LOUISIANA BLUE

ustekinumab Products

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

ustekinumab-aekn (Selarsdi®), ustekinumab-kfce (Yesintek™), ustekinumab-srlf (Imuldosa®) unbranded ustekinumab-ttwe

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Plaque Psoriasis

Based on review of available data, the Company may consider the use of ustekinumab-aekn (Selarsdi®)‡, ustekinumab-kfce (Yesintek™)‡, and ustekinumab-srlf (Imuldosa®)‡, and unbranded ustekinumab-ttwe for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for the treatment of plaque psoriasis when ALL of the following criteria are met:

Initial

- Patient is 6 years of age or older; AND
- Patient has moderate to severe plaque psoriasis; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- The requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira®, biosimilars)‡ or etanercept (Enbrel®)‡ OR other drugs such as tofacitinib (Xeljanz/XR®)‡ or apremilast (Otezla®)‡; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- Patient has failed to respond to an adequate trial of one of the following treatment modalities:
  - Ultraviolet B; OR
  - Psoralen positive Ultraviolet A; OR
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin).

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as reduced estimated body surface area affected by psoriasis, decreased erythema, induration/thickness, or scaling, and/or improvement in symptoms such as pain, itching, or burning; AND

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- The requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla).

Psoriatic Arthritis

Based on review of available data, the Company may consider the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for the treatment of psoriatic arthritis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for the treatment of psoriatic arthritis will be considered when ALL of the following criteria are met:

Initial

- Patient is 6 years of age or older; AND
- Patient has active psoriatic arthritis; AND
- The requested drug is used alone or in combination with methotrexate; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- The requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- The requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla).

Crohn's Disease

Based on review of available data, the Company may consider the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for the treatment of moderately to severely active Crohn's disease to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for the treatment of Crohn's Disease will be considered when ALL of the following criteria are met:

Initial

- Patient has a diagnosis of moderately to severely active Crohn's disease; AND
- Patient is 18 years of age or older; AND
- Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker or another biologic for the treatment of Crohn's disease such as infliximab (Remicade®‡, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio®)‡; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active Crohn's disease; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- For intravenous requests of a ustekinumab product, the requested dose will NOT exceed one of the following:
  - Patient ≤ 55 kg: 260 mg; OR
  - Patient 55 kg to 85 kg: 390 mg; OR
  - Patient > 85 kg: 520 mg

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in objective measures (e.g., fecal or serum inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or blood in stool; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active Crohn's disease.

Ulcerative Colitis

Based on review of available data, the Company may consider the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for the treatment of moderately to severely active ulcerative colitis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for the treatment of ulcerative colitis will be considered when ALL of the following criteria are met:

Initial

- Patient has a diagnosis of moderately to severely active ulcerative colitis; AND
- Patient is 18 years of age or older; AND
- Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active ulcerative colitis; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- For intravenous requests of a ustekinumab product, the requested dose will NOT exceed one of the following:
  - Patient ≤ 55 kg: 260 mg; OR
  - Patient 55 kg to 85 kg: 390 mg; OR
  - Patient > 85 kg: 520 mg

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in objective measures (e.g., fecal or serum

inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or rectal bleeding; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active ulcerative colitis.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe when any of the following criteria for their respective disease state listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- For plaque psoriasis
  - Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
  - Patient has failed to respond to an adequate trial of one of the following treatment modalities:
    - Ultraviolet B; OR
    - Psoralen positive Ultraviolet A; OR
    - Systemic therapy (i.e. methotrexate, cyclosporine, acitretin).
  - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as reduced estimated body surface area affected by psoriasis, decreased erythema, induration/thickness, or scaling, and/or improvement in symptoms such as pain, itching, or burning
- For psoriatic arthritis
  - Patient has failed treatment with one or more traditional DMARDs, such as methotrexate
  - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths
- For Crohn's disease
  - Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker or another biologic for the treatment of Crohn's disease
  - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in

objective measures (e.g., fecal or serum inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or blood in stool

- For ulcerative colitis
  - Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids
  - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in objective measures (e.g., fecal or serum inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or rectal bleeding

