Updated: 02/2020
DMMA Approved: 03/2020

Request for Prior Authorization for Humira™ (adalimumab) and adalimumab biosimilars
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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.

Humira™ (adalimumab) and adalimumab biosimilars Prior Authorization Criteria:

For all requests for Humira™ (adalimumab) and adalimumab biosimilars 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.
- For non-preferred agents, the member has had a trial and failure of a preferred agent or submitted a clinical reason for not having a trial of a preferred agent

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™, Amjevita™, Abrilada™, and Hadlima™
    - 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 involving the following clinical/laboratory parameters: Joint count, 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 moderately to severely active psoriatic arthritis indicated by the presence of at least ONE of the following:
    - Erosive Disease
    - Elevated Markers of inflammation attributable to psoriatic arthritis
    - Long-term damage that interferes with function (i.e., joint deformities)
    - Highly active disease that causes a major impairment in quality of life
    - Active PsA at many sites including dacylitis, enthesitis
    - Function-limiting PsA at a few sites
    - Rapidly progressive disease.
- 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: 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, 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™, Hyrimoz™, Amjevita™, Abrilada™ and Hadlima™
  - 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)
  - 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™, Hyrimoz™, Amjevita™, Abrilada ™and Hadlima™
  - 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)
  - 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**:
    - 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 **Hidradenitis Suppurativa** 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 hidradenitis suppurativa 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
    - Historical use of laser hair removal (not a Highmark Health Options covered benefit and not expected to be fulfilled while at Highmark Health Options)
    - 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 at least 50% reduction in total abscess and inflammatory nodule count with no increase in draining fistula count relative to baseline.
- **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, 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

HIGHMARK. Delaware HEALTH OPTIONS

Updated: 02/2020
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Humira™ (adalimumab) and adalimumab biosimilars
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 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 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 the diagnosis is **Rheumatoid Arthritis**, please answer the following questions:
   a. Is the member 18 years of age or older? ☐ Yes ☐ No
   b. Does the member have a history of trial and failure, contraindication, or intolerance to a three-month trial with methotrexate or another DMARD? ☐ Yes ☐ No

4. If the diagnosis is **Juvenile Idiopathic Arthritis**, please answer the following questions:
   a. If using Humira™, is the member 2 years of age or older? ☐ Yes ☐ No
   b. If using Cyltezo™, Amjevita, Hyrimoz or Hadlima is the member 4 years of age or older? ☐ Yes ☐ No
   c. Does the member meet any of 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 the diagnosis is **Psoriatic Arthritis**, please answer the following questions:
   a. Is the member 18 years of age or older? ☐ Yes ☐ No
   b. Does the member have moderately to severely active psoriatic arthritis indicated by the presence of at least ONE of the following:
      - Erosive Disease ☐ Yes ☐ No
      - Elevated Markers of inflammation attributable to psoriatic arthritis ☐ Yes ☐ No
      - Long-term damage that interferes with function (i.e., joint deformities) ☐ Yes ☐ No
      - Highly active disease that causes a major impairment in quality of life ☐ Yes ☐ No
      - Active PsA at many sites including dacylitis, enthesitis ☐ Yes ☐ No
      - Function-limiting PsA at a few sites ☐ Yes ☐ No
      - Rapidly progressive disease ☐ Yes ☐ No
   c. Does the member have a history of trial and failure, contraindication, or intolerance to a four-week trial of at least 2 NSAIDS? ☐ Yes ☐ No

6. If the diagnosis is **Ankylosing Spondylitis**, please answer the following questions:
   a. Is the member 18 years of age or older? ☐ Yes ☐ No
   b. Does the 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 the diagnosis is **Crohn's Disease**, please answer the following questions:
   a. If using Humira, is the member 6 years of age or older? ☐ Yes ☐ No
   b. If using Cylteza, Amjevita, Hyrimoz or Hadlima, is the member 18 years of age or older? ☐ Yes ☐ No
   c. Does the 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) ☐ Yes ☐ No
      iv. Immunomodulators (i.e., Azathioprine, 6-Mercaptopurine, Methotrexate) ☐ Yes ☐ No

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

b. If using Cylteza, Amjevita, Hyrimoz or Hadlima, is the member 18 years of age or older? ☐ Yes ☐ No
c. Does the member have clinical documentation of Crohn's disease with actively draining fistulas? ☐ Yes ☐ No
d. Does the member have a history of trial and failure, contraindications, or intolerance to conventional treatments including any 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 the diagnosis is **Ulcerative Colitis**, please answer the following questions:
   a. Is the member 18 years of age or older? ☐ Yes ☐ No
   b. Does the 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 the diagnosis is **Plaque Psoriasis**, please answer the following questions:
   a. Is the member 18 years of age or older? ☐ Yes ☐ No
   b. Does the 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 the member 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) ☐ Yes ☐ No
         2. Retinoids (i.e. Soriatane) ☐ Yes ☐ No

11. If the diagnosis is **Hidradenitis Suppurtiva**, please answer the following questions:
   a. Is the medication being prescribed Humira™? ☐ Yes ☐ No
   b. Is the member 12 years of age or older? ☐ Yes ☐ No
   c. Does the member have a documented diagnosis of moderate to severe hidradenitis suppurtiva with Hurley Stage II or III disease with at least 3 abscesses or inflammatory nodules? ☐ Yes ☐ No
   d. Has the member demonstrated 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. Does the member have historical use of laser hair removal (not a Highmark Health Options covered benefit)? ☐ 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 the diagnosis is **uveitis**, please answer the following questions:
    a. Is the medication being prescribed Humira™? ☐ Yes ☐ No
    b. Is the member 2 years of age or older? ☐ Yes ☐ No
    c. Does the member have a documented diagnosis of non-infectious intermediate, posterior, or panuveitis? ☐ Yes ☐ No
    d. Does the 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 (C-Reactive Protein), 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 clinical documentation that supports a decrease in percent of body surface area involvement when compared to baseline? Clinical documentation must be submitted. ☐ Yes ☐ No

i. Hidradenitis Suppurativa ☐ Yes ☐ No
   i. Is there at least 50% reduction in total abscess and inflammatory nodule count with no increase in draining fistula count relative to baseline? ☐ 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