



# Louisiana

## adalimumab Biosimilars

Policy # 00835

Original Effective Date: 05/08/2023

Current Effective Date: 05/08/2023

*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.*

## 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.*

## Amjevita

### Rheumatoid Arthritis

Based on review of available data, the Company may consider adalimumab-atto (Amjevita<sup>TM</sup>)<sup>‡</sup> for the treatment of rheumatoid arthritis to be **eligible for coverage**.\*\*

### Patient Selection Criteria

Coverage eligibility will be considered for adalimumab-atto (Amjevita) for the treatment of rheumatoid arthritis when all of the following criteria are met:

- Patient has moderately to severely active rheumatoid arthritis; AND
- Patient is 18 years of age or older; AND
- Requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as etanercept (Enbrel<sup>®</sup>)<sup>‡</sup> OR other drugs such as tofacitinib (Xeljanz<sup>®</sup>/XR)<sup>‡</sup> or apremilast (Otezla<sup>®</sup>)<sup>‡</sup>; AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira<sup>®</sup>)<sup>‡</sup>, tofacitinib (Xeljanz/XR), upadacitinib (Rinvoq<sup>TM</sup>)<sup>‡</sup>, or subcutaneous tocilizumab (Actemra<sup>®</sup>)<sup>‡</sup> unless there is clinical

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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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*

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

*Note:*

*The recommended dosing of adalimumab-atto (Amjevita) in rheumatoid arthritis is 40 mg every other week. Members unresponsive to 40 mg every other week after 12 weeks of therapy AND NOT on methotrexate may be approved for 40 mg once weekly dosing OR 80 mg every other week dosing.*

### **Polyarticular Juvenile Idiopathic Arthritis**

Based on review of available data, the Company may consider adalimumab-atto (Amjevita) for the treatment of polyarticular juvenile idiopathic arthritis to be **eligible for coverage.\*\***

### **Patient Selection Criteria**

Coverage eligibility will be considered for adalimumab-atto (Amjevita) for the treatment of polyarticular juvenile idiopathic arthritis when all of the following criteria are met:

- Patient has moderately to severely active polyarticular juvenile idiopathic arthritis; AND
- Patient is 2 years of age or older; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: adalimumab (Humira), etanercept (Enbrel), tofacitinib (Xeljanz), or subcutaneous tocilizumab (Actemra) unless there is clinical evidence or patient history that

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suggests that these products will be ineffective or cause an adverse reaction to the patient;  
AND

*(Note: This specific patient selection 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 test (e.g., PPD, blood test) prior to treatment.

## Psoriatic Arthritis

Based on review of available data, the Company may consider adalimumab-atto (Amjevita) for the treatment of psoriatic arthritis to be **eligible for coverage.\*\***

### Patient Selection Criteria

Coverage eligibility will be considered for adalimumab-atto (Amjevita) for the treatment of psoriatic arthritis when all of the following criteria are met:

- Patient has active psoriatic arthritis; AND
- Patient is 18 years of age or older; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- 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<sup>®</sup>)<sup>‡</sup>, secukinumab (Cosentyx<sup>®</sup>)<sup>‡</sup>, tofacitinib (Xeljanz/XR), guselkumab (Tremfya<sup>®</sup>)<sup>‡</sup>, apremilast (Otezla), upadacitinib (Rinvoq), or risankizumab-rzaa (Skyrizi<sup>®</sup>)<sup>‡</sup> 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 selection 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 test (e.g., PPD, blood test) prior to treatment.

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## **Ankylosing Spondylitis**

Based on review of available data, the Company may consider adalimumab-atto (Amjevita) for the treatment of active ankylosing spondylitis to be **eligible for coverage.\*\***

### Patient Selection Criteria

Coverage eligibility will be considered for adalimumab-atto (Amjevita) for the treatment of active ankylosing spondylitis when all of the following criteria are met:

- Patient has active ankylosing spondylitis; AND
- Patient is 18 years of age or older; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has failed treatment with non-steroidal anti-inflammatory drugs (NSAIDs), such as naproxen, 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq) 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 selection 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 test (e.g., PPD, blood test) prior to treatment.

