

Billing and Coding Guide

Plaque Psoriasis

Psoriatic Arthritis

Crohn's Disease

Ulcerative Colitis

INDICATIONS

STEQEYMA (ustekinumab-stba) is a human interleukin-12 and -23 antagonist indicated for the treatment of:

- **Plaque Psoriasis** (PsO) in adults and pediatric patients 6 years of age and older with moderate to severe PsO who are candidates for phototherapy or systemic therapy.
- **Psoriatic Arthritis** (PsA) in adults and pediatric patients 6 years of age and older with active PsA.
- **Crohn's Disease** (CD) in adult patients with moderately to severely active CD.
- **Ulcerative Colitis** (UC) in adult patients with moderately to severely active UC.

CONTRAINDICATIONS

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

IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

- **Infections.** Ustekinumab products, including STEQEYMA, may increase the risk of infections and reactivation of latent infections, including serious bacterial, mycobacterial, fungal, and viral infections requiring hospitalization. Reported infections include pneumonia, gastroenteritis, cellulitis, sepsis, cholecystitis, anal abscess, listeria meningitis, and ophthalmic herpes zoster. Avoid starting STEQEYMA in patients with active infections until resolved, and assess risks in those with chronic or recurrent infections. Advise patients to seek medical care for signs of infection. Discontinue STEQEYMA for serious infections until treated or resolved.

Please see additional Important Safety Information on page 17 and full [Prescribing Information](#).

Introduction to STEQEYMA¹

STEQEYMA (ustekinumab-stba) injection for subcutaneous or intravenous use is a human interleukin-12 and -23 antagonist biosimilar to STELARA® (ustekinumab).

Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of STEQEYMA has been demonstrated for the conditions of use (eg, indication, dosing regimen, strength, dosage form, and route of administration) described in its full Prescribing Information.

This guide is provided for informational purposes only. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and specific billing requirements. Celltrion does not make any representation or guarantees concerning reimbursement or coverage for any service or item, nor does Celltrion guarantee patient assistance to the limits described.

STEQEYMA Formulations²

FOR INTRAVENOUS INFUSION

SINGLE-DOSE VIAL



130 mg/26 mL (5 mg/mL)
NDC: 72606-029-01

FOR SUBCUTANEOUS ADMINISTRATION

PREFILLED SYRINGE



45 mg/0.5 mL
NDC: 72606-027-01

FOR SUBCUTANEOUS ADMINISTRATION

PREFILLED SYRINGE



90 mg/mL
NDC: 72606-028-01

FDA, U.S. Food & Drug Administration; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **Theoretical Risk for Particular Infections.** Genetic IL-12/IL-23 deficiencies are linked to disseminated infections (e.g., mycobacteria, salmonella, and BCG). It is unknown whether IL-12/IL-23 blockade from ustekinumab products may cause similar susceptibility. Consider diagnostic testing, such as tissue or stool cultures, based on clinical circumstances.

Plaque Psoriasis or Psoriatic Arthritis

Indications¹

STEQEYMA is indicated for the treatment of:

Adult patients with:

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

Pediatric patients 6 years and older with:

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

Dosage and Administration²

Plaque Psoriasis Adult Subcutaneous Recommended Dosage

Weight Range (kilograms)	Induction	Maintenance
100 kg or less	45 mg	45 mg at 4 weeks after the initial dose, then 45 mg every 12 weeks
More than 100 kg	90 mg	90 mg at 4 weeks after the initial dose, then 90 mg every 12 weeks

Plaque Psoriasis Pediatric Patients (6 to 17 years old) Subcutaneous Recommended Dosage

Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

Weight Range (kilograms)	Induction	Maintenance
60 kg–100 kg	45 mg	45 mg at 4 weeks after the initial dose, then 45 mg every 12 weeks
More than 100 kg	90 mg	90 mg at 4 weeks after the initial dose, then 90 mg every 12 weeks

There is no dosage form for STEQEYMA that allows weight-based dosing for pediatric patients below 60 kg.

