Yesintek™
(ustekinumab-kfce)

# CODING AND BILLING GUIDE

## INDICATIONS AND IMPORTANT SAFETY INFORMATION

### INDICATIONS

YESINTEK (ustekinumab-kfce) is a human interleukin-12 and -23 antagonist indicated for the treatment of: Adult patients with: moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy; active psoriatic arthritis (PsA); moderately to severely active Crohn's disease (CD); moderately to severely active ulcerative colitis.

Pediatric patients 6 years and older with: moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy; active psoriatic arthritis (PsA).

### IMPORTANT SAFETY INFORMATION

**Contraindications**

YESINTEK is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or to any of the excipients.

**Infections**

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

**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# Table of Contents

Yesintek™ (ustekinumab-kfce)

# Purpose of This Guide

This Coding and Billing Guide for YESINTEK (ustekinumab-kfce) is intended to support medically appropriate patient access by providing general information on coding, coverage, billing, and reimbursement to healthcare professionals and their staff who prescribe and administer YESINTEK at physician offices and hospital outpatient sites of care. YESINTEK is biosimilar to Stelara® (ustekinumab) for the indications listed.

## Disclaimer

**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 YESINTEK claims are accurate, complete, and supported by documentation in the patient's medical record. Biocon Biologics does not guarantee that payers will consider all codes appropriate for all encounter scenarios, and Biocon Biologics does not guarantee YESINTEK coverage or reimbursement.

Please note that information specific to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information in this guide is current as of February 2025.

## Reimbursement Support

Information regarding access and reimbursement support resources for YESINTEK is available through My Biocon Biologics at 1-833-61-BIOCON. Or you can visit www.YesintekHCP.com.



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# Available Formulations of YESINTEK

| Single-dose vial for intravenous (IV) infusion* | Single-dose vial for subcutaneous injection | Single-dose prefilled syringe for subcutaneous injection |
|---|---|---|
|  |  |  45 mg/0.5 mL single-dose prefilled syringe  90 mg/mL single-dose prefilled syringe |
| DOSE: **130 mg/26 mL (5 mg/mL) VIAL** NDC: 83257-026-11 *IV dose not approved for all indications. | DOSE: **45 mg/0.5 mL VIAL** NDC: 83257-024-11 | DOSE: **45 mg/0.5 mL PREFILLED SYRINGE** NDC: 83257-023-41 **90 mg/mL PREFILLED SYRINGE** NDC: 83257-025-41 |



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# CROHN'S DISEASE AND ULCERATIVE COLITIS

## YESINTEK INTRAVENOUS (IV) INDUCTION

Indicated for adult patients with: moderately to severely active Crohn's disease (CD); moderately to severely active ulcerative colitis.[1]



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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# Dosing and Administration[1]

For the treatment of Crohn's disease or ulcerative colitis, YESINTEK is administered in 2 phases: induction and maintenance. Table 1 summarizes the induction doses, provided as a single intravenous infusion.

## Induction

**Intravenous (IV) Induction: A single IV infusion dose of YESINTEK using a weight-based dosage regimen (see Table 1).**

**TABLE 1.** INITIAL YESINTEK (IV) DOSAGE[1]

| Indications | Patient Weight | Dose* | Number of 130 mg/26 mL (5 mg/mL) YESINTEK Vials |
|---|---|---|---|
| Crohn's disease or ulcerative colitis | 55 kg or less | 260 mg | 2 vials |
| | More than 55 kg to 85 kg | 390 mg | 3 vials |
| | More than 85 kg | 520 mg | 4 vials |


**Single-dose vial for intravenous (IV) infusion**

## Preparation and Administration of YESINTEK 130 mg/26 mL (5 mg/mL) Vial for IV Infusion[1]

**YESINTEK solution for IV infusion must be diluted, prepared, and infused by a healthcare professional using aseptic technique.**

1. Calculate the dose and the number of YESINTEK vials needed based on patient weight (Table 1). Each 26 mL vial of YESINTEK contains 130 mg of ustekinumab-kfce.
2. Withdraw and then discard a volume of the 0.9% Sodium Chloride Injection, USP from the 250 mL infusion bag equal to the volume of YESINTEK to be added (discard 26 mL sodium chloride for each vial of YESINTEK needed, for 2 vials—discard 52 mL, for 3 vials—discard 78 mL, for 4 vials—discard 104 mL). Alternatively, a 250 mL infusion bag containing 0.45% Sodium Chloride Injection, USP may be used.
3. Withdraw 26 mL of YESINTEK from each vial needed and add it to the 250 mL infusion bag. The final volume in the infusion bag should be 250 mL. Gently mix.
4. Visually inspect the diluted solution before infusion. Do not use if visibly opaque particles, discoloration, or foreign particles are observed.
5. Infuse the diluted solution over a period of at least 1 hour. Once diluted, the infusion should be completely administered within 4 hours of the dilution in the infusion bag.
6. Use only an infusion set with an inline, sterile, non-pyrogenic, low protein-binding filter (pore size 0.2 micrometers).
7. Do not infuse YESINTEK concomitantly in the same intravenous line with other agents.
8. YESINTEK does not contain preservatives. Each vial is for one-time use in only one patient. Discard any remaining solution. Dispose any unused medicinal product in accordance with local requirements.



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# Coding

**The initial dose of YESINTEK for Crohn's disease or ulcerative colitis is delivered by IV infusion. This section of the Coding and Billing Guide will provide coding and product information related to that service.**

## ICD-10-CM Diagnosis Codes

YESINTEK is FDA approved for the treatment of Crohn's disease and ulcerative colitis. This table includes code ranges and codes that may be applicable for these indications; additional codes may apply. For the code ranges represented here, it is necessary to code to the greatest level of specificity; a code is invalid if it does not include the full number of required characters.[2]

**TABLE 2.** ICD-10-CM DIAGNOSIS CODES*—CROHN'S DISEASE AND ULCERATIVE COLITIS

| | |
|---|---|
| **Crohn's Disease[3]** | |
| **K50.00** | Crohn's disease of small intestine without complications |
| **K50.011-K50.019†** | Crohn's disease of small intestine with complications |
| **K50.10** | Crohn's disease of large intestine without complications |
| **K50.111-K50.119†** | Crohn's disease of large intestine with complications |
| **K50.80** | Crohn's disease of both small and large intestine without complications |
| **K50.811-K50.812†** | Crohn's disease of both small and large intestine with complications |
| **K50.90** | Crohn's disease unspecified without complications |
| **K50.911-K50.919†** | Crohn's disease unspecified with complications |
| **Ulcerative Colitis[4]** | |
| **K51.00** | Ulcerative (chronic) pancolitis without complications |
| **K51.011-K51.019‡** | Ulcerative (chronic) pancolitis with complications |
| **K51.20** | Ulcerative (chronic) proctitis without complications |
| **K51.211-K51.219‡** | Ulcerative (chronic) proctitis with complications |
| **K51.30** | Ulcerative (chronic) rectosigmoiditis without complications |
| **K51.311-K51.319‡** | Ulcerative (chronic) rectosigmoiditis with complications |
| **K51.50** | Left sided colitis without complications |
| **K51.511-K51.519‡** | Left sided colitis with complications |
| **K51.80** | Other ulcerative colitis without complications |
| **K51.811-K51.819‡** | Other ulcerative colitis with complications |
| **K51.90** | Ulcerative colitis, unspecified, without complications |
| **K51.911-K51.919‡** | Ulcerative colitis, unspecified, with complications |

*These codes are not intended to be promotional, nor to encourage or suggest a use of the drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive and additional codes may apply.

†See https://www.icd10data.com/ICD10CM/Codes/K00-K95/K50-K52/K50-#K50.01 for specific Crohn's Disease complication codes.

‡See https://www.icd10data.com/ICD10CM/Codes/K00-K95/K50-K52/K51- for specific Uclerative Colitis complication codes.



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# Coding (continued)

## Healthcare Common Procedure Coding System (HCPCS) Level II Product Codes

HCPCS Level II product codes are used to report FDA-approved biologic products. The Centers for Medicare and Medicaid Services (CMS) has not yet assigned a product-specific HCPCS code for YESINTEK. Therefore, until a specific code is assigned, report YESINTEK for IV use with an unspecified HCPCS code. When reporting unspecified codes on claims, additional information may be required to be reported, including the NDC, strength and dose, and route of administration. Refer to your payer's documentation for additional information on billing unspecified HCPCS codes. An application for a product-specific HCPCS code for YESINTEK for IV use has been submitted.

**TABLE 3.** HCPCS CODES FOR YESINTEK[5]

| HCPCS Code | Description | For | Site of Care |
|---|---|---|---|
| J3490 | Unclassified drugs | YESINTEK, for intravenous injection | All sites of care |
| J3590 | Biologic not otherwise classified | YESINTEK, for intravenous injection | All sites of care |
| C9399 | Unclassified drugs or biologics | YESINTEK, for intravenous injection | Hospital outpatient department |


**Single-dose vial for intravenous (IV) infusion**

Each 1 mg dose of YESINTEK (IV) equals 1 billing unit, thus a 130 mg vial of drug represents 130 units of J3590. Inaccurate reporting of drug billing units is a common claims error and can result in denied or delayed payment. When coding for J3590, report the total number of 1 mg increments administered.

It is the healthcare provider's responsibility to determine the appropriate codes, units, and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care. Contact your payer for additional information on coverage and billing for YESINTEK.

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# Coding (continued)

**The initial dose of YESINTEK for Crohn's disease or ulcerative colitis is delivered by IV infusion. This section of the Coding and Billing Guide will provide coding and product information related to that service.**

## National Drug Code (NDC)

Drugs and biologics approved by the FDA are assigned a 3-segment NDC number that is specific to the labeler (manufacturer), product (a specific drug, strength, and dosage formulation), and package size. YESINTEK has been assigned a 10-digit NDC as listed in the prescribing information.[6]

Although the FDA uses a 10-digit format when registering NDCs, the 11-digit format is required by the Health Insurance Portability and Accountability Act (HIPAA) for claims submission without hyphens or other punctuation marks.

**TABLE 4.** NDC FOR YESINTEK (IV)[1]

| FDA-Specified 10-Digit NDC (5-3-2 format) | 11-Digit NDC (5-4-2 format) | Description |
|---|---|---|
| 83257-026-11 | 83257-0026-11 | 130 mg vial<br>Single-use vial containing 130 mg (26 mL) of ustekinumab for IV infusion |

## NDC Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and ML (milliliters) applies to drugs supplied in liquid form.[6] NDC units dispensed are based on the packaging and numeric quantity administered to the patient.

