

STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service Prior Authorization Criteria

HUMIRA® (adalimumab) and ENBREL® (etanercept)

Effective 10/01/2016

Prior Authorization Request Form

Prior authorization requests for Humira and Enbrel may be approved for their <u>FDA approved indications</u> provided the following criteria are met. Diagnoses must accompany all requests.

- Patient is eighteen (18) years of age or older (see below if diagnosed with juvenile idiopathic arthritis or pediatric Crohn's Disease);
- Initial treatment plan is done in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist); AND
- Negative tuberculin skin test before initiation of therapy; AND

THE FOLLOWING INDICATION-SPECIFIC CRITERIA MUST ALSO BE SATISFIED:

- Ankylosing spondylitis: must include documentation indicating ninety (90) day treatment history with NSAIDs (unless contraindicated).
- **Psoriasis** must have:
 - 1. Diagnosis of moderate to severe psoriasis; AND
 - 2. Prior treatment with a potent topical corticosteroid plus calcipotriol; AND
 - 3. Prior treatment with a Vitamin D analogue; AND
 - 4. Prior treatment with phototherapy; AND
 - 5. Prior ninety (90) day treatment history with a disease-modifying agent (DMARD) such as methotrexate, cyclosporine, acitretin, etc.
- **Psoriatic arthritis:** must have a documented ninety (90) day history of NSAID therapy as well as ninety (90) day trials of at least two DMARDs.
- Rheumatoid arthritis: must have documented ninety (90) day trials of at least two DMARDs.
- <u>Juvenile idiopathic arthritis</u>: Prior authorization for Humira and Enbrel may be granted if the patient is two (2) years of age or older and has failed a ninety (90) day course of therapy with methotrexate.
- <u>Crohn's Disease</u>: Humira is approvable for <u>moderate to severe</u> Crohn's disease. Enbrel is not indicated for treatment of Crohn's disease and will not be approved.



STATE OF WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES BUREAU FOR MEDICAL SERVICES



- <u>Pediatric Crohn's disease</u> (moderate to severe): For patients 6 years of age and older, prior authorization requests for Humira are approvable with documentation of an inadequate response to a 14-day trial of corticosteroids or an immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate.
- <u>Ulcerative Colitis</u>: Humira is approvable following failure or clinically significant
 adverse effects to a thirty (30) day course of aminosalicylates (e.g. sulfasalazine,
 mesalamine) requiring treatment for two (2) or more exacerbations using
 corticosteroids, such as prednisone. *Enbrel is not indicated for treatment of UC and*will not be approved.
- <u>Hidradenitis suppurativa</u>: Humira may be approved in patients 18 years of age or older who satisfy the following additional criteria:
 - 1. Has severe disease (Hurley stage III); OR
 - 2. Has moderate disease (Hurley state II) despite treatment with an oral formulary tetracycline (i.e., doxycycline) OR topical clindamycin.
- <u>Uveitis</u>: Humira may be approved in patients diagnosed with non-infectious uveitis
 who are at least 18 years of age and who have failed to respond adequately to
 corticosteroid therapy, or in whom corticosteroid therapy is inappropriate.

References

- 1) Lexi-Comp drug monographs for Humira and Enbrel (7/11/2016)
- 2) Humira Package Insert (7/2016)
- 3) Enbrel Package Insert
- 4) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
- 5) The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics
- 6) American College of Rheumatology/Spondylitis Association of America/Spondyloarhtritis Research and Treatment Network 2015 Recommendations for the Treatment of Anykylosing Spondylitis and Noradiographic Axial Spondyloarthritis
- 7) Crofford Arthritis Research & Therapy 2013, 15(Suppl 3):S2
- 8) J Braun *et al.* 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
- 9) Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults. A national clinical guideline. Edinburgh (Scotland); Scottish Intercollegiate (SIGN), 2010 Oct (SIGN publication, no. 121 (217 references)
- 10) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009
- 11) EDF Guideline for Hidradenitis Suppurativa / Acne Inversa (HS) S1 Guideline 2016-2017 (file:///C:/Users/E033601/Downloads/Guideline-on-Hidradenitis-suppurativa-S1.pdf)