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Stelara and Biosimilars for Stelara Drug List

Select FDA-approved specialty medications

Reference product

Drug name / Manufacturer	FDA-Approved Indication(s)	Administration Route	Dosages / Device Type	Prescription written for	Pharmacy to dispense
Stelara (ustekinumab) Manufacturer: • Johnson & Johnson	<ul style="list-style-type: none">• CD• PsA (6+)• PsO (6+)• UC	IV infusion: <ul style="list-style-type: none">• HCP-administered SC injection: <ul style="list-style-type: none">• Self-administered	IV: <ul style="list-style-type: none">• 130 mg/26 mL SDV SC: <ul style="list-style-type: none">• 45 mg/0.5 mL PFS• 45 mg/0.5 mL SDV• 90 mg/mL PFS	Stelara or ustekinumab	Stelara or ustekinumab

Available biosimilars

Drug name / Manufacturer	FDA-Approved Indication(s)	Administration Route / Concentration	Dosages / Device Type	Prescription written for	Pharmacy to dispense
Pyzchiva (ustekinumab-ttwe) Manufacturer: • Samsung Bioepis	<ul style="list-style-type: none">• CD• PsA (6+)• PsO (6+)• UC	SC injection: <ul style="list-style-type: none">• HCP-administered SC injection: <ul style="list-style-type: none">• Self-administered	IV: <ul style="list-style-type: none">• 130 mg/26 mL SDV SC: <ul style="list-style-type: none">• 45mg/0.5 mL PFS• 90 mg/mL PFS	Pyzchiva or ustekinumab-ttwe	Pyzchiva

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Selarsdi (ustekinumab-aekn) Manufacturer: <ul style="list-style-type: none"> Alvotect 	<ul style="list-style-type: none"> CD PsA (6+) PsO (6+) UC 	SC injection: <ul style="list-style-type: none"> Self-administered 	SC: <ul style="list-style-type: none"> 45 mg/0.5 mL PFS 45 mg/0.5 mL SDV 90 mg/mL PFS 	Selarsdi or ustekinumab-aekn	Selarsdi
Steqeyma (ustekinumab-stba) Manufacturer: <ul style="list-style-type: none"> Celltrion 	<ul style="list-style-type: none"> CD PsA (6+) PsO (6+) UC 	IV infusion <ul style="list-style-type: none"> HCP-administered SC injection: <ul style="list-style-type: none"> Self-administered 	IV: <ul style="list-style-type: none"> 130 mg/26 mL SDV SC: <ul style="list-style-type: none"> 45 mg/0.5 mL PFS 90 mg/mL PFS 	Steqeyma or ustekinumab-stba	Steqeyma
Yesintek (ustekinumab-kfce) Manufacturer: <ul style="list-style-type: none"> Biocon Biologics 	<ul style="list-style-type: none"> CD PsA (6+) PsO (6+) UC 	IV infusion <ul style="list-style-type: none"> HCP-administered SC injection: <ul style="list-style-type: none"> Self-administered 	IV: <ul style="list-style-type: none"> 130 mg/26 mL SDV SC: <ul style="list-style-type: none"> 45 mg/0.5 mL PFS 45 mg/0.5 mL SDV 90 mg/mL PFS 	Yesintek or ustekinumab-kfce	Yesintek

IV infusion must be administered by a health care professional only and is given as an induction therapy for the treatment of Crohn's disease and Ulcerative colitis.

Select common adverse reactions include: Psoriasis: nasopharyngitis, upper respiratory tract infection, headache and fatigue; Crohn's Disease, induction: vomiting; Crohn's Disease, maintenance: nasopharyngitis, injection site erythema, vulvovaginal candidiasis/mycotic infection, bronchitis, pruritus, urinary tract infection and sinusitis; Ulcerative colitis, induction: nasopharyngitis; Ulcerative colitis, maintenance: nasopharyngitis, headache, abdominal pain, influenza, fever, diarrhea, sinusitis, fatigue and nausea.

Biologics/biosimilars come in branded and unbranded products. Since branded and unbranded biologics/biosimilars share the same biologics license application (BLA), they may be changed with the corresponding unbranded or branded biosimilar as deemed by the prescription benefit plan.

FDA (U.S. Food and Drug Administration). HCP (Health care professional). IV (Intravenous). PFS (Prefilled Syringe). SC (Subcutaneous). SDV (Single Dose Vial). CD (Crohn's disease).

PsA (Psoriatic arthritis). PsO (Plaque psoriasis). UC (Ulcerative colitis).

The information contained in this communication is provided in summary form. It is not intended for use as the sole basis of clinical treatment, as a substitute for reading the original research, nor as a substitute for the knowledge, skill and judgment of the medical provider. This list is subject to change. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Specialty.