Pyzchiva®
ustekinumab-ttwe | 90 mg/1 mL

Adult Enrollment and Prescription Form

3 simple steps

to access support from Sandoz One Source

1. COMPLETE **the appropriate form**
2. SIGN & DATE **the form** (must be signed by a healthcare provider)
3. FAX **it to 1-844-422-5957**

This form can also be completed online at Sandoz-OneSource.com/PYZCHIVA

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.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information for PYZCHIVA.

Phone 1-855-726-3698
Fax 1-844-422-5957

ADULT ENROLLMENT AND PRESCRIPTION FORM

Pyzchiva® ustekinumab-ttwe | 90 mg/1 mL | SANDOZ one source®

Phone 1-855-726-3698 **Fax** 1-844-422-5957 **Website** PYZCHIVA.com/pro/

Hours Monday through Friday 8 AM–8 PM ET

***Required field**

Information requested is necessary to enroll in Sandoz One Source per patient services request. **This form should be filled out completely by the healthcare professional and the patient or their legally authorized person.**

☐ New ☐ Restart
☐ Switch from: _____

1 | SELECT SERVICES

By completing this form, I am requesting services on behalf of the patient. I would like the following services completed:

☐ **All Support Services**
☐ Co-Pay Services
☐ Benefits Investigation
☐ Injection Support

2 | PATIENT INFORMATION Please print clearly.

*First Name | Middle Initial | *Last Name | *DOB | Sex ☐ M ☐ F

*Address | *City | *State | *ZIP

Home Phone | *Mobile Phone | ☐ Interpreter Needed ☐ Hearing Impaired

*Email Address | Language

*Patient Weight (kg) | *Date Recorded

3 | INSURANCE INFORMATION Please complete this section or attach a copy of your insurance cards. ☐ Documents Included

Beneficiary/Cardholder Name | Prescription Insurance

Medical Insurance | Rx Group # | Rx ID #

Medical Insurance ID # | Group # | Rx BIN # | Rx PCN #

FOR HEALTHCARE PROFESSIONAL USE ONLY

4 | *DIAGNOSIS ☐ Plaque Psoriasis (L40._____) ☐ Psoriatic Arthritis (L40._____) ☐ Crohn's Disease (K50._____) ☐ Ulcerative Colitis (K51._____)

5 | PRESCRIBER INFORMATION

*Prescriber's Name (First, Last) | *Office Contact Name

*Site Name | *Address | *City | *State

*ZIP | *Office Phone | *Office Fax

PTAN # (required for Medicare) | Tax ID # | *NPI #

6 | INFUSION INFORMATION (For patients with Crohn's disease and ulcerative colitis only)

Infusion location: ☐ Patient's Home ☐ Prescriber's Office ☐ Infusion Site If infusion site, complete information below:

Infusion Site Name | Clinic/Hospital Affiliation

Site Street Address | Suite #

City | State | ZIP

Infusion Clinic Contact Name | Phone | Email

7 | PHARMACY PRESCRIPTION (Rx) Please complete and sign the prescription.

Patient's preferred Specialty Pharmacy ☐ Do not send to Specialty Pharmacy

PLAQUE PSORIASIS (PsO)

WEIGHT	INITIAL THERAPY 45 mg administered subcutaneously at Week 0 and Week 4	MAINTENANCE THERAPY 45 mg administered subcutaneously every 12 weeks
≤100 kg	☐ 2 single-dose 45 mg prefilled syringes ☐ 2 single-dose 45 mg vials[a] ☐ No loading dose required	☐ 1 single-dose 45 mg prefilled syringe ☐ 1 single-dose 45 mg vial[a] **Refills:** _____
WEIGHT	**INITIAL THERAPY** 90 mg administered subcutaneously at Week 0 and Week 4	**MAINTENANCE THERAPY** 90 mg administered subcutaneously every 12 weeks
>100 kg	☐ 2 single-dose 90 mg prefilled syringes ☐ No loading dose required	☐ 1 single-dose 90 mg prefilled syringe **Refills:** _____

[a]Available in Q3 2025.

Continued on the next page of this form.

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Hours Monday through Friday 8 AM–8 PM ET ***Required field**

*Patient Full Name *DOB *Mobile Phone

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PSORIATIC ARTHRITIS (PsA)

PATIENT TYPE	INITIAL THERAPY 45 mg administered subcutaneously at Week 0 and Week 4	MAINTENANCE THERAPY 45 mg administered subcutaneously every 12 weeks
Patients with PsA	☐ 2 single-dose 45 mg prefilled syringes ☐ 2 single-dose 45 mg vials[a] ☐ No loading dose required	☐ 1 single-dose 45 mg prefilled syringe ☐ 1 single-dose 45 mg vial[a] **Refills:** _____

PATIENT TYPE	INITIAL THERAPY 90 mg administered subcutaneously at Week 0 and Week 4	MAINTENANCE THERAPY 90 mg administered subcutaneously every 12 weeks
Patients with PsA and co-existent moderate-to-severe PsO weighing >100 kg	☐ 2 single-dose 90 mg prefilled syringes ☐ No loading dose required	☐ 1 single-dose 90 mg prefilled syringe **Refills:** _____

[a]Available in Q3 2025.

CROHN'S DISEASE (CD) OR ULCERATIVE COLITIS (UC)

INITIAL THERAPY Single intravenous infusion based on weight		MAINTENANCE THERAPY 90 mg administered subcutaneously every 8 weeks
WEIGHT	**NUMBER OF 130 MG VIALS**	
Up to 55 kg	☐ 2 (260 mg dose)	☐ 1 single-dose 90 mg prefilled syringe **Refills:** _____
>55 kg to 85 kg	☐ 3 (390 mg dose)	
>85 kg	☐ 4 (520 mg dose)	
N/A	☐ No loading dose required	

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. By completing and submitting this form, I certify that my patient is aware of the disclosure of their personal health information to Sandoz and its business partners for Sandoz's patient support services, including reimbursement and verification services and the services provided by field reimbursement professionals in my office, as part of the patient's treatment with this product. I certify that I have obtained any required patient authorization. I further certify that (a) any service provided through Sandoz One Source on behalf of any patient is not made in exchange for any expressed or implied agreement or understanding that I would recommend, prescribe, or use PYZCHIVA or any other Sandoz product or service for anyone, and that (b) my decision to prescribe PYZCHIVA was based solely on my determination of medical necessity as set forth herein, and that (c) I will not seek reimbursement for any medication or service provided by or through Sandoz One Source for any government program or third-party insurer. For the purposes of transmitting prescriptions, I authorize SPA (Sandoz Patient Assistance), Sandoz, and its affiliates, business partners, and agents to forward these prescriptions electronically, by facsimile, or by mail to the appropriate dispensing pharmacies on my behalf.

Prescriber's Signature (REQUIRED)

Prescriber's signature (dispense as written) Date

Prescriber's signature (substitution permissible) Date

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

Please be sure to fax both page 1 and page 2 when enrolling a patient, regardless of indication.

MLR-1541-US 02/2025

Please see Important Safety Information throughout and accompanying full Prescribing Information for PYZCHIVA.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Infections (cont'd)

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.

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.

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.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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%).

Provide the Medication Guide to your patients and encourage discussion.

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