Psoriatic Arthritis Adult Subcutaneous Recommended Dosage

Weight Range (kilograms)	Induction	Maintenance
All Adult Patients (see exception below)	45 mg	45 mg at 4 weeks after the initial dose, then 45 mg every 12 weeks
Patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg	90 mg	90 mg at 4 weeks after the initial dose, then 90 mg every 12 weeks

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **Pre-treatment Evaluation for Tuberculosis (TB).** Evaluate patients for TB prior to starting STEQEYMA. Avoid using STEQEYMA in patients with active tuberculosis. Treat latent TB before starting STEQEYMA and consider TB therapy for patients with unclear treatment history. Monitor for signs of active TB during and after treatment.

Psoriasis or Psoriatic Arthritis (Continued)

Dosage and Administration¹ (Continued)

Psoriatic Arthritis Pediatric (6 to 17 years old) Subcutaneous Recommended Dosage

Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter.

Weight Range (kilograms)	Induction	Maintenance
60 kg or more	45 mg	45 mg at 4 weeks after the initial dose, then 45 mg every 12 weeks
Patients with co-existent moderate-to-severe plaque psoriasis weighing more than 100 kg	90 mg	90 mg at 4 weeks after the initial dose, then 90 mg every 12 weeks

There is no dosage form for STEQEYMA that allows weight-based dosing for pediatric patients below 60 kg.

Dosage Forms and Strengths

Subcutaneous Injection

- **Injection:** 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe

Sample Coding

This section serves as an educational reference for coding that may be appropriate for reporting STEQEYMA and related services. Medical record documentation must support the codes reported on the claim. These codes may be appropriate when STEQEYMA is administered to patients with psoriasis or psoriatic arthritis in the following sites of care: physician's office, freestanding infusion center, home infusion services, and hospital outpatient.

Diagnosis Codes (ICD-10-CM Codes)³

This list is for informational purposes only. One or more codes may be appropriate on a claim. Please review payer policy requirements for guidance on diagnosis codes.

Psoriasis	Description
L40.0	Psoriasis vulgaris
L40.9	Psoriasis, unspecified
Psoriatic Arthritis	Description
L40.50	Arthropathic psoriasis, unspecified
L40.59	Other psoriatic arthropathy

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **Malignancies.** Ustekinumab products are immunosuppressants that may increase the risk of malignancy. Malignancies occurred in clinical trials, and IL-12/IL-23 inhibition increased malignancy risk in rodent models. The safety in patients with a history of malignancy is unknown. Post-marketing reports include rapid onset of multiple cutaneous squamous cell carcinomas in patients with risk factors for non-melanoma skin cancer. Monitor all patients, especially those over 60, with prolonged immunosuppressant use, or a history of PUVA treatment.

Psoriasis or Psoriatic Arthritis (Continued)

Sample Coding (Continued)

National Drug Code^{2,4}

The National Drug Code (NDC) is required on the claim form. While the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. The NDC unit of measure qualifier and quantity may also be required. Check payer-specific reporting requirements.

STEQEYMA	10-Digit NDC	11-digit NDC
45 mg SC prefilled syringe (1 pack)	72606-027-01	72606-0027-01
90 mg SC prefilled syringe (1 pack)	72606-028-01	72606-0028-01

SC, subcutaneous.

Administration and Billing Codes

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form.

CPT® Code

Drug administration services are reported on claim forms in both the physician office and hospital outpatient sites of care using the Current Procedural Terminology (CPT®) coding system.

Code Set	Code and Description ⁵	Location on CMS-1500 Form ⁶	Location on CMS-1450 (UB-04) Form ⁷
CPT	96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Field 24D	Field 44

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **Hypersensitivity Reactions.** If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STEQEYMA.
- **Posterior Reversible Encephalopathy Syndrome (PRES).** Cases of PRES have been reported in clinical trials and postmarketing, with symptoms like headache, seizures, confusion, visual disturbances, and imaging changes. Onset ranged from days to over a year after starting ustekinumab. Patients recovered after discontinuation and supportive care. Monitor for PRES symptoms, and if suspected, treat promptly and discontinue STEQEYMA.

Psoriasis or Psoriatic Arthritis (Continued)

Administration and Billing Codes (Continued)

HCPCS Level II Code(s)

Drugs are typically reported using product-specific Healthcare Common Procedure Coding System (HCPCS) codes (eg, Q codes) assigned by the Centers for Medicare & Medicaid Services (CMS). HCPCS units are determined by the specific HCPCS descriptor. The descriptor is not necessarily the same as the package or therapeutic dose, so the dose must be converted to billable HCPCS units to accurately complete a claim.

