IT'S ACHIEVABLE WITH PYZCHIVA®
(ustekinumab-ttwe)

The biosimilar to Stelara® (ustekinumab), brought to you by Sandoz

Pyzchiva®
ustekinumab-ttwe | 90 mg/1 mL

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.

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

SANDOZ

Why PYZCHIVA®?

When it comes to ustekinumab biosimilars, PYZCHIVA checks all the boxes.

- Approved for the **same indications** as Stelara® (ustekinumab)[1,2]
- Dosing options **you're familiar with**[1]
- Demonstrated the **same efficacy and safety** as Stelara®[3a]
- **Extended shelf life and stability** compared to Stelara®[1,2]
- Approved as **interchangeable** with Stelara®[4b]

[a]Based on results from a Phase 3, randomized, double-blind study in adult patients with moderate-to-severe plaque psoriasis who were candidates for phototherapy or systemic therapy randomized to receive either PYZCHIVA or Stelara® subcutaneously.

[b]While PYZCHIVA has been approved by the FDA as interchangeable with Stelara®, the interchangeability status is considered "provisional" until May 1, 2025, due to a settlement involving exclusivity. This is a legal designation and is unrelated to the clinical approval process for interchangeability.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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).

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PYZCHIVA® meets all FDA requirements for biosimilarity to Stelara® (ustekinumab)

Analytical studies

Confirmed matching structural and functional profiles[5]

Nonclinical research

Comparable toxicity and safety profiles[5]

Pharmacological study

Phase 1 clinical trial that demonstrated bioequivalence in PK between PYZCHIVA and Stelara®[6]

Confirmatory study

Phase 3 study that demonstrated comparable efficacy, safety, PK, and immunogenicity between PYZCHIVA and Stelara®[3]

Visit **PYZCHIVA.com/pro/evidence/** to review the results of the Phase 3 confirmatory study

PK=pharmacokinetics.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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PYZCHIVA® offers dosing options you're familiar with

Features of the single-dose prefilled syringe[1a]

45 mg/0.5 mL single-dose PFS | NDC: 61314-0651-01
90 mg/1 mL single-dose PFS | NDC: 61314-0652-01

- 29-gauge, fixed ½-inch needle, vs the Stelara® (ustekinumab) 27-gauge needle
- Fitted with a needle safety guard and needle cover
- Needle cover is not made with natural rubber latex

Single-dose vial[1b]

45 mg/0.5 mL vial for injection dosing | NDC: 61314-0651-94

Vial for infusion[1]

130 mg/26 mL vial for induction dosing[c] | NDC: 61314-0654-94

Share step-by-step instructions with your patients to help them confidently self-inject PYZCHIVA. Find the **Instructions for Use** in the full **Prescribing Information**.

[a]This presentation is not intended to compare the safety or efficacy of treatments. Please refer to the product's full Prescribing Information.
[b]Available in Q3 2025.
[c]For use in adults with Crohn's disease or ulcerative colitis.
PFS=prefilled syringe.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Malignancies

Ustekinumab products are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among patients who received ustekinumab in clinical trials.

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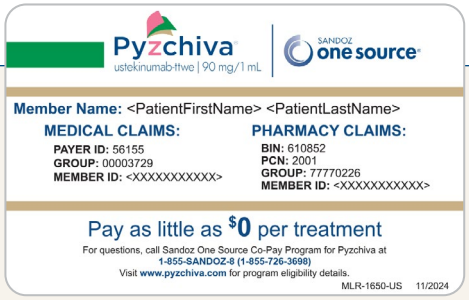
With the PYZCHIVA® Co-pay Card, eligible patients could pay as little as $0



Co-pay offer is as low as $0 for eligible, commercially insured patients.

For full Terms and Conditions, visit **PYZCHIVA.com/pro/support/**.

Providers can enroll patients online, or **patients can enroll themselves** online or over the phone

Instant access means **cards are available immediately** for those who qualify

No expiration, with automatic annual reset of card benefits

Visit **Sandoz-OneSource.com/PYZCHIVA** to enroll your patients in the Co-pay Program

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Malignancies (cont'd)

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.

