Pyzchiva®
ustekinumab-ttwe | 90 mg/1 mL

PYZCHIVA®
CODING AND BILLING GUIDE

This guide is designed to assist healthcare professionals in navigating the coding and billing processes associated with PYZCHIVA.

PYZCHIVA Q-codes:
- **Prefilled syringe and injection vial: Q9996**
- **Infusion vial: Q9997**

INDICATIONS

PYZCHIVA is indicated for the treatment of:
- patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- patients 6 years or older with active psoriatic arthritis
- adult patients with moderately to severely active Crohn's disease
- adult patients with moderately to severely active ulcerative colitis

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Infections

Ustekinumab products may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections requiring hospitalization or otherwise clinically significant infections were reported. In patients with plaque psoriasis, these included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections. In patients with psoriatic arthritis, this included cholecystitis. In patients with Crohn's disease, these included anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, and *Listeria* meningitis. In patients with ulcerative colitis, these included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

Please see additional Important Safety Information on pages 8 and 9, and full Prescribing Information for PYZCHIVA.

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About This Guide

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This guide is intended to be an educational reference, providing general information regarding the coding and billing of PYZCHIVA®. This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. All coding and billing requirements should be confirmed with each payer before submitting a claim for reimbursement. Sandoz does not guarantee coverage or payment for submitted claims.

Table of Contents

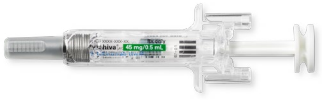
Available Formulations for PYZCHIVA[1]

Single-dose vial[a]

45 mg/0.5 mL
SC injection vial[b]

130 mg/26 mL
(5 mg/mL) IV infusion vial

Single-dose prefilled syringe for SC injection



45 mg/0.5 mL single-dose prefilled syringe

90 mg/1 mL single-dose prefilled syringe

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; IV=intravenous; NDC=National Drug Code; SC=subcutaneous; UB=Uniform Billing.

[a]IV dose is not approved for all indications.

[b]Available in Q3 2025.

Please see additional Important Safety Information on the front cover and pages 8 and 9, and full Prescribing Information for PYZCHIVA.

Coding for PYZCHIVA

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	Code	Notes
HCPCS codes	**Q9996:** Ustekinumab-ttwe subcutaneous injection, biosimilar, PYZCHIVA, 1 mg	To bill a Q-code, the billable units (quantity) must be submitted.
	Q9997: Ustekinumab-ttwe intravenous injection, biosimilar, PYZCHIVA, 1 mg	
Modifiers	**JZ:** Zero drug amount discarded/not administered to any patient[a]	JZ modifier should be billed on the same line as the product administered.
	JW: Drug amount discarded/not administered to any patient[a]	JW modifier should be billed on a separate line noting the amount of product discarded.
	TB: Drugs or biologics acquired with 340B drug pricing program discount, reported for informational purposes for select entities[b]	For more information on modifiers, visit CMS.gov.
Billable units	When billing with a Q-code, specify the billable units: **1** unit = **1** mg of PYZCHIVA.[a] For example, to bill a **130** mg vial of PYZCHIVA, list **130** units. **See samples on pages 5 and 6 for how to complete the CMS-1450 or CMS-1500 form with a Q-code.**	For more information on dosage details, see Prescribing Information for PYZCHIVA.
NDC codes (11 digit)[1]	45 mg/0.5 mL prefilled syringe: 61314-0651-01	For the 10-digit 5-3-2 code, remove the leading zero from the appropriate sequence position, as illustrated below: 61314-0651-01 (11 digit) 61314-651-01 (10 digit)
	90 mg/1 mL prefilled syringe: 61314-0652-01	
	45 mg/0.5 mL vial: 61314-0651-94	
	130 mg/26 mL (5 mg/mL) vial: 61314-0654-94	
CPT® codes	**96365:** Intravenous infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	Payer requirements regarding the use of 96365, 96372, or 96413 may vary. Consult payer policies for specific requirements.
	96372: Therapeutic, prophylactic, or diagnostic injection; subcutaneous injection or intramuscular	
	96413: Other highly complex drug or biologic agent administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	
Office visit	Relevant E&M code[cd]	See payer guidelines.

