UTAH MEDICAID PHARMACY PRIOR AUTHORIZATION REQUEST FORM

Humira (adalimumab) and Biosimilars

Member and Medication Information * indicates required field	
*Member ID:	*Member Name:
*DOB:	*Weight:
*Medication Name/ Strength:	
☐ Do Not Substitute. Authorizations will be processed for the preferred Generic/Brand equivalent unless specified.	
*Directions for use:	
Provider Information * indicates required field	
*Requesting Provider Name:	*Requesting Prescriber NPI:
Address:	
*Contact Person:	*Office Phone:
*Office Fax:	*Office Email:
Fax form and relevant documentation including: laboratory results, chart notes and/or updated provider letter to Pharmacy PA at **855-828-4992**, to prevent processing delays.	

PART I: Criteria for Approval: (*All* of the following criteria must be met) - **Then move to PART II**

1. Which medication is being requested?
   - ☐ Cyltezo 40 mg/0.8 ml **(Preferred)**
   - ☐ Hadlima 40 mg/0.8 ml **(Preferred)**
   - ☐ Humira **(Preferred)**
   - ☐ Simlandi **(Preferred)**
   - ☐ Other adalimumab brand or biosimilar (non-preferred)
2. Is the medication being prescribed by or in consultation with a provider specializing in the disease treatment? ❑ **Yes** ❑ **No**
3. Does the patient have any of the following diagnoses:? (check the applicable) ❑ **Yes** ❑ **No**
   - ☐ Ankylosing Spondylitis (AS)
   - ☐ Crohn's Disease (CD)
   - ☐ Hidradenitis Suppurativa (HS)
   - ☐ Juvenile Idiopathic Arthritis (JIA)
   - ☐ Plaque Psoriasis (PsO)
   - ☐ Psoriatic Arthritis (PsA)
   - ☐ Rheumatoid Arthritis (RA)
   - ☐ Ulcerative Colitis (UC)
   - ☐ Uveitis (UV)
   - ☐ Other - Off Label or Compendia Use (specify): _____
4. Does the requested medication and diagnosis follow FDA-approved age, dosing, monitoring and contraindications? ❑ **Yes** ❑ **No**

   *If answer is **No**, go to Part II, section 10*
5. Does the provider attest that the patient is not taking concurrent treatment or that the medication will not be used in combination with other TNF-inhibitors, biologic response modifiers or other biologic DMARDs,

Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitors (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, patient medication fill history, or submitted documentation? ❑ **Yes** ❑ **No**

PART II: Select and fill out applicable sections:

Section 1: Additional criteria for Ankylosing Spondylitis (AS) (*All* of the following criteria must be met)

1. Is the patient at least 18 years of age or older? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of Ankylosing Spondylitis demonstrated by description of baseline symptoms present in the chart notes? ❑ **Yes** ❑ **No**
3. Has the patient tried and failed, demonstrated an intolerance to, or has a contraindication to at least two different prescription strength nonsteroidal anti-inflammatory drugs (NSAID) at the maximally tolerated dose for at least 1 month each? ❑ **Yes** ❑ **No**

Section 2: Additional criteria for Crohn's Disease (CD) (*All* of the following criteria must be met)

1. Is the patient at least 6 years of age or older? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of moderately to severely active Crohn's Disease as confirmed by applicable testing such as diagnostic imaging, inflammatory biomarker, or disease activity scale and supported by description of baseline symptoms/labs present in the chart notes? ❑ **Yes** ❑ **No**

Section 3: Additional criteria for Hidradenitis Suppurativa (HS) (*All* of the following criteria must be met)

1. Is the patient at least 12 years of age or older? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of moderate to severe (Hurley Stage II or III) Hidradenitis Suppurativa demonstrated by description of baseline symptoms present in the chart notes? ❑ **Yes** ❑ **No**
3. Has the patient tried and failed an oral tetracycline antibiotic (such as doxycycline or minocycline) for at least 90 days, unless contraindicated? ❑ **Yes** ❑ **No**

Section 4: Additional criteria for Juvenile Idiopathic Arthritis (JIA) (*All* of the following criteria must be met)

1. Is the patient at least 2 years of age or older? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis demonstrated by description of baseline symptoms present in the chart notes? ❑ **Yes** ❑ **No**
3. Has the patient tried and failed, demonstrated an intolerance to, or has a contraindication to ONE NSAID or glucocorticoid for 3 months? ❑ **Yes** ❑ **No**
4. Has the patient tried and failed, demonstrated an intolerance to, or has a contraindication to methotrexate or leflunomide for 3 months, if clinically appropriate? ❑ **Yes** ❑ **No**

Section 5: Additional criteria for Plaque Psoriasis (PsO) (*All* of the following criteria must be met)

