Adalimumab-**aacf**

Adalimumab-aacf
Injection for subcutaneous use

Billing & Coding Guide

Important Safety Information for Adalimumab-aacf

SERIOUS INFECTIONS

Patients treated with Adalimumab-aacf 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 Adalimumab-aacf 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 Adalimumab-aacf use and during therapy. Initiate treatment for latent TB prior to Adalimumab-aacf 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 antifungal therapy in patients at risk for invasive fungal**

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information, including **Boxed Warning** for **SERIOUS INFECTIONS** and **MALIGNANCY** for Adalimumab-**aacf**.

FRESENIUS KABI

The Adalimumab-aacf Billing and Coding Guide provides general reimbursement information for healthcare providers.

Topics include billing, coding, coverage, and reimbursement for treatment with Adalimumab-aacf.

The content provided in this guide is for informational purposes only and is not intended as legal advice or to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare professional to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure Adalimumab-aacf claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee that payers will consider all codes appropriate for all encountered scenarios and Fresenius Kabi does not guarantee Adalimumab-Adalimumab-aacf coverage or reimbursement.

INDICATIONS AND USAGE[1]

- **Rheumatoid Arthritis (RA):** Adalimumab-aacf 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 (JIA):** Adalimumab-aacf 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 (PsA):** Adalimumab-aacf is indicated, alone or in combination with nonbiologic 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 (AS):** Adalimumab-aacf is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- **Crohn's Disease (CD):** Adalimumab-aacf 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 (UC):** Adalimumab-aacf is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

  Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque Psoriasis (Ps):** Adalimumab-aacf 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. Adalimumab-aacf should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis Suppurativa (HS):** Adalimumab-aacf is indicated for the treatment of moderate to severe hidradenitis suppurativa in adults.
- **Uveitis (UV):** Adalimumab-aacf is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.

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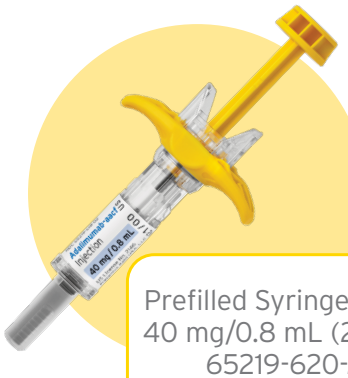
Available formulations of Adalimumab-aacf

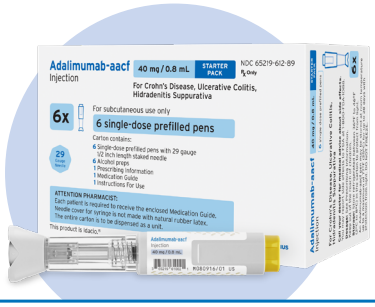
Adalimumab-aacf is available as an autoinjector pen and prefilled syringe[1]

Prefilled Autoinjector Pen Carton
40 mg/0.8 mL (2 count)
65219-612-99



Prefilled Syringe Carton
40 mg/0.8 mL (2 count)
65219-620-20

Prefilled Autoinjector Pen Starter Package for Plaque Psoriasis or Uveitis
40 mg/0.8 mL (4 Count)
NDC# 65219-612-69



Prefilled Autoinjector Pen Starter Package for Crohn's Disease, Ulcerative Colitis, or Hidradenitis Suppurativa
40 mg/0.8 mL (6 Count)
NDC# 65219-612-89

Important Safety Information (continued)

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 Adalimumab-aacf 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 Adalimumab-aacf, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Treatment with Adalimumab-aacf should not be initiated in patients with an active infection, including localized infections.
- Patients 65 years of age and older, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants (such as corticosteroids or methotrexate), may be at greater risk of infection.
- Discontinue Adalimumab-aacf if a patient develops a serious infection or sepsis. For a patient who develops a new infection during treatment with Adalimumab-aacf, closely monitor them, perform a prompt and complete diagnostic workup appropriate for an immunocompromised patient, and initiate appropriate antimicrobial therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in RA patients treated

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ICD-10 CODES

This coding information may assist you as you complete the payer forms for Adalimumab-aacf.

ICD-10-CM Codes[2] for Consideration*	
Rheumatoid Arthritis (RA)	
M05.00 - M05.9	Rheumatoid arthritis with rheumatoid factor
M06.00 - M06.09	Other rheumatoid arthritis without rheumatoid factor
Ankylosing Spondylitis (AS)	
M45.0-45.9	Ankylosing spondylitis of spinal regions
Juvenile Idiopathic Arthritis (JIA)	
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
Plaque Psoriasis (Ps)	
L40.0	Psoriasis vulgaris
L40.1	Generalized pustular psoriasis
L40.2	Acrodermatitis continua
L40.3	Pustular palmaris et plantaris
L40.4	Guttate psoriasis
L40.8	Other psoriasis
L40.9	Psoriasis, unspecified
Psoriatic Arthritis (PsA)	
L40.50	Arthropathic psoriasis, unspecified
Crohn's Disease (CD)	
K50.0-K50.9	Crohn's Disease (regional enteritis)
Ulcerative Colitis (UC)	
K51.0-K51.9	Ulcerative Colitis

*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 practices.

HCPCS

Healthcare Common Procedure Coding System (HCPCS)

HCPCS Code for Adalimumab-aacf[3*]			
Code	**Description**	**Site of Service**	**Billing Units**
Q5144	Injection, **Adalimumab-aacf**, biosimilar, 1 mg	All	1 mg

CMS Final HCPCS Coding Decision Establish a new HCPCS Level II code Q5144, "Injection, **Adalimumab-aacf**, biosimilar, 1 mg." Check with the specific payer to verify the most appropriate HCPCS codes and additional coding and billing requirements for **Adalimumab-aacf**.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing, coding, and KabiCare patient support offerings.

Important Safety Information (continued)

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 adalimumab products 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 adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including adalimumab products. 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 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 TNF-blocker treatment prior to initiating or continuing therapy in a patient with known malignancy.

MODIFIERS

Summary of Code Modifiers				
Modifier	**Description[4]**	**Indication and Placement[5-7]**	**CMS-1500 (Item 24D)**	**CMS-1450 (Box 44)**
JA	Administered via intravenous solution	For drugs that have only one HCPCS Level II (J or Q) code but multiple routes of administration, providers should append one of the following modifiers (JA or JB) to describe the given route of administration.	✓ Required by Medicare	✓ Required by Medicare
JB	Administered via subcutaneous injection	For drugs that have only one HCPCS Level II (J or Q) code but multiple routes of administration, providers should append one of the following modifiers (JA or JB) to describe the given route of administration.	✓ Required by Medicare	✓ Required by Medicare
JW	Drug amount discarded/ not administered to any patient	Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial.	✓ Required by Medicare	✓ Required by Medicare
JZ	Zero drug amount discarded/not administered to any patient	To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage).	✓ Required by Medicare	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	TB modifier is used to identify drugs or biologicals acquired through the 340B Drug Pricing Program for informational purposes. The TB modifier is required for all 340B covered entities, including hospital-based and non-hospital-based entities, for claims with dates of service beginning on or after January 1, 2025. TB modifier to be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs.	N/A	✓ Required by Medicare

IMPORTANT NOTICE: As of October 1, 2023, CMS rejects "single-dose" drug claims without modifier JZ or JW may be returned unprocessable until claims are properly submitted including waste modifiers—per Discarded Drugs and Biologicals. The JW and JZ modifier policy applies to all providers and suppliers who buy and bill single-use-vials drugs under Medicare Part B.[3] Some commercial payers may require a waste modifier.

Important Safety Information (continued)

- In clinical trials of some TNF-blockers, including adalimumab products, more cases of malignancies were observed among TNF-blocker-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimuma-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 Adalimumab-aacf.
- In adalimumab 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.

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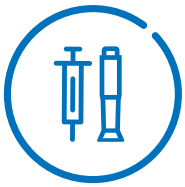
NDC Numbers



What codes do I use to bill for Adalimumab-aacf?

- A new prescription is required for **Adalimumab-aacf**.
- To ensure your patient will receive **Adalimumab-aacf**, 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. Check with the payer to confirm the correct code required when billing to **Adalimumab-aacf**.

Dosage Form	Description	10-digit NDC Code	11-digit NDC Code
Subcutaneous Injection	Prefilled Syringe, 40mg/0.8 mL, single-dose	65219-620-20	65219-0620-20
	Prefilled Autoinjector Pen,40 mg/0.8 mL, single-dose	65219-612-99	65219-0612-99
	Prefilled Autoinjector Pen Starter Pack for plaque psoriasis or uveitis, 40 mg/0.8 mL, single-dose	65219-612-69	65219-0612-69
	Prefilled Syringe Starter Pack for Crohn's Disease, ulcerative colitis, or hidradenitis suppurative, 40 mg/0.8 mL, single-dose	65219-612-89	65219-0612-89

Current Procedural Terminology (CPT) Code[8]

CPT codes are the standard coding system for reporting medical procedures and services under both public and private health insurance plans.

Type	Code	Description
CPT Code	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.

All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement.

Important Safety Information (continued)

HYPERSENSITIVITY

- Anaphylaxis and angioneurotic edema have been reported following administration of adalimumab products. If an anaphylactic or other serious allergic reaction occurs, immediately discontinue administration of Adalimumab-aacf and institute appropriate therapy. In clinical trials of adalimumab, hypersensitivity reactions (e.g., rash, anaphylactoid reaction, fixed drug reaction, non-specified drug reaction, urticaria) have been observed.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including Adalimumab-aacf, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. In some instances, HBV reactivation occurring in conjunction with TNF blocker therapy has been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.
- Exercise caution in prescribing TNF blockers for patients identified as carriers of HBV.

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Physician's Office Billing Information[9]

Adalimumab-aacf Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Enter appropriate HCPCS Q5144 and appropriate modifiers.
Number of Units in **Block 24G**: (Electronic Form: Loop 2400, SV1, 04 [03=UN])	Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit (a 40 mg syringe or pen is billed as 40 units).
Administration and Professional Service Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Indicate appropriate CPT code 96372.
Diagnosis Code Information*	
ICD-10-CM Code in **Block 21**: (Electronic Form: Loop 2300, HI, 01-2)	Indicate diagnosis using appropriate ICD-10 CM codes. Use diagnosis codes to highest level of specificity for the date of service and enter the diagnosis in priority order.

* The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for Adalimumab-aacf. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Important Safety Information (continued)

- In patients who develop HBV reactivation, stop Adalimumab-aacf and initiate effective anti-viral therapy with appropriate supportive treatment. The safety of resuming TNF blocker therapy after HBV reactivation is controlled is not known. Therefore, exercise caution when considering resumption of Adalimumab-aacf therapy in this situation and monitor patients closely

NEUROLOGICAL REACTIONS

- Use of TNF blocking agents, including adalimumab products, has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disease, including multiple sclerosis (MS) and optic neuritis, and peripheral demyelinating disease, including Guillain-Barré syndrome.
- Exercise caution in considering the use of Adalimumab-aacf in patients with preexisting or recent-onset central or peripheral nervous system demyelinating disorders; discontinuation of Adalimumab-aacf should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

HEMATOLOGICAL REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with adalimumab products.
- Consider stopping Adalimumab-aacf if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

- Worsening or new onset congestive heart failure (CHF) may occur; exercise caution and monitor carefully.

AUTOIMMUNITY

- Treatment with adalimumab products 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 Adalimumab-aacf should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating Adalimumab-aacf 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 Adalimumab-aacf *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 adalimumab clinical trials (>10%) were: infections (e.g. upper respiratory, sinusitis), injection site reactions, headache and rash.

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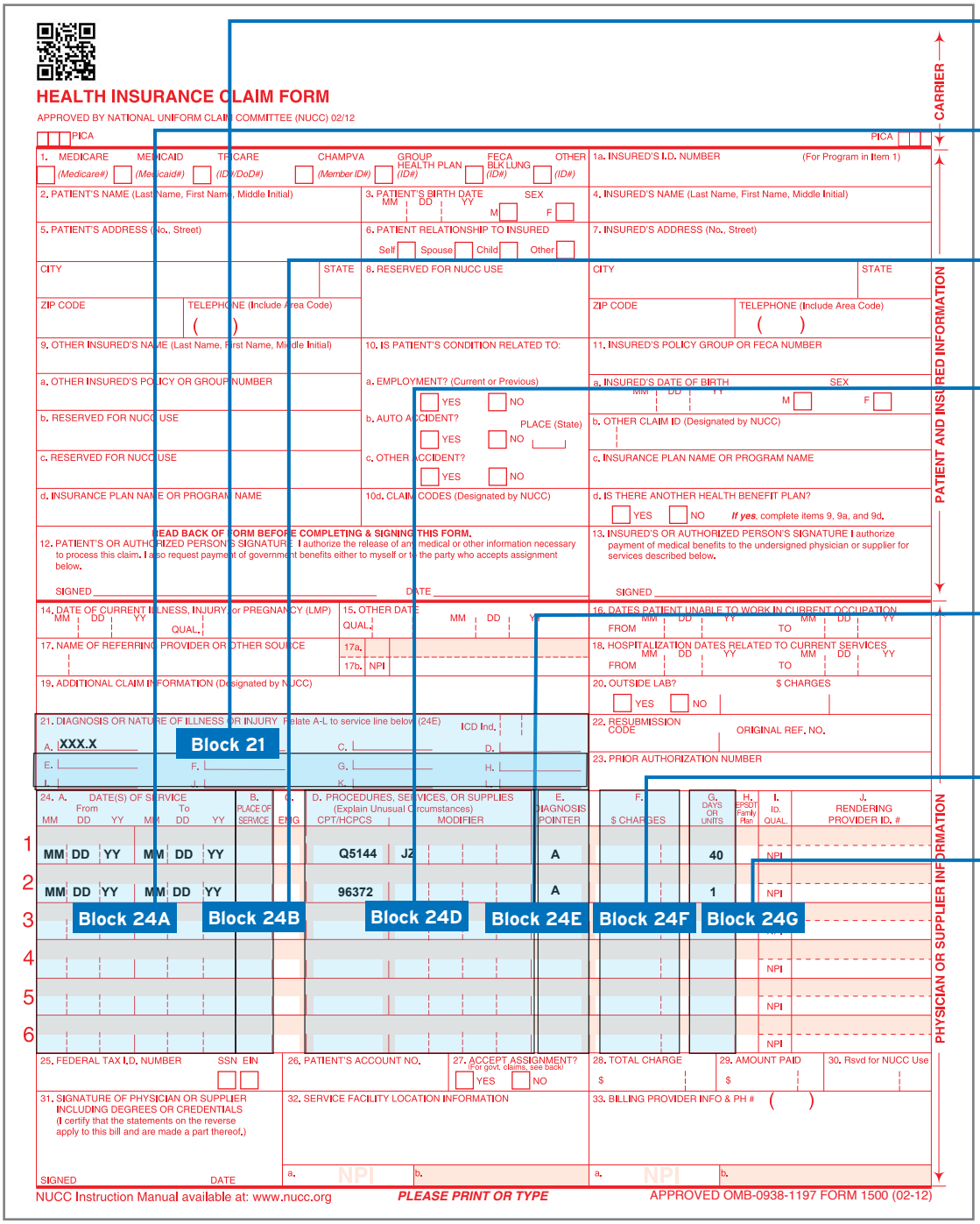
Sample CMS 1500 Claim Form
(physician office site of service)[9]

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure **Adalimumab-aacf** claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee **Adalimumab-aacf** coverage or reimbursement.



Block 21: Diagnosis

Enter appropriate ICD-10-CM diagnosis code(s).

Block 24A: Date(s) of Service

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

Block 24B: Place of Service

Enter Place of Service Code such as 11 for physician office

Block 24D: Procedures, Services, or Supplies

Enter appropriate HCPCS and CPT codes. For example:

- Drug: HCPCS Code Q5144 (billable as 40 units)
- Administration: 96372 for subcutaneous injection

Block 24E: Diagnosis Pointer

Refer to the diagnosis for this service from line 21, enter only 1 diagnosis pointer per line.

Block 24F: $ Charges

Indicate total charges.

Block 24G: Units

Q5144/96372-Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit (a 40 mg syringe or pen is billed as 40 units).

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Hospital/Institutional Billing[10]

Adalimumab-aacf Coding Information*	
Revenue Code in **Form Location (FL) 42**: (Electronic Form: Loop 2400, SV201)	List revenue codes in ascending order.
Coding Information in **FL 44**: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Enter appropriate HCPCS/Modifiers and CPT codes. Q5144—Injection, **Adalimumab-aacf**, biosimilar, 1 mg.
Service Units in **FL 46**: (Electronic Form: Loop 2400, SV205)	Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit (a 40 mg syringe or pen is billed as 40 units).
Administration and Professional Service Coding Information*	
Revenue Code in **FL 42**: (Electronic Form: Loop 2400, SV201)	Appropriate revenue code for the cost center in which the service is performed.
Description in **FL 43**: (Not required by Medicare)	Enter narrative description of corresponding revenue code (e.g., clinic, lab, infusion).
Coding Information in **FL 44**: (Electronic Form: Loop 2400, SV202-2 [SV202-1=HC/HP])	Enter appropriate CPT codes and modifiers.
Diagnosis Code Information*	
ICD-10-CM Code in **FL 67**: (Electronic Form: Loop 2300, HI01-2 [HI01-1=BK])	Appropriate ICD-10-CM code(s) for patient condition. Sequencing of codes may vary based on patient's condition and payer's policy.

*The sample codes are informational and not intended to be directive or a guarantee of reimbursement and include potential codes that would include FDA-approved indications for **Adalimumab-aacf**. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Important Safety Information (continued)

INDICATIONS

- **Rheumatoid Arthritis (RA):** Adalimumab-aacf 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 (JIA):** Adalimumab-aacf 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 (PsA):** Adalimumab-aacf 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 (AS):** Adalimumab-aacf is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
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- **Ulcerative Colitis (UC):** Adalimumab-aacf is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

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

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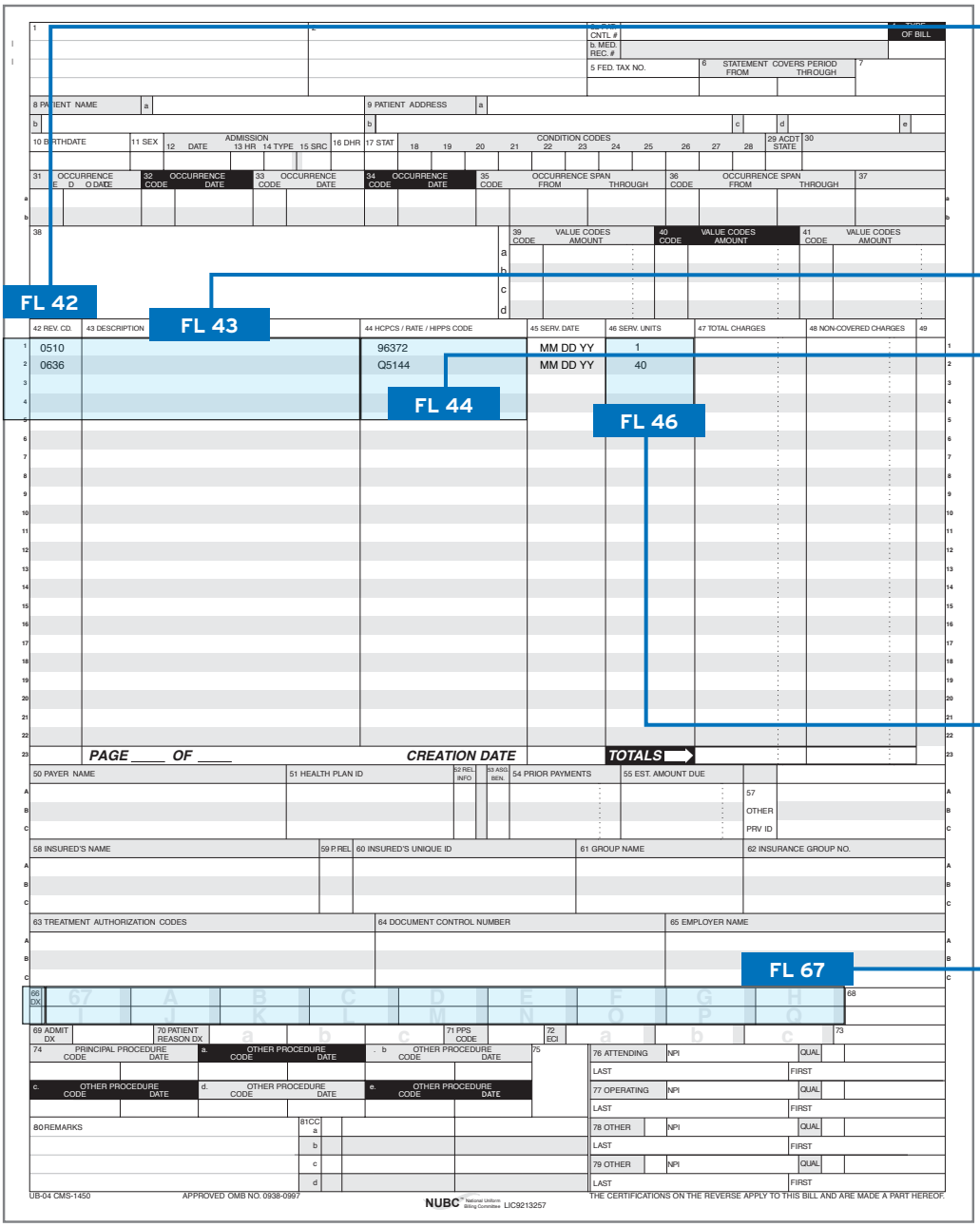
Sample CMS 1450 (UB-04) Claim Form