Accurate NDC coding typically requires reporting the following components[6]:

- The NDC with 11 digits in a 5-4-2 format (this may require converting a 10-digit NDC)
- The correct NDC unit of measure (ie, UN, ML)
- The number of NDC units administered
- The qualifier, N4, in front of the NDC

Example: the coding format for a 390 mg dose of YESINTEK IV from single-dose vials: **N483257002611 ML78**

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# Coding (continued)

## HCPCS Level I / CPT Codes

Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT® coding system. The following codes may be used to report the intravenous administration of YESINTEK:

**TABLE 5.** CPT CODES FOR YESINTEK (IV) ADMINISTRATION[7]

| Code | Description |
|---|---|
| 96365 | Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour |
| 96366 | IV infusion for therapy, prophylaxis, or diagnosis; each additional hour |


**Single-dose vial for intravenous (IV) infusion**

It is the healthcare provider's responsibility to determine the appropriate codes, units, and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care. Contact your payer for additional information on coverage and billing for YESINTEK.

## Revenue Codes

National Uniform Billing Committee (NUBC) hospital revenue codes are required to bill for hospital services and items like biologics. Each line item on a CMS-1450 (UB-04) or the 837I electronic claim format, must have an assigned revenue code. The revenue codes below may be applicable to hospital claims for YESINTEK.

**TABLE 6.** REVENUE CODES FOR YESINTEK[8]

| Code | Description |
|---|---|
| 0260 | IV Therapy, General |
| 0636 | Pharmacy, drugs requiring detailed coding |

For additional support, you may visit YesintekHCP.com or contact us at 1-833-61-BIOCON.

CPT=current procedural technology.

# Coding (continued)

## HCPCS and Current Procedural Technology (CPT®) Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance, but not changed in its definition or code. They provide additional information about a service or procedure. Table 7 summarizes modifiers that may be applicable to coding and billing YESINTEK intravenous (IV) use in physician offices and hospital outpatient departments (HOPDs).

**TABLE 7.** SUMMARY OF CODE MODIFIERS

| Modifier | Description | Indication and Placement | CMS-1500 (Item 24D) | CMS-1450 (Box 44) |
|---|---|---|---|---|
| 25 | Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional on the same day of the procedure or other service[7] | • Reported if patient requires distinct E/M service in addition to the infusion procedure[7]<br>• Must be substantiated by documentation that supports the relevant criteria for the reported E/M code[7]<br>• Append the modifier to the appropriate E/M code[7] | ✓Required by Medicare | ✓Required by Medicare |
| PO* | Excepted services provided at an off-campus, outpatient, provider-based department of a hospital[5] | • To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim[9] | N/A | ✓Required by Medicare |
| PN* | Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[5] | • To be reported on each claim line for non-excepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim[9] | N/A | ✓Required by Medicare |
| JW | Drug amount discarded/not administered to any patient[5] | • Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial[10]<br>• Append the modifier to the drug code on a line separate from that reporting the administered dose[10]<br>• Required to be reported with unclassified HCPCS codes J3490 or J3590, when the product is administered in a physician's office or freestanding center[10]<br>• Does not apply to C9399 reporting for hospital outpatient claims[10] | ✓Required by Medicare | ✓Required by Medicare |
| JZ | Zero drug amount discarded/not administered to any patient[5] | • To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage)[11]<br>• Required to be reported with unclassified HCPCS codes J3490 or J3590, when the product is administered in a physician's office or freestanding center[10]<br>• Does not apply to C9399 reporting for hospital outpatient claims[10] | ✓Required by Medicare | ✓Required by Medicare |
| TB | Drug or biological acquired with 340B Drug Pricing Program discount[5] | • Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes[9]<br>• To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[9] | N/A | ✓Required by Medicare |

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations or satellite facilities of a hospital, or a provider-based department that is on campus.[9]

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# Coding (continued)

## Same-Day Evaluation and Management (E/M) Services

It may be necessary to provide E/M services on the same day as a drug administration procedure. Depending on the payer, E/M services that are medically necessary, separate and distinct from the drug administration procedure, and documented appropriately, are generally covered. CMS has a specific policy regarding use of CPT® code 99211 (level 1 medical visit for an established patient) in the physician office. The policy states: ***CPT® code 99211 cannot be paid if it is billed, with or without modifier 25, with a chemotherapy or non-chemotherapy drug administration code.***[12]

Thus, CPT code 99211 cannot be paid by Medicare on the same day as an office-based infusion of YESINTEK.[12]

Payer policies vary. For information and assistance, please visit YesintekHCP.com or contact us at 1-833-61-BIOCON.


**Single-dose vial for intravenous (IV) infusion**



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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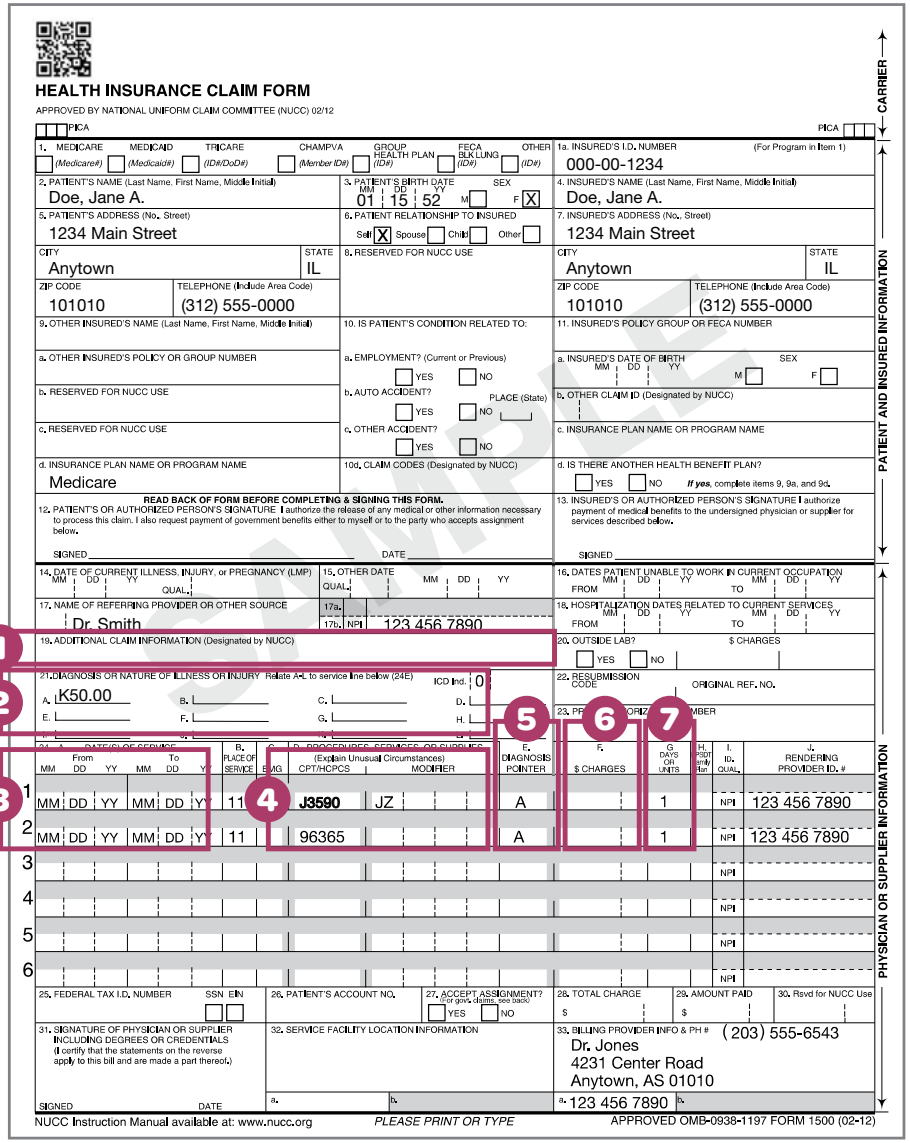
# Sample Claim Forms



HEALTH INSURANCE CLAIM FORM

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

PICA

| | |
|---|---|
| 1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#) | 1a. INSURED'S I.D. NUMBER (For Program in Item 1): 000-00-1234 |
| 2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, Jane A. | 3. PATIENT'S BIRTH DATE: 01 15 52 SEX: M F X |
| 4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, Jane A. | |
| 5. PATIENT'S ADDRESS (No., Street): 1234 Main Street | 6. PATIENT RELATIONSHIP TO INSURED: Self X Spouse Child Other |
| 7. INSURED'S ADDRESS (No., Street): 1234 Main Street | |
| CITY: Anytown STATE: IL | 8. RESERVED FOR NUCC USE |
| CITY: Anytown STATE: IL | |
| ZIP CODE: 101010 TELEPHONE (Include Area Code): (312) 555-0000 | |
| ZIP CODE: 101010 TELEPHONE (Include Area Code): (312) 555-0000 | |
| 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial) | 10. IS PATIENT'S CONDITION RELATED TO: |
| 11. INSURED'S POLICY GROUP OR FECA NUMBER | |
| a. OTHER INSURED'S POLICY OR GROUP NUMBER | a. EMPLOYMENT? (Current or Previous) YES NO |
| a. INSURED'S DATE OF BIRTH SEX | |
| b. RESERVED FOR NUCC USE | b. AUTO ACCIDENT? YES NO PLACE (State) |
| b. OTHER CLAIM ID (Designated by NUCC) | |
| c. RESERVED FOR NUCC USE | c. OTHER ACCIDENT? YES NO |
| c. INSURANCE PLAN NAME OR PROGRAM NAME | |
| d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare | 10d. CLAIM CODES (Designated by NUCC) |
| d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d. | |

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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

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

| | |
|---|---|
| 14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL. | 15. OTHER DATE QUAL. MM DD YY |
| 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO | |
| 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Smith | 17a. 17b. NPI 123 456 7890 |
| 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO | |
| 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) | 20. OUTSIDE LAB? YES NO $ CHARGES |
| 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0: A. K50.00 B. C. D. E. F. G. H. | 22. RESUBMISSION CODE ORIGINAL REF. NO. |
| | 23. PRIOR AUTHORIZATION NUMBER |

| 24. A. DATE(S) OF SERVICE From MM DD YY | To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. # |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | MM DD YY | MM DD YY | 11 | | J3590 | JZ | A | | 1 | | NPI | 123 456 7890 |
| 2 | MM DD YY | MM DD YY | 11 | | 96365 | | A | | 1 | | NPI | 123 456 7890 |
| 3 | | | | | | | | | | | NPI | |
| 4 | | | | | | | | | | | NPI | |
| 5 | | | | | | | | | | | NPI | |
| 6 | | | | | | | | | | | NPI | |

| | | | | | |
|---|---|---|---|---|---|
| 25. FEDERAL TAX I.D. NUMBER SSN EIN | 26. PATIENT'S ACCOUNT NO. | 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO | 28. TOTAL CHARGE $ | 29. AMOUNT PAID $ | 30. Rsvd for NUCC Use |

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

32. SERVICE FACILITY LOCATION INFORMATION a. b.

33. BILLING PROVIDER INFO & PH # (203) 555-6543
Dr. Jones
4231 Center Road
Anytown, AS 01010
a. 123 456 7890 b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER | PATIENT AND INSURED INFORMATION | PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

## YESINTEK for IV Use

### Physician Office Sample Claim Form (CMS-1500): 390 mg IV Induction Dose

**1 Box 19 ADDITIONAL CLAIM INFORMATION**

When billing an unclassified HCPCS product code such as J3590, Medicare and other payers may require additional information to be reported here, including the name of the drug, strength, and dosage. See your MAC for additional reporting requirements.

