Updated: 02/2019
PARP Approved: 04/2019

Prior Authorization Criteria

Humira™ (adalimumab) and adalimumab biosimilars

All requests for Humira™ (adalimumab) and adalimumab biosimilars require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Humira™ (adalimumab) and adalimumab biosimilars (Cyltezo™, Hyrimoz™ and Amjevita™) all of the following criteria must be met:

- The prescribing physician must be a Rheumatologist, Gastroenterologist, Ophthalmologist, or Dermatologist.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines.

Coverage may be provided with a diagnosis of **Rheumatoid Arthritis** and the following criteria is met:

- Member is 18 years of age or older.
- Member must have a history of trial and failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD.
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**
  - Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Juvenile Idiopathic Arthritis** and the following criteria is met:

- For Humira ™ only
  - Member is 2 years of age or older.
- For Cyltezo™, Hyrimoz™ and Amjevita™
  - Member is 4 year of age or older
- Member must meet ONE of the following:
  - The member has an AJC (active joint count)>0 and continued disease activity after 3 months of MTX or leflonamide.
  - The member has an AJC (active joint count)>0 and continued disease activity after 1 month of anakinra (may require prior authorization).
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**

  - Reauthorization benefit will be approved if there evidence of positive clinical response of involving the following clinical/laboratory parameters: Joint count, limitation of motion, functional assessment, the physician and the patient's/parent global assessment, ESR (erythrocyte sedimentation rate), and/or CRP (C-Reactive Protien).
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Psoriatic Arthritis** and the following criteria is met:

- Member is 18 years of age or older.
- Member has active psoriatic arthritis or clinical features that suggest psoriatic arthritis in the absence of psoriasis.
- **Initial Duration of Approval**:
  - 6 months
- **Reauthorization Criteria**
  - Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein).
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Ankylosing Spondylitis** and the following criteria is met:

- Member must be 18 years of age or older
- Member must have a history of trial and failure, contraindication, or intolerance to a four-week trial each of at least 2 NSAIDs.
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
  - Reauthorization benefit will be approved if there is evidence of positive clinical response involving the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, and/or occiput-to-wall measurement.
  - **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Crohn's Disease** and the following criteria is met:

- For Humira™ only
  - Member must be 6 years of age or older
- For Cyltezo™ and Amjevita™
  - Member is 18 year of age or older
- Member must have a history of trial and failure, contraindication, or intolerance to steroids (*i.e.*, prednisone).

- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Fistulizing Crohn's Disease** and the following criteria is met:

- For Humira™ only
  - Member must be 6 years of age or older
- For Cyltezo™ and Amjevita™
  - Member is 18 year of age or older
- Member must have clinical documentation of Crohn's disease with actively draining fistulas.
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria:**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Ulcerative Colitis** and the following criteria is met:

- Member must be 18 years of age or older
- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including ONE of the following for at least 3 months:
  - Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®)
  - Steroids (*i.e.*, prednisone)
  - Immunomodulators (*i.e.*, Azathioprine, 6-Mercaptopurine, Methotrexate)
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria:**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Plaque Psoriasis** and the following criteria is met:

- Member must be 18 years of age or older
- Member must have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals.
- Members must have therapeutic failure of a three-month trial or a contraindication to BOTH of the following:

    - Psoralens with UVA light (PUVA) or UVB light
    - Systemic treatments including ONE of the following:
        - Immunomodulators (i.e. Methotrexate, Cyclosporine)
        - Retinoids (i.e. Soriatane)
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval**: 12 months

Coverage may be provided with a diagnosis of **Hidradentitis Supportiva** and the following criteria is met:

- Medication prescribed is Humira™
- Member must be 12 years of age or older.
- Member has a documented diagnosis of moderate to severe hidradentitis supportive with Hurley Stage II or III disease with at least 3 abscesses or inflammatory nodules
- The Member has demonstrated an inadequate response, intolerance or contraindication to at least three of the following conventional treatment measures:
    - Local hygiene and ordinary hygiene
    - Weight reduction in patients who are obese
    - Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate)
    - Application of warm compresses with sodium chloride solution or Burow's solution
    - Laser hair removal
    - Cessation of cigarette smoking
    - Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria**:
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **Uveitis** and the following criteria is met:

- Medication prescribed is Humira™
- Member must be 2 years of age or older.
- Member must have a documented diagnosis of non-infectious intermediate, posterior, and/or panuveitis.
- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including ONE of the following for at least 3 months of each medication:
    - Steroids (*i.e.*, prednisone)

