



Prior Authorization Approval Criteria

Stelara (ustekinumab)

Generic name:	Ustekinumab
Brand name:	Stelara
Medication class:	Immunologic Agent
FDA-approved uses:	Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
Available dosage forms:	45mg and 90mg single use vials for injection
Usual dose:	Stelara is administered by subcutaneous injection. For patients weighing ≤ 100 kg = 45mg initially and 4 weeks later, followed by 45mg every 12 weeks For patients weighing > 100 kg = 90mg initially and 4 weeks later, followed by 90mg every 12 weeks
Approximate yearly cost: (based on AWP 2009)	For patients ≤ 100 kg - \$27,978.00/year (the first year would be about \$33,573.00 since they receive an induction dose at 0 and 4 weeks.) For Patients > 100 kg - \$55,956.00/year
Duration of therapy:	Indefinite

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must be clinically diagnosed with moderate to severe plaque psoriasis.
- Must be a candidate for phototherapy or systemic therapy
- Must have tried and failed or intolerant to at least one corticosteroid.
- Must have tried and failed or intolerant to methotrexate
- Must have tried and failed or intolerant to Enbrel and Humira.
- Must be 18 years of age or older.
- Must have a negative tuberculosis test or received treatment if tested positive.

Caution:

- Increased risk of serious infections.
- Increased risk of cancer.

Contraindication:

- None known at this time.

Not approved if:

- Patient does not meet the above stated criteria.

Special considerations:

- Stelara is not approved for self-injection.

- Cancer might be a bigger concern with Stelara than the other TNF inhibitors
- Might be a better option in patients who can't take other TNF inhibitors due to demyelinating disease (multiple sclerosis, ect) or heart failure.
- Stelara will carry a REMS (Risk Evaluation and Mitigation Strategy).

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 03/10/10

Revised: 03/14/12