WellMed Doctors helping patients for more than 25 years	Effective Date: 12/21/22	Revision Date(s): 1/18/2019, 04/09/2020, 05/13/2021, 08/19/22
Department: PHARMACY	MMC Review/ Approval Date(s): 3/12/2019, 5/12/2020, 5/25/2021, 11/08/22	Total Number of Page(s): 9

Policy Number: 014.003

Title: Coverage Determination Policy for Guselkumab (Tremfya)

Regions: ☒ Texas ☐ Florida ☐ Indiana ☐ New Jersey ☒ New Mexico

Impacted Areas:

- ☒ Network Management/Provider Services
- ☐ Member services
- ☐ Quality Management
- ☐ Credentialing
- ☐ IT
- ☐ Administration
- ☐ Compliance/delegation
- ☒ Utilization Management
- ☐ Case management
- ☐ Disease management
- ☒ Claims
- ☐ Human resources
- ☐ Finance
- ☒ Pharmacy
- ☐ ALL

Available LCD/NCD/LCA: A53127 & A52571 **Self-Administered Drug (SAD) List**

Disclaimer:

WellMed Coverage Determination Policies are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support WellMed coverage decision making. WellMed may modify these Policy Guidelines at any time. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the WellMed Coverage Determination Policies is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Doctors helping patients for more than 25 years

Title: Coverage Determination Policy for Guselkumab (Tremfya)

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Coverage Policy Number: 014.003

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage **Determination:**

a) ***Tremfya (guselkumab) for subcutaneous administration is excluded from Medicare Part B coverage because it is on the self-administered drug exclusion list and is therefore not a covered benefit. See LCAA52800. All requests for subcutaneous guselkumab must include documented medical justification as to why the patient is unable to self-administer subcutaneous doses. Requests for subcutaneous guselkumab should generally be covered under the member's pharmacy benefit.***

- Medicare rules expect that if a patient is *clinically able* to self-administer a drug and there is no clear medical justification to do otherwise, then the patient must either self-administer that drug or self-pay for the alternative. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug.

- Medicare considers the following factors to be unrelated to medical decision making: 1. Patient convenience, 2. Patient co-pays and financial liability. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

b) Due to serious safety considerations outlined in the warnings and precautions, **documentation to support member has been screened for TB and serious infections should be included** for all request.

Initial**/New Requests**

Guselkumab is proven and medically necessary for the treatment of:

1. **Plaque Psoriasis (Moderate to Severe)** when ALL of the following criteria are met**:**
   a. Diagnosis of moderate to severe plaque psoriasis
   b. Patient is a candidate for phototherapy OR systemic therapy
   c. Patient is not receiving guselkumab in combination with any of the following
      - Biologic DMARDs [e.g. Humira (adalimumab), Cimzia (certolizumab), simponi (golimumab), Cosentyx (secukinumab), Orencia abatacept)]
      - Janus Kinase inhibitor [e.g. Xeljanz (tofacitinib)]
      - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
   d. The requested dosage is within FDA approved dosing (refer to FDA approved dosing section)
2. **Psoriatic arthritis** when ALL of the following criteria are met**:**
   a. Diagnosis of active psoriatic arthritis
   b. Patient is not receiving guselkumab in combination with any of the following
      - Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
      - Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
      - Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]
   c. The requested dosage is within FDA approved dosing (refer to FDA approved dosing section)

Renewal/**Continuation of Therapy Requests**

1. For all renewal requests, there must be clear documentation of positive clinical response to guselkumab therapy

AND

2. Patient is not receiving guselkumab in combination with any of the following
    a) Biologic DMARDs [e.g. Humira (adalimumab), Cimzia (certolizumab), simponi (golimumab), Cosentyx (secukinumab), Orencia abatacept)]
    b) Janus Kinase inhibitor [e.g. Xeljanz (tofacitinib)]
    c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

FDA Approved **Dose and Indications**

FDA approved indications	**Approved Dosing**
Plaque psoriasis (Moderate to severe)	• 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter
Psoriatic Arthritis	• 100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter. (May be administered alone or in combination with a conventional disease-modifying antirheumatic drug (cDMARD), such as methotrexate)

General **Background:**

Guselkumab (Tremfya) is a biologic disease-modifying antirheumatic drug (DMARD) that modulates the immune system. It works by blocking interleukin (IL)-23, a chemical messenger involved in autoimmune attacks. Guselkumab also inhibits the release of cytokines and chemokines which promote inflammation.

