

Ustekinumab:

**Imuldosa®; Otulfi™; Pyzchiva®; Selarsdi™; Starjemza™;
 Stelara®; Steqeyma®; Ustekinumab§; Ustekinumab-aauz§;
 Ustekinumab-aekn§; Ustekinumab-auub§; Ustekinumab-
 stba§; Ustekinumab-ttwe§; Wezlana™; Yesintek™
 (Intravenous/Subcutaneous)**

Document Number: M-0117

Last Review Date: 05/05/2026**Date of Origin: 02/15/2011**

Dates Reviewed: 03/2011, 06/2011, 09/2011, 12/2011, 03/2012, 06/2012, 09/2012, 03/2013, 06/2013, 09/2013, 11/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 06/2015, 09/2015, 12/2015, 03/2016, 06/2016, 9/2016, 10/2016, 11/2016, 03/2017, 06/2017, 09/2017, 10/2017, 03/2018, 06/2018, 10/2018, 10/2019, 12/2019, 07/2020, 08/2020, 10/2021, 04/2022, 06/2022, 09/2022, 08/2023, 10/2023, 12/2023, 06/2024, 08/2024, 10/2024, 11/2024, 01/2025, 02/2025, 03/2025, 04/2025, 05/2025, 07/2025, 08/2025, 09/2025, 11/2025, 03/2026, 05/2026

I. Length of Authorization ^{1-9,44-52}

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
 - Crohn's Disease and Ulcerative Colitis: Prior authorization validity will be provided initially for 8 weeks.
 - Immune Checkpoint Inhibitor-Related Toxicities: Prior authorization validity will be provided initially for a one-time intravenous induction dose plus up to 3 subcutaneous maintenance doses.
 - Supportive therapy in combination with marnetegrane autotemcel (Kresladi™): Prior authorization validity will be provided initially for up to 3 total doses
- Renewal: Prior authorization validity may be renewed for 12 months (365 days) thereafter, unless otherwise specified.
 - Dose escalation requests for Crohn's Disease and Ulcerative Colitis: Prior authorization validity will be provided for 3 months (90 days) with continued renewal every 12 months (365 days) thereafter (*See Section V for continuation details*).
 - Immune Checkpoint Inhibitor-Related Toxicities: Prior authorization validity may not be renewed.
 - Supportive therapy in combination with marnetegrane autotemcel (Kresladi™): Prior authorization validity may not be renewed §

§ Note: *Retreatment with marnetegrane autotemcel is considered investigational. While limited retreatment was reported for a single patient in the pivotal clinical study, the available evidence is insufficient to establish the safety and effectiveness of repeat administration. Requests for retreatment*

will therefore be reviewed on a case-by-case basis, taking into account the totality of clinical circumstances and supporting documentation.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Indication	Max Units
Plaque Psoriasis & Psoriatic Arthritis with co-existent moderate-severe Plaque Psoriasis	<u>Subcutaneous Loading:</u> 90 billable units (90 mg) at weeks 0 & 4; maintenance dosing 12 weeks later <u>Subcutaneous Maintenance:</u> 90 billable units (90 mg) every 12 weeks
Psoriatic Arthritis	<u>Subcutaneous Loading:</u> 45 billable units (45mg) at weeks 0 & 4; maintenance dosing 12 weeks later <u>Subcutaneous Maintenance:</u> 45 billable units (45 mg) every 12 weeks
Crohn's Disease & Ulcerative Colitis	<u>Intravenous Induction:</u> 520 billable units (520 mg) x 1 dose <u>Subcutaneous Maintenance:</u> 90 billable units (90 mg) 8 weeks after induction & every 8 weeks thereafter
Immune Checkpoint Inhibitor-Related Toxicities	<u>Intravenous Induction:</u> 520 billable units (520 mg) x 1 dose <u>Subcutaneous Maintenance:</u> 90 billable units (90 mg) 8 weeks after induction & every 8 weeks thereafter x 3 doses
Supportive therapy in combination with marnetegrane autotemcel (Kresladi™)	<u>Subcutaneous:</u> 90 billable units (90 mg) for a total of 3 doses

III. Initial Approval Criteria ¹⁻⁹

For groups in scope for the Site of Care (SOC) specialty infusion program, all program requirements are met.

Self-administered injectable medications are not covered when supplied in a provider's office, clinic or facility.

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**

- Provider will confirm that member is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria

For Commercial Members Only

Selarsdi (ustekinumab-aekn), **Yesintek** (ustekinumab-kfce), AND **Steqeyma** (ustekinumab-stba) are the preferred ustekinumab products.

- If the request is for any other ustekinumab biosimilar, patients must have failed, or have a contraindication or intolerance to Selarsdi (ustekinumab-aekn), Yesintek (ustekinumab-kfce), AND Steqeyma (ustekinumab-stba).
- If the request is for Stelara, patient must try and have an inadequate response, contraindication, or intolerance to ALL ustekinumab biosimilar products; **AND**

For Medicaid Members Only

- **For EOCCO:**

- **Selarsdi** (ustekinumab-aekn), **Yesintek** (ustekinumab-kfce), AND **Steqeyma** (ustekinumab-stba) are the preferred ustekinumab products.

- If the request is for any other ustekinumab biosimilar, patients must have failed, or have a contraindication or intolerance to Selarsdi (ustekinumab-aekn), Yesintek (ustekinumab-kfce), AND Steqeyma (ustekinumab-stba).
 - If the request is for Stelara, patients must try and have an inadequate response, contraindication, or intolerance to ALL ustekinumab biosimilar products; AND

- **For OHSU Health Services:**

- **Yesintek** (ustekinumab-kfce) and **Steqeyma** (ustekinumab-stba) are the preferred ustekinumab products;

- If the request is for Stelara or any other ustekinumab biosimilar, patients must have failed, or have a contraindication or intolerance to Yesintek (ustekinumab-kfce) AND Steqeyma (ustekinumab-stba); **AND**

- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Provider will confirm member will not receive live vaccines during therapy; **AND**

- Member is not on concurrent treatment with another biologic therapy or targeted synthetic therapy; **AND**

Plaque Psoriasis (PsO) † ^{1-9,38,53-57}

- Member is at least 6 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
 - Involvement of at least 10% of body surface area (BSA); **OR**
 - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
 - Incapacitation or serious emotional consequences due to plaque location (e.g., hands, feet, head and neck, genitalia, etc.) or with intractable pruritis; **AND**
- Member meets ALL of the following ¶:
 - Member did not respond adequately (or is not a candidate) to a 4-week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, roflumilast, retinoic acid derivatives, and/or vitamin D analogues) §; **AND**
 - Member did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least ONE non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate) §; **AND**
 - Member did not respond adequately (or is not a candidate***) to a 3-month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol) §