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as **not medically necessary**).**

Based on review of available data, the Company considers the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe for indications other than those listed above to be **investigational.***

ustekinumab (Stelara®), Unbranded Ustekinumab, ustekinumab-auub (Wezlana™), ustekinumab-aauz (Otulfi®), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma®), ustekinumab-ttwe (Pyzchiva®),

When Services May Be Eligible for Coverage

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- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Plaque Psoriasis

Based on review of available data, the Company may consider the use of ustekinumab (Stelara®)‡, unbranded Ustekinumab, ustekinumab-auub (Wezlana™)‡, ustekinumab-aauz (Otulfi®)‡, unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma®)‡, and

ustekinumab-ttwe (Pyzchiva®)‡ for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva) for the treatment of plaque psoriasis when ALL of the following criteria are met:

Initial

- Patient is 6 years of age or older; AND
- Patient has moderate to severe plaque psoriasis; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- The requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has failed to respond to an adequate trial of one of the following treatment modalities:
  - Ultraviolet B; OR
  - Psoralen positive Ultraviolet A; OR
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin); AND

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as

- reduced estimated body surface area affected by psoriasis, decreased erythema, induration/thickness, or scaling, and/or improvement in symptoms such as pain, itching, or burning; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- The requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla).

Psoriatic Arthritis

Based on review of available data, the Company may consider the use of ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva) for the treatment of psoriatic arthritis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva) for the treatment of psoriatic arthritis will be considered when ALL of the following criteria are met:

Initial

- Patient is 6 years of age or older; AND
- Patient has active psoriatic arthritis; AND
- The requested drug is used alone or in combination with methotrexate; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- The requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- The requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla).

Crohn's Disease

Based on review of available data, the Company may consider the use of ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva) for the treatment of moderately to severely active Crohn's disease to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva) for the treatment of Crohn's Disease will be considered when ALL of the following criteria are met:

Initial

- Patient has a diagnosis of moderately to severely active Crohn's disease; AND
- Patient is 18 years of age or older; AND
- Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker or another biologic for the treatment of Crohn's disease such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active Crohn's disease; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND

- For intravenous requests of a ustekinumab product, the requested dose will NOT exceed one of the following:
  - Patient ≤ 55 kg: 260 mg; OR
  - Patient 55 kg to 85 kg: 390 mg; OR
  - Patient > 85 kg: 520 mg
- For subcutaneous requests of a ustekinumab product: Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For intravenous requests of a ustekinumab product, there is clinical evidence or patient history that suggests the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in objective measures (e.g., fecal or serum inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or blood in stool; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active Crohn's disease.

Ulcerative Colitis

Based on review of available data, the Company may consider the use of ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva), for the treatment of moderately to severely active ulcerative colitis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva), for the treatment of ulcerative colitis will be considered when ALL of the following criteria are met:

Initial

- Patient has a diagnosis of moderately to severely active ulcerative colitis; AND
- Patient is 18 years of age or older; AND
- Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active ulcerative colitis; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- For intravenous requests of a ustekinumab product, the requested dose will NOT exceed one of the following:
  - Patient ≤ 55 kg: 260 mg; OR
  - Patient 55 kg to 85 kg: 390 mg; OR
  - Patient > 85 kg: 520 mg
- For subcutaneous requests of a ustekinumab product: Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For intravenous requests of a ustekinumab product, there is clinical evidence or patient history that suggests the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Continuation

- Patient has received an initial authorization; AND
- Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in objective measures (e.g., fecal or serum inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or rectal bleeding; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- The requested drug is NOT being used concurrently with other biologic products such as infliximab (Remicade, biosimilars), adalimumab (Humira, biosimilars), or vedolizumab (Entyvio) for the treatment of moderately to severely active ulcerative colitis.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva) when any of the following criteria for their respective disease state listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- For plaque psoriasis
    - Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
    - Patient has failed to respond to an adequate trial of one of the following treatment modalities:
        - Ultraviolet B; OR
        - Psoralen positive Ultraviolet A; OR
        - Systemic therapy (i.e. methotrexate, cyclosporine, acitretin).
    - Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe
    - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as reduced estimated body surface area affected by psoriasis, decreased erythema, induration/thickness, or scaling, and/or improvement in symptoms such as pain, itching, or burning
- For psoriatic arthritis
    - Patient has failed treatment with one or more traditional DMARDs, such as methotrexate
    - Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe
    - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in clinical signs and/or symptoms such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths
- For Crohn's disease
    - Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker or another biologic for the treatment of Crohn's disease
    - For subcutaneous requests of a ustekinumab product: Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with

EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe
    - For intravenous requests of a ustekinumab product, there is clinical evidence or patient history that suggests the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe will be ineffective or cause an adverse reaction to the patient
    - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in objective measures (e.g., fecal or serum inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or blood in stool
- For ulcerative colitis
    - Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids
    - For subcutaneous requests of a ustekinumab product: Patient has tried and failed treatment with THREE of the following after at least TWO months of therapy with EACH product: ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), or unbranded ustekinumab-ttwe
    - For intravenous requests of a ustekinumab product, there is clinical evidence or patient history that suggests the use of ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), ustekinumab-srlf (Imuldosa), and unbranded ustekinumab-ttwe will be ineffective or cause an adverse reaction to the patient
    - For continuation requests: Patient has experienced a beneficial clinical response from baseline (prior to therapy with the requested drug) as evidenced by improvement in objective measures (e.g., fecal or serum inflammatory markers, endoscopic findings, reduced corticosteroid use) or in symptoms such as pain, fatigue, stool frequency, or rectal bleeding

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz,unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva)when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as **not medically necessary**).**

Based on review of available data, the Company considers the use of ustekinumab (Stelara), unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva) for indications other than those listed above to be **investigational.***

Background/Overview

Stelara is a monoclonal antibody that inhibits proteins that contribute to the overproduction of skin cells. It is a biologic drug that inhibits interleukin-12 and interleukin-23. Stelara has several biosimilars available, including ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), unbranded ustekinumab-ttwe, unbranded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aauz, unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), ustekinumab-srlf (Imuldosa), and ustekinumab-ttwe (Pyzchiva). A biosimilar product is a biological product that is approved based on demonstration that it is highly similar to an already approved biological reference product. The biosimilar must also demonstrate that it has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. Biosimilar products can only be approved by the U.S. Food and Drug Administration (FDA) if they have the same mechanism of action, route of administration, dosage form, and strengths as the reference product as well as only the indications and conditions of use that have been approved by the FDA for the reference product. Stelara and its biosimilars are available in 45 mg and 90 mg subcutaneous dosage forms as well as 130 mg single dose vials. The 130 mg vials are used for the treatment of Crohn's disease and ulcerative colitis. Dosing varies per indication. In general, for adults with plaque psoriasis, for patients weighing less than or equal to 100 kg, the dose of Stelara and the biosimilars is 45 mg administered subcutaneously at week 0 and 4, then 45 mg administered subcutaneously every 12 weeks thereafter. For those adults with plaque psoriasis weighing greater than 100 kg, the dose is 90 mg subcutaneously at week 0 and 4, and then 90 mg subcutaneously every 12 weeks thereafter. For patients 6-17 years of age with plaque psoriasis or psoriatic arthritis, weight based subcutaneous dosing is recommended (see package insert for details) and follows the same schedule (week 0 and 4, then 12 weeks thereafter). The recommended dose for adults with psoriatic arthritis is 45 mg administered subcutaneously at week 0 and 4 and then 45 mg administered subcutaneously every 12 weeks thereafter. Those adult patients with coexistent moderate to severe plaque psoriasis that weigh over 100 kg should follow the plaque psoriasis dosing. Crohn's disease and ulcerative colitis treatment is dosed with a weight based intravenous loading dose at week 0 (see package insert for details) and then 90 mg subcutaneous every 8 weeks.