[a]Effective January 1, 2024, CMS may reject applicable claims that do not report modifier JZ or JW.[2]

[b]As of January 1, 2025, CMS requires all 340B-covered entities, including hospital-based and non-hospital-based entities, to report the TB modifier on claims for drugs acquired through the 340B program. This replaces the JG modifier, which will no longer be used on claim lines for separately payable Part B drugs and biologicals after December 31, 2024.[3]

[c]Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.[4]

[d]Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.[4]

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Diagnosis Codes

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ICD-10-CM code example(s)[5] Allowable diagnosis codes may vary by payer	
Crohn's disease The treatment of adult patients with moderately to severely active Crohn's disease.	
K50.01	Crohn's disease of small intestine with complications
K50.10	Crohn's disease of large intestine without complications
K50.11	Crohn's disease of large intestine with complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.81	Crohn's disease of both small and large intestine with complications
K50.90	Crohn's disease unspecified without complications
K50.91	Crohn's disease unspecified with complications
Ulcerative colitis The treatment of adult patients with moderately to severely active 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
Psoriasis The treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.	
L40.0	Psoriasis vulgaris
L40.9	Psoriasis, unspecified
Psoriatic Arthritis The treatment of adults and pediatric patients 6 years of age and older with active psoriatic arthritis.	
L40.50	Arthropathic psoriasis, unspecified
L40.59	Other psoriatic arthropathy

These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use.
ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; UOM=unit of measure.

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Sample Annotated CMS-1450 (UB-04) Form

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Use the annotated sample provided to assist in completion of the CMS-1450 form.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)

Enter the appropriate revenue code corresponding with the HCPCS code in Box 44 (eg, 0636 revenue code for drugs requiring detailed coding, and/or 0250 for general pharmacy). The description should include qualifier N4 immediately followed by the 11-digit NDC. Next, enter the appropriate qualifier for the correct dispensing UOM (eg, ML [milliliter]) followed by the quantity (up to 3 decimal places).

Then enter the appropriate revenue code corresponding with the CPT code in Box 44 (eg, 0260 for IV therapy or 0510 for general clinic services).

Note: Consult payer policies for NDC and UOM reporting requirements.

SERVICE UNITS (BOX 46)

Report units of service.

For HCPCS:
For Q9997, each 130 mg vial of PYZCHIVA® used is listed as 130 billable units. Therefore, 2 vials used equal 260 billable units.

For CPT:
For 96365, 1 unit represents the first hour of infusion. For 96372 and 96413, 1 unit represents 1 subcutaneous injection.

