**09-J2000-87**

**Original Effective Date: 09/15/17**

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**Revised: 10/15/19**

# Subject: Guselkumab (Tremfya®) Injection

**THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.**



## 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 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 is 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.

Psoriasis is a chronic, inflammatory disease that affects approximately 3% of the adult US population. Approximately 80% of patients with psoriasis have limited disease, and, for the majority of these patients, topical treatments are safe, effective, and convenient. However, some patients require systemic treatment. Without appropriate treatment, patients may experience substantial disease burden and decreased quality of life. The American Academy of Dermatology (AAD) guidelines state that methotrexate is a logical first choice of systemic agent, because it is the most cost-effective systemic psoriasis agent with the longest safety follow-up data. Cyclosporine is cited as particularly useful in the treatment of significant flares of psoriasis unresponsive to other therapies. Intermittent, short-term therapy (12 to 16 weeks) is the most frequently recommended regimen, with treatment withdrawn once significant improvement is achieved. When relapse occurs, cyclosporine therapy is reinstituted at the previously established effective dose, or maintenance therapy for up to 1 year can be used. Acitretin is also mentioned as an important oral option, despite is being normally less effective than other traditional systemic agents, due to its lack of immunosuppression and value in patients with known infection, active malignancy, or HIV. The AAD and National Psoriasis Foundation (NPF) are expected to release updated joint guidelines for the management of psoriasis with non-biologics in 2020. The AAD-NPF did release a joint guideline in 2019 for the management and treatment of psoriasis with biologics. The prior AAD

guidelines did not include many of the biologics approved in the past decade. The 2019 guidelines provide the following recommendations regarding guselkumab: 8.1 - Guselkumab is recommended as a monotherapy treatment option for use in adult patients with moderate-to-severe plaque psoriasis (Strength of recommendation A), 8.2 - The recommended dose of guselkumab is 100 mg by self-administered subcutaneous injection at wk 0, wk 4, and every 8 wk thereafter (A), and 8.3 - Guselkumab is recommended as a monotherapy treatment option in adult patients with scalp, nail, and plaque-type palmoplantar psoriasis (A).

The safety and efficacy of guselkumab leading to FDA-approval was assessed in three multicenter, randomized, double-blind trials (VOYAGE 1 VOYAGE 2, and NAVIGATE). All enrolled subjects were 18 years of age and older with moderate-to-severe plaque psoriasis who were eligible for systemic therapy or phototherapy. Subjects had an Investigator's Global Assessment (IGA) score of 3 or greater (i.e., moderate) on a 5-point scale of overall disease severity, a Psoriasis Area and Severity Index (PASI) score 12 or greater, and a minimum affected body surface area (BSA) of 10%. Subjects with guttate, erythrodermic, or pustular psoriasis were excluded.

In VOYAGE 1 and VOYAGE 2, a total of 1,443 subjects were randomized to guselkumab (100 mg at Weeks 0 and 4 and every 8 weeks thereafter), placebo, or adalimumab (80 mg at Week 0 and 40 mg at Week 1, followed by 40 mg every other week thereafter). Both trials assessed the responses at Week 16 compared to placebo for the two co-primary endpoints of: (1) proportion of subjects who achieved an IGA score of 0 (i.e., cleared) or 1 (i.e., minimal) and (2) proportion of subjects who achieved at least a 90% reduction from baseline in the PASI composite score (PASI 90). Key secondary endpoints included comparisons between guselkumab and adalimumab at Week 16, 24, and 48 for the proportions of subjects who achieved an IGA score of 0 or 1, a PASI 90, and a PASI 75 response. In both trials, subjects were predominantly men and white, with a mean age of 44 years, and a mean weight of 90 kg. At baseline, subjects had a median affected BSA of approximately 21%, median PASI score of 19, and 18% had a history of psoriatic arthritis. Approximately 24% of subjects had an IGA score of severe. In both trials, 23% had received prior biologic systemic therapy. The primary and several secondary endpoint results can be seen in Tables 1 and 2.

## Table 1: Primary Efficacy Results at Week 16 in VOYAGE 1 and VOYAGE 2

| | VOYAGE 1 | | VOYAGE 2 | |
|---|---|---|---|---|
| **Endpoints** | **Guselkumab (n=329)** | **Placebo (n=174)** | **Guselkumab (n=496)** | **Placebo (n=248)** |
| IGA response of 0 or 1 | 280 (85%) | 12 (7%) | 417 (84%) | 21 (8%) |
| PASI 90 response | 241 (73%) | 5 (3%) | 347 (70%) | 6 (2%) |

