Medical Coverage Policy | Ustekinumab (Stelara®)
Intravenous Use for Crohn's Disease

Blue Cross Blue Shield of Rhode Island

EFFECTIVE DATE: 04|01|2017
POLICY LAST UPDATED: 04|18|2017

OVERVIEW

This policy documents the coverage criteria for Ustekinumab (Stelara®) intraveneous use for the initial loading dose for Crohn's disease (CD). The maintenance dosage of Ustekinumab (Stelara) is given as a self-administered injection and it is covered as a pharmacy benefit.

MEDICAL CRITERIA

For the initial loading dose of Ustekinumab (Stelara) for moderate to severe Crohn's disease:

- The patient is 18 years of age or older

AND

- There is documentation in the medical record that the patient has had an inadequate response to one or more of the following conventional therapies or such therapy is contraindicated or not tolerated:
  - 5-Aminosalicylcates
  - Sulfasalazine (Azulfidine, Azulfidine EN-tabs)
  - Mesalamine (Asacol, Pentasa Lialda, Apriso)
  - Systemic corticosteroinds (e.g., prednisone)
  - Azathioprine (Imuran)
  - 6-Mercaptopurine
  - Methotrexate
  - Cyclosporine (Neoral, Sandimmune)
  - Antibiotics (e.g., metronidazole)

AND

- There is documentation in the medical record that the patient had an inadequate response, intolerance, or contraindication to ONE of the following medications: Humira (adalimumab), Cimzia (certilizumab pegol), Remicade (infliximab), Entyvio (vedolizumab), Tysabri (natalizumab)

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Ustekinumab (Stelara) for the initial intravenous loading dose for Crohn's disease is medically necessary when the medical criteria listed above have been met.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable infusion coverage/benefits.

Specialty Pharmacy

For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

BACKGROUND

Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with symptoms that often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. The treatment of Crohn's disease is focused on stopping the inflammation and preventing flare-ups. The type of treatment depends on the type and severity of symptoms. Mild symptoms may respond to an antidiarrheal medicine. Treatment for individuals who may be having mild to moderate symptoms include aminosalicylates and antibiotics whereas individuals with severe symptoms may be treated with corticosteroids, immunomodulators, or biologics.

Ustekinumab is a human IgG1 monoclonal antibody that binds with specificity to the p40 protein subunit used by both the 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. The cytokines IL-12 and IL-23 have been identified as contributors to the chronic inflammation that is a characteristic of Crohn's disease.

In September 2016, the U.S. Food and Drug Administration (FDA) approved Ustekinumab for use in adult patients with moderately to severely active Crohn's disease who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed, or were intolerant to treatment with one or more TNF blockers.

CODING

BlueCHiP for Medicare and Commercial Products
For claims with date of service prior to July 1, 2017:
When the medical criteria are met, claims must be filed with the appropriate unlisted HCPCS drug code and the 11-digit NDC number. Claims filed with C9487 for Ustekinumab, for intravenous injection, 1 mg will be denied as use alternate code.

For Claims with date of service on or after July 1, 2017:
The following code is medically necessary when the criteria are met:
Q9989 Ustekinumab, for Intravenous Injection, 1 mg (Code deleted 12/31/2017)
J3358 Ustekinumab, for intravenous injection, 1 mg (New code effective 1/1/2018)

RELATED POLICIES

None

PUBLISHED

Provider Update, June 2017

REFERENCES:

1. Stelara [Product Information], Horsham, PA. Janssen Biotech, Inc.; September 2016. Available at: https://www.stelarainfo.com/pdf/prescribinginformation