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Subject: Guselkumab (Tremfya®) Injection

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DESCRIPTION:

Guselkumab (Tremfya) is an injectable human monoclonal antibody that selectively binds to the p19 subunit of interleukin 23 (IL-23) and inhibits its interaction with the IL-23 receptor. Guselkumab inhibits the release of proinflammatory cytokines and chemokines mediated by IL-23. Guselkumab was first approved by the US Food and Drug Administration (FDA) in July 2017 for "the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy." Guselkumab was the first biologic agent that specifically targets the IL-23 pathway to be approved by the FDA for the treatment of plaque psoriasis. Ustekinumab (Stelara) was FDA-approved for plaque psoriasis in 2009, but inhibits both IL-12 and IL-23 via the p40 subunit found on both interleukins. In July 2020, the FDA approved the additional indication of treatment of adult patients with active psoriatic arthritis. In September 2024, the FDA approved a new indication for the treatment of moderately to severely active ulcerative colitis (UC) in adults. A new intravenous (IV) formulation of guselkumab was also approved at this same time. The treatment of UC requires three IV induction doses.

Psoriatic Arthritis (PsA)

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis, most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis, particularly spondyloarthritis and RA, and other management strategies of the cutaneous manifestations of psoriasis.

The American Academy of Dermatology (AAD) recommends initiating MTX in most patients with moderate to severe PsA. After 12 to 16 weeks of MTX therapy with appropriate dose escalation, the

AAD recommends adding or switching to a TNF inhibitor if there is minimal improvement on MTX monotherapy.

The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and the following:

- Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient and health care provider to be due to PsA based on the presence of one of the following:
    - Actively inflamed joints
    - Dactylitis
    - Enthesitis
    - Axial disease
    - Active skin and/or nail involvement
    - Extraarticular manifestations such as uveitis or inflammatory bowel disease
- Disease severity includes level of disease activity at a given time point and the presence/absence of poor prognostic factors and long-term damage
- Severe PsA disease includes the presence of 1 or more of the following:
    - Erosive disease
    - Elevated markers of inflammation (ESR, CRP) attributable to PsA
    - Long-term damage that interferes with function (i.e., joint deformities)
    - Highly active disease that causes a major impairment in quality of life
    - Active PsA at many sites including dactylitis, enthesitis
    - Function limiting PsA at a few sites
    - Rapidly progressive disease
- Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, local glucocorticoid injections
- Treatment recommendations for active disease:
    - Treatment naïve patients first line options include oral small molecules (OSM), TNF biologics, IL-17 inhibitor, and IL-12/23 inhibitor
        - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe psoriasis, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitor
        - Biologics (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe psoriasis
    - Previous treatment with OSM and continued active disease:

        - Switch to a different OSM (except apremilast) in patients without severe PsA or severe PS, contraindications to TNF biologics, prefers oral therapy OR add on apremilast to current OSM therapy
        - May add another OSM (except apremilast) to current OSM therapy for patients that have exhibited partial response to current OSM in patients without severe PsA or severe PS, contraindications to TNF biologics, or prefers oral therapy
        - Biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) monotherapy
    - Previous treatment with a biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) and continued active disease:
        - Switch to another biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) monotherapy or add MTX to the current TNF biologic

Psoriasis (PS)

Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful.

Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.

The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:

- Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face):
    - Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac)
    - Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus)
- Severe (5% or more of BSA or involving the genitals, hands, feet, and face):
    - Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids
    - 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA
- Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin

The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes intractable pruritus. The AAD psoriasis treatment guidelines recommend the following:

