Policy Title:	Stelara (ustekinumab) (IV)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	11/20/2019, 12/20/2019		
Revision Date:	12/20/2019		

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

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

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:

- Patient is 18 years or older; AND
- Patient has documented moderate to severely active Crohn's disease or documented moderate to severe Ulcerative Colitis; AND
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; AND
- Patient is free of any clinically important active infections; AND
- Patient is not on concurrent treatment with a TNF-inhibitor, biologic response modifier or other non-biologic agent (i.e., apremilast); AND
- Physician has assessed baseline disease severity utilizing an objective measure or tool; AND

Crohn's Disease:

- 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); AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial of a TNF modifier; OR

Ulcerative Colitis:

- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with ONE of the following conventional oral agents: mesalamine, corticosteroids, 6-mercaptopurine, or azathioprine; AND
- Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum (3) month trial on previous therapy with a TNF modifier such as adalimumab (Humira), golimumab (Simponi), or infliximab (Inflectra, Renflexis, Avsola, or Remicade); AND
- 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 for Medicaid and Exchange ONLY**

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = 1 mg)**
Crohn's Disease/ Ulcerative Colitis	Intravenous Induction Dose (one-time only): • ≤ 55 kg: 260 mg • 55 kg to 85 kg: 390 mg • > 85 kg: 520 mg	Intravenous Induction (J3358): 520 billable units

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

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
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg

References:

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