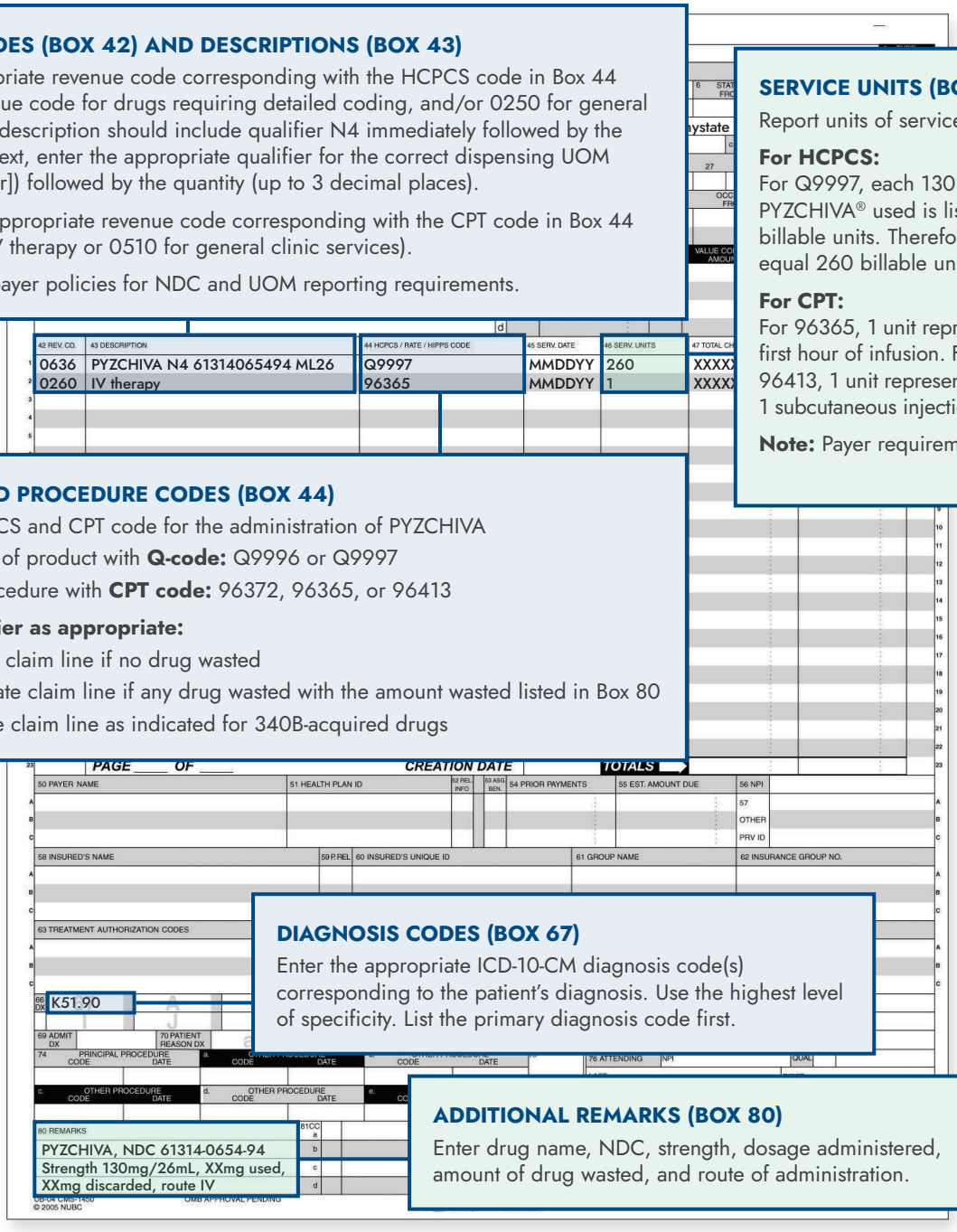
Note: Payer requirements may vary.

PRODUCT AND PROCEDURE CODES (BOX 44)

- Enter the HCPCS and CPT code for the administration of PYZCHIVA
- Document use of product with **Q-code:** Q9996 or Q9997
- Document procedure with **CPT code:** 96372, 96365, or 96413

Indicate modifier as appropriate:

- JZ on the same claim line if no drug wasted
- JW on a separate claim line if any drug wasted with the amount wasted listed in Box 80
- TB on the same claim line as indicated for 340B-acquired drugs



DIAGNOSIS CODES (BOX 67)

Enter the appropriate ICD-10-CM diagnosis code(s) corresponding to the patient's diagnosis. Use the highest level of specificity. List the primary diagnosis code first.

ADDITIONAL REMARKS (BOX 80)

Enter drug name, NDC, strength, dosage administered, amount of drug wasted, and route of administration.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare professionals may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare professionals are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see additional Important Safety Information on the front cover and pages 8 and 9, and full Prescribing Information for PYZCHIVA.

