Plasma Exchange (PE)

Policy # 00249
Original Effective Date: 03/19/2010
Current Effective Date: 12/14/2020

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: Immunoglobulin Therapy is addressed separately in medical policy 00170.

Note: Hematopoietic Cell Transplantation for Autoimmune Diseases is addressed separately in medical policy 00050.

When Services Are 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.*

Based on review of available data, the Company may consider plasma exchange (PE) to be **eligible for coverage**** for the conditions listed below:

AUTOIMMUNE DISEASES

- Severe symptomatic cryoglobulinemia (MC) with manifestations such as cryoglobulinemic nephropathy, skin ulcers, sensory motor neuropathy, widespread vasculitis;
- Catastrophic antiphospholipid syndrome

HEMATOLOGIC CONDITIONS

- ABO-incompatible (ABOi) hematopoietic stem cell transplantation, major ABOi hematopoietic cells;
- Hyperviscosity syndromes associated with multiple myeloma or Waldenström's macroglobulinemia;
- Idiopathic thrombocytopenic purpura (ITP) in emergency situations;
- Thrombotic thrombocytopenic purpura (TTP);
- Atypical hemolytic uremic syndrome (HUS);
- Post-transfusion purpura;

- HELLP syndrome of pregnancy (a severe form of preeclampsia, characterized by hemolysis [H], elevated liver enzymes [EL], and low platelet [LP] counts);
- Myeloma with acute renal failure

NEUROLOGIC CONDITIONS

- Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome); primary treatment;
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP);
- Multiple sclerosis(MS), with acute fulminant central nervous system (CNS) demyelination;
- Myasthenia gravis in crisis or as part of preoperative preparation;
- Neuromyelitis optica spectrum disorders (NMOSD), acute attack/relapse refractory to glucocorticoids;
- Paraproteinemia polyneuropathy; immunoglobulin A, G, M;
- N-methyl-D-aspartate receptor antibody encephalitis;
- Progressive multifocal leukoencephalopathy associated with natalizumab

RENAL DISEASES

- Anti-glomerular basement membrane (GBM) disease (Goodpasture syndrome);
- Anti-neutrophil cytoplasmic antibody (ANCA)–associated vasculitis (eg, Microscopic polyangiitis, granulomatous polyangiitis, renal limited vasculitis, rapidly progressive glomerulonephritis) with associated renal failure or diffuse alveolar hemorrhage;
- Dense deposit disease with factor H deficiency and/or elevated C3 nephritic factor.

TRANSPLANTATION

- ABO-incompatible solid organ transplantation:
  - Kidney;
  - Heart (infants);
  - Liver, ABOi living donor, desensitization;
- Renal transplantation: antibody-mediated rejection; human leukocyte antigen (HLA) desensitization;
- Focal segmental glomerulosclerosis after renal transplant.

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MISCELLANEOUS/OTHER

- Wilson disease, fulminant

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 plasma exchange (PE) to be **investigational*** in all other conditions, including, but not limited to, the following:

- Acute disseminated encephalomyelitis;
- Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome) in children <10 years old with mild or moderate forms (e.g. ambulatory children with mild, non-progressive disease);
- Acute liver failure; except indications noted as eligible for coverage (e.g. Wilson disease);
- Amyotrophic lateral sclerosis;
- Amyotrophic lateral sclerosis;
- Anti-neutrophil cytoplasmic antibody (ANCA)–associated vasculitis (eg, Microscopic polyangiitis granulomatous polyangiitis, renal limited vasculitis, rapidly progressive glomerulonephritis) without associated renal failure or diffuse alveolar hemorrhage;
- Aplastic anemia;
- Asthma;
- Autoimmune hemolytic anemia; warm autoimmune hemolytic anemia; cold agglutinin disease;
- Chronic fatigue syndrome;
- Coagulation factor inhibitors;
- Cryoglobulinemia, except for severe symptomatic cryoglobulinemia (MC) with manifestations as noted above;
- Dermatomyositis and polymyositis;
- Focal segmental glomerulosclerosis (other than after renal transplant);
- Heart transplant rejection treatment;
- Hemolytic uremic syndrome (HUS), typical (diarrheal-related);
- Idiopathic thrombocytopenic purpura, refractory or nonrefractory;