  - Immunomodulators (*i.e.,* Azathioprine, 6-Mercaptopurine, Methotrexate)
- **Initial Duration of Approval**: 6 months
- **Reauthorization Criteria:**
  - Reauthorization benefit will be approved if there is sustained improvement in ocular inflammation or there was no worsening of ocular co-morbidities.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

Updated: 02/2019
PARP Approved: 04/2019

Humira™ (adalimumab) and adalimumab biosimilars (Cyltezo™ and Amjevita™)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1. Is the medication being prescribed by or in association with a rheumatologist, gastroenterologist, ophthalmologist, or dermatologist? ☐ Yes ☐ No

2. Which of the following diagnoses will the medication be used for:
   Please check the one that applies
   a. Rheumatoid Arthritis ☐ Yes ☐ No
   b. Juvenile Idiopathic Arthritis ☐ Yes ☐ No
   c. Psoriatic Arthritis ☐ Yes ☐ No
   d. Ankylosing Spondylitis ☐ Yes ☐ No
   e. Crohn's Disease ☐ Yes ☐ No
   f. Fistulizing Crohn's Disease ☐ Yes ☐ No
   g. Ulcerative Colitis ☐ Yes ☐ No
   h. Plaque Psoriasis ☐ Yes ☐ No
   i. Hidradentitis Supportiva ☐ Yes ☐ No
   j. Uveitis ☐ Yes ☐ No
   k. Other Diagnosis: _____

3. If member is using for a diagnosis of Rheumatoid Arthritis, answer the following questions:
   a. Is member 18 years of age or older? ☐ Yes ☐ No

b. Is member must have a history of trial and failure, contraindication, or intolerance to a three-month trial with methotrexate, or another DMARD. ☐ Yes ☐ No

4. If member is using for a diagnosis of Juvenile Idiopathic Arthritis, answer the following questions:

   a. If using Humira™, is member 2 years of age or older?
   ☐ Yes ☐ No

   b. If using Cyltezo™ or Amjevita, is member 4 years of age or older?
   ☐ Yes ☐ No

   c. Does the member must meet any or the following?
   Please check all that apply:

      i. The member has an AJC (active joint count)>0 and continued disease activity after 3 months of MTX or leflonamide. ☐ Yes ☐ No

      ii. The member has an AJC (active joint count)>0 and continued disease activity after 1 month of anakinra
      ☐ Yes ☐ No

5. If member is using for a diagnosis of Psoriatic Arthritis, answer the following questions:
   a. Is member 18 years of age or older? ☐ Yes ☐ No

   b. Does the member have active psoriatic arthritis or clinical features that suggest psoriatic arthritis in the absence of psoriasis?
   ☐ Yes ☐ No

6. If member is using for diagnosis of Ankylosing Spondylitis, answer the following questions:

   a. Is member 18 years of age or older? ☐ Yes ☐ No

   b. Does member have a history of trial and failure, contraindication, or intolerance to a four- week trial each of at least 2 NSAIDs? ☐ Yes ☐ No

7. If member is using for diagnosis of Crohn's Disease, answer the following questions:

   a. If using Humira, is member 6 years of age or older? ☐ Yes ☐ No

   b. If using Cylteza, or Amjevita, is member 18 years of age or older? ☐ Yes ☐ No

   c. Does member have a history of trial and failure, contraindication, or intolerance to steroids (i.e., prednisone)?
   ☐ Yes ☐ No

8. If member is using for diagnosis of Fistulizing Crohn's Disease, answer the following questions:
   a. If using Humira, is member 6 years of age or older? ☐ Yes ☐ No

   b. If using Cylteza, or Amjevita, is member 18 years of age or older? ☐ Yes ☐ No

c. Does member have clinical documentation of Crohn's disease with actively draining fistulas?
☐ Yes ☐ No

9. If member is using for diagnosis of Ulcerative Colitis, answer the following questions?
   a. Is member 18 years of age or older? ☐ Yes ☐ No

   b. Does member have a history of trial and failure, contraindications, or intolerance to conventional treatments including any the of the following for at least 3 months of each medication:
   (Please check all that apply)

      i. Aminosalicylates, 5-ASAs (i.e., Sulfasalazine, Pentasa, Asacol, Colazal)
      ☐ Yes ☐ No

      ii. Steroids (i.e., prednisone) ☐ Yes ☐ No

      iii. Immunomodulators (i.e., Azathioprine, 6-Mercaptopurine, Methotrexate)
      ☐ Yes ☐ No