- Mild to moderate disease (less than 5% of BSA):
  - Topical corticosteroids (strength of recommendation A)
  - Off-label use of 0.1% tacrolimus for psoriasis involving the face as well as inverse psoriasis (strength of recommendation B)
  - Long-term use (up to 52 weeks) of topical vitamin D analogs including calcipotriene, calcitriol, tacalcitol, and maxacalcitol (strength of recommendation A)
  - Use of calcipotriene foam and calcipotriene plus betamethasone dipropionate gel for the treatment of mild to moderate scalp psoriasis (strength of recommendation A)
  - Use of tacalcitol ointment or calcipotriene combined with hydrocortisone for facial psoriasis (strength of recommendation B)
  - Vitamin D analogs in combination with topical corticosteroids (strength of recommendation A)
  - Topical tazarotene alone or in combination with narrowband ultraviolet B (NB-UVB) (strength of recommendation B), or topical corticosteroids (strength of recommendation A)
  - Topical salicylic acid alone or in combination with topical corticosteroids (strength of recommendation B)
  - Coal tar preparations (strength of evidence A)
- Moderate to severe disease without PsA (5% or more of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
  - Methotrexate (adults) (strength of evidence A)
  - Methotrexate is less effective than TNF-inhibitors (strength of evidence B)
  - Combination therapy with methotrexate and NB-UVB (adult patients) (strength of evidence B)
  - Cyclosporine for patients with severe, recalcitrant (strength of recommendation A), erythrodermic, generalized pustular, and/or palmoplantar psoriasis (strength of recommendation B)
  - Acitretin as monotherapy or in combination with psoralen plus ultraviolet light (PUVA) or broad band ultraviolet light (BB-UVA [strength of evidence B])
  - If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
  - Apremilast (strength of recommendation A)
  - TNF-α inhibiters monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence B) or in combination with acitretin (strength of evidence C)
  - TNF-α inhibitors should be considered as a preferred treatment option for patients with concomitant PsA
  - Infliximab (strength of evidence A)
  - IL-12/IL-23 Inhibitors monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence C) or in combination with acitretin or methotrexate (strength of evidence B)

- IL-12/IL-23 inhibitors in combination with apremilast or cyclosporine (strength of evidence C)
- IL-17 inhibitors monotherapy (strength of evidence A)
- IL-23 inhibitors monotherapy for moderate to severe plaque psoriasis or as monotherapy for generalized pustular psoriasis (strength of evidence B)

*Strength of recommendation and descriptions

Strength of recommendation	Description
A	Recommendation based on consistent and good-quality patient-oriented evidence
B	Recommendation based on inconsistent or limited-quantity patient-oriented evidence
C	Recommendation based on consensus, opinion, case studies, or disease-oriented evidence

Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA. Primary failure is defined as initial nonresponse to treatment. Primary failure to a TNF-α inhibitor does not preclude successful response to a different TNF-α inhibitor. Failure of another biologic therapy does not preclude successful response to ustekinumab.

The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:

- The preferred assessment instrument for determining disease severity is BSA
- Target response after treatment initiation should be BSA ≤1% after 3 months
- Acceptable response is either a BSA ≤3% or a BSA improvement ≥75% from baseline at 3 months after treatment initiation

INFLAMMATORY BOWEL DISEASE

Ulcerative Colitis (UC)

Ulcerative colitis (UC) is a chronic immune-mediated inflammatory condition affecting the large intestine associated with inflammation of the rectum, but that can extend to involve additional areas of the colon. The American College of Gastroenterology (ACG) recommends a treat-to-target approach and recommend therapeutic management should be guided by diagnosis (i.e., Montreal classification), assessment of disease activity (i.e., mild, moderate, and severe), and disease prognosis. The ACG treatment recommendations are further broken down into induction therapies and maintenance of remission. The 2019 ACG treatment guidelines recommend the following for therapeutic management of UC[37]:

<u>Induction of remission</u>:

- Mildly active disease:
  - Rectal 5-ASA at a dose of 1 g/day with or without oral 5-ASA at a dose of at least 2 g/day for left-sided UC

- Rectal 5-ASA at a dose of 1 g/day for ulcerative proctitis
- Oral 5-ASA at a dose of at least 2 g/day for extensive UC
- Add oral budesonide multi-matrix (MMX) 9 mg/day for patients that are intolerant or non-responsive to oral and/or rectal and oral 5-ASA at appropriate doses