Plaque Psoriasis

Psoriasis is a common skin condition that is characterized by frequent episodes of redness, itching and thick, dry silvery scales on the skin. It is most commonly seen on the trunk, elbows, knees, scalp, skin folds and fingernails. This condition can appear suddenly or gradually and may affect people of any age; it most commonly begins between the ages of 15 and 35. Psoriasis is not contagious. It is an inherited disorder related to an inflammatory response in which the immune system targets the body's own cells. It may be severe in immunosuppressed people or those who have other autoimmune disorders such as rheumatoid arthritis. The diagnosis is based on the appearance of the skin. A skin biopsy or scraping and culture of the skin patch may be needed to rule out other disorders. If joint pain is present and persistent, an x-ray may be used to evaluate for psoriatic arthritis. Treatment is focused on control of the symptoms and prevention of secondary infections.

Lesions that cover all or most of the body may be acutely painful and require hospitalization. The body loses vast quantities of fluid and becomes susceptible to severe secondary infections that can involve internal organs and even progress to septic shock.

Psoriatic Arthritis
Psoriatic arthritis is an inflammatory arthritis that occurs in individuals with psoriasis. The arthritic portion typically presents asymmetrically and the psoriasis may precede or follow joint involvement. The joints most commonly affected are the distal interphalangeal joints of the fingers and toes. Diagnosis of psoriatic arthritis requires both clinical and radiological observations. In patients with psoriatic arthritis, the arthritic remissions tend to be more frequent and complete than rheumatoid arthritis, but progression to chronic arthritis with crippling can occur. Treatment for psoriatic arthritis is similar to that of rheumatoid arthritis and included disease modifying anti-rheumatic drugs, such as methotrexate. Phototherapy may also be an effective treatment option.

Crohn's Disease
Crohn's disease is a chronic autoimmune disease that can affect any part of the gastrointestinal tract but most commonly occurs in the ileum. As a result of the immune attack, the intestinal wall becomes thick, and deep ulcers may form. In addition to the bowel abnormalities, Crohn's disease can also affect other organs in the body. Typically, first line treatments such as corticosteroids, 6-MP and azathioprine are used to treat this condition.

Ulcerative Colitis
Ulcerative colitis is a chronic, episodic, inflammatory disease of the large intestine and rectum characterized by bloody diarrhea. This disease usually begins in the rectal area and may eventually extend through the entire large intestine. Repeated episodes of inflammation lead to thickening of the wall of the intestine and rectum with scar tissue. Death of colon tissue or sepsis may occur with severe disease. The goals of treatment are to control the acute attacks, prevent recurrent attacks and promote healing of the colon. Hospitalization is often required for severe attacks. Typically, first line treatments such as corticosteroids, 6-mercaptopurine and azathioprine are used to treat this condition.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The FDA approved Stelara on September 25, 2009, for the treatment of adult patients (18 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. In September of 2013, Stelara was approved for the treatment of adults with active psoriatic arthritis. In September of 2016, Stelara gained FDA approval for the treatment of moderately to severely active Crohn's disease in those that have failed standard therapy (corticosteroids, immunomodulators) or those that have failed therapy with a TNF blocker. Stelara was also approved in October of 2017 for the treatment of patients 12 years of age and older with plaque psoriasis. In October of 2019, Stelara gained approved for the treatment of moderate to severe ulcerative colitis. During this update, the actual indication for Crohn's disease changed to simply state that the drug is for the treatment of moderate to severe Crohn's disease. In July of 2020, the

FDA updated the labeled age for psoriasis to 6 years of age and older. In July of 2022, the FDA updated the labeled age for psoriatic arthritis to 6 years of age and older. Between 2023 and 2025, biosimilars for Stelara were approved. These include Wezlana, Selarsdi, Steqeyma, Pyzchiva, Yesintek, Imuldosa, and Otulfi with several of these branded products also having an unbranded counterpart. All of the biosimilars are approved for the same indications as Stelara.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Plaque Psoriasis

