Overview
Tremfya (guselkumab) is an interleukin-23 blocker (IL-23) indicated for:
- Moderate-to-severe plaque psoriasis
- Psoriatic arthritis

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Tremfya excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Psoriatic Arthritis (PsA)
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. BOTH of the following:
   a. Paid claims or physician documented inadequate response, adverse reaction, or contraindication to Stelara
   b. ONE of the following:
      i. Paid claims or physician documented inadequate response or adverse reaction to ONE anti-TNF agent that is FDA-approved for the requested indication
ii. Contraindication to ALL anti-TNF agents that are FDA-approved for the requested indication

3. Appropriate dosing

NOTE: DMARD trial is not required in members with active psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not sufficiently controlled with NSAIDs

Moderate to Severe Plaque Psoriasis
Prescriber provides documentation of ALL of the following:
1. Appropriate diagnosis
2. ONE of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to ONE conventional therapy (see appendix B)
      i. topical agent
      ii. phototherapy
      iii. systemic agent
   b. Contraindication to ALL conventional therapies:
      i. topical agents
      ii. phototherapy
      iii. systemic agents
   c. Paid claims or physician documented inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for plaque psoriasis
3. Appropriate dosing
4. Prescriber provides clinical rationale for use of Tremfya instead of Stelara®

Continuation of Therapy
Reauthorization requires physician documentation of continuation of therapy, positive response to therapy, FDA approved indication and appropriate dosing.

Limitations
1. Initial approvals will be granted for:
   a. Plaque Psoriasis: 3 months.
   b. All other diagnosis: 6 months.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

| Tremfya Inj 100mg/mL | 100mg per 8 weeks |
| Tremfya Pen Inj 100mg/mL |

Appendix
Appendix A: Dosing

| Tremfya® (guselkumab) | Plaque Psoriasis: SQ: 100 mg initially at week 0 and 4; followed by 100 mg every eight weeks |

Appendix B. Conventional Therapies for Plaque Psoriasis

| Conventional Treatment Lines | Agents Used |

399 Revolution Drive, Suite 810, Somerville, MA 02145 | allwayshealthpartners.org

AllWays Health Partners includes AllWays Health Partners, Inc. and AllWays Health Partners Insurance Company
Topical Agents | emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors  
Systemic Agents | Traditional DMARDs: methotrexate, apremilast, acitretin  
Phototherapy | ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix C: Off-Label Indications
More Frequent/High Doses
Requests for more frequent or higher doses of injectable biologics may be approved if ALL of the following is provided:
1. Documentation of severe disease
2. ONE of the following:
   a. Paid claims or physician documented inadequate response or adverse reaction to ONE other injectable biologic which is FDA-approved for the requested indication
   b. Contraindication to ALL other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

References

Review History
03/01/2018: Implemented
02/20/2019: Reviewed P&T Mtg
11/17/2021 – Reviewed and Updated for Nov P&T; matched MH UPPL; updated to reflect criteria changes based on literature; added appendix for higher dose/more frequent dosing
11/17/2021 – Updated per MH UPPL: criteria for Taltz revised for psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis based on contract. Additionally, recertification criteria regarding Cosentyx requests approved for ankylosing spondylitis or non-radiographic axial
spondyloarthritis prior to Taltz require was removed as this is no longer a requirement in the criteria. Effective 01/01/2022.

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