Getting Started

HUMIRA COMPLETE

HUMIRA Complete offers information, support, and resources designed around you and your child.

Use this checklist to start and stay on track with your child's prescribed treatment plan.

1 NAVIGATE INSURANCE AND SAVINGS

Get support from your child's Nurse Ambassador.*

- [ ] Connect with your child's Ambassador. They will call you within a few days, but if you need help sooner, reach out at **1.800.4HUMIRA** (1.800.448.6472).†
- [ ] Write down the name and phone number of your child's Ambassador so you can find it easily.
- [ ] Ask your child's Ambassador about your savings options. They can also connect you with an Insurance Specialist to help navigate the insurance process.

Ambassador Name: _____

Ambassador Phone: _____

2 GETTING YOUR CHILD'S PRESCRIPTION

A specialty pharmacy will help fill your child's HUMIRA prescription and arrange delivery.

- [ ] Ask your child's health care professional for the name and phone number of the specialty pharmacy.
- [ ] Write down the information so you can find it easily.
- [ ] Write down the date of your child's first injection: _____ /_____ /_____
- [ ] Call the Specialty Pharmacy to confirm your delivery address at least 2 weeks before your child's first injection.

Specialty Pharmacy Name: _____

Specialty Pharmacy Phone: _____

3 PREPARING YOUR CHILD TO INJECT AT HOME

Get step-by-step instructions for injecting HUMIRA. Don't try to inject HUMIRA yourself until your doctor has decided you can and you've been shown the right way to give injections to your child. Read the entire Patient Instructions for Use found in your HUMIRA package for full directions on how to inject your child.

- [ ] Watch injection training videos at **HUMIRA.com/training** or use your phone's camera to scan the QR code at the right.
- [ ] Ask your child's Ambassador any additional questions you have about injection training or taking HUMIRA.

Not enrolled?

Go to **HUMIRA.com/start** to sign up, or chat with us live 24/7.

*Nurse Ambassadors are provided by AbbVie and do not work under the direction of your health care professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

†Help is available Monday through Friday from 8:00 AM to 8:00 PM ET, except for holidays.

Please see Uses and Important Safety Information on page 2.

Please see full Prescribing Information, including Medication Guide, and discuss with your child's doctor.

HUMIRA® adalimumab

HUMIRA Uses[1]

HUMIRA is a prescription medicine used:

- **To treat moderate to severe Crohn's disease (CD) in adults and children 6 years of age and older.**
- **To treat moderate to severe ulcerative colitis (UC) in adults and children 5 years of age and older.** It is not known if HUMIRA is effective in people who stopped responding to or could not tolerate anti-TNF medicines.

Important Safety Information About HUMIRA® (adalimumab)[1]

What is the most important information I should know about HUMIRA?

You should discuss the potential benefits and risks of HUMIRA with your doctor. HUMIRA is a TNF blocker medicine that can lower the ability of your immune system to fight infections. You should not start taking HUMIRA if you have any kind of infection unless your doctor says it is okay.

- **Serious infections have happened in people taking HUMIRA. These serious infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some people have died from these infections.** Your doctor should test you for TB before starting HUMIRA, and check you closely for signs and symptoms of TB during treatment with HUMIRA, even if your TB test was negative. If your doctor feels you are at risk, you may be treated with medicine for TB.
- **Cancer.** For children and adults taking TNF blockers, including HUMIRA, the chance of getting lymphoma or other cancers may increase. There have been cases of unusual cancers in children, teenagers, and young adults using TNF blockers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma. This type of cancer often results in death. If using TNF blockers including HUMIRA, your chance of getting two types of skin cancer (basal cell and squamous cell) may increase. These types are generally not life-threatening if treated; tell your doctor if you have a bump or open sore that doesn't heal.

What should I tell my doctor BEFORE starting HUMIRA?