Code Set	Code and Description ⁸	Location on CMS-1500 Form ⁶	Location on CMS-1450 (UB-04) Form ⁷
HCPCS	Q5099 Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg	Field 24D	Field 44

Modifiers

Modifier	Description ^{9,10}	Location on CMS-1500 Form ⁶	Location on CMS-1450 (UB-04) Form ⁷
JA	Administered intravenously	Field 24D	Field 44
JB	Administered subcutaneously	Field 24D	Field 44
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes	Field 24D	Field 44
JW	Amount of drug discarded/not administered to any patient	Field 24D	Field 44
JZ	No amount of drug was discarded from a single-vial/dose drug and not administered to any patient	Field 24D	Field 44
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	Field 24D	Field 44

Note on product and administration coding:

If you order STEQEYMA through a specialty pharmacy or the Celltrion CONNECT® Patient Assistance Program, you should not seek reimbursement for the product; however, your patient's health plan may still require that you include the J-code on the claim with a zero or nominal charge in order for them to reimburse the drug administration procedure.

Remember to submit a claim for reimbursement for services associated with STEQEYMA.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **Immunizations.** Ensure patients receive all age-appropriate immunizations before starting STEQEYMA. Avoid live vaccines during treatment and for one year before and after discontinuation. Do not administer BCG vaccines during this time. Use caution with live vaccines for household contacts due to the risk of shedding and transmission. Non-live vaccines may have a reduced immune response during STEQEYMA treatment.

Psoriasis or Psoriatic Arthritis (Continued)

The sample claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

Sample CMS-1500 Claim Form—Physician Office⁶

Example for a 90 mg SC injection

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

1. MEDICARE ☐ MEDICAID ☒ TRICARE ☐ CHAMPVA ☐ GROUP HEALTH PLAN ☐ FECA ☐ OTHER ☐ 1a. INSURED'S I.D. NUMBER (For Program in Item 1) PICA ☐

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S. 3. PATIENT'S BIRTH DATE
MM DD YY 02 12 70 SEX M ☒ F ☐ 4. INSURED'S NAME (Last Name, First Name, Middle Initial)
Doe, Jane S.

5. PATIENT'S ADDRESS (No., Street)
123 Main Street 6. PATIENT RELATIONSHIP TO INSURED
Self ☒ Spouse ☐ Child ☐ Other ☐ 7. INSURED'S ADDRESS (No., Street)
123 Main Street

CITY Anytown STATE AZ CITY Anytown STATE AZ
ZIP CODE 12333 TELEPHONE (Include Area Code) (999) 123-9876 ZIP CODE 12333 TELEPHONE (Include Area Code) (999) 123-9876

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 ☐ b. AUTO ACCIDENT? YES ☐ NO ☐ PLACE (State) c. OTHER ACCIDENT? YES ☐ NO ☐ b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME 10d. CLAIM CODES (Designated by NUCC) d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES ☐ NO ☐ If yes, complete items 9, 10a, and 10d.

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: DATE:

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) QUAL: 15. OTHER DATE QUAL: 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. NPI 321 654 7890 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) 20. OUTSIDE LAB? YES ☐ NO ☐ \$ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-4, to service line below (24E) ICD 10: K50.80 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. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. ICD 10: QUAL: I. E. QUAL: J. RENDERING PROVIDER ID, #

1. N472606002801 Q5099 JZ A 90 NPI 321 654 7890

2. 96372 JB A 1 NPI 321 654 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? YES ☐ NO ☐ 28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rev'd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED: DATE: 32. SERVICE FACILITY LOCATION INFORMATION a. NPI b. NPI 33. BILLING PROVIDER INFO & PH # a. NPI b. NPI

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

Field 19: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC. This is a necessary field.

Note: Some payers may also request the Wholesale Acquisition Cost (WAC) price to be included.

Field 21: Indicate the most medically appropriate diagnosis code. (ICD-10-CM)

Field 23: If required, report the prior authorization number here.

Field 24A: If a line item NDC information is required, it will be entered in the shaded portion of item 24A. NDCs must be billed with the N4 qualifier before the NDC.

