

## Corporate Medical Policy

### Ustekinumab (Stelara®)

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<b>Origination:</b>	02/2010
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#### Description of Procedure or Service

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Plaque psoriasis is the most common form of psoriasis. It is characterized by raised, inflamed, red lesions covered with a silvery-white buildup of dead skin cells (scales). These are found primarily on the trunk, elbows, knees, scalp and finger or toe nails. The cause of psoriasis is related to the immune system, and more specifically, a type of white blood cell called a T lymphocyte or T cell. Normally, T-cells travel throughout the body to detect and fight off foreign substances, such as viruses or bacteria. If you have psoriasis, however, the T-cells attack healthy skin cells by mistake as if to heal a wound or to fight an infection. Normally, skin cells mature and shed after about a month. In psoriasis, the cell maturation speeds up, taking only three to four days. Because the lower layer of skin cells divides more rapidly than normal, dead cells accumulate in thicker patches on the skin's outermost layer (called the epidermis). Chief complaints of patients with moderate to severe psoriasis include scaling, itching, redness, and tightness of the skin with burning sensations. Exposed skin, especially cracked or bleeding areas, can act as potential sites of infection. Approximately 10% of patients who have psoriasis also develop an associated inflammation of their joints. Patients who have inflammatory arthritis and psoriasis are diagnosed as having psoriatic arthritis. Psoriatic arthritis can cause inflammation in body tissues away from the joints other than the skin, such as in the eyes, heart, lungs, and kidneys.

Initial treatment for stable plaque psoriasis is topical, including corticosteroids, emollients, anthralin, tar, retinoids, calcipotriene (Vitamin D analogue), and salicylic acid. Though corticosteroids are the mainstay of topical therapy, continuous use of these agents can cause tachyphylaxis (wearing off effect) and several side effects. Other treatments for plaque psoriasis include phototherapy, immunosuppressants, and systemic retinoids. Conservative treatment for psoriatic arthritis involves a combination of anti-inflammatory medications (NSAIDs) and exercise. If progressive inflammation and joint destruction occur despite NSAIDs treatment, more potent medications such as methotrexate (Rheumatrex, Trexall), corticosteroids, and antimalarial medications (such as hydroxychloroquine, or Plaquenil) may be used.

Crohn's disease is an idiopathic, chronic inflammatory condition that affects the intestinal tract. It can occur anywhere in the GI tract from the mouth to the anus. The characteristic presentation in Crohn's disease is abdominal pain and diarrhea, which may be complicated by intestinal fistulization or obstruction. Unpredictable flares and remissions characterize the long-term course.

Ustekinumab (Stelara®) is a human IgG1 $\kappa$  monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL-23 cytokines. IL-12 and IL-23 are naturally occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. In *in vitro* models, ustekinumab was shown to disrupt IL-12 and IL-23 mediated signaling and cytokine cascades by disrupting the interaction of these cytokines with a shared cell-surface receptor chain, IL-12  $\beta$ 1.

Ustekinumab (Stelara®) is indicated for:

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- Treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- Treatment of adult patients with active psoriatic arthritis, alone or in combination with methotrexate
- Treatment of adult patients with moderately to severely active Crohn's disease
- Treatment of adult patients with moderately to severely active ulcerative colitis

## Related Policies:

Infliximab (Remicade<sup>®</sup>) and Infliximab Biosimilars

Light Therapy for Dermatologic Conditions

Ultraviolet Light Therapy in the Home Setting (UVB)

Immunopharmacologic Monitoring of Therapeutic Serum Antibodies AHS – G2105

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

## Policy

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**BCBSNC will provide coverage for Ustekinumab (Stelara<sup>®</sup>) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

Coverage for Ustekinumab (Stelara<sup>®</sup>) requires prior review.

## When Ustekinumab (Stelara<sup>®</sup>) is covered

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Ustekinumab (Stelara<sup>®</sup>) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis in patients age 6 years or older when:

1. One of the following:
  - a) The patient has tried and failed, is intolerant to, or has a clinical contraindication to phototherapy (e.g., PUVA or broadband or narrowband UVB); OR
  - b) The patient has tried and failed, is intolerant to, or has a clinical contraindication to systemic therapy [e.g., methotrexate (oral or intramuscular), cyclosporine, or acitretin]; AND
2. One of the following:
  - a) The patient has body surface area (BSA) involvement of at least 5%; OR
  - b) The patient has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment; AND
3. The patient is not using ustekinumab in combination with another biologic agent; AND
4. The patient is being managed by a dermatologist; AND
5. If Stelara 90 mg is requested, ONE of the following:
  - a) The patient has failed (had an inadequate response to) a trial of 45 mg for at least 3 months; OR
  - b) The patient weighs >100 kg (see Policy Guidelines)

