BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS:
IMULDOSA™ (ustekinumab-srlf) IV & SQ
OTULFI™ (ustekinumab-aauz) IV & SQ
PYZCHIVA® (ustekinumab-ttwe) IV & SQ
SELARSDI™ (ustekinumab-aekn) IV & SQ
STARJEMZA™ (ustekinumab-hmny) IV & SQ
STELARA® (ustekinumab) IV & SQ
STEQEYMA® (ustekinumab-stba) IV & SQ
UNBRANDED USTEKINUMAB (ustekinumab) IV & SQ
USTEKINUMAB-AAUZ (ustekinumab-aauz) 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/or 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.

Medical Necessity Requirements for STELARA (ustekinumab) and STELARA BIOSIMILARS

ORIGINAL EFFECTIVE DATE: 04/01/2019 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 11/20/2025

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS

Section A: Crohn's Disease (CD)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Gastroenterologist or is in consultation with a Gastroenterologist

Indication
- Moderately to severely active Crohn's Disease

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Moderate to severe active Crohn's disease as indicated by **ONE** of the following:
  - Crohn's Disease Activity Index (CDAI) greater than 220 in adults
  - Pediatric Crohn's Disease Activity Index (PCDAI) greater than 30
  - At least **FIVE** of the following signs and symptoms:
    1. Anemia
    2. Chronic intermittent diarrhea
    3. Crampy abdominal pain
    4. Elevated serum C-reactive protein and/or fecal calprotectin
    5. Extraintestinal manifestations (arthritis, eye/skin disorders, biliary tract involvement, kidney stones)
    6. Fatigue
    7. Fistulas
    8. Perianal disease (anal fissures, anorectal abscess)
    9. Weight loss or growth failure in children

Alternative Therapies
- Failure (trial for at least three months), contraindication, intolerance, or is not a candidate for **ONE or MORE** of the following:
  - 6-mercaptopurine
  - Azathioprine
  - Methotrexate
  - Oral corticosteroids
- **For Imuldosa (IV & SQ) and Yesintek (IV & SQ):** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)
- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)

- Ustekinumab aauz (SQ) (**preferred**)
- Imuldosa (IV & SQ)
- Yesintek (IV & SQ)

Safety

- Does **NOT** have **ANY** of the following:
  - Active serious infections (opportunistic, fungal, tuberculosis, localized infections, sepsis, Hepatitis B or C)
    1. Serologic tests for Hepatitis B and C within previous 12 months
    2. Screening for latent tuberculosis completed; if positive, treatment initiated
  - Concurrent use of live vaccines
- No FDA label contraindications
- No concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, JAK inhibitors such as Cibinqo, Olumiant, Opzelura, Rinvoq, Xeljanz)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (Hepatitis B/C serology, TB screening)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Gastroenterologist or is in consultation with a Gastroenterologist

Clinical Response

- Positive clinical response documented:
  - First renewal request: **ONE** of the following:
    1. At least 20 percent improvement in Crohn's disease signs and symptoms
    2. CDAI decrease greater than 70 from baseline or CDAI less than 150 (remission)
    3. PCDAI less than or equal to 30 in children (mild disease or remission)
  - Subsequent renewals:
    1. Evidence of disease stability or improvement with no progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Alternative Therapies

- **For Imuldosa (IV & SQ) and Yesintek (IV & SQ):** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:

  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)
- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)
  - Ustekinumab aauz (SQ) (**preferred**)
  - Imuldosa (IV & SQ)
  - Yesintek (IV & SQ)

Safety
- No new contraindications or significant adverse effects
- Does **NOT** have **ANY** of the following:
  - Active serious infections
  - Concurrent use of live vaccines
- No concomitant use with biologic immunomodulators or other potent immunosuppressants

Documentation Requirements
- Chart notes
- Evidence of improvement or stability
- Lab results confirming safe use

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Section B: Plaque Psoriasis (Ps also as PsO)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Dermatologist or is in consultation with a Dermatologist

