



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

MRN: \_\_\_\_\_

DOB: \_\_\_\_\_

## STANDARD Stelara® (ustekinumab) PLAN OF TREATMENT FOR GASTROENTEROLOGY

**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 2<sup>nd</sup> and 3<sup>rd</sup> 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:** \*For IV dose only Administered 30 minutes prior to infusion as selected:

*\*Product information does not suggest premedication*

Acetaminophen: <input type="checkbox"/> 650 mg PO <input type="checkbox"/> 500 mg PO <input type="checkbox"/> 325 mg PO	Diphenhydramine: <input type="checkbox"/> 25 mg PO, <input type="checkbox"/> 50 mg PO, <input type="checkbox"/> 25 mg IVP, <input type="checkbox"/> 50 mg IVP or Fexofenadine <input type="checkbox"/> 60 mg or <input type="checkbox"/> 180 mg, <input type="checkbox"/> Cetirizine 10 mg, <input type="checkbox"/> Loratadine 10 mg Methylprednisolone <input type="checkbox"/> 40 mg IVP <input type="checkbox"/> 125 mg IVP or other _____ mg IVP Famotidine: <input type="checkbox"/> 20 mg PO, <input type="checkbox"/> 40 mg PO, <input type="checkbox"/> 20 mg IVP, <input type="checkbox"/> 40 mg IVP
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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 (Substitution

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](http://www.palmettoinfusion.com)*



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### 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](http://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

\_\_\_\_\_ 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.**