Field 24D: Indicate appropriate HCPCS as required by the payer. Include the appropriate CPT® code to report the administration procedure.

Field 24E: Enter the diagnosis code reference letter as shown in box 21. Enter only 1 diagnosis pointer.

Field 24G: Enter the number of HCPCS units.

Psoriasis or Psoriatic Arthritis (Continued)

The claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

CMS-1450 (UB-04) Claim Form—Hospital Outpatient Departments⁷

Example for a 90 mg SC injection

1 Facility Name Street Address City, State, Zip Phone		2 Pay-to name Street Address City, State, Zip		3a RPT. CONT. # b. MED. REQ. # 5 FED. TAX NO.		4 TYPE OF BILL											
8 PATIENT NAME a Jane S. Doe		9 PATIENT ADDRESS b Anytown		c AZ 012333		d US											
10 BIRTHDATE 03/23/970		11 SEX F		12 DATE 12		13 ADMISSION 13 VIS. 14 TYPE 15 SRC		16 DHP		17 STAT		18 19 20 21		22 CONDITION CODES 22 23 24 25 26 27 28		29 ADIT 30 STATE	
31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE		34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE SPAN FROM THROUGH		37 OCCURRENCE SPAN FROM THROUGH		38		39	
42 ICD-9-CM 0636		43 DESCRIPTION Steqeyma		44 HCPCS / RATE / HIPS CODE Q5099		45 SERV. DATE MM-DD-YY		46 SERV. UNITS 90		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49		50	
0940		Other therapeutic services		96372		MM-DD-YY		1									
50 PRIOR NAME		51 HEALTH PLAN ID		52 PRIOR PAYMENTS		53 EST. AMOUNT DUE		54 NPI		55		56		57		58	
59 INSURED'S NAME		60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.		63		64		65		66		67	
68 TREATMENT AUTHORIZATION CODES		69 DOCUMENT CONTROL NUMBER		70 EMPLOYER NAME		71		72		73		74		75		76	
77 K50.80		78		79		80		81		82		83		84		85	
79 ADMIT DATE		80 PATIENT REASON DX		81 OTHER PROCEDURE DATE		82 OTHER PROCEDURE DATE		83 OTHER PROCEDURE DATE		84 OTHER PROCEDURE DATE		85 OTHER PROCEDURE DATE		86 OTHER PROCEDURE DATE		87 OTHER PROCEDURE DATE	
88 REMARKS STEQEYMA 90 mg SC NDC 72606-0028-01		89		90		91		92		93		94		95		96	
97		98		99		100		101		102		103		104		105	

Field 42: Include appropriate revenue codes corresponding with the HCPCS code in box 44. Then enter the appropriate revenue code corresponding with the CPT® code in box 44.

Field 43: Provide drug name, strength, NDC, and quantity.

Field 44: Indicate appropriate HCPCS and CPT® codes and modifiers as required by the payer.

Field 46: Enter the number of HCPCS units.

Field 47: Indicate total charges.

Field 56: Indicate the appropriate NPI number.

Field 66: Indicate the most medically appropriate diagnosis code.

Field 80: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC. This is a necessary field.

NPI, National Provider Identifier.

Crohn's Disease or Ulcerative Colitis

Indications¹

STEQEYMA is indicated for the treatment of:

Adult patients with:

- Moderately to severely active Crohn's disease
- Moderately to severely active ulcerative colitis

Dosage and Administration¹

Crohn's Disease and Ulcerative Colitis Adult Intravenous Recommended Dosage

INDUCTION

Intravenous (IV) Induction: A single IV infusion of STEQEYMA using a weight-based dosage regimen.

Weight Range (kilograms)	Dosage
Up to 55 kg	260 mg (2 vials)
More than 55 kg to 85 kg	390 mg (3 vials)
More than 85 kg	520 mg (4 vials)

MAINTENANCE

The maintenance doses of STEQEYMA for Crohn's disease or ulcerative colitis are delivered by subcutaneous injection.