## **Crohn's Disease**

Based on review of available data, the Company may consider adalimumab-atto (Amjevita) for the treatment of Crohn's disease to be **eligible for coverage.\*\***

### Patient Selection Criteria

Coverage eligibility will be considered for adalimumab-atto (Amjevita) for the treatment of Crohn's disease when all of the following criteria are met:

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- Patient has moderately to severely active Crohn's disease; AND
- Patient is 6 years of age or older; AND
- Patient has failed treatment with conventional therapies such as corticosteroids, 6-mercaptopurine, or azathioprine 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); 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 this product will be ineffective or cause an adverse reaction to the patient; AND  
*(Note: This specific patient selection 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 test (e.g., PPD, blood test) prior to treatment.

### Plaque Psoriasis

Based on review of available data, the Company may consider adalimumab-atto (Amjevita) for the treatment of plaque psoriasis to be **eligible for coverage.\*\***

#### Patient Selection Criteria

Coverage eligibility will be considered for adalimumab-atto (Amjevita) for the treatment of plaque psoriasis when all of the following criteria are met:

- Patient has moderate to severe chronic plaque psoriasis; AND
- Patient is 18 years of age or older; AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND

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- Patient has greater than 10% of body surface area (BSA) or less than or equal to 10% BSA with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia); AND  
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: adalimumab (Humira), etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara), secukinumab (Cosentyx), guselkumab (Tremfya), or risankizumab (Skyrizi) 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*
- Patient has failed to respond to an adequate trial of one of the following treatment modalities unless there is clinical evidence or patient history that suggests the use of these treatments will be ineffective or cause an adverse reaction to the patient:
  - Ultraviolet B; or
  - Psoralen positive Ultraviolet A; or
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin).*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*

### Ulcerative Colitis

Based on review of available data, the Company may consider adalimumab-atto (Amjevita) for the treatment of ulcerative colitis to be **eligible for coverage.\*\***

#### Patient Selection Criteria

Coverage eligibility will be considered for adalimumab-atto (Amjevita) for the treatment of ulcerative colitis when all of the following criteria are met:

- Patient has moderately to severely active ulcerative colitis; AND
- Patient is 18 years of age or older; AND
- Patient has failed treatment with conventional therapies such as corticosteroids, azathioprine, or 6-mercaptopurine 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 selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met)*

- Patient has failed treatment with adalimumab (Humira) after at least TWO months of therapy unless there is clinical evidence or patient history that suggests this product will be ineffective or cause an adverse reaction to the patient; AND

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

- Requested drug is NOT used in combination with other biologic DMARDs, such as etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of adalimumab-atto (Amjevita) 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:
  - Patient has failed treatment with one or more traditional DMARDs, such as methotrexate
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), tofacitinib (Xeljanz/XR), upadacitinib (Rinvoq), or subcutaneous tocilizumab (Actemra)
- For polyarticular juvenile idiopathic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs, such as methotrexate
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: adalimumab (Humira), etanercept (Enbrel), tofacitinib (Xeljanz), or subcutaneous tocilizumab (Actemra)
- For psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs, such as methotrexate
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira),

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ustekinumab (Stelara), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), guselkumab (Tremfya), apremilast (Otezla), upadacitinib (Rinvoq), or risankizumab-rzaa (Skyrizi)

- For ankylosing spondylitis:
  - Patient has failed treatment with NSAIDs, such as naproxen
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq)
- For Crohn's disease:
  - Patient has failed treatment with conventional therapies such as corticosteroids, 6-mercaptopurine, or azathioprine
  - Patient has failed treatment with adalimumab (Humira) after at least TWO months of therapy
- For plaque psoriasis:
  - Patient has greater than 10% of BSA or less than or equal to 10% BSA with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
  - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: adalimumab (Humira), etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara), secukinumab (Cosentyx), guselkumab (Tremfya), or risankizumab (Skyrizi)
  - Patient has failed to respond to an adequate trial of one of the following treatment modalities:
    - Ultraviolet B
    - Psoralen positive Ultraviolet A
    - Systemic therapy (i.e. methotrexate, cyclosporine, acitretin)
- For ulcerative colitis:
  - Patient has failed treatment with conventional therapies such as corticosteroids, azathioprine, or 6-mercaptopurine
  - Patient has failed treatment with adalimumab (Humira) after at least TWO months of therapy