Guselkumab is indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and for adult patients with active psoriatic arthritis. Specific contraindications or black box warning have not been determined for this medication. Patients should be evaluated for active infection and tuberculosis (TB) prior to initiating therapy. It is recommended for patient to be brought up to date with all immunizations before starting guselkumab. Live vaccines should not be given concurrently.

Medicare does not have a National Coverage Determination (NCD) for Guselkumab (TremfyaTM). Local Coverage Determinations (LCDs) does not exist at this time. Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Medicare requires not only that the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

Precautions and Warnings

- Infections: Tremfya (guselkumab) may increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Tremfya (guselkumab) until the infection resolves.
- Tuberculosis (TB): Evaluate for TB prior to initiating treatment with Tremfya (guselkumab).
- Serious hypersensitivity reactions, including anaphylaxis, may occur. If a serious hypersensitivity reaction occurs, discontinue Tremfya and initiate appropriate therapy.

Clinical Evidence:

Plaque Psoriasis

Nakamura M et al reported efficacy and safety of guselkumab in patients with moderate-to-severe plaque psoriasis in phase III clinical trials. The results of two phase III, multicenter, randomized, double-blind, placebo- and comparator-controlled clinical trials, VOYAGE 1 and VOYAGE 2 were summarized. VOYAGE 1 compares the efficacy and safety of guselkumab to placebo and adalimumab in patients with moderate-to-severe psoriasis. Primary end points were the proportions of patients who meet an Investigator Global Assessment (IGA) score of cleared/minimal disease (IGA 0/1). Patients with 90% or greater improvement in the Psoriasis Area and Severity Index (PASI) score from baseline (PASI 90) at week 16 were considered as part of primary end point. Patient-reported outcomes (i.e. psoriasis symptoms, health-related quality of life) were reported as secondary outcomes. All subjects were randomized to one of three treatment arms: (1) Guselkumab 100 mg at weeks 0, 4, 12, and every 8 weeks (2) placebo at weeks 0, 4, and 12 followed by guselkumab 100 mg at weeks 16, 20, and every 8 weeks through (3) adalimumab 80 mg at week 0, 40 mg at week 1, and 40 mg every 2 weeks. Subjects in the guselkumab group achieved superior primary end points and all major secondary end points than those in placebo and adalimumab groups (all $P < 0.001$). Adverse events reported were comparable across treatment groups.

In VOYAGE 2, subjects were first randomized to one of three treatment arms: (1). Guselkumab 100 mg at weeks 0, 4, 12, and 20; (2). Placebo at weeks 0, 4, and 12, then guselkumab at weeks 16 and 20; (3). adalimumab 80 mg at week 0, 40 mg at week 1, and every 2 weeks thereafter through week 23. Primary and secondary end points measures were similar to those in VOYAGE1. Guselkumab was found to be superior to placebo and adalimumab for all primary and major secondary end points, (all $P < 0.001$). Adverse events in all groups were comparable. The phase III clinical trial concluded that guselkumab is superior to placebo at week 16 and is better able to clear or almost clear psoriasis plaques compared to adalimumab. Further studies are recommended to validate the long-term efficacy and safety profile of guselkumab.

Psoriatic Arthritis

Deodhar et al. (2020) conducted a multicenter, double-blind, randomized, placebo-controlled, phase 3 trial (DISCOVER-1) to evaluate guselkumab in adults with active psoriatic arthritis**.** Eligibility criteria included inadequate response to or intolerance of standard treatment, including at least 4 months of apremilast, at least 3 months of non-biologic disease-modifying antirheumatic drugs (DMARDs), or at least 4 weeks of non-steroidal anti-inflammatory drugs for psoriatic arthritis. About 30% of study participants could have previously received one or two TNF inhibitors. There were 381 patients randomly assigned (1:1:1) to subcutaneous guselkumab 100 mg every 4 weeks (n=128), guselkumab 100 mg at weeks 0, 4 and then every 8 weeks (n=127), or placebo (n=126). 362 patients continued study treatment up to week 24. The primary endpoint was American College of Rheumatology 20% improvement (ACR20) at week 24 in all patients per assigned treatment group using non-responder imputation. Safety was assessed in all patients per treatment received. The primary endpoint was met: ACR20 at week 24 was achieved by significantly greater proportions of patients in the guselkumab every 4 weeks group and every 8 weeks group than in the placebo group, with percentage differences versus placebo of 37% for the every 4 weeks group and 30% for the every 8 weeks group (both $p<0{\cdot}0001$). Serious adverse events up to week 24 occurred in no patients receiving guselkumab every 4 weeks, four (3%) patients receiving guselkumab every 8 weeks, and five (4%) patients receiving placebo. Up to week 24, one patient in the placebo group died from cardiac failure and two had serious infections; no guselkumab-treated patient died or had

serious infections. The authors concluded that guselkumab demonstrated a favorable benefit-risk profile and might be an effective treatment option for patients with active psoriatic arthritis.

Mease et al. (2020) conducted a multicenter, phase 3, double-blind, placebo-controlled study (DISCOVER-2) to evaluate guselkumab in biologic-naive patients with active psoriatic arthritis (at least five swollen joints, at least five tender joints, and C-reactive protein ≥0·6 mg/dL) despite standard therapies. Patients were randomly assigned (1:1:1) to subcutaneous injections of guselkumab 100 mg every 4 weeks; guselkumab 100 mg at weeks 0, 4, then every 8 weeks; or placebo. The primary endpoint was ACR20 response at week 24 in all patients per assigned treatment group. Safety was assessed in all patients per treatment received. A total of 1153 patients were screened, of whom 741 were randomly assigned to receive guselkumab every 4 weeks (n=246), every 8 weeks (n=248), or placebo (n=247). One patient in the every 4 weeks group and one in the placebo group did not start treatment, and the remaining 739 patients started treatment; 716 patients continued treatment up to week 24. Significantly greater proportions of patients in the guselkumab every 4 weeks group (156 [64%] of 245 [95% CI 57-70]) and every 8 weeks group (159 [64%] of 248 [58-70]) than in the placebo group (81 [33%] of 246 [27-39]) achieved an ACR20 response at week 24 (percentage differences vs placebo 31% [95% CI 22-39] for the every 4 weeks group and 31% [23-40] for the every 8 weeks group; both p<0·0001). Up to week 24, serious adverse events occurred in eight (3%) of 245 patients receiving guselkumab every 4 weeks (three serious infections), three (1%) of 248 receiving guselkumab every 8 weeks (one serious infection), and seven (3%) of 246 receiving placebo (one serious infection). No deaths occurred. The authors concluded that guselkumab was efficacious and demonstrated an acceptable benefit-risk profile in patients with active psoriatic arthritis who were naive to treatment with biologics.

HCPCS Code:

HCPCS Code:	Description:
J1628	Tremfya (Guselkumab) subcut soln 100 MG/1 ML

Acronyms:

Disease Modifying Antirheumatic Drugs (DMARDs), National Coverage Determination (NCD), Local Coverage Determinations (LCD), Phosphodiesterase 4 (PDE4), Food and Drug Administration (FDA), Tuberculosis (TB), Investigator Global Assessment (IGA), Psoriasis Area and Severity Index (PASI), conventional disease-modifying antirheumatic drug (cDMARD), American College of Rheumatology 20% improvement (ACR20)

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