Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

HUMIRA® (adalimumab)

NDC CODING:

662700150064**

DESCRIPTION:

Humira is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis and plaque psoriasis.

APPROVAL DURATION:

Approval duration: 3 years for all diagnoses except Ulcerative Colitis (UC)
For UC, initial approvals are for 8 weeks and all renewals are yearly

Quantity limits: Every other week dosing: 2 vials per 28 days OR

- **Moderate to Severe Rheumatoid Arthritis:** once weekly dosing if patient is not taking concomitant methotrexate: 4 vials per 28 days
- **Crohn's Disease & UC:** induction dose of 160 mg with an 80 mg dose at week two, followed by maintenance dose of 40 mg every other week beginning at week four
    - One Humira Pen – Crohn's Disease/Ulcerative Colitis Starter Package (1 kit = 6 doses) one time
- **Chronic Moderate to Severe Plaque Psoriasis:** induction dose of 80 mg one time only as initial dose, followed by 40 mg every other week starting one week after initial dose
- **Pediatric patients** (20 mg/ 0.4 ml, 1 kit = 2 doses): 2 vials per 28 days for every other week dosing

CRITERIA FOR HUMIRA

I. None of the following are present:
   A. Tuberculosis or a history of recurrent infection, chronic current infection, or clinically important infection
   B. Patients who have not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis
   C. Latex allergy as Humira prefilled syringe cover contains latex
   D. Individuals with moderate to severe congestive heart failure (CHF) or patients who develop new symptoms or worsening symptoms of pre-existing CHF
   E. Using Humira in combination with other TNF blockers, Kineret (anakinra), or Orencia (abatacept).

II. Rheumatoid Arthritis
   A. Patient must be 18 years of age or older
   B. Patient must have moderately to severely active rheumatoid arthritis (RA)
   C. Patient has had an inadequate response to one or more nonbiologic disease modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated:
      i. Auranofin (Ridaura)
      ii. Azathioprine (Imuran)

iii. Cyclophosphamide (Cytoxan or Neosar)
iv. Cyclosporine (Neoral or Sandimmune)
v. Gold sodium thiomalate (Myochrysine)
vi. Hydroxychloroquine (Plaquenil)
vii. Leflunomide (Arava)
viii. Methotrexate
ix. Minocycline (Minocin or Dynacin)
x. Penicillamine (Cuprimine, Depen)
xi. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)

III. Psoriatic Arthritis
A. Patient is 18 years of age or older
B. Patient has active arthritis, with at least 3 swollen joints and 3 tender joints
C. Patient has arthritis in any of the following distributions:
i. Distal interphalangeal joint involvement
ii. Polyarticular arthritis, without rheumatoid nodules
iii. Arthritis mutilans
iv. Asymmetric arthritis
v. Ankylosing spondylitis-like arthritis
D. Patient has had an inadequate response to one or more nonbiologic disease nonbiologic modifying anti-rheumatic agents (DMARDs), or such therapy is contraindicated or not tolerated:
i. Auranofin (Ridaura)
ii. Azathioprine (Imuran)
iii. Cyclophosphamide (Cytoxan or Neosar)
iv. Cyclosporine (Neoral or Sandimmune)
v. Gold sodium thiomalate (Myochrysine)
vi. Hydroxychloroquine (Plaquenil)
vii. Leflunomide (Arava)
viii. Methotrexate
ix. Minocycline (Minocin or Dynacin)
x. Penicillamine (Cuprimine, Depen)
xi. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
E. None of the following are present:
i. Currently receiving systemic psoriasis therapy (except for methotrexate, glucocorticoids, salicylates, non-steroidal anti-inflammatory drugs, or analgesics) or immunosuppressive therapy
ii. Pregnant women or nursing mothers

IV. Active Ankylosing Spondylitis
A. Patient is 18 years of age or older AND
B. Patient has had an inadequate response to conventional treatment, or such therapy is contraindicated or not tolerated:
i. Non-steroidal anti-inflammatory drugs (ibuprofen, naproxen, others)
ii. Methotrexate
iii. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)

V. Crohn's Disease (CD)
A. Patient is 18 years of age or older AND

B. Patient has had an inadequate response to conventional therapy, or such therapy is contraindicated or not tolerated:
   i. 5-Aminosalicylates
      1. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
      2. Mesalamine (Asacol, Pentasa, Lialda, Apriso)
   ii. Systemic corticosteroids (e.g., prednisone)
   iii. Azathioprine (Imuran)
   iv. 6-Mercaptopurine
   v. Methotrexate
   vi. Cyclosporine (Neoral, Sandimmune)
   vii. Antibiotics (e.g., metronidazole)

