gainwell

Cytokine and CAM Antagonists: Miscellaneous Utilization Management Criteria

Therapeutic Class:	Cytokine and CAM Antagonists: Miscellaneous
Non-Preferred Agents:	Entyvio (vedolizumab), Orencia (abatacept) vial, Otezla XR (apremilast), Sotyktu (deucravacitinib), Spevigo (spesolimab-sbzo), Uplizna (inebilizumab-cdon), Velsipity (etrasimod)
Preferred Agents:	Orencia (abatacept) Clickject/syringe, Otezla (apremilast)
Implementation Date:	1/1/2026
Prepared For:	CT
PDL Status:	Non-preferred
Purpose:	The targeted immune modulators included in this criteria are a heterogenous group of medications designed and approved to target specific disease states. Through a variety of mechanisms of action these drugs work to regulate the immune response and by addressing autoimmune and chronic inflammatory diseases. Approved uses for these agents include rheumatoid arthritis (abatacept), polyarticular juvenile idiopathic arthritis (abatacept), psoriatic arthritis (abatacept and apremilast), plaque psoriasis (apremilast and deucravacitinib), generalized pustular psoriasis (spesolimab), Crohn's disease (vedolizumab), ulcerative colitis (vedolizumab and etrasimod), oral ulcers associated with Behçet's Disease (apremilast), prophylaxis of acute graft-versus-host disease (abatacept), neuromyelitis optima spectrum disorder (inebilizumab), and immunoglobulin G4-related disease (inebilizumab) .

Generic Name	Brand Name	Approved Indications	Route of Administration	Biosimilar/Generic Availability
Abatacept	Orencia®, Orencia® Clickject™	RA, pJIA, PsA, prophylaxis of GVHD	IV, SC	No
Apremilast	Otezla®	PSA, PsO, oral ulcers of Behçet's Disease	PO	No
Deucravacitinib	Sotyktu™	PsO	PO	No
Etrasimod	Velsipity™	UC	PO	No
Inebilizumab	Uplizna®	NMOSD, IgG4-RD	IV	No
Spesolimab-sbzo	Spevigo®	GPP	IV, SC	No
Vedolizumab	Entyvio®	CD, UC	IV, SC	No

Abbreviations: CD, Crohn disease; GPP, generalized pustular psoriasis; GVHD, graft versus host disease; IV, intravenous; NMOSD, neuromyelitis optica spectrum disorder; pJIA, polyarticular juvenile idiopathic arthritis; PO, orally; PSA, psoriatic arthritis; PsO, plaque psoriasis; RA, rheumatoid arthritis; SC, subcutaneous; UC, ulcerative colitis

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes.

General Approval Criteria:

- Claim is for preferred agent **OR**
- Requested quantity in accordance with FDA approved product labelling
- For specific formulation requests
    - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
    - **For generic requests when a therapeutically equivalent brand is preferred:** Provider must provide a documented medical reason the preferred brand formulation cannot be used
    - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Initial Therapy – All the following must be met:

- **For Entyvio**
    - Prescribed by or in consultation with a gastroenterologist
    - Diagnosis of moderately to severely active ulcerative colitis **OR** moderately to severely active Crohn's disease
    - Trial of a preferred tumor necrosis factor inhibitor (TNFi)(30 days) or preferred ustekinumab biosimilar **OR** documented adverse event/adverse reaction or contraindication
    - Patient age is 18 years and older
- **For Orencia vials**
    - Prescribed by or in consultation with a specialist familiar with the treated disease state
    - Not used in combination with other potent immunosuppressants (i.e. biologic disease-modifying antirheumatic drugs or Janus kinase inhibitors)
    - Patient has been screened for tuberculosis (TB)
    - For use in the prophylaxis of graft-versus-host disease
        - Patient age is 2 years and older
        - Must use in combination with a calcineurin inhibitor and methotrexate
        - Documentation patient is undergoing hematopoietic stem cell transplantation
    - For all other approved indications: must provide medical reason patient cannot use Orencia Clickject or syringe **OR** documented trial and failure of preferred Orencia product
- **For Otezla XR**
    - Prescribed by or in consultation with a specialist familiar with the treated disease state
    - Diagnosis of:
        - Adult patients – One of the following
            - Active psoriatic arthritis
            - Plaque psoriasis in patients who are candidates for phototherapy or systemic therapy
            - Oral ulcers associated with Behçet's disease
        - Pediatric patients 6 years of age and older and weighing 50 kg or more– One of the following
            - Active psoriatic arthritis
            - Moderate to severe plaque psoriasis in patients who are candidates for phototherapy or systemic therapy

- Trial of a preferred Otezla formulation (30 days)
- Documented medical reason preferred Otezla formulation cannot be used

- **For Sotyktu**
  - Prescribed by or in consultation with a dermatologist
  - Diagnosis of moderate to severe plaque psoriasis
  - Patient is a candidate for systemic therapy or phototherapy
  - Not used in combination with other potent immunosuppressants
  - Patient has been screened for tuberculosis (TB)
  - Liver function tests confirm patient does NOT have severe hepatic impairment (Child-Pugh C), *claim will deny if present as Sotyktu is not recommended in patients with severe hepatic impairment*
  - Trial of a preferred tumor necrosis factor inhibitor (TNFi)(30 days) or preferred ustekinumab biosimilar **OR** documented adverse event/adverse reaction or contraindication
  - Patient age is 18 years and older
- **For Spevigo**
  - Prescribed by or in consultation with a dermatologist or other specialist familiar with the treated disease state
  - Diagnosis of generalized pustular psoriasis (GPP)
  - Patient has been screened for tuberculosis (TB)
  - Patient age is 12 years and older
  - Patient weighs at least 40 kg
  - Intravenous formulation is limited to treatment of acute flares
    - Approval limited to 1 month for flares
  - Subcutaneous formulation is limited to use in the prevention of flares
- **For Uplizna**
  - Prescribed by or in consultation with a specialist familiar with the treated disease state
  - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive **OR** immunoglobulin G4-related disease (IgG4-RD)
  - For immunoglobulin G4-related disease
    - Patient has experienced a prior disease flare requiring treatment with corticosteroids **OR** has had an adverse reaction/adverse event or contraindication to corticosteroids
  - Patient does not have active hepatitis B, active or untreated latent tuberculosis, or other active infections
  - Patient age is 18 years and older
- **For Velsipity**
  - Prescribed by or in consultation with a gastroenterologist
  - Diagnosis of moderately to severely active ulcerative colitis
  - Patient has not experienced myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the last 6 months
  - Patient does not have a history or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.
  - Trial of a preferred tumor necrosis factor inhibitor (TNFi)(30 days) or preferred ustekinumab biosimilar **OR** documented adverse event/adverse reaction or contraindication

- The following assessments have been completed prior to initiation
  - Complete blood count
  - Cardiac evaluation
  - Liver function tests
  - Ophthalmic assessment
- Patient age is 18 years and older

Initial PA length: 1 year (1 month for Spevigo IV dosing indicated for flares)

Exclusion Criteria: Approval criteria not met

Continuation Therapy: Documented compliance on current therapy regimen **AND** Documented continued clinical benefit **AND**

- For specific formulation requests
  - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
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  - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Continuation Length: 1 year

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Revision History

Date	Version	Revisions
11/7/2025	V1	Document approved by DSS

