UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Stelara -ARIZONA

Program	Prior Authorization
Medication	Stelara (ustekinumab)

1. Background:

Stelara (ustekinumab) is a human interleukin-12 and -23 antagonist indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. It is also indicated for active psoriatic arthritis, alone or in combination with methotrexate. In addition, it is also indicated for moderately to severely active Crohn's disease in patients who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or patients who have failed or were intolerant to treatment with one or more TNF blockers.

Stelara IV is not a pharmacy benefit for the UnitedHealthcare Community Plan

2. Coverage Criteria:

A. <u>Plaque Psoriasis</u>

1. <u>Initial Authorization</u>

a. Diagnosis of moderate to severe plaque psoriasis

-AND-

b. Prescribed or recommended by a dermatologist

-AND-

c. Patient is not receiving Stelara in combination with any of the following:

(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. One of the following:

(1) History of failure, contraindication, or intolerance to both of the following:

(b) Humira (adalimumab)
(c) Enbrel (etanercept)

-OR-

(2) For continuation of prior Stelara therapy

-AND-

e. One of the following:

(1) Requested medication is Stelara 45 mg/0.5 mL

-OR-

(2) Both of the following:

(a) Requested medication is Stelara 90 mg/1 mL

-AND-

(b) Patient's weight is > 100 kg (220 lbs)

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Stelara therapy

-AND-

b. Patient is not receiving Stelara in combination with any of the following:

(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. Initial Authorization

a. One of the following:

(1) Both of the following:

(a) Requested medication is Stelara 45 mg/0.5 mL

-AND-

(b) Diagnosis of active psoriatic arthritis

-OR-

(2) All of the following:

(a) Requested medication is Stelara 90 mg/1 mL

-AND-

(b) Patient's weight is > 100 kg (220 lbs)

-AND-

(c) Diagnosis of active psoriatic arthritis

-AND-

(d) Diagnosis of co-existent moderate to severe psoriasis

-AND-

b. Prescribed or recommended by a rheumatologist or dermatologist

-AND-

c. Patient is not receiving Stelara in combination with any of the following:

(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

d. One of the following:

(1) History of failure, contraindication, or intolerance to all of the following:

(a) Humira (adalimumab)
(b) Enbrel (etanercept)

-OR-

(2) For continuation of prior Stelara therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Stelara therapy

-AND-

b. Patient is not receiving Stelara in combination with any of the following:

(1) Biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(2) Janus kinase inhibitor [eg, Xeljanz (tofacitinib)]
(3) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Crohn's Disease (CD)

1. Initial Authorization for Maintenance Dosing

a. Stelara 90 mg/1 mL will be approved based on **all** of the following criteria:

(1) Diagnosis of moderately to severely active Crohn's disease

-AND-

(2) **One** of the following:

(a) History of failure, contraindication or intolerance to Humira (adalimumab)

-OR-

(b) For continuation of prior Stelara therapy

-AND-

(3) Patient is not receiving Stelara in combination with **any** of the following:

(a) Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(4) Prescribed by or in consultation with a gastroenterologist

Authorization will be issued for 12 months.

2. Reauthorization

(1) Documentation of positive clinical response to Stelara therapy

-AND-

(2) Patient is not receiving Stelara in combination with **any** of the following:

(a) Biologic DMARD [e.g., Remicade/Inflectra (infliximab), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus Kinase Inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

Authorization will be issued for 12 months.

3. References:

1. Stelara Prescribing Information. Centocor Ortho Biotech Inc., September 2013.
2. Griffiths CEM, Strober BE, van der Kerkhof P, et al. Comparison of ustekinumab and etanercept for moderate-to-severe psoriasis. N Engl J Med. 2010;362:118-28.
3. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol. 2008;58:826-50.
4. Krader CG. Ustekinumab demonstrates safety, efficacy in psoriasis treatment trials. Dermatology Times; published on January 1, 2011. Available at: http://www.modernmedicine.com/modernmedicine/Modern+Medicine+Now/Ustekinumab-demonstrates-safety-efficacy-in-psoria/ArticleStandard/Article/detail/702769. January 17, 2013.

5. Menter, A, Korman N, Elmets C, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis section 6. Case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011;64(1):137-174.
6. Griffiths CEM, Strober BE, van de Kerkhof P, Ho V, et al. Comparison of ustekinumab and etanercept for moderate-to-severe psoriasis. N Engl J Med. 2010;362:118-128.
7. Ryan C, Leonardi CL, Kueger JG, Kimball AB, et al. Association between biologic therapies for chronic plaque psoriasis and cardiovascular events: a meta-analysis of randomized controlled trials. JAMA. 2011;306(8):864-871.
8. Per clinical consult with psoriasis specialist, January 3, 2012.
9. Papp KA, Griffiths CE, Gordon K et al. Long-term safety of ustekinumab in patients with moderate-to-severe psoriasis: final results from 5 years of follow-up. Br J Dermatol. 2013;168(4):844-854
10. Tzellos T, Kyrgidis A, Trigoni A, Zouboulis CC. Association of ustekinumab and briakinumab with major adverse cardiovascular events. Dermatoendocrinol. 2012;4(3):320-3
11. Per clinical consult with dermatology specialist, April 18, 2013.
12. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012;148(1):95-102

Program	Program type – Prior Authorization
Change Control	
Date	Change
August 2017	New policy specific to Arizona.