infliximab-axxq (Avsola®)

Policy # 00712
Original Effective Date: 09/14/2020
Current Effective Date: 12/11/2023

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.

Note: infliximab (Remicade®, Infliximab) is addressed separately in medical policy 00217.

Note: infliximab-dyyb (Inflectra®) is addressed separately in medical policy 00539.

Note: infliximab-abda (Renflexis®) is addressed separately in medical policy 00607.

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.*

Ankylosing Spondylitis

Based on review of available data, the Company may consider the use of infliximab-axxq (Avsola®)‡ for the treatment of ankylosing spondylitis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for infliximab-axxq (Avsola) for the treatment of ankylosing spondylitis will be considered when ALL of the following criteria are met:

- Patient has a diagnosis of active ankylosing spondylitis; AND
- Patient has failed treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or has documented contraindications to NSAIDs; 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 infliximab (Remicade®, Infliximab)‡ OR infliximab-abda (Renflexis®)‡ after at least 2 months of therapy, 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 tuberculin (TB) test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Crohn's Disease

Based on review of available data, the Company may consider the use of infliximab-axxq (Avsola) for the treatment of Crohn's disease to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for infliximab-axxq (Avsola) for the treatment of Crohn's disease will be considered when the following criteria are met:

- Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy, 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; AND
- Patient meets EITHER of the following criteria:
  - Patient is an adult or child greater than or equal to 6 years of age with moderately to severely active Crohn's disease AND has had an inadequate response to conventional therapy (e.g., mesalamine, corticosteroids, 6-mercaptopurine/azathioprine or azathioprine monotherapy); OR
  - Patient is an adult with fistulizing Crohn's disease requesting the drug in order to reduce the number of draining enterocutaneous and rectovaginal fistulas and to maintain fistula closure.

Ulcerative Colitis

Based on review of available data, the Company may consider the use of infliximab-axxq (Avsola) for the treatment of ulcerative colitis to be **eligible for coverage**.**

Infliximab-axxq (Avsola®)

Policy # 00712
Original Effective Date: 09/14/2020
Current Effective Date: 12/11/2023

Patient Selection Criteria
Coverage eligibility for infliximab-axxq (Avsola) for the treatment of ulcerative colitis will be considered when ALL of the following criteria are met:

- Patient is an adult or child greater than or equal to 6 years of age with moderately to severely active ulcerative colitis; AND
- Patient had an inadequate response to conventional therapy (e.g. corticosteroids, sulfasalazine, mesalamine, balsalazide, azathioprine, cyclosporine, or 6-mercaptopurine); AND
- Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy, 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.

Rheumatoid Arthritis
Based on review of available data, the Company may consider the use of infliximab-axxq (Avsola) in combination with methotrexate for the treatment of rheumatoid arthritis to be **eligible for coverage**.**

Patient Selection Criteria
Coverage eligibility for infliximab-axxq (Avsola) in combination with methotrexate for the treatment of rheumatoid arthritis will be considered when ALL of the following criteria are met:

- Patients has a diagnosis of moderately to severely active rheumatoid arthritis; AND
- Patient has failed methotrexate monotherapy; 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 infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy, 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.

Psoriatic Arthritis

Based on review of available data, the Company may consider the use of infliximab-axxq (Avsola) for the treatment of psoriatic arthritis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for infliximab-axxq (Avsola) for the treatment of psoriatic arthritis will be considered when ALL of the following criteria are met:

- Patient has a diagnosis of psoriatic arthritis; AND
- Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs); 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 infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy, 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.

