PLASMA EXCHANGE AND PLASMAPHERESIS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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PLASMA EXCHANGE AND PLASMAPHERESIS (cont.)

Description:

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 (ASFA) definitions for these procedures are as follows:

Apheresis:
A procedure in which an individual’s blood or donor blood is passed through a medical device which separates out one or more components of blood and returns the remainder with or without extracorporeal treatment or replacement of the separated component.

Plasma Exchange:
A therapeutic procedure in which an individual’s blood is passed through a medical device which separates out plasma from other components of blood, the plasma is removed and replaced with a replacement solution such as colloid solution (e.g., albumin and/or plasma) or a combination of crystalloid/colloid solution.

Plasmapheresis:
A procedure in which an individual’s blood or donor blood is passed through a medical device which separates out plasma from the other components of blood and the plasma is removed (i.e., less than 15% of total plasma volume) without the use of replacement solution.
PLASMA EXCHANGE AND PLASMAPHERESIS (cont.)

Criteria:

➢ Plasma exchange and plasmapheresis are considered **medically necessary** for **ANY** of the following:

1. Autoimmune:
   - Severe multiple manifestations of mixed cryoglobulinemia (MC) such as cryoglobulinemic nephropathy, skin ulcers, sensory motor neuropathy and widespread vasculitis in combination with immunosuppressive treatment
   - Catastrophic antiphospholipid syndrome

2. Hematologic:
   - ABO incompatible hematopoietic progenitor cell transplantation
   - Hyperviscosity syndromes associated with:
     - Multiple myeloma
     - Waldenstrom's macroglobulinemia
   - Idiopathic thrombocytopenic purpura in emergency situations
   - Thrombotic thrombocytopenic purpura (TTP)
   - Atypical hemolytic uremic syndrome
   - Post-transfusion purpura
   - HELLP (Hemolysis, Elevated Liver, Low Platelet) syndrome of pregnancy
   - Myeloma with acute renal failure

3. Neurological:
   - Acute inflammatory demyelinating polyneuropathy (Guillain-Barre syndrome)
     - Severity grade 1-2 within two weeks of onset
     - Severity grade 3-5 within four weeks of onset
     - Children less than 10 years old with severe Guillain-Barre syndrome
   - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
   - Multiple sclerosis, with acute fulminant Central Nervous System (CNS) demyelination
   - Myasthenia gravis in crisis or as part of preoperative preparation
   - Paraproteinemia polyneuropathy; IgA or IgG
PLASMA EXCHANGE AND PLASMAPHERESIS (cont.)

Criteria: (cont.)

- Plasma exchange and plasmapheresis are considered medically necessary for ANY of the following:

4. Renal:
   - Anti-glomerular basement membrane disease (Goodpasture’s syndrome)
   - ANCA (antineutrophil cytoplasmic antibody-associated vasculitis (e.g., Wegener’s granulomatosis, also known as granulomatosis with polyangiitis or GPA) with associated renal failure
   - Dense deposit with factor H deficiency and/or elevated C3 Nephritic factor

5. Transplantation:
   - Prior to solid organ transplantation in individuals at high risk of antibody mediated rejection including, but not limited to:
     - Individuals receiving an ABO incompatible organ
     - Highly sensitized individuals (e.g., prior blood transfusions, transplants or pregnancies)
   - Following solid organ transplantation as a treatment for antibody mediated rejection
   - Kidney transplantation recipient in whom a high level of antibodies to a potential donor exists in an attempt to prevent or reduce graft/organ rejection. (Often combined with immune globulin therapy)
   - Focal segmental glomulerulosclerosis after renal transplant
PLASMA EXCHANGE AND PLASMAPHERESIS (cont.)

Criteria: (cont.)