Indication
- Moderate to severe plaque psoriasis

Age Requirement
- 6 years or older

Baseline Clinical Evaluation
- **ALL** of the following:
  - Candidate for photochemotherapy or phototherapy
  - Plaque psoriasis involves greater than or equal to 10 percent body surface area (BSA) OR less than 10 percent BSA but includes sensitive areas or areas that significantly impact daily function (palms, soles, head/neck, genitalia)
  - Psoriasis Area and Severity Index (PASI) of at least 10

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS

Alternative Therapies

- Documented failure (trial for at least three months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - A trial of at least **TWO** topical agents (anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)
  - A trial of **ONE** immunosuppressive treatment (cyclosporine, methotrexate)
  - A trial of Ultraviolet Light therapy (photochemotherapy [psoralen plus UVA], phototherapy [UV light therapy], or excimer laser)
- **For Imuldosa (IV & SQ) and Yesintek (IV & SQ):** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)
- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)
  - Ustekinumab aauz (SQ) (**preferred**)
  - Imuldosa (IV & SQ)
  - Yesintek (IV & SQ)

Safety

- Does **NOT** have **ANY** of the following:
  - Active serious infections (opportunistic, fungal, tuberculosis, localized infections, sepsis, Hepatitis B or C)
    1. Serologic tests for Hepatitis B and C within previous 12 months
    2. Screening for latent tuberculosis completed; if positive, treatment initiated
  - Concurrent use of live vaccines
- No FDA-label contraindications
- No concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, JAK inhibitors such as Cibinqo, Olumiant, Opzelura, Rinvoq, Xeljanz)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (Hepatitis B/C serology, TB screening)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Dermatologist or is in consultation with a Dermatologist

Clinical Response
- Positive clinical response documented:
  - First renewal request: At least 20 percent improvement in PASI
  - Subsequent renewals: Evidence of disease stability or improvement with no progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Alternative Therapies
- **For Imuldosa and Yesintek:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)
- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)
  - Ustekinumab aauz (SQ) (**preferred**)
  - Imuldosa (IV & SQ)
  - Yesintek (IV & SQ)

Safety
- No new contraindications or significant adverse effects
- Does **NOT** have **ANY** of the following:
  - Active serious infections
  - Concurrent use of live vaccines
- No concomitant use with biologic immunomodulators or other potent immunosuppressants

Documentation Requirements
- Chart notes
- Evidence of improvement or stability
- Lab results confirming safe use

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Section C: Psoriatic Arthritis (PsA)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Dermatologist or Rheumatologist or is in consultation with a Dermatologist or Rheumatologist

Indication

- Moderate to severe active psoriatic arthritis

Age Requirement

- 6 years or older

Baseline Clinical Evaluation

- Psoriatic arthritis is identified by **ONE or more** of the following:
  - Predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by **ALL** of the following:
    1. Radiographic evidence of axial disease (e.g., sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
    2. Symptoms (e.g., limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months' duration
    3. 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
  - Predominantly non axial disease, and failure (used for greater than or equal to 3 consecutive months), intolerance, or contraindication per FDA label to methotrexate or NSAIDs

Alternative Therapies

- **For Imuldosa (IV & SQ) and Yesintek (IV & SQ):** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)
- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)
  - Ustekinumab aauz (SQ) (**preferred**)
  - Imuldosa (IV & SQ)
  - Yesintek (IV & SQ)

Safety

- Does **NOT** have **ANY** of the following:
  - Active serious infections (opportunistic, fungal, tuberculosis, localized infections, sepsis, Hepatitis B or C)
    1. Serologic tests for Hepatitis B and C within previous 12 months
    2. Screening for latent tuberculosis completed; if positive, treatment initiated
  - Concurrent use of live vaccines
- No FDA-label contraindications
- No concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, JAK inhibitors such as Cibinqo, Olumiant, Opzelura, Rinvoq, Xeljanz)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (Hepatitis B/C serology, TB screening)
  - Supporting clinical documentation

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification
- Continues to be seen by a Dermatologist or Rheumatologist or in consultation with a Dermatologist or Rheumatologist

