

guselkumab subcutaneous injection (TREMIFYA)

Diagnosis Considered for Coverage:

- Plaque Psoriasis (PsO)
- Psoriatic arthritis (PsA)

Coverage Criteria:

2. For diagnosis of psoriatic arthritis, approve if:

For request WITH prior targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors, Orencia, Otezla) treatment

- Not being used in combination with other targeted immunotherapies, **and**
- Dose does not exceed FDA label maximum, **and**

Coverage Duration: one year

For request WITHOUT prior targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors, Orencia, Otezla) treatment

- Being prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response or intolerable side effect with one DMARD agent OR patient has a medical reason why methotrexate, leflunomide, and sulfasalazine cannot be used, **and**
- Not being used in combination with other targeted immunotherapies, **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: one year

3. For diagnosis of moderate to severe Plaque Psoriasis, approve if:

INITIAL AUTHORIZATION (INDUCTION THERAPY)

For request WITH prior targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, Otezla) treatment

- Not being used in combination with a targeted immunomodulator, **and**
- Document baseline PASI or BSA prior to targeted immunotherapy treatment, **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: 24 weeks

For request WITHOUT prior targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, Otezla) treatment

- Being prescribed by or in consultation with a rheumatologist or dermatologist, **and**
- Inadequate response, intolerable side effect, or contraindication to one of the

following: methotrexate, cyclosporine (Neoral), acitretin (Soriatane), or PUVA/UVB, **and**

- Not being used in combination with a targeted immunomodulator, **and**
- Dose does not exceed FDA label maximum, **and**
- One of the following:
 - Baseline PASI score is 10 or more prior to initiating targeted immunologic therapy (eg. Enbrel, Humira, Stelara, Cosentyx, Otezla, Taltz), **or**
 - Baseline BSA is 3% or more prior to initiating targeted immunologic therapy (eg. Enbrel, Humira, Stelara, Cosentyx, Otezla, Taltz), **or**
 - Sensitive area is involved (i.e. groin, face, etc.), **or**
 - Disease is otherwise debilitating.

Coverage Duration: 24 weeks

REAUTHORIZATION

- Patient has shown improvement in the baseline PASI (or BSA if provided on initial request) score AFTER THE END of the induction course, **and**
- Not being used in combination with Otezla or another targeted biologic (i.e. TNF inhibitors, IL inhibitors), **and**
- Dose does not exceed FDA label maximum.

Coverage Duration: one year

Effective: 1/3/2024