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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 adalimumab-atto (Amjevita) when the patient selection criteria are not met (with the exception of those denoted above as **not medically necessary\*\***) OR for use in any other indication than those listed above to be **investigational.\***

## **Background/Overview**

Amjevita is a biosimilar to Humira. Biosimilar means that the biological product, Amjevita, is approved based on data demonstrating that it is highly similar to an FDA-approved biological product known as a reference product, Humira, and that there are no clinically meaningful differences between the biosimilar product and the reference product. The biosimilarity of Amjevita has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its package insert. Amjevita carries very similar indications to Humira, with very few exceptions. Amjevita is currently approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, ulcerative colitis, plaque psoriasis, and Crohn's disease (including pediatric Crohn's disease).

### **Rheumatoid Arthritis**

Rheumatoid arthritis 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 traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

### **Polyarticular Juvenile Idiopathic Arthritis**

Polyarticular juvenile idiopathic arthritis includes the inflammation of joints and presence of arthritis in children. Polyarticular juvenile idiopathic arthritis typically occurs in a symmetrical manner with knees, wrists, and ankles most frequently affected. However certain subgroups of children do have predominantly asymmetrical involvement. Typically, first line treatments such as traditional

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DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

### **Psoriatic Arthritis**

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

### **Ankylosing Spondylitis**

Ankylosing spondylitis 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.

### **Crohn's Disease**

Crohn's disease is a chronic autoimmune disease that can affect any part of the gastrointestinal tract but most commonly occurs in the ileum. As a result of the immune attack, the intestinal wall becomes thick, and deep ulcers may form. In addition to the bowel abnormalities, Crohn's disease can also affect other organs in the body. Typically, first line treatments such as corticosteroids, 6-mercaptopurine and azathioprine are used to treat this condition.

### **Plaque Psoriasis**

Psoriasis is a common skin condition that is caused by an increase in production of skin cells. It is characterized by frequent episodes of redness, itching and thick, dry silvery scales on the skin. It is most commonly seen on the trunk, elbows, knees, scalp, skin folds and fingernails. This condition can appear suddenly or gradually and may affect people of any age; it most commonly begins between the ages of 15 and 35. Psoriasis is not contagious. It is an inherited disorder related to an inflammatory response in which the immune system produces too much TNF-alpha. It may be severe in immunosuppressed people or those who have other autoimmune disorders such as rheumatoid arthritis. Typical treatments for severe cases of plaque psoriasis include ultraviolet therapy or systemic therapies such as methotrexate or cyclosporine.

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## **Ulcerative Colitis**

Ulcerative colitis 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-mercaptopurine and azathioprine are used to treat this condition.

## **Disease-Modifying Anti-Rheumatic Drugs**

Traditional DMARDs are typically used for the treatment of inflammatory conditions. These drugs slow the disease process by modifying the immune system.

- methotrexate
- cyclosporine
- sulfasalazine
- mercaptopurine
- gold compounds

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Amjevita is currently approved for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, ulcerative colitis, plaque psoriasis, and Crohn's disease (including pediatric Crohn's disease).

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The clinical trial information in the Amjevita package insert mimic those of the Humira package insert. Repeating the mention of these trials is beyond the scope of this policy.

## References

1. Amjevita [package insert]. Amgen. Thousand Oaks, California. Updated July 2022.

## Policy History

Original Effective Date: 05/08/2023

Current Effective Date: 05/08/2023

04/06/2023 Medical Policy Committee review

04/12/2023 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 04/2024

\*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. Food and Drug Administration (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 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,

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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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**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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