- Inclusion body myositis;
- Lambert-Eaton myasthenic syndrome (LEMS);
- Multiple sclerosis (MS) with chronic progressive or relapsing remitting course;
- Neuromyelitis optica spectrum disorders (NMOSD), except when refractory to glucocorticoids;
- Mushroom poisoning;
- Myasthenia gravis with anti-MuSK antibodies;
- Overdose and poisoning (other than mushroom poisoning);
- Paraneoplastic syndromes;
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS);
- Pemphigus vulgaris;
- Phytanic acid storage disease (Refsum disease);
- POEMS (polyneuropathy, organomegaly, endocrinopathy, M protein, skin changes);
- Psoriasis;
- Red blood cell alloimmunization in pregnancy;
- Rheumatoid arthritis;
- Sepsis;
- Scleroderma (systemic sclerosis);
- Stiff person syndrome;
- Sydenham chorea (SC);
- Systemic lupus erythematosus (including systemic lupus erythematosus nephritis);
- Thyrotoxicosis; and
- Hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenström macroglobulinemia).

Policy Guidelines

Patients receiving plasma exchange (PE) as a treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) should meet the diagnostic criteria for CIDP, which were established by the American Academy of Neurology in 1991 and have not been updated since. The use of PE in patients with acute, life-threatening complications of chronic autoimmune diseases, such as rheumatoid arthritis and systemic lupus erythematosus, may need to be considered on an

individual basis. An example of such a situation would be the development of a severe vasculitis, for which it is hypothesized that the use of PE can acutely lower the level of serum autoantibodies until an alternative long-term treatment strategy can be implemented. However, in these situations, the treatment goals and treatment duration with PE need to be clearly established before its initiation; without such treatment goals, the use of an acute short- term course of PE may insidiously evolve to a chronic use of PE with uncertain benefit.

Background/Overview

TERMINOLOGY

The terms therapeutic apheresis, plasmapheresis, and plasma exchange (PE) are often used interchangeably, but when properly used denote different procedures. The American Society for Apheresis definitions for these procedures are as follows:

Apheresis is a procedure in which blood of the patient or donor is passed through a medical device that separates out one or more components of blood and returns remainder with or without extracorporeal treatment or replacement of the separated component.

Plasmapheresis is a procedure in which blood of a patient or the donor is passed through a medical device that separates plasma from the other components of blood and the plasma is removed (ie, <15% of total plasma volume) without the use of replacement solution.

Plasma exchange is a therapeutic procedure in which blood of the patient is passed through a medical device that separates plasma from other components of blood, the plasma is removed, and it is replaced with a replacement solution such as colloid solution (eg, albumin and/ or plasma) or a combination of crystalloid/colloid solution.

This evidence review addresses only PE as a therapeutic apheresis procedure.

PLASMA EXCHANGE

The rationale for PE is based on the fact that circulating substances, such as toxins or autoantibodies, can accumulate in the plasma. Also, it is hypothesized that removal of these factors can be therapeutic in certain situations. PE is a symptomatic therapy, because it does not remove the source of the pathogenic factors. Therefore the success of PE depends on whether the pathogenic substances

are accessible through the circulation and whether their rate of production and transfer to the plasma component can be adequately addressed by PE. For example, PE can rapidly reduce levels of serum autoantibodies; however, through a feedback mechanism, this rapid reduction may lead to a rebound overproduction of the same antibodies. This rebound production of antibodies is thought to render the replicating pathogenic clone of lymphocytes more vulnerable to cytotoxic drugs; therefore, PE is sometimes used in conjunction with cyclophosphamide.

Applications
Applications of PE can be broadly subdivided into 2 general categories: (1) acute self-limited diseases, in which PE is used to acutely lower the circulating pathogenic substance; and (2) chronic diseases, in which there is ongoing production of pathogenic autoantibodies. Because PE does not address underlying pathology, and, because of the phenomenon of rebound antibody production, its use in chronic diseases has been more controversial than in acute self-limited diseases.