**2 Box 21 DIAGNOSIS**

Enter the appropriate diagnosis code (eg, K50.00 for Crohn's disease of small intestine without complications).

**3 Box 24A NDC INFORMATION**

If line item NDC information is required, it will be entered in the shaded portion on Row 1 of this section. Payer requirements for NDC entries may vary.

**4 Box 24D PROCEDURES/SERVICES/SUPPLIES**

Enter appropriate CPT and HCPCS codes and modifiers, if required. For example: YESINTEK J3590; Infusion Services CPT 96365.

Applicable Modifiers: See page 11.

**5 Box 24E DIAGNOSIS POINTER**

Enter the letter (A-L) from Box 21 for the diagnosis that corresponds to the line item. Enter only the diagnosis code(s) related to the service on a single line item.

**6 Box 24F $ CHARGES**

Enter the total charges.

**7 Box 24G UNITS**

Enter the appropriate number of units of service.

- CPT 96365—Enter 1 unit for first hour of infusion

Subsequent time above an hour and a half would be reported with the add-on code 96366 with a unit count reflecting the amount of additional time.

It is the healthcare provider's responsibility to determine the appropriate codes and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care.



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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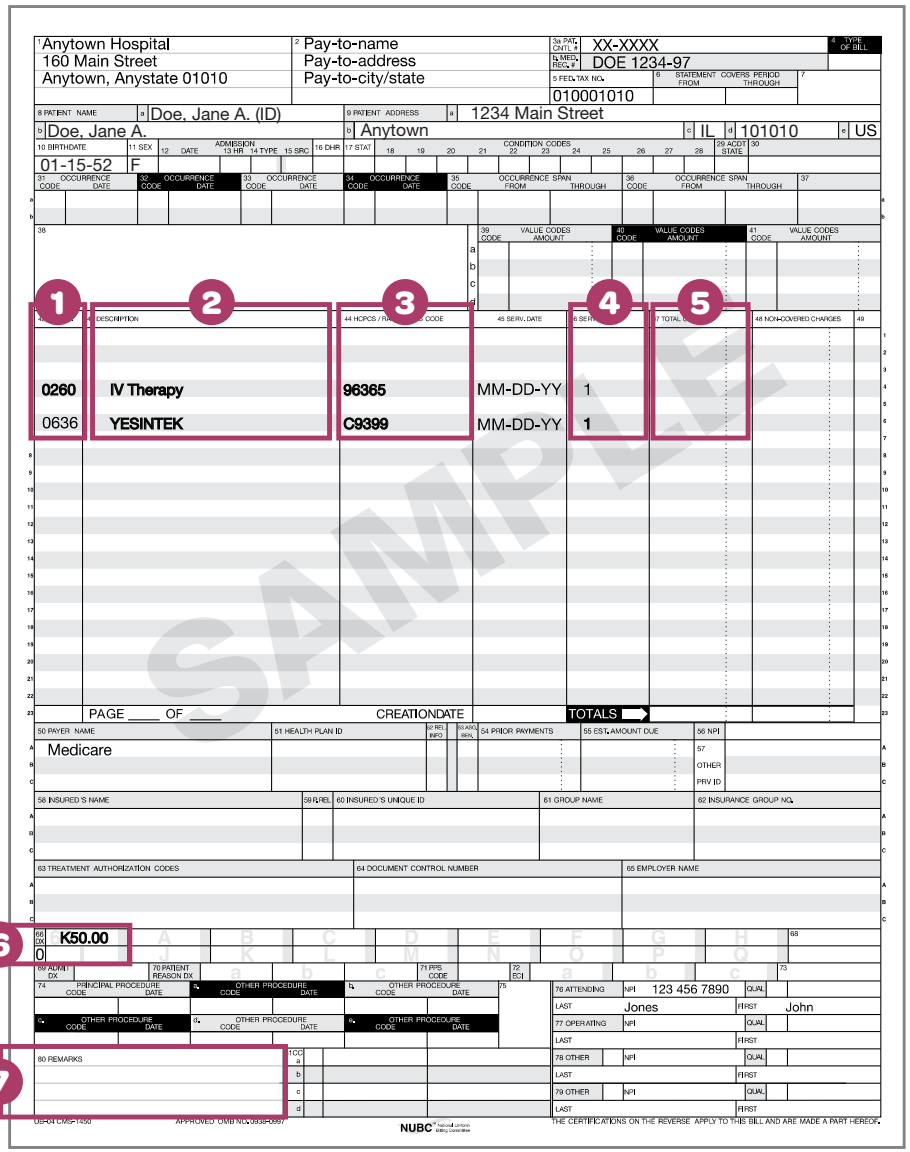
# Sample Claim Forms (continued)




## YESINTEK for IV Use

### HOPD Sample Claim Form (CMS-1450/UB-04): 390 mg IV Induction Dose

**1 FIELD 42**

List revenue codes in ascending order.

**2 FIELD 43**

Enter narrative description for corresponding revenue code (eg, IV therapy, drug). If line item NDC information is required, it will be entered in the unshaded portions of Field 43.[13] Payer requirements of NDC entries may vary.

**3 FIELD 44**

Enter appropriate CPT, HCPCS codes, and modifiers as required by the payer.

**YESINTEK**

C9399, unclassified drugs/biologics

**Infusion Services**

CPT 96365 (Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour)

Applicable Modifiers: See page 11.

**4 FIELD 46**

Enter the appropriate number of units of service:

- C9399—Report 1 unit for the unclassified HCPCS code for the YESINTEK product
- 96365—Enter 1 unit for the first hour of infusion

**5 FIELD 47**

Indicate charges.

**6 FIELD 67**

Indicate diagnosis using appropriate ICD-10-CM codes. Using diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

**7 FIELD 80**

When billing an unclassified HCPCS product code such as C9399, Medicare and other payers may require additional information to be reported here, such as the NDC, the quantity administered, and applicable unit of measurement. See your MAC for additional reporting requirements.

It is the healthcare provider's responsibility to determine the appropriate codes and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care.



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# CROHN'S DISEASE AND ULCERATIVE COLITIS

## SUBCUTANEOUS MAINTENANCE INJECTION

Indicated for the treatment of adults with moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis.[1]



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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# Dosing and Administration[1]

## Maintenance

**The MAINTENANCE doses of YESINTEK for Crohn's disease or ulcerative colitis are delivered by subcutaneous injection.**

Maintenance Dosage Regimen: The recommended maintenance dosage is a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.

**TABLE 1.** MAINTENANCE YESINTEK DOSAGE[1]

| Indications | Dose | Frequency |
|---|---|---|
| Crohn's disease or ulcerative colitis | 90 mg | • 8 weeks after initial IV<br>• Every 8 weeks thereafter |


**Single-dose vial for subcutaneous injection**

There are 2 available formulations for the maintenance dosage regimen, NOT to be used for intravenous induction therapy:

- 90 mg/mL single-dose prefilled syringe
- 45 mg/0.5 mL single-use vial

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# Dosing and Administration[1] (continued)

This section of the Coding and Billing Guide will provide coding and product information related to the subcutaneous injection of the 45 mg/0.5 mL single-dose vial only.


**Single-dose vial for subcutaneous injection**

## Preparation and Administration of YESINTEK for Subcutaneous Injection

YESINTEK is intended for use under the guidance and supervision of a physician. YESINTEK should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. The appropriate dose should be determined by a healthcare provider.

If a physician determines that it is appropriate, a patient may self-inject or a caregiver may inject YESINTEK after proper training in subcutaneous injection technique. Patients should be instructed to follow the directions provided in the Instructions for Use.

## General Considerations for Administration

- YESINTEK is intended for use under the guidance and supervision of a healthcare provider. YESINTEK should only be administered to patients who will be closely monitored and have regular follow-up visits with a healthcare provider. The appropriate dose should be determined by a healthcare provider using the patient's current weight at the time of dosing. In pediatric patients, it is recommended that YESINTEK be administered by a healthcare provider. If a healthcare provider determines that it is appropriate, a patient may self-inject or a caregiver may inject YESINTEK after proper training in subcutaneous injection technique. Instruct patients to follow the directions provided in the Instructions for Use.
- It is recommended that each injection be administered at a different anatomic location (such as upper arms, gluteal regions, thighs, or any quadrant of abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, or indurated. When using the single-dose vial, a 1 mL syringe with a 27-gauge, ½-inch needle is recommended.
- Prior to administration, visually inspect YESINTEK for particulate matter and discoloration. YESINTEK is a clear, colorless to pale yellow solution. Do not use YESINTEK if it is discolored or cloudy, or if other particulate matter is present. YESINTEK does not contain preservatives; therefore, discard any unused product remaining in the vial and/or syringe.
- Each vial of YESINTEK for subcutaneous use contains 45 mg of ustekinumab in 0.5 mL. Determine the dose and number of YESINTEK vials needed based on the indication.
- Draw required dose using the Instructions for Use.



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# Coding

## National Drug Code (NDC)

Drugs and biologics approved by the FDA are assigned a 3-segment NDC number that is specific to the labeler (manufacturer), product (a specific drug, strength, and dosage formulation), and package size. Branded YESINTEK and unbranded ustekinumab-kfce have been assigned 10-digit NDCs as listed in the prescribing information.[6]

Although the FDA uses a 10-digit format, the 11-digit format is required by HIPAA for claims submission without hyphens or punctuation marks.

