Otulfi®
ustekinumab-aauz

OTULFI® (ustekinumab-aauz)
Injection for subcutaneous or intravenous use

Billing & Coding Guide

Please see additional Important Safety Information throughout this brochure and click to see full Prescribing Information and Medication Guide for OTULFI® (ustekinumab-aauz).

FRESENIUS KABI

OTULFI® (ustekinumab-aauz) Billing and Coding Guide

The OTULFI® Billing and Coding Guide provides general reimbursement information for healthcare providers.

Topics include billing, coding, coverage, and reimbursement for treatment with OTULFI®.

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 OTULFI® 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 OTULFI® coverage or reimbursement.

INDICATIONS AND USAGE[1]

OTULFI® is an interleukin-12 and -23 antagonist indicated for treatment of:

Adult patients with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis
- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Pediatric patients ≥6 years of age with:

- Moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Active psoriatic arthritis

Important Safety Information (continued) for OTULFI® (ustekinumab-aauz)

OTULFI (ustekinumab-aauz) is contraindicated in patients with clinically significant hypersensitivity to ustekinumab products or to any of the excipients in OTULFI (ustekinumab-aauz).

Infections

Ustekinumab products may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections were observed in patients receiving ustekinumab products.

Serious infections requiring hospitalization, or otherwise clinically significant infections, reported in clinical trials included the following:

- Plaque psoriasis: diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, urinary tract infections
- Psoriatic arthritis: cholecystitis
- Crohn's disease: anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, *Listeria* meningitis
- Ulcerative colitis: gastroenteritis, ophthalmic herpes zoster, pneumonia, listeriosis

Avoid initiating treatment with OTULFI (ustekinumab-aauz) in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks

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AVAILABLE FORMULATIONS OF OTULFI® (ustekinumab-aauz)

OTULFI® is available as [a vial/vials] and prefilled syringes[1]

Single-dose vial for intravenous infusion

130 mg/26 mL (5 mg/mL)
(NDC# 65219-828-05)

Coding for single-dose vial for intravenous infusion is included in this billing guide.

Single-dose vial for subcutaneous injection

45 mg/0.5 mL (90 mg/mL)
(Add NDC#)

Single-dose prefilled syringe for subcutaneous injection

45 mg/0.5 mL
(NDC# 65219-824-01)

90 mg/mL
(NDC# 65219-826-26)

and benefits of treatment prior to initiating use of OTULFI (ustekinumab-aauz) in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur while on treatment with OTULFI (ustekinumab-aauz).

Discontinue OTULFI (ustekinumab-aauz) for serious or clinically significant infections until the infection resolves or is adequately treated.

Theoretical Risk for Vulnerability to Particular Infections

Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), *Salmonella* (including nontyphi strains), and *Bacillus Calmette-Guerin* (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients.

It is not known whether patients with pharmacologic blockade of IL-12/IL-23 from treatment with ustekinumab products may be susceptible to these types of infections. Consider appropriate diagnostic testing (e.g., tissue culture, stool culture, as dictated by clinical circumstances).

Pre-Treatment Evaluation of Tuberculosis (TB)

Evaluate patients for TB prior to initiating treatment with OTULFI (ustekinumab-aauz).

Avoid administering OTULFI (ustekinumab-aauz) to patients with active TB infection. Initiate treatment of latent TB before administering OTULFI (ustekinumab-aauz). Consider anti-TB therapy prior to initiation of OTULFI (ustekinumab-aauz) in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed.

Closely monitor patients receiving OTULFI (ustekinumab-aauz) for signs and symptoms of active TB during and after treatment.

ICD-10 CODES

This coding information may assist you as you complete the payer forms for OTULFI® (ustekinumab-aauz).