Plaque Psoriasis

Based on review of available data, the Company may consider the use of infliximab-axxq (Avsola) for the treatment of plaque psoriasis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for infliximab-axxq (Avsola) for the treatment of plaque psoriasis will be considered when ALL of the following criteria are met:

- Patient is an adult with chronic severe (i.e. extensive and/or disabling) plaque psoriasis; AND

- Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy, 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; AND
- Patient has greater than 10% of body surface area affected OR less than or equal to 10% of body surface area affected involving sensitive areas or areas that would significantly impact daily function (e.g. 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 to respond to an adequate trial of ONE of the following treatment modalities:
  - 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.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of infliximab-axxq (Avsola) 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 ankylosing spondylitis:
  - Patient has failed treatment with NSAIDs or has documented contraindications to NSAIDs
  - Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy.
- For Crohn's disease:
  - Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy.
- For ulcerative colitis:

    - Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy.
- For rheumatoid arthritis:
    - Patient has failed methotrexate monotherapy
    - Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy.
- For psoriatic arthritis:
    - Patient has failed treatment with one or more DMARDs
    - Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy.
- For plaque psoriasis:
    - Patient has failed treatment with infliximab (Remicade, Infliximab) OR infliximab-abda (Renflexis) after at least 2 months of therapy
    - Patient has greater than 10% of body surface area affected OR less than or equal to 10% of body surface area affected involving sensitive areas or areas that would significantly impact daily function (e.g. palms, soles of feet, head/neck, or genitalia)
    - Patient has failed to respond to an adequate trial of ONE of the following treatment modalities:
        - Ultraviolet B; OR
        - Psoralen positive Ultraviolet A; OR
        - Systemic therapy (e.g. methotrexate, cyclosporine, acitretin).

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 infliximab-axxq (Avsola) when 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

Avsola, a biosimilar to Remicade, carries the same indications as Remicade. A biosimilar product is a biological product that is approved based on demonstration that it is highly similar to an already

approved biological reference product. The biosimilar must also demonstrate that is has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products. Biosimilar products can only be approved by the FDA if they have the same mechanism of action, route of administration, dosage form, and strengths as the reference product as well as only the indications and conditions of use that have been approved by the FDA for the reference product. Avsola is supplied as 100 mg of infliximab-axxq in a 20 mL vial. Please refer to the package insert for dosing information.

Other biosimilars of Remicade include Inflectra®‡ and Renflexis. A branded Infliximab product from Janssen is also available on the market.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Avsola was approved by the FDA in December of 2019. As previously mentioned Avsola carries the same indications as Remicade.

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.

Adult Crohn's Disease
The safety and efficacy of infliximab for active Crohn's Disease were assessed in 2 randomized, double-blind, placebo-controlled clinical studies in 653 patients with moderate to severely active Crohn's Disease with an inadequate response to prior conventional therapies. In the single dose trial, 15% of placebo patients achieved a clinical response at week 4 vs. 81% of patients receiving 5 mg/kg of infliximab. Additionally, 4% of placebo patients and 48% of patients receiving infliximab achieved clinical remission at week 4. In the multidose trial, subjects were randomized to receive placebo at weeks 2 and 6, then every 8 weeks; the 5 mg/kg infliximab maintenance group received 5 mg/kg at weeks 2 and 6, then every 8 weeks. The 10 mg/kg infliximab maintenance group received

5 mg/kg at weeks 2 and 6, then 10 mg/kg ever 8 weeks. At week 2, 57% of patients were in clinical response. At week 30, 25% of subjects in the placebo maintenance group were in clinical remission vs. 39% (p=0.022) in the infliximab 5 mg/kg maintenance group and 46% (p=0.001) in the infliximab 10 mg/kg infliximab maintenance group. In the placebo maintenance group, 11% of subjects in remission were able to discontinue corticosteroid use vs. 25% (p=0.059) and 34% (p=0.005) in the infliximab 5 mg/kg and 10 mg/kg infliximab maintenance groups.

Fistulizing Crohn's Disease
The safety and efficacy of infliximab were assessed in 2 randomized, double-blind, placebo-controlled studies in patients with fistulizing Crohn's disease with fistulas that were of at least 3 months duration. In the first trial, 94 patients received 3 doses of either placebo or infliximab at weeks 0, 2, and 6. Fistula response was seen in 68% of patients in the 5 mg/kg infliximab group (p=0.002) and 56% of patients in the 10 mg/kg infliximab group (p=0.021) vs. 26% of subjects in the placebo arm. Closure of all fistulas was achieved in 52% of patients treated with infliximab vs. 13% of placebo treated patients (p<0.001). In the second trial, subjects had to have at least 1 draining enterocutaneous fistula. All patients received 5 mg/kg of infliximab at weeks 0, 2, and 6. Patients were randomized to placebo or 5 mg/kg maintenance doses at week 14 and then every 8 weeks through week 46. The primary endpoint was the time from randomization to loss of response among those patients who were in fistula response. At week 14, 65% of patients were in fistula response. Patients randomized to maintenance with infliximab had a longer time to loss of fistula response compared to the placebo maintenance group. At week 54, 38% of patients treated with infliximab had no draining fistulas compared with 22% of placebo treated patients (p=0.02).

