



**Idacio**<sup>®</sup>  
adalimumab-aacf

# Access & Reimbursement Guide

Information to Support the Access & Reimbursement Process for IDACIO<sup>®</sup>

## INDICATIONS

IDACIO<sup>®</sup> (adalimumab-aacf) is FDA-approved for the following indications similar to HUMIRA<sup>®</sup> (adalimumab)<sup>\*1</sup>: Rheumatoid Arthritis (RA) | Ankylosing Spondylitis (AS) | Juvenile Idiopathic Arthritis (JIA) | Psoriatic Arthritis (PsA) | Plaque Psoriasis (PsO) | Ulcerative Colitis (UC) | Crohn's Disease (CD)

\* IDACIO<sup>®</sup> is not currently approved in indications for which HUMIRA<sup>®</sup> maintains regulatory exclusivity protection: moderate to severe ulcerative colitis in pediatric patients 5 years and older, moderate to severe hidradenitis suppurativa in patients 12 years and older, and non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years and older.

## Important Safety Information

### SERIOUS INFECTIONS

Patients treated with IDACIO<sup>®</sup> (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 IDACIO<sup>®</sup> 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 IDACIO<sup>®</sup> use and during therapy. Initiate treatment for latent TB prior to IDACIO<sup>®</sup> use.

Please see Important Safety Information throughout this brochure and click to see accompanying [Full Prescribing Information](#), including **Boxed WARNING**, Medication Guide, and Instructions for Use for IDACIO<sup>®</sup> (adalimumab-aacf).



## INDICATIONS<sup>1</sup>

IDACIO<sup>®</sup> is a tumor necrosis factor (TNF) blocker indicated for:

- **Rheumatoid Arthritis (RA):** 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 RA.
  - **Juvenile Idiopathic Arthritis (JIA):** reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.
  - **Psoriatic Arthritis (PsA):** reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
  - **Ankylosing Spondylitis (AS):** reducing signs and symptoms in adult patients with active AS.
  - **Crohn's Disease (CD):** treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
  - **Ulcerative Colitis (UC):** treatment of moderately to severely active ulcerative colitis in adult patients.
- Limitations of Use:** Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.
- **Plaque Psoriasis (Ps) :** 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.

## Important Safety Information (continued)

- 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 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 IDACIO<sup>®</sup> 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 IDACIO<sup>®</sup>, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

## SAFETY CONSIDERATIONS<sup>1</sup>

### Serious Infections

Patients treated with IDACIO<sup>®</sup> 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 rate type of T-cell lymphoma, and other malignancies, some fatal, have been reported in patients treated with TNF blockers, including IDACIO<sup>®</sup>.

### Other Serious Adverse Reactions

Patients treated with IDACIO<sup>®</sup> may also 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.

Treatment with IDACIO<sup>®</sup> 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 IDACIO<sup>®</sup> if a patient develops a serious infection or sepsis. For a patient who develops a new infection during treatment with IDACIO<sup>®</sup>, 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

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.

## ICD-10-CM diagnosis codes<sup>2\*</sup>

### 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
M45.0-45.9	Ankylosing spondylitis of spinal regions

### 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.

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.



## How do I provide my patients with IDACIO<sup>®</sup>?

- The correct NDC must be used to ensure a correct pharmacy dispense.
- To ensure your patient will receive IDACIO<sup>®</sup>, please select the appropriate dosing from the Enrollment and Prescription Form or when prescribing electronically.

## National Drug Code (NDC)<sup>1</sup>

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 IDACIO<sup>®</sup>, a 0 is added in front of 556 to create 0556, and in front of 554 to create 0554). Check with the payer to confirm the correct code required when billing to IDACIO<sup>®</sup>.

NDC Number (PK)	10-digit NDC Code	11-digit NDC Code
IDACIO <sup>®</sup> Prefilled Syringe (PFS) 40 mg/0.8 mL (2-count)	65219-556-18	65219-0556-18
IDACIO <sup>®</sup> Prefilled Autoinjector Pen (PEN) 40 mg/0.8 mL (2-count)	65219-554-08	65219-0554-08



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).