ICD-10-CM Codes[2] for Consideration*	
Crohn's Disease	
K50.00	Crohn's disease of small intestine without complications
K50.01	Crohn's disease of small intestine with complications
K50.10	Crohn's disease of large intestine without complications
K50.11	Crohn's disease of large intestine with complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.81	Crohn's disease of both small and large intestine with complications
K50.90	Crohn's disease unspecified without complications
K50.91	Crohn's disease unspecified with complications
Ulcerative Colitis	
K51.00	Ulcerative (chronic) pancolitis without complications
K51.01	Ulcerative (chronic) pancolitis with complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.21	Ulcerative (chronic) proctitis with complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.50	Left-sided colitis without complications
K51.51	Left-sided colitis with complications
K51.81	Other ulcerative colitis with complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.91	Ulcerative colitis, unspecified, with complications
Psoriatic Arthritis	
L40.50	Arthropathic psoriasis, unspecified
L40.59	Other psoriatic arthropathy
Plaque Psoriasis	
L40.0	Psoriasis vulgaris
L40.9	Psoriasis, unspecified

*ICD-10-CM diagnosis codes consist of 3 to 7 alphanumeric characters, providing increasing levels of specificity. A 3-character code is appropriate only when there is no need for additional subdivision. A code is invalid if it has not been coded to the full number of characters required for that code.

These codes are not all-inclusive; appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Fresenius Kabi does not make any representation or guarantee concerning reimbursement or coverage for any item or service. Many payers will not accept unspecified codes. If you use an unspecified code, please check with your payer.

HCPCS

Healthcare Common Procedure Coding System (HCPCS)

HCPCS Code for OTULFI®[3]*			
Code	**Description**	**Site of Service**	**Billing Units**
Q9999	Injection, ustekinumab-aauz (OTULFI®), biosimilar, 1 mg	All	1 mg

Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment.

Payment status indicator

Identifies whether a service represented by a CPT or HCPCS code is payable under the Outpatient Prospective Payment System (OPPS) Ambulatory Payment Classification (APC) or another payment system. Only 1 status indicator is assigned to each CPT or HCPCS code.

Payment status indicator[4]		
HCPCS Code	**Description**	**Status indicator**
Q9999	Injection, ustekinumab-aauz (OTULFI®), biosimilar, 1 mg	[Add code]

[Add code] Pass-Through Drugs and Biologicals Paid under OPPS; separate APC payment includes pass-through amount.

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)

Malignancies

Ustekinumab products are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among subjects who received ustekinumab in clinical trials. In rodent models, inhibition of IL-12/IL-23p40 increased the risk of malignancy.

The safety of ustekinumab products has not been evaluated in patients who have a history of malignancy or who have a known malignancy.

There have been reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving ustekinumab products who had pre-existing risk factors for developing non-melanoma skin cancer (NMSC). Monitor all patients receiving OTULFI (ustekinumab-aauz) for the appearance of NMSC. Closely follow patients >60 years of age, those with a medical history of prolonged immunosuppressant therapy, and those with a history PUVA treatment.

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with ustekinumab products. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue OTULFI (ustekinumab-aauz).

Posterior Reversible Encephalopathy Syndrome (PRES)

Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have

MODIFIERS

Summary of Code Modifiers				
Modifier	**Description[3]**	**Indication and Placement[4-6/5-7]**	**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

When using miscellaneous code, amount wasted is captured in CMS 1500 Form Block 19 & CMS 1450 Form FL 80 and claim form should not include separate line for JW.

NDC Numbers and CPT Codes

What codes do I use to bill for OTULFI® (ustekinumab-aauz)?

- A new prescription is required for OTULFI®.
- To ensure your patient will receive OTULFI®, 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 OTULFI®.

Dosage Form	Description	10-digit NDC Code	11-digit NDC Code
IV Infusion	130 mg/26 mL (5 mg/mL), single-dose vial	65219-828-05	65219-0828-05
SC Injection	45 mg/0.5 mL, single-dose prefilled syringe	65219-824-01	65219-0824-01
	90 mg/mL, single-dose prefilled syringe	65219-826-26	65219-0826-26
	[45 mg/0.5 mL, single-dose vial]	[65219-822-05]	[65219-0822-05]

Current Procedural Terminology (CPT) Code

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	96XXX	Consult the policy for the patient's health plan to confirm the correct administration code.

All coding and documentation requirements should be confirmed with each payer before submitting a claim for reimbursement. Medicare requires detailed documentation to support a complex infusion code claim.

Important Safety Information (continued)

Non-live vaccinations received during a course of OTULFI (ustekinumab-aauz) may not elicit an immune response sufficient to prevent disease.

Noninfectious Pneumonia

Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of ustekinumab products. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. Patients improved with discontinuation of therapy and in certain cases, administration of corticosteroids. If diagnosis is confirmed, discontinue OTULFI (ustekinumab-aauz) and institute appropriate treatment.

Most Common Adverse Reactions

The most common adverse reactions (≥3%) seen in patients treated with OTULFI (ustekinumab-aauz) are:

- Psoriasis: nasopharyngitis, upper respiratory tract infection, headache, fatigue
- Crohn's disease, induction: vomiting
- Crohn's disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, sinusitis
- Ulcerative colitis, induction: nasopharyngitis
- Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, nausea

Physician's Office Billing Information[7/8]

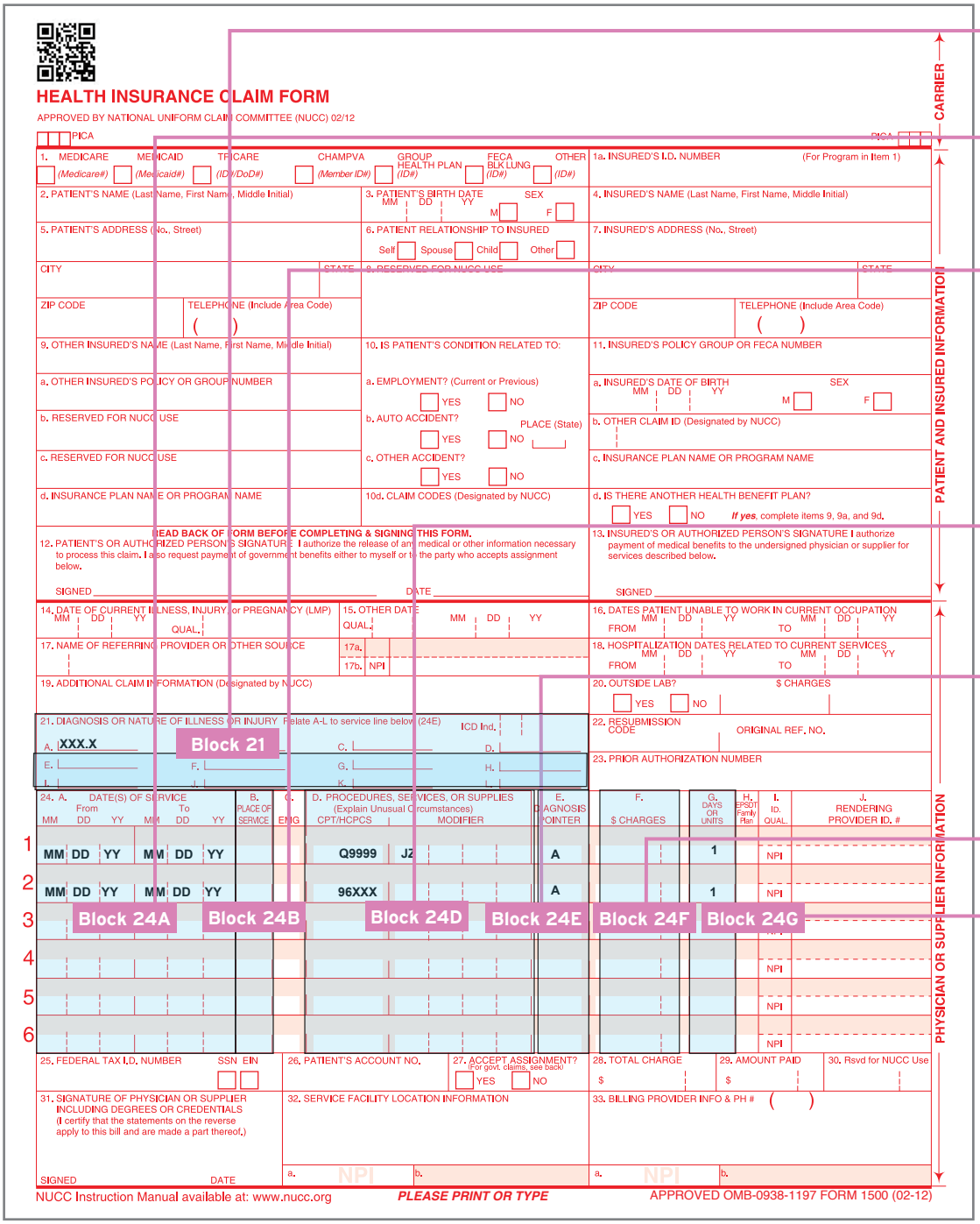
OTULFI® (ustekinumab-aauz) Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Enter appropriate HCPCS Q9999 and appropriate modifiers.
Number of Units in **Block 24G**: (Electronic Form: Loop 2400, SV1, 04 [03=UN])	Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit.
Administration and Professional Service Coding Information*	
Coding Information in **Block 24D**: (Electronic Form: Loop 2400, SV1, 01-2)	Indicate appropriate CPT codes 93XXX.
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 OTULFI®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

Sample CMS 1500 Claim Form

(physician office site of service)[7/8]

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 OTULFI® (ustekinumab-aauz) claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee OTULFI® 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

A place of service code (11-Office, 12-Home, 19-Off Campus-Outpatient Hospital, or 49-Independent Clinic) should be used when billing for office (other than hospital), home infusion, or ambulatory infusion suite (AIS) services.

Block 24D: Drug Code

Q9999-Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit.

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

Q9999/96XXX-Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit; 1 vial = 130 mg.

Hospital/Institutional Billing[8/9]

OTULFI® (ustekinumab-aauz) 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. Q9999—Injection, ustekinumab-aauz (OTULFI®), 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.
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. 96XXX—Enter 1 unit for the first hour of infusion.
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 OTULFI®. Other codes may be more appropriate given internal system guidelines, payer requirements, practice patterns, and the services rendered.

The JW and JZ modifier requirement applies to all separately payable drugs from single-dose containers assigned status indicators "G" (pass-through drugs and biologicals) or "K" (non-pass-through drugs) under the OPPS for which there is a discarded amount.

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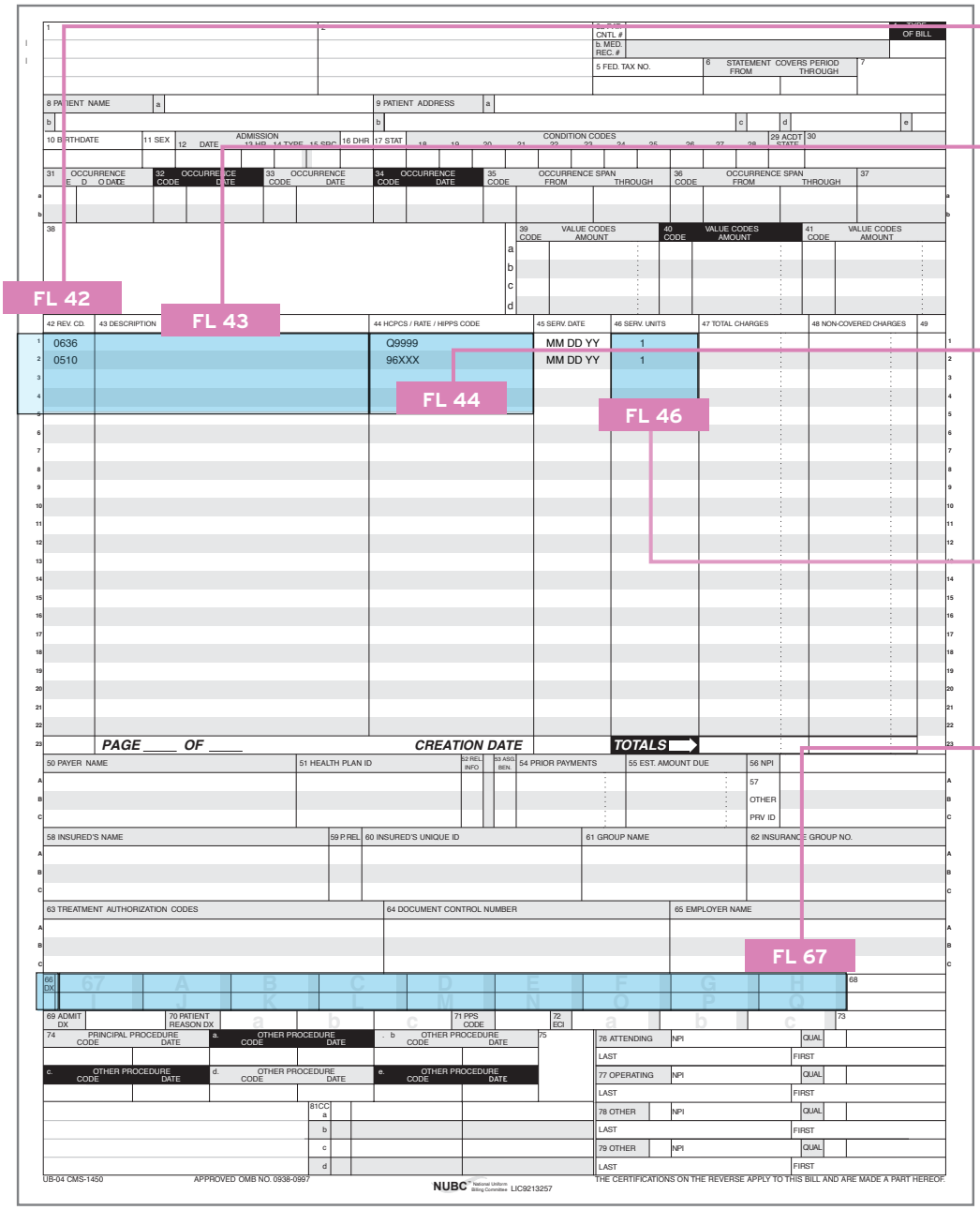
Sample CMS 1450 (UB-04) Claim Form

(hospital outpatient site of service)[8/9]

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 OTULFI® (ustekinumab-aauz) claims are accurate, complete, and supported by documentation in the patient's medical record. KabiCare does not guarantee OTULFI® coverage or reimbursement.



FL 42

Enter the appropriate revenue code and procedure description.

FL 43

Enter NDC or narrative description.

FL 44

Q9999—Injection, ustekinumab-aauz (OTULFI®), biosimilar, 1 mg.
96XXX—Enter 1 unit for the first hour of infusion. (OTULFI®), biosimilar, 1 mg.

FL 46

Q9999—Enter the drug quantity in HCPCS units according to the dose, with 1 mg = 1 unit.
96XXX—Enter 1 unit for the first hour of infusion.

FL 67

Appropriate ICD-10-CM code(s) for patient 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:

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OTULFI® (ustekinumab-aauz) treatment approval process

Benefits verification

Complete a thorough assessment and investigation of benefits before administering OTULFI® (ustekinumab-aauz) 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

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Notes

Otulfi®
ustekinumab-aauz

OTULFI® (ustekinumab-aauz) 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. OTULFI®. 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. 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. **[4. Add reference] [4/5]** 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. **[5/6].** 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. **[6/7].** 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. **[7/8].** 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. **[8/9].** 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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