**TABLE 2.** YESINTEK SINGLE-DOSE VIAL FOR SUBCUTANEOUS INJECTION NDC[1]

| FDA-Specified 10-Digit NDC (5-3-2 format) | 11-Digit NDC (5-4-2 format) | Description |
|---|---|---|
| 83257-024-11 | 83257-0024-11 | 45 mg single-dose vial containing 45 mg of YESINTEK per 0.5 mL solution |


Single-dose vial for subcutaneous injection

## NDC Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and ML (milliliters) applies to drugs supplied in liquid form.[6] NDC units dispensed are based on the packaging and numeric quantity administered to the patient.

Accurate NDC coding typically requires reporting the following components[6]:

- The NDC with 11 digits in a 5-4-2 format (this may require converting a 10-digit NDC)
- The correct NDC unit of measure (ie, UN, ML)
- The number of NDC units dispensed
- The qualifier, N4, in front of the NDC

Example: the coding format for a 90 mg dose of YESINTEK from single-dose vials: **N483257002411 ML1**

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# Coding (continued)

## Healthcare Common Procedure Code System (HCPCS) Level II Codes

HCPCS Level II product codes are used to report FDA-approved biologic products. The Centers for Medicare and Medicaid Services (CMS) has not yet assigned a product-specific HCPCS code for YESINTEK. Therefore, until a specific code is assigned, report YESINTEK for subcutaneous injection with an unspecified HCPCS code. When reporting unspecified codes on claims, additional information may be required to be reported, including the NDC, strength and dose, and route of administration. Refer to your payer's documentation for additional information on billing unspecified HCPCS codes. An application for a product-specific HCPCS code for YESINTEK for subcutaneous use has been submitted.


**Single-dose vial for subcutaneous injection**

**TABLE 3.** HCPCS CODES FOR YESINTEK[5]

| Code | Description | For | Site of Care |
|---|---|---|---|
| J3490 | Unclassified drugs | YESINTEK, subcutaneous injection | All sites of care |
| J3590 | Biologic not otherwise classified | YESINTEK, subcutaneous injection | All sites of care |
| C9399 | Unclassified drugs or biologics | YESINTEK, subcutaneous injection | Hospital outpatient department |

It is the healthcare provider's responsibility to determine the appropriate codes, units, and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care. Contact your payer for additional information on coverage and billing for YESINTEK.

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# Coding (continued)

## HCPCS Level I / Current Procedural Technology (CPT®) Codes

Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT coding system. The following code may be used to report the subcutaneous administration of YESINTEK:

**TABLE 4.** CPT CODE FOR YESINTEK FOR SUBCUTANEOUS INJECTION[7]

| Code | Description |
|---|---|
| 96372 | Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular |


**Single-dose vial for subcutaneous injection**

**Please refer to the summary of code modifiers on the next page for details.**

It is the healthcare provider's responsibility to determine the appropriate codes, units, and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care. Contact your payer for additional information on coverage and billing for YESINTEK.

## Revenue Codes

National Uniform Billing Committee (NUBC) hospital revenue codes are required to bill for hospital services and items like biologics. Each line item on a CMS-1450 (UB-04) or the 837I electronic claim format, must have an assigned revenue code. The revenue codes below may be applicable to hospital claims for YESINTEK for subcutaneous use:

**TABLE 5.** REVENUE CODES FOR YESINTEK FOR SUBCUTANEOUS INJECTION[8]

| Code | Description |
|---|---|
| 0636 | Pharmacy, drugs requiring detailed coding |
| 0940 | Other therapeutic services - General |

# Coding (continued)

## HCPCS and CPT Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance, but not changed in its definition or code. They provide additional information about a service or procedure. Table 6 summarizes modifiers that may be applicable to coding and billing YESINTEK intravenous (IV) use in physician offices and hospital outpatient departments (HOPDs).

**TABLE 6.** SUMMARY OF CODE MODIFIERS

| Modifier | Description | Indication and Placement | CMS-1500 (Item 24D) | CMS-1450 (Box 44) |
|---|---|---|---|---|
| 25 | Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional on the same day of the procedure or other service[7] | • Reported if patient requires distinct E/M service in addition to the infusion procedure[7]<br>• Must be substantiated by documentation that supports the relevant criteria for the reported E/M code[7]<br>• Append the modifier to the appropriate E/M code[7] | ✓Required by Medicare | ✓Required by Medicare |
| PO* | Excepted services provided at an off-campus, outpatient, provider-based department of a hospital[5] | • To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim[9] | N/A | ✓Required by Medicare |
| PN* | Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[5] | • To be reported on each claim line for non-excepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim[9] | N/A | ✓Required by Medicare |
| JW | Drug amount discarded/not administered to any patient[5] | • Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial[10]<br>• Append the modifier to the drug code on a line separate from that reporting the administered dose[10]<br>• Required to be reported with unclassified HCPCS codes J3490 or J3590, when the product is administered in a physician's office or freestanding center[10]<br>• Does not apply to C9399 reporting for hospital outpatient claims[10] | ✓Required by Medicare | ✓Required by Medicare |
| JZ | Zero drug amount discarded/not administered to any patient[5] | • To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage)[11]<br>• Required to be reported with unclassified HCPCS codes J3490 or J3590, when the product is administered in a physician's office or freestanding center[10]<br>• Does not apply to C9399 reporting for hospital outpatient claims[10] | ✓Required by Medicare | ✓Required by Medicare |
| TB | Drug or biological acquired with 340B Drug Pricing Program discount[5] | • Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes[9]<br>• To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[9] | N/A | ✓Required by Medicare |

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations or satellite facilities of a hospital, or a provider-based department that is on campus.[9]

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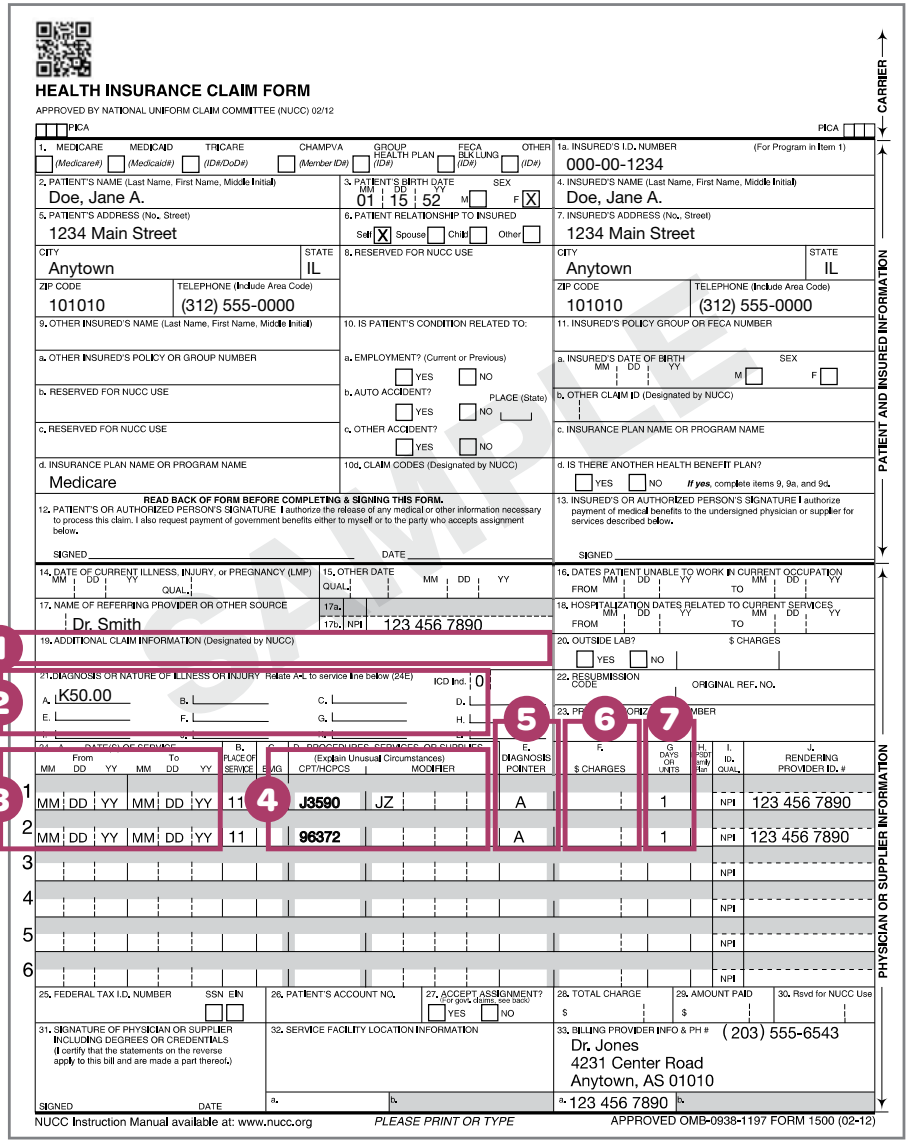
# Sample Claim Forms



HEALTH INSURANCE CLAIM FORM

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

PICA

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

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 000-00-1234

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, Jane A.

3. PATIENT'S BIRTH DATE: 01 15 52 SEX: M [ ] F [X]

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, Jane A.

5. PATIENT'S ADDRESS (No., Street): 1234 Main Street

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 1234 Main Street

CITY: Anytown STATE: IL

8. RESERVED FOR NUCC USE

CITY: Anytown STATE: IL

ZIP CODE: 101010 TELEPHONE (Include Area Code): (312) 555-0000

ZIP CODE: 101010 TELEPHONE (Include Area Code): (312) 555-0000

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

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [ ]

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

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [ ] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [ ]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

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

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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

SIGNED _____ DATE _____

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

SIGNED _____

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

15. OTHER DATE QUAL. MM DD YY

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

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Smith

17a.

17b. NPI 123 456 7890

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. K50.00 B. C. D. E. F. G. H.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

| 24. A. DATE(S) OF SERVICE From MM DD YY | To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. # |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 MM DD YY | MM DD YY | 11 | | J3590 | JZ | A | | 1 | | NPI | 123 456 7890 |
| 2 MM DD YY | MM DD YY | 11 | | 96372 | | A | | 1 | | NPI | 123 456 7890 |
| 3 | | | | | | | | | | NPI | |
| 4 | | | | | | | | | | NPI | |
| 5 | | | | | | | | | | NPI | |
| 6 | | | | | | | | | | NPI | |

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

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

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

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

32. SERVICE FACILITY LOCATION INFORMATION a. b.

33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010 a. 123 456 7890 b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

## YESINTEK for Subcutaneous Injection

### Physician Office Sample Claim Form (CMS-1500): 90 mg Subcutaneous Injection Maintenance Dose

**1 Box 19 ADDITIONAL CLAIM INFORMATION**

When billing an unclassified HCPCS product code such as J3590, Medicare and other payers may require additional information to be reported here, including the name of the drug, strength, and dosage. See your MAC for additional reporting requirements.