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Sandoz One Source offers support services for your patients and your practice

Case Managers

- Provide education about PYZCHIVA®
- Help identify opportunities for savings

Injection support

- Personalized, 1:1 training options available
- Nurse support to answer treatment questions

Reimbursement support

- Sandoz One Source Case Managers provide expert assistance with processes for approval and reimbursement, including benefits verification and investigation as well as billing and coding support

Insurance support

- Assistance for patients in:
  - Navigating and understanding their health plan benefits
  - Identifying a pharmacy that will ship their medication

3 ways to enroll your patients

Enroll online

Complete the online Sandoz One Source enrollment form at **Sandoz-OneSource.com/PYZCHIVA**

Enroll via fax

Download the Sandoz One Source Enrollment Form and fax the completed form to **1-844-422-5957**

Enroll via phone

Call **1-855-SANDOZ-8 (1-855-726-3698)** to speak with a live Sandoz One Source Case Manager

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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.

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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%).

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Backed by Sandoz—a trusted partner and a global leader in generic and biosimilar medications

We are committed to **increasing access for patients** by bringing high-quality, more affordable, and potentially life-changing biologic treatments to market worldwide.

Our **unparalleled heritage** in biosimilars is built upon:

25+
YEARS
of biosimilar development[7]

20+
MOLECULES
in development[7]

10+
FDA-APPROVED BIOSIMILARS
in the United States[7,8]

1st
BIOSIMILAR APPROVED
in the United States and throughout much of the world[7]

Sandoz has the experience you want in a biosimilar partner from...

A to Z

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From the first dose through the continuation of therapy,

Team PYZCHIVA® is here for you

Contact your **PYZCHIVA Sales Specialist** for questions related to:

- Clinical information about PYZCHIVA
- Insurance coverage
- In-office educational resources

Contact your **PYZCHIVA Field Reimbursement Manager** for questions related to:

- Patient-level reimbursement support[a]
- Patient-level insurance coverage[a]
- In-office educational resources

You can also contact a **Sandoz Medical Science Liaison** if you would like more information about biosimilars or PYZCHIVA.

[a]Patient consent must be on file.

References: 1. PYZCHIVA. Prescribing Information. Sandoz Inc; 2024. **2.** Stelara. Prescribing Information. Janssen Biotech Inc; 2024. **3.** Feldman SR, Narbutt J, Girolomoni G, et al. A randomized, double-blind, phase III study assessing clinical similarity of SB17 (proposed ustekinumab biosimilar) to reference ustekinumab in subjects with moderate-to-severe plaque psoriasis. *J Am Acad Dermatol*. 2024:S0190-9622(24)00663-7. doi:10.1016/j.jaad.2024.04.045 **4.** Jeremias S. FDA approves Samsung Bioepis' Pyzchiva, a biosimilar to Stelara. The Center for Biosimilars. July 1, 2024. Accessed February 3, 2025. https://www.centerforbiosimilars.com/view/fda-approves-samsung-bioepis-pyzchiva-a-biosimilar-to-stelara **5.** US Food and Drug Administration. *Biosimilar Regulatory Review and Approval*. Updated December 13, 2022. Accessed February 3, 2025. https://www.fda.gov/media/151061/download?attachment **6.** Jeong H, Kang T, Lee J, Im S. 41531 A phase 1, randomized, double-blind, single-dose comparative pharmacokinetic study comparing SB17 (proposed ustekinumab biosimilar) with reference ustekinumab in healthy subjects. *J Am Acad Dermatol*. 2023;89(3 suppl):AB9. doi:10.1016/j.jaad.2023.07.042 **7.** Sandoz website. Accessed February 3, 2025. https://www.sandoz.com **8.** Jeremias S. FDA approves Avzivi, the fifth biosimilar to Avastin. The Center for Biosimilars. December 19, 2023. Accessed February 3, 2025. https://www.centerforbiosimilars.com/view/fda-approved-avzivi-the-fifth-biosimilar-to-avastin

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PYZCHIVA offers **dosing options** you're familiar with[1]

With the PYZCHIVA Co-pay Program, eligible patients could **pay as little as $0**

25+

PYZCHIVA is **backed by Sandoz**, a trusted partner and global leader in biosimilars with **25+ years of experience**[7]

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