HUMIRA® (adalimumab) CITRATE-FREE REFERRAL AND PRESCRIPTION FORM

Sign and fax this form to Complete by AbbVie at 877-314-8427 or the pharmacy of your choice. For questions, please call 800-448-6472.

GASTROENTEROLOGY

PATIENT AND PRESCRIBER INFORMATION

PATIENT INFORMATION SSN (Last 4 ONLY) ____ | ____ | ____ | ____

First Name: _____ MI: _____

Last Name: _____

DOB: _____ Weight (lbs): _____ Sex: ☐ M ☐ F

Address: _____

City/State/Zip: _____

Primary Phone: _____ ☐ H ☐ W ☐ M

Alternate Phone: _____ ☐ H ☐ W ☐ M

Drug Allergies: _____

PRESCRIBER INFORMATION ☐ MD ☐ DO ☐ Other: _____

Prescriber Name: _____

Specialty: ☐ Gastro ☐ Other: _____

NPI/Provider #: _____ State License #: _____

Office Name: _____

Contact: _____

Address: _____

City/State/Zip: _____

Phone: _____ Fax: _____

INSURANCE INFORMATION

Fax a copy of the front and back of prescription insurance card(s) or fill in the information below

Primary Insurance: _____

Phone: _____

Cardholder ID #: _____ Group #: _____

PCN: _____ BIN: _____

Policyholder Name: _____ DOB: _____

Secondary Insurance: _____

Phone: _____

Cardholder ID #: _____ Group #: _____

PCN: _____ BIN: _____

Policyholder Name: _____ DOB: _____

BV

BENEFIT VERIFICATION ONLY ☐ I do **not** want to prescribe HUMIRA at this time, but please verify drug coverage.

CLINICAL AND PRESCRIPTION INFORMATION

PATIENT'S DIAGNOSIS Date of Diagnosis: _____

☐ Adult Crohn's Disease ICD-10: _____

☐ Ulcerative Colitis ICD-10: _____

☐ Pediatric Crohn's Disease ICD-10: _____

☐ Other (include code): _____

Prior medications: _____

TB Test (Date) _____ ☐ Pos _____ ☐ Neg _____

Please attach any clinical or office notes relevant to therapy.

SHIPPING PREFERENCE Date needed: _____

☐ Deliver medication to the patient

☐ Deliver medication to the prescriber

PRESCRIPTION

☐ New ☐ Restart ☐ Continuing

Current filling pharmacy: _____

Adult Crohn's Disease or Ulcerative Colitis

Starting Therapy

☐ **Pen:** HUMIRA Starter Pkg 80 mg/0.8 mL *NDC: 0074-0124-03*
☐ Two 80 mg SQ inj. Day 1, one 80 mg SQ inj. Day 15
☐ One 80 mg SQ inj. Day 1, one 80 mg SQ inj. Day 2, one 80 mg SQ inj. Day 15
#3 No Refills

Ongoing Therapy

Or ☐ **Syringe:** HUMIRA 40 mg/0.4 mL *NDC: 0074-0243-02*
☐ **Pen:** HUMIRA 40 mg/0.4 mL *NDC: 0074-0554-02*
One 40 mg SQ inj. Day 29 & QOW thereafter ☐ #2 (1 month) ☐ #6 (3 month) Refills: ____

Pediatric Crohn's Disease

Starting Therapy

▸ **Weight 17 kg (37 lbs) to <40 kg (88 lbs)**

☐ **Syringe:** HUMIRA Starter Pkg 80 mg/0.8 mL, 40 mg/0.4 mL *NDC: 0074-0067-02*
One 80 mg SQ inj. Day 1, one 40 mg SQ inj. Day 15 #2 No Refills

▸ **Weight ≥40 kg (88 lbs)**

Or ☐ **Syringe:** HUMIRA Starter Pkg 80 mg/0.8 mL *NDC: 0074-2540-03*
☐ **Pen:** HUMIRA Starter Pkg 80 mg/0.8 mL *NDC: 0074-0124-03*
☐ Two 80 mg SQ inj. Day 1, one 80 mg SQ inj. Day 15
☐ One 80 mg SQ inj. Day 1, one 80 mg SQ inj. Day 2, one 80 mg SQ inj. Day 15
#3 No Refills

