Support Every Step of the Way

A Commitment to Improving the Patient Experience

abbvie

When prescribing HUMIRA for your patients with moderate to severe CD or UC, consider following …

2 STEPS FOR A SMART START

STEP 1:
Prescribe induction dosing, followed by maintenance dosing

STEP 2:
Enroll patients in HUMIRA Complete

The American College of Gastroenterology Practice Guidelines for CD and UC state:

Successful induction of remission is a key goal of therapy[10,11]

STEP 1: Dosing[1]

Beginning patients on the correct induction dose is an important first step in treatment

29 GAUGE NEEDLE

Induction Dose and Corresponding NDC

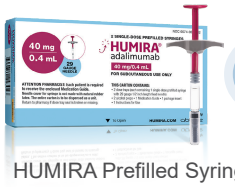
HUMIRA Pen 80 mg/0.8 mL Crohn's Disease and Ulcerative Colitis Starter Pack (3 count)

NDC 0074-0124-03

Induction Dose Regimen

160 mg DAY 1*	**2**	80 mg/0.8 mL PENS
80 mg DAY 15	**1**	80 mg/0.8 mL PEN

Maintenance Dose and Corresponding NDC Starting at Day 29



HUMIRA Prefilled Syringe Carton 40 mg/0.4 mL

NDC 0074-0243-02

OR

HUMIRA Pen Carton 40 mg/0.4 mL

NDC 0074-0554-02

Maintenance Dose Regimen

40 mg **DAY 29** and every other week thereafter	**1**	40 mg/0.4 mL PEN OR SYRINGE

Indications[1]

Adult Crohn's Disease (CD): 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. HUMIRA is indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab.

Ulcerative Colitis (UC): 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.

Safety Considerations[1]

Serious Infections

Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. These infections include active tuberculosis (TB), reactivation of latent TB, invasive fungal infections, and bacterial, viral, and other infections due to opportunistic pathogens. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Malignancies

Lymphoma, including a rare type of T-cell lymphoma, and other malignancies, some fatal, have been reported in patients treated with TNF blockers, including HUMIRA.

Other Serious Adverse Reactions

Patients treated with HUMIRA also may be at risk for other serious adverse reactions, including anaphylaxis, hepatitis B virus reactivation, demyelinating disease, cytopenias, pancytopenia, heart failure, and a lupus-like syndrome.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 5 and 6.

Please click here for full Prescribing Information.

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STEP 1: Dosing[1] (cont.)

Tips

- A new prescription is required for HUMIRA Citrate-free (80 mg/0.8 mL induction, 40 mg/0.4 mL maintenance)
  - If patients are within their annual prescription cycle, prior authorization is likely not required

Including the correct NDC is the best way to ensure the pharmacy dispenses HUMIRA Citrate-free

Dosing and Administration Considerations[1]

- Prior to initiating HUMIRA and periodically during therapy, patients should be evaluated for active TB and tested for latent infection

Crohn's Disease

- In a maintenance clinical trial, among patients who were not responsive by week 12, therapy continued beyond 12 weeks did not result in significantly more responses
- The use of HUMIRA in CD beyond 1 year has not been evaluated in controlled clinical studies

Ulcerative Colitis

- Only continue HUMIRA in patients who have shown evidence of clinical remission by 8 weeks (day 57) of therapy

*Administered as two 80 mg injections in 1 day or as one 80 mg injection per day for 2 consecutive days.

HUMIRA COMPLETE

Simple 1-step ENROLLMENT using any of the following options:

- Enrollment fax form
- 1.800.4HUMIRA (1.800.448.6472)
- HUMIRA Complete Pro

"The best thing about having an Ambassador has been having someone who is there to talk to, no matter how silly the question is."
—Logan B.

STEP 2: HUMIRA Complete

See How HUMIRA Complete Resources Support Your Patients

Nurse Ambassadors*
Nurse Ambassadors are committed to helping patients start and stay on track with their prescribed HUMIRA treatment plan

HUMIRA Complete Pro (HCPro)
Technology that streamlines the prescription process for patients

HUMIRA Complete Savings Card

HUMIRA Complete App
Designed to help your patients establish a treatment routine

Help reinforce self-injection training

At home | Online at HUMIRA.com | By phone† with registered nurses

Medication reminders

Email | Text | Phone

*Ambassadors do not provide medical advice and are trained to direct patients to speak with their healthcare professional about any treatment-related questions, including further referrals.
†Nurses can provide immediate assistance Monday through Friday from 8:00AM to 8:00PM ET. For all other times, one of our nurses will return your patient's call within 1 hour.

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HUMIRA Citrate-free: Redesigned With Your Patients in Mind

Changes they can see*

Thinner needle (29 gauge vs 27 gauge)[2]

50% less volume[1]

The same therapeutic amount of HUMIRA is now injected in half the volume (for the HUMIRA 40-mg dosage form, the volume is 0.4 mL instead of 0.8 mL)

Revised packaging

HUMIRA Citrate-free comes in a blue box featuring the 29-gauge needle

Changes they can't see*

Less pain immediately following injection[2†]

No citrate buffers[1,2]

Sodium citrate, known to cause pain,[3-6] and other inactive ingredients have been removed

Self-Administration Considerations

Before HUMIRA is self-injected, instruct the patient on proper injection technique and monitor as necessary. Refer patient to the Medication Guide for proper storage.

*The instructions for storing HUMIRA Citrate-free are not affected by the removal of inactive ingredients, change in volume, or modifications to the Pen. Although the injection may feel different, patients should continue to follow proper injection technique.

†Injection site pain immediately following injection as measured using a 0-10 cm visual analog scale: HUMIRA 40 mg/0.4 mL vs HUMIRA 40 mg/0.8 mL.

95% of patients reported mild or greater burning or stinging upon injection with the original HUMIRA presentation, but physicians stated that **only 18%** of their patients personally reported discomfort[7,8]

When asking patients about their IBD, also ask about their HUMIRA injection experience

Discussing the Transition to Citrate-free With Patients

EXPLAIN that what makes the Citrate-free formulation different is **what has been removed—the compound known to cause pain**; therefore, the pain immediately following injection may be reduced[2]

ADVISE patients that although the injection may feel different, they should **continue to follow proper injection technique**

TELL patients to **confirm the injection is complete** before removing the Pen or syringe

INSTRUCT patients to **look for the blue box** featuring the 29-gauge needle

REINFORCE that HUMIRA Citrate-free has the **same efficacy and safety profile** they've come to count on[1,9]

Please see Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 5 and 6.

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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.

Please see additional Important Safety Information continued on page 6.

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IMPORTANT SAFETY INFORMATION[1] (cont.)

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.

Please click here for full Prescribing Information.

References

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