Stelara (ustekinumab)
Pyzchiva* (ustekinumab-ttwe)
Selarsdi* (ustekinumab-aekn)

*These medications are included in this policy but are not available on the market as of yet

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe plaque psoriasis (PsO)
    a. 6 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
        i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
    c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight – 0.75 mg/kg every 12 weeks
        ii. Subcutaneous administration: Patients 6-17 years of age 60 kg to 100 kg weight and adult patients less than or equal to 100 kg weight – 45 mg every 12 weeks
        iii. Subcutaneous administration: Patients greater than 100 kg weight – 90 mg every 12 weeks
    d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products [Enbrel (all ages) or Humira (age 12+ only)] if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Active psoriatic arthritis (PsA)
    a. 6 years of age or older
    b. Inadequate treatment response, intolerance or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)

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c. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
    i. Subcutaneous administration: Patients 18 years of age or older - 45 mg every 12 weeks
    ii. Subcutaneous administration: Patients 6 years of age or older, weight greater than 100 kg, with concurrent moderate to severe plaque psoriasis – 90 mg every 12 weeks
    iii. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight - 0.75 mg/kg every 12 weeks
    iv. Subcutaneous administration: Patients 6-17 years of age and greater than or equal to 60 kg weight - 45 mg every 12 weeks
d. Age 12+, Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Moderate to severely active Crohn's disease (CD)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
    c. Prescriber will initiate dosing with a single intravenous infusion with **ONE** of the following:
        i. IV infusion: 55 kg or less – 260 mg
        ii. IV infusion: >55 kg to 85 kg – 390 mg
        iii. IV infusion: More than 85 kg – 520 mg
    d. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 90 mg every 8 weeks
    e. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Moderate to severely active ulcerative colitis (UC)
    a. 18 years of age or older
    b. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 2)

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c. Prescriber will initiate dosing with a single intravenous infusion with **ONE** of the following:
   i. IV infusion: 55 kg or less – 260 mg
   ii. IV infusion: >55 kg to 85 kg – 390 mg
   iii. IV infusion: More than 85 kg – 520 mg
d. Prescriber will not exceed the FDA labeled maintenance dose of the following:
   i. Subcutaneous administration: 90 mg every 8 weeks
e. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

AND ALL of the following for **ALL** diagnoses:

1. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
4. **NOT** given concurrently with live vaccines

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Plaque psoriasis (PsO)	<u>Weight ≤100kg</u> 45 mg SC vial/syringe <u>Weight > 100kg</u> 90 mg SC syringe	5 units per 365 days (dosed initially, 4 weeks later, then every 12 weeks)
Psoriatic arthritis (PsA)	45 mg SC vial/syringe **<u>Concurrent moderate to severe plaque psoriasis and weight > 100kg</u>**	

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	90 mg SC syringe	
Crohn's disease (CD) Ulcerative colitis (UC)	130 mg IV vial 90 mg SC syringe	<u>Weight ≤55kg</u> (2 IV vials) + 1 SC syringe per 56 days <u>Weight > 55kg to 85kg</u> (3 IV vials) + 1 SC syringe per 56 days <u>Weight > 85kg</u> (4 IV vials) + 1 SC syringe per 56 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Plaque psoriasis (PsO)
    a. 6 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight – 0.75 mg/kg every 12 weeks
        ii. Subcutaneous administration: Patients 6-17 years of age and 60 kg to 100 kg weight and adult patients less than or equal to 100 kg weight – 45 mg every 12 weeks
        iii. Subcutaneous administration: Patients greater than 100 kg weight – 90 mg every 12 weeks
    c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products [Enbrel (all ages) or Humira (age 12+ only)] if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

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2. Psoriatic arthritis (PsA)
    a. 6 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of **ONE** of the following:
        i. Subcutaneous administration: Patients 18 years of age or older - 45 mg every 12 weeks
        ii. Subcutaneous administration: Patients 6 years of age or older, weight greater than 100 kg, with concurrent moderate to severe plaque psoriasis – 90 mg every 12 weeks
        iii. Subcutaneous administration: Patients 6-17 years of age and less than 60 kg weight - 0.75 mg/kg every 12 weeks
        iv. Subcutaneous administration: Patients 6-17 years of age and greater than or equal to 60 kg weight - 45 mg every 12 weeks
    c. Age 12+, Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

3. Crohn's disease (CD)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 90 mg every 8 weeks
    c. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

4. Ulcerative colitis (UC)
    a. 18 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Subcutaneous administration: 90 mg every 8 weeks
    c. Blue Focus **only:** Patient **MUST** have tried the preferred product (Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

Stelara (ustekinumab)
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AND ALL of the following for **ALL** diagnoses:

1. Condition has improved or stabilized with Stelara
2. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
4. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Plaque psoriasis (PsO)	Weight ≤100kg 45 mg SC vial/syringe Weight > 100kg 90 mg SC syringe	1 unit per 84 days
Psoriatic arthritis (PsA)	45 mg SC vial/syringe **Concurrent moderate to severe plaque psoriasis and weight > 100kg** 90 mg SC syringe	
Crohn's disease (CD)	90 mg SC syringe	1 SC syringe per 56 days
Ulcerative colitis (UC)		

Duration 18 months

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name

Stelara (ustekinumab)
Pyzchiva* (ustekinumab-ttwe)
Selarsdi* (ustekinumab-aekn)

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azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR

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upadactinib	Rinvoq

Appendix 2 – List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission a. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine

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5. Pouchitis:
    a. Metronidazole, ciprofloxacin
    b. Alternative: rectal mesalamine