Tell your doctor about all of your health conditions, including if you:

- Have an infection, are being treated for infection, or have symptoms of an infection
- Get a lot of infections or infections that keep coming back
- Have diabetes
- Have TB or have been in close contact with someone with TB, or were born in, lived in, or traveled where there is more risk for getting TB
- Live or have lived in an area (such as the Ohio and Mississippi River valleys) where there is an increased risk for getting certain kinds of fungal infections, such as histoplasmosis, coccidioidomycosis, or blastomycosis. These infections may happen or become more severe if you use HUMIRA. Ask your doctor if you are unsure if you have lived in these areas
- Have or have had hepatitis B
- Are scheduled for major surgery
- Have or have had cancer
- Have numbness or tingling or a nervous system disease such as multiple sclerosis or Guillain-Barré syndrome
- Have or had heart failure
- Have recently received or are scheduled to receive a vaccine. HUMIRA patients may receive vaccines, except for live vaccines. Children should be brought up to date on all vaccines before starting HUMIRA
- Are allergic to rubber, latex, or any HUMIRA ingredients
- Are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed
- Have a baby and you were using HUMIRA during your pregnancy. Tell your baby's doctor before your baby receives any vaccines

Also tell your doctor about all the medicines you take. You should not take HUMIRA with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

What should I watch for AFTER starting HUMIRA?

HUMIRA can cause serious side effects, including:

- **Serious infections.** These include TB and infections caused by viruses, fungi, or bacteria. Symptoms related to TB include a cough, low-grade fever, weight loss, or loss of body fat and muscle.
- **Hepatitis B infection in carriers of the virus.** Symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.
- **Allergic reactions.** Symptoms of a serious allergic reaction include hives, trouble breathing, and swelling of your face, eyes, lips, or mouth.
- **Nervous system problems.** Signs and symptoms include numbness or tingling, problems with your vision, weakness in your arms or legs, and dizziness.
- **Blood problems** (decreased blood cells that help fight infections or stop bleeding). Symptoms include a fever that does not go away, bruising or bleeding very easily, or looking very pale.
- **Heart failure** (new or worsening). Symptoms include shortness of breath, swelling of your ankles or feet, and sudden weight gain.
- **Immune reactions including a lupus-like syndrome.** Symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or rash on your cheeks or arms that gets worse in the sun.
- **Liver problems.** Symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of your stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis** (new or worsening). Symptoms include red scaly patches or raised bumps that are filled with pus.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Common side effects of HUMIRA include injection site reactions (pain, redness, rash, swelling, itching, or bruising), **upper respiratory infections** (sinus infections), **headaches, rash**, and **nausea**. These are not all of the possible side effects with HUMIRA. Tell your doctor if you have any side effect that bothers you or that does not go away.

Remember, tell your doctor right away if you have an infection or symptoms of an infection, including:

- Fever, sweats, or chills
- Muscle aches
- Cough
- Shortness of breath
- Blood in phlegm
- Weight loss
- Warm, red, or painful skin or sores on your body
- Diarrhea or stomach pain
- Burning when you urinate
- Urinating more often than normal
- Feeling very tired

HUMIRA is given by injection under the skin.

This is the most important information to know about HUMIRA. For more information, talk to your health care provider.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

If you are having difficulty paying for your medicine, AbbVie may be able to help. Visit AbbVie.com/myAbbVieAssist to learn more.

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

Please see full Prescribing Information, including Medication Guide, and discuss with your child's doctor.

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HUMIRA® adalimumab

HUMIRA COMPLETE

HG-120123-P12

Two-Page Form Faxing Instructions:
Fax to HUMIRA Complete **1.678.727.0690**

Enrollment and Prescription Form

The health care professional (HCP) and the parent or legal guardian should fill out this form completely before leaving the office.
Sections in **PLUM** (1, 2, 3, 4) are necessary for enrollment into HUMIRA Complete. Required fields are marked with an asterisk (*).

1 PATIENT'S INFORMATION - To be completed by child's parent or legal guardian. Please print clearly.

First Name*: Last Name*: Date of Birth: / / Gender (check one): ☐ M ☐ F

Name of Patient's Parent or Guardian*: Relationship to Patient:

Address*: City*: State*: ZIP*:

Home Phone*: Parent/Guardian Mobile Phone:

Parent/Guardian Email*: ☐ Spanish interpreter needed

- Best Time to Call (Monday-Friday): ☐ Anytime ☐ Morning ☐ Afternoon ☐ Evening
- When did you start on treatment?* ☐ Not Yet Started ☐ 0-3 Months Ago ☐ 4-6 Months Ago ☐ 7-12 Months Ago ☐ Over 12 Months Ago

- ☐ I consent to receive HUMIRA Complete automated and recurring text messages from "Complete Treatment Support," including services updates and marketing messages, refill reminders, and prescription notifications to the above mobile number. Message and data rates may apply. I am not required to consent as a condition of receiving goods or services. I can reply HELP for help. I can reply STOP to opt out at any time. View privacy notice at **https://privacy.abbvie/privacy-policies/us-privacy-policy.html** and mobile T&Cs at **https://abbv.ie/USMobileTerms**.