Indications	Dose	Frequency
Crohn's disease or ulcerative colitis	90 mg	8 weeks after initial IV infusion, then every 8 weeks thereafter

Dosage Forms and Strengths

Intravenous Infusion

- Injection: 130 mg/26 mL (5 mg/mL) solution in a single-dose vial

Subcutaneous Injection

- Injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled syringe

Sample Coding

This section serves as an educational reference for coding that may be appropriate for reporting STEQEYMA and/or related services. Medical record documentation must support the codes reported on the claim. These codes may be appropriate when STEQEYMA is administered to patients with Crohn's disease or ulcerative colitis in the following sites of care: physician's office, freestanding infusion center, home infusion services, and hospital outpatient.

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **Noninfectious Pneumonia.** Noninfectious pneumonia, including interstitial, eosinophilic, and cryptogenic organizing pneumonia, has been reported with ustekinumab, presenting as cough, dyspnea, and interstitial infiltrates after 1–3 doses.

Crohn's Disease or Ulcerative Colitis (Continued)

Sample Coding (Continued)

Diagnosis Codes (ICD-10-CM Codes)

This list is for informational purposes only. One or more codes may be appropriate on a claim. Please review payer policy requirements for guidance on diagnosis codes.

Code ¹¹⁻¹⁵	Crohn's Disease
K50.00	Crohn's disease of small intestine without complications
K50.01	Crohn's disease of small intestine with complications
K50.10	Crohn's disease of large intestine without complications
K50.11	Crohn's disease of large intestine with complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.81	Crohn's disease of both small and large intestine with complications
K50.90	Crohn's disease, unspecified, without complications
K50.91	Crohn's disease, unspecified, with complications

Code ¹⁶⁻²¹	Ulcerative Colitis
K51.00	Ulcerative (chronic) pancolitis without complications
K51.01	Ulcerative (chronic) pancolitis with complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.21	Ulcerative (chronic) proctitis with complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.31	Ulcerative (chronic) rectosigmoiditis with complications
K51.50	Left sided colitis without complications
K51.51	Left sided colitis with complications
K51.80	Other ulcerative colitis without complications
K51.81	Other ulcerative colitis with complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.91	Ulcerative colitis, unspecified, with complications

IMPORTANT SAFETY INFORMATION (continued)

Warnings and Precautions (continued):

- **Noninfectious Pneumonia (continued).** Serious cases included respiratory failure and prolonged hospitalization. Patients improved with discontinuation and corticosteroids. Discontinue STEQEYMA and treat if confirmed.

Crohn's Disease or Ulcerative Colitis (Continued)

Sample Coding (Continued)

National Drug Code^{2,4}

The National Drug Code (NDC) is required on the claim form. While the FDA uses a 10-digit format when registering NDCs, payers often require an 11-digit NDC format on claim forms for billing purposes. The NDC unit of measure qualifier and quantity may also be required. Check payer-specific reporting requirements.

STEQEYMA	10-Digit NDC	11-Digit NDC
130 mg IV (1 pack)	72606-029-01	72606-0029-01
45 mg SC prefilled syringe (1 pack)	72606-027-01	72606-0027-01
90 mg SC prefilled syringe (1 pack)	72606-028-01	72606-0028-01

Administration and Billing Codes

This section reviews general coding guidelines for drug administration services coded by physician offices using the CMS-1500 claim form and by hospital outpatient departments using the CMS-1450 (UB-04) claim form.

CPT® Code

Drug administration services are reported on claim forms in both the physician office and hospital outpatient sites of care using the Current Procedural Terminology (CPT®) coding system.

Code Set	Code and Description ^{22,23}	Location on CMS-1500 Form ⁶	Location on CMS-1450 (UB-04) Form ⁷
CPT	Intravenous infusion, 96365 Intravenous (IV) infusion code for the initial hour of therapy, prophylaxis, or diagnostic infusion Subcutaneous injection, 96372 Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular	Field 24D	Field 44

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

The most common adverse reactions ($\geq 3\%$) reported in patients receiving ustekinumab were:

- **Psoriasis:** nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- **CD induction:** vomiting.
- **CD maintenance:** nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.

Crohn's Disease or Ulcerative Colitis (Continued)

Administration and Billing Codes (Continued)

HCPCS Level II Code(s)

Drugs are typically reported using product-specific Healthcare Common Procedure Coding System (HCPCS) codes (eg, Q codes) assigned by the CMS. HCPCS units are determined by the specific HCPCS descriptor. The descriptor is not necessarily the same as the package or therapeutic dose, so the dose must be converted to billable HCPCS units to accurately complete a claim.

