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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 1 mg)</th>
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</thead>
<tbody>
<tr>
<td>Moderate-to-severe plaque psoriasis and active psoriatic arthritis</td>
<td>Dose does not exceed 100 mg at week 0 and week 4, followed by 100 mg every 8 weeks</td>
<td>100 units at week 0 and week 4, followed by 100 units every 8 weeks</td>
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</tbody>
</table>
**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:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>J1628</td>
<td>Injection, guselkumab, 1mg</td>
</tr>
</tbody>
</table>

**References:**