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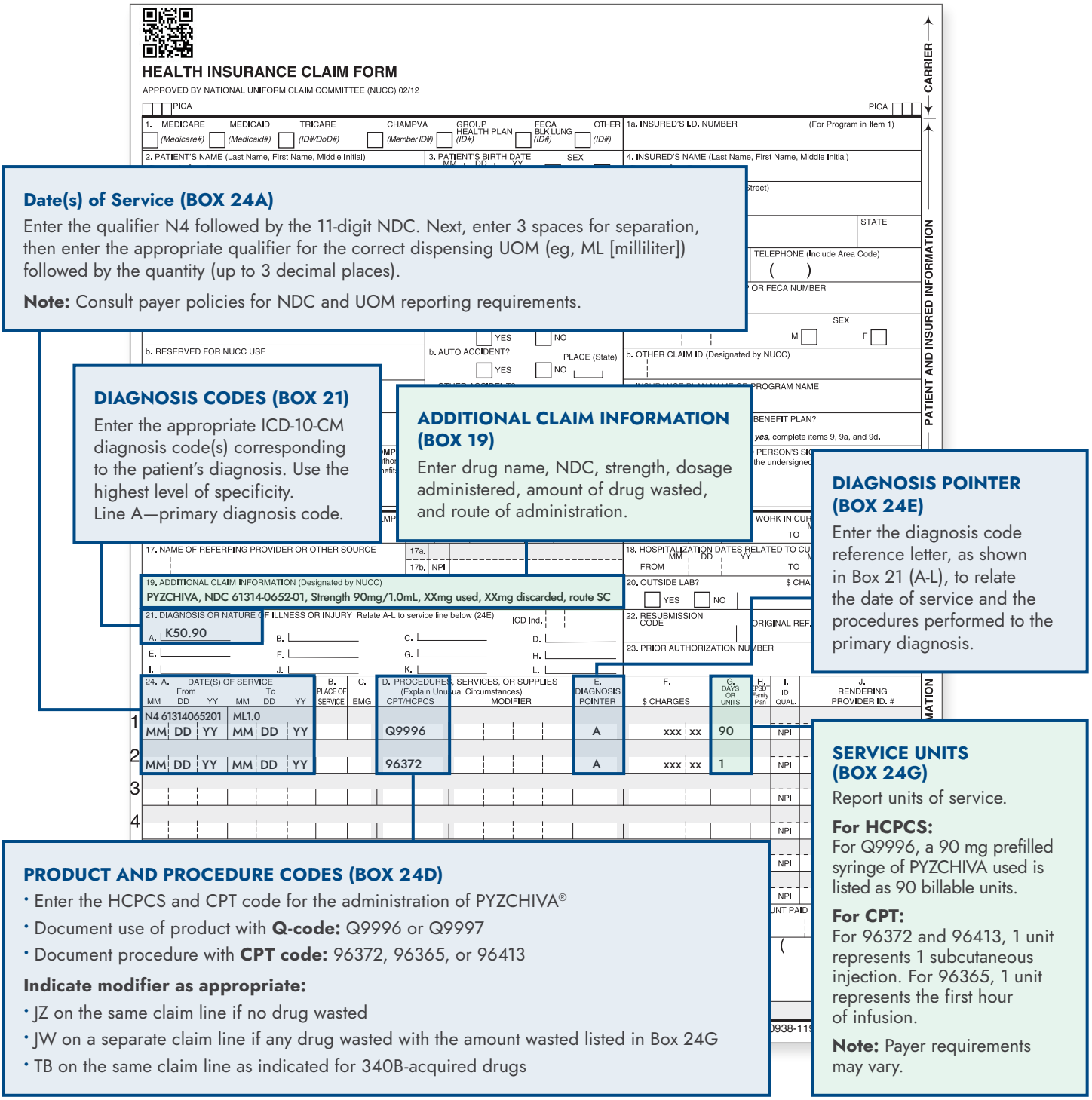
Sample Annotated CMS-1500 Form

Use the annotated sample provided to assist in completion of the CMS-1500 form.



Date(s) of Service (BOX 24A)

Enter the qualifier N4 followed by the 11-digit NDC. Next, enter 3 spaces for separation, then enter the appropriate qualifier for the correct dispensing UOM (eg, ML [milliliter]) followed by the quantity (up to 3 decimal places).