**2 Box 21 DIAGNOSIS**

Enter the appropriate diagnosis code (eg, K50.00 for Crohn's disease of small intestine without complications).

**3 Box 24A NDC INFORMATION**

If line item NDC information is required, it will be entered in the shaded portion on Row 1 of this section. Payer requirements for NDC entries may vary.

**4 Box 24D PROCEDURES/SERVICES/SUPPLIES**

Enter appropriate CPT and HCPCS codes and modifiers, if required.
For example: YESINTEK J3590; subcutaneous injection administration CPT 96372
Applicable Modifiers: See page 21.

**5 Box 24E DIAGNOSIS POINTER**

Enter the letter (A-L) from Box 21 for the diagnosis code(s) related to the service on a single line item.

**6 Box 24F $ CHARGES**

Enter the total charges.

**7 Box 24G UNITS**

- J3590

Until a product-specific HCPCS code is assigned, report the YESINTEK product with an unclassified code such as J3590; unclassified codes are reported with a unit of 1, and additional information on dose administered is included in Box 19.

- 96372—Enter 1 unit for injection

It is the healthcare provider's responsibility to determine the appropriate codes and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care.



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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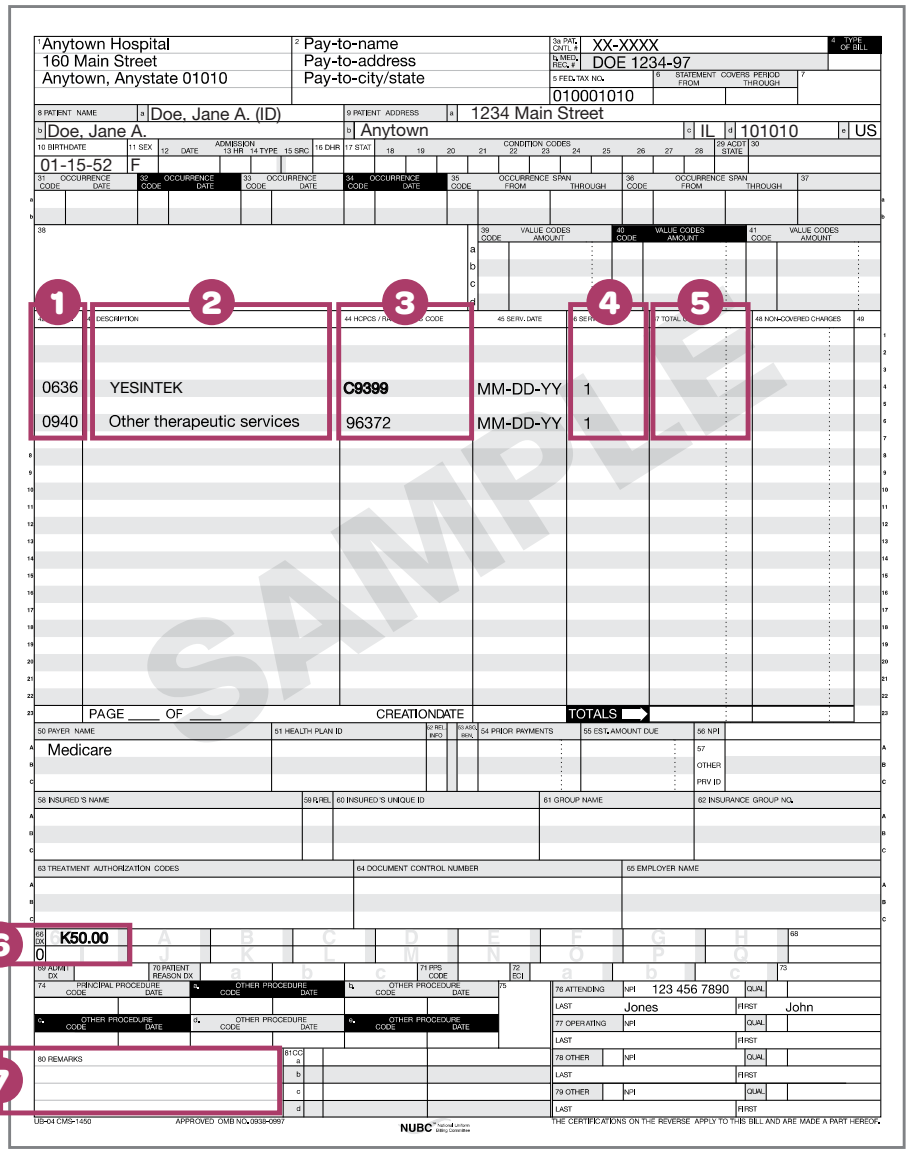
# Sample Claim Forms (continued)




## YESINTEK for Subcutaneous Injection

### HOPD Sample Claim Form (CMS-1450/UB-04): 90 mg Subcutaneous Injection Maintenance Dose

**1 FIELD 42**

List revenue codes in ascending order.

**2 FIELD 43**

Enter narrative description for corresponding revenue code (eg, Other therapeutic services). If line item NDC information is required, it will be entered in the unshaded portions of Field 43.[13] Payer requirements of NDC entries may vary.

**3 FIELD 44**

Enter appropriate CPT, HCPCS codes, and modifiers as required by the payer.

**YESINTEK**

C9399, unclassified drugs/biologics

**Drug Administration**

CPT 96372: Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

Applicable Modifiers: See page 21.

**4 FIELD 46**

Enter the appropriate number of units of service:

- C9399—Report 1 unit for the unclassified HCPCS code for the YESINTEK product.

**5 FIELD 47**

Indicate charges.

**6 FIELD 67**

Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

**7 FIELD 80**

When billing an unclassified HCPCS product code such as C9399, Medicare and other payers may require additional information to be reported here, such as the NDC, the quantity administered, and applicable unit of measurement. See your MAC for additional reporting requirements.

It is the healthcare provider's responsibility to determine the appropriate codes and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care.



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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# PLAQUE PSORIASIS AND PSORIATIC ARTHRITIS

## YESINTEK SUBCUTANEOUS INJECTION

Indicated for the treatment of adult patients and pediatric patients 6 years and older with moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy, or adult patients with active psoriatic arthritis (PsA).[1]



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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# Dosing and Administration[1]

YESINTEK dosing for plaque psoriasis or psoriatic arthritis may be weight-based. Induction and maintenance doses are administered by subcutaneous injection.

**TABLE 1.** YESINTEK SUBCUTANEOUS INJECTION DOSING TABLE[1]

| Indication | Patient Weight | Induction | Maintenance | YESINTEK Vials 45 mg/0.5 mL |
|---|---|---|---|---|
| Plaque Psoriasis *Adult* | 100 kg or less | 45 mg | 45 mg at 4 weeks after initial dose then 45 mg every 12 weeks | 1 vial |
| | More than 100 kg | 90 mg | 90 mg at 4 weeks after initial dose then 90 mg every 12 weeks | 2 vials |
| Plaque Psoriasis *Pediatric Patients (6-17 years old)* | Less than 60 kg | 0.75 mg/kg | 0.75 mg/kg at 4 weeks after initial dose then 0.75 mg/kg every 12 weeks | <1 vial |
| | 60 kg-100 kg | 45 mg | 45 mg at 4 weeks after initial dose then 45 mg every 12 weeks | 1 vial |
| | More than 100 kg | 90 mg | 90 mg at 4 weeks after initial dose then 90 mg every 12 weeks | 2 vials |
| Psoriatic Arthritis | All adult patients (see exception below) | 45 mg | 45 mg at 4 weeks after initial dose then 45 mg every 12 weeks | 1 vial |
| | Patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg | 90 mg | 90 mg at 4 weeks after initial dose then 90 mg every 12 weeks | 2 vials |

There are 2 available dosage forms for subcutaneous injection:

- 45 mg/0.5 mL or 90 mg/mL single-dose prefilled syringe
- 45 mg/0.5 mL single-dose vial


**Single-dose vial for subcutaneous injection**



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# Dosing and Administration[1] (continued)

This section of the Coding and Billing Guide will provide coding and product information related to the subcutaneous injection of the 45 mg/0.5 mL single-dose vial only.

## General Considerations for Administration

- YESINTEK is intended for use under the guidance and supervision of a healthcare provider. YESINTEK should only be administered to patients who will be closely monitored and have regular follow-up visits with a healthcare provider. The appropriate dose should be determined by a healthcare provider using the patient's current weight at the time of dosing. In pediatric patients, it is recommended that YESINTEK be administered by a healthcare provider. If a healthcare provider determines that it is appropriate, a patient may self-inject or a caregiver may inject YESINTEK after proper training in subcutaneous injection technique. Instruct patients to follow the directions provided in the Instructions for Use included with their medication.
- It is recommended that each injection be administered at a different anatomic location (such as upper arms, gluteal regions, thighs, or any quadrant of abdomen) than the previous injection, and not into areas where the skin is tender, bruised, erythematous, or indurated. When using the single-dose vial, a 1-mL syringe with a 27-gauge, ½-inch needle is recommended.
- Prior to administration, visually inspect YESINTEK for particulate matter and discoloration. YESINTEK is a colorless to pale yellow solution. Do not use YESINTEK if it is discolored or cloudy, or if other particulate matter is present. YESINTEK does not contain preservatives; therefore, discard any unused product remaining in the vial and/or syringe.
- Each vial of YESINTEK for subcutaneous use contains 45 mg of ustekinumab in 0.5 mL. Determine the dose and number of YESINTEK vials needed based on the indication.
- Draw required dose using the Instructions for Use.


