Updated: 08/2018
PARP Approved: 08/2018

Prior Authorization Criteria

(Humira™ (adalimumab) and adalimumab biosimilars (Cyltezo™ and Amjevita™)

All requests for Brand Name (generic medication) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

The following agents are on formulary:

- Humira™
- All other biosimilars are considered non-formulary and require documentation of failure with Humira™ in addition to meeting the criteria outlined below.
- Members who are currently established on a biosimilar will not be required to change to a preferred or formulary product.

For all requests for Humira™ (adalimumab) and adalimumab biosimilars (Cyltezo™ 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 documented, significant improvement with prior courses of treatment
    - **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™ 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 of 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 is documented, significant improvement with prior courses of treatment
  - **Reauthorization Duration of Approval**: 12 months

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

- Member must be 18 years of age or older
- Member has moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or documented history of psoriasis.
- Member must have a history of trial and failure, contraindication, or intolerance to ALL of the following:
  - Member without axial disease:
    - Four- week trial each of at least 2 NSAIDs.
    - Eight week trial of methotrexate or other DMARD
  - Member with axial disease
    - Four- week trial each of at least 2 NSAIDs.
  - Member with psoriatic arthritis with enthesitis
    - 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 documented, significant improvement with prior courses of treatment
  - **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 documented, significant improvement with prior courses of treatment.
  - **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 conventional treatments including two or more of the following for at least 3 months of each medication:
  - Aminosalicylates, 5-ASAs (*i.e.,* Sulfasalazine, Pentasa®, Asacol®, Colazal®)
  - Antibiotics (*i.e.,* Metronidazole, Ciprofloxacin)
  - Steroids (*i.e.,* prednisone, Entocort®)
  - 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 **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.
- Member must have a history of trial and failure, contraindication, or intolerance to conventional treatments including all of the following for at least 3 months of each medication:
  - Antibiotics (*i.e.,* Metronidazole, Ciprofloxacin)
  - 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 **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 all of the following for at least 3 months:
    - Aminosalicylates, 5-ASAs (*i.e.*, Sulfasalazine, Pentasa®, Asacol®, Colazal®)
    - Steroids (*i.e.*, prednisone, Entocort®)
    - 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 at least ONE 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**:
    - Clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline must be submitted
    - **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 18 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 absceses 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

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

- Medication prescribed is Humira™
- Member must be 18 years of age or older.
- Member must have a documented diagnosis of non-infectious intermediate, posterior, and 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, Entocort®)
  - 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 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

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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:
Health Options 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 moderately to severely active psoriatic arthritis which must include documentation of either active psoriatic lesions or documented history of psoriasis?
   ☐ Yes ☐ No

   c. Does member have a history of trial and failure, contraindication, or intolerance to any of the following:
   Please check all that apply
      i. Member without axial disease:
         1. Four- week trial each of at least 2 NSAIDs. ☐ Yes ☐ No

         2. Eight week trial of methotrexate or other DMARD ☐ Yes ☐ No

      ii. Member with axial disease
         1. Four- week trial each of at least 2 NSAIDs. ☐ Yes ☐ No

      iii. Member with psoriatic arthritis with enthesitis
         1. Four- week trial each of at least 2 NSAIDs ☐ 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 conventional treatments including any 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. Antibiotics (i.e., Metronidazole, Ciprofloxacin) ☐ Yes ☐ No
        iii. Steroids (i.e., prednisone, Entocort) ☐ Yes ☐ No
        iv. Immunomodulators (i.e., Azathioprine, 6-Mercaptopurine, Methotrexate)
        ☐ 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

    d. 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. Antibiotics (i.e., Metronidazole, Ciprofloxacin) ☐ Yes ☐ No

        ii. Immunomodulators (i.e., Azathioprine, 6-Mercaptopurine, Methotrexate)
        ☐ 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, Entocort) ☐ 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 18 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 absceses 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 18 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, Entocort®) ☐ 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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date