Protocol for Biological Response Modifiers in the Treatment of Plaque Psoriasis
Approved July 2021

Preferred Agents: ADALIMUMAB-ADAZ, ADALIMUMAB-FKJP, HADLIMA, ENBREL, OTEZLA

Non-Preferred Anti-Tumor Necrosis Factors (TNFs):
All Non-Preferred Adalimumab Biosimilar Products, Infliximab Products, Cimzia, and Simponi require trial and failure of a preferred adalimumab product AND Enbrel, where indicated, in addition to all other clinical criteria.

Non-Preferred Cytokines and Cell Adhesion Molecule (CAM) Antagonists:
Require trial and failure of a preferred adalimumab product AND one additional preferred product (Enbrel, Otezla), where indicated, in addition to all other clinical criteria. This requirement does not apply to Skyrizi or Taltz.

Adalimumab-adaz
Adalimumab-fkjp
Cimzia (certolizumab)
Cosentyx (secukinumab) [≥ 6 years old]
Enbrel (etanercept) [≥ 4 years old]
Humira (adalimumab)
Hadlima (adalimumab-bwwd)
Ilumya (tildrakizumab)
Otezla (apremilast)
Remicade (infliximab)
Siliq (bradalumab)
Skyrizi (risankizimab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab) [≥ 6 years old]
Taltz (ixekizumab) [≥ 6 years old]
Tremfya (guselkumab)

Background:

Biologic response modifiers (BRMs), also known as immunomodulators, are the class of medications that target the disease-causing mechanism. They are used in autoimmune diseases as first-line medications or after the failure of conventional agents. Serious infections are the most severe complications and require screening before initiation, and monitoring while patients are taking the medications.

Criteria for Approval:

A. Patient meets **ALL** the following:

1. Diagnosis of moderate to severe plaque psoriasis
2. Medication is used for an adult patient except where otherwise indicated
3. Patient must have clinical documentation of a diagnosis of moderate to severe plaque psoriasis characterized by greater than or equal to 3% body surface involved or disease affecting crucial body areas such as hands, feet, face, or genitals.
4. History of trial and failure of at least **ONE** of the following conventional therapies at maximally tolerated doses (for 3 months) unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):
    i. Methotrexate
    ii. Cyclosporine
    iii. Acitretin
    iv. Topical Vitamin D analogs (e.g. calcitriol)
    v. Topical corticosteroids
    vi. Calcineurin inhibitors (e.g. tacrolimus or pimecrolimus)
    vii. Topical retinoic acid derivatives
    viii. Phototherapy
5. Initial prescription is written by or in consultation with a dermatologist
6. Patient does not have any contraindications to therapy
7. Patient is not receiving medication with another BRM
8. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

9. Prior to initiation of therapy, patient is tested for tuberculosis (TB) [where applicable]
10. Weight must be received for drugs that have weight-based dosing for any dose change request

Initial Approval Duration: 6 months

Continuation of therapy:

1. Documentation of positive clinical response to therapy (less than 3 percent of BSA involvement or 75 percent improvement compared with baseline)
2. Patient is not receiving medication with another BRM
3. Patient is monitored for active TB during treatment (where applicable)
4. Patient is monitored for lymphoma and other malignancies during treatment (where applicable)

Renewal Approval Duration: 6 months

Note: Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with Siliq

References:

1. Cimzia [packet insert] UCB, Inc. 1950 Lake Park Drive Smyrna, GA 30080. September 2019
2. Cosentyx [packet insert] Novartis Pharmaceuticals Corporation East Hanover, NJ 07936. June 2020
3. Enbrel [packet insert] Amgen. Thousand Oaks, CA 91320. April 2021
4. Humira [packet insert] AbbVie Inc. North Chicago, IL 60064. February 2121
5. Ilumya [packet insert] Merck & Co. Inc., White House Station, NJ 08889. March 2018
6. Otezla [packet insert] Amgen Inc. Thousand Oaks, CA 91320. June 2020
7. Remicade [packet insert] Janssen Biotech, Inc. Horsham, PA 19044. November 2013
8. Skyrizi [packet insert] AbbVie Inc. North Chicago, IL 60064. April 2021
9. Siliq [packet insert] Bausch Health US, LLC Bridgewater, NJ 08807. April 2020
10. Stelara [packet insert] Janssen Biotech, Inc., Horsham, PA 19044. December 2020
11. Taltz [packet insert] Eli Lilly and Company, Indianapolis, IN 46285. March 2021
12. Tremfya [packet insert] Janssen Biotech, Inc., Horsham, PA 19044. July 2020
13. Menter A et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. A Am Acad Dermatol 2019;80:1029-72
14. Pardasani AG, Feldman SR, Clark AR. Treatment of psoriasis: An algorithm-based approach for primary care physicians. Am Fam Physician 2000;61(3):725-733.
15. Clinical Pharmacology (online database). Tampa FL: Gold Standard Inc.: 2019. Updated periodically 16. Feldman SR. Treatment of psoriasis in adults. UpToDate February 2021. Accessed online 5.3.21 @ https://www.uptodate.com/contents/treatment-of-psoriasis-in-adults
17. Kim WB. Diagnosis and management of psoriasis. Can Fam Physician. 2017 Apr; 63(4): 278–285
18. Wu, JJ. Contemporary Management of Moderate to Severe Psoriasis. Am J Manag Care. 2017;23:S403- S416