(hospital outpatient site of service)[10]

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure **Adalimumab-aacf** claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee **Adalimumab-aacf** coverage or reimbursement.



FL 42

Enter the appropriate revenue code and procedure description.
For example:
- 0510: clinic—general classification (for SC injection administered in the clinic)
- 0636: drugs requiring detailed coding

FL 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.

FL 44

Enter appropriate HCPCS and CPT codes and modifiers.
For example:
- Drug: HCPCS Code Q5144
- Administration: 96372 for subcutaneous injection

FL 46

Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit (a 40 mg synige or pen is billed as 40 units).

FL 67

Indicate the diagnosis using the ICD10-CM code that supports the medical justification for your patient's condition.

Additional documentation for filing your claim

In addition to the CMS 1500 or CMS 1450 (UB-04) claim form, the payer may request the following:

- Patient medical history
- Physician clinical notes
- PA number
- May require an invoice
- Drug-identifying information (e.g., NDC)
- Letter of medical necessity
- Letter of appeal

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KabiCare Reimbursement and Payment Support

KabiCare provides comprehensive access and support resources for patients including but not limited to:

Enrollment Support

- **Case Management Support** – KabiCare helps your team navigate insurance processes and provides information related to your patient's insurance coverage. After enrollment is complete and insurance is confirmed, your patient will receive a phone call from KabiCare to review their benefits and discuss other KabiCare resources that may be available.
- **Provider Access** – Centralized provider portal for submitting enrollments and checking patient status.

Insurance Support

- **Bridge to Therapy** – The Bridge to Therapy Program provides commercially insured patients access to treatment without delay while they are waiting for insurance approval. Eligibility criteria apply.*
- **Benefits Investigation** – Once your patient is enrolled, KabiCare conducts the benefits investigation on behalf of the patient to confirm insurance coverage details. The information is provided to you, your practice, and your patient to aid in patient access.
- **Prior Authorization Support** – If a prior authorization is needed, KabiCare will provide the appropriate forms to the office for completion and will help follow up on the status.
- **Billing & Coding Support** – KabiCare offers reimbursement resources to help you submit claims and understand eligibility for reimbursement.†
- **Claims Appeals Support** – Should a claim or prior authorization be denied, KabiCare will provide the appropriate appeal documentation and the information required to contest the denial similar to the prior authorization process. Visit KabiCare.us for a Sample Letter of Medical Necessity and Sample Letter of Appeal.

* Eligibility criteria apply. Patients are not eligible for commercial copay support and Bridge to Therapy program if the prescription is eligible to be reimbursed, in whole or in part by any state or federal healthcare programs.

† Terms and conditions apply.

‡ Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Fresenius Kabi has no control over these programs.

§ Clinical support provided by KabiCare™ is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

KabiCare Contact Information

Financial Support

- **Commercial Copay Support** – If your patient has commercial or private insurance, they may be eligible* for the copay program that lowers their out-of-pocket costs to as little as $0/month for treatment with an annual maximum.
- **Patient Assistance Program** – If your patient does not have insurance or their plan does not cover their medication, they may be eligible for additional assistance through the Patient Assistance Program or through independent nonprofit assistance programs. Eligibility criteria apply.‡

Clinical Support

- **Clinical Support** – KabiCare clinical support can provide medication counseling, offer self-injection training for applicable products, and answer questions your patient may have about their Fresenius Kabi biosimilar.§
- **Specialty Pharmacy Support** – The Patient Support Guide will coordinate with the specialty pharmacy to ensure proper triage of the prescription with benefit details to facilitate a timely dispense.

