Policy Title:	Stelara (ustekinumab) (IV)		
Policy Number:	000633	**Department:**	PHA
Effective Date:	12/12/2018		
Review Date:	12/12/2018		
Revision Date:	12/12/2019		

Purpose: To support safe, effective and appropriate use of Stelara (ustekinumab).

Scope: Medicaid, Exchange, Integrity

Policy Statement:

Stelara (ustekinumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Stelara (ustekinumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria Coverage:

- Patient is 18 years or older;
- Patient has documented moderate to severely active Crohn's disease;
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment;
- Patient is free of any clinically important active infections;
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast);
- Physician has assessed baseline disease severity utilizing an objective measure or tool;
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate);
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier (e.g. adalimumab, certolizumab, or infliximab)
- Dose is within FDA guidelines:

- ≤ 55 kg: 260 mg
- > 55 kg to 85 kg: 390 mg
- > 85 kg: 520 mg

Coverage durations:

- Once (one time dose) for 2 months
  ** For members that meet criteria, Stelara 90 mg (subcutaneous dose) will be approved for every 8 weeks thereafter for 4 months**

Investigational use: Stelara (ustekinumab) is considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in one of the above listed resources. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Additional information:

Indications (IV):

- indicated for the treatment of 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 treatment with a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF blockers

***Dosing*:**

- Intravenous Induction Dose (one-time only):
- ≤ 55 kg: 260 mg
- > 55 kg to 85 kg: 390 mg
- > 85 kg: 520 mg
- Subcutaneous Maintenance Dose: 90 mg given 8 weeks after the initial IV dose, then every 8 weeks thereafter

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis(specify substance or drug), initial, up to 1 hour
96366	Intravenous infusion ,Each additional hour
J3358	Injection, ustekinumab, 1mg

References:

1. Stelara package insert. Horsham, PA: Janssen Biotech, Inc.; June 2018.