By enrolling, you may receive your own Nurse Ambassador provided by AbbVie. Ambassadors do not work under the direction of your health care professional (HCP) or give medical advice. They are trained to direct patients to their HCP for treatment-related advice, including further referrals.

- ☐ I consent to the collection, use, and disclosure of my health-related personal data to receive communications from AbbVie regarding its products, programs, services, clinical trials, research opportunities, and for online targeted advertising, as further described in the "**How we may use Personal Data**," "**How we disclose Personal Data**," and "**Cookies and similar tracking and data collection technologies**" sections of our **Privacy Notice**. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting "**Your Privacy Choices**" on AbbVie's website.

For information on how we collect and process your personal data, including the categories we collect, purposes for their collection, and disclosures to third parties, visit **https://abbv.ie/PrivacyPatient**.
Through my submission of the HUMIRA Complete Enrollment and Prescription Form, I consent to the collection, use, and disclosure of my personal health data, as described in the Privacy Notice above and in AbbVie's Privacy Notice in the "**How We May Disclose Personal Data**" section. My consent is required to process sensitive personal data under certain privacy laws, and I have the right to withdraw my consent by visiting "**Your Privacy Choices**" on AbbVie's website.

2 INSURANCE INFORMATION - Please attach insurance cards, if available.

Beneficiary/Cardholder Name:

Medical Insurance:

Medical Insurance ID #:

Group #:

Prescription Insurance:

Rx Group #:

Rx ID #:

Rx Bin #:

Rx PCN #:

▼ TO BE COMPLETED BY A HEALTH CARE PROFESSIONAL ▼

3 DIAGNOSIS* ☐ Pediatric Crohn's Disease ☐ Pediatric Ulcerative Colitis ICD-10: Date of Diagnosis: ___/___/___

4 PRESCRIBER INFORMATION I would like to receive a copy: ☐ **Benefits Verification summary** ☐ Prior Authorization form

Prescriber's Name (First, Last)*:

NPI #*:

Office Phone*:

Office Contact Name:

Office Fax*:

Address*:

City*:

State*: ZIP*:

Email:

5 CLINICAL INFORMATION

Prior Therapies:

Weight:

Concomitant Medications:

Drug Allergies:

TB Test (Date): ___/___/___ ☐ Pos ☐ Neg

Fax any necessary clinical/office notes to the preferred Specialty Pharmacy only.

CONTINUE FILLING OUT FORM ON PG.5

IMPORTANT INFORMATION: The categories of personal information collected on this form include prescriber name, address, NPRI, etc. **The personal information collected will be used for program management and to perform research and analytics. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit https://privacy.abbvie.**

Please share this information with your patient.

Please see Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on page 4.

Please see full Prescribing Information.

INDICATIONS[1]

- **Crohn's Disease:** HUMIRA is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis:** HUMIRA is indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older.

Limitations of Use:
The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers.

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 full Prescribing Information.

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HUMIRA® adalimumab

Enrollment and Prescription Form (Second Page)

6 PATIENT'S INFORMATION - To be completed by child's parent or legal guardian. Please print clearly.

First Name*: Last Name*: Date of Birth: / /

7 PRESCRIBER INFORMATION

Prescriber's Name (First, Last)*: _____ NPI #*: _____ Office Phone: _____

8 INJECTION TRAINING

☐ I request supplemental injection training and/or administration, if needed, for this patient. Order valid for up to one year.
Fill out and sign pharmacy prescription below.

