UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tremfya

Program	Prior Authorization
Medication	Tremfya® (guselkumab)
Markets in Scope	Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2017
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

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 **one** of the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **all** of the following:

(a) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(b) Greater than or equal to 3% body surface area involvement, palmoplantar, facial, or genital involvement, or severe scalp psoriasis

-AND-

(c) **Both** of the following:

i. History of failure to **one** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

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- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

-AND-

ii. History of failure to a 3 month trial of methotrexate at maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)

-AND-

(d) History of failure, contraindication, or intolerance to **two** of the following preferred biologic products (document drug, date, and duration of trial):

i. Humira (adalimumab)
ii. Enbrel (etanercept)
iii. Cimzia (certolizumab)
iv. Ilumya (tildrakizumab)

-AND-

(e) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

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

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(g) Prescribed by or in consultation with a dermatologist

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-OR-

(2) **All** of the following:

(a) Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

(b) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

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

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(d) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tremfya** will be approved based on **all** 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:

i. Biologic DMARD [e.g., Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Cosentyx (secukinumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

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-AND-

(3) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. Initial Authorization

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

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **all** of the following:

(a) Diagnosis of active psoriatic arthritis

-AND-

(b) History of failure to a 3 month trial of methotrexate at the maximally indicated dose within the last 6 months, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-AND-

(c) History of failure, contraindication, or intolerance to **two** of the following preferred biologic products (document drug, date, and duration of trial):

(a) Humira (adalimumab)
(b) Enbrel (etanercept)
(c) Cimzia (certolizumab)

-AND-

(d) History of failure, contraindication, or intolerance to Cosentyx (secukinumab)

-AND-

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

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i. Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(f) Prescribed by or in consultation with **one** of the following:

i. Rheumatologist
ii. Dermatologist

-OR-

(2) **All** of the following:

(a) Patient is currently on Tremfya therapy as documented by claims history or medical records (document date and duration of therapy)

-AND-

(b) Diagnosis of active psoriatic arthritis

-AND-

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

i. Biologic DMARD [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia abatacept)]
ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(d) Prescribed by or in consultation with **one** of the following:

i. Rheumatologist

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ii. Dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. Tremfya will be approved based on **all** 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), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)]
(b) Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)]
(c) Phosphodiesterase 4 (PDE4) inhibitor [e.g. Otezla (apremilast)]

-AND-

(3) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

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 may be in place.

4. References:

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1. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
2. Menter A, Gottlieb A, Feldman. SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
7. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
8. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, 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 Jul;65(1):137-74.

Program	Prior Authorization - Tremfya (guselkumab)
Change Control	
Date	Change
9/2017	New Program
9/2017	Added Otezla as a preferred product for upcoming PDL change
2/2018	Removed Otezla as a step therapy medication
2/2019	Minor revisions to language/formatting to align with other psoriasis programs. Added Cimzia as a step therapy medication. Updated references.
11/2019	Revised Cosentyx requirement to match other IL-23 programs. Updated references.
12/2019	Revised prerequisite therapies and added documentation of drug, date, and duration of trials.
1/2020	Revised biologic step therapy medications due to PDL changes.

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5/2020	Added prescriber requirement. Minor updates to prerequisite therapy requirements. Changed BSA requirement to 3% to align with current psoriasis guidelines.
12/2020	Added review criteria for psoriatic arthritis due to new indication. Added preferred product criteria and COT criteria. Updated background and references.

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