- Moderately active disease:
  - Oral budesonide multi-matrix (MMX) 9 mg/day for induction of remission
- Moderately to severely active disease:
  - Oral systemic corticosteroids, TNF inhibitors (i.e., adalimumab, golimumab, or infliximab), tofacitinib, or vedolizumab to induce remission
  - Combination of infliximab with thiopurine therapy when using infliximab for induction
  - Switch to tofacitinib or vedolizumab for induction in patients that have failed TNF inhibitors
  - Patients with initial response to TNF inhibitors that lose response should have antibody levels and serum drug levels tested to assess reason for loss of response. If serum levels are adequate, use of another TNF inhibitor is not likely to be of benefit.

<u>Maintenance of remission</u>:

- Previously mildly active disease:
  - Rectal 5-ASA at a dose of 1 g/day in patients with ulcerative proctitis
  - Oral 5-ASA at a dose of at least 2 g/day in patients with left-sided or extensive UC
- Previously moderately to severely active disease:
  - Thiopurines in patients that achieved remission due to corticosteroid induction
  - Continue TNF inhibitors (i.e., adalimumab, golimumab, or infliximab) for remission due to TNF induction
  - Continue vedolizumab for remission due to vedolizumab induction
  - Continue tofacitinib for remission due to tofacitinib induction

The American Gastroenterology Association (AGA) published recommendations for the management of mild to moderate UC:

- Use either standard-dose mesalamine (2-3 g/day) or diazo-bonded 5-ASA for patients with extensive UC for induction of remission and maintenance of remission
- May add rectal mesalamine to oral 5-ASA in patients with extensive or left-sided UC for induction of remission and maintenance of remission
- Use high dose mesalamine (>3 g/day) with rectal mesalamine in patients with suboptimal response to standard-dose mesalamine, diazo-bonded 5-ASA, or with moderate disease activity for induction of remission and maintenance of remission
- Add either oral prednisone or budesonide MMX in patients that are refractory to optimized oral and rectal 5-ASA regardless of disease extent

The American Gastroenterology Association (AGA) published recommendations for the management of moderate to severe UC.

- Standard of care is to continue agents initiated for induction therapy as maintenance therapy, if they are effective (excluding corticosteroids and cyclosporine)
- Adult outpatients with moderate to severe UC:
  - Infliximab, adalimumab, golimumab, vedolizumab, tofacitinib or ustekinumab are strongly recommended over no treatment
  - Biologic naïve patients:
    - infliximab or vedolizumab are conditionally recommended over adalimumab for induction of remission
    - Recommend tofacitinib only be used in the setting of a clinical or registry study
  - Previous exposure to infliximab, particularly those with primary non-response, ustekinumab or tofacitinib are conditionally recommended over vedolizumab or adalimumab for induction of remission
  - Conditionally recommend against use of thiopurine monotherapy for induction, but may be used for maintenance of remission over no treatment

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

NOTE: The self-administered products with prerequisites for certain indications are as follows:

Table 1

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c (Directed to THREE step 1 agents)
	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors				
Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**,

						Idacio**, Yuflyma**, Yusimry**
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	Bimzelx
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cimzia, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Kevzara, Yuflyma**, Yusimry**
Psoriatic Arthritis (PsA)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi, Skyrizi, Stelara, **Tremfya** Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Rheumatoid Arthritis (RA)	SQ: Enbrel, Hadlima, Humira, Simlandi	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, Humira, or Simlandi is a required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Dermatological Disorders						
Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Simlandi, Skyrizi, Stelara, **Tremfya** Oral: Otezla	N/A	Oral: Sotyktu	SQ: Cimzia	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Bimzelx, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Taltz,