9 PHARMACY PRESCRIPTION - Select medication, fill out and sign corresponding prescription below.

Patient's preferred Specialty Pharmacy: _____ ☐ Check if faxed to Specialty Pharmacy

Key: ■ HUMIRA Citrate-free (CF) ■ HUMIRA with citrate-buffers

Starting Therapy:

Pediatric Crohn's Disease *(17 kg [37 lbs] to <40 kg [88 lbs]):*

☐ SYRINGE HUMIRA Starter Pack (CF) **80 mg/0.8 mL, 40 mg/0.4 mL**
SIG: 80 mg SC inj on Day 1, 40 mg SC inj on Day 15
#2 syringes No Refills

Pediatric Crohn's Disease *(≥40 kg [88 lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA Starter Pack (CF) **80 mg/0.8 mL**
☐ SYRINGE HUMIRA Starter Pack (CF) **80 mg/0.8 mL**

Choose 1 SIG
☐ 160 mg SC inj on Day 1, 80 mg SC inj on Day 15
☐ 80 mg SC inj on Day 1, Day 2, and Day 15
#QS No Refills

Pediatric Ulcerative Colitis *(20 kg [44 lbs] to <40 kg [88 lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA (CF) **40 mg/0.4 mL**
☐ SYRINGE HUMIRA (CF) **40 mg/0.4 mL**
SIG: 80 mg SC inj on Day 1, 40 mg SC inj on Day 8 and Day 15
#4 No Refills

Pediatric Ulcerative Colitis *(≥40 kg [88 lbs]):*

☐ PEN HUMIRA Starter Pack (CF) **80 mg/0.8 mL**

Choose 1 SIG
☐ 160 mg SC inj on Day 1, 80 mg SC inj on Day 8 and Day 15
☐ 80 mg SC inj on Day 1, Day 2, Day 8, and Day 15
#4 pens No Refills

Ongoing Therapy:

Pediatric Crohn's Disease *(17 kg [37 lbs] to <40 kg [88 lbs]):*

☐ SYRINGE HUMIRA (CF) **20 mg/0.2 mL**
SIG: 20 mg SC inj every other week

Choose 1 Quantity
☐ #2 (1 month)
☐ #6 (3 months) Refills: _____

Pediatric Crohn's Disease *(≥40 kg [88 lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA (CF) **40 mg/0.4 mL** ☐ SYRINGE HUMIRA (CF) **40 mg/0.4 mL**
☐ PEN HUMIRA **40 mg/0.8 mL** ☐ SYRINGE HUMIRA **40 mg/0.8 mL**
SIG: 40 mg SC inj every other week

Choose 1 Quantity
☐ #2 (1 month)
☐ #6 (3 months) Refills: _____

Pediatric Ulcerative Colitis *(20 kg [44 lbs] to <40 kg [88 lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA (CF) **40 mg/0.4 mL** ☐ SYRINGE HUMIRA (CF) **40 mg/0.4 mL**
☐ SYRINGE HUMIRA (CF) **20 mg/0.2 mL**

Choose 1 SIG ☐ 40 mg SC inj every other week ☐ 20 mg SC inj every week

Choose 1 Quantity
☐ 1-month supply
☐ 3-month supply Refills: _____

Pediatric Ulcerative Colitis *(≥40 kg [88 lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA (CF) **80 mg/0.8 mL** ☐ PEN HUMIRA (CF) **40 mg/0.4 mL**
☐ SYRINGE HUMIRA (CF) **40 mg/0.4 mL**

Choose 1 SIG ☐ 80 mg SC inj every other week ☐ 40 mg SC inj every week

Choose 1 Quantity
☐ 1-month supply
☐ 3-month supply Refills: _____

PRESCRIBER CERTIFICATION: I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed HUMIRA to the previously identified patient and that I provided the patient with a description of the HUMIRA Complete patient support program. I authorize HUMIRA Complete to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan (if applicable).

Prescriber's signature required (sign below) (Physician attests this is his/her legal signature. NO STAMPS)

SIGN HERE _____ **Dispense as written** _____ **Date** _____ **Substitution allowed** _____ **Date**

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

10 HUMIRA COMPLETE PRESCRIPTION - For Pediatric Ulcerative Colitis Only - required in the event a patient experiences an insurance delay or denial

Eligible patients must have (1) commercial insurance, (2) a valid Rx for HUMIRA, and (3) experienced a delay or denial in insurance determination. See program Terms and Conditions on page 6. Please complete the full form as well as this section and sign below. **Prescription to be filled through an AbbVie-authorized pharmacy.** I understand that faxing this form to HUMIRA Complete will result in an original copy being simultaneously transmitted to the AbbVie-authorized pharmacy under this section.