**Single-dose vial for subcutaneous injection**



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# Coding

## ICD-10-CM Diagnosis Codes

YESINTEK is FDA approved for the treatment of psoriatic arthritis and psoriasis. This table includes code ranges and codes that may be applicable for these indications; additional codes may apply. For the codes represented here, it is necessary to code to the greatest level of specificity; a code is invalid if it does not include the full number of required characters.[2]

**TABLE 2.** ICD-10-CM DIAGNOSIS CODES*—PSORIATIC ARTHRITIS AND PSORIASIS

| | |
|---|---|
| **Psoriatic Arthritis[14]** | |
| **L40.50** | Arthropathic psoriasis, unspecified |
| **L40.51** | Distal interphalangeal psoriatic arthropathy |
| **L40.52** | Psoriatic arthritis mutilans |
| **L40.53** | Psoriatic spondylitis |
| **L40.54** | Psoriatic juvenile arthropathy |
| **L40.59** | Other psoriatic arthropathy |
| **Psoriasis[14]** | |
| **L40.0** | Psoriasis vulgaris |
| **L40.9** | Psoriasis, unspecified |

*These codes are not intended to be promotional, nor to encourage or suggest a use of the drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive and additional codes may apply.


**Single-dose vial for subcutaneous injection**

# Coding (continued)

## National Drug Code (NDC)

Drugs and biologics approved by the FDA are assigned a 3-segment NDC number that is specific to the labeler (manufacturer), product (a specific drug, strength, and dosage formulation), and package size. YESINTEK and unbranded ustekinumab have been assigned 10-digit NDCs as listed in the prescribing information.[6]

Although the FDA uses a 10-digit format, the 11-digit format is required by HIPAA for claims submission without hyphens or punctuation marks.

**TABLE 3.** YESINTEK SINGLE-DOSE VIAL FOR SUBCUTANEOUS INJECTION NDC[1]

| 10-Digit NDC (5-3-2 format) | 11-Digit NDC (5-4-2 format) | Description |
|---|---|---|
| 83257-024-11 | 83257-0024-11 | Single-dose vial containing 45 mg of YESINTEK per 0.5 mL solution |

## NDC Units

The NDC unit of measure is determined by how the drug is supplied. In the outpatient setting, UN (unit) applies to drugs supplied in a vial in powder form, requiring reconstitution before administration, and mL (milliliters) applies to drugs supplied in liquid form.[6] NDC units dispensed are based on the packaging and numeric quantity administered to the patient (see examples below using 45 mg and 90 mg doses of YESINTEK and unbranded ustekinumab-kfce).

Accurate NDC coding typically requires reporting the following components[6]:

- The NDC with 11 digits in a 5-4-2 format (this may require converting a 10-digit NDC)
- The correct NDC unit of measure (ie, UN, ML)
- The number of NDC units dispensed
- The qualifier, N4, in front of the NDC

Example: the coding format for a 45 mg dose of YESINTEK from single-dose vials: **N483257003211 ML0.5**

# Coding (continued)

## Healthcare Common Procedure Code System (HCPCS) Level II Codes

HCPCS Level II product codes are used to report FDA-approved biologic products. The Centers for Medicare and Medicaid Services (CMS) has not yet assigned a product-specific HCPCS code for YESINTEK. Therefore, until a specific code is assigned, report YESINTEK for subcutaneous injection with an unspecified HCPCS code. When reporting unspecified codes on claims, additional information may be required to be reported, including the NDC, strength and dose, and route of administration. Refer to your payer's documentation for additional information on billing unspecified HCPCS codes. An application for a product-specific HCPCS code for YESINTEK for subcutaneous use has been submitted.

**TABLE 4.** HCPCS CODES FOR YESINTEK[5]

| Code | Description | For | Site of Care |
|---|---|---|---|
| J3490 | Unclassified drugs | YESINTEK/ustekinumab-kfce, subcutaneous injection | All sites of care |
| J3590 | Biologic not otherwise classified | YESINTEK/ustekinumab-kfce, subcutaneous injection | All sites of care |
| C9399 | Unclassified drugs or biologics | YESINTEK/ustekinumab-kfce, subcutaneous injection | Hospital outpatient department |

It is the healthcare provider's responsibility to determine the appropriate codes, units, and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care. Contact your payer for additional information on coverage and billing for YESINTEK.

# Coding (continued)

## HCPCS Level I / Current Procedural Technology (CPT®) Codes

Drug administration services are reported on claim forms in both the physician office (CMS-1500) and hospital outpatient (CMS-1450) sites of care using the CPT coding system. The following code may be used to report the subcutaneous administration of YESINTEK:

**TABLE 5.** CPT CODE FOR YESINTEK FOR SUBCUTANEOUS INJECTION[7]

| Code | Description |
|---|---|
| 96372 | Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular |

**Please refer to the summary of code modifiers on page 31 for details.**

It is the healthcare provider's responsibility to determine the appropriate codes, units, and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care. Contact your payer for additional information on coverage and billing for YESINTEK.

## Revenue Codes

National Uniform Billing Committee (NUBC) hospital revenue codes are required to bill for hospital services and items like biologics. Each line item on a CMS-1450 (UB-04) or the 837I electronic claim format, must have an assigned revenue code. The revenue codes below may be applicable to hospital claims for YESINTEK for subcutaneous use:

**TABLE 6.** REVENUE CODES FOR YESINTEK FOR SUBCUTANEOUS INJECTION[8]

| Code | Description |
|---|---|
| 0636 | Pharmacy, drugs requiring detailed coding |
| 0940 | Other therapeutic services - General |

# Coding (continued)

## HCPCS and Current Procedural Technology (CPT®) Modifiers

Modifiers are used to report or indicate that a service or procedure has been altered by some specific circumstance, but not changed in its definition or code. They provide additional information about a service or procedure. Table 7 summarizes modifiers that may be applicable to coding and billing YESINTEK intravenous (IV) use in physician offices and hospital outpatient departments (HOPDs).

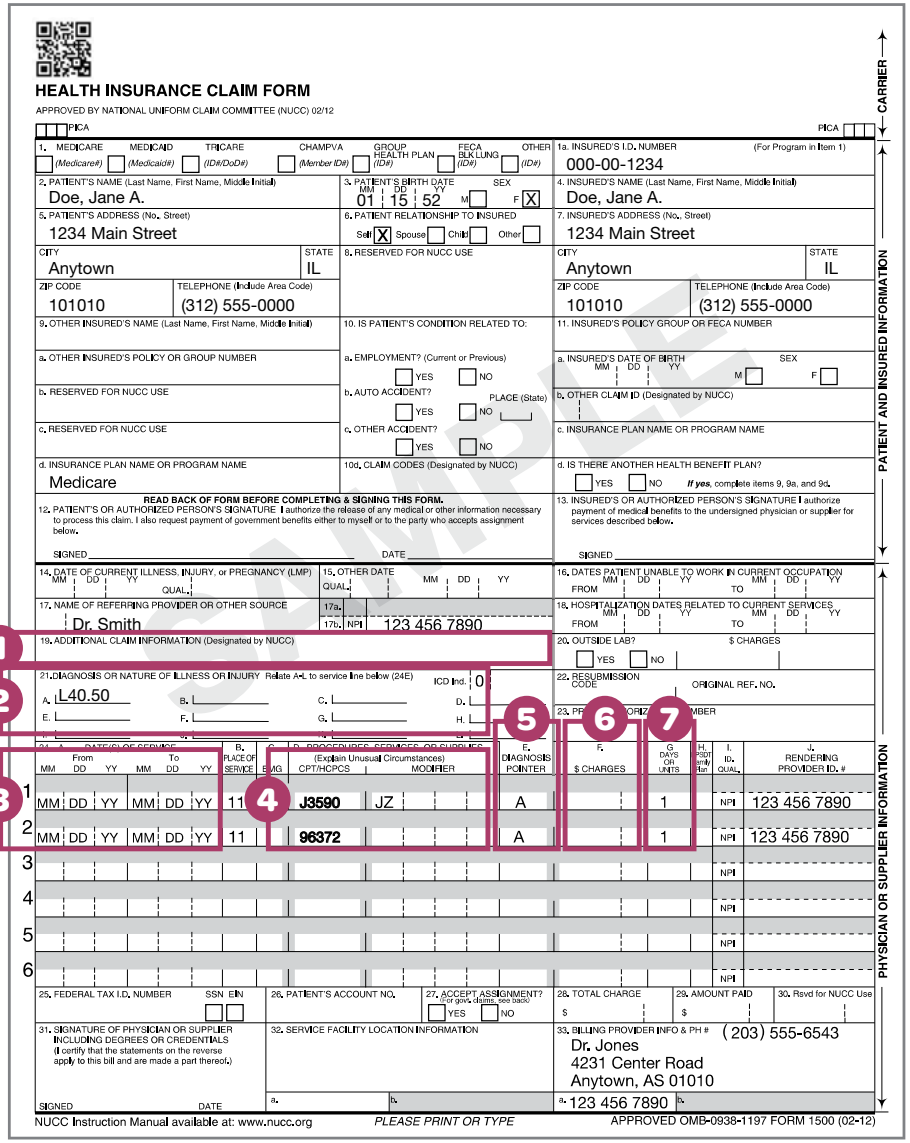
**TABLE 7.** SUMMARY OF CODE MODIFIERS

| Modifier | Description | Indication and Placement | CMS-1500 (Item 24D) | CMS-1450 (Box 44) |
|---|---|---|---|---|
| 25 | Significant, separately identifiable evaluation and management (E/M) service by the same physician or other qualified healthcare professional on the same day of the procedure or other service[7] | • Reported if patient requires distinct E/M service in addition to the infusion procedure[7]<br>• Must be substantiated by documentation that supports the relevant criteria for the reported E/M code[7]<br>• Append the modifier to the appropriate E/M code[7] | ✓Required by Medicare | ✓Required by Medicare |
| PO* | Excepted services provided at an off-campus, outpatient, provider-based department of a hospital[5] | • To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim[9] | N/A | ✓Required by Medicare |
| PN* | Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[5] | • To be reported on each claim line for non-excepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim[9] | N/A | ✓Required by Medicare |
| JW | Drug amount discarded/not administered to any patient[5] | • Applies only to the unused drug that is discarded after applicable dose has been administered from a single-use vial[10]<br>• Append the modifier to the drug code on a line separate from that reporting the administered dose[10]<br>• Required to be reported with unclassified HCPCS codes J3490 or J3590, when the product is administered in a physician's office or freestanding center[10]<br>• Does not apply to C9399 reporting for hospital outpatient claims[10] | ✓Required by Medicare | ✓Required by Medicare |
| JZ | Zero drug amount discarded/not administered to any patient[5] | • To be used for single-dose containers or single-use packages when the entire amount has been administered to the patient (no wastage)[11]<br>• Required to be reported with unclassified HCPCS codes J3490 or J3590, when the product is administered in a physician's office or freestanding center[10]<br>• Does not apply to C9399 reporting for hospital outpatient claims[10] | ✓Required by Medicare | ✓Required by Medicare |
| TB | Drug or biological acquired with 340B Drug Pricing Program discount[5] | • Must be reported by hospitals designated as "select entities" (rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals) to identify 340B drugs for informational purposes[9]<br>• To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[9] | N/A | ✓Required by Medicare |

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations or satellite facilities of a hospital, or a provider-based department that is on campus.[9]

Yesintek™ (ustekinumab-kfce)

# Sample Claim Forms



HEALTH INSURANCE CLAIM FORM

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

PICA

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

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 000-00-1234

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, Jane A.

