HUMIRA Is Approved for the Treatment of Moderate to Severe CHRONIC PLAQUE PSORIASIS

Please review the following information when dispensing a HUMIRA prescription for Plaque Psoriasis

Step 1:

Verify dosing schedule and prescription quantity

The starting dose for HUMIRA in plaque psoriasis, outlined on the next page, differs from dosing for HUMIRA in other approved disease states.

Review prescription schedule and dosing with patients to ensure that patients understand starting dose and continuing dose schedules.

Step 2:

Verify insurance reimbursement approval and refer patients to myHUMIRA by calling 1-800-4HUMIRA

Health plans will likely require prior authorization for HUMIRA in the treatment of Psoriasis. myHUMIRA (1-800-4HUMIRA) is available free of charge to HUMIRA patients and providers. Service include:

- Reimbursement support
- 24/7 nurse support
- Self-injection training
- Self-injection reminders

Step 3:

Order and receive product

When reimbursement has been approved, order HUMIRA for pharmacy dispensing. HUMIRA is generally available within 24 hours. Note: HUMIRA can be ordered without going through the steps suggested in this document.

Step 4:

Dispense product

- Review refrigeration requirements with patient
- Counsel patient about health plan's refill policy
- Training assistance with starting injections is available at:
  - Physician (at physician's office)
  - myHUMIRA (at patient's home or physician's office)

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HUMIRA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HUMIRA should only be administered to patients who will be closely monitored and have regular folluw-up visits with a physician.

Please see last page for Important Safety Information. Please see accompanying full Prescribing Information and/or go to www.HUMIRA.com

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HUMIRA dosing for Chronic Plaque Psoriasis

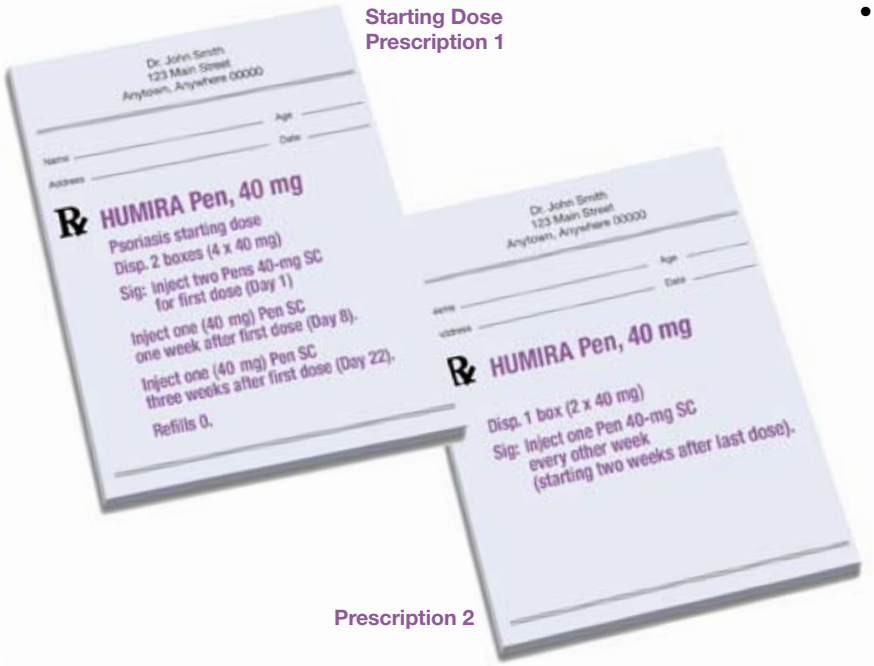
Remember every-other-week dosing[1]

STARTING DOSING (80 mg)	40 mg (x2)	
1 WEEK LATER, BEGIN EVERY-OTHER-WEEK DOSING	40 mg	

HUMIRA dosing regimen plaque psoriasis

- **Initial dose of two 40-mg HUMIRA® Pens (80 mg), followed by one 40-mg HUMIRA Pen every other week starting 1 week after the initial dose**

How to prescribe the HUMIRA Pen for Plaque Psoriasis[1]



HUMIRA dosing regimen psoriatic arthritis

- **Every-other-week dosing with 1 HUMIRA Pen (40 mg)**

It is recommended that healthcare professionals train and supervise patients during administration of the initial dose.

For self-injection assistance, patients should call 1-800-4HUMIRA.

Complete injection instructions are available in the Medication Guide in the HUMIRA box.

Small (27-gauge) needle.

