BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS: OTULFI™ (ustekinumab-aauz) IV & SQ PYZCHIVA® (ustekinumab-ttwe) IV & SQ SELARSDI™ (ustekinumab-aekn) IV & SQ STELARA® (ustekinumab) IV & SQ STEQEYMA® (ustekinumab-stba) IV & SQ UNBRANDED USTEKINUMAB (ustekinumab) IV & SQ USTEKINUMAB-AEKN (ustekinumab-aekn) SQ WEZLANA™ (ustekinumab-auub) IV & SQ YESINTEK™ (ustekinumab-kfce) IV &SQ

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

Section A. Crohn's Disease (CD):

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS

- **Criteria for initial therapy:** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active Crohn's disease:

1. Request is for **ONE** of the following: Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV&SQ), Stelara (IV&SQ), Steqeyma (IV&SQ), Unbranded Ustekinumab (IV&SQ), Ustekinumab-aekn (SQ) Wezlana (IV&SQ), Yesintek (IV&SQ)

2. Prescriber is a Gastroenterologist

3. Individual is 18 years of age or older

4. Individual has a confirmed diagnosis of moderate to severe active Crohn's disease as indicated by **ONE** of the following:
    a. Crohn's disease activity index (CDAI) greater than 220 in adults
    b. Pediatric Crohn's disease activity index (PCDAI) greater than 30
    c. **At least 5** of the following signs and symptoms:
        i. Anemia
        ii. Chronic intermittent diarrhea (with or without food)
        iii. Crampy abdominal pain
        iv. Elevated serum C-reactive protein level and/or fecal calprotectin
        v. Extraintestinal manifestations such as arthritis or arthropathy, eye and skin disorders, biliary tract involvement, and kidney stones
        vi. Fatigue
        vii. Fistulas
        viii. Perianal disease (e.g., anal fissures, anorectal abscess)
        ix. Weight loss or growth failure in children

5. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE or MORE** of the following [Note this criterion is waived if the individual already has tried an FDA-approved Crohn's disease biologic]:
    a. 6-mercaptopurine
    b. Azathioprine
    c. Methotrexate
    d. Oral corticosteroids

6. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
    a. Steqeyma (IV&SQ)
    b. Wezlana (IV&SQ) (LW)
    c. Yesintek (IV&SQ)

7. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
        i. Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months

ii. Screening for latent tuberculosis infection with a tuberculin skin test or blood test has been done and if positive, treatment has been initiated
b. Concurrent use of live vaccines

8. There are **NO** FDA-label contraindications

9. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in or is in consultation with a Gastroenterologist

2. Individual's condition has responded while on therapy with response defined as the following:
   a. **With first request for continuation ONE of the following:**
      i. AT LEAST a 20% improvement in the signs and symptoms of Crohn's disease
      ii. Decrease in Crohn's disease activity index of more than 70 from baseline or a Crohn's disease activity index of < 150 (in remission) in adults
      iii. Pediatric Crohn disease activity index (PCDAI) ≤ 30 in children indicating mild disease or disease remission
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications per FDA label or other significant adverse drug effects that may exclude continued use

5. Individual does **NOT** have **ANY** of the following:
   a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
   b. Concurrent use of live vaccines

6. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
   a. Steqeyma (IV&SQ)
   b. Wezlana (IV&SQ) (LW)
   c. Yesintek (IV&SQ)

7. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Renewal Duration: 12 months

Section B. Plaque Psoriasis (Ps also as PsO):

- **Criteria for initial therapy:** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderate to severe plaque psoriasis:

1. Request is for **ONE** of the following: Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV&SQ), Stelara (IV&SQ), Steqeyma (IV&SQ), Unbranded Ustekinumab (IV&SQ), Ustekinumab-aekn (SQ), Wezlana (IV&SQ), Yesintek (IV&SQ)