## Table 2: Secondary Efficacy Analysis of North America Sites (US and Canada) in VOYAGE 1 and VOYAGE 2

| | VOYAGE 1 | | VOYAGE 2 | |
|---|---|---|---|---|
| **Endpoints** | **Guselkumab (n=115)** | **Adalimumab (n=115)** | **Guselkumab (n=160)** | **Adalimumab (n=81)** |
| **IGA response of 0 or 1 (cleared or minimal)** | | | | |
| Week 16 | 97 (84%) | 70 (61%) | 119 (74%) | 50 (62%) |
| Week 24 | 97 (84%) | 62 (54%) | 119 (74%) | 46 (57%) |
| Week 48 | 91 (79%) | 62 (54%) | NA | NA |
| **IGA response of 0 (cleared)** | | | | |

| | | | | |
|---|---|---|---|---|
| Week 24 | 61 (53%) | 27 (23%) | 76 (48%) | 23 (28%) |
| Week 48 | 54 (47%) | 28 (24%) | NA | NA |
| **PASI 75 response** | | | | |
| Week 16 | 105 (91%) | 80 (70%) | 132 (83%) | 51 (63%) |
| **PASI 90 response** | | | | |
| Week 16 | 84 (73%) | 47 (41%) | 102 (64%) | 34 (42%) |
| Week 24 | 92 (80%) | 51 (44%) | 113 (71%) | 41 (51%) |
| Week 48 | 84 (73%) | 53 (46%) | NA | NA |

NAVIGATE evaluated the efficacy of 24 weeks of treatment with guselkumab in subjects (n=268) who had not achieved an adequate response, defined as IGA of 2 or more at Week 16 after initial, treatment with ustekinumab (Stelara) (dosed 45 mg or 90 mg according to the subject's baseline weight at Week 0 and Week 4). These subjects were randomized to either continue with ustekinumab treatment every 12 weeks or switch to guselkumab 100 mg at Weeks 16, 20, and every 8 weeks thereafter. The primary endpoint was the number of visits at which randomized patients achieved IGA 0 or 1 and ≥2 grade improvement (from week 16) from week 28 to 40. Secondary endpoints include PASI 90 and PASI 100 responses. The baseline characteristics for randomized subjects were similar to those observed in VOYAGE 1 and VOYAGE 2. A greater proportions of patients achieved IGA 0 or 1 and ≥2-grade improvement at week 28 (31.1% vs. 14.3%; p=0.001) and week 52 (36.3% vs. 17.3%; p<0.001) with guselkumab initiation vs. ustekinumab continuation. In addition, at week 52 more guselkumab-treated patients achieved PASI 90 (51.1% vs. 24.1%; p<0.001) and PASI100 (20% vs. 7.5%; p=0.003).

Regarding the use of systemic agent during pregnancy, while methotrexate must be avoided in women who are pregnant or trying to become pregnant, cyclosporine and anti-TNF biologics are considered to be low-risk options during pregnancy if systemic therapy cannot be avoided. While not a first-line agent for psoriasis, sulfasalazine has adequate data supporting safe use (pregnancy Category B), and is consider a preferred DMARD if given with folic acid when systemic treatment is clinically necessary.

## 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 preferred self-administered biologic products for certain indications are:

- Axial spondyloarthritis - adalimumab (Humira), etanercept (Enbrel), golimumab (Simponi), and secukinumab (Cosentyx)
- Crohn's disease - adalimumab (Humira) and ustekinumab (Stelara)
- Hidradenitis suppurativa - adalimumab (Humira)
- Plaque psoriasis - adalimumab (Humira), etanercept (Enbrel), guselkumab (Tremfya), risankizumab (Skyrizi), secukinumab (Cosentyx), and ustekinumab (Stelara)
- Polyarticular juvenile idiopathic arthritis - adalimumab (Humira) and etanercept (Enbrel),
- Psoriatic arthritis - adalimumab (Humira), etanercept (Enbrel), golimumab (Simponi), secukinumab (Cosentyx), and ustekinumab (Stelara)

- Rheumatoid arthritis - adalimumab (Humira), etanercept (Enbrel), and golimumab (Simponi)
- Ulcerative colitis - adalimumab (Humira) and golimumab (Simponi)
- Uveitis - adalimumab (Humira)

Initiation of guselkumab (Tremfya) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1", "2", and "3"):

1. Guselkumab will be used for the treatment of an indication listed in Table 3, and **ALL** indication-specific and maximum-allowable dose criteria are met
2. The member is 18 years of age or older
3. Guselkumab will **NOT** be administered in combination with **ANY** of the following:
    a. abatacept (Orencia)
    b. adalimumab (Humira)
    c. anakinra (Kineret)
    d. apremilast (Otezla)
    e. baricitinib (Olumiant)
    f. brodalumab (Siliq)
    g. certolizumab (Cimzia)
    h. etanercept (Enbrel)
    i. golimumab (Simponi, Simponi Aria)
    j. infliximab products (Remicade, Inflectra, Renflexis)
    k. ixekizumab (Taltz)
    l. risankizumab (Skyrizi)
    m. sarilumab (Kevzara)
    n. secukinumab (Cosentyx)
    o. tildrakizumab-asmn (Ilumya)
    p. tocilizumab (Actemra)
    q. tofacitinib (Xeljanz, Xeljanz XR)
    r. upadacitinib (Rinvoq)
    s. ustekinumab (Stelara)
    t. vedolizumab (Entyvio)

