Palmetto Infusion Services
COMPLIANCE

MRN:_____

Phone: 1-800-809-1265 Fax: 1-866-872-8920

DOB: _____

STANDARD Stelara® (ustekinumab) PLAN OF TREATMENT FOR GASTROENTEROLOGY

(Re) Certification Period From_____**to** _____

NOTE: Patient ***may be ineligible*** to receive ustekinumab if receiving antibiotics for active infectious process, antifungal therapy, active fever and/or suspected infection, new-onset or deterioration neurological changes, and/or surgery.

1. Patient Name:_____Height (inches):_____Weight (lbs):_____

2. Allergies: _____

3. Diagnosis: *** Please complete the 2nd and 3rd digits to complete the ICD-10 code for billing**

☐ **K50.0**_____Crohn's Disease (small intestine) ☐ **K50.8**_____Crohn's Disease (small & large intestine)

☐ **K50.1**_____Crohn's Disease (large intestine) ☐ **K50.9**_____**Crohn's Disease, Unspecified**

☐ Other **ICD-10 Code**:_____**Diagnosis description:** _____

4.* Pre-medications:** ☐ None ***OR Administered 30 minutes prior to infusion as selected:

****Product information does not suggest premedication***

Acetaminophen:
- □ 650 mg PO
- □ 500 mg PO
- □ 325 mg PO

Diphenhydramine: □ 25 mg PO, □ 50 mg PO, □ 25 mg IVP, □ 50 mg IVP or
Fexofenadine □ 60 mg or □ 180 mg, □ Cetirizine 10 mg, □ Loratadine 10 mg
Methylprednisolone □ 40 mg IVP □ 125 mg IVP or other_____mg IVP
Famotidine: □ 20 mg PO, □ 40 mg PO, □ 20 mg IVP, □ 40 mg IVP

Pre-medicate with other: _____

Dose:

☐ Stelara® (ustekinumab) Single IV induction dose per 250 ml Sodium Chloride 0.9% IV to infuse over at least 1 hour with 0.22-micron filter

Stelara® (ustekinumab) dose will be based on the following guidelines as provided by Janssen Biotech, Inc.

Body Weight of Patient	Dose	Number of 130mg/26 ml (5mg/ml) Stelara® Vials
less than 55kg	260 mg	2
55-85 kg	390	3
greater than 85kg	520 mg	4

☐ Maintenance adult dosage: STELARA® 90 mg Subcutaneous 8 weeks after initial IV dosing and every 8 weeks thereafter. (*Administer as subcutaneous injection to upper arm, thigh, or abdomen.) Service provided in ambulatory infusion center after insurance approval.*

Special orders: _____

If adverse drug reaction occurs, utilize the ADVERSE DRUG REACTION GUIDELINES

5. Physician's Signature:_____/_____Date: _____

No Stamp Signatures (Dispense as written) (Substitution permitted)

Printed Physician's Name with Credentials:_____NPI: _____

6. Fax updated supporting clinical MD notes with each order renewal or change in orders

Infusion order forms and Adverse Drug Reaction Guidelines are available at www.palmettoinfusion.com

Revised 12/18/18

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DOB: _____

Guidelines for Prescribing Stelara® (ustekinumab)

(Required documentation with all initial referrals)

Patient Name:_____ **Referral Date:** _____

____ Include signed and completed **Plan of Treatment**. *(MD must complete sections 1-6)*
(Infusion order forms & Standard Adverse Reactions orders are available at www.palmettoinfusion.com under Agency/MD tab)

____ Include patient demographic information and insurance information. (Copy of insurance cards if available)

____ **Supporting clinical MD notes to include any past tried and/or failed therapies, intolerance, outcomes or contraindications to conventional therapy. Include any lab results and/or tests to support diagnosis.**

- STELARA® (ustekinumab) is indicated for the treatment of adult patients with moderately to severely active Crohn's disease who have: failed/intolerant to treatment with immunomodulators or corticosteroids, but never failed treatment with a tumor necrosis factor (TNF) blocker, or failed/intolerant to treatment with one or more TNF blockers.

____ If patient is switching biological therapies, then MD must specify wash-out period prior to starting Stelara® as specified of_____weeks. Last known biological therapy:_____and last date received:_____.

____ Other as requested: _____

_____

_____

Pre-Screening: **(TB and Hepatitis screening results must be available prior to start of therapy and within last 12 months.)**

____ **Required TB screening results: PPD or QuantiFERON Gold Test.**
(* If screening results are positive or indeterminate, then a negative CXR result is required.)

____ **Required Hepatitis screening to include: Hepatitis B Surface Antigen results.**

** Warnings/Precautions: **Serious Infections:** STELARA® (ustekinumab) may increase the risk of infections and reactivation of latent infections. In patients with Crohn's disease, serious or other clinically significant infections included anal abscess, gastroenteritis, ophthalmic herpes, pneumonia, and *Listeria meningitis*. **Reversible Posterior Leukoencephalopathy Syndrome (RPLS):** One case of reversible posterior leukoencephalopathy syndrome (RPLS) was observed in clinical studies of psoriasis and psoriatic arthritis. No cases of RPLS were observed in clinical studies of Crohn's disease. If RPLS is suspected, administer appropriate treatment and discontinue STELARA®. RPLS is a neurological disorder, which can present with headache, seizures, confusion, and visual disturbances. RPLS has been associated with fatal outcomes. Evaluation of immunizations should be completed prior to and live vaccines should not be given before or concurrently with STELARA ®. See full prescribing information.

Palmetto Infusion Services will complete insurance verification and submit all required clinical documentation to the patient's insurance company for eligibility. Our office will notify you if any further information is required. We will review financial responsibility with the patient and refer them to any available Co-pay assistance as required. Thank you for the referral.

Please fax all information to 1-866-872-8920 or call 1-800-809-1265 for assistance.

Revised 6/4/18