§ NOTE: Does not apply to OHSU Medicaid Members (i.e., OHSU Health Services)

For Medicaid Members Only

- **For OHSU Health Services:**

- Documented inadequate response to TWO separate 3-month trials with the following oral agents: methotrexate, cyclosporine, acitretin, or phototherapy OR all are contraindicated or not tolerated ¶; **AND**
 - Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following:
 - adalimumab-fkjp, Hadlima, or infliximab; **OR**
- Patient is continuing treatment

¶ *Note: For members already established on biologic therapy, targeted synthetic therapy, or those with > 10% BSA involvement, trial and failure of topical agents, non-biologic systemic agents, and phototherapy is not required.*

Adult Psoriatic Arthritis (PsA) † ^{1-9,17,58,68}

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
 - For members with predominantly axial disease OR enthesitis, a failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory drug (NSAID), unless use is contraindicated §; **OR**
 - For members with peripheral arthritis OR dactylitis, a failure of at least a 3-month trial of ONE conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, sulfasalazine, leflunomide, hydroxychloroquine, etc.) §; **OR**
 - Member is already established on biologic or targeted synthetic therapy for the treatment of PsA §

§ **NOTE:** Does not apply to OHSU Medicaid Members (i.e., OHSU Health Services)

For Medicaid Members Only

For OHSU Health Services:

For Axial or Severe Enthesitis PsA

- Documented inadequate response to TWO separate 1 month trials with oral prescription strength nonsteroidal anti-inflammatory drugs (NSAIDs) OR a prescription strength oral NSAID and parenteral glucocorticoid injection; **AND**

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following:
 - adalimumab-fkjp or Hadlima; **OR**
 - Patient is continuing treatment
- Not Axial or Enthesitis PsA
- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab-fkjp or Hadlima; **AND**
 - Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of methotrexate; **OR**
 - Documented inadequate response to ONE separate 3-month trial with the following oral agents: leflunomide or sulfasalazine OR all are contraindicated or not tolerated; **OR**
 - Patient is continuing treatment

Juvenile Psoriatic Arthritis (JPsA) † 1-9,59,60

- Member is at least 6 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active polyarticular disease; **AND**
- May be used as a single agent or in combination with methotrexate; **AND**
 - Member has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) (e.g., methotrexate, leflunomide, sulfasalazine, etc.) §; **OR**
 - Member is already established on biologic or targeted synthetic therapy for the treatment of JPsA §

§ NOTE: Does not apply to OHSU Medicaid Members (i.e., OHSU Health Services)

For Medicaid Members Only

For OHSU Health Services:

For Axial or Severe Enthesitis PsA

- Documented inadequate response to TWO separate 1 month trials with oral prescription strength nonsteroidal anti-inflammatory drugs (NSAIDs) OR a prescription strength oral NSAID and parenteral glucocorticoid injection; **AND**
 - Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following:
 - adalimumab-fkjp or Hadlima; **OR**
- Patient is continuing treatment

Not Axial or Enthesitis PsA

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab-fkjp or Hadlima; **AND**
 - Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of methotrexate; **OR**
 - Documented inadequate response to ONE separate 3-month trial with the following oral agents: leflunomide or sulfasalazine OR all are contraindicated or not tolerated; **OR**

Patient is continuing treatment

Adult Crohn's Disease (CD) † 1-9,26,32,70,73,77,78

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month* trial of corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, or methotrexate) §; **OR**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier (e.g., adalimumab, certolizumab, or infliximab) § ; **OR**
 - Member has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary §; **OR**
 - Member is already established on biologic or targeted synthetic therapy for the treatment of CD §

**Three months of corticosteroids are not required if early non-response is confirmed.*

§ NOTE: Does not apply to OHSU Medicaid Members (i.e., OHSU Health Services)

For Medicaid Members Only

For OHSU Health Services:

- Documented inadequate response to TWO separate 3-month trials with the following oral agents: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate, mesalamine OR all are contraindicated or not tolerated; **AND**
 - Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following:
 - adalimumab-fkjp, Hadlima, or infliximab; **OR**
- Patient is continuing treatment

Pediatric Crohn's Disease (CD) †^{1,80}

- Member is at least 2 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month* trial of corticosteroids or immunomodulators (e.g., azathioprine, etc.) §; **OR**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier (e.g., adalimumab or infliximab) §; **OR**
 - Member has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary §; **OR**
 - Member is already established on biologic or targeted synthetic therapy for the treatment of CD §

**Three months of steroids are not required if early non-response is confirmed.*

§ NOTE: Does not apply to OHSU Medicaid Members (i.e., OHSU Health Services)

For Medicaid Members Only

For OHSU Health Services:

- Documented inadequate response to TWO separate 3-month trials with the following oral agents: 6-mercaptopurine, azathioprine, corticosteroid, methotrexate, mesalamine OR all are contraindicated or not tolerated; **AND**
 - For members 6 years of age and older: member must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of TWO of the following:
 - adalimumab-fkjp, Hadlima, or infliximab; **OR**
- Patient is continuing treatment

Ulcerative Colitis (UC) † 1-9,27,65,74,76,79

- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Documented moderate to severe active disease; **AND**
 - Documented failure or ineffective response to a minimum 3-month* trial of conventional therapy [aminosalicylates, corticosteroids or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate, etc.) at maximum tolerated doses, unless there is a contraindication or intolerance to use §; **OR**
 - Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier (e.g., adalimumab, golimumab, or infliximab) §; **OR**
 - Member is already established on a biologic or targeted synthetic therapy for the treatment of UC §

**Three months of corticosteroids are not required if early non-response is confirmed.*

§ NOTE: Does not apply to OHSU Medicaid Members (i.e., OHSU Health Services)

For Medicaid Members Only

For OHSU Health Services:

- Documented inadequate response to TWO separate 3-month trials with the following oral agents: 6-mercaptopurine, azathioprine, corticosteroid, or aminosalicylates (sulfasalazine, mesalamine, balsalazide) OR all are contraindicated or not tolerated; **AND**
 - Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following:
 - adalimumab-fkjp or Hadlima; **OR**

- Patient is continuing treatment

Management of Immune Checkpoint Inhibitor-Related Toxicities ‡^{43,44}

- Member has been receiving therapy with an immune checkpoint inhibitor; **AND**
 - Member has diarrhea or colitis that is refractory to infliximab and/or vedolizumab; **AND**
 - Member has mild (G1) diarrhea or colitis with persistent or progressive symptoms and is lactoferrin/calprotectin positive; **OR**
 - Member has moderate (G2) to severe (G3-4) diarrhea or colitis