Also, plasmapheresis has been used in the setting of solid organ transplantation. It has been used as a technique to desensitize high-risk patients before transplant and also as a treatment of antibody-mediated rejection reaction occurring after transplant. Before transplant, plasmapheresis has been most commonly used to desensitize patients receiving an ABO mismatched kidney, often in combination with a splenectomy. As a treatment of antibody-mediated rejection, plasmapheresis is often used in combination with intravenous immunoglobulin or anti-CD20 therapy (ie, rituximab).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The U.S. Food and Drug Administration has a compliance program to ensure that source plasma, source leukocytes, and therapeutic exchange plasma for further manufacture into products for human use are safe, pure, potent, and appropriately labeled. The compliance program covers products intended for use both in injectable drug products (eg, immune globulin, albumin) and non-injectable products (eg, in vitro devices such as blood bank reagents).

Product code for therapeutic exchange plasma: 57DI-65.

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Rationale/Source

Plasma exchange (PE) is a procedure in which the plasma is isolated, then discarded and replaced with a fluid such as albumin. PE is a nonspecific therapy, because the entire plasma is discarded. PE has been used in a wide variety of acute and chronic conditions, as well as in the setting of solid organ transplantation.

Data from published studies clinical input and/or guidelines from the American Society for Apheresis support the use of PE for selected autoimmune, hematologic, neurologic, renal, and transplantation conditions.

Supplemental Information

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received through 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2012. There was consensus or near-consensus that plasma exchange (PE) for dense deposit disease with factor H deficiency and/or elevated C3 nephritis factor, catastrophic antiphospholipid syndrome, focal segmental glomerulosclerosis after renal transplant, and myeloma with acute renal failure may be considered medically necessary. Input was mixed on the medical necessity of hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenström macroglobulinemia). Also, there was no consensus about an optimal creatinine threshold for instituting PE in patients with renal failure associated with antineutrophil cytoplasmic antibody-associated vasculitis or other diagnoses.

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Comprehensive Cancer Network

In the current National Comprehensive Cancer Network guidelines on multiple myeloma (v.2.2018), use of plasmapheresis to improve renal function is a category 2B recommendation. Plasmapheresis should also be used as adjunctive therapy for hyperviscosity.

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American Academy of Neurology
In 2011, the American Academy of Neurology issued evidence-based guidelines on plasmapheresis for the treatment of neurologic disorders. The primary conclusions, based on the evidence review, are provided in Table 1.

Table 1. Guidelines on Use Plasmapheresis to Treat Neurologic Disorders

Recommendation	Conclusion
Acute inflammatory demyelinating polyneuropathy/Guillain-Barré syndrome	Established effective
Chronic inflammatory demyelinating polyneuropathy, short-term treatment	Established effective
Relapses in multiple sclerosis	Probably effective
Fulminant demyelinating central nervous system disease	Possibly effective
Chronic or secondary progressive multiple sclerosis	Established ineffective
Myasthenia gravis	Insufficient evidence
Sydenham chorea	Insufficient evidence
Acute obsessive-compulsive disorder and tics in PANDAS	Insufficient evidence

PANDAS: pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections.

In 2003, the American Academy of Neurology published a practice parameter on Guillain-Barré syndrome (GBS). The following are the key findings: (1) treatment with plasma exchange (PE) or intravenous immunoglobulin hastens recovery from GBS; (2) combining the 2 treatments is not beneficial; and (3) steroid treatment given alone is not beneficial. The American Academy of Neurology's recommendations are:

- PE is recommended for adults with GBS who are non-ambulant and who seek treatment within 4 weeks of the onset of neuropathic symptoms;
- PE should be considered for ambulant patients examined within 2 weeks of the onset of neuropathic symptoms);
- PE is a treatment option for children with severe GBS.

American Society for Apheresis
In 2016, the American Society for Apheresis updated its guidelines on the use of therapeutic apheresis (Seventh Special Issue). Previously, the guidelines had been updated in 2013 (Sixth Special Issue). The following is a description of the Society categories (see Table 2), 2013 recommendations (see Table 3), and new indications added in 2016 (see Table 4).