Ustekinumab (Stelara<sup>®</sup>) may be considered medically necessary for the treatment of active psoriatic arthritis in adult patients (18 years of age or older) when:

1. The patient is not using ustekinumab in combination with another biologic agent;

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AND

2. If Stelara 90 mg is requested, ONE of the following:
  - a) The patient has a coexistent diagnosis of moderate to severe plaque psoriasis AND the patient has failed (had an inadequate response to) a trial of 45 mg for at least 3 months; OR
  - b) The patient has a coexistent diagnosis of moderate to severe plaque psoriasis AND the patient is >100 kg (see Policy Guidelines)

Ustekinumab (Stelara®) may be considered medically necessary for the treatment of moderately to severely active Crohn's disease in adult patients (18 years of age or older) when:

1. The patient is not using ustekinumab in combination with another biologic agent; AND
2. The patient has tried and failed, is intolerant to, or has a clinical contraindication to conventional therapy (e.g., corticosteroids, 5-aminosalicylate, azathioprine, 6-mercaptopurine, metronidazole, methotrexate); AND
3. For patients new to Stelara therapy, an initial intravenous infusion of ustekinumab was administered within the last 2 months (see Policy Guidelines); AND
4. The patient will not be treated with the 45 mg injection

Ustekinumab (Stelara®) may be considered medically necessary for the treatment of moderately to severely active ulcerative colitis in adult patients (18 years of age or older) when:

1. The patient is not using ustekinumab in combination with another biologic agent; AND
2. The patient has tried and failed, is intolerant to, or has a clinical contraindication to conventional therapy (e.g., corticosteroids, 5-aminosalicylate, azathioprine, 6-mercaptopurine, metronidazole, methotrexate); AND
3. For patients new to Stelara therapy, an initial intravenous infusion of Stelara was administered within the last 2 months (see Policy Guidelines); AND
4. The patient will not be treated with the 45mg injection

## **When Ustekinumab (Stelara®) is not covered**

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Ustekinumab (Stelara®) is considered investigational and therefore not covered when the criteria listed above are not met.

Coverage is not provided for the simultaneous use of more than one biologic drug.

## **Policy Guidelines**

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Ustekinumab (Stelara®) should only be administered by a healthcare provider to patients who will be closely monitored and have regular follow-up visits with a physician. In pediatric patients, it is recommended that Stelara be administered by a healthcare provider. After proper training in subcutaneous injection technique, a patient may self inject with Stelara if a physician determines that it is appropriate. The first self-injection should be performed under the supervision of a qualified healthcare professional. If a patient or caregiver is to administer Stelara, they should be instructed in injection techniques and their ability to inject subcutaneously should be assessed to ensure the proper administration of Stelara. Refer to the FDA Medication Guide for Stelara® at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/125261s086lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125261s086lbl.pdf)

# Ustekinumab (Stelara®)

Ustekinumab (Stelara®) may increase the risk of infections and reactivation of latent infections. Serious bacterial, fungal, and viral infections, some requiring hospitalization, were reported. In patients with psoriasis, serious infections included diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis and urinary tract infections. In patients with psoriatic arthritis, serious infections included cholecystitis. In patients with Crohn's disease, serious or other clinically significant infections included anal abscess, gastroenteritis, ophthalmic herpes, pneumonia, and listeria meningitis. In patients with ulcerative colitis, serious or other clinically significant infections included gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

Patients should be evaluated for tuberculosis (TB) infection prior to initiating treatment with ustekinumab (Stelara®). It should not be given to patients with active TB. Anti-tuberculosis therapy should be considered in patients with a past history of latent or active tuberculosis when an adequate course of treatment cannot be confirmed prior to initiation of ustekinumab (Stelara®).

Ustekinumab (Stelara®) is an immunosuppressant and may increase the risk of malignancy.

Prior to initiating therapy with ustekinumab (Stelara®), patients should receive all immunizations appropriate for age as recommended by current immunization guidelines. Patients being treated with ustekinumab (Stelara®) should not receive live vaccines.