Effective December 17, 2024, Q5099 was added to Medicare's Self-Administered Drug (SAD) list and will not be covered by Medicare. This primarily affects traditional fee-for-service Medicare. Commercial Medicare can make their own independent decisions to follow traditional Medicare or make their own coverage criteria. For Medicare Advantage and Medicare Part D, please work with your Celltrion Field Reimbursement Manager (FRM) for STEQEYMA benefit verifications.

Code Set	Code and Description ⁸	Location on CMS-1500 Form ⁶	Location on CMS-1450 (UB-04) Form ⁷
HCPCS	Q5099 Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg	Field 24D	Field 44

Modifiers

Modifier	Description ^{9,10}	Location on CMS-1500 Form ⁶	Location on CMS-1450 (UB-04) Form ⁷
JA	Administered intravenously	Field 24D	Field 44
JB	Administered subcutaneously	Field 24D	Field 44
JG	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes	Field 24D	Field 44
JW	Amount of drug discarded/not administered to any patient	Field 24D	Field 44
JZ	No amount of drug was discarded from a single-vial/dose drug and not administered to any patient	Field 24D	Field 44
TB	Drug or biological acquired with 340B Drug Pricing Program discount, reported for informational purposes for select entities	Field 24D	Field 44

Note on product and administration coding:

If you order STEQEYMA through a specialty pharmacy or the Celltrion CONNECT® Patient Assistance Program, you should not seek reimbursement for the product; however, your patient's health plan may still require that you include the J-code on the claim with a zero or nominal charge in order for them to reimburse the drug administration procedure.

Remember to submit a claim for reimbursement for services associated with STEQEYMA.

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

- **UC induction:** nasopharyngitis.
- **UC maintenance:** nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.

Crohn's Disease or Ulcerative Colitis (Continued)

The claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

CMS-1500 Claim Form—Physician Office⁶

Example of a 130 mg IV induction dose

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

1. MEDICARE ☐ **MEDICAID** ☒ **TRICARE** ☐ **CHAMPVA** ☐ **GROUP HEALTH PLAN** ☐ **FECA** ☐ **BACKLUNG** ☐ **OTHER** ☐

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

3. PATIENT'S BIRTH DATE MM DD YY
02 12 70

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

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

6. PATIENT RELATIONSHIP TO INSURED
Self ☒ Spouse ☐ Child ☐ Other ☐

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

8. RESERVED FOR NUCC USE

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

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 below.)

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

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) MM DD YY
01 01 20

15. OTHER DATE MM DD YY

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

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
John Smith, MD

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
STEQEYMA 130 mg IV NDC 72606-0029-01

20. OUTSIDE LAB? ☐ YES ☒ NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)
K50.80

22. RESUBMISSION CODE ☐ YES ☒ NO

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY
01 01 20 01 01 20

B. PLACE OF SERVICE ☐ EMG ☐ OTHER

C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)
Q5099 for IV JZ

E. DIAGNOSIS POINTER A

F. CHARGES \$ 130

G. CPT CODE 96365

H. ICD-10 CODE JA

I. RENDERING PROVIDER ID # 321 654 7890

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? ☐ YES ☒ NO

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Rev'd 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.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH #

34. SIGNATURE **DATE**

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

Field 19: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC. This is a necessary field.

Note: Some payers may also request the Wholesale Acquisition Cost (WAC) price to be included.

Field 21: Indicate the most medically appropriate diagnosis code. (ICD-10-CM)

Field 23: If required, report the prior authorization number here.

Field 24A: If a line item NDC information is required, it will be entered in the shaded portion of item 24A. NDC codes must be billed with the N4 qualifier before the NDC code.

Field 24D: Indicate appropriate HCPCS as required by the payer. Include the appropriate CPT® code to report the administration procedure.

Field 24E: Enter the diagnosis code reference letter as shown in box 21. Enter only 1 diagnosis pointer.

Field 24G: Enter the amount of drug in HCPCS units according to dose; STEQEYMA 130 mg vial = 1 unit.

