Clinical Policy: Ixekizumab (Taltz)

Reference Number: PA.CP.PHAR.257
Effective Date: 01/18
Last Review Date 08/17
Line of Business: Medicaid

Revision Log

Description
Ixekizumab (Taltz™) is a humanized interleukin-17A antagonist.

FDA Approved Indication(s)
Taltz is indicated for the treatment of adults with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Taltz is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of moderate to severe PsO defined as one of the following:
   a. Greater than 5% of body surface area is affected;
   b. Palms, soles, face and neck, body folds, or genitalia is involved;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. Failure of at least one oral systemic therapy for PsO (e.g., methotrexate, cyclosporine, acitretin, or thioguanine) in combination with phototherapy or topical therapy (e.g., corticosteroids, calcipotriene, tazarotene) for ≥ 3 consecutive months unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of adalimumab (*Humira is preferred*), used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization is required for adalimumab*
6. Tuberculosis (TB) test within the past 12 months in negative, or if positive, active TB has been ruled out and the patient has received treatment for latent TB infection;
7. Dose does not exceed 160 mg/dose at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Plaque Psoriasis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies;
2. Member is responding positively to therapy (examples: sign/symptom reduction, no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed 80 mg every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
TB: tuberculosis
PsO: plaque psoriasis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Plaque Psoriasis	160 mg (two 80 mg injections) at week 0, then 80 mg at weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks	80 mg every 4 weeks

VI. Product Availability

- 80 mg/mL solution in a single-dose prefilled autoinjector
- 80 mg/mL solution in a single-dose prefilled syringe

VII. References

1. Taltz Prescribing Information. Indianapolis, IN: Eli Lilly and Company; July 2017. Available at http://uspl.lilly.com/taltz/taltz.html#pi / Accessed August 3, 2017.
2. Menter A, Korman NJ, Elmets CA, , et al. American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009 Sep; 61(3):451-85.
3. Menter A, Gottlieb A, Feldman SR, et al. American Academy of Dermatology. 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 May; 58(5):826-50.

Reviews, Revisions, and Approvals	Date	Approval Date