KabiCare
Patient support from Fresenius Kabi

Call 1-833-KABICARE
(1-833-522-4227)
Monday through Friday
8 a.m. to 8 p.m. ET
(excluding holidays)

Fax 1-833-302-1420

Visit our website at KabiCare.us

To learn more about the KabiCare patient support program, please scan the QR code:

Please see Important Safety Information throughout this brochure and click to see Full Prescribing Information, including **Boxed Warning** for **SERIOUS INFECTIONS** and **MALIGNANCY** for Adalimumab-**aacf**.

Adalimumab-aacf treatment approval process

Benefits verification

Complete a thorough assessment and investigation of benefits before administering **Adalimumab-aacf** to determine that the patient's coverage is in effect at the time of injection and to see if any additional information is required to obtain coverage.

Benefits verification checklist

Confirm the following with the patient's insurance plan:

- The patient is actively covered
- Insurance policy effective and termination dates
- Whether the patient has a secondary insurer (in addition to primary)
- Whether the product is covered under medical benefit, pharmacy benefit, or both
- The insurance holder's name and relationship to the patient
- In-network or out-of-network coverage
- HCPCS Q-Code, CPT® code for administration, diagnosis code, and number of units covered
- Whether a prior authorization (PA) and supplemental documentation/medical record is required
- The patient's financial responsibility (copay, coinsurance percentage, deductible)
- The policy limits, including exclusions or documentation requirements
- If uninsured, whether the patient may be eligible for the Patient Assistance Program

Please contact KabiCare for assistance

Important Safety Information (continued)

- **Plaque Psoriasis (Ps):** Adalimumab-aacf 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. Adalimumab-aacf should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.
- **Hidradenitis Suppurativa (HS):** Adalimumab-aacf is indicated for the treatment of moderate to severe hidradenitis suppurativa in adults.
- **Uveitis (UV):** Adalimumab-aacf is indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.

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Notes

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Adalimumab-**aacf**

Adalimumab-aacf offers resources to help your patients start and stay on prescribed therapy

We are dedicated to providing your patients with ongoing support to help them access Fresenius Kabi medications as prescribed.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing, coding, and KabiCare patient support offerings.

References: 1. Adalimumab-aacf. Prescribing information. Fresenius Kabi, LLC; 2024. **2.** Centers for Medicare & Medicaid Services. ICD Code Lists: Valid ICD-10 List [excel file]. https://www.cms.gov/medicare/coordination-benefits-recovery/overview/icd-code-lists. Page last modified October 29, 2024. Accessed January 10, 2025. **3.** Centers for Medicare & Medicaid Services (CMS). Transmittal 13032: Hospital Outpatient Prospective Payment System (OPPS) Updates for January 2025. Published January 3, 2025. https://www.cms.gov/files/document/r13032cp.pdf. Accessed May 5, 2025. **4.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update: January 2025 Alpha-Numeric HCPCS Files [zip file]. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update. Page last modified December 17, 2024. Accessed January 10, 2025. **5.** Enhanced claim editor program: Route of administration modifiers JA and JB. April 16, 2024. https://provcomm.ibx.com/pnc-ibc/news/Pages/Enhanced-Claim-Editor-Program-Route-of-Administration-Modifiers-JA-and-JB.aspx. Accessed January 20, 2025. **6.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17: Drugs and Biologicals. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf. Revised February 15, 2024. Accessed January 10, 2025. **7.** Centers for Medicare & Medicaid Services. Medicare Part B inflation rebate guidance: Use of the 340B Modifier. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf. Accessed January 10, 2025. **8.** American Medical Association. CPT® code 96372: Injection of drug/substance under skin or into muscle. American Medical Association. Published January 1, 2025. https://www.ama-assn.org/practice-management/cpt/cpt-code-96372-injection-drugsubstance-under-skin-or-muscle. Accessed April 28, 2025. **9.** Medicare claims processing manual, Chapter 26 - Completing and Processing Form CMS-1500 Data Set. cms.gov. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf. Accessed January 15, 2025. **10.** Medicare claims processing manual, Chapter 25 - Completing and Processing the Form CMS-1450 Data Set. cms.gov. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25pdf.pdf. Accessed January 15, 2025.

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