BlueCross BlueShield
Federal Employee Program

Stelara (ustekinumab)
Pyzchiva* (ustekinumab-ttwe)
Selarsdi* (ustekinumab-aekn)

*These medications are included in this policy but are not available on the market as of yet

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Stelara and its biosimilars are human interleukin-12 (IL-12) and interleukin-23 (IL-23) antagonists indicated for the treatment of plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Stelara and its biosimilars targets IL-12 and IL-23, reducing inflammation and relieving 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 and ulcerative colitis (1-3).

Regulatory Status

FDA-approved indications: Stelara and its biosimilars are human interleukin-12 and -23 antagonists indicated for the treatment of: (1-3)

Adult patients with:

1. Moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy
2. Active psoriatic arthritis (PsA)
3. Moderately to severely active Crohn's disease (CD)
4. Moderately to severely active ulcerative colitis (UC)

Pediatric patients 6 years and older with:

1. Moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy
2. Active psoriatic arthritis (PsA)

Stelara and its biosimilars may increase the risk of infections and reactivation of latent infections such as bacterial, fungal, and viral infections. Stelara and its biosimilars 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, sepsis, and cholecystitis (1-3).

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Evaluate patients for tuberculosis infection prior to initiating treatment with Stelara or its biosimilars. Do not administer Stelara or its biosimilars to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering Stelara or its biosimilars. Consider anti-tuberculosis therapy prior to initiation of Stelara or its biosimilars in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Stelara or its biosimilars should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1-3).

Stelara and its biosimilars are immunosuppressants and may increase the risk of malignancy. Malignancies were reported among subjects who received Stelara or its biosimilars. There have been post-marketing reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving Stelara or its biosimilars who had pre-existing risk factors for developing non-melanoma skin cancer. All patients receiving Stelara or its biosimilars 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 (1-3).

Safety and effectiveness of Stelara and its biosimilars in pediatric patients less than 6 years of age with plaque psoriasis have not been established (1-3).

Safety and effectiveness of Stelara and its biosimilars in pediatric patients less than 18 years of age with psoriatic arthritis, Crohn’s disease, or ulcerative colitis have not been established (1-3).

Summary

Stelara and its biosimilars are human interleukin-12 (IL-12) and interleukin-23 (IL-23) antagonists indicated for the treatment of plaque psoriasis, psoriatic arthritis, Crohn’s disease, and ulcerative colitis. Stelara and its biosimilars target IL-12 and IL-23, reducing inflammation and relieving symptoms of joint pain, swelling, stiffness, plaque thickness, scaling, and redness in psoriatic

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arthritis and plaque psoriasis, and have been shown to significantly decrease disease activity in patients with moderately to severely active Crohn's disease and ulcerative colitis. Stelara and its biosimilars may increase the risk of infections and reactivation of latent infections such as bacterial, fungal, and viral infections. Stelara and its biosimilars should not be given to patients with any clinically important active infection until the infection resolves or is adequately treated. Stelara and its biosimilars should not be administered to patients with active TB. Stelara and its biosimilars may increase the risk of malignancy (1-3).

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

References

1. Stelara [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2024.
2. Selarsdi [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2024.
3. Pyzchiva [package insert]. Princeton, NJ: Sandoz Inc.; June 2024.