						Yuflyma**, Yusimry**
Inflammatory Bowel Disease						
Crohn's Disease (CD)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, Humira, or Simlandi are required Step 1 agents)	SQ: Entyvio	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yusimry**, Zymfentra
Ulcerative Colitis (UC)	SQ: Hadlima, Humira, Simlandi, Skyrizi, Stelara, Tremfya	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima, Humira, or Simlandi is a required Step 1 agent)	N/A	SQ: Entyvio, Omvoh Oral: Zeposia (Hadlima, Humira, Rinvoq, Simlandi, Skyrizi, Stelara, Tremfya, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**, Zymfentra Oral: Velsipity
Other						
Uveitis	SQ: Hadlima, Humira, Simlandi	N/A	N/A	N/A	N/A	SQ: Abrilada**, Adalimumab-ryvk**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Yuflyma**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators						
Alopecia Areata (AA) Atopic Dermatitis (AD) Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem	N/A	N/A	N/A	N/A	N/A	N/A

Inflammatory Disease (NOMID) Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

Note: Hadlima, Humira, and Simlandi are required Step 1 agents

Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as **ONE** product

Note: Branded generic available for Cyltezo, Hulio, Hyrimoz, Idacio, and Yuflyma are included as a target at the same step level in this program

SUBCUTANEOUS TREMFYA (PHARMACY BENEFIT)

Initiation of guselkumab (Tremfya) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "5"):

1. **ONE** of the following ("a", "b", or "c"):
    a. The member has been treated with guselkumab (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with guselkumab (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed
    c. **BOTH** of the following ('i" and "ii"):
        i. Guselkumab will be used for the treatment of an indication listed in Table 2, and **ALL** of the indication-specific criteria are met
        ii. **EITHER** of the following if the member has an FDA-approved indication ("I" or "II")
            I. The member's age is within FDA labeling for the requested indication for guselkumab
            II. The prescriber has provided information in support of using guselkumab for the member's age
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, dermatologist for PS, gastroenterologist for UC) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to guselkumab
4. Member will **NOT** be using guselkumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla

(apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]

5. **ANY** of the following ("a", "b", or "c"):
    a. The dosage does not exceed the following based on the indication for use:
        - Ulcerative colitis - 100 mg every 8 weeks (starting 8 weeks after the last IV induction dose), OR 200 mg every 4 weeks (starting 4 weeks after that last IV induction dose)
            - QL: 100 mg/mL pen - 1 pen/ 56 days
            - QL: 100 mg/mL syringe - 1 syringe/56 days
            - QL: 200 mg/2 mL pen - 1 pen/28 days
            - QL: 200 mg/2 mL syringe - 1 syringe/28 days
        - PS and PsA:
            - Loading dose – 100 mg at weeks 0 and 4
            - Maintenance dose - 100 mg every 8 weeks (56 days), starting 8 weeks after week 4 (i.e., on week 12)
                - QL: 100 mg/mL pen - 1 pen/56 days
                - QL: 100 mg/mL syringe - 1 syringe/56 days
    b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
    c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval duration: UC – 12 months. PS and PsA - Loading dose (doses on week 0 and 4) for 3 months, then maintenance dose for 9 additional months [12 months for total duration of approval]

Table 2

Diagnosis	**Criteria**
Active psoriatic arthritis (PsA)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy

	OR 2. The member has an intolerance or hypersensitivity to **ONE** of the conventional agents used in the treatment of PsA **OR** 3. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of PsA **OR** 4. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 5. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA
Moderate to severe plaque psoriasis (PS)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PS **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PS **OR** 4. The member has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences)