## ICD-10-CM diagnosis codes<sup>2\*</sup>

### Plaque Psoriasis (Ps)

ICD-10 code	Description
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)

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

\*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.



## How do I provide my patients with IDACIO®?

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

## National Drug Code (NDC)<sup>1</sup>

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 IDACIO®, a 0 is added in front of 556 to create 0556, and in front of 554 to create 0554). Check with the payer to confirm the correct code required when billing to IDACIO®.

NDC Number (PK)	10-digit NDC Code	11-digit NDC Code
IDACIO® Prefilled Syringe (PFS) 40 mg/0.8 mL (2-count)	65219-556-18	65219-0556-18
IDACIO® Prefilled Autoinjector Pen (PEN) 40 mg/0.8 mL (2-count)	65219-554-08	65219-0554-08

Starter Packages	10-digit NDC Code	11-digit NDC Code
IDACIO® Prefilled Autoinjector Pen Starter Package for Plaque Psoriasis 40 mg/0.8 mL (4-count)	65219-554-28	65219-0554-28



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).

## ICD-10-CM diagnosis codes<sup>2\*</sup>

### 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

\*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.

## Important Safety Information (continued)

### 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.
- 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.



## How do I provide my patients with IDACIO®?

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

## National Drug Code (NDC)<sup>1</sup>

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 IDACIO®, a 0 is added in front of 556 to create 0556, and in front of 554 to create 0554). Check with the payer to confirm the correct code required when billing to IDACIO®.

NDC Number (PK)	10-digit NDC Code	11-digit NDC Code
IDACIO® Prefilled Syringe (PFS) 40 mg/0.8 mL (2-count)	65219-556-18	65219-0556-18
IDACIO® Prefilled Autoinjector Pen (PEN) 40 mg/0.8 mL (2-count)	65219-554-08	65219-0554-08

Starter Packages	10-digit NDC Code	11-digit NDC Code
IDACIO® Prefilled Autoinjector Pen Starter Package for Crohn's Disease and Ulcerative Colitis 40 mg/0.8 mL (6-count)	65219-554-38	65219-0554-38



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).

## Healthcare Common Procedure Coding System (HCPCS) codes<sup>3</sup>

HCPCS code	Description	Payer Type
Q5131	Injection, adalimumab-aacf (IDACIO®), biosimilar, 20 mg	Commercial, Medicare

CMS Final HCPCS Coding Decision Establish a new HCPCS Level II code Q5131, "Injection, adalimumab-aacf (IDACIO®), biosimilar, 20 mg."

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

## CMS-1500 and CMS-1450 commercial Medicare coding<sup>4,5\*</sup>

Procedure Type	CPT Code
Office visit, new patient	99202-99205
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 above are only suggestions. The codes you need may vary by patient.

### Important Safety Information (continued)

- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-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 IDACIO®.
- 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.

#### 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 IDACIO® and institute appropriate therapy. In clinical trials of adalimumab,

## 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.



**Contact your IDACIO® Immunology Sales Specialist to connect with a Field Reimbursement Manager who is available to share the latest updates in payer coverage.**

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 IDACIO®, 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.

In patients who develop HBV reactivation, stop IDACIO® 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 IDACIO® therapy in this situation and monitor patients closely.

# Sample CMS 1500 Claim Form

(physician office site of service)

# Sample CMS 1450 (UB-04) Claim Form

(hospital outpatient site of service)



**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

**Box 19:** Additional Information  
Enter the appropriate drug-identifying information as required by payer (e.g., brand/generic drug name, NDC 11-digit format, dose administered, route of administration, etc.)

**Box 21:** Diagnosis  
Enter appropriate ICD-10-CM diagnosis code(s)

**24A: Date(s) of Service**  
If line item NDC information is required, enter it in the shaded portion of item 24a

**Box 24B:** Place of Service  
Enter Place of Service Code such as 11 for physician office

**Box 24D:** Procedures, Services, or Supplies  
Enter appropriate HCPCS and CPT codes. For example:  
- Drug: HCPCS Code Q5131  
- Administration: 96372 for subcutaneous injection

**24E: Diagnosis Pointer**  
Refer to the diagnosis for this service from line 21, enter only 1 diagnosis pointer per line.

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

**Box 24G:** Units  
Enter the number of units, (e.g., Injection, adalimumab-aacf (IDACIO®) 20 mg, a 40 mg syringe would be 2 billing units)

**Box 19: Additional Information**  
Enter the appropriate drug-identifying information as required by payer (e.g., brand/generic drug name, NDC 11-digit format, dose administered, route of administration, etc.)

**Box 21: Diagnosis**  
Enter appropriate ICD-10-CM diagnosis code(s)

**24A: Date(s) of Service**  
If line item NDC information is required, enter it in the shaded portion of item 24a

**Box 24B: Place of Service**  
Enter Place of Service Code such as 11 for physician office

**Box 24D: Procedures, Services, or Supplies**  
Enter appropriate HCPCS and CPT codes. For example:  
- Drug: HCPCS Code Q5131  
- Administration: 96372 for subcutaneous injection

**24E: Diagnosis Pointer**  
Refer to the diagnosis for this service from line 21, enter only 1 diagnosis pointer per line.

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

**Box 24G: Units**  
Enter the number of units, (e.g., Injection, adalimumab-aacf (IDACIO®) 20 mg, a 40 mg syringe would be 2 billing units)

**Form Location (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 Q5131  
- Administration: 96372 for subcutaneous injection

**FL 46**  
Enter the billing units (e.g., IDACIO® 20 mg, is one billing unit, a 40 mg. syringe would be 2 billing units).

**FL 66**  
Identify the type of ICD diagnosis code used (e.g., enter a "0" for ICD-10-CM).

**FL 67**  
Indicate the diagnosis using the ICD10-CM code that supports the medical justification for your patient's condition.

**FL 80**  
Additional details you may want to include are the drug name, drug strength, unit of measure, (20 mg), number of units administered/discarded, total dosage, route of administration, and 11 digit NDC. Commercial plans may require a prior authorization.

**Form Location (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 Q5131  
- Administration: 96372 for subcutaneous injection

**FL 46**  
Enter the billing units (e.g., IDACIO® 20 mg, is one billing unit, a 40 mg. syringe would be 2 billing units).

**FL 66**  
Identify the type of ICD diagnosis code used (e.g., enter a "0" for ICD-10-CM).

**FL 67**  
Indicate the diagnosis using the ICD10-CM code that supports the medical justification for your patient's condition.

**FL 80**  
Additional details you may want to include are the drug name, drug strength, unit of measure, (20 mg), number of units administered/discarded, total dosage, route of administration, and 11 digit NDC. Commercial plans may require a prior authorization.

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 IDACIO® claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee IDACIO® coverage or reimbursement.

## Additional documentation for filing your claim

In addition to the CMS-1500 or CMS1450 (UB-04) claim form, the payer may request the following:

- Patient medical history
- Physician clinical notes
- Letter of medical necessity (see sample at [www.idaciohcp.com/idacio-hcp-resources/LOMN](http://www.idaciohcp.com/idacio-hcp-resources/LOMN))
- PA number
- Drug-identifying information (eg, NDC)
- Letter of appeal (see sample at [www.idaciohcp.com/idacio-hcp-resources/LOA](http://www.idaciohcp.com/idacio-hcp-resources/LOA))
- May require an invoice



### Sample Format: Letter of Medical Necessity

[Today's Date]

[Medical Director Name]  
 [Payer Name]  
 [Payer Street Address]  
 [Payer City, State, Zip]

[Insert Member ID#] [Insert Member Group Number]

**RE:** [Patient Full Name]  
 [Patient Policy Number]  
 [Patient Member ID/ Group Number]  
 [Patient Date of Birth]  
 [Patient Diagnosis/ ICD-10]  
 [Date of Diagnosis]  
 [Prior Authorization or Claim Number]  
 [Date(s) of Service]

To Whom It May Concern:

I am writing to provide additional information to support my [Prior Authorization/ Claim] for the treatment of [Patient Name] with IDACIO® (adalimumab-aacf) injection.

