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

EFFECTIVE DATE: 06|01|2018
POLICY LAST UPDATED: 07|16|2019

OVERVIEW

This policy documents the coverage criteria for ustekinumab (Stelara®) intraveneous use for the initial loading dose for Crohn's disease (CD) that would be administered by a physician. The maintenance dosage of Ustekinumab (Stelara) is given as a self-administered injection and it is covered as a pharmacy benefit. Refer to member benefits for additional preauthorization requirements.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

For the initial loading dose (single treatment), ustekinumab (Stelara) for moderate to severe Crohn's disease is medically necessary when all of the following criteria are met:

- 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)

PRIOR AUTHORIZATION

Prior authorization is required for BlueCHiP for Medicare

POLICY STATEMENT

BlueCHiP for Medicare

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

Note: for additional coverage beyond the single treatment, refer to the member's pharmacy benefits for preauthorization requirements.

COVERAGE

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

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.

J3358 Ustekinumab, for intravenous injection, 1 mg

RELATED POLICIES

None

PUBLISHED

Provider Update, September 2019
Provider Update, June 2018
Provider Update, June 2017

REFERENCES:

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

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