	OR 5. The member has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS
Moderately to severely active ulcerative colitis (UC)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** of the conventional agents used in the treatment of UC **OR** c. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of UC **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of UC **OR** e. The member has severe disease and/or risk factors for disease complications for which initial treatment with guselkumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors **AND** 2. The member has received Tremfya IV for induction therapy, **OR** the member is new to therapy and will receive Tremfya IV for induction therapy
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of guselkumab (Tremfya) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for guselkumab has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with guselkumab therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, dermatologist for PS, gastroenterologist for UC) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to guselkumab
5. Member will **NOT** be using guselkumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", or "c"):
    a. The dosage does not exceed the following based on the indication for use:
        - Ulcerative colitis - 100 mg every 8 weeks (starting 8 weeks after the last IV induction dose), OR 200 mg every 4 weeks (starting 4 weeks after that last IV induction dose)
            - QL: 100 mg/mL pen - 1 pen/ 56 days
            - QL: 100 mg/mL syringe - 1 syringe/56 days
            - QL: 200 mg/2 mL pen - 1 pen/28 days
            - QL: 200 mg/2 mL syringe - 1 syringe/28 days
        - Other indications - 100 mg every 8 weeks (56 days)
            - QL: 100 mg/mL pen - 1 pen/56 days
            - QL: 100 mg/mL syringe - 1 syringe/56 days
    b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit
    c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval duration: 12 months

INTRAVENOUS TREMFYA (MEDICAL BENEFIT)

Initiation of intravenous (IV) guselkumab (Tremfya) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1" to "6"):

1. Intravenous guselkumab will be used for the treatment of an indication listed in Table 3, and **ALL** of the indication-specific and maximum-allowable dose criteria are met
2. **EITHER** of the following if the member has an FDA-approved indication ("a" or "b")
    a. The member's age is within FDA labeling for the requested indication for guselkumab
    b. The prescriber has provided information in support of using guselkumab for the member's age
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., gastroenterologist for UC) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does NOT have any FDA labeled contraindications to IV guselkumab
5. Member will **NOT** be using IV guselkumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. For the UC indication only - member has not received a previous dose of guselkumab (IV or SC) in the past 6 months, **UNLESS** the member is completing the second and/or third dose(s) of the initial three IV doses for induction

Approval duration: UC - 3 months (to allow 3 total IV doses). Other indications - Up to 12 months.

Table 3

Indication	Criteria	Max Allowable Dosage
Moderately to severely active ulcerative colitis (UC)	**ONE** of the following: 1. The member has tried and had an inadequate response to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to ONE of the conventional agents used in the treatment of UC **OR** 3. The member has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of UC	• 200 mg IV every 4 weeks for a total of 3 doses (i.e., Week 0, Week 4, and Week 8) • Maintenance therapy with subcutaneous guselkumab is started either 4 weeks or 8 weeks after the last IV dose (i.e., Week 12 or 16)

	OR 4. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of UC **OR** 5. The member has severe disease and/or risk factors for disease complications for which initial treatment with guselkumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors	
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a	Maximum dose supported by the FDA labeled indication or maximum dose supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2A

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Indicated for (1) the treatment of adults with moderate-to-severe plaque psoriasis (PS) who are candidates for systemic therapy or phototherapy, (2) the treatment of adult patients with active psoriatic arthritis (PsA), and (3) the treatment of adult patients with moderately to severely active ulcerative colitis (UC).
- For both PS and PsA, the recommended dose is 100 mg as a subcutaneous (SC) injection at Week 0, Week 4, and every 8 weeks thereafter. For psoriatic arthritis, the product labeling states that guselkumab may be administered alone or in combination with a conventional DMARD (e.g., methotrexate). A patient may self-inject after proper training in SC injection technique. The prefilled syringe should be removed from the refrigerator to allow the solution to reach room temperature (about 30 minutes) before injection
- For UC, the recommended induction dosage is 200 mg administered by IV infusion over at least one hour at Week 0, Week 4, and Week 8. The recommended maintenance dosage of is either:
    - 100 mg administered by SC injection at Week 16, and every 8 weeks thereafter, or
    - 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter

Use the lowest effective recommended dosage to maintain therapeutic response. The solution for IV infusion must be diluted, prepared, and infused by a healthcare professional.

Dose Adjustments

- No specific guidelines for dosage adjustments for renal or hepatic impairment are available. It appears that no dosage adjustments are needed.