Crohn's Disease or Ulcerative Colitis (Continued)

The claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

CMS-1450 (UB-04) Claim Form—Hospital Outpatient Departments⁷

Example of a 130 mg IV induction dose

1 Facility Name Street Address City, State, Zip Phone										2 Pay-to name Street Address City, State, Zip										3a PAC CONT. # 3b MED. REQ. # 5 FEE TAX NO.										XX-XXX STATEMENT COVERS PERIOD FROM THROUGH										4 TYPE OF BILL																			
8 PATIENT NAME Jane S. Doe										9 PATIENT ADDRESS 123 Main Street										10 CITY Anytown										11 AZ 12333										12 US																			
13 BIRTHDATE 03/23/1970										14 SEX F										15 ADMISSION DATE 13 HR 14 TYPE 15 SRC										16 DHR										17 STAT										18 CONDITION CODES 22 23 24 25 26 27 28 29 ADULT 30									
19 OCCURRENCE DATE										20 OCCURRENCE DATE										21 OCCURRENCE DATE										22 OCCURRENCE DATE										23 OCCURRENCE DATE										24 OCCURRENCE DATE									
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Field 42: Include appropriate revenue codes corresponding with the HCPCS code in box 44. Then enter the appropriate revenue code corresponding with the CPT® code in box 44.

Field 43: Provide drug name, strength, NDC, and quantity.

Field 44: Indicate appropriate HCPCS and CPT® codes and modifiers as required by the payer.

Field 46: Enter the amount of drug in HCPCS units according to dose; STEQEYMA 130 mg vial = 1 unit.

Field 47: Indicate total charges.

Field 56: Indicate the appropriate NPI number.

Field 66: Indicate the most medically appropriate diagnosis code.

Field 80: Payers require drug name, route of administration, NDC, and total dosage. Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC. This is a necessary field.

Crohn's Disease or Ulcerative Colitis (Continued)

The claim form provided below is only an example. It is always the provider's responsibility to determine the appropriate healthcare setting and to submit true and correct claims for the products and services rendered. Providers should contact third-party payers for specific information on their coding, coverage, payment policies, and fee schedules.

CMS-1450 (UB-04) Claim Form—Hospital Outpatient Departments⁷

Example of a 90 mg SC maintenance dose

1 Facility Name Street Address City, State, Zip Phone		2 Pay-to name Street Address City, State, Zip		3a PAC CNTL # b. MED REC # c. FED. TAX NO.		4 TYPE OF BILL	
8 PATIENT NAME a. Jane S. Doe		9 PATIENT ADDRESS b. 123 Main Street		c. AZ 01 12333		d. US	
10 BIRTHDATE 03/23/970		11 SEX F		12 DATE 03/23/970		13 HRT 14 TYPE 15 SRC	
16 DHR 17 STAT 18 19 20 21		22 CONDITION CODES 23 24 25 26 27 28		29 ADITY STATE		30	
31 OCCURRENCE DATE 32 OCCURRENCE CODE		33 OCCURRENCE DATE 34 OCCURRENCE CODE		35 OCCURRENCE DATE 36 OCCURRENCE CODE		37 OCCURRENCE DATE 38 OCCURRENCE CODE	
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Patient Support Programs Created to Provide Treatment Access to as Many Patients as Possible

CELLTRION CONNECT PATIENT SUPPORT PROGRAM

Celltrion CONNECT helps hub-enrolled patients understand and navigate their insurance coverage and identify resources that may help them afford their treatment

CELLTRION CARES® CO-PAY PROGRAM

Commercially insured patients may be able to receive financial assistance through Celltrion CARES® Co-pay Assistance Program

CELLTRION nurseconnector Connecting Through the Treatment Journey

Provides a dedicated Nurse Connector™ to support patients along their treatment journey through product education and injection training

CELLTRION inFORM ACCESS SOLUTIONS FOR PATIENTS & PRACTICES

A dedicated team of Field Reimbursement Managers (FRMs) to assist patients and providers navigate all aspects of medication access

Comprehensive Patient Support Offered by Celltrion CONNECT®

CELLTRION CONNECT PATIENT SUPPORT PROGRAM



Financial Assistance

- Patient insurance benefit verifications (BV)
- Prior authorization (PA) assistance
- Appeal support
- Co-pay Assistance Program (Celltrion CARES®) for your commercially insured patients
- Financial support for qualified eligible patients



