SAFETY CONSIDERATIONS

**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 Indications and additional Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15. Please click here for full Prescribing Information.
INDICATIONS

- **Rheumatoid Arthritis**: HUMIRA is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, 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.

- **Juvenile Idiopathic Arthritis**: HUMIRA is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

- **Psoriatic Arthritis**: HUMIRA is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis.

- **Ankylosing Spondylitis**: HUMIRA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

- **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.

- **Plaque Psoriasis**: 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.

- **Hidradenitis Suppurativa**: HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

- **Uveitis**: HUMIRA is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

SAFETY CONSIDERATIONS

**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 Indications and additional Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15.

Please click here for full Prescribing Information.
Overview of relevant rheumatology codes

ICD-10-CM diagnosis codes²*

### Rheumatoid Arthritis (RA)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M05.00 - M05.9</td>
<td>Rheumatoid arthritis with rheumatoid factor</td>
</tr>
<tr>
<td>M06.00 - M06.09</td>
<td>Other rheumatoid arthritis without rheumatoid factor</td>
</tr>
</tbody>
</table>

### Ankylosing Spondylitis (AS)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M45.0-45.9</td>
<td>Ankylosing spondylitis of spinal regions</td>
</tr>
</tbody>
</table>

### Uveitis (UV)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H20.9</td>
<td>Unspecified iridocyclitis; Uveitis NOS</td>
</tr>
<tr>
<td>H44.11 - H44.119</td>
<td>Panuveitis</td>
</tr>
<tr>
<td>H44.13 - H44.139</td>
<td>Sympathetic uveitis</td>
</tr>
</tbody>
</table>

### Juvenile Idiopathic Arthritis (JIA)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M08.00 - M08.09</td>
<td>Unspecified juvenile rheumatoid arthritis</td>
</tr>
<tr>
<td>M08.20 - M08.29</td>
<td>Juvenile rheumatoid arthritis with systemic onset</td>
</tr>
<tr>
<td>M08.40 - M08.48</td>
<td>Pauciarticular juvenile rheumatoid arthritis</td>
</tr>
<tr>
<td>M08.8</td>
<td>Other juvenile arthritis</td>
</tr>
</tbody>
</table>

*The codes shown above are only general suggestions and are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use. This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15. Please click here for full Prescribing Information.
How do I provide my patients with HUMIRA Citrate-free?

- A new prescription is required for HUMIRA Citrate-free
- The correct NDC must be used to ensure a correct pharmacy dispense
- To ensure your patient will receive HUMIRA Citrate-free, please select the appropriate dosing from the Enrollment and Prescription Form or when prescribing electronically

National Drug Code (NDC)¹

Electronic data exchange standards usually require the use of an 11-digit NDC. To convert a 10-digit NDC to an 11-digit NDC, a leading zero is added to the middle sequence of numbers (in the case of HUMIRA, a 0 is added in front of 0074 to create 00074). Check with the payer to confirm the correct code required when billing for HUMIRA.

<table>
<thead>
<tr>
<th>HUMIRA Citrate-free dose*</th>
<th>10-digit NDC code</th>
<th>11-digit NDC code</th>
</tr>
</thead>
<tbody>
<tr>
<td>HUMIRA Pen Carton – 40 mg/0.4 mL</td>
<td>0074-0554-02</td>
<td>00074-0554-02</td>
</tr>
<tr>
<td>HUMIRA Pen Carton – 80 mg/0.8 mL</td>
<td>0074-0124-02</td>
<td>00074-0124-02</td>
</tr>
<tr>
<td>Prefilled Syringe Carton – 40 mg/0.4 mL</td>
<td>0074-0243-02</td>
<td>00074-0243-02</td>
</tr>
<tr>
<td>Prefilled Syringe Carton – 20 mg/0.2 mL</td>
<td>0074-0616-02</td>
<td>00074-0616-02</td>
</tr>
<tr>
<td>Prefilled Syringe Carton – 10 mg/0.1 mL</td>
<td>0074-0817-02</td>
<td>00074-0817-02</td>
</tr>
<tr>
<td>HUMIRA Pen 40 mg/0.4 mL – Uveitis Starter Package</td>
<td>0074-0554-04</td>
<td>00074-0554-04</td>
</tr>
<tr>
<td>HUMIRA Pen 80 mg/0.8 mL and 40 mg/0.4 mL – Uveitis Starter Package</td>
<td>0074-1539-03</td>
<td>00074-1539-03</td>
</tr>
</tbody>
</table>

*Only citrate-free doses relevant to rheumatology are shown here. For complete dosing information, including HUMIRA with citrate-buffers, refer to the full Prescribing Information for HUMIRA.