Supportive therapy in combination with marnetegrane autotemcel (Kresladi™)^{81,82}

- Member is scheduled to receive treatment with marnetegrane autotemcel for severe Leukocyte Adhesion Deficiency-I (LAD-I); **AND**
- Therapy is being used to prevent the member from having hyperinflammatory bone marrow microenvironment

***Examples of contraindications to phototherapy (PUVA or UVB) include the following: 39,40,57

- Xeroderma pigmentosum
- Other rare photosensitive genodermatoses (e.g., trichothiodystrophy, Cockayne syndrome, Bloom syndrome, Rothmund-Thomson syndrome) (*UVB only*)
- Genetic disorders associated with increased risk of skin cancer (e.g., Gorlin syndrome, oculocutaneous albinism) (*UVB only*)
- Pregnancy or lactation (*PUVA only*)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (*PUVA only*), or treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant member (*UVB only*)
- Photosensitizing medications (*PUVA only*)
- Severe liver, renal, or cardiac disease (*PUVA only*)
- Young age < 12 years old (*PUVA only*)
- Anatomical location has been deemed ineligible for phototherapy (i.e., face, genital, scalp, or nail)

Note: Members who do not have access to phototherapy will be reviewed on a case-by-case basis

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria¹⁻⁹

Prior authorization validity may be renewed based upon the following criteria:

For Commercial Members Only

Selarsdi (ustekinumab-aekn), **Yesintek** (ustekinumab-kfce), AND **Steqeyma** (ustekinumab-stba) are the preferred ustekinumab products.

- If the request is for any other ustekinumab biosimilar, patients must have failed, or have a contraindication or intolerance to Selarsdi (ustekinumab-aekn), Yesintek (ustekinumab-kfce), AND Steqeyma (ustekinumab-stba).
- If the request is for Stelara, patient must try and have an inadequate response, contraindication, or intolerance to ALL ustekinumab biosimilar products; **AND**

For Medicaid Members Only

- **For EOCCO:**

- **Selarsdi** (ustekinumab-aekn), **Yesintek** (ustekinumab-kfce), AND **Steqeyma** (ustekinumab-stba) are the preferred ustekinumab products.

- If the request is for any other ustekinumab biosimilar, patients must have failed, or have a contraindication or intolerance to Selarsdi (ustekinumab-aekn), Yesintek (ustekinumab-kfce), AND Steqeyma (ustekinumab-stba).
- If the request is for Stelara, patients must try and have an inadequate response, contraindication, or intolerance to ALL ustekinumab biosimilar products; **AND**

- **For OHSU Health Services:**

- **Yesintek** (ustekinumab-kfce) and **Steqeyma** (ustekinumab-stba) are the preferred ustekinumab products

- If the request is for Stelara or any other ustekinumab biosimilar, patients must have failed, or have a contraindication or intolerance to Yesintek (ustekinumab-kfce) and Steqeyma (ustekinumab-stba); **AND**

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, malignancy, severe hypersensitivity reactions, posterior reversible encephalopathy syndrome (PRES) or reversible posterior leukoencephalopathy syndrome (RPLS), non-infectious pneumonia, etc.; **AND**

Plaque Psoriasis (PsO) ^{53,57,61,66,67}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total

BSA involvement $\leq 1\%$), and/or an improvement on a disease activity scoring tool [e.g., Psoriasis Area and Severity Index (PASI) score ≤ 3 , physician's global assessment (PGA) score ≤ 1 , etc.].

Adult Psoriatic Arthritis (PsA) ^{23,62,69}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, improvement on imaging (X-ray, ultrasound, or MRI), and/or an improvement on a disease activity scoring tool.

Juvenile Psoriatic Arthritis (JPsA) ^{63,64,69}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, improvement on imaging (X-ray, ultrasound, or MRI), and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

Adult Crohn's Disease (CD) ^{42,71,72}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight regain, hematocrit, presence of extra-intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, improvement in biomarker levels [i.e., fecal calprotectin or serum C-reactive protein (CRP)], and/or an improvement on a disease activity scoring tool (e.g., Harvey-Bradshaw Index score, etc.).

Pediatric Crohn's Disease (CD) ^{42,65,71,72}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight regain, hematocrit, presence of extra-intestinal complications, tapering or discontinuation of corticosteroid therapy, use of anti-diarrheal drugs, improvement in biomarker levels [i.e., fecal calprotectin or serum C-reactive protein (CRP)], and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Harvey-Bradshaw Index score].

Ulcerative Colitis (UC) ^{27-31,75}

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, endoscopic activity, tapering or discontinuation of corticosteroid therapy, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), and/or an improvement on a disease activity scoring tool.

V. Dosage/Administration ^{1-9,43-52}

Indication	Dose
Plaque Psoriasis	<u>Adult Subcutaneous Loading Dose:</u> • ≤100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later
	<u>Adult Subcutaneous Maintenance Dose:</u> • ≤100 kg: 45 mg every 12 weeks • >100 kg: 90 mg every 12 weeks
	<u>Pediatric Subcutaneous Loading Dose:</u> • <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later (NOTE: This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana/Ustekinumab-auub, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek) • 60 – 100 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <u>Pediatric Subcutaneous Maintenance Dose:</u> • <60 kg: 0.75 mg/kg every 12 weeks (NOTE: This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana/Ustekinumab-auub, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek) • 60 – 100 kg: 45 mg every 12 weeks • >100 kg: 90 mg every 12 weeks
Psoriatic Arthritis	<u>Adult Subcutaneous Loading Dose:</u> • 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later
	<u>Adult Subcutaneous Maintenance Dose:</u> • 45 mg every 12 weeks • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg every 12 weeks
	<u>Pediatric Subcutaneous Loading Dose:</u> • <60 kg: 0.75 mg/kg at weeks 0 & 4, then begin maintenance dosing 12 weeks later (NOTE: This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana/Ustekinumab-auub, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek)