Ustekinumab was evaluated for the treatment of plaque psoriasis in two multicenter, randomized, double-blind, placebo-controlled studies (Ps Study 1 and Ps Study 2). These studies enrolled 1,996 patients age 18 years and older with plaque psoriasis who had a minimum body surface area involvement of 10% and were candidates for phototherapy or systemic therapy. The patients were given either placebo, ustekinumab 45 mg of ustekinumab 90 mg. In both studies, the endpoints were the proportion of subjects who achieved at least a 75% reduction in the PASI score (PASI 75) from baseline to week 12 and treatment success on the Physician's Global Assessment. In regard to the primary endpoints in Ps Study 1, 3% of placebo patients reached PASI 75 vs. 67% in the ustekinumab 45 mg group vs. 66% in the ustekinumab 90 mg group. In regard to the primary endpoints in Ps Study 2, 4% of placebo patients reached PASI 75 vs. 67% in the 45 mg group vs. 76% in the 90 mg group.

Ustekinumab in adolescent subjects (12-17 years of age) with plaque psoriasis was studied in a multi-center randomized, double-blind, placebo-controlled study. Subjects were randomized to receive ustekinumab or placebo. The endpoints were the proportion of patients who achieved a PGA score of 0 or 1, PASI 75, and PASI 90 at week 12. Subjects were followed for up to 60 weeks. In regard to PGA, 69.4% of the ustekinumab group achieved a PGA of 0 or 1 vs. 5.4% in the placebo group. In regard to PASI 75, 80.6% of the ustekinumab group achieved a PASI 75 vs. 10.8% in the placebo group. In regard to PASI 90, 61.1% of the ustekinumab group achieved PASI 90 vs. 5.4% in the placebo group.

Use of ustekinumab in children 6 to 11 years with moderate to severe plaque psoriasis is supported by evidence from an open-label, single-arm, efficacy, safety and pharmacokinetics study (Ps Study 4) in 44 subjects.

Psoriatic Arthritis

Ustekinumab was evaluated in psoriatic arthritis in two randomized, double-blind, placebo-controlled studies in adult patients with psoriatic arthritis despite therapy with non-steroidal anti-inflammatory drugs or disease modifying anti-rheumatic agents. These studies included 927 patients,

and those patients were randomized to receive ustekinumab 45 mg, 90 mg, or placebo. The primary endpoint of the studies was the percentage of patients achieving ACR20 response at week 24. In both studies, a greater proportion of patients achieved ACR20, ACR50, and PASI 75 response in the ustekinumab 45 mg and 90 mg groups compared to placebo at week 24. In PsA study 1, ACR20 was achieved in 23% of placebo patients, 42% of ustekinumab 45 mg patients, and 50% of ustekinumab 90 mg patients. In PsA study 2, ACR20 was achieved in 20% of placebo patients, 44% of ustekinumab 45 mg patients, and 44% of ustekinumab 90 mg patients.

The safety and effectiveness of ustekinumab have been established for treatment of psoriatic arthritis in pediatric patients 6 to 17 years old. Use of ustekinumab in these age groups is supported by evidence from adequate and well controlled studies of ustekinumab in adults with psoriasis and psoriatic arthritis, pharmacokinetic data from adult patients with psoriasis, adult patients with psoriatic arthritis and pediatric patients with psoriasis, and safety data from two clinical studies in 44 pediatric patients 6 to 11 years old with psoriasis and 110 pediatric patients 12 to 17 years old with psoriasis. The observed pre-dose (trough) concentrations are generally comparable between adult patients with psoriasis, adult patients with psoriatic arthritis and pediatric patients with psoriasis, and the pharmacokinetic exposure is expected to be comparable between adult and pediatric patients with psoriatic arthritis.

Crohn's Disease
Ustekinumab was evaluated in 3 randomized, double-blind, placebo-controlled clinical studies in adult patients with moderately to severely active Crohn's disease. There were two 8-week intravenous induction studies (CD-1 and CD-2) followed by a 44-week subcutaneous randomized withdrawal maintenance study (CD-3) representing 52 weeks of therapy.