For additional guidance on coding, please refer to the Department of Health and Human Services Evaluation and Management Services guide available at [www.cms.gov](http://www.cms.gov).

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15.

Please click here for full Prescribing Information.
## Overview of relevant dermatology codes

### ICD-10-CM diagnosis codes

#### Plaque psoriasis (Ps)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L40.0</td>
<td>Psoriasis vulgaris</td>
</tr>
<tr>
<td>L40.1</td>
<td>Generalized pustular psoriasis</td>
</tr>
<tr>
<td>L40.2</td>
<td>Acrodermatitis continua</td>
</tr>
<tr>
<td>L40.3</td>
<td>Pustulosis palmaris et plantaris</td>
</tr>
<tr>
<td>L40.4</td>
<td>Guttate psoriasis</td>
</tr>
<tr>
<td>L40.8</td>
<td>Flexural psoriasis</td>
</tr>
<tr>
<td>L40.9</td>
<td>Psoriasis, unspecified</td>
</tr>
</tbody>
</table>

#### Psoriatic Arthritis (PsA)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L40.50</td>
<td>Arthropathic psoriasis, unspecified</td>
</tr>
</tbody>
</table>

#### Hidradenitis Suppurativa (HS)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L73.2</td>
<td>Hidradenitis suppurativa</td>
</tr>
</tbody>
</table>

*The codes shown above are only general suggestions and are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use. This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies.*
How do I provide my patients with HUMIRA Citrate-free?

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National Drug Code (NDC)¹

Electronic data exchange standards usually require the use of an 11-digit NDC. To convert a 10-digit NDC to an 11-digit NDC, a leading zero is added to the middle sequence of numbers (in the case of HUMIRA, a 0 is added in front of 0074 to create 00074). Check with the payer to confirm the correct code required when billing for HUMIRA.

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<tr>
<th>HUMIRA Citrate-free dose*</th>
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<tr>
<td>HUMIRA Pen Carton – 40 mg/0.4 mL</td>
<td>0074-0554-02</td>
<td>00074-0554-02</td>
</tr>
<tr>
<td>HUMIRA Pen Carton – 80mg/0.8mL</td>
<td>0074-0124-02</td>
<td>00074-0124-02</td>
</tr>
<tr>
<td>Prefilled Syringe Carton – 40 mg/0.4 mL</td>
<td>0074-0243-02</td>
<td>00074-0243-02</td>
</tr>
<tr>
<td>HUMIRA Pen 40 mg/0.4 mL – Starter Package for Hidradenitis Suppurativa</td>
<td>0074-0554-06</td>
<td>00074-0554-06</td>
</tr>
<tr>
<td>HUMIRA Pen 80 mg/0.8 mL – Starter Package for Hidradenitis Suppurativa</td>
<td>0074-0124-03</td>
<td>00074-0124-03</td>
</tr>
<tr>
<td>HUMIRA Pen 40 mg/0.4 mL – Psoriasis or Adolescent Hidradenitis Suppurativa Starter Package</td>
<td>0074-0554-04</td>
<td>00074-0554-04</td>
</tr>
<tr>
<td>HUMIRA Pen 80 mg/0.8 mL and 40 mg/0.4 mL – Psoriasis or Adolescent Hidradenitis Suppurativa Starter Package</td>
<td>0074-1539-03</td>
<td>00074-1539-03</td>
</tr>
</tbody>
</table>

*Only citrate-free doses relevant to dermatology are shown here. For citrate-free rheumatology dosing, please see page 4 of this document. For complete dosing information, including HUMIRA with citrate-buffers, refer to the full Prescribing Information for HUMIRA.