Pediatric Crohn's Disease
The safety and efficacy of infliximab were assessed in a randomized, open-label study in 112 pediatric patients aged 6 to 17 years old with moderately to severely active Crohn's disease and an inadequate response to conventional therapies. Subjects received 5 mg/kg of infliximab at weeks 0, 2, and 6. At week 10, 103 subjects were randomized to a maintenance regimen of 5 mg/kg of infliximab given either ever 8 weeks or every 12 weeks. At week 30, 73% (p<0.01) of subjects in the 8 week group had achieved a clinical response and 60% (p<0.05) had achieved a clinical remission. At week 30, 47% of subjects in the 12 week group had achieved a clinical response and 35% had achieved a clinical remission. At week 54, 64% (p<0.01) of subjects in the 8 week group had achieved a clinical response and 56% (p<0.01) had achieved a clinical remission. At week 54, 33% of subjects in the 12 week group had achieved a clinical response and 24% had achieved a

clinical remission. The results demonstrated that there were more responses and remissions in the 8 week group.

Ulcerative Colitis
The safety and efficacy of infliximab were assessed in 2 randomized, double-blind, placebo-controlled clinical studies in 728 subjects with moderately to severely active ulcerative colitis with an inadequate response to conventional oral therapies. Subjects were randomized to either 5 mg/kg or 10 mg/kg of infliximab at weeks 0, 2, 6, and every 8 weeks thereafter. In both ulcerative colitis studies, greater percentages of patients in both infliximab groups achieved clinical response, clinical remission, and mucosal healing than in the placebo group. Each of the effects was maintained through the end of each trial. In addition, a greater proportion of patients in the infliximab groups demonstrated sustained response and sustained remission than in the placebo groups.

Pediatric Ulcerative Colitis
The safety and effectiveness of infliximab in pediatric patients aged 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy are supported by evidence from adequate and well controlled studies in adults. Additional safety and pharmacokinetic data were collected in an open label pediatric ulcerative colitis trial in 60 pediatric patients aged 6-17 years of age. All patients received induction dosing of 5 mg/kg of infliximab at weeks 0, 2, and 6. Patients who did not respond to infliximab at week 8 received no further infliximab. At week 8, 45 patients were randomized to a maintenance regimen of 5 mg/kg of infliximab given either every 8 weeks through week 46 or every 12 weeks through week 42. Of the 60 patients treated, 44 were in clinical response at week 8. At week 8, 24 of 60 patients were in clinical remission as measured by the Mayo score and 17 of 51 patients were in remission as measured by the Pediatric Ulcerative Colitis Activity Index (PUCAI) score. At week 54, 8 of 21 patients in the every 8 week maintenance group and 4 of 22 patients in the every 12 weeks group achieved remission as measured by the PUCAI score.

Rheumatoid Arthritis
The safety and efficacy of infliximab were assessed in 2 multicenter, randomized, double-blind, pivotal trials which compared placebo plus methotrexate versus one of four various doses/schedules of infliximab plus methotrexate. In the first study, all doses/schedules of infliximab plus methotrexate resulted in improvement in signs and symptoms as measured by the ACR20, with a higher percentage of subjects achieving an ACR20, 50, and 70 compared to placebo plus

methotrexate. This improvement was noted in week 2 and remained through week 102. Greater effects on each component of ACR 20 were observed in all patients treated with infliximab plus methotrexate as compared to placebo plus methotrexate. More patients treated with infliximab reached a major clinical response than placebo treated patients. Similar results were noted in the second trial as well.