- Plasma exchange and plasmapheresis for all other indications not previously listed are considered experimental or investigational based upon:
  
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These indications include, but are not limited to:

- Acute disseminated encephalomyelitis
- Acute inflammatory demyelinating polyneuropathy (Guillain-Barre syndrome) in children less than 10 years old with mild or moderate forms
- Acute liver failure
- Amyotrophic lateral sclerosis
- ANCA-associated rapidly progressive glomerulonephritis (Wegener’s granulomatosis or GPA without renal failure)
- Aplastic anemia
- Asthma
- Autoimmune hemolytic anemia; warm autoimmune hemolytic anemia; cold agglutinin disease
- Chronic fatigue syndrome
- Coagulation factor inhibitors
- Cryoglobulinemia; except for severe mixed cryoglobulinemia as noted above
- Dermatomyositis and polymyositis
- Focal segmental glomerulosclerosis (other than after renal transplant)
- Hemolytic uremic syndrome (HUS); typical (diarrheal-related)
- Hyperviscosity syndromes with renal failure (other than associated with multiple myeloma or Waldenstrom’s macroglobulinemia)
- Idiopathic thrombocytopenic purpura; refractory or non-refractory
- Inclusion body myositis
- Lambert-Eaton syndrome
- Multiple sclerosis; chronic progressive or relapsing remitting
- Mushroom poisoning
- Myasthenia gravis with anti-MuSK antibodies
- Neuromyelitis optica (NMO)
- Overdose and poisoning (other than mushroom poisoning)
- Paraneoplastic Syndromes
- Paraproteinemic polyneuropathy; IgM
- Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS)
- Pemphigus vulgaris
- Phytic acid storage disease (Refsum’s disease)
- POEMS (polyneuropathy, organomegaly endocrinopathy, M protein, skin changes
- Psoriasis
PLASMA EXCHANGE AND PLASMAPHERESIS (cont.)

Criteria: (cont.)

- Plasma exchange and plasmapheresis for all other indications not previously listed are considered experimental or investigational based upon: (cont.)
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome.

These indications include, but are not limited to: (cont.)

- Pruritus secondary to cholestatic liver disease
- Red blood cell alloimmunization in pregnancy
- Rheumatoid arthritis
- Scleroderma (systemic sclerosis)
- Sepsis
- Stiff person syndrome
- Sydenham’s chorea (SC)
- Systemic lupus erythematosus (SLE [systemic lupus erythematosus] nephritis)
- Thyrotoxicosis

Resources:

Literature reviewed 06/16/15. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 06/11/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


PLASMA EXCHANGE AND PLASMAPHERESIS (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filling a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díi kwe’átah niilíningíí Blue Cross Blue Shield of Arizona haada yít’éego bína’idilkidgo éi doddgo Háída bíjá aniyeedííí t’áadoo le’é yina’idilkidgo beehaz’ánii hólo dií t’áá hazaak’e’hií háká a’doooolgo bee haz’a doo baq’á ilínígóií. Atá’ halne’ígíí kojj’ bič’hí’ hodilihin 877-475-4799.

Chinese: 如果您，或是您正在协助的对象，有关插入项目的名称 Blue Cross Blue Shield of Arizona 方面的问题，您有权利免费以您的母语得到帮助和讯息。洽询一位翻译员，拨打电話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viễn, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدك بخصوص Blue Cross Blue Shield of Arizona الضرورة بلغتك من دون آية تكلفة. للتحدث مع مترجم فيصل ب. 877-475-4799.
PLASMA EXCHANGE AND PLASMAPHERESIS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasaling, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역시와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi: 
آگر شما یا کسی که شما به آن کمک می‌کنید، سوالی در مورد اطلاعاتی که درباره راه راه موارد گرانه که توسط Blue Cross Blue Shield of Arizona ارائه می‌شود، داشتی باشید، شما می‌توانید با 877-475-4799 تماس حاصل نمایید.

Assyrian: 
Blue Cross Blue Shield of Arizona, ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین نین نیتیا، ین ن

Serbo-Croatian: Ukoiko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodioceom, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่ต้องจ่ายค่าบริการ ที่โทรศัพท์ 877-475-4799