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15. Please click here for full Prescribing Information.
Overview of relevant gastroenterology codes

ICD-10-CM diagnosis codes

### Crohn's Disease (CD)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K50.0-K50.9</td>
<td>Crohn’s Disease [regional enteritis]</td>
</tr>
</tbody>
</table>

### Ulcerative Colitis (UC)

<table>
<thead>
<tr>
<th>ICD-10 code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K51.0-K51.9</td>
<td>Ulcerative Colitis</td>
</tr>
</tbody>
</table>

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### SELECTED INDICATIONS

**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.

### SAFETY CONSIDERATIONS

**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 immunsuppressants 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.

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**National Drug Code (NDC)**

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<td>00074-0243-02</td>
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<tr>
<td>Prefilled Syringe Carton – 20 mg/0.2 mL</td>
<td>0074-0616-02</td>
<td>00074-0616-02</td>
</tr>
<tr>
<td>Prefilled Syringe Carton – 10 mg/0.1 mL</td>
<td>0074-0817-02</td>
<td>00074-0817-02</td>
</tr>
<tr>
<td>HUMIRA Pen 40 mg/0.4 mL - Crohn’s Disease or Ulcerative Colitis Starter Pack</td>
<td>0074-0554-06</td>
<td>00074-0554-06</td>
</tr>
<tr>
<td>HUMIRA Pen 80 mg/0.8 mL - Crohn’s Disease or Ulcerative Colitis Starter Pack</td>
<td>0074-0124-03</td>
<td>00074-0124-03</td>
</tr>
<tr>
<td>HUMIRA Pen 80 mg/0.8 mL – Pediatric Ulcerative Colitis Starter Pack</td>
<td>0074-0124-04</td>
<td>00074-0124-04</td>
</tr>
<tr>
<td>HUMIRA Prefilled Syringe 80 mg/0.8 mL - Pediatric Crohn’s Disease Starter Package</td>
<td>0074-2540-03</td>
<td>00074-2540-03</td>
</tr>
<tr>
<td>HUMIRA Prefilled Syringe 80 mg/0.8 mL and 40 mg/0.4 mL - Pediatric Crohn’s Disease and Pediatric Ulcerative Colitis Starter Package</td>
<td>0074-0067-02</td>
<td>00074-0067-02</td>
</tr>
</tbody>
</table>

*Only citrate-free doses relevant to gastroenterology are shown here. For complete dosing information, including HUMIRA with citrate-buffers, refer to the full Prescribing Information for HUMIRA.

For additional guidance on coding, please refer to the Department of Health and Human Services Evaluation and Management Services guide available at [www.cms.gov](http://www.cms.gov)

Please see Indications and Important Safety Information, including 
BOXED WARNING on Serious Infections and Malignancy, on pages 14-15.
Please click here for full [Prescribing Information](http://www.cms.gov).
Billing codes for HUMIRA

Healthcare Common Procedure Coding System (HCPCS) code

<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>Description</th>
<th>Payer type</th>
</tr>
</thead>
<tbody>
<tr>
<td>J0135</td>
<td>Injection, adalimumab</td>
<td>Commercial, Medicare</td>
</tr>
</tbody>
</table>

Check with the specific payer to verify the most appropriate HCPCS codes and additional coding and billing requirements for HUMIRA.

CMS-1500 and CMS-1450 commercial and Medicare coding

<table>
<thead>
<tr>
<th>Procedure type</th>
<th>CPT code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office visit, new patient</td>
<td>99201-99205</td>
</tr>
<tr>
<td>Office visit, established patient</td>
<td>99211-99215</td>
</tr>
<tr>
<td>Prolonged service without direct patient contact by the physician or non-physician practitioner</td>
<td>99358</td>
</tr>
<tr>
<td>Hospital outpatient visit (CMS-1450, Medicare only)</td>
<td>G0463</td>
</tr>
</tbody>
</table>

*The codes shown are only suggestions. The codes you need may vary by patient.

Considerations when using evaluation and management CPT® codes

HCP services are generally billed using evaluation and management codes, which may be accompanied by prolonged service codes when appropriate.

For support in person or over the phone, call an Access Specialist at 1.877.COMPLETE (1.877.266.7538)

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15. Please click here for full Prescribing Information.
Completing a CMS-1500 form

Sample CMS-1500, use to submit claims to commercial insurance and Medicare for HUMIRA administered in your office

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15.
Please click here for full Prescribing Information.
Completing a CMS-1500 form (cont’d)

If you are purchasing HUMIRA from a distributor and need to submit a claim for reimbursement, you can use the CMS-1500 form.

1. Item 19: When completing a claim for a drug that does not have a permanent HCPCS code, include the drug name, drug strength, unit of measure, number of units administered (and discarded), total dosage, route of administration, and 11-digit NDC.

2. Item 21: Indicate the diagnosis using the appropriate ICD-10 code (see pages 3, 5 and 7 for codes). The “ICD Indicator” identifies the ICD code set being reported. Enter 0 (zero) as a single digit between the vertical, dotted lines.

3. Item 24A: If line item NDC information is required, enter it in the shaded portion of Item 24A.

4. Item 24B: Enter 11 (in place of a service code for physician offices).

5. Item 24D: Indicate appropriate CPT® and HCPCS codes. See page 9 of this guide for codes.

6. Item 24E: Refer to the diagnosis for this service (see Item 21 above). Enter only 1 diagnosis pointer per line.

7. Item 24F: Typically, enter average wholesale price (AWP), invoice price, or whichever price method is stated in your contract with the payer.

8. Item 24G: Enter the number of units.

For support in person or over the phone, call an Access Specialist at 1.877.COMPLETE (1.877.266.7538)

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies. For more information, please call an Access Specialist at 1.877.COMPLETE (1.877.266.7538).

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15. Please click here for full Prescribing Information.
Sample CMS-1450, use to submit claims to commercial insurance and Medicare for HUMIRA administered in a hospital outpatient setting.

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15. Please click here for full Prescribing Information.
Completing a CMS-1450 form (cont’d)

If you are purchasing HUMIRA from a distributor and need to submit a claim for reimbursement, you can use the CMS-1450 form.

1. **Locator Box 42**: List revenue codes in ascending order.

2. **Locator Box 43**: Enter narrative description of corresponding revenue code (e.g., clinic, lab general). If line item NDC information is required, enter it in the unshaded portions of Locator Box 43. Payer requirements for NDC entries may vary.

3. **Locator Box 44**: Indicate appropriate CPT® and HCPCS codes as required by the payer. See page 9 of this guide for codes.

4. **Locator Box 46**: Enter the number of units.

5. **Locator Box 67**: Indicate the diagnosis using the ICD-10-CM code that supports medical justification for your patient’s condition (see pages 3, 5 and 7 for ICD codes).

6. **Locator Box 80**: Additional details you may want to include are the drug name, drug strength, unit of measure, number of units administered (and discarded), total dosage, route of administration, and 11-digit NDC. PA (or pre-certification) code may also be required by commercial plans.

For support in person or over the phone, call an Access Specialist at 1.877.COMPLETE (1.877.266.7538)

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies. For more information, please call an Access Specialist at 1.877.COMPLETE (1.877.266.7538).

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 14-15. Please click here for full Prescribing Information.
INDICATIONS

- **Rheumatoid Arthritis:** HUMIRA is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, 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.

- **Juvenile Idiopathic Arthritis:** HUMIRA is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.

- **Psoriatic Arthritis:** HUMIRA is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis.

- **Ankylosing Spondylitis:** HUMIRA is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

- **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.

- **Plaque Psoriasis:** 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.

- **Hidradenitis Suppurativa:** HUMIRA is indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

- **Uveitis:** HUMIRA is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION

**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 possible increased risk for infections and other potential pharmacological interactions.

Please see additional Important Safety Information continued on page 15.

Please click here for full Prescribing Information.
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.

References:

Please click here for full Prescribing Information.