Key: ■ HUMIRA Citrate-free (CF)

Starting Therapy:

Pediatric Ulcerative Colitis *(20 kg [44 lbs] to <40 kg [88lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA (CF) **40 mg/0.4 mL**
☐ SYRINGE HUMIRA (CF) **40 mg/0.4 mL**
SIG: 80 mg SC inj on Day 1, 40 mg SC inj on Day 8 and Day 15
#4 No Refills

Pediatric Ulcerative Colitis *(≥40 kg [88lbs]):*

PEN HUMIRA Starter Pack (CF) **80 mg/0.8 mL**

Choose 1 SIG
☐ 160 mg SC inj on Day 1, 80 mg SC inj on Day 8 and Day 15
☐ 80 mg SC inj on Day 1, Day 2, Day 8, and Day 15
#4 pens No Refills

Ongoing Therapy:

Pediatric Ulcerative Colitis *(20 kg [44 lbs] to <40 kg [88 lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA (CF) **40 mg/0.4 mL** ☐ SYRINGE HUMIRA (CF) **40 mg/0.4 mL**
☐ SYRINGE HUMIRA (CF) **20 mg/0.2 mL**

Choose 1 SIG ☐ 40 mg SC inj every other week ☐ 20 mg SC inj every week

Choose 1 Quantity
☐ 1-month supply
☐ 3-month supply Refills: _____

Pediatric Ulcerative Colitis *(≥40 kg [88 lbs]):*

Choose 1 Presentation
☐ PEN HUMIRA (CF) **80 mg/0.8 mL** ☐ PEN HUMIRA (CF) **40 mg/0.4 mL**
☐ SYRINGE HUMIRA (CF) **40 mg/0.4 mL**

Choose 1 SIG ☐ 80 mg SC inj every other week ☐ 40 mg SC inj every week

Choose 1 Quantity
☐ 1-month supply
☐ 3-month supply Refills: _____

PRESCRIBER CERTIFICATION: I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that I am the prescriber who has prescribed HUMIRA to the previously identified patient and that I provided the patient with a description of the HUMIRA Complete patient support program. I authorize HUMIRA Complete to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy. I understand that the no charge resource through HUMIRA Complete may support patients who are experiencing a delay in insurance coverage for HUMIRA until coverage is obtained, and I confirm that I will support the above-identified patient in seeking to secure such coverage as I deem appropriate. I certify that I will not seek reimbursement from any third party payor for any no charge product dispensed by an AbbVie authorized pharmacy.

Prescriber's signature required (sign below) (Physician attests this is his/her legal signature. NO STAMPS)

SIGN HERE _____ **Dispense as written** _____ **Date** _____ **Substitution allowed** _____ **Date**

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

IMPORTANT INFORMATION: The categories of personal information collected on this form include prescriber name, address, NPRI, etc. **The personal information collected will be used for program management and to perform research and analytics. For more information about the categories of personal information collected by AbbVie and the purposes for which AbbVie uses personal information, visit https://privacy.abbvie.**

Please share this information with your patient.

Please see Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on page 6.

Please see full Prescribing Information.

INDICATIONS[1]

- **Crohn's Disease:** HUMIRA is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- **Ulcerative Colitis:** HUMIRA is indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older.

  Limitations of Use:
  The effectiveness of HUMIRA has not been established in patients who have lost response to or were intolerant to TNF blockers.

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.

HUMIRA COMPLETE PRESCRIPTION TERMS AND CONDITIONS

Eligible patients must have commercial insurance, a valid prescription for HUMIRA® (adalimumab) for an FDA approved indication and the plan has delayed, denied or not yet made a formulary decision for HUMIRA. Once the patient's insurance plan has made a formulary decision and established a process for reviewing coverage requests for HUMIRA, continued eligibility for the program requires the submission of a Prior Authorization prior to the next scheduled dose and appeal of the coverage denial every 180 days. Program provides HUMIRA at no charge to patients for up to two years or until they receive insurance coverage approval, whichever occurs earlier, and is not contingent on purchase requirements of any kind. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Offer subject to change or discontinuance without notice. This is not health insurance and program does not guarantee insurance coverage. No claims for payment may be submitted to any third-party for product dispensed by Program. Limitations may apply.

Please see full Prescribing Information.

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HUMIRA® adalimumab