## Recommended Dosage and Administration

Plaque psoriasis:

- **Subcutaneous** adult dosing regimen
  - For patients 100 kg or less, the recommended dose is 45 mg subcutaneously initially and 4 weeks later, followed by 45 mg every 12 weeks
  - For patients greater than 100 kg, the recommended dose is 90 mg subcutaneously initially and 4 weeks later, followed by 90 mg every 12 weeks
  - In patients weighing more than 100 kg, 45 mg was also shown to be efficacious in clinical studies; however, 90 mg resulted in greater efficacy in these patients
- **Subcutaneous** pediatric (6-17 years old) dosing regimen
  - Administration is subcutaneously at weeks 0 and 4, then every 12 weeks thereafter
  - The recommended dosing regimen is weight-based, with patients weighing less than 60 kg receiving 0.75 mg/kg, 60 kg to 100 kg receiving 45 mg, and greater than 100 kg receiving 90 mg

Psoriatic arthritis:

- **Subcutaneous** adult dosing regimen
  - The recommended dosing regimen is 45 mg subcutaneously initially and 4 weeks later, followed by 45 mg subcutaneously every 12 weeks
  - For patients with coexisting moderate-to-severe plaque psoriasis weighing greater than 100 kg, the dose is 90 mg subcutaneously initially and 4 weeks later, followed by 90 mg every 12 weeks

Crohn's disease and ulcerative colitis:

- **Intravenous induction** adult dosing regimen
  - A single intravenous infusion dose using weight-based dosing is recommended, with patients weighing 55 kg or less receiving 260 mg, greater than 55 kg to 85 kg receiving 390 mg, and greater than 85 kg receiving 520 mg
- **Subcutaneous maintenance** adult dosing regimen
  - The recommended maintenance dosing regimen is a subcutaneous 90 mg dose given 8 weeks after the initial intravenous dose, then every 8 weeks thereafter

## **Billing/Coding/Physician Documentation Information**

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# Ustekinumab (Stelara<sup>®</sup>)

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: J3357, J3358*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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National Institutes of Health (NIH) Clinical Trial NCT01077362. A Study of the Safety and Efficacy of Ustekinumab in Patients With Psoriatic Arthritis With and Without Prior Exposure to Anti-TNF Agents. <http://clinicaltrials.gov/ct2/show/study/NCT01077362?term=Ustekinumab&rank=20>

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Specialty Matched Consultant Advisory Panel review 10/2020

## Policy Implementation/Update Information

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- 3/02/10 New policy issued. Ustekinumab (Stelara™) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis in patients who are 18 years of age or older; and have already been treated with phototherapy (i.e., PUVA or broadband or narrowband UVB) unless the patient is not a candidate for phototherapy or phototherapy is not available to the patient; and have already been treated with or are not a candidate for any other systemic treatments such as methotrexate (oral or IM), cyclosporin, and acitretin (Soriatane®). Notification date 3/02/10 for effective date of 6/08/10. (adn)
- 8/31/10 Billing Information updated to include code J3490. (mco)
- 1/1/11 J3490 and J3590 deleted from policy. New code specific to injection of Ustekinumab (Stelara™) added to Billing/Coding section: J3357. (mco)
- 2/15/11 Specialty Matched Consultant Advisory Panel review 1/2011. References updated. (mco)
- 7/1/11 Added quantity limitations to Policy Guidelines. Medical director review 6/2011. Notification date 7/1/11 for effective date of 10/1/11. (lpr)
- 2/7/12 Specialty Matched Consultant Advisory Panel review 1/2012. References updated. No changes to Policy Statements. (mco)
- 2/12/13 References updated. Updated related policies. Specialty Matched Consultant Advisory Panel review 1/2013. Trademark symbol ™ replaced throughout policy with Registered trademark symbol®. (mco)
- 7/16/13 Added the following statement to the Policy Guidelines section: “After proper training in subcutaneous injection technique, a patient may self inject with STELARA® if a physician determines that it is appropriate. The first self-injection should be performed under the supervision of a qualified healthcare professional. If a patient or caregiver is to administer STELARA®, he/she should be instructed in injection techniques and their ability to inject subcutaneously should be assessed to ensure the proper administration of STELARA®. Refer to the FDA Medication Guide for Stelara® at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/125261s086lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125261s086lbl.pdf)” References updated. Medical Director review 6/2013. (mco)
- 10/15/13 FDA prescribing information updated 9/2013. Description section updated. “When Covered” section updated to include the following statement: “Ustekinumab (Stelara®) may be considered medically necessary for the treatment of active psoriatic arthritis in patients who are 18 years of age or older. Ustekinumab (Stelara®) may be used alone or in

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combination with methotrexate for the treatment of active psoriatic arthritis.”  
References updated. Medical Director review 10/2013. (mco)