	• ≥60 kg: 45 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg at weeks 0 & 4, then begin maintenance dosing 12 weeks later <u>Pediatric Subcutaneous Maintenance Dose:</u> • <60 kg: 0.75 mg/kg every 12 weeks (NOTE: This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana/Ustekinumab-auub, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek) • ≥60 kg: 45 mg every 12 weeks • Co-existing moderate to severe plaque psoriasis AND weighing >100 kg: 90 mg every 12 weeks
Crohn's Disease	<u>Adult Intravenous Induction Dose (one-time only):</u> • ≤ 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg <u>Adult Subcutaneous Maintenance Dose:</u> • 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter
	<u>Pediatric Intravenous Induction Dose (one-time only):</u> • 10 kg to 25 kg: 10 mg/kg • > 25 kg to 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • >85 kg: 520 mg <u>Pediatric Subcutaneous Maintenance Dose:</u> • 10 kg to 35 kg: 2.5 mg/kg given 8 weeks after the initial IV dose, then every 8 weeks thereafter (NOTE: This dosing ONLY applies to Pyzchiva, Stelara/Ustekinumab, Wezlana/Ustekinumab-auub, Selarsdi/Ustekinumab-aekn, Otulfi/Ustekinumab-aauz, Starjemza, Steqeyma, and Yesintek) • > 35 kg: 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter
Ulcerative Colitis and Immune Checkpoint Inhibitor-Related Toxicities	<u>Intravenous Induction Dose (one-time only):</u> • ≤ 55 kg: 260 mg • > 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg <u>Subcutaneous Maintenance Dose:</u> • 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter (Note Immune Checkpoint Inhibitor Related Toxicity: Administer a one-time IV induction dose plus up to 3 subcutaneous maintenance doses only)
Supportive therapy in combination with marnetegrane autotemcel (Kresladi™)	<u>Subcutaneous Dose:</u> • Administer 0.75 mg/kg subcutaneously approximately 2 weeks before initiation of mobilization with granulocyte colony-stimulating factor and plerixafor and 1 to 2 weeks before marnetegrane autotemcel (Kresladi) infusion for up to a maximum of 3 total doses. (Note: Use is limited to the subcutaneous formulation only)

- Crohn's Disease & Ulcerative Colitis dose escalation⁴⁵⁻⁵² (up to the maximum dose and frequency specified below) may occur upon clinical review on a case-by-case basis provided that the member has:
 - Shown an initial response to therapy; **AND**
 - Received the initial intravenous loading dose as specified above; **AND**
 - Received a minimum of one subcutaneous maintenance dose as specified above; **AND**
 - Responded to therapy (by treatment week 16*) with subsequent loss of response; **AND**
 - Dose escalation must not exceed the following limits:
 - 90 mg subcutaneously every 4 weeks (certain members may benefit from a smaller reduction in interval if they become symptomatic 5, 6, or 7 weeks after the prior administration)
 - Prior authorization validity will be provided for 3 months with continued approval (as specified in Sections I & IV) contingent upon demonstration of clinical improvement and ustekinumab levels (if available)**
 - Members who do not regain response at a 4-week interval should discontinue therapy
 - Members who are responding to therapy may continue with their current dosing**

***Note:**

- Request for dose escalation prior to week 16 will be evaluated considering the member's clinical picture regarding severity of inflammation, factors which may result in subtherapeutic response to standard dosing (e.g., hypoalbuminemia, prior TNF-I failure), timing of response and breakthrough/loss of response, presence of perianal fistula; **AND**
- ustekinumab trough (if available)** is <4.5 micrograms/mL

**ustekinumab trough levels must be obtained (if this is a covered test under the benefit).

- Members who are well-controlled with a trough >4.5 micrograms/mL may be candidates to increase the interval between administrations from 4 weeks to 6 weeks. Response should be assessed after 3 months at this every 6-week interval. Those members demonstrating loss of response may decrease the interval back to 90 mg subcutaneously every 4 weeks.
- Members whose trough is <4.5 micrograms/mL are candidates to decrease the interval between administrations from 8 weeks to as frequently as 4 weeks. Some members may benefit from one additional IV loading dose in conjunction with this more frequent maintenance dosing interval.

VI. Billing Code/Availability Information

HCPSC Code(s):

- J3357 – Ustekinumab, for subcutaneous injection, 1 mg; 1 billable unit = 1 mg (*Stelara SQ Only; Includes unbranded biologic[§]*)
- J3358 – Ustekinumab, for intravenous injection, 1 mg; 1 billable unit = 1 mg (*Stelara IV Only; Includes unbranded biologic[§]*)
- J3590 – Unclassified biologics (*Discontinue use on 07/01/2026*)
- C9399 – Unclassified drugs or biologicals (*Discontinue use on 07/01/2026*)

- Q5137 – Injection, ustekinumab-auub (wezlana), biosimilar, subcutaneous, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic[§])*
- Q5138 – Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic[§])*
- Q9996 – Injection, ustekinumab-ttwe (pyzchiva), subcutaneous, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic[§])*
- Q9997 – Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic[§])*
- Q9998♦ – Injection, ustekinumab-aekn (selarsdi), biosimilar, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic[§])*
- Q9999♦ – Injection, ustekinumab-aauz (otulfi), biosimilar, 1mg; 1 billable unit = 1 mg *(Includes unbranded biologic[§])*
- Q5098♦ – Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg; 1 billable unit = 1 mg
- Q5100♦ – Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg; 1 billable unit = 1 mg
- Q5099♦ – Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg; 1 billable unit = 1 mg *(Includes unbranded biologic[§])*
- Q5164♦ – Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg; 1 billable unit = 1 mg *(Effective 07/01/2026)*

♦ **Note:** CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.

NDC(s):

- Subcutaneous
 - Stelara 45 mg/0.5 mL single-dose prefilled syringe: 57894-0060-xx
 - Stelara 90 mg/mL single-dose prefilled syringe: 57894-0061-xx
 - Stelara 45 mg/0.5 mL single-dose vial: 57894-0060-xx
 - Wezlana 45 mg/0.5 mL single-dose prefilled syringe: 84612-0076-xx and 84612-0876-xx
 - Wezlana 90 mg/mL single-dose prefilled syringe: 84612-0089-xx and 84612-0889-xx
 - Wezlana 45 mg/0.5 mL single-dose vial: 84612-0055-xx and 84612-0855-xx
 - Yesintek 45 mg/0.5 mL single-dose prefilled syringe: 83257-0023-xx
 - Yesintek 90 mg/mL single-dose prefilled syringe: 83257-0025-xx
 - Yesintek 45 mg/0.5 mL single-dose vial: 83257-0024-xx
 - Steqeyma 45 mg/0.5 mL single-dose prefilled syringe: 72606-0027-xx
 - Steqeyma 90 mg/mL single-dose prefilled syringe: 72606-0028-xx
 - Steqeyma 45 mg/0.5 mL single-dose vial: 72606-0060-xx

