ORTHOPEDIC APPLICATIONS OF PLATELET-RICH PLASMA OR AUTOLOGOUS PROTEIN SOLUTION

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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ORTHOPEDIC APPLICATIONS OF PLATELET-RICH PLASMA OR AUTOLOGOUS PROTEIN SOLUTION (cont.)

**Description:**

Blood is drawn from an individual and centrifuged at high speeds to create an autologous concentrated platelet rich plasma (PRP) that contains a biologically active mixture of growth factors without the potential for an immune response. PRP has been investigated in the operating room as an adjunct to a variety of periodontal, reconstructive and orthopedic procedures with the intent of promoting hemostasis and accelerating healing. PRP injections have been proposed as a primary treatment of miscellaneous conditions, such as epicondylitis, plantar fasciitis, and Dupuytren’s contracture. PRP has been investigated as an injection directly into the tissue as well as injection for tendon and ligament pain.

There are numerous PRP preparation systems available including Aurix™ System and SafeBlood®. Both are considered autologous wound healing factors and can be prepared at the bedside using a portable centrifuge. The PRP may be mixed with various reagents to create a gel-like substance that is applied to a wound, or may be mixed with autograft and allograft bone prior to application to an orthopedic surgical site. Other PRP preparation systems that may be used in the operating room, include, but are not limited to:

- Elmd-500 autotransfusion system
- GPS®II
- Magellan™ Autologous Platelet Separator
- Medtronic Electromedic
- Plasma Saver device
- Smart PreP® device

Autologous protein solution (APS) contains concentrated white blood cells, platelets, and plasma proteins in a small volume of plasma. An investigational device called the nSTRIDE® APS Kit is designed to produce an autologous therapy to treat pain and function associated with knee osteoarthritis. It is designed to separate anti-inflammatory cytokines and growth factors from an individual’s blood to create an autologous solution that will be injected directly in the knee joint.
ORTHOPEDIC APPLICATIONS OF PLATELET-RICH PLASMA OR AUTOLOGOUS PROTEIN SOLUTION (cont.)

Criteria:

For Recombinant and Autologous Platelet-Derived Growth Factors for wound healing, see BCBSAZ Medical Coverage Guideline #O283, “Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Non-Orthopedic Conditions”.

➢ Use of platelet-rich plasma or autologous protein solution for all orthopedic indications is 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, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Primary indications (injection) include, but are not limited to:

- Achilles tendinopathy
- Lateral epicondylitis
- Osteochondral lesions
- Osteoarthritis
- Plantar fasciitis

Adjunctive indications include, but are not limited to:

- ACL reconstruction
- Hip fracture
- Long-bone nonunion
- Patellar tendon repair
- Rotator cuff repair
- Spinal fusion
- Subacromial decompression surgery
- Total knee arthroplasty
ORTHOPEDIC APPLICATIONS OF PLATELET-RICH PLASMA OR AUTOLOGOUS PROTEIN SOLUTION (cont.)

Resources:

Literature reviewed 05/15/18. 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.


ORTHOEPIDIC APPLICATIONS OF PLATELET-RICH PLASMA OR AUTOLOGOUS PROTEIN SOLUTION (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 filing 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/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: Díí kwe’é atah nilíngiií Blue Cross Blue Shieid of Arizona haada yit’éego bíná’idílkiidgo éí doocdagó Háída bíjá aniyeedííi t’aadoo le’e yína’idílkiidgo beehaz’ániiíi hoqó díí t’aá házaadk’ehjí háká a’doowolgo bee haz’á doo bqah ilíngóó. Atá’ halné’ígii kojí bich’í’ hödíihiníí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 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 thêm thông tin bằng ngôn ngữ của mình miễn phí. Đã nói chuyện với một thống dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعده أسئلة بخصوص خدمة Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.
ORTHOPEDIC APPLICATIONS OF PLATELET-RICH PLASMA OR AUTOLOGOUS PROTEIN SOLUTION (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 kaparatan ka na makakuha ng tulung at impormasyon sa iyong wika ng walang gastos. Upang makauap ang isang tagasalin, 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 통역사와 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 несете 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: اگر شما یا کسی که شما به او کمک می‌کنید، سوال‌های مربوط به Blue Cross Blue Shield of Arizona را داشته باشید، حق جلوگیری از هزینه و دریافت کمک‌های رایگان را دارید. شما می‌توانید با 877-475-4799 تماس حاصل نمایید.

Assyrian: یاری‌تان و یا کسی که به شما کمک می‌کند، مسأله‌ای در مورد Blue Cross Blue Shield of Arizona را داشته باشند، شما حق دریافت پاسخ‌های رایگان و هزینه‌زا را دارید. شما می‌توانید با 877-475-4799 تماس حاصل نمایید.

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

Thai: หากคุณหรือคู่พี่คุณถามคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสมควรจะได้รับควมยุยงและข้อมูลภาษา ของคุณได้โดยไม่เสียเงิน ติดต่อเราได้ที่ 877-475-4799.