VI. Chronic Moderate to Severe Plaque Psoriasis
   A. Patient is 18 years of age or older
   B. Patient has a diagnosis of moderate to severe plaque psoriasis with either of the following:
   C. Patient has greater than 10% of body surface area with plaque psoriasis OR
   D. Less than or equal to 10% of body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) AND
   E. Disease is not controlled with topical therapy; AND
   F. Patient has had an inadequate response to systemic therapies, or such therapy is contraindicated or not tolerated
      i. Methotrexate
      ii. Acitretin (Soriatane)
      iii. Cyclosporine (Neoral, Sandimmune)

VII. Diagnosis of Juvenile Idiopathic Arthritis (JIA):
   A. Patient has a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis
   B. Patient is at least 4 years of age

VIII. Ulcerative Colitis (UC)
   A. Patient is 18 years of age or older
   B. Patient has had an inadequate response to convention therapy, or such therapy is contraindicated or not tolerated:
      i. Sulfasalazine (Azulfidine, Azulfidine Entabs)
      ii. Mesalamine (Asacol, Pentasa, Apriso, Lialda, Rowasa, Canasa)
      iii. Azathioprine (Imuran)
      iv. 6-mercaptopurine
      v. Budesonide (Entocort EC, Uceris)
   C. For renewals, the patient must have achieved clinical remission while on Humira

CRITERIA QUESTIONS

1. Does the patient have any of the following conditions? If yes, please circle.
   A. Currently receiving other TNF antagonists, abatacept (Orencia), or anakinra (Kineret)
   B. Tuberculosis, invasive fungal infections, other active serious infections, or a history of recurrent

infections C. Has not had a tuberculin skin test (TST) or a CDC-recommended equivalent to rule out latent tuberculosis D. Latex allergy as Humira prefilled syringe cover contains latex E. Individuals with moderate to severe congestive heart failure (CHF) or patients who develop new symptoms or worsening symptoms of pre-existing CHF
Exclusion A (combo with other TNFs) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: use in combination with another TNF inhibitor, Orencia, or Kineret. Exclusion B (tuberculosis) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: active or untreated tuberculosis or any other active serious/recurrent infection. Exclusion C (no tuberculin skin test) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: no documented tuberculin skin test (TST), or a CDC-recommended equivalent, to rule out latent tuberculosis. Exclusion D (latex allergy) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: latex allergy as Humira prefilled syringe cover contains latex. Exclusion E (CHF) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: moderate to severe congestive heart failure (CHF) or patients who develop new symptoms or worsening symptoms of pre-existing CHF. None = GO TO Q2
2. What is the member's diagnosis? A. Rheumatoid arthritis B. Crohn's disease C. Psoriatic arthritis D. Active anklyosis spondylitis E. Polyarticular juvenile idiopathic arthritis F. Chronic plaque psoriasis G. Ulcerative colitis H. Other
If rheumatoid arthritis = GO TO Q5 If Crohn's disease = GO TO Q10 If Psoriatic arthritis = GO TO Q12 If active anklyosis spondylitis = GO TO Q26 If polyarticular juvenile idiopathic arthritis = GO TO Q3 If chronic plaque psoriasis = GO TO Q17 If ulcerative colitis = GO TO Q23 If other diagnosis = DENY. The plan requires an FDA approved condition in order to provide coverage for the prescribed drug. Based on the information provided, the member does not have an FDA approved indication such as moderate to severe rheumatoid arthritis.

Polyarticular Juvenile Idiopathic Arthritis:

3. Is the member 4 years of age or older?
If Yes = GO TO Q4 If No = DENY. The plan requires the member to be at least 4 years of age or older in order to provide coverage for the drug. Based on the information provided, this requirement was not met.
4. Does the member have moderate to severe Polyarticular JIA?
If Yes = Approve x 3 years If No = DENY. The plan requires an FDA approved condition in order to provide coverage for the prescribed drug. Based on the information provided, the member does not have an FDA approved indication such as moderate to severe polyarticular juvenile idiopathic arthritis.