- Pyzchiva 45 mg/0.5 mL single-dose prefilled syringe: 61314-0651-xx and 83457-0651-xx
- Pyzchiva 90 mg/mL single-dose prefilled syringe: 61314-0652-xx and 83457-0652-xx
- Pyzchiva 45 mg/0.5 mL single-dose vial: 61314-0651-xx
- Otulfi 45 mg/0.5 mL single-dose prefilled syringe: 65219-0824-xx
- Otulfi 90 mg/mL single-dose prefilled syringe: 65219-0826-xx
- Otulfi 45 mg/0.5 mL single-dose vial: 65219-0822-xx
- Imuldosa 45 mg/0.5 mL single-dose prefilled syringe: 69448-0017-xx and 51407-0929-xx
- Imuldosa 90 mg/mL single-dose prefilled syringe: 69448-0018-xx and 51407-0930-xx
- Selarsdi 45 mg/0.5 mL single-dose prefilled syringe: 51759-0505-xx and 51759-0709-xx
- Selarsdi 90 mg/mL single-dose prefilled syringe: 51759-0607-xx, 51750-0710-xx, and 50090-7769-xx
- Selarsdi 45 mg/0.5 mL single-dose vial: 51759-0505-xx and 51759-0709-xx
- Starjemza 45 mg/0.5 mL single-dose prefilled syringe: 00143-9168-xx
- Starjemza 90 mg/mL single-dose prefilled syringe: 00143-9170-xx
- Starjemza 45 mg/0.5 mL single-dose vial: 00143-9169-xx
- Ustekinumab 45 mg/0.5 mL single-dose prefilled syringe: 57894-0440-xx (*§Unbranded biologic of Stelara*)
- Ustekinumab 90 mg/mL single-dose prefilled syringe: 57894-0441-xx (*§Unbranded biologic of Stelara*)
- Ustekinumab 45 mg/0.5 mL single-dose vial: 57894-0440-xx (*§Unbranded biologic of Stelara*)
- Ustekinumab-aekn 45 mg/0.5 mL single-dose prefilled syringe: 51759-0709-xx and 51759-0413-xx (*§Unbranded biologic of Selarsdi*)
- Ustekinumab-aekn 90 mg/mL single-dose prefilled syringe: 51759-0710-xx and 51759-0414-xx (*§Unbranded biologic of Selarsdi*)
- Ustekinumab-aekn 45 mg/0.5 mL single-dose vial: 51759-0709-xx (*§Unbranded biologic of Selarsdi*)
- Ustekinumab-ttwe 45 mg/0.5 mL single-dose prefilled syringe: 82009-0160-xx (*§Unbranded biologic of Pyzchiva*)
- Ustekinumab-ttwe 90 mg/mL single-dose prefilled syringe: 82009-0162-xx (*§Unbranded biologic of Pyzchiva*)
- Ustekinumab-aauz 45 mg/0.5 mL single-dose prefilled syringe: 65219-0862-xx (*§Unbranded biologic of Otulfi*)
- Ustekinumab-aauz 90 mg/mL single-dose prefilled syringe: 65219-0866-xx (*§Unbranded biologic of Otulfi*)
- Ustekinumab-aauz 45 mg/0.5 mL single-dose vial: 65219-0864-xx (*§Unbranded biologic of Otulfi*)

- Ustekinumab-stba 45 mg/0.5 mL single-dose prefilled syringe: 72606-0055-xx (*§Unbranded biologic of Steqeyma*)
- Ustekinumab-stba 90 mg/mL single-dose prefilled syringe: 72606-0056-xx (*§Unbranded biologic of Steqeyma*)
- Ustekinumab-auub 45 mg/0.5 mL single-dose prefilled syringe: 55513-0129-xx (*§Unbranded biologic of Wezlana*)
- Ustekinumab-auub 90 mg/mL single-dose prefilled syringe: 55513-0158-xx (*§Unbranded biologic of Wezlana*)
- Ustekinumab-auub 45 mg/0.5 mL single-dose vial: 55513-0147-xx (*§Unbranded biologic of Wezlana*)
- Ustekinumab-auub 45 mg/0.5 mL single-dose prefilled autoinjector: 55513-0169-xx (*§Unbranded biologic of Wezlana*)
- Ustekinumab-auub 90 mg/mL single-dose prefilled autoinjector: 55513-0173-xx (*§Unbranded biologic of Wezlana*)
- Intravenous
 - Stelara 130 mg/26 mL (5 mg/mL) single-dose vial: 57894-0054-xx
 - Wezlana 130 mg/26 mL (5 mg/mL) single-dose vial: 84612-0066-xx
 - Yesintek 130 mg/26 mL (5 mg/mL) single-dose vial: 83257-0026-xx
 - Steqeyma 130 mg/26 mL (5 mg/mL) single dose vial: 72606-0029-xx
 - Pyzchiva 130 mg/26 mL (5 mg/mL) single-dose vial: 61314-0654-xx
 - Otulfi 130 mg/26 mL (5 mg/mL) single-dose vial: 65219-0828-xx
 - Imuldosa 130 mg/26 mL (5 mg/mL) single-dose vial: 69448-0019-xx and 51407-0931-xx
 - Selarsdi 130 mg/26 mL (5 mg/mL) single-dose vial: 51759-0708-xx and 51759-0711-xx
 - Starjemza 130 mg/26 mL (5 mg/mL) single-dose vial: 00143-9171-xx
 - Ustekinumab 130 mg/26 mL (5 mg/mL) single-dose vial: 57894-0444-xx (*§Unbranded biologic of Stelara*)
 - Ustekinumab-aekn 130 mg/26 mL (5 mg/mL) single-dose vial: 51759-0711-xx (*§Unbranded biologic of Selarsdi*)
 - Ustekinumab-ttwe 130 mg/26 mL (5 mg/mL) single-dose vial: 82009-0163-xx (*§Unbranded biologic of Pyzchiva*)
 - Ustekinumab-aaaz 130 mg/26 mL (5 mg/mL) single-dose vial: 65219-0868-xx (*§Unbranded biologic of Otulfi*)
 - Ustekinumab-stba 130 mg/26 mL (5 mg/mL) single-dose vial: 72606-0057-xx (*§Unbranded biologic of Steqeyma*)
 - Ustekinumab-auub 130 mg/26 mL (5 mg/mL) single-dose vial: 55513-0165-xx (*§Unbranded biologic of Wezlana*)

§An unbranded biologic is the same as the brand biologic and uses the same cell-line as the brand-name reference biologic.