Drug Availability

Subcutaneous Injection:

- 100 mg/1 mL in a single-dose prefilled syringe
- 100 mg/1 mL in a single-dose One-Press patient-controlled injector
- 200 mg/2 mL in a single-dose prefilled pen (Tremfya Pen).
- 200 mg/2 mL in a single-dose prefilled syringe.

Intravenous Infusion:

- 200 mg/20 mL (10 mg/mL) solution in a single-dose vial

Store in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF). Store in original carton until time of use. Protect from light until use. Do not freeze. Do not shake. Not made with natural rubber latex.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients

Precautions/Warnings

- **Adverse Reactions**: The most common (≥1%) adverse reactions associated with guselkumab treatment include upper respiratory infections, headache, injection site reactions, arthralgia, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections.
- **Infections**: Guselkumab may increase the risk of infection. In clinical trials for plaque psoriasis, infections occurred in 23% of subjects in the guselkumab group versus 21% of subjects in the placebo group through 16 weeks of treatment. A similar risk of infection was seen in trials for psoriatic arthritis and ulcerative colitis. Consider the risks and benefits prior to initiating guselkumab in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops or if an infection is not responding to standard therapy, monitor the patient closely and discontinue guselkumab until the infection resolves.
- **Tuberculosis (TB)**: Evaluate patients for TB infection prior to initiating treatment with guselkumab. Do not administered guselkumab to patients with active tuberculosis infection.

- **Hypersensitivity Reactions**: Serious hypersensitivity reactions have been reported with postmarket use of guselkumab. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue guselkumab and initiate appropriate therapy.
- **Immunizations**: Avoid using live vaccines concurrently with guselkumab.
- **CYP450 Substrates**: The formation of CYP450 enzymes can be altered by increased levels of certain cytokines during chronic inflammation, and treatment with guselkumab may modulate serum levels of some cytokines. Therefore, upon initiation or discontinuation of guselkumab in patients who are receiving concomitant drugs which are CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) and consider dosage modification of the CYP450 substrate.
- **Pregnancy**: There are no available data on use in pregnant women to inform a drug associated risk of adverse developmental outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, guselkumab may be transmitted from the mother to the developing fetus. A study in pregnant cynomolgus monkeys given weekly guselkumab doses up to 30-times the maximum recommended human dose found no evidence of malformations or embryofetal toxicity. View the prescribing information for additional details.

BILLING/CODING INFORMATION:

HCPCS Coding

J1628	Injection, guselkumab, 1 mg [for both IV and SC formulations]

ICD-10 Diagnosis Codes That Support Medical Necessity of Intravenous Infusion (J1628; NDC 57894-0650-02):

K51.00 - K51.919	Ulcerative colitis

ICD-10 Diagnosis Codes That Support Medical Necessity of Subcutaneous Injection (J1628; NDCs 57894-0640-01, 57894-0640-11, 57894-0651-02, and 57894-0651-22):

L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
K51.00 - K51.919	Ulcerative colitis

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

DEFINITIONS:

DMARDs: An acronym for disease-modifying antirheumatic drugs. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., baricitinib, tofacitinib, apremilast), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD (boDMARD).

Plaque psoriasis: It is the most common form of psoriasis. It affects 80 to 90% of people with psoriasis. Plaque psoriasis typically appears as raised areas of inflamed skin covered with silvery white scaly skin. These areas are called plaques.

Psoriatic arthritis (PsA): joint inflammation that occurs in about 5% to 10% of people with psoriasis (a common skin disorder). It is a severe form of arthritis accompanied by inflammation, psoriasis of the skin or nails, and a negative test for rheumatoid factor. Enthesitis refers to inflammation of entheses, the site where ligaments or tendons insert into the bones. It is a distinctive feature of PsA and does not occur with other forms of arthritis. Common locations for enthesitis include the bottoms of the feet, the Achilles' tendons, and the places where ligaments attach to the ribs, spine, and pelvis.