10. If member using for diagnosis of Plaque Psoriasis, answer the following questions?

   a. Is member 18 years of age or older? ☐ Yes ☐ No

   b. Does Member have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 5% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals?
   ☐ Yes ☐ No

   c. Does members have therapeutic failure to a three- month trial or a contraindication to any of the following:

   Please check all that apply
      i. Psoralens with UVA light (PUVA) or UVB light
      ☐ Yes ☐ No

      ii. Systemic treatments including ONE of the following:
         1. Immunomodulators (i.e. Methotrexate, Cyclosporine)
         2. Retinoids (i.e. Soriatane)
      ☐ Yes ☐ No

11. If member using for diagnosis of Hidradentitis Supportiva, answer the following questions:
   a. Is the medication being prescribed Humira?
   ☐ Yes ☐ No

   b. Is member 12 years of age or older?
   ☐ Yes ☐ No

c. Does member have a documented diagnosis of moderate to severe hidradentitis supportive with Hurley Stage II or III disease with at least 3 abscesses or inflammatory nodules
☐ Yes ☐ No

d. Has member demonstrate an inadequate response, intolerance or contraindication to any of the following conventional treatment measures:
Please check all that apply
   i. Local hygiene and ordinary hygiene ☐ Yes ☐ No
   ii. Weight reduction in patients who are obese ☐ Yes ☐ No
   iii. Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate) ☐ Yes ☐ No
   iv. Application of warm compresses with sodium chloride solution or Burow's solution ☐ Yes ☐ No
   v. Laser hair removal ☐ Yes ☐ No
   vi. Cessation of cigarette smoking ☐ Yes ☐ No
   vii. Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride
   ☐ Yes ☐ No

12. If member using for diagnosis of uveitis, answer the following questions:

a. Is the medication being prescribed Humira? ☐ Yes ☐ No

b. Is member 2 years of age or older? ☐ Yes ☐ No

c. Does member have a documented diagnosis of non-infectious intermediate, posterior, and panuveitis? ☐ Yes ☐ No

d. Does member have a history of trial and failure, contraindication, or intolerance to conventional treatments including any of the following for at least 3 months of each medication:
   i. Steroids (*i.e.,* prednisone) ☐ Yes ☐ No
   ii. Immunomodulators (*i.e.,* Azathioprine, 6-Mercaptopurine, Methotrexate)
   ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION

1. Which of the following diagnoses will the medication be used for:
Please check the one that applies
   a. Rheumatoid Arthritis ☐ Yes ☐ No

i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
☐ Yes ☐ No

b. Juvenile Idiopathic Arthritis ☐ Yes ☐ No
   i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
   ☐ Yes ☐ No

c. Psoriatic Arthritis ☐ Yes ☐ No
   i. If yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Number of swollen joints, number of tender joints, patient's assessment of pain, member's global assessment of disease activity, HAQ score, and/or CRP (C-Reactive Protein)?
   ☐ Yes ☐ No

d. Ankylosing Spondylitis ☐ Yes ☐ No
   i. Is yes, is there evidence of positive clinical response involving the following clinical/laboratory parameters: Patient global assessment, back pain, BASFI (Bath Ankylosing Spondylitis Functional Index, CRP, Modified Schober's test, chest expansion, occiput-to-wall measurement?
   ☐ Yes ☐ No

e. Crohn's Disease ☐ Yes ☐ No
   i. Is there documented, significant improvement with prior courses of treatment?
   ☐ Yes ☐ No

f. Fistulizing Crohn's Disease ☐ Yes ☐ No
   i. Is there documented, significant improvement with prior courses of treatment?
   ☐ Yes ☐ No

g. Ulcerative Colitis ☐ Yes ☐ No
   i. Is there documented, significant improvement with prior courses of treatment?
   ☐ Yes ☐ No

h. Plaque Psoriasis ☐ Yes ☐ No
   i. Is there documented, significant improvement with prior courses of treatment?

   ☐ Yes ☐ No

i. Hidradentitis Supportiva
   i. Is there documented, significant improvement with prior courses of treatment?
   ☐ Yes ☐ No

j. Uveitis ☐ Yes ☐ No
   i. Is there sustained improvement in ocular inflammation or there was no worsening of ocular co-morbidities?
   ☐ Yes ☐ No

k. Other Diagnosis: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE	
Prescribing Provider Signature	Date