In brief, treatment of [Patient Name] with IDACIO is medically appropriate and necessary and should be a covered and reimbursed service. This letter outlines [Patient Name]'s medical history, prognosis, and treatment rationale.

**Summary of Patient's History**  
 [You may want to briefly explain why this particular patient needs IDACIO; consider describing patient's symptoms, therapy to date, patient risk factors, a summary of your professional opinion of the patient's likely prognosis without this specific product, and any other pertinent information.]

**Rationale for Treatment**  
 Given the patient's history, condition, and the published data supporting use of IDACIO, I believe treatment of [Patient Name] with IDACIO is warranted, appropriate, and medically necessary.

Please call my office at the number listed below if I can provide any additional information. I look forward to receiving your timely response and approval of this [Prior Authorization/ Claim].

Sincerely,

\_\_\_\_\_  
 (Signature)  
 [Physician Name]  
 [Physician Street Address]  
 [Physician City, State, Zip]  
 [Participating Provider Number]

### Sample Format: Letter of Appeal

[Today's Date]

Attn: Appeals Department

[Payer Name]  
 [Payer Street Address]  
 [Payer City, State, Zip]

**Re:** [Patient Full Name]  
 [Patient Date of Birth]  
 [Patient Member ID]  
 [Patient Policy/ Group Number]  
 [Prior Authorization or Claim Number]  
 [Patient Diagnosis/ ICD-10]  
 [Date of Diagnosis]  
 [Date(s) of Service]

To Whom It May Concern:

This letter serves as a request for reconsideration of payment of a denied [Prior Authorization/ Claim] for IDACIO® (adalimumab-aacf) Injection for my patient, [Patient Name], on [Date(s) of Service].

This patient has been under my care for the confirmed diagnosis and treatment of [patient diagnosis]. You had indicated that IDACIO is not covered because [reason for denial].

[You may want to explain why this particular patient specifically needs IDACIO. Consider providing a tailored account of patient's history and medical needs, describing patient's symptoms, therapy to date, additional patient risk factors, and any other pertinent information, including how IDACIO has been effective for this specific patient, that supports this patient's need for IDACIO.]

The attached Brief Summary provides the approved clinical information for IDACIO. IDACIO has been administered as a medically necessary part of this patient's treatment.

I would appreciate reconsideration of coverage for the [Prior Authorization/ Claim] for the date(s) of service referenced above for [Patient Name].

Thank you very much in advance for your time and consideration. Please call my office at the number listed below to discuss how we can facilitate a better patient outcome in an expedited fashion. I am happy to provide any additional needed information. My office hours are as follows: [days/ times]

Sincerely,

\_\_\_\_\_  
 (Signature)  
 [Physician Name]  
 [Physician Street Address]  
 [Physician City, State, Zip]  
 [Participating Provider Number]



## Comprehensive support to enable patient access

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

 <b>FINANCIAL SUPPORT</b> programs, including copay assistance for eligible patients with out-of-pocket costs as little as \$0/month*	 <b>BRIDGE TO THERAPY</b> program to avoid treatment delay while waiting for insurance approval†	 <b>PERSONAL SUPPORT</b> including nurse educators and field reimbursement managers‡
 <b>CLINICAL INSIGHTS</b> program that provides therapeutic drug monitoring for eligible patients*	 <b>DEDICATED SUPPORT</b> to address access challenges	 <b>CENTRALIZED PATIENT SUPPORT PORTAL</b> with real-time status updates

\*Terms and conditions apply.  
 †Eligibility criteria apply. Patients are not eligible for Bridge to Therapy or Clinical Insights Program if the prescription is eligible to be reimbursed, in whole or in part by any state or federal healthcare program.  
 ‡Nurse support provided by KabiCare is not meant to replace discussions with a healthcare provider regarding a patient's care and treatment.