Table 2. American Society for Apheresis Categories

Category	Description
I	Diseases for which TA is accepted as first-line treatment, either as a primary standalone treatment or in conjunction with other treatments. Note that this designation need not imply that TA is mandatory in all cases.
II	Diseases for which TA is accepted as second-line treatment, either as a standalone treatment or in conjunction with other treatments.
III	Diseases for which the optimum role of TA is not established and treatment decisions on an individual basis are recommended.
IV	Disorders for which published evidence suggests or demonstrates that TA is ineffective or harmful.

TA: therapeutic apheresis.

Table 3. American Society for Apheresis 2013 Key Recommendations

Disease Group/Name/Condition	2013 Category
Autoimmune	
Catastrophic antiphospholipid syndrome	II
Cryoglobulinemia	I
Pemphigus vulgaris	III
Systemic lupus erythematosus	
Manifestations other than nephritis	NC
Severe	II
Nephritis	IV
Hematologic	
ABO-incompatible hematopoietic progenitor cell transplantation	II
Aplastic anemia	III
Pure red blood cell aplasia	III
Autoimmune hemolytic anemia:	
Warm autoimmune hemolytic anemia	III
Cold agglutinin disease	II
Coagulation factor inhibitors	IV
Hyperviscosity in monoclonal gammopathies	I

ABO: A, B, and O blood types; AIDP: acute inflammatory demyelinating polyneuropathy; ANCA: antineutrophil cytoplasmic antibody; CNS: central nervous system; DAH: diffuse alveolar hemorrhage; HLA: human leukocyte antigen; HUS: hemolytic uremic syndrome; Ig: immunoglobulin; IVIg: intravenous immunoglobulin; NC: not categorized; PANDAS: pediatric

autoimmune neuropsychiatric disorders associated with streptococcal infection; PRA: Panel Reactive Antibody; SC: Sydenham chorea.

Table 4. American Society for Apheresis New Indications in 2016

Atopic (neuro-) dermatitis (atopic eczema), recalcitrant	III
Cardiac neonatal lupus	III
Complex regional pain syndrome	III
Erythropoietic porphyria, liver disease	III
Hashimoto encephalopathy: steroid-responsive encephalopathy associated with autoimmune thyroiditis	II
Postpartum	III
Antepartum	IV
Hematopoietic cell transplantation, human leukocyte antigen desensitization	III
Hemophagocytic lymphohistiocytosis; hemophagocytic syndrome; macrophage activating syndrome	III
N-methyl-D-aspartate receptor antibody encephalitis	I
Prevention of Rhesus D alloimmunization after red blood cell exposure	III
Progressive multifocal leukoencephalopathy associated with natalizumab	I
Pruritus due to hepatobiliary diseases	III
Thrombotic microangiopathy, coagulation mediated	III
Vasculitis	
HBV-PAN	II
Idiopathic PAN	IV
EGPA	III
Behçet disease	III

EGPA: eosinophilic granulomatosis with polyangiitis; HBV: hepatitis B virus; PAN: polyarteritis nodosa.
[a] severe form of preeclampsia, characterized by hemolysis, elevated liver enzymes, and low platelet counts.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

MEDICARE NATIONAL COVERAGE
The national coverage determination for apheresis (therapeutic pheresis), last revised in 1992, states:

> "For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

Apheresis is covered for the following indications:

- Plasma exchange for acquired myasthenia gravis;
- Leukapheresis in the treatment of leukemia;
- Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- Plasmapheresis or plasma exchange as a last resort treatment of thrombotic thrombocytopenic purpura (TTP);
- Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;
- Plasma perfusion of charcoal filters for treatment of pruritus of cholestatic liver disease; Plasma exchange in the treatment of Goodpasture's Syndrome;
- Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
- Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
- Treatment of Guillain-Barre Syndrome; and

- Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration."

