UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2021 P 1230-5 |
| Program | Prior Authorization/Notification |
| Medication | Tremfya® (guselkumab) |
| P&T Approval Date | 9/2017, 9/2018, 9/2019, 9/2020, 9/2021 |
| Effective Date | 12/1/2021;<br>Oxford only: N/A |

**1. Background:**

Tremfya (guselkumab) is an interleukin-23 blocker indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Tremfya is also indicated for the treatment of adult patients with active psoriatic arthritis.

**2. Coverage Criteria:**

**A. Plaque Psoriasis**

**1. Initial Authorization**

**a.** Tremfya will be approved based on **both** of the following criteria:

(1) Diagnosis of moderate to severe plaque psoriasis

**-AND-**

(2) Patient is not receiving Tremfya in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a.** Tremfya will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Tremfya therapy

**-AND-**

(2) Patient is not receiving Tremfya in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

**Authorization will be issued for 12 months.**

**B. Psoriatic Arthritis**

**1. Initial Authorization**

**a.** Tremfya will be approved based on **both** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

**-AND-**

(2) Patient is not receiving Tremfya in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

**Authorization will be issued for 12 months.**

**2. Reauthorization**

**a.** Tremfya will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Tremfya therapy

**-AND-**

(2) Patient is not receiving Tremfya in combination with **any** of the following:

(a) Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

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| **Authorization will be issued for 12 months.** |

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits, Step Therapy, and/or Medical Necessity may be in place.

**4. Reference:**

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.

| Program | Prior Authorization/Notification - Tremfya (guselkumab) |
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| **Change Control** | |
| 9/2017 | New program |
| 9/2018 | Annual review. No changes. |
| 9/2019 | Annual review. No changes. |
| 9/2020 | Annual review. Changed psoriasis reauthorization duration to 12 months. Added review criteria for psoriatic arthritis. Updated background and reference. |
| 9/2021 | Annual review with no change to coverage criteria. |