### Important Safety Information (continued)

#### 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 IDACIO® in patients with pre-existing or recent-onset central or peripheral nervous system demyelinating disorders; discontinuation of IDACIO® should be considered if any of these disorders develop.

#### 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 IDACIO® if significant hematologic abnormalities occur.

#### CONGESTIVE HEART FAILURE

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

## Contact KabiCare



**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](http://KabiCare.us)

**IDACIO® offers additional educational tools and resources, including:**

- Sampling
- Payer Access
- Educational resources
- Coverage tool
- Video resources
- Demo kits

#### 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 IDACIO® should not receive live vaccines. Pediatric patients, if possible, should be brought up to date with all immunizations before initiating IDACIO® therapy. The safety of administering live or live-attenuated vaccines in infants exposed to adalimumab products 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.

#### INDICATIONS

- Rheumatoid Arthritis (RA): 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 RA.
- Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.



**IDACIO<sup>®</sup> (adalimumab-aacf) is proven highly similar to Humira (adalimumab)<sup>1</sup> with features and support to help you start or transition your patients with ease.**

## NDC Codes<sup>1</sup>

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 IDACIO<sup>®</sup>, a 0 is added in front of 556 to create 0556, and in front of 554 to create 0554). Check with the payer to confirm the correct code required when billing to IDACIO<sup>®</sup>.

## Rheumatology

NDC Number (PK)	10-digit NDC Code	11-digit NDC Code
IDACIO <sup>®</sup> Prefilled Syringe (PFS) 40 mg/0.8 mL (2-count)	65219-556-18	65219-0556-18
IDACIO <sup>®</sup> Prefilled Autoinjector Pen (PEN) 40 mg/0.8 mL (2-count)	65219-554-08	65219-0554-08

## Dermatology

NDC Number (PK)	10-digit NDC Code	11-digit NDC Code
IDACIO <sup>®</sup> Prefilled Syringe (PFS) 40 mg/0.8 mL (2-count)	65219-556-18	65219-0556-18
IDACIO <sup>®</sup> Prefilled Autoinjector Pen (PEN) 40 mg/0.8 mL (2-count)	65219-554-08	65219-0554-08
Starter Packages	10-digit NDC Code	11-digit NDC Code
IDACIO <sup>®</sup> Autoinjector Pen Starter Package for Plaque Psoriasis 40 mg/0.8 mL (4-count)	65219-554-28	65219-0554-28

## Gastroenterology

NDC Number (PK)	10-digit NDC Code	11-digit NDC Code
IDACIO <sup>®</sup> Prefilled Syringe (PFS) 40 mg/0.8 mL (2-count)	65219-556-18	65219-0556-18
IDACIO <sup>®</sup> Prefilled Autoinjector Pen (PEN) 40 mg/0.8 mL (2-count)	65219-554-08	65219-0554-08
Starter Packages	10-digit NDC Code	11-digit NDC Code
IDACIO <sup>®</sup> Autoinjector Pen Starter Package for Crohn's Disease and Ulcerative Colitis 40 mg/0.8 mL (6-count)	65219-554-38	65219-0554-38

**To learn more about coverage for IDACIO<sup>®</sup>, contact your field reimbursement manager.**

Please see Important Safety Information throughout this brochure and click to see accompanying [Full Prescribing Information](#), including **Boxed WARNING**, Medication Guide, and Instructions for Use for IDACIO<sup>®</sup> (adalimumab-aacf).