Note: Consult payer policies for NDC and UOM reporting requirements.

DIAGNOSIS CODES (BOX 21)

Enter the appropriate ICD-10-CM diagnosis code(s) corresponding to the patient's diagnosis. Use the highest level of specificity.
Line A—primary diagnosis code.

ADDITIONAL CLAIM INFORMATION (BOX 19)

Enter drug name, NDC, strength, dosage administered, amount of drug wasted, and route of administration.

DIAGNOSIS POINTER (BOX 24E)

Enter the diagnosis code reference letter, as shown in Box 21 (A-L), to relate the date of service and the procedures performed to the primary diagnosis.

PRODUCT AND PROCEDURE CODES (BOX 24D)

- Enter the HCPCS and CPT code for the administration of PYZCHIVA®
- Document use of product with **Q-code:** Q9996 or Q9997
- Document procedure with **CPT code:** 96372, 96365, or 96413

Indicate modifier as appropriate:

- JZ on the same claim line if no drug wasted
- JW on a separate claim line if any drug wasted with the amount wasted listed in Box 24G
- TB on the same claim line as indicated for 340B-acquired drugs

SERVICE UNITS (BOX 24G)

Report units of service.

For HCPCS:
For Q9996, a 90 mg prefilled syringe of PYZCHIVA used is listed as 90 billable units.

For CPT:
For 96372 and 96413, 1 unit represents 1 subcutaneous injection. For 96365, 1 unit represents the first hour of infusion.

Note: Payer requirements may vary.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare professionals may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare professionals are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

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Coding and Billing Tips

Best practices to avoid claim denials and/or billing errors:

Provide appropriate documentation in the patient's medical record to justify the coding.

Ensure you have all the necessary product information, including the drug name, NDC, strength, dosage administered, amount of drug wasted, and route of administration.

Monitor payer coding and coverage policies.

Common reasons for claim denial

- Incorrect or transposed patient information
- Incorrect modifier or lack of modifier
- Invalid codes—CPT, HCPCS, ICD-10-CM
- Service not deemed a medical necessity
- Missing or incorrect number of units
- Insufficient information to process the claim (eg, missing NDC, prior authorization number, invalid NPI)

Please call **1-855-SANDOZ-8 (1-855-726-3698)** if you require additional guidance.

NPI=National Provider Identifier.

Please see additional Important Safety Information on the front cover and pages 8 and 9, and full Prescribing Information for PYZCHIVA.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd)

Avoid initiating treatment with PYZCHIVA® in patients with any clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of PYZCHIVA 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 PYZCHIVA and discontinue PYZCHIVA 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 products may be susceptible to these types of infections. Consider appropriate diagnostic testing (e.g., tissue culture, stool culture as dictated by clinical circumstances).

Pre-treatment Evaluation for Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating treatment with PYZCHIVA. Avoid administering PYZCHIVA to patients with active TB infection. Initiate treatment of latent TB prior to administering PYZCHIVA. Closely monitor patients receiving PYZCHIVA for signs and symptoms of active TB during and after treatment.

Malignancies

Ustekinumab products are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among patients who received ustekinumab in clinical trials. The safety of ustekinumab products has not been evaluated in patients who have a history of malignancy or who have a known malignancy. There have been reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving ustekinumab products who had risk factors for developing non-melanoma skin cancer. Monitor all patients receiving PYZCHIVA, especially those greater than 60 years of age, those with a medical history of prolonged immunosuppressant therapy, and those with a history of PUVA treatment, for the appearance of non-melanoma skin cancer.

Hypersensitivity Reactions

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

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 product initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab products.

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

Please see additional Important Safety Information on the front cover, page 9, and full Prescribing Information for PYZCHIVA.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Immunizations

Prior to initiating therapy with PYZCHIVA, patients should receive all age-appropriate immunizations as recommended by current immunization guidelines. Patients being treated with PYZCHIVA should avoid receiving live vaccines. Avoid administering BCG vaccines during treatment, 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 PYZCHIVA products due to the potential risk of shedding from the household contact and transmission to patient. Non-live vaccinations received during a course of PYZCHIVA may not elicit an immune response sufficient to prevent disease.

