Golimumab for Intravenous Infusion

NDC CODE(S) 57894-0350-XX SIMPONI ARIA 50MG/4ML Solution (JANSSEN BIOTECH)

DESCRIPTION

Golimumab is a human IgG1K monoclonal antibody specific for tumor necrosis factor alpha (TNFα), a cytokine protein. It is considered an immune modulator and TNF-blocker. Golimumab binds to bioactive forms of human TNFα and inhibits their biological activity by preventing them from binding to their receptors. Elevated TNFα levels are found in the blood, synovium, and joints in multiple chronic inflammatory conditions.

POLICY

- Golimumab for intravenous infusion for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Ankylosing Spondylitis (AS)
  - Polyarticular Juvenile Idiopathic Arthritis (pJIA)
  - Psoriatic Arthritis (PsA)
  - Rheumatoid Arthritis (RA)
- Golimumab for intravenous infusion for the treatment for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL

- Golimumab for intravenous infusion is considered **medically appropriate** if **ALL** of the following criteria are met:
  - Individual is 18 years of age or older unless otherwise specified
  - Individual has been screened and evaluated for and will receive ongoing monitoring for the presence of **ALL** of the following prior to initiating treatment:
    - Latent tuberculosis (TB) infection
    - Hepatitis B virus (HBV)
    - Active infection, including clinically important localized infections
  - Individual will not receive live vaccines while receiving agent
  - Individual is not on concurrent treatment with another TNF inhibitor, a biologic response modifier or non-biologic agent (e.g., apremilast, tofacitinib, baricitinib)
  - Physician has assessed baseline disease severity utilizing an objective measure/tool
  - Diagnosis of **ANY ONE** of the following:
    - Ankylosing Spondylitis (AS) if **ALL** of the following:
      - Documented active disease
      - Adequate trial and failure of minimum of **TWO** (2) non-steroidal anti-inflammatory agents (NSAIDS) unless use is contraindicated
    - Polyarticular Juvenile Idiopathic Arthritis (pJIA) if **ALL** of the following:
      - Individual is 2 years of age or older
      - Documented moderate to severe active polyarticular disease
      - Used as a single agent or in combination with methotrexate
      - Minimum 1-month trial and failure (unless contraindicated or intolerant) of prior therapy with **ANY ONE** of the following:
        - Oral non-steroidal anti-inflammatory drugs (NSAIDs)

- Oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.)
- Psoriatic Arthritis (PsA) if **ALL** of the following:
  - Individual is 2 years of age or older
  - Disease is documented active disease that is **ANY ONE** of the following:
    - Predominantly axial disease **OR** active enthesitis and/or dactylitis after an adequate trial with failure of at least **TWO** (2) non-steroidal anti-inflammatory agents (NSAIDs) unless use is contraindicated
    - Peripheral arthritis after a trial and failure of at least a 3 month trial of **ONE** oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine
- Rheumatoid Arthritis (RA) if **ALL** of the following:
  - Documented moderate to severe active disease
  - Minimum 3 month trial and failure of previous therapy with one oral disease modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, auranofin, hydroxychloroquine sulfate, penicillamine, sulfasalazine or leflunomide
  - Treatment in combination with methotrexate unless contraindicated

RENEWAL CRITERIA

- Golimumab for intravenous infusion is considered **medically appropriate** for renewal if **ALL** of the following criteria are met:
  - Individual continues to meet initial approval criteria other than prerequisite therapies
  - Absence of unacceptable toxicity from the drug, e.g., severe infections, cardiotoxicity/heart failure, neurotoxicity, lupus-like syndrome, malignancy, demyelinating disorders, severe hypersensitivity reactions, severe hematologic cytopenias, including but not limited to, pancytopenia, leukopenia, neutropenia, thrombocytopenia, etc.
  - Ongoing monitoring for TB and other infections
  - Disease response as indicated for **ANY ONE** of the following:
    - Ankylosing Spondylitis by improvement in signs and symptoms compared to baseline such as total back pain, physical function, morning stiffness, and/or an improvement on a disease activity scoring tool (e.g., ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index [BASDAI])
    - Polyarticular Juvenile Idiopathic Arthritis (pJIA) by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool (e.g., an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score [JADAS] or the American College of Rheumatology Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables)
    - Psoriatic Arthritis by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool (i.e., defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria [PsARC], one of which must be joint tenderness or swelling score, with no worsening in any of the four criteria.)
    - Rheumatoid Arthritis by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool (e.g. an improvement on a composite scoring index such as Disease Activity Score-28 [DAS28] of 1.2 points or more or a ≥20% improvement on the American College of Rheumatology-20 [ACR20] criteria)

INDICATION(S)	DOSAGE & ADMINISTRATION
Rheumatoid Arthritis, Ankylosing Spondylitis	Administer a 2 mg/kg intravenous infusion at weeks 0, and 4, then every 8 weeks thereafter

Psoriatic Arthritis	**Adult:** Administer a 2 mg/kg intravenous infusion at weeks 0 and 4, then every 8 weeks thereafter. **Pediatric:** Administer an 80 mg/m2 given as an intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter.
Polyarticular Juvenile Idiopathic Arthritis	Administer an 80 mg/m2 given as an intravenous infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter

LENGTH OF AUTHORIZATION

Coverage will be provided for 6 months and may be renewed

Click here to view **DOSAGE LIMITS**

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with **Tennessee** Code Annotated **Section 56-7-2352** regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

Deodhar, A., Reveille, J. D., Harrison, D. D., Kim, L. Lo, K., Leu, J. H., Hsia, E. C. (2017). Safety and efficacy of golimumab administered intravenously in adults with ankylosing spondylitis: results through week 28 of the GO-ALIVE study. *The Journal of Rheumatology.* Retrieved January 11, 2018 from http://www.jrheum.org/content/early/2017/12/18/jrheum.170487.

Kavanaugh, A., Husni, M. E., Harrison, D. D., Kim, L., Lo, K. H., Leu, J. H., Hsia, E., C. (2017, October). Safety and efficacy of intravenous golimumab in patients with active psoriatic arthritis: results through week twenty-four of the GO-VIBRANT study. *Arthritis and Rheumatology,* 69 (11), 2151-2161.

Lexicomp Online. (2020, September). AHFS DI. *Golimumab*. Retrieved November 12, 2020 from Lexicomp Online with AHFS.

MICROMEDEX Healthcare Series. Drugdex Evaluations. (2020, October). *Golimumab*. Retrieved November 12, 2020 from MICROMEDEX Healthcare Series.

U. S. Food and Drug Administration. (2020, September). Center for Drug Evaluation and Research. *Simponi Aria® (golimumab) injection for intravenous use*. Retrieved November 12, 2020 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125433s030s031lbl.pdf.

EFFECTIVE DATE 4/2/21

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