## Table 3

| **Indications and Specific Criteria** | | |
|---|---|---|
| **Indication** | **Criteria** | **Maximum Allowable Dosage** |
| Plaque psoriasis | When **BOTH** of the following are met ("1" and "2"):<br><br>1. Member's disease is moderate to severe as | Initial:<br><br>• 100 mg at Weeks 0 |

| | | |
|---|---|---|
| | evidenced by **EITHER** of the following before or after systemic drug therapy ("a" or "b"):<br>a. Psoriasis covers 10% or more of member's BSA<br>b. Psoriasis covers less than 10% of member's BSA, but affects crucial body areas necessary for daily living activities (i.e., face, palms of hands, soles of feet, or genitals)<br>2. **EITHER** of the following* ("a" or "b"):<br>a. Member has had an inadequate response to at least 3 months of continuous treatment with maximally tolerated methotrexate (e.g., titrated to a dosage of 25 mg per week)<br>b. **BOTH** of the following ("i" and "ii"):<br>i. Member has a contraindication to or intolerable adverse effects with methotrexate [the specific contraindication and/or adverse effect(s) must be provided]<br>ii. Member has had an inadequate response to at least 3 months of continuous treatment with **EITHER** oral cyclosporine (at a dosage of at least 4 mg/kg per day) or acitretin (at a dosage of at least 25 mg per day), **OR** has a contraindication to and/or intolerable adverse effects with **BOTH** cyclosporine and acitretin [the specific contraindication(s) and/or adverse effect(s) must be provided; pregnancy is not considered a contraindication to the use of cyclosporine] | and 4<br><br>Maintenance:<br>• 100 mg every 8 weeks starting at Week 12 (i.e., Weeks 12, 20, 28, etc.) |
| **Approval duration**: 16 weeks | | |
| *__NOTE:__ If the member has had an inadequate response to previous biologic therapy, other than guselkumab, that is FDA-approved for the requested indication listed in Table 3, the member is **NOT** required to have had an inadequate therapeutic response to non-biologic prerequisite therapy (e.g., for psoriasis, if member has previously had an inadequate response to etanercept, but does not have a history of inadequate response to methotrexate, they do not have to try methotrexate to meet medical necessity criteria). | | |

Continuation of guselkumab (Tremfya) **meets the definition of medical necessity** when **ALL** of the following criteria are met ("1", "2", "3", and "4"):

1. An authorization or reauthorization for guselkumab has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of a condition listed in Table 3, **OR** the member has previously met **ALL** indication-specific initiation criteria
2. Member has demonstrated a beneficial clinical response to guselkumab therapy
3. Guselkumab will **NOT** be administered in combination with **ANY** of the following:

a. abatacept (Orencia)
b. adalimumab (Humira)
c. anakinra (Kineret)
d. apremilast (Otezla)
e. baricitinib (Olumiant)
f. brodalumab (Siliq)
g. certolizumab (Cimzia)
h. etanercept (Enbrel)
i. golimumab (Simponi, Simponi Aria)
j. infliximab products (Remicade, Inflectra, Renflexis)
k. ixekizumab (Taltz)
l. risankizumab (Skyrizi)
m. sarilumab (Kevzara)
n. secukinumab (Cosentyx)
o. tildrakizumab-asmn (Ilumya)
p. tocilizumab (Actemra)
q. tofacitinib (Xeljanz, Xeljanz XR)
r. upadacitinib (Rinvoq)
s. ustekinumab (Stelara)
t. vedolizumab (Entyvio)

4. The dosage of guselkumab does not exceed 100 mg every 8 weeks

**Approval duration**: 12 months

## 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 the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- The recommended dose is 100 mg as a subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter. A patient may self-inject after proper training in subcutaneous injection technique. The prefilled syringe should be removed from the refrigerator to allow the solution to reach room temperature (about 30 minutes) before injection

**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**

- 100 mg/1 mL in a single-use prefilled syringe
- Store in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF)

## 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, infections occurred in 23% of subjects in the guselkumab group versus 21% of subjects in the placebo group through 16 weeks of treatment. 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 due to the possibility of transmission of infection by the vaccine.
- **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:

The following codes may be used to describe:

## HCPCS Coding

| | |
|---|---|
| J1628 | Injection, guselkumab, 1mg |

## ICD-10 Diagnoses Codes That Support Medical Necessity

| | |
|---|---|
| L40.0 | Psoriasis vulgaris |

## 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:** BCBSF 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:

**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.

## RELATED GUIDELINES:

**Adalimumab (Humira), 09-J0000-46**

**Apremilast (Otezla) Tablet, 09-J2000-19**

**Brodalumab (Siliq) Injection, 09-J2000-74**

**Etanercept (Enbrel), 09-J0000-38**

**Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), and infliximab-abda (Renflexis)], 09-J0000-39**

**Ixekizumab (Taltz), 09-J2000-62**

**Psoralens with Ultraviolet A (PUVA), 09-10000-16**

**Risankizumab (Skyrizi), 09-J3000-45**

**Secukinumab (Cosentyx), 09-J2000-30**

**Tildrakizumab-asmn (Ilumya), 09-J3000-04**

**Ustekinumab (Stelara), 09-J1000-16**

## OTHER:

None

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## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 09/11/19.

## GUIDELINE UPDATE INFORMATION:

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|---|---|
| 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. |