- 2/11/14 Specialty Matched Consultant Advisory Panel review 1/2014. Medical Director review 1/2014. No changes to Policy Statements. (mco)
- 5/27/14 “When Covered” section revised as follows: “Ustekinumab (Stelara™) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis in patients who are 18 years of age or older; and have already been treated with phototherapy (i.e., PUVA or broadband or narrowband UVB) unless the patient is not a candidate for phototherapy or phototherapy is not available to the patient; **or** have already been treated with or are not a candidate for any other systemic treatments such as methotrexate (oral or IM), cyclosporin, and acitretin (Soriatane®).” Medical Director review 5/2014. (mco)
- 3/31/15 References updated. Specialty Matched Consultant Advisory Panel review 1/2015. Medical Director review 1/2015. (td)
- 12/30/15 When Covered section revised to state, “Ustekinumab (Stelara®) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis in patients who are 18 years of age or older and: 1.one of the following: a)The patient has tried and failed, is intolerant to, or has a clinical contraindication to phototherapy (i.e., puva or broadband or narrowband uvb); or b) The patient has tried and failed, is intolerant to, or has a clinical contraindication to systemic therapy (methotrexate (oral or IM), cyclosporine, or acitretin); and 2. One of the following: a) The patient has Body Surface Area (BSA) involvement of at least 5%; OR b)The patient has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment AND 3.The patient is not using stelara in combination with another biologic agent AND 4.The patient is being managed by a dermatologist AND 5. If Stelara 90 mg is requested and the patient is new to therapy with Stelara, ONE of the following: a) The patient has a diagnosis of psoriasis AND the patient has failed (had an inadequate response to) a trial of 45mg for at least 3 months OR b)The patient weighs >100kg Ustekinumab (Stelara®) may be considered medically necessary for the treatment of active psoriatic arthritis in patients who are 18 years of age or older and:1.The patient has tried and failed, is intolerant to, or has a clinical contraindication to phototherapy (i.e., puva or broadband or narrowband uvb) and 2.The patient is not using stelara in combination with another biologic agent AND 3.If Stelara 90 mg is requested and the patient is new to therapy with Stelara, ONE of the following: a) The patient has a diagnosis of psoriasis AND the patient has failed (had an inadequate response to) a trial of 45mg for at least 3 months OR b)The patient has a dual diagnosis of psoriasis AND psoriatic arthritis AND the patient is >100kg . Medical Director review 1/2016. Specialty Matched Consultant Advisory Panel review 1/27/2016. **Policy noticed 2/29/2016 for effective date 4/29/16.** (td)
- 12/30/16 Policy updated to include new indication for treatment of Crohn’s Disease. Ustekinumab (Stelara®) may be considered medically necessary for the treatment of moderately to severely active Crohn’s disease in patients who are 18 years of age or older if: 1. The patient has tried and failed, is intolerant to, or has a clinical contraindication to conventional therapy (e.g., corticosteroids, 5-aminosalicylate, azathioprine, 6-mercaptopurine, metronidazole, methotrexate); AND 2. For patients new to therapy, therapy will begin with an initial intravenous infusion of Stelara; AND 3. The patient will not be treated with the 45mg injection; AND 4. In two months following the intravenous infusion of Stelara, the patient will begin therapy with subcutaneous injections of Stelara. Codes J3490, J3590, C9399 added to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 11/30/2016. (an)

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- 1/27/17 In the “When Covered” section regarding medical necessity of Stelara for the indication of active psoriatic arthritis, the requirement for prior phototherapy was deleted. (an)
- 3/31/17 Added code C9487 to Billing/Coding section. (an)
- 6/30/17 Effective July 1, 2017: code C9487 deleted from Billing/Coding section and code Q9989 added. (an)
- 12/15/17 The following statement was added to the covered indications: Ustekinumab (stelara®) may be considered medically necessary for the treatment of moderate to severe plaque psoriasis in adolescent patients, age 12 years or older, who are candidates for phototherapy or systemic therapy. Reference added. Codes C9487, Q9989 deleted. Code J3358 added. Specialty Matched Consultant Advisory Panel review 11/29/17. (an)
- 11/9/18 Updated Policy Guidelines section to provide clarification of dosing per specific indication. Added reference of policy “Measurement of Serum Antibodies to Infliximab, Adalimumab, Vedolizumab and Ustekinumab” to related policies in Description section. Minor typographical and grammatical changes made for clarity. References added. Specialty Matched Consultant Advisory Panel review 10/24/18. (krc)
- 10/29/19 Specialty Matched Consultant Advisory Panel review 10/16/2019. No change to policy intent. (krc)
- 2/11/20 New indication added to “When Covered” section for moderate to severe ulcerative colitis. Updated “Description” and “Policy Guidelines” sections with addition of new indication. Minor edits made throughout policy for clarity. Removed codes J3490, J3590, and C9399 from Billing/Coding section. References added. Medical Director review 1/2020. (krc)
- 11/10/20 Updated “When Covered” section for plaque psoriasis to include coverage for patients age 6 years and older. Minor edits made throughout policy for clarity. Reference added. Specialty Matched Consultant Advisory Panel review 10/21/2020. (krc)

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