



Louisiana

golimumab (Simponi Aria[®], Simponi[®])

Policy # 00223

Original Effective Date: 07/22/2009

Current Effective Date: 01/01/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Simponi Aria[®]†

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Rheumatoid Arthritis

Based on review of available data, the Company may consider the use of intravenous (IV) golimumab (Simponi Aria) for the treatment of rheumatoid arthritis (RA) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of intravenous (IV) golimumab (Simponi Aria) for the treatment of rheumatoid arthritis (RA) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active rheumatoid arthritis (RA); AND
- Simponi Aria is used in combination with methotrexate (MTX) unless there is a contraindication to taking methotrexate (MTX) or a history of methotrexate (MTX) intolerance; AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Simponi Aria is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira[®])[‡] OR other drugs such as apremilast (Otezla[®])[‡] or tofacitinib (Xeljanz/XR[®])[‡]; AND
- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Psoriatic Arthritis

Based on review of available data, the Company may consider the use of intravenous (IV) golimumab (Simponi Aria) for the treatment of psoriatic arthritis (PsA) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of intravenous (IV) golimumab (Simponi Aria) for the treatment of psoriatic arthritis (PsA) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND

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- Patient has active psoriatic arthritis (PsA); AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Simponi Aria is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Ankylosing Spondylitis

Based on review of available data, the Company may consider the use of intravenous (IV) golimumab (Simponi Aria) for the treatment of ankylosing spondylitis (AS) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of intravenous (IV) golimumab (Simponi Aria) for the treatment of active ankylosing spondylitis (AS) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active ankylosing spondylitis (AS); AND
- Patient has failed treatment with non steroidal anti-inflammatory drugs (NSAIDs) or has documented contraindications to non steroidal anti-inflammatory drug (NSAID) usage; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Simponi Aria is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of intravenous (IV) golimumab (Simponi Aria) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as not **medically necessary****).

Based on review of available data, the Company considers the use of intravenous (IV) golimumab (Simponi Aria) for indications other than those listed above to be **investigational.***

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of intravenous (IV) golimumab (Simponi Aria) when any of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary****:

- For rheumatoid arthritis (RA) and psoriatic arthritis (PsA):
 - Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs)
- For ankylosing spondylitis (AS):
 - Patient has failed treatment with non steroidal anti-inflammatory drugs (NSAIDs) or has documented contraindications to non steroidal anti-inflammatory drug (NSAID) usage

Simponi^{®†}

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Rheumatoid Arthritis

Based on review of available data, the Company may consider the use of subcutaneous (SC) golimumab (Simponi) for the treatment of rheumatoid arthritis (RA) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of subcutaneous (SC) golimumab (Simponi) for the treatment of rheumatoid arthritis (RA) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active rheumatoid arthritis (RA); AND
- Subcutaneous (SC) Simponi is used in combination with methotrexate (MTX) unless there is a contraindication to taking methotrexate (MTX) or a history of methotrexate (MTX) intolerance; AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); AND
- *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Subcutaneous (SC) Simponi is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: tocilizumab (Actemra^{®†}), etanercept (Enbrel^{®†}), adalimumab (Humira), or tofacitinib (Xeljanz/XR) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

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*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Psoriatic Arthritis

Based on review of available data, the Company may consider the use of subcutaneous (SC) golimumab (Simponi) for the treatment of psoriatic arthritis (PsA) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of subcutaneous (SC) golimumab (Simponi) for the treatment of psoriatic arthritis (PsA) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active psoriatic arthritis (PsA); AND
- Subcutaneous (SC) Simponi is used alone or in combination with methotrexate (MTX); AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); AND

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Subcutaneous (SC) Simponi is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), ustekinumab (Stelara^{®†}), or secukinumab (Cosentyx^{®‡}) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Ankylosing Spondylitis

Based on review of available data, the Company may consider the use of subcutaneous (SC) golimumab (Simponi) for the treatment of ankylosing spondylitis (AS) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of subcutaneous (SC) golimumab (Simponi) for the treatment of active ankylosing spondylitis (AS) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active ankylosing spondylitis (AS); AND

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- Patient has failed treatment with non steroidal anti-inflammatory drugs (NSAIDs) or has documented contraindications to non steroidal anti-inflammatory drug (NSAID) usage; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Subcutaneous (SC) Simponi is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), or secukinumab (Cosentyx) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Ulcerative Colitis

Based on review of available data, the Company may consider the use of subcutaneous (SC) golimumab (Simponi) for the treatment of ulcerative colitis (UC) to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of subcutaneous (SC) golimumab (Simponi) for the treatment of ulcerative colitis (UC) will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has moderately to severely active ulcerative colitis (UC); AND
- Patient has demonstrated corticosteroid dependence OR has failed treatment with oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine; AND
- Subcutaneous (SC) Simponi is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with adalimumab (Humira) after at least two months of therapy (unless there is clinical evidence or patient history that suggests that the this product will be ineffective or cause an adverse reaction to the patient); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has a negative TB (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of subcutaneous (SC) golimumab (Simponi) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as not **medically necessary****).

Based on review of available data, the Company considers the use of subcutaneous (SC) golimumab (Simponi) for indications other than those listed above to be **investigational.***

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of subcutaneous (SC) golimumab (Simponi) when any of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary****:

- For rheumatoid arthritis (RA):
 - Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs)
 - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: tocilizumab (Actemra), etanercept (Enbrel), adalimumab (Humira), or tofacitinib (Xeljanz/XR)
- For psoriatic arthritis (PsA):
 - Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs)
 - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), ustekinumab (Stelara), or secukinumab (Cosentyx)
- For ankylosing spondylitis (AS):
 - Patient has failed treatment with non steroidal anti-inflammatory drugs (NSAIDs) or has documented contraindications to non steroidal anti-inflammatory drug (NSAID) usage
 - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), or secukinumab (Cosentyx)
- For ulcerative colitis (UC):
 - Patient has failed treatment with adalimumab (Humira) after at least two months of therapy

Background/Overview

SC Simponi is a tumor necrosis factor (TNF) blocker approved for the treatment of RA, PsA, AS, and UC. A new IV formulation, with the name of Simponi Aria, has been approved for used in patients with RA, PsA, and AS. Tumor necrosis factor is a naturally occurring cytokine that is involved with the inflammatory and immune responses. Excessive activation of immune effector cells and overproduction of TNF can cause severe inflammation and tissue damage. Inhibition of TNF activity in certain inflammatory diseases may alleviate symptoms and prevent disease progression. For RA, PsA, and AS, the SC dosing is 50 mg once

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monthly. For UC, the SC dosing is 200 mg initially, then 100 mg at week 2, and then 100 mg every month thereafter. Simponi Aria is given at 2 mg/kg at weeks 0 and 4, then every 8 weeks.

Rheumatoid Arthritis

RA is a chronic (long-term) disease that causes inflammation of the joints and surrounding tissues. It can also affect other organs. It is considered an autoimmune disease. In an autoimmune disease, the immune system confuses healthy tissue for foreign substances. Typically first line treatments such as DMARDs are used to treat this condition. An example of a DMARD would include MTX.

Psoriatic Arthritis

PsA is an arthritis that is often associated with psoriasis of the skin. Typically first line treatments such as DMARDs are used to treat this condition. An example of a DMARD would include MTX.

Ankylosing Spondylitis

AS is a chronic inflammatory disease that affects the joints between the vertebrae of the spine, and the joints between the spine and the pelvis. It eventually causes the affected vertebrae to fuse or grow together. Nonsteroidal anti-inflammatory drugs such as ibuprofen or naproxen are used to reduce inflammation and pain associated with the condition. Corticosteroid therapy or medications to suppress the immune system may be prescribed to control various symptoms.

Ulcerative Colitis

UC is a chronic, episodic, inflammatory disease of the large intestine and rectum characterized by bloody diarrhea. This disease usually begins in the rectal area and may eventually extend through the entire large intestine. Repeated episodes of inflammation lead to thickening of the wall of the intestine and rectum with scar tissue. Death of colon tissue or sepsis may occur with severe disease. The goals of treatment are to control the acute attacks, prevent recurrent attacks and promote healing of the colon. Hospitalization is often required for severe attacks. Typically, first line treatments such as corticosteroids, 6-MP and Azathioprine are used to treat this condition.

Disease-Modifying Anti-Rheumatic Drugs

DMARDs are typically used to treat various inflammatory conditions. These drugs slow the disease process by modifying the immune system:

- MTX
- Cyclosporine
- Sulfasalazine
- Mercaptopurine
- Gold Compounds

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

SC Simponi is approved by the FDA for the treatment of adults with moderately to severely active RA in combination with MTX, active PsA, active AS, and moderate to severe UC. Simponi Aria is FDA approved for the treatment of adults with moderate to severe RA, PsA, and AS.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Large, randomized, double-blind trials in patients with RA who were MTX-naïve (GO-BEFORE) or -experienced (GO-FORWARD) have shown that Simponi 50 or 100mg every 4 weeks, in combination with MTX, was more effective than MTX alone for improving signs and symptoms of arthritis at weeks 14 and/or 24, according to ACR (American College of Rheumatology) criteria. In patients with active RA despite previous treatment with anti-TNF agents (GO-AFTER), Simponi 50 or 100mg every 4 weeks was more effective than placebo for improving ACR responses at weeks 14 and 24; most patients in the study received concomitant MTX. In patients with PsA in the GO-REVEAL study, significantly more Simponi than placebo recipients achieved a > or = 20% improvement in ACR criteria at week 14. Simponi was also superior to placebo for improving the signs and symptoms of ankylosing spondylitis in the GO-RAISE study; significantly more Simponi than placebo recipients achieved a > or = 20% improvement in the Assessment in Ankylosing Spondylitis (ASAS) criteria at week 14. In the 5 phase III trials in patients with RA, PsA or AS, there was no clear evidence of improved ACR or ASAS responses with the 100mg dosage compared with the 50mg dosage of Simponi. The tolerability profile of Simponi was generally consistent with that of other anti-TNF agents. UC was studied in two trials, the UC-1 and UC-2 trials. In the UC-1 trial, a greater proportion of patients achieved clinical response, clinical remission and had improvement of endoscopic appearance of the mucosa. In UC-2, a greater proportion of patients maintained clinical response through week 54.

Simponi Aria for the treatment of RA was evaluated in one multi-center, randomized, double-blind, placebo controlled trial in 592 adult patients. Patients were randomized to receive either Simponi Aria 2mg/kg or placebo at weeks 0, 4, and every 8 weeks in addition to MTX. A greater percentage of patients treated with Simponi Aria plus MTX achieved ACR20 at week 14 and ACR 50 at week 24 versus patients treated with placebo. Simponi Aria was evaluated in active PsA in 480 patients. The primary endpoint was the percentage of patients achieving an ACR20 response at week 14. At week 14, 22% of the subjects in the placebo group achieved an ACR20 while 75% in the Simponi Aria group achieved an ACR20 at week 14. The efficacy and safety of Simponi Aria in AS was evaluated in 208 patients. The primary endpoint was the percentage of patients achieving an ASAS20 response at week 16. At week 16, 26% of placebo patients achieved an ASAS20 vs. 73% in the Simponi Aria group.

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Policy History

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07/02/2009	Medical Director review
07/22/2009	Medical Policy Committee approval. New policy.
07/01/2010	Medical Director approval
07/21/2010	Medical Policy Implementation Committee approval. Changed the recommendation in the coverage section to read, "prior to receiving treatment with golimumab, all patients have a negative cancer history" instead of a "negative cancer screening".
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2011	Medical Policy Committee review
11/16/2011	Medical Policy Implementation Committee approval. Added criteria for rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis stating that patients must have failed treatment with adalimumab (Humira) or etanercept (Enbrel) before using golimumab (Simponi) after two months of use. Noted that the reason for denial will be not medically necessary if this criterion is not met. The not medically necessary denial statement is also incorporated into the Investigational and Not Medically Necessary coverage sections.
02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. Cancer criteria removed from policy.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Added a new indication for Ulcerative colitis with similar criteria as other similar drugs. Reworded the investigational and not medically necessary sections. Relocated PPD to each indication instead of a note. Updated some background info.
10/10/2013	Medical Policy Committee review

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- 10/16/2013 Medical Policy Implementation Committee approval. Added "Simponi Aria" to the title. Modified the title since there is a new formulation of the drug that has been approved. Added new product: Simponi Aria and gave similar criteria as infused products with indication of Rheumatoid Arthritis. Changed the requirement for subcutaneous Simponi to trying both Humira AND Enbrel first for Rheumatoid Arthritis, Psoriatic Arthritis, and Ankylosing Spondylitis. Modified the not medically necessary section to reflect changes
- 07/16/2014 Coding updates due to new code for 2014, J1602- Golimumab being added for review.
- 10/02/2014 Medical Policy Committee review
- 10/15/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
- 10/08/2015 Medical Policy Committee review
- 10/21/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 10/06/2016 Medical Policy Committee review
- 10/19/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
- 11/02/2017 Medical Policy Committee review
- 11/15/2017 Medical Policy Implementation Committee approval. Changed first line drugs for RA to Actemra, Enbrel, Humira, Xeljanz/XR, AS to Enbrel, Humira, Cosentyx, PsA to Enbrel, Humira, Stelara, Cosentyx for SubQ Simponi. Updated background and rationale. Added new indications for Simponi Aria (psoriatic arthritis and ankylosing spondylitis).

Next Scheduled Review Date: 11/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT[®]), copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J1602

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Louisiana

golimumab (Simponi Aria[®], Simponi[®])

Policy # 00223

Original Effective Date: 07/22/2009

Current Effective Date: 01/01/2018

ICD-10 Diagnosis	L40.50-L40.59	M05.00-M05.079	M05.09	M05.20-M05.279
	M05.29-M05.30	M05.311-M05.379	M05.39-M05.40	M05.411-M05.479
	M05.49-M05.50	M05.511-M05.579	M05.59-M05.60	M05.611-M05.679
	M05.69-M05.70	M05.711-M05.779	M05.79-M05.80	M05.811-M05.879
	M05.89-M05.9	M06.00-M06.079	M06.08-M06.09	M06.1
	M06.20-M06.279	M06.28-M06.30	M06.311-M06.379	M06.38-M06.39
	M06.80-M06.879	M06.88-M06.9	M08.00-M08.079	M08.08-M08.1
	M08.20-M08.279	M08.28-M08.29	M08.1, M08.3	M08.40-M08.479
	M08.48	M08.80-M08.879	M08.88-M08.89	M08.90-M08.979
	M08.98-M08.99	M45.0-M45.9	M48.8X1-M48.8X9	

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient’s illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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