RELATED GUIDELINES:

Abatacept (Orencia), 09-J0000-67
Adalimumab Products, 09-J0000-46
Apremilast (Otezla) Tablet, 09-J2000-19
Bimekizumab (Bimzelx), 09-J4000-70
Brodalumab (Siliq) Injection, 09-J2000-74
Certolizumab Pegol (Cimzia), 09-J0000-77
Deucravacitinib (Sotyktu), 09-J4000-37
Etanercept (Enbrel), 09-J0000-38
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Infliximab Products, 09-J0000-39
Ixekizumab (Taltz), 09-J2000-62
Natalizumab (Tysabri) Injection, 09-J0000-73
Psoralens with Ultraviolet A (PUVA), 09-10000-16

Risankizumab (Skyrizi), 09-J3000-45
Secukinumab (Cosentyx), 09-J2000-30
Tildrakizumab-asmn (Ilumya), 09-J3000-04
Tofacitinib (Xeljanz, Xeljanz XR) Tablets, 09-J1000-86
Ustekinumab (Stelara), 09-J1000-16
Vedolizumab (Entyvio), 09-J2000-18

OTHER:

Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy

Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Ebglyss (lebrikizumab-lbkz)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Omvoh (mirikizumab-mrkz)
Orencia (abatacept)
Remicade (infliximab)
Renflexis (infliximab-abda)

Riabni (rituximab-arrx)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi Aria (golimumab)
Skyrizi (risankizumab-rzaa)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tyruko (natalizumab-sztn)
Tysabri (natalizumab)
Wezlana (ustekinumab-auub)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zymfentra (infliximab-dyyb

Table 1: Conventional Synthetic DMARDs

DMARD Generic Name	DMARD Brand Name
Auranofin (oral gold)	Ridaura
Azathioprine	Imuran
Cyclosporine	Neoral, Sandimmune
Hydroxychloroquine	Plaquenil
Leflunomide	Arava
Methotrexate	Rheumatrex, Trexall
Sulfasalazine	Azulfidine, Azulfidine EN-Tabs

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 10/09/24.

GUIDELINE UPDATE INFORMATION:

09/15/17	New Medical Coverage Guideline.
01/01/18	Revision to guideline consisting of updating the preferred self-administered biologic products according to indication for use. Secukinumab (Cosentyx) is now a preferred product for plaque psoriasis. Addition of HCPCS code C9029.
07/01/18	Revision to guideline consisting of updating the position statement.
10/15/18	Review and revision to to guideline consisting of updating the references.
01/01/19	Revision: HCPCS code updates. Added J1628 and removed C9029 and J3590.
09/01/19	Revision to guideline consisting of updating the position statement and references.
10/15/19	Review and revision to guideline consisting of updating the description, position statement, precautions, and references.
07/01/20	Revision to guideline consisting of updating the description and position statement.
01/01/21	Review and revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding, definitions, related guidelines, other, and references.
03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.
09/15/21	Update to Table 1 in Position Statement.
11/15/21	Revision to guideline consisting of updating the position statement.
01/01/22	Review and revision to guideline consisting of updating the position statement, other section, and references.
02/15/22	Update to Table 1 in Position Statement.
03/15/22	Revision to guideline consisting of updating the position statement and other sections.
05/15/22	Update to Table 1 in Position Statement.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Update to Table 1 in Position Statement.
01/01/23	Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination.
04/15/23	Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/23	Revision to guideline consisting of updating the position statement and other section. Amjevita and Hadlima added as Step 1a agents. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
01/01/24	Review and revision to guideline consisting of updating the position statement, other section, and references. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/24	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Updates to the positioning of agents in Table 1. Removal

	of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
10/01/24	Update to Table 1 in Position Statement.
11/15/24	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding, related guidelines, other section, and references based on the new FDA-approved indication for UC in adults. Position statement divided into one section for “SUBCUTANEOUS TREMFYA (PHARMACY BENEFIT)” and one section for “INTRAVENOUS TREMFYA (MEDICAL BENEFIT)”.