For CD-1 and CD-2, induction of clinical response at week 6 and clinical remission at week 8 was evaluated. CD-1 included patients that had failed or were intolerant to TNF inhibitors, while CD-2 included patients that were intolerant or had failed treatment with steroids, an immunomodulator, or both. There were 1.409 patients randomized in these two trials. The clinical response at week 6 for the placebo groups was 21% and 29% in trials CD-1 and CD-2, respectively. The clinical response at week 6 in the ustekinumab group was 34% and 56% for trials CD-1 and CD-2, respectively. The clinical remission at week 8 was 7% and 20% in the placebo groups for trials CD-1 and CD-2, respectively. The clinical remission at week 8 was 21% and 40% for trials CD-1 and CD-2, respectively. In these two studies, a greater proportion of patients treated with ustekinumab achieved clinical response at week 6 and clinical remission at week 8 compared to placebo. Clinical response and remission were significant as early as week 3 in ustekinumab treated patients and continued to improve through week 8.

CD-3 (the maintenance study) evaluated 388 patients who achieved clinical response at week 8 of induction with ustekinumab in studies CD-1 and CD-2. Patients were randomized to receive subcutaneous ustekinumab 90 mg every 8 weeks of placebo for 44 weeks. At 52 weeks from initiation of the induction dose, 36% of placebo patients had reached a clinical remission vs. 53% of

patients in the ustekinumab treatment group. At the same time point, 44% of placebo patients had a clinical response vs. 59% in the ustekinumab group. At week 44, 47% of patients who received ustekinumab were steroid free and in clinical remission compared to 30% of patients in the placebo group.

Ulcerative Colitis
Ustekinumab was evaluated in two randomized, double-blind, placebo-controlled clinical studies (UC-1 and UC-2) in adult patients with moderately to severely active ulcerative colitis who had an inadequate response to or failed to tolerate a biologic (i.e., TNF blocker and/or Entyvio), corticosteroids, and/or 6-MP or azathioprine therapy. The 8-week intravenous induction study (UC-1) was followed by the 44-week subcutaneous randomized withdrawal maintenance study (UC-2) for a total of 52 weeks of therapy. Patients in these studies may have received other concomitant therapies including aminosalicylates, immunomodulatory agents (azathioprine, 6-mercaptopurine, or methotrexate), and oral corticosteroids (prednisone).

In UC-1, 961 patients were randomized at week 0 to a single intravenous administration of ustekinumab of approximately 6 mg/kg, 130 mg (a lower dose than recommended), or placebo. Patients enrolled in UC-1 had to have failed therapy with corticosteroids, immunomodulators or at least one biologic. The primary endpoint was clinical remission at week 8. Clinical remission with a definition of: Mayo stool frequency subscore of 0 or 1, Mayo rectal bleeding subscore of 0 (no rectal bleeding), and Mayo endoscopy subscore of 0 or 1. A Mayo endoscopy subscore of 0 is defined as normal or inactive disease and a Mayo subscore of 1 is defined as presence of erythema, decreased vascular pattern and no friability. In UC-1, a significantly greater proportion of patients treated with ustekinumab (at the recommended dose of approximately 6 mg/kg dose) were in clinical remission and response and achieved endoscopic improvement and histologic-endoscopic mucosal improvement compared to placebo (19% vs. 7%).

UC-2 evaluated 523 patients who achieved clinical response 8 weeks following the intravenous administration of either induction dose of ustekinumab in UC-1. These patients were randomized to receive a subcutaneous maintenance regimen of either 90 mg ustekinumab every 8 weeks, or every 12 weeks (a lower dose than recommended), or placebo for 44 weeks. The primary endpoint was the proportion of patients in clinical remission at week 44. The secondary endpoints included the proportion of patients maintaining clinical response at week 44, the proportion of patients with endoscopic improvement at week 44, the proportion of patients with corticosteroid-free clinical remission at week 44, and the proportion of patients maintaining clinical remission at week 44 among patients who achieved clinical remission 8 weeks after induction. In UC-2, 45% of ustekinumab patients achieved remission vs. 26% of placebo patients at week 44.

References

1. Stelara. [package insert]. Horsham, PA; Janssen Biotech, Inc., Revised April 2025.
2. U.S. Food and Drug Administration. Center for Drug Evaluation and Research. FDA Labeling Information. Ustekinumab (Stelara) http://www.fda.gov.
3. Selarsdi [package insert]. Alvotech USA, Inc. Leesburg, Virginia. Updated February 2025.