VII. References

1. Stelara/Ustekinumab [package insert]. Horsham, PA; Janssen Biotech, Inc.; April 2026. Accessed April 2026.
2. Wezlana/Ustekinumab-auub [package insert]. Thousand Oaks, CA; Amgen Inc.; October 2025. Accessed February 2026.
3. Selarsdi/Ustekinumab-aekn [package insert]. Leesburg, VA; Alvotek USA Inc.; December 2025. Accessed February 2026.
4. Pyzchiva/Ustekinumab-ttwe [package insert]. Yeonsu-gu, Incheon; Samsung Bioepis Co., Ltd.; November 2025. Accessed February 2026.
5. Otulfi/Ustekinumab-aaaz [package insert]. Lake Zurich, IL; Fresenius Kabi USA, LLC; January 2026; Accessed February 2026.
6. Imuldosa [package insert]. Raleigh, NC; Accord BioPharma Inc; November 2025; Accessed February 2026.
7. Yesintek [package insert]. Cambridge, MA; Biocon Biologics Inc.; January 2026; Accessed February 2026.
8. Steqeyma/Ustekinumab-stba [package insert]. Yeonsu-gu, Incheon; Celltrion, Inc.; December 2025; Accessed February 2026.
9. Starjemza [package insert]. Guangzhou, Guangdong, China; Bio-Thera Solutions, Ltd.; May 2025; Accessed February 2026.
10. Leonardi CL, Kimball AB, Papp KA, et al, "Efficacy and Safety of Ustekinumab, a Human Interleukin-12/23 Monoclonal Antibody, in Patients With Psoriasis: 76-Week Results from a Randomised, Double-Blind, Placebo-Controlled Trial (PHOENIX 1)," *Lancet*, 2008, 371(9625): 1665-74.
11. Papp KA, Langley RG, Lebwohl M, et al, "Efficacy and Safety of Ustekinumab, a Human Interleukin-12/23 Monoclonal Antibody, in Patients With Psoriasis: 52-Week Results from a Randomised, Double-Blind, Placebo-Controlled Trial (PHOENIX 2)," *Lancet*, 2008, 371(9625): 1675-84.
12. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012 Jan;148(1):95-102.
13. Papp KA, Griffiths CE, Gordon K, et al. Long-term safety of ustekinumab in patients with moderate-to-severe psoriasis: final results from 5 years of follow-up. *Br J Dermatol*. 2013 Apr;168(4):844-54.
14. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50. doi: 10.1016/j.jaad.2008.02.039.

15. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008 May;58(5):851-64.
16. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2015 Dec 7. pii: annrheumdis-2015-208337. doi: 10.1136/annrheumdis-2015-208337.
17. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019 Jan;71(1):5-32. Doi: 10.1002/art.40726.
18. Lichtenstein GR, Hanauer SB, Sandborn WJ, Practice Parameters Committee of American College of Gastroenterology. Management of Crohn's disease in adults. *Am J Gastroenterol*. 2009;104(2):465.
19. Terdiman JP, Gruss CB, Heidelbaugh JJ, et al. American Gastroenterological Association Institute guideline on the use of thiopurines, methotrexate, and anti-TNF- α biologic drugs for the induction and maintenance of remission in inflammatory Crohn's disease. *Gastroenterology*. 2013 Dec;145(6):1459-63. doi: 10.1053/j.gastro.2013.10.047.
20. Gomollón F, Dignass A, Annese V, et al. EUROPEAN Evidence-based consensus on the diagnosis and management of Crohn's disease 2016: Part 1: Diagnosis and medical management. *J Crohns Colitis*. 2016 Sep 22. pii: jjw168.
21. Harbord M, Eliakim R, Bettenworth D, et al. Third European Evidence-based Consensus on Diagnosis and Management of Ulcerative Colitis. Part 2: Current Management. *J Crohns Colitis*. 2017 Jan 28. doi: 10.1093/ecco-jcc/jjx009.
22. National Institute for Health and Care Excellence. NICE 2012. Crohn's Disease: Management. Published 10 October 2012. Clinical Guideline [CG152]. <https://www.nice.org.uk/guidance/cg152/resources/crohns-disease-management-pdf-35109627942085>.
23. National Institute for Health and Care Excellence. NICE 2017. Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs. Published 24 May 2017. Technology Appraisal Guidance [TA445]. <https://www.nice.org.uk/guidance/ta445>. Accessed February 2026.
24. National Institute for Health and Care Excellence. NICE 2008. Infliximab for the treatment of adults with psoriasis. Published 23 January 2008. Technology Appraisal Guidance [TA134]. <https://www.nice.org.uk/guidance/ta134/resources/infliximab-for-the-treatment-of-adults-with-psoriasis-pdf-82598193811141>.
25. Smith CH, Jabbar-Lopez ZK, Yiu ZK, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. *Br J Dermatol*. 2017 Sep;177(3):628-636. doi: 10.1111/bjd.15665.

26. Lichtenstein GR, Loftus EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2018; 113:481–517; doi: 10.1038/ajg.2018.27
27. Sands BE, Sandborn WJ, Panaccione R, et al. UNIFI Study Group. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. *N Engl J Med*. 2019 Sep 26;381(13):1201-1214. doi: 10.1056/NEJMoa1900750.
28. Lewis JD, Chuai S, Nessel L, et al. Use of the Non-invasive Components of the Mayo Score to Assess Clinical Response in Ulcerative Colitis. *Inflamm Bowel Dis*. 2008 Dec; 14(12): 1660–1666. doi: 10.1002/ibd.20520
29. Paine ER. Colonoscopic evaluation in ulcerative colitis. *Gastroenterol Rep (Oxf)*. 2014 Aug; 2(3): 161–168.
30. Walsh AJ, Bryant RV, Travis SPL. Current best practice for disease activity assessment in IBD. *Nature Reviews Gastroenterology & Hepatology* 13, 567–579 (2016) doi:10.1038/nrgastro.2016.128
31. Kornbluth, A, Sachar, DB; Practice Parameters Committee of the American College of Gastroenterology. Ulcerative colitis practice guidelines in adults: American College Of Gastroenterology, Practice Parameters Committee. *Am J Gastroenterol*. 2010 Mar;105(3):501-23.
32. Feagan BG, Sandborn WJ, Gasink C, UNITI–IM-UNITI Study Group et al. Ustekinumab as Induction and Maintenance Therapy for Crohn's Disease. *N Engl J Med*. 2016 Nov 17;375(20):1946-1960. doi: 10.1056/NEJMoa1602773.
33. Leonardi CL, Kimball AB, Papp KA, PHOENIX 1 study investigators. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 76-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 1). *Lancet*. 2008;371(9625):1665.
34. Papp KA, Langley RG, Lebwohl M, PHOENIX 2 study investigators. Efficacy and safety of ustekinumab, a human interleukin-12/23 monoclonal antibody, in patients with psoriasis: 52-week results from a randomised, double-blind, placebo-controlled trial (PHOENIX 2). *Lancet*. 2008;371(9625):1675.
35. Landells I, Marano C, Hsu MC, et al. Ustekinumab in adolescent patients age 12 to 17 years with moderate-to-severe plaque psoriasis: results of the randomized phase 3 CADMUS study. *J Am Acad Dermatol*. 2015;73(4):594.
36. McInnes IB, Kavanaugh A, Gottlieb AB, PSUMMIT 1 Study Group. Efficacy and safety of ustekinumab in patients with active psoriatic arthritis: 1 year results of the phase 3, multicentre, double-blind, placebo-controlled PSUMMIT 1 trial. *Lancet*. 2013;382(9894):780. Epub 2013 Jun 13.
37. Ritchlin C, Rahman P, Kavanaugh A, PSUMMIT 2 Study Group. Efficacy and safety of the anti-IL-12/23 p40 monoclonal antibody, ustekinumab, in patients with active psoriatic arthritis despite conventional non-biological and biological anti-tumour necrosis factor therapy: 6-month and 1-year results of the phase 3, multicentre, double-blind, placebo-controlled, randomised PSUMMIT 2 trial. *Ann Rheum Dis*. 2014;73(6):990. Epub 2014 Jan 30.

38. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2019 Feb 13. pii: S0190-9622(18)33001-9. <https://doi.org/10.1016/j.jaad.2018.11.057>.
39. Richard EG. (2025). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmets CA, Corona R (Eds.), *UpToDate*. Last updated: Jan 24, 2025. Accessed on: February 4, 2026. Available from [https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20\(PUVA\)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1](https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20(PUVA)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1).
40. Lui H, Kalia S. (2025). UVB phototherapy (broadband and narrowband). In Elmets CA, Corona R (Eds.), *UpToDate*. Last updated: Aug 18, 2025; Accessed on February 4, 2026. Available from [https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20\(broadband%20and%20narrowband&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1](https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20(broadband%20and%20narrowband&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1).
41. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020 Jun;79(6):700-712. doi: 10.1136/annrheumdis-2020-217159.
42. National Institute for Health and Care Excellence. NICE 2019. Crohn's Disease: Management. Published 03 May 2019. Clinical Guideline [NG129]. <https://www.nice.org.uk/guidance/ng129/resources/crohns-disease-management-pdf-66141667282885>.
43. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ustekinumab. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2026.
44. Thomas AS, Ma W, Wang Y. Ustekinumab for Refractory Colitis Associated with Immune Checkpoint Inhibitors. *N Engl J Med* 2021;384:581-583.
45. Mathurin Fumery M, Laurent Peyrin-Biroulet L, Stéphane Nancey S, et al. Effectiveness and safety of ustekinumab intensification at 90 Mg every four weeks In Crohn's disease: a multicenter study. *Journal of Crohn's and Colitis, Elsevier - Oxford University Press*, 2021, 15 (2), pp.222-227.
46. Haider, S., et al. Ustekinumab dose escalation improves clinical responses in refractory Crohn's disease *Therap Adv Gastroenterol*. 2020; 13: 1756284820959245. Published online 2020 Oct 13.
47. Ollech JE et al, Effectiveness of Ustekinumab Dose Escalation in Patients with Crohn's Disease. *Clin Gastroenterol Hepatol*. 2020 Feb 26.
48. Kopylov U, Hanzel J, Liefferinckx C, et al. Effectiveness of ustekinumab dose escalation in Crohn's disease patients with insufficient response to standard-dose subcutaneous maintenance therapy. *Aliment Pharmacol Ther* 2020;52:135-42.

49. Ma C, Fedorak RN, Kaplan GG, et al. Long-term Maintenance of Clinical, Endoscopic, and Radiographic Response to Ustekinumab in Moderate-to-Severe Crohn's Disease: Real-world Experience from a Multicenter Cohort Study. *Inflamm Bowel Dis* 2017;23:833-9.
50. Dalal R, Njie C, Gupta S, Allegretti JR. Predictors of Ustekinumab Failure After Dose Intensification Among Patients With Crohn's Disease *American College of Gastroenterology*; 2020. p. S0646.
51. Battat R, Kopylov U, Bessissow T, et al. Association between ustekinumab trough concentrations and clinical, biomarker, and endoscopic outcomes in patients with Crohn's disease. *Clin Gastroenterol Hepatol*, 15 (2017), pp. 1427-1434.
52. Cheifetz AS, Abreu MT, Afif W, et al. A Comprehensive Literature Review and Expert Consensus Statement on Therapeutic Drug Monitoring of Biologics in Inflammatory Bowel Disease. *Am J Gastroenterol* 2021 Accession Number: 34388143 DOI: 10.14309/ajg.0000000000001396.
53. Smith CH, Yiu ZZN, Bale T, et al; British Association of Dermatologists' Clinical Standards Unit. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update. *Br J Dermatol*. 2020 Oct;183(4):628-637. Doi: 10.1111/bjd.19039.
54. National Institute for Health and Care Excellence. NICE 2017. Psoriasis: assessment and management. Published 24 October 2012. Clinical guideline [CG153]. <https://www.nice.org.uk/guidance/CG153>. Accessed February 2026.
55. National Institute for Health and Care Excellence. NICE 2013. Psoriasis. Published 06 August 2013. Quality standard [QS40]. <https://www.nice.org.uk/guidance/qs40>. Accessed February 2026.
56. Elmetts CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol*. 2019 Sep;81(3):775-804. Doi: 10.1016/j.jaad.2019.04.042.
57. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020 Jan;82(1):161-201. Doi: 10.1016/j.jaad.2019.08.049.
58. American Academy of Dermatology Work Group. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011 Jul;65(1):137-74. Doi: 10.1016/j.jaad.2010.11.055.
59. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *Arthritis Care & Research*, Vol. 71, No. 6, June 2019, pp 717–734 DOI 10.1002/acr.23870.
60. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis:

recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum.* 2013 Oct;65(10):2499-512.

61. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. *J Am Acad Dermatol.* 2017 Feb; 76(2):290-298. Doi: 10.1016/j.jaad.2016.10.017.
62. Mease PJ. Measures of psoriatic arthritis: Tender and Swollen Joint Assessment, Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Modified Nail Psoriasis Severity Index (mNAPSI), Mander/Newcastle Enthesitis Index (MEI), Leeds Enthesitis Index (LEI), Spondyloarthritis Research Consortium of Canada (SPARCC), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Leeds Dactylitis Index (LDI), Patient Global for Psoriatic Arthritis, Dermatology Life Quality Index (DLQI), Psoriatic Arthritis Quality of Life (PsAQOL), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Psoriatic Arthritis Response Criteria (PsARC), Psoriatic Arthritis Joint Activity Index (PsAJAI), Disease Activity in Psoriatic Arthritis (DAPSA), and Composite Psoriatic Disease Activity Index (CPDAI). *Arthritis Care Res (Hoboken).* 2011 Nov;63 Suppl 11:S64-85. Doi: 10.1002/acr.20577.
63. Ringold S, Bittner R, Neggi T, et al. Performance of rheumatoid arthritis disease activity measures and juvenile arthritis disease activity scores in polyarticular-course juvenile idiopathic arthritis: Analysis of their ability to classify the American College of Rheumatology pediatric measures of response and the preliminary criteria for flare and inactive disease. *Arthritis Care Res (Hoboken).* 2010 Aug;62(8):1095-102.
64. Consolaro A, Giancane G, Schiappapietra B, et al. Clinical outcome measures in juvenile idiopathic arthritis. *Pediatric Rheumatology* 18 April 2016 14:23.
65. Raine T, Bonovas S, Burisch J, et al. ECCO Guidelines on therapeutics in ulcerative colitis: medical treatment. *J Crohns Colitis.* 2022 Jan 28. 16 (1):2-17. Doi: 10.1093/ecco-jcc/jjab178
66. Foley P, Mahar PD, Smith SD, et al. Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Considerations for paediatric patients. *Australas J Dermatol.* 2024 May 13. doi:10.1111/ajd.14303
67. Foley P, Gebaur K, Sullivan J, et al. Australian consensus: Treatment goals for moderate to severe psoriasis in the era of targeted therapies – Adult patients. *Australas J Dermatol.* 2023 Nov;64(4):467-487. doi:10.1111/ajd.14138
68. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis.* 2024 May 15;83(6):706-719. doi: 10.1136/ard-2024-225531. PMID: 38499325
69. Tiwari V, Brent LH. Psoriatic Arthritis. [Updated 2024 Jan 7]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024. <https://www.ncbi.nlm.nih.gov/books/NBK547710/>. Accessed February 9, 2026.

70. Gordon H, Minozzi S, Kopylov U, et al. ECCO Guidelines on Therapeutics in Crohn's Disease: Medical Treatment, Journal of Crohn's and Colitis, 2024; <https://doi.org/10.1093/ecco-icc/ijae091>
71. Ranasinghe IR, Tian C, Hsu R. Crohn Disease. [Updated 2025 Dec 01]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025. <https://www.ncbi.nlm.nih.gov/books/NBK436021/>. Accessed April 20, 2026.
72. Ananthakrishnan AN, Alder J, Chachu KA, et al. AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Crohn's Disease. Gastroenterology. 2023 Dec;165(6):1367-1399. doi: 10.1053/j.gastro.2023.09.029. PMID: 37981354.
73. Feuerstein JD, Ho EY, Schmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021 Jun;160(7):2496-2508. doi: 10.1053/j.gastro.2021.04.022. PMID: 34051983; PMCID: PMC8988893.
74. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158(5):1450-1461. doi:10.1053/j.gastro.2020.01.006.
75. Singh S, Ananthakrishnan AN, Nguyen NH, et al. AGA Clinical Practice Guideline on the Role of Biomarkers for the Management of Ulcerative Colitis. Gastroenterology. 2023 Mar;164(3):344-372. doi: 10.1053/j.gastro.2022.12.007. PMID: 36822736.
76. Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. Gastroenterology. 2024 Dec;167(7):1307-1343. doi: 10.1053/j.gastro.2024.10.001. PMID: 39572132.
77. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. Gastroenterology. 2025 Dec;169(7):1397-1448. doi: 10.1053/j.gastro.2025.09.038. Erratum in: Gastroenterology. 2026 Feb;170(2):441. doi: 10.1053/j.gastro.2025.12.013. PMID: 41274746.
78. Lichtenstein GR, Loftus EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2025; 120(6):1225-1264. <https://doi.org/10.14309/ajg.0000000000003465>
79. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. Am J Gastroenterol. 2025 Jun 3;120(6):1187-1224. doi: 10.14309/ajg.0000000000003463. PMID: 40701556.
80. Van Rhee PF, Aloia M, Assa A, et al. The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update. J Crohns Colitis. 2020 Oct 7;14:161. doi: 10.1093/ecco-icc/ijaa161.
81. Kresladi [package insert]. Cranbury, NJ; Rocket Pharmaceuticals, Inc; March 2026. Accessed April 2026.

82. Booth C, Sevilla J, Almarza E, et al. Lentiviral Gene Therapy for Severe Leukocyte Adhesion Deficiency Type 1. N Engl J Med. 2025 May 1;392(17):1698-1709. doi: 10.1056/NEJMoa2407376. PMID: 40305711.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

Subcutaneous

ICD-10	ICD-10 Description
D71.1	Leukocyte adhesion deficiency
K50.00	Crohn’s disease of small intestine without complications
K50.011	Crohn’s disease of small intestine with rectal bleeding
K50.012	Crohn’s disease of small intestine with intestinal obstruction
K50.013	Crohn’s disease of small intestine with fistula
K50.014	Crohn’s disease of small intestine with abscess
K50.018	Crohn’s disease of small intestine with other complication
K50.019	Crohn’s disease of small intestine with unspecified complications
K50.10	Crohn’s disease of large intestine without complications
K50.111	Crohn’s disease of large intestine with rectal bleeding
K50.112	Crohn’s disease of large intestine with intestinal obstruction
K50.113	Crohn’s disease of large intestine with fistula

Medical Necessity Criteria

ICD-10	ICD-10 Description
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications

Medical Necessity Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

ICD-10	ICD-10 Description
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis
L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified

Medical Necessity Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

ICD-10	ICD-10 Description
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
M08.80	Other juvenile arthritis, unspecified site
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, other specified site
M08.89	Other juvenile arthritis, multiple sites
M08.9A	Juvenile arthritis, unspecified, other specified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder

Medical Necessity Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

ICD-10	ICD-10 Description
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
R19.7	Diarrhea, unspecified

Intravenous

ICD-10	ICD-10 Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication

Medical Necessity Criteria

ICD-10	ICD-10 Description
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
K50.919	Crohn's disease, unspecified, with unspecified complications
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding

Medical Necessity Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

ICD-10	ICD-10 Description
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess

Medical Necessity Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

ICD-10	ICD-10 Description
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications
K52.1	Toxic gastroenteritis and colitis
R19.7	Diarrhea, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC