Policy Applies to: Commercial and Medicare plans

Background:
Golimumab is a fully human anti–TNF-alfa (TNF-α) monoclonal antibody. The constant regions of the heavy and light chains of golimumab are identical in amino acid sequence to the corresponding constant regions of the human/mouse chimeric monoclonal antibody, infliximab. In contrast to infliximab, the heavy and light variable regions of golimumab are human sequence. Golimumab binds to both the soluble and transmembrane bioactive forms of human TNFα. This interaction prevents the binding of TNFα to its receptors, thereby inhibiting the biological activity of TNFα (a cytokine protein). TNF, a naturally occurring cytokine, is involved in normal inflammatory and immune responses and plays an important role in the inflammatory responses associated with rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. Golimumab has been approved for the treatment of these immunologic disorders and is self-administered by subcutaneous injection.

Approval Criteria: When a benefit, golimumab may be approved when all of the following criteria are met:

1. The member should be under the supervision of a rheumatologist or dermatologist AND
2. Golimumab is to be used in combination with methotrexate for the treatment of adult patients with moderately to severely active rheumatoid arthritis OR
3. Golimumab is to be used alone or in combination with methotrexate for the treatment of adult patients with active psoriatic arthritis OR
4. Golimumab is to be used for reducing the signs and symptoms in patients with ankylosing spondylitis AND
5. Golimumab should not be used in conjunction with Enbrel®, Remicade®, Amevive®, Humira™, or Kineret®.

Use of golimumab for disease states outside of its FDA-approved indications should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.

Duration of authorization:

If approved, up to a lifetime authorization may be granted.

References:


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