Ankylosing Spondylitis
The safety and efficacy of infliximab were assessed in a randomized, multicenter, double-blind, placebo-controlled study in 279 patients with active ankylosing spondylitis. At 24 weeks, improvement in the signs and symptoms of ankylosing spondylitis, as measured by the proportion of patients achieving a 20% improvement in ASAS response criteria (ASAS 20), was seen in 60% of patients in infliximab group vs. 18% of patients in the placebo group ($p<0.001$). Improvement was observed at week 2 and maintained through week 24. At 24 weeks, the proportions of patients achieving a 50% and a 70% improvement in the signs and symptoms of ankylosing spondylitis, as measured by ASAS response criteria (ASAS 50 and ASAS 70, respectively), were 44% and 28%, respectively, for patients receiving infliximab, compared to 9% and 4%, respectively, for patients receiving placebo ($p<0.001$, infliximab vs. placebo). A low level of disease activity (defined as a value <20 [on a scale of 0 -100 mm] in each of the 4 ASAS response parameters) was achieved in 22% of patients treated with infliximab vs. 1% in placebo-treated patients ($p<0.001$).

Psoriatic Arthritis
The safety and efficacy of infliximab were assessed in a multicenter, double-blind, placebo-controlled study in 200 adult patients with active psoriatic arthritis despite therapy with NSAIDs or DMARDs. Subjects received either infliximab or placebo. At week 16, placebo patients with <10% improvement from baseline in both swollen and tender joint counts were switched to infliximab induction. At week 24, all placebo treated patients crossed over to infliximab induction. Dosing continued for all patients through week 46. Treatment with infliximab resulted in improvement in signs and symptoms, as assessed by the ACR criteria, with 58% of patients treated with infliximab achieving ACR 20 at week 14, compared with 11% of placebo-treated patients ($p< 0.001$). The response was similar regardless of concomitant use of methotrexate. At 6 months, the ACR 20/50/70 responses were achieved by 54%, 41%, and 27%, respectively, of patients receiving infliximab compared to 16%, 4%, and 2%, respectively, of patients receiving placebo. Similar responses were seen in patients with each of the subtypes of psoriatic arthritis, although few patients were enrolled with the arthritis mutilans and spondylitis with peripheral arthritis subtypes.

Infliximab-axxq (Avsola®)

Policy # 00712
Original Effective Date: 09/14/2020
Current Effective Date: 12/11/2023

Plaque Psoriasis
The safety and efficacy of infliximab were assessed in 3 randomized, double-blind, placebo-controlled studies in subjects 18 years of age and older with chronic, stable plaque psoriasis and who were candidates for systemic therapy or phototherapy. The three studies evaluated placebo versus various doses of infliximab. In all three studies, the primary endpoint was the proportion of patients who achieved a reduction in score of at least 75% from baseline at week 10 by the Psoriasis Area Sensitivity Index (PASI 75). In study 1, 80% of subjects on 5 mg/kg of infliximab achieved a PASI 75 at week 10 compared with 3% of patients on placebo. In study 2, 70% and 75% of patients on 3 mg/kg and 5 mg/kg infliximab achieved a PASI 75 at week 10, respectively, compared with 2% on placebo. In study 3, 72% and 88% of patients on 3 mg/kg and 5 mg/kg infliximab achieved a PASI 75 at week 10, respectively, compared with 6% on placebo.

References

1. Avsola [package insert]. Amgen, Inc. Thousand Oaks, California. Updated September 2021.

Policy History

Original Effective Date: 09/14/2020
Current Effective Date: 12/11/2023

08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. New policy.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. No change to coverage.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. Added Renflexis as an option to use prior to Avsola.
11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. Added the branded Infliximab from Janssen as an option to try and fail.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2024

Infliximab-axxq (Avsola®)

Policy # 00712
Original Effective Date: 09/14/2020
Current Effective Date: 12/11/2023

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 2022 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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	Q5121
ICD-10 Diagnosis	All related Diagnoses

Infliximab-axxq (Avsola®)

Policy # 00712
Original Effective Date: 09/14/2020
Current Effective Date: 12/11/2023

*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, 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.

Infliximab-axxq (Avsola®)

Policy # 00712
Original Effective Date: 09/14/2020
Current Effective Date: 12/11/2023

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

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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.