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HUMIRA is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function in patients with psoriatic arthritis. **HUMIRA** is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Please see Important Safety Information on next page. Please see accompanying full prescribing information and/or go to www.HUMIRA.com

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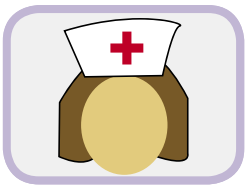
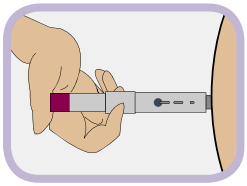
myHUMIRA

A support program making it easy for you and your patients

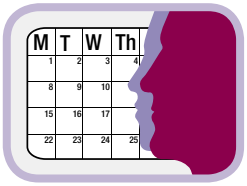
Reimbursement support



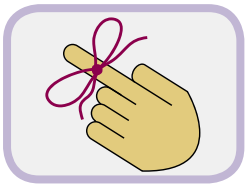
24/7 nurse support



Self-injection training at patient's home or physician's office



Free sharps containers and disease-management tools



Self-injection reminders

To access these services, patients should call

1-800-4HUMIRA

Monday through Friday, 8 am to 8 pm EST

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Please see Important Safety Information on next page. Please see accompanying full prescribing information and/or go to www.HUMIRA.com

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HUMIRA Indications and Important Safety Information

HUMIRA is indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. **HUMIRA** is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function in patients with psoriatic arthritis. **HUMIRA** is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis. **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 the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HUMIRA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Risk of Serious Infections

Tuberculosis (TB), invasive fungal infections, and other opportunistic infections, have been observed in patients receiving HUMIRA. Some infections have been fatal. Anti-TB treatment of patients with latent TB infection reduces the risk of reactivation in patients receiving HUMIRA. However, active TB has developed in patients receiving HUMIRA whose screening for latent TB infection was negative. Patients should be evaluated for TB risk factors and be tested for latent TB prior to initiating HUMIRA and during therapy. When TB skin testing is performed, an induration size of 5mm or greater should be considered positive, even if vaccinated previously with Bacille Calmette-Guerin (BCG). Treatment of latent TB should be initiated prior to therapy with HUMIRA. Physicians should monitor patients receiving HUMIRA for signs and symptoms of active TB, including patients who tested negative for latent TB.

Serious infections and sepsis, including fatalities, have been reported with the use of TNF-blocking agents, including HUMIRA. Many of these infections occurred in patients predisposed to infections because of concomitant immunosuppressive therapy in addition to their underlying disease. Patients who develop a new infection while using HUMIRA should be monitored closely. Treatment should be discontinued if a patient develops a serious infection. Do not start HUMIRA in patients with active infection (including chronic or localized). Exercise caution in patients with a history of recurrent infection or with underlying conditions, which may predispose patients to infections, or patients who have resided in regions where TB and histoplasmosis are endemic.

Malignancies

More cases of malignancies have been observed among patients receiving TNF blockers, including HUMIRA, compared to control patients in clinical trials. These malignancies, other than lymphoma and non-melanoma skin cancer, were similar in type and number to what would be expected in the general population. In the controlled and open-label portions of HUMIRA clinical trials, there was an approximately 3 fold higher rate of lymphoma than expected in the general population. The potential role of TNF-blocking therapy in the development of malignancies is not known.

Hypersensitivity

Anaphylaxis and angioneurotic edema have been reported rarely following HUMIRA administration.

Hepatitis B Reactivation

Use of TNF-blockers, including HUMIRA, may increase the risk of reactivation of hepatitis B (HBV) in patients who are chronic carriers. Some cases have been fatal. Patients at risk for HBV infection should be evaluated for prior evidence of HBV infection before initiating TNF blocker therapy. For patients identified as carriers of HBV, exercise caution when prescribing HUMIRA, with careful evaluation and monitoring prior to and during treatment. HUMIRA should be stopped and antiviral therapy should be initiated in patients who develop hepatitis B reactivation.

Neurologic Reactions

TNF-blocking agents, including HUMIRA, have been associated in rare cases with new onset or exacerbation of demyelinating disease. Exercise caution when considering HUMIRA for patients with these disorders.

Hematologic Reactions

Rare reports of pancytopenia including aplastic anemia have been reported with TNF-blocking agents. Medically significant cytopenia (e.g. thrombocytopenia, leukopenia) has been infrequently reported with HUMIRA. The causal relationship of these reports to HUMIRA remains unclear.

Congestive Heart Failure

Worsening congestive heart failure (CHF) has been observed with TNF-blocking agents, including HUMIRA, and new onset CHF has been reported with TNF-blocking agents.

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 lupus-like syndrome develop.

Drug Interactions

Serious infections were seen in studies with concurrent use of anakinra and another TNF-blocking agent, therefore, the combination of HUMIRA and anakinra is not recommended. Patients on HUMIRA should not receive live vaccines.

Adverse Events

Most frequent adverse events vs placebo from rheumatoid arthritis placebo-controlled studies were injection site reactions (20% vs 14%), upper respiratory infection (17% vs 13%), injection site pain (12% vs 12%), headache (12% vs 8%), rash (12% vs 6%), and sinusitis (11% vs 9%).
Discontinuations due to adverse events were 7% for HUMIRA vs 4% for placebo.

In HUMIRA clinical trials for ankylosing spondylitis, psoriatic arthritis, Crohn's disease and plaque psoriasis the safety profile for patients treated with HUMIRA was similar to the safety profile seen in patients with rheumatoid arthritis.
In the placebo-controlled clinical trials in plaque psoriasis, the incidence of arthralgia was 3% in HUMIRA-treated patients versus 1% in controls.

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Reference 1: HUMIRA full prescribing information.

Please see accompanying full prescribing information and/or go to www.HUMIRA.com

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