate may benefit from increasing the frequency to 40 mg every week.

Juvenile Idiopathic Arthritis
The recommended dose of HUMIRA for patients 2 years of age and older with polyarticular juvenile idiopathic arthritis (JIA) is based on weight as shown below:
10kg (22 lbs) to <15kg (33 lbs): 10mg every other week
15 kg (33 lbs) to <30 kg (66 lbs): 20 mg every other week
≥30 kg (66 lbs): 40 mg every other week

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ADALIMUMAB

**DOSING (CONTINUED)**

**Adult Crohn's Disease and Ulcerative Colitis**
Initial dose (Day 1) is 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every other week.

**Adult Hidradenitis Suppurativa**
Initial dose (Day 1) is 160 mg (four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg two weeks later (Day 15). Two weeks later (Day 29) begin a maintenance dose of 40 mg every week.

**Plaque Psoriasis**
80 mg initial dose followed by 40 mg every other week starting one week after initial dose.

**Pediatric Crohn's Disease**

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<td><strong>Day 1</strong></td>
<td>80 mg x1 (Two 40mg injections in one day)</td>
<td>160mg x1 (Four 40mg injections in one day or two 40mg injections for 2 days)</td>
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<tr>
<td><strong>Day 15</strong></td>
<td>40 mg x1</td>
<td>80mg x1</td>
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<tr>
<td><strong>Day 29</strong></td>
<td>20 mg every other week</td>
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**DOSAGE FORMS AND STRENGTHS**
40 mg/0.8 mL in a single-use prefilled pen (HUMIRA Pen)
40 mg/0.8 mL in a single-use prefilled glass syringe
20 mg/0.4 mL in a single-use prefilled glass syringe
10mg/0.2 mL in a single-use prefilled glass syringe

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Client Approval: 11/15