2. Prescriber is a Dermatologist

3. Individual is 6 years of age or older

4. Individual has a diagnosis of moderate to severe plaque psoriasis, as indicated by **ALL** of the following:
    a. Individual is a candidate for photochemotherapy or phototherapy
    b. Plaque psoriasis involves ≥ 10% body surface area (BSA) **or** plaque psoriasis involves < 10% BSA but includes sensitive areas or areas that significantly impact daily function (e.g., palms, soles of feet, head/neck, or genitalia)
    c. A Psoriasis Area and Index (PASI) of at least 10

5. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for a treatment regimen that includes **ALL** of the following:
    a. A trial of least **TWO** topical agents (e.g., anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)
    b. A trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
    c. A trial of Ultraviolet Light therapy (e.g., Photochemotherapy (i.e., psoralen plus ultraviolet A therapy), Phototherapy (i.e., ultraviolet light therapy), or Excimer laser)

6. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
    a. Steqeyma (IV&SQ)
    b. Wezlana (IV&SQ) (LW)
    c. Yesintek (IV&SQ)

7. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
        i. Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months

ii. Screening for latent tuberculosis infection with a tuberculin skin test or blood test has been done and if positive, treatment has been initiated

b. Concurrent use of live vaccines

8. There are **NO** FDA-label contraindications

9. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in or is in consultation with a Dermatologist

2. Individual's condition has responded while on therapy with response defined as the following:
   a. **With first request for continuation:** AT LEAST a 20% improvement in PASI (see Definitions section)
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications per FDA label or other significant adverse drug effects that may exclude continued use

5. Individual does **NOT** have **ANY** of the following:
   a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
   b. Concurrent use of live vaccines

6. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
   a. Steqeyma (IV&SQ)
   b. Wezlana (IV&SQ) (LW)
   c. Yesintek (IV&SQ)

7. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Renewal Duration: 12 months

Section C. Psoriatic Arthritis (PsA):

- **Criteria for initial therapy:** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for active psoriatic arthritis:

1. Request is for **ONE** of the following: Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV&SQ), Stelara (IV&SQ), Steqeyma (IV&SQ), Unbranded Ustekinumab (IV&SQ), Ustekinumab-aekn (SQ), Wezlana (IV&SQ), Yesintek (IV&SQ)

2. Prescriber is a Rheumatologist or Dermatologist

3. Individual is 6 years of age or older

4. Individual has a confirmed diagnosis of moderate to severe active psoriatic arthritis is identified by **ONE or more** of the following:
    a. Predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by **ALL** of the following:
        i. Radiographic evidence of axial disease (e.g., sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
        ii. Symptoms (e.g., limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months' duration
        iii. Failure, contraindication per FDA label, or intolerance to 1 or more different NSAIDs (at maximum recommended doses) over total period of at least 4 or more weeks of therapy
    b. Predominantly non-axial disease, and failure (used for ≥ 3 consecutive months), intolerance, or contraindication per FDA label to methotrexate or NSAIDs

5. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
        i. Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months
        ii. Screening for latent tuberculosis infection with a tuberculin skin test or blood test has been done and if positive, treatment has been initiated
    b. Concurrent use of live vaccines

6. There are **NO** FDA-label contraindications

7. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
    a. Steqeyma (IV&SQ)
    b. Wezlana (IV&SQ) (LW)
    c. Yesintek (IV&SQ)

8. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in or is in consultation with a Dermatologist

2. Individual's condition has responded while on therapy with response defined as the following:
   a. **With first request for continuation**: AT LEAST a 20% improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID-3, SDAI (see Definitions section)
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications per FDA label or other significant adverse drug effects that may exclude continued use

5. Individual does **NOT** have **ANY** of the following:
   a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
   b. Concurrent use of live vaccines

6. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
   a. Steqeyma (IV&SQ)
   b. Wezlana (IV&SQ) (LW)
   c. Yesintek (IV&SQ)

7. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Renewal Duration: 12 months

Section D. Ulcerative Colitis (UC):

- **Criteria for initial therapy:** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active ulcerative colitis (UC):

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STELARA AND STELARA BIOSIMILARS

1. Request is for **ONE** of the following: Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV&SQ), Stelara (IV&SQ), Steqeyma (IV&SQ), Unbranded Ustekinumab (IV&SQ), Ustekinumab-aekn (SQ), Wezlana (IV&SQ), Yesintek (IV&SQ)

2. Prescriber is a Gastroenterologist

3. Individual is 18 years of age or older

4. Individual has a confirmed diagnosis of moderate to severe active ulcerative colitis, as indicated by **ONE** of the following:
    a. American College of Gastroenterology Ulcerative Colitis activity index rating of moderate to severe disease in adults
    b. Pediatric ulcerative colitis activity index (PUCAI) greater than or equal to 35
    c. **At least 5** of the following signs and symptoms:
        i. Anemia
        ii. Bloody diarrhea or visible blood in stool
        iii. Bowel movements 4-6 or more times per day
        iv. Colicky abdominal pain
        v. Elevated fecal calprotectin
        vi. Elevated serum C-reactive protein or erythrocyte sedimentation rate
        vii. Fatigue
        viii. Fever
        ix. Tenesmus
        x. Urgency
        xi. Weight loss or delayed growth in children

5. Individual has documented failure (used for $\geq$ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE or more** of the following: [Note: this criterion is waived if the individual already has tried an FDA-approved Ulcerative Colitis biologic]
    a. 6-mercaptopurine
    b. Azathioprine
    c. Oral corticosteroids
    d. Salicylates (such as mesalamine, sulfasalazine, balsalazide, olsalazine)

6. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for $\geq$ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
    a. Steqeyma (IV&SQ)
    b. Wezlana IV or SQ (LW)
    c. Yesintek (IV&SQ)

7. Individual does **NOT** have **ANY** of the following:
    a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
        i. Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months
        ii. Screening for latent tuberculosis infection with a tuberculin skin test or blood test has been done and if positive, treatment has been initiated

b. Concurrent use of live vaccines

8. There are **NO** FDA-label contraindications

9. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Stelara or Stelara Biosimilars is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in or is in consultation with a Gastroenterologist

2. Individual's condition has responded while on therapy with response defined as the following:
   a. **With first request for continuation ONE of the following:**
      i. AT LEAST a 20% improvement in signs and symptoms of ulcerative colitis
      ii. American College of Gastroenterology Ulcerative Colitis activity index rating of mild disease or disease in remission in adults
      iii. Pediatric ulcerative colitis activity index (PUCAI) of ≤ 34 in children indicating mild disease or disease remission
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications per FDA label or other significant adverse drug effects that may exclude continued use

5. Individual does **NOT** have **ANY** of the following:
   a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
   b. Concurrent use of live vaccines

6. **For Otulfi (IV&SQ), Pyzchiva (IV&SQ), Selarsdi (IV& SQ, Stelara (IV&SQ) and Unbranded Ustekinumab (IV&SQ), and Ustekinumab-aekn (SQ):** Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
   a. Steqeyma (IV&SQ)
   b. Wezlana (IV&SQ) (LW)
   c. Yesintek (IV&SQ)

7. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Renewal Duration: 12 months

Section E. Measurement of Antibodies to Biologic/Immunologic Agents:

- Measurement of antibodies for biologic or immunologic agents in an individual receiving treatment, either alone or as a combination test, which includes the measurement of serum levels for the biologic or immunologic agents is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
3. Insufficient evidence to support improvement of the net health outcome; or
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
5. Insufficient evidence to support improvement outside the investigational setting.

These measurements include, *but are not limited to:*

- Anser™ ADA

Section F. Other:

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Benefit Type:

Pharmacy Benefit:
OTULFI SQ
PYZCHIVA SQ
SELARSDI SQ
STELARA SQ
STEQEYMA SQ
UNBRANDED USTEKINUMAB SQ
USTEKINUMAB-AEKN SQ
WEZLANA SQ
YESINTEK SQ

Medical Benefit:
OTULFI IV
PYZCHIVA IV

SELARSDI IV
STELARA IV
STEQEYMA IV
WEZLANA IV
UNBRANDED USTEKINUMAB IV
YESINTEK IV

Coding:

HCPCS: C9399, J3590, Q5138, Q9997, Q9998, Q9999

Definitions:

Adult: Age 18 years and older.

Crohn's Disease Activity Index:
Sum each factor after adjustment with a weighting factor

Clinical or laboratory variable	Weighting factor	Factor Sum
Number of liquid or soft stools each day for seven days	x 2	
Abdominal pain (graded 0 = none, 1 = mild, 2 = moderate, 3 = severe) each day for 7 days	x 5	
General well-being (assessed from 0 = well, 1 = slightly under par, 2 = poor, 3 = very poor, 4 = terrible) each day for 7 days	x 7	
Presence of complications†	x 20	
Taking Lomotil (diphenoxylate/atropine) or opiates for diarrhea (0 = No, 1 = Yes)	x 30	
Presence of an abdominal mass (0 = none, 2 = questionable, 5 = definite)	x 10	
Hematocrit of < 0.47 in men and < 0.42 in women	x 6	
Percentage deviation from standard weight [1 – (ideal/observed)] x 100	x 1	
† **Complications**: one point each is added for each: • the presence of joint pains (arthralgia) or frank arthritis • inflammation of the iris or uveitis • presence of erythema nodosum, pyoderma gangrenosum, or aphthous ulcers • anal fissures, fistulae or abscesses • other fistulae • fever during the previous week		
Total CDAI		
Remission of CD: CDAI < 150 Severe CD: CDAI > 450 CD response: decrease in CDAI of > 70		

Pediatric Crohn disease activity index (PCDAI):

HISTORY: Recall from previous week		
Abdominal Pain	None	0 points
	Mild – Brief, does not interfere with activities	5 points
	Moderate or severe – Daily, longer lasting, affects activities, nocturnal	10 points

Stools (per day)	0-1 liquid stools, no blood	0 points
	Up to 2 semi-formed stools with small blood, or 2-5 liquid stools without blood	5 points
	Gross bleeding, or ≥6 liquid stools, or nocturnal diarrhea	10 points
Patient functioning, general well-being	No limitations of activities, well	0 points
	Occasional difficulty in maintaining age-appropriate activities, below par	5 points
	Frequent limitation of activity, very poor	10 points
Laboratory		
Hematocrit (%) <10 years	>33	0 points
	28 t32	2.5 points
	<28	5 points
Hematocrit (%) 11-19 years (females)	≥34	0 points
	29 to 33	2.5 points
	<29	5 points
Hematocrit (%) 11-14 years (males)	≥ 35	0 points
	30 to 34	2.5 points
	<30	5 points
Hematocrit (%) 15 to 19 years (male)	≥37	0 points
	32 to 36	2.5 points
	<32	5 points
ESR (mm/hour)	<20	0 points
	20 to 50	2.5 points
	>50	5 points
Albumin (g/dl)	≥3.5	0 points
	3.1 to 3.4	5 points
	≤3	10 points
Examination		
Weight	Weight gain, weight stable, or voluntary weight loss	0 points
	Involuntary weight stable, or weight loss 1 to 9%	5 points
	Weight loss ≥10%	10 points
Height (at diagnosis)	<1 channel decrease*	0 points
	1 to 2 channel decrease	5 points
	≥2 channel decrease	10 points
Height (at follow-up)	High velocity ≥-1 SD	0 points
	High velocity between -1 and -2 SD	5 points
	High velocity ≤-2 SD	10 points
Abdomen	No tenderness, no mass	0 points
	Tenderness, or mass without tenderness	5 points
	Tenderness, involuntary guarding, definite mass	10 points
Perirectal disease	None, asymptomatic tags	0 points
	1 to 2 indolent fistula(e), scant drainage, no tenderness	5 points
	Active fistula, drainage, tenderness, or abscess	10 points
Extraintestinal manifestations (Fever ≥38.5°C for 3 days over past week, definite arthritis, uveitis,	None	0 points
	1	5 points
	≥2	10 points

erythema nodosum, pyoderma gangrenosum)		

The PCDAI is interpreted as follows: a score of 0 to 10 indicates inactive disease, 11 to 30 indicates mild disease activity, and >30 indicates moderate to severe disease activity. A decrease in PCDAI of ≥12.5 points reflects a clinical response (improvement from moderate/severe to mild/inactive disease)
ESR: erythrocyte sedimentation rate; SD: standard deviation.
* A "channel decrease" refers to serial height measurements that deviate across the width of a major curve on a standard height-for-age chart. For example, decreasing from the 40th to 20th percentile is a 1-channel decrease.

Psoriasis Area and Severity Index (PASI):

	Head	Upper Extremities	Trunk	Lower extremities
1. Redness[1]				
2. Thickness[1]				
3. Scale[1]				
4. Sum of rows 1,2 and 3				
5. Area score[2]				
6. Score of row 4 x row 5 x the area multiplier	row 4 x row 5 x 0.1	row 4 x row 5 x 0.2	Row 4 x row 5 x 0.3	Row 4 x row 5 x 0.4
7. Sum row 6 for each column for PASI score				

Steps in generating PASI score:
(a) Divide body into four areas: head, arms, trunk to groin, and legs to top of buttocks.
(b) Generate an average score for the erythema, thickness, and scale for each of the 4 areas (0 = clear; 1–4 = increasing severity)[1].
(c) Sum scores of erythema, thickness, and scale for each area.
(d) Generate a percentage for skin covered with psoriasis for each area and convert that to a 0–6 scale (0 = 0%; 1 = <10%; 2 = 10–<30%; 3 = 30–<50%; 4 = 50–<70%; 5 = 70–<90%; 6 = 90–100%).
(e) Multiply score of item (c) above times item (d) above for each area and multiply that by 0.1, 0.2, 0.3, and 0.4 for head, arms, trunk, and legs, respectively.
(f) Add these scores to get the PASI score.

[1] Erythema, induration and scale are measured on a 0–4 scale (none, slight, mild, moderate, severe)
[2] Area scoring criteria (score: % involvement)
0: 0 (clear)
1: <10%
2: 10–<30%
3: 30–<50%
4: 50–<70%
5: 70–<90%
6: 90–<100%

Feldman, SR and Krueger, GG. Psoriasis assessment tools in clinical trials. Ann Rheum Dis 2005; 64 (Suppl III): ii65-ii68.

Ulcerative Colitis Activity (Adults):

American College of Gastroenterology Ulcerative Colitis Activity Index				
	Remission	Mild	Moderate-severe	Fulminant
Stools (no./d)	Formed	< 4	> 6	> 10
Blood in stools	None	Intermittent	Frequent	Continuous
Urgency	None	Mild, occasional	Often	Continuous
Hemoglobin	Normal	Normal	< 75% of normal	Transfusion needed
ESR	< 30	< 30	> 30	> 30
CRP (mg/L)	Normal	Elevated	Elevated	Elevated
Fecal calprotectin (mg/g)	< 150-200	> 150-200	> 150-200	> 150-200
Endoscopy (Mayo sub-score)	0-1	1	2-3	3

UCEIS	0-1	2-4	5-8	7-8
The above factors are general guides for disease activity. With the exception of remission, a patient does not need to have all the factors to be considered in a specific category. CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; UCEIS, Ulcerative Colitis Endoscopic Index of Severity.				

Endoscopic Assessment of Disease Activity		
Endoscopic Features	UCEIS Score	Mayo Score
Normal	0	0
Erythema, decreased vascular pattern, mild friability	1-3	1
Marked erythema, absent vascular pattern, friability, erosions	4-6	2
Spontaneous bleeding, ulceration	7-8	3

Pediatric ulcerative colitis activity index (PUCAI)

Abdominal pain	No pain	0 points
	Pain can be ignored	5 points
	Pain cannot be ignored	10 points
Rectal Bleeding	None	0 points
	Small amount only, in <50% of stools	10 points
	Small amount with most stools	20 points
	Large amount (>50% of the stool content)	30 points
Stool consistency of most stools	Formed	0 points
	Partially formed	5 points
	Completely unformed	10 points
Number of stools er 24 hours	0 to 2	0 points
	3 to 5	5 points
	6 to 8	10 points
	>8	15 points
Nocturnal stools (any episode causing wakening)	No	0 points
	Yes	10 points
Activity level	No limitation of activity	0 points
	Occasional limitation of activity	5 points
	Severe restricted activity	10 points
Sum (0-85) PUCAI scores are interpreted as follows: 0 to 9 – Remission 10 to 34 – Mild disease 35 to 64 – Moderate disease 65 to 85 – Severe disease		

STELARA AND STELARA BIOSIMILARS					
Proprietary Name	**NDCs Available**	**Classification**	**Prefilled Syringe**	**IV Vial**	**FDA Labeled Indications**
PREFERRED					
STEQEYMA *(ustekinumab-stba)* CELLTRION, Inc.	72606-0029-01 (IV) 72606-0027-01 (45/0.5 PFS, LW) 72606-0028-01 (90/ml PFS, LW)	*351(k)* *Biosimilar*	✓	✓	*CD, UC, Pso, PsA*
WEZLANA™ *(ustekinumab-auub)* Optum Health Solutions Limited	84612-0066-01 (IV) 84612-0055-01(SQ vial, LW) 84612-0076-01 (45/0.5 PFS, LW) 84612-0089-01 (90/ml PFS, LW)	*351(k)* *Interchangeable*	✓	✓	*CD, UC, Pso, PsA*
YESINTEK *(ustekinumab-kfce)* Biocon Biologics	83257-0026-11 (IV) 83257-0024-11 (SQ vial, LW) 83257-0023-41 (45/0.5 PFS, LW) 83257-0025-41 (90/ml PFS, LW)	*351(k)* *Biosimilar*	✓	✓	*CD, UC, Pso, PsA*

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS

NON-PREFERRED					
OTULFI™ *(ustekinumab-aauz)* FRESENIUS KABI USA	65219-0828-05 (IV) 65219-0824-01 (45/0.5 PFS, LW) 65219-0826-26 (90/ml PFS, LW)	*351(k) Biosimilar*	✓	✓	*CD, UC, Pso, PsA*
PYZCHIVA® *(ustekinumab-ttwe)* SANDOZ	61314-0654-94 (IV) 61314-0651-01 (45/0.5 PFS, LW) 61314-0652-01 (90/ml PFS, LW)	*351(k) Biosimilar*	✓	✓	*CD, UC, Pso, PsA*
SELARSDI™ *(ustekinumab-aekn)* TEVA Pharmaceuticals USA	51759-0708-13 (IV) 51759-0505-32 (45/0.5 PFS, LW) 51759-0607-32 (90/ml PFS, LW)	*351(k) Biosimilar*	✓	✓	*CD, UC, Pso, PsA*
STELARA™ *(ustekinumab)* Janssen Biotech	57894-0054-27 (IV) 57894-0060-02 (SQ vial) 57894-0060-03 (45/0.5 PFS) 57894-0061-03 (90/ml PFS)	*351(a) Reference Product*	✓	✓	*CD, UC, Pso, PsA*
UNBRANDED USTEKINUMAB *(ustekinumab)* Janssen Biotech	57894-0444-01 (IV) 57894-0440-03 (SQ vial) 57894-0440-01 (45/0.5 PFS) 57894-0441-01 (90/mL PFS)		✓	✓	*CD, UC, Pso, PsA*
USTEKINUMAB-AEKN *(ustekinumab-aekn)* TEVA Pharmaceuticals USA	51759-0709-32 PFS 51759-0710-32 PFS	*351(k) Biosimilar*	✓	✗	*CD, UC, Pso, PsA*

PFS = Prefilled syringe; LW = Low WAC; HW = High WAC

Resources:

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Yesintek subcutaneous or intravenous injection product information by Biocon Biologics Inc. 11-2024. Available at https://www.accessdata.fda.gov. Accessed January 30, 2025.

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