Rheumatoid Arthritis:
5. Does the patient have moderate to severe RA?
If Yes = GO TO Q6 If No = DENY. The plan requires an FDA approved condition in order to provide coverage for the prescribed drug. Based on the information provided, the member does not have an FDA approved indication such as moderate to severe active rheumatoid arthritis.
6. Is patient 18 years of age or older?
If YES = GO TO Q7 If NO = DENY. The plan requires the member to be 18 years of age or older in order to provide coverage of the prescribed drug. Based on the information provided, the member does not meet this requirement.
7. Did the patient have an inadequate response to a trial of any of the following nonbiologic disease modifying anti-rheumatic agents (DMARDs) or such therapy is contraindicated or not tolerated? If yes, please circle. A. Auranofin (Ridaura) B. Azathioprine (Imuran) C. Cyclophosphamide (Cytoxan or Neosar) D. Cyclosporine (Neoral or Sandimmune) E. Gold sodium thiomalate (Myochrysine) F. Hydroxychloroquine (Plaquenil) G. Leflunomide (Arava) H. Methotrexate I. Minocycline (Minocin or Dynacin) J. Penicillamine (Cuprimine, Depen) K. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
If YES = GO TO Q8 If NO = DENY. The plan provides coverage of the prescribed drug for RA when the member has tried and had an inadequate response to a nonbiologic disease modifying anti-rheumatic agent (DMARD) or has a documented contraindication/intolerance preventing use of such. Based on the information provided, this requirement was not met.
8. What will be the frequency of the dosing of Humira? Please circle A. Every two weeks B. Every week C. More frequently than once a week
If every 2 weeks = Approve x 3 years (2 vials per 28 days) If every week = GO TO Q9 If more frequently than once a week = DENY. The plan provides coverage of the prescribed drug for rheumatoid arthritis for once a week or every other week dosing. Based on the information provided, this requirement was not met.

9. Will the patient be taking Humira concomitantly with methotrexate?
If YES = DENY. The plan provides coverage of the prescribed drug for rheumatoid arthritis for once weekly dosing when not used concomitantly with methotrexate. Based on the information provided, this requirement was not met. If NO = Approve x 3 years (4 vials per 28 days)

Crohn's Disease:
10. Has the patient had an inadequate response to a trial of any of the conventional therapies or such therapy is contraindicated or not tolerated? If yes, please circle. A. 5-Aminosalicylates: Sulfasalazine (Azulfidine, Azulfidine EN-tabs) or Mesalamine (Asacol, Pentasa, Lialda, Apriso) B. Systemic corticosteroids (e.g., prednisone) C. Azathioprine (Imuran) D. 6-Mercaptopurine E. Methotrexate F. Cyclosporine (Neoral, Sandimmune) G. Antibiotics (e.g., metronidazole)
If YES = Go to Q11 If NO = DENY. The plan provides coverage of the prescribed drug for Crohn's disease when the member has tried and had an inadequate response to conventional therapy (such as sulfasalazine, mesalamine, systemic corticosteroids, azathioprine, methotrexate, etc.) or has a documented contraindication/intolerance preventing use of all conventional therapies. Based on the information provided, this requirement was not met.
11. Is patient 18 years of age or older?
If YES = Approve x 3 years If NO = DENY. The plan requires the member to be 18 years of age or older in order to provide coverage of the prescribed drug. Based on the information provided, the member does not meet this requirement.

Psoriatic Arthritis:
12. Does the patient have active arthritis, with 3 or more swollen joints and 3 or more tender joints?
If YES = GO TO Q13 If NO = DENY. The plan provides coverage of the prescribed drug when the member has active arthritis with at least 3 swollen joints and 3 tender joints. Based on the information provided, this requirement was not met.
13. Does the patient have arthritis in any of the following distributions? If yes, please circle. A. Distal interphalangeal joint involvement B. Polyarticular arthritis, without rheumatoid nodules C. Arthritis mutilans D. Asymmetric arthritis E. Ankylosing spondylitis-like arthritis
If YES = GO TO Q14 If NO = DENY. The plan provides coverage of the prescribed drug when the member has distal interphalangeal joint involvement, polyarticular arthritis without rheumatoid nodules, arthritis mutilans, asymmetric arthritis, or ankylosing spondylitis-like arthritis. Based on the information provided, this requirement was not met.
14. Has the patient had an inadequate response to or failed any of the following disease modifying antirheumatic agents (DMARDs) or such therapy is contraindicated or not tolerated? If yes, please circle. A. Auranofin (Ridaura)

B. Azathioprine (Imuran) C. Cyclophosphamide (Cytoxan or Neosar) D. Cyclosporine (Neoral or Sandimmune) E. Gold sodium thiomalate (Myochrysine) F. Hydroxychloroquine (Plaquenil) G. Leflunomide (Arava) H. Methotrexate I. Minocycline (Minocin or Dynacin) J. Penicillamine (Cuprimine, Depen) K. Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
If YES = GO TO Q15 If NO = DENY. The plan provides coverage of the prescribed drug for active psoriatic arthritis when the member has tried and had an inadequate response to disease modifying antirheumatic agents (DMARDs) or has a documented contraindication/intolerance preventing use. Based on the information provided, this requirement was not met.
15. Does the patient have any of the following conditions? If yes, please circle. A. Currently receiving systemic psoriasis therapy (except for methotrexate, glucocorticoids, salicylates, non-steroidal anti-inflammatory drugs, or analgesics) B. Currently receiving other immunosuppressive therapy C. Pregnant women or nursing mothers
Exclusion A (other systemic psoriasis therapy) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: use of systemic psoriasis therapy (except for methotrexate, glucocorticoids, salicylates, non-steroidal anti-inflammatory drugs, or analgesics). Exclusion B (immunosuppressive therapy) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: use in combination with other immunosuppressive therapy. Exclusion C (pregnancy) = DENY. The plan does not cover the prescribed drug when there is a contraindication (which means there is a safety concern preventing the use of the drug). Based on the information provided, the member has the following contraindication to therapy: pregnancy or nursing. None = GO TO Q16
16. Is patient 18 years of age or older?
If YES = Approve x 3 years If NO = DENY. The plan requires the member to be 18 years of age or older in order to provide coverage of the prescribed drug. Based on the information provided, the member does not meet this requirement.

