HUMIRA COMPLETE

Guide to billing and coding

Overview of relevant codes

INDICATIONS[1]

- **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.

DMARD, disease-modifying antirheumatic drug; TNF, tumor necrosis factor.

Please see additional Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 13 and 14.

Please click here for full Prescribing Information.

HUMIRA® adalimumab

Overview of relevant rheumatology codes

ICD-10-CM diagnosis codes[2]*

Rheumatoid Arthritis (RA)

ICD-10 code	Description
M05.00 - M05.9	Rheumatoid arthritis with rheumatoid factor
M06.00 - M06.09	Other rheumatoid arthritis without rheumatoid factor

Ankylosing Spondylitis (AS)

ICD-10 code	Description
M45.0 - M45.9	Ankylosing spondylitis of spinal regions

Uveitis (UV)

ICD-10 code	Description
H20.9	Unspecified iridocyclitis; Uveitis NOS
H44.11 - H44.119	Panuveitis
H44.13 - H44.139	Sympathetic uveitis

Juvenile Idiopathic Arthritis (JIA)

ICD-10 code	Description
M08.00 - M08.09	Unspecified juvenile rheumatoid arthritis
M08.20 - M08.29	Juvenile rheumatoid arthritis with systemic onset
M08.40 - M08.48	Pauciarticular juvenile rheumatoid arthritis
M08.8	Other juvenile arthritis

***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.**
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NOS, not otherwise specified.

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 13 and 14.

Please click here for full Prescribing Information.

HUMIRA dosing and NDC codes for rheumatology

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.

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

*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**

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 13 and 14.

Please click here for full Prescribing Information.

HUMIRA COMPLETE

HUMIRA® adalimumab

Overview of relevant dermatology codes

ICD-10-CM diagnosis codes[2]*

Plaque psoriasis (Ps)

ICD-10 code	Description
L40.0	Psoriasis vulgaris
L40.8	Flexural psoriasis
L40.9	Psoriasis, unspecified

Psoriatic Arthritis (PsA)

ICD-10 code	Description
L40.50	Arthropathic psoriasis, unspecified

Hidradenitis Suppurativa (HS)

ICD-10 code	Description
L73.2	Hidradenitis suppurativa

***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.**
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Providers are encouraged to contact third-party payers for specific information about their coverage policies.

HUMIRA dosing and NDC codes for dermatology

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.

HUMIRA Citrate-free dose*	10-digit NDC code	11-digit NDC code
HUMIRA Pen Carton – 40 mg/0.4 mL	0074-0554-02	00074-0554-02
HUMIRA Pen Carton – 80 mg/0.8 mL	0074-0124-02	00074-0124-02
Prefilled Syringe Carton – 40 mg/0.4 mL	0074-0243-02	00074-0243-02
HUMIRA Pen 40 mg/0.4 mL – Starter Package for Hidradenitis Suppurativa	0074-0554-06	00074-0554-06
HUMIRA Pen 80 mg/0.8 mL – Starter Package for Hidradenitis Suppurativa	0074-0124-03	00074-0124-03
HUMIRA Pen 40 mg/0.4 mL – Psoriasis or Adolescent Hidradenitis Suppurativa Starter Package	0074-0554-04	00074-0554-04
HUMIRA Pen 80 mg/0.8 mL and 40 mg/0.4 mL – Psoriasis or Adolescent Hidradenitis Suppurativa Starter Package	0074-1539-03	00074-1539-03

*Only citrate-free doses relevant to dermatology are shown here. For citrate-free rheumatology dosing, please see page 3 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 13 and 14.

Please click here for full Prescribing Information.

HUMIRA COMPLETE

HUMIRA® adalimumab

Overview of relevant gastroenterology codes

ICD-10-CM diagnosis codes[2]*

Crohn's Disease (CD)

ICD-10 code	Description
K50.0 - K50.9	Crohn's Disease [regional enteritis]

Ulcerative Colitis (UC)

ICD-10 code	Description
K51.0 - K51.9	Ulcerative Colitis

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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.

