Clinical Oversight Review Board (CORB) Criteria for Prescribing

Ustekinumab IV (Stelara IV)

Notes:

- Quantity Limits: No (N/A – IV medication)
- Note: Quantity limits do apply to subcutaneous ustekinumab
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- **Trial of a second TNF-inhibitor is NOT required if the patient experienced primary or secondary treatment failure with the first TNF-inhibitor despite a therapeutic drug level

Non-Formulary **ustekinumab IV (Stelara IV)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **ustekinumab IV (Stelara IV)** will be covered under the medical benefit for 1 dose when the following criteria are met:

1. Patient has a diagnosis of moderate to severe Crohn's disease
- Prescriber is a gastroenterologist
- Patient has failed an adequate trial of, or patient has an allergy or intolerance* to the following:
  - At least 2 tumor necrosis factor (TNF)-inhibitors**
    - Infliximab product
    - Adalimumab product (criteria based)
    - Certolizumab (criteria based)

2. Patient has a diagnosis of moderate to severe ulcerative colitis
- Prescriber is a gastroenterologist
- Patient has failed an adequate trial of, or patient has an allergy or intolerance* to all of the following:
  - Infliximab product
  - Tofacitinib (criteria based)