Chronic Plaque Psoriasis:
17. Is patient 18 years of age or older?
If YES = GO TO Q18 If NO = DENY. The plan requires the member to be 18 years of age or older in order to provide coverage of the prescribed drug. Based on the information provided, the member does not meet this requirement.
18. Does the patient have moderate to severe plaque psoriasis?
If YES = GO TO Q19 If NO = DENY. The plan requires an FDA approved condition in order to provide coverage for the prescribed drug. Based on the information provided, the member does not have an FDA approved indication such as moderate to severe chronic plaque psoriasis.

19. Is at least 10% of the patient's body surface area affected by psoriasis?
If Yes = Go to Q21 If No = Go to Q20
20. Does the patient have plaque psoriasis involving sensitive areas of the body or involving areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia)?
If YES = GO TO Q21 If NO = DENY. The plan provides coverage of the prescribed drug for plaque psoriasis when the patient has at least 10% of body surface area affected by psoriasis or involves sensitive areas (such as palms, soles of feet, head/neck, or genitalia) that would significantly impact daily function. Based on the information provided, this requirement was not met.
21. Is the patient's disease controlled by topical therapy?
If YES = DENY. The plan provides coverage of the prescribed drug for plaque psoriasis when the patient has disease that is inadequately controlled by topical therapy. Based on the information provided, this requirement was not met. If NO = GO TO Q22
22. Does the patient have an inadequate response to any of the listed systemic therapies or such therapy is contraindicated or not tolerated? If yes, please circle. **A. Methotrexate** **B. Acitretin (Soriatane)** **C. Cyclosporine (Neoral, Sandimmune)**
If YES = Approve x 3 years If NO = DENY. The plan provides coverage of the prescribed drug for chronic plaque psoriasis when the member has tried and had an inadequate response to systemic therapies (such as methotrexate, cyclosporine, etc.) or has a documented contraindication/intolerance preventing use. Based on the information provided, this requirement was not met.

Ulcerative Colitis:
23. Is this request for induction or maintenance?
If induction = GO TO Q24 If maintenance = GO TO Q25
24. Does the patient have an inadequate response to any of the listed systemic therapies or such therapy is contraindicated or not tolerated? If yes, please circle. **A. sulfasalazine (Azulfidine, Azulfidine Entabs)** **B. Mesalamine (Asacol, Pentasa, Apriso, Lialda, Rowasa, Canasa)** **C. Azathioprine (Imuran)** **D. 6-mercaptopurine** **E. Budesonide (Entocort EC, Uceris)**
If YES = Approve x 8 weeks If NO = DENY. The plan provides coverage of the prescribed drug for ulcerative colitis when the member has tried and had an inadequate response to conventional therapies (such as methotrexate, sulfasalazine, etc.) or has a documented contraindication/intolerance preventing use. Based on the information provided, this requirement was not met.
25. Has the patient achieved clinical remission?
If YES = Approve x 1 year If NO = DENY. The plan provides continued coverage of the prescribed drug for ulcerative colitis when the member achieved clinical remission after use of Humira in 8 weeks, consistent with the package insert. Based on the information provided, this requirement was not met.

Active anklyosis spondylitis:
26. Is the member 18 years of age or older?
If Yes = GO TO Q27 If No = DENY. The plan requires the member to be at least 18 years of age or older in order to provide coverage for the drug. Based on the information provided, this requirement was not met.
27. Does the patient have an inadequate response to conventional treatment, or such therapy is contraindicated or not tolerated? If yes, please circle. A. **Non-steroidal anti-inflammatory drugs (ibuprofen, naproxen, others)** B. **Methotrexate** C. **Sulfasalazine (Azulfidine, Azulfidine EN-tabs)**
If Yes = Approve x 3 years If No = DENY. The plan requires an FDA approved condition in order to provide coverage for the prescribed drug. Based on the information provided, the member does not have an FDA approved indication such as RA, active anklyosis spondylitis, polyarticular juvenile idiopathic arthritis, etc.