Noninfectious Pneumonia

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

Allergen Immunotherapy

Ustekinumab products 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

The most common adverse reactions (≥3% and higher than that with placebo) in adults from plaque psoriasis clinical trials for ustekinumab 45 mg, ustekinumab 90 mg, or placebo were nasopharyngitis (8%, 7%, 8%), upper respiratory tract infection (5%, 4%, 5%), headache (5%, 5%, 3%), and fatigue (3%, 3%, 2%), respectively. The safety profile in pediatric subjects was similar to the safety profile from studies in adults with plaque psoriasis. In psoriatic arthritis (PsA) clinical trials, a higher incidence of arthralgia and nausea was observed in ustekinumab-treated patients when compared with placebo-treated patients (3% vs 1% for both). In the Crohn's disease induction trials, common adverse reactions (≥3% of patients treated with ustekinumab and higher than placebo) reported through Week 8 for ustekinumab 6 mg/kg intravenous single infusion or placebo included: vomiting (4% vs 3%). In the Crohn's disease maintenance trial, common adverse reactions (≥3% of patients treated with ustekinumab and higher than placebo) reported through Week 44 for ustekinumab 90 mg subcutaneous injection or placebo were nasopharyngitis (11% vs 8%), injection site erythema (5% vs 0%), vulvovaginal candidiasis/mycotic infection (5% vs 1%), bronchitis (5% vs 3%), pruritus (4% vs 2%), urinary tract infection (4% vs 2%), and sinusitis (3% vs 2%). In the ulcerative colitis induction trial, common adverse reactions (≥3% of patients treated with ustekinumab and higher than placebo) reported through Week 8 for ustekinumab 6 mg/kg intravenous single infusion or placebo included nasopharyngitis (7% vs 4%). In the ulcerative colitis maintenance trial, common adverse reactions (≥3% of patients treated with ustekinumab and higher than placebo) reported through Week 44 for ustekinumab 90 mg subcutaneous injection or placebo were nasopharyngitis (24% vs 20%), headache (10% vs 4%), abdominal pain (7% vs 3%), influenza (6% vs 5%), fever (5% vs 4%), diarrhea (4% vs 1%), sinusitis (4% vs 1%), fatigue (4% vs 2%), and nausea (3% vs 2%).

Please see additional Important Safety Information on the front cover and page 8, and full Prescribing Information for PYZCHIVA.

References: 1. PYZCHIVA. Prescribing information. Sandoz Inc; 2024. **2.** Centers for Medicare & Medicaid Services. Chapter 17 - Drugs and Biologicals. In: *Medicare Claims Processing Manual*. Revised February 15, 2024. Accessed February 6, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf **3.** Centers for Medicare & Medicaid Services. *Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier.* Updated November 2024. Accessed February 6, 2025. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf **4.** Centers for Medicare & Medicaid Services. Chapter 12 – Physicians/nonphysician practitioners. In: *Medicare Claims Processing Manual*. Revised June 6, 2024. Accessed February 6, 2025. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf **5.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM tabular list of diseases and injuries. Accessed February 6, 2025. https://www.cms.gov/files/zip/2024-code-tables-tabular-and-index-updated-06/29/2023.zip

For More Support

SANDOZ one source®

The Sandoz One Source Program offers customized support services for patients who are prescribed PYZCHIVA®.

These services include:

- Comprehensive insurance verifications
- Information on co-pay claims denials
- Coding and billing information
- Co-pay assistance for eligible patients

Visit **Sandoz-OneSource.com/PYZCHIVA/** or call **1-855-SANDOZ-8 (1-855-726-3698)**, Monday to Friday 8 AM to 8 PM ET to get started.

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- Infusion vial: Q9997

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

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

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