Clinical Response
- Positive clinical response documented:
  - First renewal request: At least 20 percent improvement in **ANY** of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID 3, SDAI in PASI
  - Subsequent renewals: Evidence of disease stability or improvement with no progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Alternative Therapies
- **For Imuldosa and Yesintek:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)
- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)
  - Ustekinumab aauz (SQ) (**preferred**)
  - Imuldosa (IV & SQ)
  - Yesintek (IV & SQ)

Safety
- No new contraindications or significant adverse effects
- Does NOT have **ANY** of the following:
  - Active serious infections
  - Concurrent use of live vaccines
- No concomitant use with biologic immunomodulators or other potent immunosuppressants

Documentation Requirements
- Chart notes
- Evidence of improvement or stability
- Lab results confirming safe use

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

ORIGINAL EFFECTIVE DATE: 04/01/2019 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 11/20/2025

Section D: Ulcerative Colitis (UC)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Gastroenterologist or is in consultation with a Gastroenterologist

Indication

- Moderately to severely active ulcerative colitis

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- Moderate to severe active ulcerative colitis as indicated by **ONE** of the following:
  - American College of Gastroenterology Ulcerative Colitis activity index rating of moderate to severe disease in adults
  - Pediatric ulcerative colitis activity index (PUCAI) greater than or equal to 35
  - At least **FIVE** of the following signs and symptoms:
    1. Anemia
    2. Bloody diarrhea or visible blood in stool
    3. Bowel movements 4 to 6 or more times per day
    4. Colicky abdominal pain
    5. Elevated fecal calprotectin
    6. Elevated serum C-reactive protein or erythrocyte sedimentation rate
    7. Fatigue
    8. Fever
    9. Tenesmus
    10. Urgency
    11. Weight loss or delayed growth in children

Alternative Therapies

- Failure (trial for at least three months), contraindication, intolerance, or is not a candidate for **ONE** or **MORE** of the following:
  - 6 mercaptopurine
  - Azathioprine
  - Oral corticosteroids
  - Salicylates (mesalamine, sulfasalazine, balsalazide, olsalazine)
- **For Imuldosa (IV & SQ) and Yesintek (IV & SQ):** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)

- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)
  - Ustekinumab aauz (SQ) (**preferred**)
  - Imuldosa (IV & SQ)
  - Yesintek (IV & SQ)

Safety

- Does **NOT have ANY** of the following:
  - Active serious infections (opportunistic, fungal, tuberculosis, localized infections, sepsis, Hepatitis B or C)
    1. Serologic tests for Hepatitis B and C within previous 12 months
    2. Screening for latent tuberculosis completed; if positive, treatment initiated
  - Concurrent use of live vaccines
- No FDA-label contraindications
- No concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, JAK inhibitors such as Cibinqo, Olumiant, Opzelura, Rinvoq, Xeljanz)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (Hepatitis B/C serology, TB screening)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Gastroenterologist or is in consultation with a Gastroenterologist

Clinical Response

- Positive clinical response documented:
  - First renewal request: **ONE** of the following:
    1. At least 20 percent improvement in signs and symptoms of ulcerative colitis
    2. American College of Gastroenterology Ulcerative Colitis activity index rating of mild disease or remission in adults
    3. PUCAI less than or equal to 34 in children (mild disease or remission)
  - Subsequent renewals: Evidence of disease stability or improvement with no progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Alternative Therapies

- **For Imuldosa and Yesintek:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Starjemza (IV & SQ)
  - Ustekinumab aauz (SQ)
- **For Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Unbranded Ustekinumab, Ustekinumab aekn, Wezlana:** Failure (greater than or equal to six months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
  - Starjemza (IV & SQ) (**preferred**)
  - Ustekinumab aauz (SQ) (**preferred**)
  - Imuldosa (IV & SQ)
  - Yesintek (IV & SQ)