Ongoing Therapy

▸ **Weight 17 kg (37 lbs) to <40 kg (88 lbs)**

☐ **Syringe:** HUMIRA 20 mg/0.2 mL *NDC: 0074-0616-02*
One 20 mg SQ inj. Day 29 & QOW thereafter ☐ #2 (1 month) ☐ #6 (3 month) Refills: ____

▸ **Weight ≥40 kg (88 lbs)**

Or ☐ **Syringe:** HUMIRA 40 mg/0.4 mL *NDC: 0074-0243-02*
☐ **Pen:** HUMIRA 40 mg/0.4 mL *NDC: 0074-0554-02*
One 40 mg SQ inj. Day 29 & QOW thereafter ☐ #2 (1 month) ☐ #6 (3 month) Refills: ____

Other ☐ HUMIRA _____ SIG: _____ Qty: _____ Refills: _____

PRESCRIBER SIGNATURE: PRESCRIBER MUST MANUALLY SIGN (RUBBER STAMPS, SIGNATURE BY OTHER OFFICE PERSONNEL FOR THE PRESCRIBER, AND COMPUTER-GENERATED SIGNATURES WILL NOT BE ACCEPTED), OR SEND AN ELECTRONIC PRESCRIPTION TO THE PHARMACY.

_____ _____

☐ Dispense as written/Do not substitute **Date** **☐ Substitution permitted/Brand exchange permitted** **Date**

I authorize the pharmacy and its employees to serve as my agent for the sole purpose of obtaining patient benefit information and the necessary prior authorization forms when dealing with Health Plans and Pharmacy Benefits Managers (PBMs), if the plan or PBM requires such authorization.

For states requiring handwritten expressions of Product Selection, use this area (e.g., medically necessary, may not substitute, dispense as written, etc.)

Please see Important Safety Information on next page.

Please see accompanying full Prescribing Information, including BOXED WARNING, or visit www.rxabbvie.com/pdf/humira.pdf.

INDICATIONS for HUMIRA® (adalimumab)[1]

HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy, and reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

HUMIRA is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate.

HUMIRA is indicated for inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine, or 6-mercaptopurine. The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to anti-TNF agents.

IMPORTANT SAFETY INFORMATION[1]

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.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before HUMIRA use and during therapy. Initiate treatment for latent TB prior to HUMIRA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with HUMIRA prior to initiating therapy in patients: 1. with chronic or recurrent infection, 2. who have been exposed to TB, 3. with a history of opportunistic infection, 4. who resided in or traveled in regions where mycoses are endemic, 5. with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HUMIRA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start HUMIRA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated with rituximab who received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of HUMIRA with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including HUMIRA. Postmarketing 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 of these patients had received treatment with azathioprine or 6-mercaptopurine 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.

- Consider the risks and benefits of HUMIRA treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among HUMIRA-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for HUMIRA-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy, for the presence of NMSC prior to and during treatment with HUMIRA.
- In HUMIRA clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.
- Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSENSITIVITY

- Anaphylaxis and angioneurotic edema have been reported following HUMIRA administration. If a serious allergic reaction occurs, stop HUMIRA and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including HUMIRA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.
- Exercise caution in patients who are carriers of HBV and monitor them during and after HUMIRA treatment.
- Discontinue HUMIRA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming HUMIRA after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including HUMIRA, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome.
- Exercise caution when considering HUMIRA for patients with these disorders; discontinuation of HUMIRA should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with HUMIRA.
- Consider stopping HUMIRA if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have been observed with HUMIRA; exercise caution and monitor carefully.

AUTOIMMUNITY

- Treatment with HUMIRA may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on HUMIRA should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating HUMIRA therapy.
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the *in utero* exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to HUMIRA *in utero* is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE REACTIONS

- The most common adverse reactions in HUMIRA clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

Reference: 1. HUMIRA Injection [package insert]. North Chicago, IL: AbbVie Inc.

Please see accompanying full Prescribing Information, including BOXED WARNING, or visit www.rxabbvie.com/pdf/humira.pdf.