TNF, tumor necrosis factor.

Please see Indications and additional Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 13 and 14.

Please click here for full Prescribing Information.

HUMIRA dosing and NDC codes for gastroenterology

How do I provide my patients with HUMIRA Citrate-free?

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- 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.

HUMIRA Citrate-free dose*	10-digit NDC code	11-digit NDC code
HUMIRA Pen Carton – 40 mg/0.4 mL	0074-0554-02	00074-0554-02
HUMIRA Pen Carton – 80 mg/0.8 mL	0074-0124-02	00074-0124-02
Prefilled Syringe Carton – 40 mg/0.4 mL	0074-0243-02	00074-0243-02
Prefilled Syringe Carton – 20 mg/0.2 mL	0074-0616-02	00074-0616-02
Prefilled Syringe Carton – 10 mg/0.1 mL	0074-0817-02	00074-0817-02
HUMIRA Pen 40 mg/0.4 mL – Crohn's Disease or Ulcerative Colitis Starter Pack	0074-0554-06	00074-0554-06
HUMIRA Pen 80 mg/0.8 mL – Crohn's Disease or Ulcerative Colitis Starter Pack	0074-0124-03	00074-0124-03
HUMIRA Pen 80 mg/0.8 mL – Pediatric Ulcerative Colitis Starter Pack	0074-0124-04	00074-0124-04
HUMIRA Prefilled Syringe 80 mg/0.8 mL – Pediatric Crohn's Disease Starter Package	0074-2540-03	00074-2540-03
HUMIRA Prefilled Syringe 80 mg/0.8 mL and 40 mg/0.4 mL – Pediatric Crohn's Disease Starter Package	0074-0067-02	00074-0067-02

*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**

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 13 and 14.

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HUMIRA COMPLETE

HUMIRA® adalimumab

Billing codes for HUMIRA

Healthcare Common Procedure Coding System (HCPCS) code[3]

HCPCS code	Description	Payer type
J0135	Injection, adalimumab	Commercial, Medicare

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[4]*

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

***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 13 and 14.

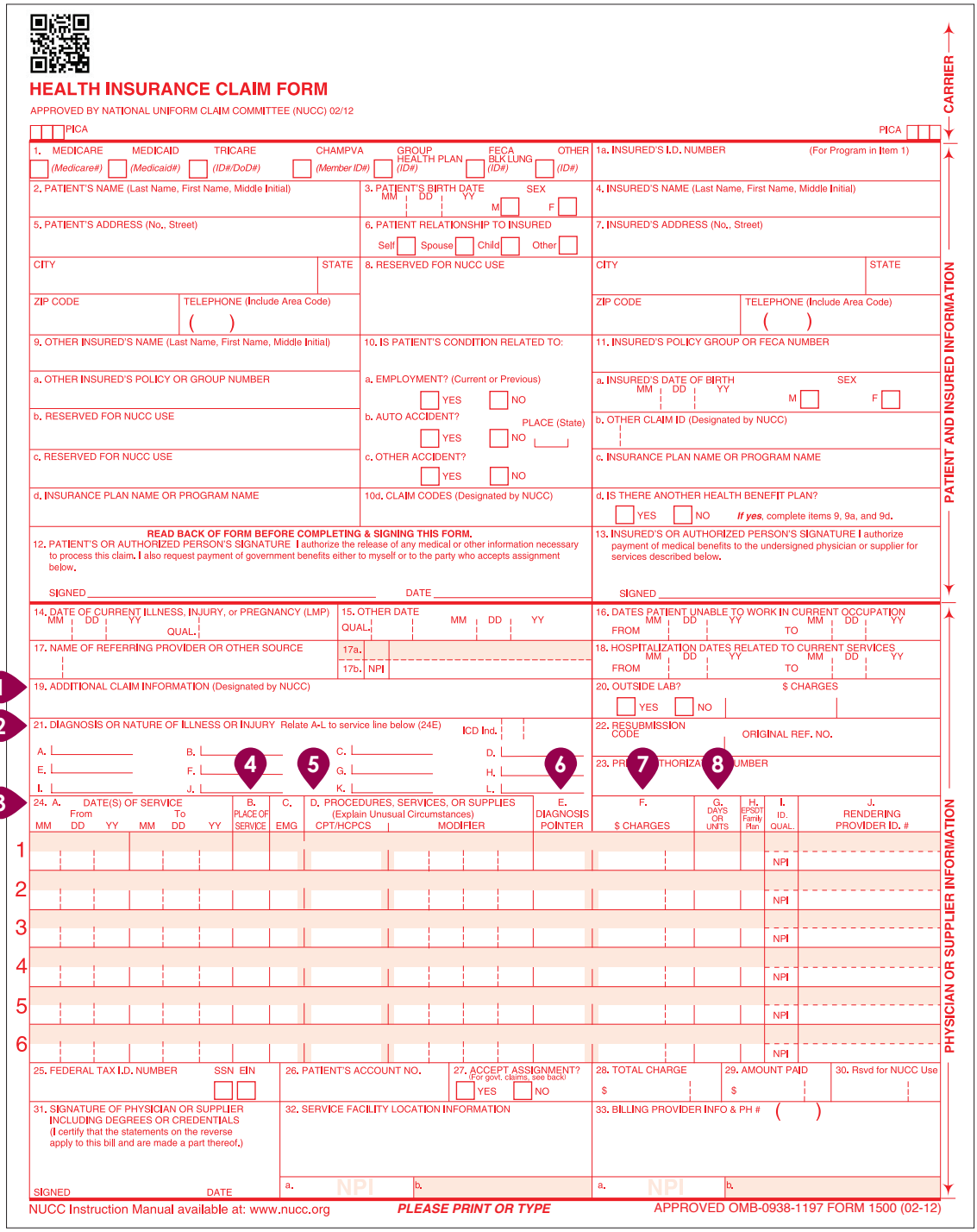
Please click here for full Prescribing Information.

HUMIRA COMPLETE

HUMIRA® adalimumab

Completing a CMS-1500 form

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



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

1 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

2 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

3 24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI
2 NPI
3 NPI
4 NPI
5 NPI
6 NPI

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

4 5 6 7 8

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 13 and 14.

Please click here for full Prescribing Information.

HUMIRA COMPLETE

HUMIRA® adalimumab

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-CM code (see pages 2, 4, and 6 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 8 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.