4. Yesintek [package insert]. Biocon Biologics Inc. Cambridge, Massachusetts. Updated November 2024.
5. Pyzchiva [package insert]. Sandoz Inc. Princeton, New Jersey. Updated December 2024.
6. Wezlana [package insert]. Amgen Inc. Thousand Oaks, California. Updated December 2024.
7. Otulfi [package insert]. Fresenius Kabi USA, LLC. Lake Zurich, Illinois. Updated March 2025.
8. Steqeyma [package insert]. Celltrion, Inc. Republic of Korea. Updated April 2025.
9. Imuldosa [package insert]. Accord BioPharma Inc. Raleigh, North Carolina. Updated October 2024.

Policy History

Original Effective Date: 11/18/2009
Current Effective Date: 01/01/2026

11/12/2009	Medical Policy Committee approval
11/18/2009	Medical Policy Implementation Committee approval. New policy.
11/04/2010	Medical Policy Committee approval
11/16/2010	Medical Policy Implementation Committee approval. No change to policy coverage.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. Reworded and reformatted the coverage section for clarity. Coverage eligibility unchanged.
10/10/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. Added the new indication of Psoriatic Arthritis. Added criteria that requires Humira AND Enbrel prior to use of Stelara for Plaque psoriasis and psoriatic arthritis. Changed title since the drug gained a new indication. Modified the not medically necessary section to reflect changes.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Removed the requirement that Humira AND Enbrel be used prior to Stelara.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review
11/16/2016	Medical Policy Implementation Committee approval. Added the new indication for Crohn's Disease. Updated Background info/rationale to coincide with new indication.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review

12/20/2017	Medical Policy Implementation Committee approval. Changed the age to 12 years of age for plaque psoriasis. Updated TB language. Updated background info.
01/01/2018	Coding update
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. No change to coverage.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. Added a new FDA approved indication for ulcerative colitis. Changed the criterion for prior therapy failure under Crohn's disease to not medically necessary. Updated relevant background information to reflect the new indication
11/05/2020	Medical Policy Committee review
11/11/2020	Medical Policy Implementation Committee approval. Updated the age to 6 years of age for plaque psoriasis to match the FDA package insert. Removed the requirement for the use of Humira prior to Stelara in ulcerative colitis. Updated relevant background information.
11/04/2021	Medical Policy Committee review
11/10/2021	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. Updated the age requirement for psoriatic arthritis to 6 years of age (previously 18 years of age) per the updated FDA package insert.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/19/2024	Coding update
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Updated eligibility criteria to include FDA approved dosing of Stelara's intravenous dosage form to ensure intent of policy is met.
12/11/2024	Coding update
03/25/2024	Coding update
06/05/2025	Medical Policy Committee review
06/11/2025	Medical Policy Implementation Committee approval. Changed title of policy from "ustekinumab (Stelara)" to "ustekinumab Products" to reflect availability of biosimilars. Added biosimilars, ustekinumab-aekn (Selarsdi), ustekinumab-kfce (Yesintek), unbranded ustekinumab-ttwe, branded Ustekinumab, ustekinumab-auub (Wezlana), ustekinumab-aauz (Otulfi), unbranded ustekinumab-aekn, ustekinumab-stab (Steqeyma), and ustekinumab-ttwe (Pyzchiva), to the policy with criteria. Updated relevant sections.

Policy # 00242
Original Effective Date: 11/18/2009
Current Effective Date: 01/01/2026

10/02/2025 Medical Policy Committee review
10/08/2025 Medical Policy Implementation Committee approval. Moved Stelara to the section of the policy where the preferred ustekinumab alternatives must be tried and failed prior to therapy. Added new drugs, Imuldosa and unbranded ustekinumab-aauz, to the policy with criteria.
Next Scheduled Review Date: 10/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J3358, Q5098, Q5099, Q5100, Q5138, Q9997, Q9998, Q9999 Add code effective 01/01/2026: C9399 Delete codes effective 01/01/2025: J3357, Q5137
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.