3. PATIENT'S BIRTH DATE: 01 15 52 SEX: M [ ] F [X]

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, Jane A.

5. PATIENT'S ADDRESS (No., Street): 1234 Main Street

6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]

7. INSURED'S ADDRESS (No., Street): 1234 Main Street

CITY: Anytown STATE: IL

8. RESERVED FOR NUCC USE

CITY: Anytown STATE: IL

ZIP CODE: 101010 TELEPHONE (Include Area Code): (312) 555-0000

ZIP CODE: 101010 TELEPHONE (Include Area Code): (312) 555-0000

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

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES [ ] NO [ ]

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

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES [ ] NO [ ] PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES [ ] NO [ ]

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

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

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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

SIGNED _____ DATE _____

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

SIGNED _____

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

15. OTHER DATE QUAL. MM DD YY

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

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Smith

17a.

17b. NPI 123 456 7890

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES [ ] NO [ ] $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. L40.50 B. C. D. E. F. G. H.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

| 24. A. DATE(S) OF SERVICE From MM DD YY | To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS | MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. # |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 MM DD YY | MM DD YY | 11 | | J3590 | JZ | A | | 1 | | NPI | 123 456 7890 |
| 2 MM DD YY | MM DD YY | 11 | | 96372 | | A | | 1 | | NPI | 123 456 7890 |
| 3 | | | | | | | | | | NPI | |
| 4 | | | | | | | | | | NPI | |
| 5 | | | | | | | | | | NPI | |
| 6 | | | | | | | | | | NPI | |

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

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

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

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

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. b.

33. BILLING PROVIDER INFO & PH # (203) 555-6543
Dr. Jones
4231 Center Road
Anytown, AS 01010

a. 123 456 7890 b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

## YESINTEK for Subcutaneous Injection

### Physician Office Sample Claim Form (CMS-1500)

**1 Box 19 ADDITIONAL CLAIM INFORMATION**

When billing an unclassified HCPCS product code such as J3590, Medicare and other payers may require additional information to be reported here, including the name of the drug, strength, and dosage. See your MAC for additional reporting requirements.

**2 Box 21 DIAGNOSIS**

Enter the appropriate diagnosis code (eg, L40.50 for Arthropathic psoriasis, unspecified).

**3 Box 24A NDC INFORMATION**

If line item NDC information is required, it will be entered in the shaded portion on Row 1 of this section. Payer requirements for NDC entries may vary.

**4 Box 24D PROCEDURES/SERVICES/SUPPLIES**

Enter appropriate CPT and HCPCS codes and modifiers, if required. For example: YESINTEK J3590; subcutaneous injection administration.

Applicable Modifiers: See page 31.

**5 Box 24E DIAGNOSIS POINTER**

Enter the letter (A-L) from Box 21 for the diagnosis code(s) related to the service on a single line item.

**6 Box 24F $ CHARGES**

Enter the total charges.

**7 Box 24G UNITS**

- J3590
  Until a product-specific HCPCS code is assigned, report the YESINTEK product with an unclassified code such as J3590; unclassified codes are reported with a unit of 1, and additional information on dose administered is included in Box 19.
- 96372—Enter 1 unit for injection

It is the healthcare provider's responsibility to determine the appropriate codes and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care.



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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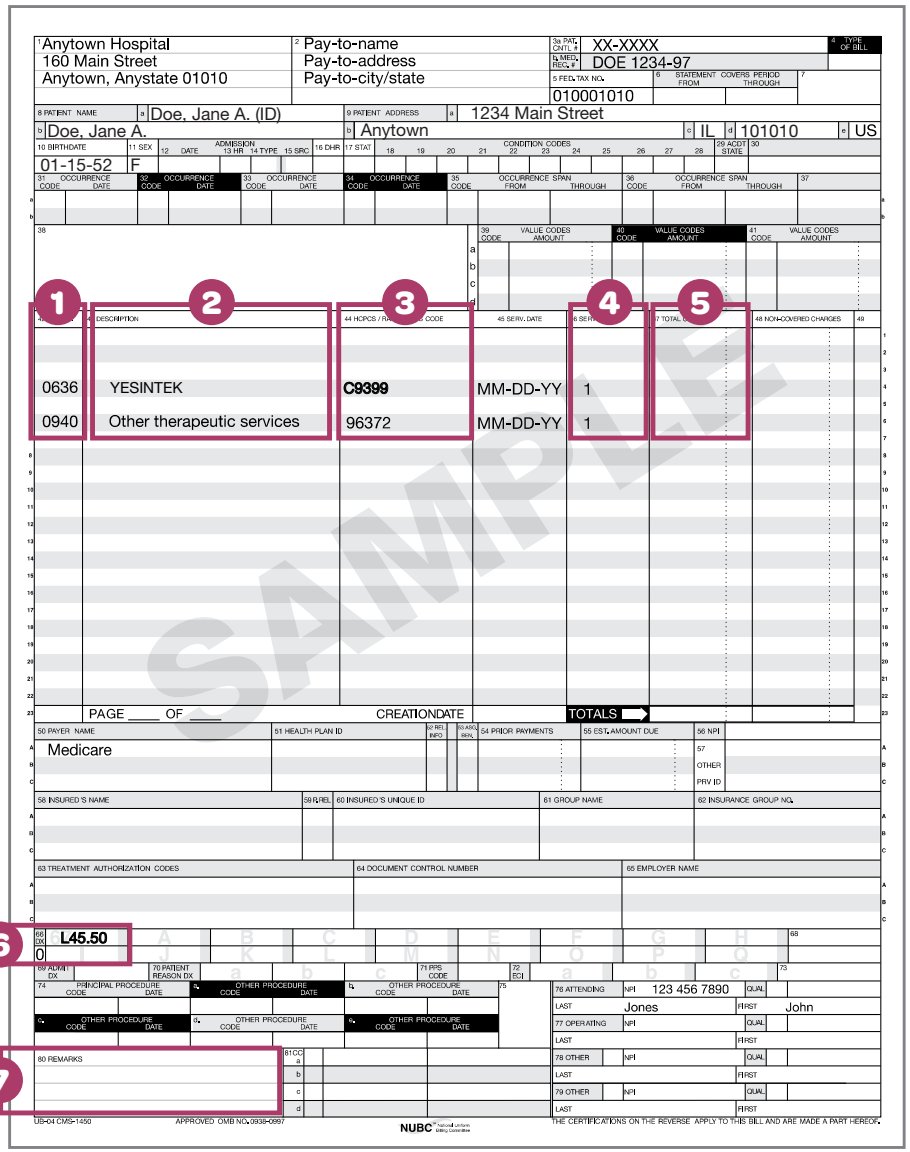
# Sample Claim Forms (continued)




## YESINTEK for Subcutaneous Injection

### HOPD Sample Claim Form (CMS-1450) (UB-04)

**1 FIELD 42**

List revenue codes in ascending order.

**2 FIELD 43**

Enter narrative description for corresponding revenue code (eg, Other therapeutic services). If line item NDC information is required, it will be entered in the unshaded portions of Field 43.[13] Payer requirements of NDC entries may vary.

**3 FIELD 44**

Enter appropriate CPT, HCPCS codes, and modifiers as required by the payer.

**YESINTEK**

C9399, unclassified drugs/biologics

**Drug Administration**

CPT 96372: Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

Applicable Modifiers: See page 31.

**4 FIELD 46**

Enter the appropriate number of units of service:

- C9399—Report 1 unit for the unclassified HCPCS code for the YESINTEK product.

**5 FIELD 47**

Indicate charges.

**6 FIELD 67**

Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

**7 FIELD 80**

When billing an unclassified HCPCS product code such as C9399, Medicare and other payers may require additional information to be reported here, such as the NDC, the quantity administered, and applicable unit of measurement. See your MAC for additional reporting requirements.

It is the healthcare provider's responsibility to determine the appropriate codes and modifiers. Coverage, billing, and reimbursement policies may vary by payer, plan, and setting of care.



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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# COVERAGE & SUPPORT



Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.

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# Coverage Considerations

Third-party payers (eg, commercial insurers, Medicare, Medicaid) will generally cover parenteral drugs and biologics for their FDA-approved indications and the associated professional administration services. However, benefits may vary depending on the payer and the specific plan in which a patient is enrolled.

## Eligibility and Coverage Criteria

Eligibility and benefit confirmation, and demonstrated medical necessity, are key to ensuring submitted claims will be covered. It is important to review the payer's published medical policies and check the patient's eligibility against all criteria, including patient diagnoses, treatment history for the condition, and other stipulations of coverage.

Medicare National Coverage Determinations (NCDs) and Medicare Administrative Contractors (MACs) Local Coverage Determinations (LCDs) define medical necessity requirements for Medicare coverage. These documents contain guidance on covered diagnoses, required documentation, and limitations of coverage for specific services in accordance with medical necessity.

## Prior Authorization Overview

A prior authorization (PA) is a requirement imposed by a payer for the provider to obtain approval prior to administering a drug or performing a procedure or service. It is used to help payers ensure that the therapy is medically necessary and serves as a preliminary determination of coverage, but the payer reserves the right to review documentation before or after claim payment to make a final determination. Payers typically have standard processes that must be followed for healthcare providers to submit a PA request. These may include calling a specific department, filling out and faxing a form, or writing a letter of medical necessity. Evidence of medical necessity may include:

- The expected outcome of a prescribed therapy
- Potential consequences of not using that therapy
- The reason(s) why alternatives are not clinically appropriate

An adequately supported and appropriately submitted PA is more likely to result in a favorable coverage decision. If for some reason a patient cannot meet a payer's requirements for the drug they need, they have the right to request a coverage determination, also known as requesting an exception.

# Coverage Considerations (continued)

## Administrative Considerations

Other considerations may be involved in a payer's coverage policies for an item or service:

Does the payer's contract specifically indicate the sites of care that may bill for infusion services or infused drugs?

- A small portion of payers have exclusive contracts with designated preferred providers for infusion services
- This may include certain clinics or specialty pharmacies that deliver drugs to healthcare providers or other infusion centers

Does the payer cover the therapy only when provided through a specific treatment site?

- Payers may have site-specific coverage rules that restrict provision of infused therapies
- For example, currently Medicare does not cover infusions when they are billed by Medicare-certified ambulatory surgery centers
- Payers also may restrict coverage for certain infused drugs in the home or hospital outpatient setting

Is the billing provider a "participating" member of, or "in-network" provider for, that particular plan?

- Payers contract with providers to deliver services to the plan's members
- Providers are thus "participating" or within that plan's network, requiring them to abide by the contract charge structure when providing care for that plan's members

Is the plan willing to grant in-network status when a service is otherwise out of network?

- In some cases (eg, when there there are no available in-network providers), health plans may grant in-network status for a provider and related services
- In such cases, the provider accepts the in-network rate and the patient will be able to access in-network cost-sharing
- It may be helpful to contact a payer to ask for a service to be converted to in-network status

If required by the plan, has the appropriate referral or prior authorization been obtained?

- Many plans require that non-emergency services be pre-approved or that a primary care physician make the referral for specialty care
- Failing to obtain appropriate referrals or pre-authorization can result in non-payment by the plan

# Coverage Considerations (continued)

## Exception Request

An exception request is a specific type of coverage determination that asks a payer to reconsider a coverage denial or to deviate from standard process. It provides the payer an opportunity to influence, or make more patient-specific, a coverage decision-making process when the payer's coverage policies do not meet a patient's unique needs. An exception request again requires the prescriber to submit evidence of medical necessity. It is helpful to specifically respond to the reason(s) coverage was denied (eg, drug not on formulary, dose restrictions, step therapy, etc). An exception request that is appropriately submitted and adequately supported is more likely to result in a favorable payer decision. If the request is not granted, the payer will provide the patient with a written explanation and include information about how to request an appeal.

## Appeals

Appeals are a response to a payer's denial of benefits the enrollee believes they are entitled to receive. The appeals process typically includes a series of progressive steps and specific timelines. If supporting an appeal, contact the payer for guidance as individual policies may vary. Steps patients or providers can take to support an appeal include:

- Submitting supporting evidence to counter the specific reason for the denial
- Presenting the patient's story in a manner that leads to the therapeutic request (eg, events leading to current condition, results of previous therapies, expected clinical progression)
- Expressing willingness to collaborate (eg, offer contact information, invite discussion with medical director or specialist)

Following a positive coverage decision at any stage, it is important to provide feedback to the payer and reinforce that their decision resulted in a positive patient outcome.

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## My Biocon Biologics™ provides patient access support

In addition to this Coding & Billing Guide, Biocon Biologics offers the following services and tools to help you and your patients with YESINTEK™ from the start.

### Benefits Investigation
Handles research of insurance coverage and patient cost-sharing, while providing a full summary of benefits

### Bridge Program*
Helps minimize authorization-related treatment delays for existing patients and deliver prescriptions to their door

### Prior Authorization (PA) Support
Helps you with verifying the enrollment status of your patient's insurance plan

### IV Savings Program†
Gives eligible new patients savings up to $100 in out-of-pocket costs associated with the initial induction dose for gastrointestinal conditions

### Quick Start Program*
Provides a way for new patients to quickly begin therapy if the PA or appeal process takes 5 days or longer

### Instructional Injection Video
Educates patients through a step-by-step video tutorial on how to properly inject YESINTEK

**Some services listed may not be available at launch. For the latest updates on all programs, please check with My Biocon Biologics.**

*Eligibility restrictions apply. For Bridge Program and Quick Start Program terms and conditions, visit www.YesintekHCP.com/bridgeprogramtermsandconditions.
†Eligibility restrictions apply. Not valid for uninsured patients or patients who are covered by a state- or federally funded healthcare program. For full terms and conditions, visit www.Yesintek.com/IVsavingsprogram.


## COPAY ASSISTANCE‡

We'll help you identify and enroll your eligible patients who may **pay as little as $0** in out-of-pocket costs.

‡Eligibility restrictions apply. Not valid for uninsured patients or patients who are covered by a state- or federally funded healthcare program. For full terms and conditions, visit www.Yesintek.com/copay.

**Enroll your patients today at YesintekHCP.com.**

# Appendix

## Sample Letter of Medical Necessity

Payers may request a letter of medical necessity to support coverage of YESINTEK. The letter explains why the drug was medically necessary for the specific patient and may include supporting documentation (eg, medical records, peer-reviewed literature, prescribing information). The letter may be submitted as part of a PA request, with the claim form, or in response to a payer's additional document request.

The following is a sample letter of medical necessity, or you may use another form or format. The letter should include patient-specific information, should be on your letterhead and signed by the prescriber, and should be submitted to a payer to support a PA request or claim for YESINTEK.

[Date]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address] [Insert City, State ZIP]

Insured Member Name: [Insert Member Name]
Policy Number: [Insert Member Policy Number]
Group Number: [Insert Group Number]

**Patient:** [Insert Patient Name]
**Date of Birth:** [Insert Patient DOB]
**Diagnosis:** [Insert Diagnosis] [Insert ICD]
**Dose and Frequency:** [Insert Dose & Frequency]

Dear [Insert Name of Medical Director or Name of Individual Responsible for Prior Authorization],

I am writing on behalf of my patient, [Insert Patient Name], to request **authorization** to receive treatment with YESINTEK™ for [Insert Indication]. My request is supported by the following:

**Summary of Patient's Diagnosis and History**

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

[Insert:

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patient)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with YESINTEK

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

**Rationale for Treatment**

[Insert summary statement for rationale for treatment such as: considering the patient's history, condition, and the Full Prescribing Information supporting uses of YESINTEK, I believe treatment with YESINTEK at this time is medically necessary and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for YESINTEK for this patient, such as the Full Prescribing Information, peer-reviewed journal articles, and clinical guidelines.]

[Given the urgent nature of this request,] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,

[Insert Healthcare Provider's Name and Participating Provider Number]

Enclosures [Include Full Prescribing Information and the additional support noted above]

# Appendix (continued)

## Sample Letter of Appeal

In some cases, a claim denial may be overturned after a phone call to a payer representative. If not, an appeal letter may be submitted in response to a payer's decision for underpayment or nonpayment, as detailed in the explanation of benefits (EOB) or remittance advice. In addition to filing the appeal within timely filing limits, understanding the reasons the payer denied the claim is critical for filing a successful appeal. The following sample letter of appeal or another form may be used to submit additional documentation to the patient's payer when appealing a denied claim.

[Date]

[Insert Name of Medical Director]
[Insert Payer Name]
[Insert Address] [Insert City, State ZIP]

Insured Member Name: [Insert Member Name]
Policy Number: [Insert Member Policy Number]
Group Number: [Insert Group Number]

**Patient:** [Insert Patient Name]
**Date of Birth:** [Insert Patient DOB]

Dear [Insert Contact Name],

This letter serves as a request for payment of a denied claim representing charges for YESINTEK™ (ustekinumab-kfce), a biosimilar administered to [Insert Patient Name] on [Insert Date of Service]. [Insert Patient Name] has a diagnosis of [Insert Diagnosis] [Insert ICD] and is under my treatment care. You have indicated that YESINTEK is not covered by [Insert Payer Name] because of [Insert Reason for Denial]. My request for approval is supported by the following:

**Summary of Patient's Diagnosis and History**

[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

[Insert:

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patient)
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with YESINTEK

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

**Rationale for Treatment**

[You may consider including documents that provide additional clinical information to support the recommendation for YESINTEK for this patient, such as the Full Prescribing Information, peer-reviewed journal articles, and clinical guidelines.]

I believe YESINTEK is a medically necessary part of [Insert Patient Name]'s treatment at this time. I request that a specialist who is familiar with YESINTEK review this appeal letter as I am confident your reconsideration of this claim would yield appropriate payment. Please contact me at [Insert Phone Number] if you require any additional information.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Insert Healthcare Provider's Name and Participating Provider Number]

Enclosures [Include Full Prescribing Information and the additional support noted above]

Yesintek™
(ustekinumab-kfce)

# IMPORTANT SAFETY INFORMATION

## INDICATIONS

YESINTEK (ustekinumab-kfce) is a human interleukin-12 and -23 antagonist indicated for the treatment of: Adult patients with: moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy; active psoriatic arthritis (PsA); moderately to severely active Crohn's disease (CD); moderately to severely active ulcerative colitis.

Pediatric patients 6 years and older with: moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy; active psoriatic arthritis (PsA).

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

YESINTEK is contraindicated in patients with clinically significant hypersensitivity to ustekinumab or to any of the excipients.

### Infections

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

Serious infections requiring hospitalization or otherwise clinically significant infections:

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

Treatment with YESINTEK should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of YESINTEK 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 YESINTEK and discontinue YESINTEK 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, Salmonella, 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 may be susceptible to these types of infections. Consider 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 YESINTEK.

Do not administer YESINTEK to patients with active tuberculosis infection. Initiate treatment of latent TB before administering YESINTEK. Closely monitor patients receiving YESINTEK for signs and symptoms of active TB during and after treatment.

**Malignancies:** YESINTEK is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among patients who received ustekinumab in clinical trials.

The safety of ustekinumab 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 who had risk factors for developing non-melanoma skin cancer (NMSC).



**Please refer to the Dosage and Administration section of the Full Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer YESINTEK. Please see Important Safety Information for YESINTEK on pages 41 and 42.**

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# IMPORTANT SAFETY INFORMATION (continued)

**Malignancies: (continued)**
All patients receiving YESINTEK, especially those >60 years of age, those with a history of PUVA or prolonged immunosuppressant treatment, should be monitored for the appearance of NMSC.

**Hypersensitivity Reactions:** Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with ustekinumab. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue YESINTEK.

**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 also been reported in post-marketing experience in patients with psoriasis, psoriatic arthritis and Crohn's disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after ustekinumab initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab.

Monitor all patients treated with YESINTEK for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue YESINTEK.

**Immunizations:** Prior to initiating therapy with YESINTEK, patients should receive all age-appropriate immunizations as recommended by current immunization guidelines. Patients being treated with YESINTEK should avoid receiving live vaccines. Avoid administering BCG vaccines during treatment with YESINTEK or for one year prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving YESINTEK because of the potential risk for shedding from the household contact and transmission to patient.

Non-live vaccinations received during a course of YESINTEK 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. 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 YESINTEK and institute appropriate treatment.

**Allergen Immunotherapy:** YESINTEK may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

**Most Common Adverse Reactions**

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

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