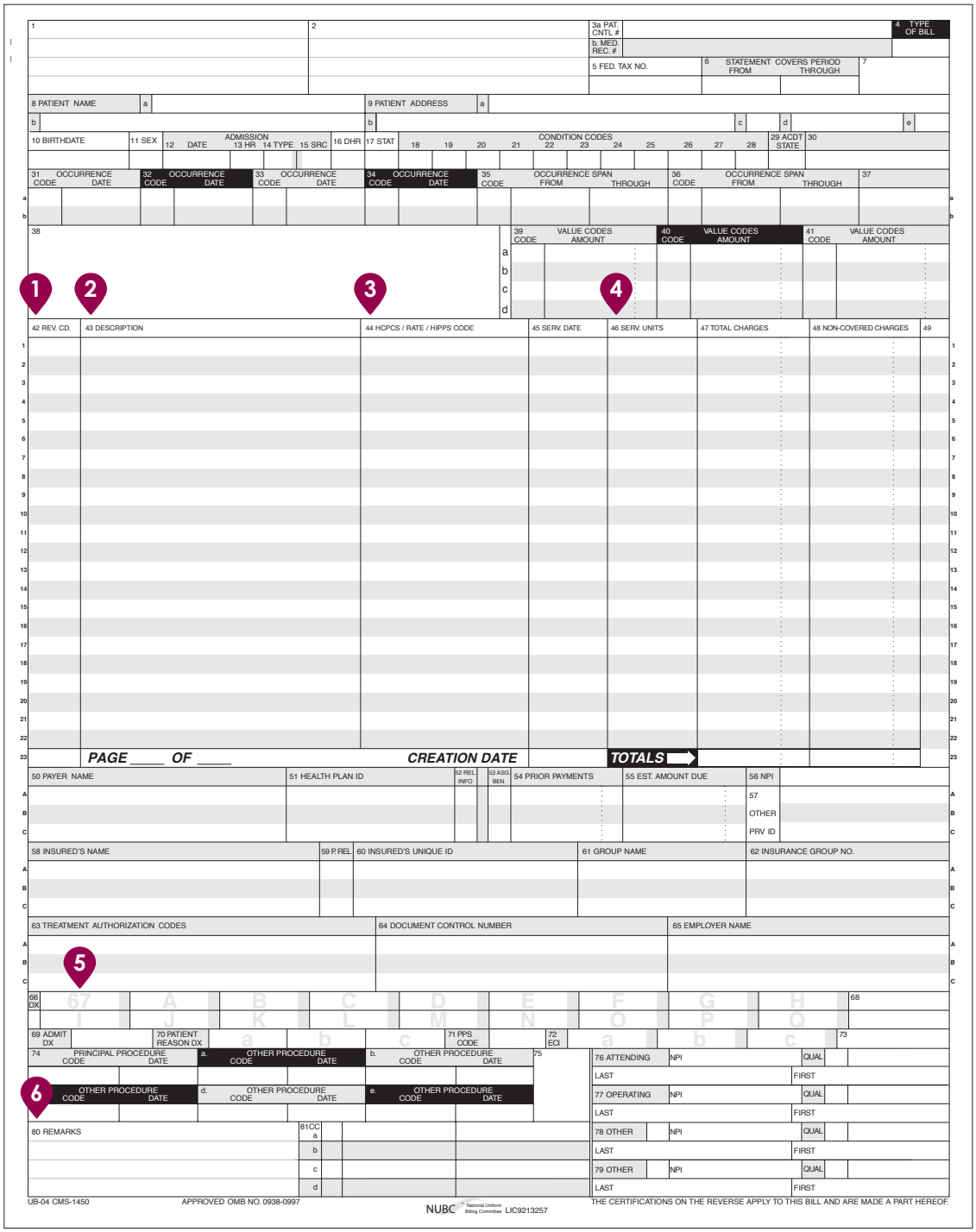
8. **Item 24G:** Enter the number of units.

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).

Completing a CMS-1450 form

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 13 and 14.

Please click here for full Prescribing Information.

HUMIRA COMPLETE

HUMIRA® adalimumab

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 (eg, 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 8 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 2, 4, and 6 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.

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PA, prior authorization.

Please see Indications and Important Safety Information, including BOXED WARNING on Serious Infections and Malignancy, on pages 13 and 14.

Please click here for full Prescribing Information.

HUMIRA COMPLETE

HUMIRA® adalimumab

Indications and Important Safety Information for HUMIRA® (adalimumab)

INDICATIONS[1]

- **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[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.

DMARD, disease-modifying antirheumatic drug; TNF, tumor necrosis factor.

Please see additional Important Safety Information, including BOXED WARNING continued on page 14.

Please click here for full Prescribing Information.

HUMIRA® adalimumab

Important Safety Information for HUMIRA® (adalimumab)[1] (cont'd)

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.

TNF, tumor necrosis factor.

References: 1. HUMIRA Injection [package insert]. North Chicago, IL: AbbVie Inc. **2.** Centers for Disease Control and Prevention. ICD-10-CM Tabular list 2022. Updated February 11, 2022. **3.** Centers for Medicare and Medicaid Services. HCPCS NOC Codes. Accessed May 7, 2020. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File **4.** Center for Medicare and Medicaid Services. Medicare Risk Adjustment Model CPT/HCPCS Filtering Included List. Accessed May 7, 2020. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/CPT-HCPCS.html

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HUMIRA®
adalimumab