Healthcare Provider Resources

- Online portal
- Sample Letters of Medical Exception and Appeal
- Downloadable brochures
- Downloadable Enrollment Form
- Downloadable Billing and Coding Guide



Patient Resources

- Nursing Patient Support Program
- Injection support
- Educational materials

www.celltrionconnect.com
1-877-81CONNC (1-877-812-6662)

INDICATIONS

STEQEYMA (ustekinumab-stba) is a human interleukin-12 and -23 antagonist indicated for the treatment of:

- **Plaque Psoriasis (PsO)** in adults and pediatric patients 6 years of age and older with moderate to severe PsO who are candidates for phototherapy or systemic therapy.
- **Psoriatic Arthritis (PsA)** in adults and pediatric patients 6 years of age and older with active PsA.
- **Crohn's Disease (CD)** in adult patients with moderately to severely active CD.
- **Ulcerative Colitis (UC)** in adult patients with moderately to severely active UC.

CONTRAINDICATIONS

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

IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

- **Infections.** Ustekinumab products, including STEQEYMA, may increase the risk of infections and reactivation of latent infections, including serious bacterial, mycobacterial, fungal, and viral infections requiring hospitalization. Reported infections include pneumonia, gastroenteritis, cellulitis, sepsis, cholecystitis, anal abscess, listeria meningitis, and ophthalmic herpes zoster. Avoid starting STEQEYMA in patients with active infections until resolved, and assess risks in those with chronic or recurrent infections. Advise patients to seek medical care for signs of infection. Discontinue STEQEYMA for serious infections until treated or resolved.
- **Theoretical Risk for Particular Infections.** Genetic IL-12/IL-23 deficiencies are linked to disseminated infections (e.g., mycobacteria, salmonella, and BCG). It is unknown whether IL-12/IL-23 blockade from ustekinumab products may cause similar susceptibility. Consider diagnostic testing, such as tissue or stool cultures, based on clinical circumstances.
- **Pre-treatment Evaluation for Tuberculosis (TB).** Evaluate patients for TB prior to starting STEQEYMA. Avoid using STEQEYMA in patients with active tuberculosis. Treat latent TB before starting STEQEYMA and consider TB therapy for patients with unclear treatment history. Monitor for signs of active TB during and after treatment.
- **Malignancies.** Ustekinumab products are immunosuppressants that may increase the risk of malignancy. Malignancies occurred in clinical trials, and IL-12/IL-23 inhibition increased malignancy risk in rodent models. The safety in patients with a history

of malignancy is unknown. Post-marketing reports include rapid onset of multiple cutaneous squamous cell carcinomas in patients with risk factors for non-melanoma skin cancer. Monitor all patients, especially those over 60, with prolonged immunosuppressant use, or a history of PUVA treatment.

Hypersensitivity Reactions. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STEQEYMA.

Posterior Reversible Encephalopathy Syndrome (PRES).

Cases of PRES have been reported in clinical trials and postmarketing, with symptoms like headache, seizures, confusion, visual disturbances, and imaging changes. Onset ranged from days to over a year after starting ustekinumab. Patients recovered after discontinuation and supportive care. Monitor for PRES symptoms, and if suspected, treat promptly and discontinue STEQEYMA.

Immunizations. Ensure patients receive all age-appropriate immunizations before starting STEQEYMA. Avoid live vaccines during treatment and for one year before and after discontinuation. Do not administer BCG vaccines during this time. Use caution with live vaccines for household contacts due to the risk of shedding and transmission. Non-live vaccines may have a reduced immune response during STEQEYMA treatment.

Noninfectious Pneumonia. Noninfectious pneumonia, including interstitial, eosinophilic, and cryptogenic organizing pneumonia, has been reported with ustekinumab, presenting as cough, dyspnea, and interstitial infiltrates after 1–3 doses. Serious cases included respiratory failure and prolonged hospitalization. Patients improved with discontinuation and corticosteroids. Discontinue STEQEYMA and treat if confirmed.

Adverse Reactions

The most common adverse reactions ($\geq 3\%$) reported in patients receiving ustekinumab were:

- **Psoriasis:** nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- **CD induction:** vomiting.
- **CD maintenance:** nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.
- **UC induction:** nasopharyngitis.
- **UC maintenance:** nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.



References:

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