STELARA
(ustekinumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Stelara is a biologic medicine that targets an underlying cause of psoriatic arthritis and plaque psoriasis, an overactive immune system. Psoriatic arthritis and plaque psoriasis is caused by inflammation due to high levels of 2 proteins (IL-12 and IL-23) found in the blood. Similarly, the cytokines IL-12 and IL-23 have been implicated as important contributors to the chronic inflammation that is a hallmark of Crohn’s Disease. Stelara targets these 2 proteins and reduces inflammation which relieves symptoms of joint pain, swelling, stiffness, plaque thickness, scaling, and redness in psoriatic arthritis and plaque psoriasis, and has been shown to significantly decrease disease activity in patients with moderately to severely active Crohn’s Disease (1).

Regulatory Status
FDA- approved indication: Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of adult patients with: (1)
1. Moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy
2. Active psoriatic arthritis (PsA), alone or in combination with methotrexate
3. Moderately to severely active Crohn’s disease (CD) who have
   a. Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or
   b. Failed or were intolerant to treatment with one or more TNF blockers
4. Adolescent patients (12 years or older) with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy

Stelara may increase the risk of infections and reactivation of latent infections such as bacterial, fungal, and viral infections. Stelara should not be given to patients with any clinically important active infection until the infection resolves or is adequately treated. Serious infections that require hospitalization may occur such as diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, and cholecystitis (1).

Evaluate patients for tuberculosis infection prior to initiating treatment with Stelara. Do not administer Stelara to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to
administering Stelara. Consider anti-tuberculosis therapy prior to initiation of Stelara in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Stelara should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1).

Stelara is an immunosuppressant and may increase the risk of malignancy. Malignancies were reported among subjects who received Stelara. There have been post marketing reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving Stelara who had pre-existing risk factors for developing non-melanoma skin cancer. All patients receiving Stelara should be monitored for the appearance of non-melanoma skin cancer. Patients greater than 60 years of age, those with a medical history of prolonged immunosuppressant therapy and those with a history of PUVA treatment should be followed closely (1).

Safety and effectiveness of Stelara in pediatric patients less than 18 years of age have not been established (1).

**Summary**

Stelara is a human interleukin-12 and -23 antagonist indicated for the treatment of patients with moderate to severe plaque psoriasis (Ps) who are candidates for phototherapy or systemic therapy and for the treatment for active psoriatic arthritis (PsA), alone or in combination with methotrexate. Additionally, Stelara is also indicated for patients with moderately to severely active Crohn’s disease (CD). Stelara may increase the risk of infections and reactivation of latent infections such as bacterial, fungal, and viral infections. Stelara should not be given to patients with any clinically important active infection until the infection resolves or is adequately treated. Stelara should not be administered to patients with active TB. Stelara may increase the risk of malignancy (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Stelara while maintaining optimal therapeutic outcomes.

**References**