1. Is the patient at least 18 years of age or older? ❑ **Yes** ❑ **No**
2. Has the patient been diagnosed with moderate to severe plaque psoriasis involving greater than 3% body surface area? ❑ **Yes** ❑ **No**
3. If less than 3% of the body is involved, is there scalp, palmar, foot, or groin involvement causing significant disability? ❑ **Yes** ❑ **No**
4. Has the patient tried and failed at least **ONE** of the following medications for at least 3 months, or does the patient have a contraindication to all 3, if clinically appropriate? ❑ **Yes** ❑ **No**
   - ☐ methotrexate

- ☐ cyclosporine
- ☐ acitretin therapy

Section 6: Additional criteria for Psoriatic Arthritis (PsA) (*All* of the following criteria must be met)

1. Is the patient at least 18 years of age or older? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of active psoriatic arthritis demonstrated by description of baseline symptoms present in the chart notes? ❑ **Yes** ❑ **No**
3. Has the patient had an adequate trial and failure of at least **ONE** of the following disease-modifying antirheumatic drugs (DMARDs) for at least 3 months, unless all are contraindicated: methotrexate, leflunomide, sulfasalazine, azathioprine, if clinically appropriate? ❑ **Yes** ❑ **No**

Section 7: Additional criteria for Rheumatoid Arthritis (RA) (*All* of the following criteria must be met)

1. Is the patient at least 18 years of age or older? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of moderately to severely active rheumatoid arthritis demonstrated by description of baseline symptoms present in the chart notes? ❑ **Yes** ❑ **No**
3. Has the patient had an adequate trial and failure of at least **ONE** disease modifying antirheumatic drug (DMARD) for at least 3 months (e.g. hydroxychloroquine, leflunomide, methotrexate, sulfasalazine) or a contraindication to all, if clinically appropriate? ❑ **Yes** ❑ **No**

Section 8: Additional criteria for Ulcerative Colitis (UC) (*All* of the following criteria must be met)

1. Is the patient at least 5 years of age or older? ❑ **Yes** ❑ **No**
2. Does the patient have a diagnosis of moderately to severely active Ulcerative Colitis as confirmed by applicable testing such as diagnostic imaging, inflammatory biomarker, or disease activity scale and supported by description of baseline symptoms/labs present in the chart notes? ❑ **Yes** ❑ **No**
3. Has the patient had an adequate trial and failure of at least **ONE** of the following for at least 2 months, or a contraindication to all? ❑ **Yes** ❑ **No**
   - ☐ High dose oral 5-aminosalicyclic acid drug
   - ☐ Topical 5-aminosalicylic acid drug

Section 9: Additional criteria for Uveitis (UV) (*All* of the following criteria must be met)

1. Is the patient at least 2 years of age or older? ❑ **Yes** ❑ **No**
2. Has the patient been diagnosed with non-infectious uveitis classified as intermediate, posterior, or panuveitis demonstrated by description of baseline symptoms present in the chart notes? ❑ **Yes** ❑ **No**
3. Has the patient had a trial and failure of at least ONE systemic corticosteroid at the maximum indicated dose or intravitreal steroid for at least 3 months, if clinically appropriate? ❑ **Yes** ❑ **No**

Section 10: Other - Off Label or Compendia Use of FDA-Approved Drugs Additional Criterion:

1. Does the submitted clinical documentation show an adequate trial and failure of at least **ONE** FDA-labeled and Medicaid preferred medication, if applicable? ❑ **Yes** ❑ **No**
2. Does the provider attest that the requested drug is being used for a medically accepted indication that is supported by information from the appropriate *compendia** of current literature. Including at least (1) major multi-site study or three (3) smaller studies published in JAMA, NEJM, Lancet, or other peer review specialty medical journals in the most recent years? ❑ **Yes** ❑ **No**

* Compendia use must be recommended by generally accepted compendia such as American Hospital Formulary Service Drug Information (AHFS), United States Pharmacopeia-Drug Information (USP-DI), the Micromedex Information System, Pediatric and Neonatal Lexi-Drugs, or clinical guidelines.

PART III: Non-Preferred adalimumab Criteria (PART 1 & PART II MUST also be met)

1. For requests of any non-preferred biosimilar, other than the preferred above, has the patient tried **ALL** of the preferred adalimumab products? ❑ **Yes** ❑ **No**

Reauthorization Criteria:

1. Has the provider submitted updated chart notes demonstrating positive clinical response? ❑ **Yes** ❑ **No**

Initial Authorization: Up to six (6) months
Reauthorization: Up to one (1) year

Note:

- WARNING: SERIOUS INFECTIONS AND MALIGNANCY
  - SERIOUS INFECTIONS
    - Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
    - Discontinue HUMIRA if a patient develops a serious infection or sepsis.
  - MALIGNANCY
    - Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including HUMIRA. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including HUMIRA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6–MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

PROVIDER CERTIFICATION

I hereby certify this treatment is indicated, necessary and meets the guidelines for use.

_____ _____

Prescriber's Signature Date