Safety

- No new contraindications or significant adverse effects
- Does **NOT have ANY** of the following:
  - Active serious infections
  - Concurrent use of live vaccines
- No concomitant use with biologic immunomodulators or other potent immunosuppressants

Documentation Requirements

- Chart notes
- Evidence of improvement or stability
- Lab results confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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

PHARMACY COVERAGE GUIDELINE

STELARA AND STELARA BIOSIMILARS

Criteria for Off-Label Use Requests:

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:
IMULDOSA SQ
OTULFI SQ
PYZCHIVA SQ
SELARSDI SQ
STARJEMZA SQ
STELARA SQ
STEQEYMA SQ
UNBRANDED USTEKINUMAB SQ
USTEKINUMAB-AEKN SQ
USTEKINUMAB-AAUZ SQ
WEZLANA SQ
YESINTEK SQ

Medical Benefit:
IMULDOSA IV
OTULFI IV
PYZCHIVA IV
SELARSDI IV
STARJEMZA IV
STELARA IV
STEQEYMA IV
UNBRANDED USTEKINUMAB IV
WEZLANA IV
YESINTEK IV

Coding:

HCPCS: C9399, J3358, J3590, Q5099, Q5100, Q5138, Q9996, 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, erythema nodosum, pyoderma gangrenosum)	None	0 points
	1	5 points
	≥2	10 points

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**
1st LINE PREFERRED					
STARJEMZA™ *(ustekinumab-hmny)* HIKMA PHARMACEUTICALS USA	00143-9171-01 (IV) 00143-9169-01 (45/0.5 SQ vial, LW) 00143-9168-01 (45/0.5 PFS, LW) 00143-9170-01 (90/ml PFS, LW)	*351(k) Interchangeable*	✓	✓	*CD, UC, Pso, PsA*
USTEKINUMAB-AAUZ *(ustekinumab-aauz)* FRESENIUS KABI USA	65219-0862-01 (45/0.5 PFS) 65219-0866-26 (90/1ml PFS)	*351(k) Interchangeable*	✓	✕	*CD, UC, Pso, PsA*
2nd LINE PREFERRED					
IMULDOSA™ *(ustekinumab-srlf)* ACCORD BIOPHARMA	69448-0019-26 (IV) 69448-0017-63 (45/0.5 PFS, LW) 69448-0018-63 (90/ml PFS, LW)	*351(k) Biosimilar*	✓	✓	*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) Interchangeable*	✓	✓	*CD, UC, Pso, PsA*
NON-PREFERRED					
OTULFI™ *(ustekinumab-aauz)* FRESENIUS KABI USA	65219-0828-05 (IV) 65219-0822-05 (45/0.5 SQ vial, LW) 65219-0824-01 (45/0.5 PFS, LW) 65219-0826-26 (90/ml PFS, LW)	*351(k) Interchangeable*	✓	✓	*CD, UC, Pso, PsA*
PYZCHIVA® *(ustekinumab-ttwe)* SANDOZ	61314-0654-94 (IV) 61314-0651-94 (SQ vial) 61314-0651-01 (45/0.5 PFS, LW) 61314-0652-01 (90/ml PFS, LW)	*351(k) Interchangeable*	✓	✓	*CD, UC, Pso, PsA*
SELARSDI™ *(ustekinumab-aekn)* TEVA Pharmaceuticals USA	51759-0708-13 (IV) 51759-0505-13 (45/0.5 SQ vial, LW) 51759-0505-32 (45/0.5 PFS, LW) 51759-0607-32 (90/ml PFS, LW)	*351(k) Interchangeable*	✓	✓	*CD, UC, Pso, PsA*
STELARA™ *(ustekinumab)* Janssen Biotech	57894-0054-27 (IV) 57894-0060-02 (SQ vial) 57894-0060-03 (45/0.5 PFS)	*351(a) Reference Product*	✓	✓	*CD, UC, Pso, PsA*

	57894-0061-03 (90/ml PFS)				
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) Interchangeable*	✓	✓	*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 (45/0.5 PFS) 51759-0710-32 (90/ml PFS)	*351(k) Interchangeable*	✓	✕	*CD, UC, Pso, PsA*
WEZLANA™ *(ustekinumab-auub)* NUVAILA 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*

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

Resources:

Imuldosa (ustekinumab-srlf) subcutaneous or intravenous injection product information, revised by Accord BioPharma Inc. 10-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Otulfi (ustekinumab-aauz) subcutaneous or intravenous injection product information, revised by Fresenius Kabi USA, LLC. 05-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Pyzchiva (ustekinumab-ttwe) subcutaneous or intravenous injection product information, revised by Sandoz, Inc. 06-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Selarsdi (ustekinumab-aekn) subcutaneous or intravenous injection product information, revised by Teva Pharmaceuticals USA, Inc. 02-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Starjemza (ustekinumab-hmny) subcutaneous or intravenous injection product information, revised by Hikma Pharmaceuticals USA, Inc. 05-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Stelara (ustekinumab) subcutaneous or intravenous injection product information, revised by Janssen Biotech, Inc. 06-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Steqeyma (ustekinumab-stba) subcutaneous or intravenous injection product information, revised by Celltrion USA, Inc. 02-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Wezlana (ustekinumab-auub) subcutaneous or intravenous injection product information, revised by Amgen, Inc. 03-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 10, 2025.

Yesintek (ustekinumab) subcutaneous or intravenous injection product information, revised by Biocon Biologics Inc. 11-2024. Available at https://www.accessdata.fda.gov. Accessed November 10, 2025.

Ustekinumab subcutaneous or intravenous injection product information, revised by Janssen Biotech, Inc. 04-2025. Available at https://www.accessdata.fda.gov. Accessed November 10, 2025.

Ustekinumab-aauz subcutaneous or intravenous injection product information, revised by Fresenius Kabi USA, LLC. 08-2025. Available at https://www.accessdata.fda.gov. Accessed February 02, 2026.

Ustekinumab-aekn subcutaneous or intravenous injection product information, revised by Teva Pharmaceuticals, Inc. 02-2025. Available at https://www.accessdata.fda.gov. Accessed November 10, 2025.

Reguerio M, Al Hashash J. Overview of the medical management of mild (low risk) Crohn disease in adults. In: UpToDate, Kane SV, Robson KM (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated July 28, 2025. Accessed February 02, 2026.

Al Hashash J, Reguerio M. Medical management of moderate to severe Crohn disease in adults. In: UpToDate, Kane SV, Robson KM (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated October 31, 2025. Accessed February 02, 2026.

Feldman SR, Bhutani T. Chronic plaque psoriasis in adults: Overview of management. In: UpToDate, Dellavalle RP, Merola JF, Givens J, Ofori, AO (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated July 08, 2024. Accessed February 02, 2026.

Feldman SR, Lewitt GM. Chronic plaque psoriasis in adults: Treatment of disease amenable to topical therapy. In: UpToDate, Dellavalle RP, Merola JF, Givens J, Ofori, AO (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated June 16, 2025. Accessed February 02, 2026.

Feldman SR, Soung J. Chronic plaque psoriasis in adults: Treatment of disease requiring phototherapy or systemic therapy. In: UpToDate, Dellavalle RP, Merola JF, Ofori AO, Givens J (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated January 16, 2026. Accessed February 02, 2026.

Orbai AM, Scher JU. Treatment of psoriatic arthritis. In UpToDate, Sieper J, Seo P (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated January 29, 2026. Accessed February 02, 2026.

Al Hashash J, Reguerio M. Medical management of low-risk adult patients with mild to moderate ulcerative colitis. In: UpToDate, Kane SV, Meyer C (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated January 30, 2026. Accessed February 02, 2026.

Cohen RD, Stein AC. Management of moderate to severe ulcerative colitis in adults. In: UpToDate, Kane SV, Meyer C (Eds), UpToDate, Waltham, MA.: UpToDate Inc. Available at http://uptodate.com. Literature review through January 2026. Topic last updated April 04, 2025. Accessed February 02, 2026.