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Policy History

Original Effective Date: 03/19/2010
Current Effective Date: 12/14/2020

03/05/2010	Medical Policy Committee approval
03/19/2010	Medical Policy Implementation Committee approval. New policy.
03/03/2011	Medical Policy Committee review
03/16/2011	Medical Policy Implementation Committee approval. Added "post-transfusion purpura" as eligible for coverage into the hematologic section. Deleted "ANCA-associated rapidly progressive glomerulonephritis (Wegener's granulomatosis)" from investigational statement since it belongs in the eligible for coverage section only. Deleted unnecessary language ("manifestations other than nephritis; nephritis") from systematic lupus erythematosus bullet in the investigational statement.
03/01/2012	Medical Policy Committee review
03/21/2012	Medical Policy Implementation Committee approval. Added a new investigational indication. SLE 03/07/2013 Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Two indications moved from investigational to eligible for coverage. New indication added to renal and transplantation sections. New investigational indication added.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. No change to coverage.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. Added neuromyelitis optica to list of INV conditions.
09/08/2016	Medical Policy Committee review

09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
04/09/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. Added neuromyelitis optica to coverage statement and removed it from investigational indications.
11/02/2017 Medical Policy Committee review
11/15/2017 Medical Policy Implementation Committee approval. N-methyl-D-aspartate receptor antibody encephalitis and progressive multifocal leukoencephalopathy associated with natalizumab added to the Neurological Conditions that are eligible for coverage.
11/08/2018 Medical Policy Committee review
11/21/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2019 Medical Policy Committee review
11/13/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019 Coding update
09/14/2020 Coding update
11/05/2020 Medical Policy Committee review
11/11/2020 Medical Policy Implementation Committee approval. Revisions made in the coverage section for Autoimmune Diseases, Hematological Conditions, Neurological Conditions, Renal Diseases and Transplantation. Added "Miscellaneous/Other" category to the coverage section to include Wilson disease. Investigational indications revised according to the coverage changes.
10/01/2021 Coding update
Next Scheduled Review Date: 11/2021

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 2019 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	36456, 36514
HCPCS	No codes
ICD-10 Diagnosis	A41.0-A41.9, A81.1-A81.2, A83.1-A83.5, C88.0, C90.0, D59.0-D59.9, D61.0-D61.9, D68.0-D68.9, D68.61, D69.0-D69.9, D89.1-D89.2, D89.89, E05.0-E05.9, E88.0-E88.9, G12.21, G13.0-G13.1, G25.4-G25.5, G36.0, G60.1, G61.81-G61.82, G62, G70.0-G70.9, G72.41, J45.2-J45.9, K72.00-K72.01, L10.0, L10.8, L94.0-L94.3, M05.1-M05.4, M31.0, M31.30-M31.31, M32.0-M32.9, M33.0-M33.9, N04.0-N04.A, N05.6, N08, O14.20-O14.24, P55.1, Q87.80-Q87.89, R53.82, T40.7-T40.9, T62.0, T80.30-T80.39, T86.1, Z94.1, Z94.3 Codes added eff 1/1/2020: D81.31-D81.39 Codes added eff 10/1/2020: D59.10-D59.19, M05.7A, M05.8A, M06.0A, M06.8A, M08.0A, M08.2A, M08.4A, M08.9A, N05.A, T40.411A-T40.411S,

	T40.412A-T40.412S, T40.413A-T40.413S, T40.414A-T40.414S, T40.415A-T40.415S, T40.416A-T40.416S, T40.421A-T40.421S, T40.22A-T40.22S, T40.423A-T40.423S, T40.424A-T40.424S, T40.425A-T40.425S, T40.26A-T40.26S, T40.491A-T40.491S, T40.492A-T40.492S, T49.493A-T49.493S, T40.494A-T40.494S, T40.495A-T40.495S, T40.496A-T40.496S, T86.8401-T86.8409, T86.8411-T86.8419, T86.8421-T86.8429, T86.8481-T86.8489, T86.8491-T86.8499 Add codes eff 10/1/2021: M31.10-M31.19, T40.711A-T40.74S, T40.715A-T40.715S, T40.716A-T40.716S

*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 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:

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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.