Blue Cross Blue Shield of Vermont and The Vermont Health Plan
Prior Approval Guidelines
Humira ® (adalimumab)

Description: Adalimumab binds specifically to tumor necrosis factor (TNF) (a naturally occurring cytokine involved in the body’s inflammatory and immune responses.) and blocks its interaction with cell surface TNF receptors.

FDA Indications:
Rheumatoid Arthritis (RA) & Psoriatic Arthritis: For reduction in signs and symptoms, inducing major clinical response, inhibition of the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid or psoriatic arthritis who have not responded to one or more DMARD therapies. DMARDs include: Hydroxychloroquine (Plaquenil®), Azathioprine (Imuran®), Sulfasalazine (Azulfidine®), Cyclophosphamide (Cytoxan®), Cyclosporine Neoral®/Sandimmune®, Methotrexate (Rheumatrex®), Leflunomide (Arava®), Gold Sodium Thiomalate, (Myochrime ®), Auranofin (Ridaura®), Penicillamine (Cupramine®)

Ankylosing Spondylitis: Reducing signs & symptoms in patients with active ankylosing spondylitis. (for those with joint involvement – must trial methotrexate)

Crohn’s Disease: Reducing signs & symptoms and inducing & maintaining clinical remission in adults with moderately to severely active Crohn’s disease with inadequate response to conventional therapies and those non-responsive or intolerant to infliximab.

Psoriasis: Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

Ulcerative Colitis: Indicated for the treatment of moderate-severe ulcerative colitis in adults who have had an inadequate response to other immunosuppressants, such as corticosteroids, azathioprine, and 6-mercaptopurine.

Pediatric Crohns Disease: For reducing signs and symptoms, and achieving and maintaining clinical remission, in children six years of age and older with Crohn’s disease who have had an inadequate response to corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, methotrexate).

Juvenile Idiopathic Arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.

Hidradenitis Suppurativa: indicated for the adult treatment of moderate to severe hidradenitis suppurativa.

Panuveitis: adult treatment of non-infectious intermediate, posterior and panuveitis.

Warning/Precautions:
•Serious infections including tuberculosis, invasive fungal infections & opportunistic infections. Evaluate for tuberculosis & latent infection prior to initiating therapy.
•Malignancies; In controlled portions of clinical trials more cases of malignancies observed among patients receiving TNG blockers. Patients with RA at higher risk for development of lymphoma.
•Hypersensitivity Reactions; •Hepatitis B Reactivation; •Neurological Reactions
•Hematological Reactions
•Anakinra- Serious infections seen in clinical studies with concurrent use of anakinra.
•Heart Failure- Worsening of CHF noted with TNF blockers
•Vaccinations- Pts. on Humira may not receive live vaccines.
•Immunosuppression- May alter host defenses against infection & malignancy

Reasons for Prior Authorization: ☒ Cost ☒ Potential for misuse ☒ Toxicity

Criteria for Approval:
1) Diagnosis is an FDA-Labeled Indication (moderately to severely active Rheumatoid Arthritis, Ankylosing Spondylitis, Crohns Disease, Psoriasis, Ulcerative Colitis, Pediatric Crohns Disease(6yoa+), Juvenile Idiopathic Arthritis(2yoa+), Hidradenitis Suppurativa, Panuveitis) and
2) Patient has demonstrated a negative tuberculin test and
3) Patient has no contraindications to treatment (see below) and
4) Patient is at least 18 years of age or older.
5) Patient has psoriasis involve a Body Surface Area >or equal to 10%?
6) Patient has had a trial and failure of a DMARD
7) Patient has had a trial and failure of Methotrexate

Initial Approvals: Initial approval will be for 3 months patient should be evaluated for response to therapy. If patient is responding to therapy, an additional 12 months will be approved, annually
• Dispensed in ONLY 30 days supplies

Benefit Approvals
Approval will be for an initial 3 month period, all subsequent renewals will be for 12 months

Reasons for Denial of Benefit:
1) Patient has the following contraindication
a) History of hypersensitivity to adalimumab or any of its components
2) Patient does not meet above criteria

References: