Policy Title:	Tremfya (guselkumab) (Subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/13/2019, 1/29/2020, 7/15/2021, 4/14/2022		
Revision Date:	12/13/2019, 1/29/2020, 7/15/2021		

Purpose: To support safe, effective and appropriate use of Tremfya (guselkumab).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:

Tremfya (guselkumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Tremfya (guselkumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria

- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB)
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Moderate to severe plaque psoriasis

- Member is 18 years of age and older; AND
- Tremfya is prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- At least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected; AND
- Member meets either of the following criteria:
    - Member has had an inadequate response to at least a 3 month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin; OR
    - Member has had an inadequate response to at least a 3 month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced; AND

- Tremfya will not be used concomitantly with any other biologic DMARD (e.g., adalimumab, infliximab) or targeted synthetic DMARD (e.g., apremilast, tofacitinib); AND
- Dose falls within FDA guidelines

Active psoriatic arthritis (PsA)

- Member is 18 years of age and older; AND
- Tremfya is prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
- Documented moderate to severe active disease and member meets either of the following criteria:
    - If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
    - If member has peripheral arthritis, member has experienced an inadequate response to a ≥ 3 consecutive month trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, unless intolerance experienced

Continuation of Therapy Criteria:

- Authorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Tremfya as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = 1 mg)**
Moderate-to-severe plaque psoriasis and active psoriatic arthritis	Dose does not exceed 100 mg at week 0 and week 4, followed by 100 mg every 8 weeks	100 units at week 0 and week 4, followed by 100 units every 8 weeks

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

HCPCS/CPT Code	Description
J1628	Injection, guselkumab, 1mg

References:

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; July 2020.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol.* 2009;61:451-485.
3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011;65(1):137-174.
4. Reich K, Armstrong, AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the phase III, double-blind, placebo- and active comparator–controlled VOYAGE 2 trial. *Am J Clin Dermatol.* 2017;76(3):418-431.
5. Blauvelt A, Papp KA, Griffiths, CEM, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: Results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *Am J Clin Dermatol.* 2017;76(3):405-417.