

Pyzchiva[®] (ustekinumab-ttwe) – New biosimilar approval

- On July 1, 2024, [Samsung Bioepis](#) and [Sandoz](#) announced the FDA approval of [Pyzchiva \(ustekinumab-ttwe\)](#), biosimilar to Janssen's [Stelara[®] \(ustekinumab\)](#).
 - [Wezlana \(ustekinumab-auub\)](#) was the first FDA-approved biosimilar that is interchangeable to Stelara.
 - [Selarsdi \(ustekinumab-aekn\)](#) was the second biosimilar approved to Stelara. It was only approved as a subcutaneous formulation.
- Pyzchiva, Wezlana, Selarsdi and Stelara share the following indications:
 - Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy
 - Adults and pediatric patients 6 years and older with active psoriatic arthritis (PsA).
- Pyzchiva, Wezlana and Stelara also share the following indications:
 - Adult patients with moderately to severely active Crohn's disease (CD)
 - Adult patients with moderately to severely active ulcerative colitis (UC).
- The approval of Pyzchiva is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Stelara.
- Warnings and precautions for Pyzchiva include infections; theoretical risk for vulnerability to particular infections; pre-treatment evaluation for tuberculosis; malignancies; hypersensitivity reactions; posterior reversible encephalopathy syndrome; immunizations; and noninfectious pneumonia.
- The most common adverse reactions (≥ 3%) with Pyzchiva use in psoriasis were nasopharyngitis, upper respiratory tract infection, headache, and fatigue.
- The most common adverse reaction (≥ 3%) with Pyzchiva use in CD, induction was vomiting.
- The most common adverse reactions (≥ 3%) with Pyzchiva use in CD, maintenance were nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection, and sinusitis.
- The most common adverse reaction (≥ 3%) with Pyzchiva use in UC, induction was nasopharyngitis.
- The most common adverse reactions (≥ 3%) with Pyzchiva use in UC, maintenance were nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue, and nausea.
- The recommended dosage of Pyzchiva for adult patients with PsO is 45 mg subcutaneously (SC) initially and 4 weeks later, followed by 45 mg every 12 weeks in those weighing ≤ 100 kg. For those weighing > 100 kg, the dose is 90 mg SC initially and 4 weeks later, followed by 90 mg every 12 weeks.

- The recommended dosage of Pyzchiva for PsO in pediatric patients (6 – 17 years old) is administered SC at weeks 0 and 4, then every 12 weeks thereafter and based on body weight as follows: 60 to 100 kg, 45 mg; and > 100 kg, 90 mg.
- There is no dosage form for Pyzchiva that allows weight-based dosing for pediatric patients below 60 kg (132 pounds).
- The recommended dosage of Pyzchiva for adult patients with PsA is 45 mg SC initially and 4 weeks later, followed by 45 mg every 12 weeks.
 - The recommended dosage of Pyzchiva for PsA in pediatric patients (6 – 17 years old) is administered SC at weeks 0 and 4, then every 12 weeks thereafter and based on body weight as follows: > 60 kg, 45 mg.
 - There is no dosage form for Pyzchiva that allows weight-based dosing for pediatric patients below 60 kg (132 pounds).
- The recommended induction dosage of Pyzchiva in adult patients with CD and UC is a single intravenous (IV) infusion using the weight-based dosage regimen as follows: ≤ 55 kg, 260 mg; >55 kg to 85 kg, 390 mg; and > 85 kg, 520 mg.
 - The recommended maintenance dosage of Pyzchiva in adult patients with CD and UC is a 90 mg dose administered SC 8 weeks after the initial IV dose, then every 8 weeks thereafter.
- Pyzchiva is intended for use under the guidance and supervision of a physician. Pyzchiva should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician. The appropriate dose should be determined by a healthcare provider using the patient's current weight at the time of dosing. In pediatric patients, it is recommended that Pyzchiva be administered by a healthcare provider. If a physician determines that it is appropriate, a patient may self-inject, or a caregiver may inject Pyzchiva after proper training in SC injection technique.
 - Refer to the Pyzchiva drug label for additional dosing details.
- Sandoz's launch plans for Pyzchiva are pending. Pyzchiva will be available as single-dose vials containing 130 mg/26 mL (5 mg/mL) for IV infusion and single-dose prefilled syringes containing 45 mg/0.5 mL and 90 mg/mL for SC injection.
- Samsung Bioepis has signed a [settlement agreement](#) with Johnson & Johnson (Janssen) allowing the company to sell Pyzchiva "beginning on February 22, 2025."



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