Medical Policy

** PARAMOUNT

Platelet Rich Plasma

Policy Number: PG0293 Last Review: 05/02/2022 HMO AND PPO ELITE (MEDICARE ADVANTAGE) MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual
 policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or
 guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede
 this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional

X Facility - Outpatient

DESCRIPTION:

Wound healing is a dynamic, interactive process that involves multiple cells and proteins. There are three progressive stages of normal wound healing, and the typical wound healing duration is about 4 weeks. While cutaneous wounds are a disruption of the normal, anatomic structure and function of the skin, subcutaneous wounds involve tissue below the skin's surface. Wounds are categorized as either acute, where the normal wound healing stages are not yet completed but it is presumed they will be, resulting in orderly and timely wound repair, or chronic, where a wound has failed to progress through the normal wound healing stages and repair itself within a sufficient time period.

The blood contains small solid components (red cells, white cells and platelets). The platelets are best known for their importance in clotting blood. However, platelets also contain an abundance of proteins called growth factors (GFs) and cytokines which are suggested to promote healing and/or tissue growth enhancing the body's inherent capacity to repair and regenerate. Growth factors are groups of proteins capable of stimulating cellular growth, proliferation and cellular differentiation. They occur in a wide range of tissues and are important for regulating a variety of cellular processes.

Growth factors that are derived from platelets assist in the process of blood vessel formation (angiogenesis) and can be obtained either by using recombinant DNA technology or through centrifuged autologous blood. Platelet rich plasma (PRP), including autologous platelet derived growth factors (PDGF), autologous platelet concentrate (APC) and autologous platelet gel (APG), also known as autologous growth factors or "buffy coat," are harvested from a patient's own (autologous) blood. Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products, and (2) PRP (such as AutoloGel). PRP has been proposed for numerous indications including wound care, orthopedic indications, abdominal surgery and oral/dental procedures. The use of PRP has been proposed as a treatment for various musculoskeletal conditions and as an adjunctive procedure in orthopedic surgeries.

The PRP is used by physicians in clinical settings in treating chronic, non-healing wounds, open, cutaneous wounds, soft tissue and bone.

POLICY:

Paramount Commercial Insurance Plans

Platelet Rich Plasma (0232T, G0460, G0465, S9055) is non-covered, procedures considered experimental and unproven.

Elite (Medicare Advantage) Plans

- Autologous Platelet Rich Plasma (G0465) is covered for the coverage indications listed below
- Procedure G0460 requires a prior authorization, coverage end-dated 12/31/2021
- ➤ Procedure G0465 requires a prior authorization, effective 1/1/2022
- > POS codes 11, 19, 22, and 49
- An ICD-10 diagnosis codes for diabetes mellitus and for chronic ulcers is required. See the covered diagnosis codes listing below

Procedures 0232T and S9055 are non-covered Effective 01/01/2022 procedure G0460 is non-covered

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

Paramount considers platelet-rich plasma injection experimental and investigational for ALL indications including the following (not an all-inclusive list) because its effectiveness has not been established.

- Alopecia areata
- Ankle sprain
- Avascular necrosis of the hip
- Cerebral palsy
- Crohn's disease-related perianal fistula
- Gastrocnemius (calf) tear
- Hip fractures
- Hip osteoarthritis
- Knee osteoarthritis
- Osteonecrosis of the jaw
- Periodontal disease, gingival recession and dental surgery
- Plantar fasciitis
- Temporomandibular joint (TMJ) osteoarthritis
- Tendonopathies (e.g., elbow, heel, knee, and shoulder)
- Total knee arthroplasty
- Wound healing (e.g., surgical wounds; chronic wounds; lower extremity ulcers)

Elite (Medicare Advantage) Plans

Effective November 9, 2021

Paramount will cover autologous PRP for the treatment of chronic non-healing diabetic wounds, per the Centers for Medicare & Medicaid Services (CMS) under section 1862(a)(1)(A) of the Social Security Act (the Act), for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers.

For claims with dates of service on or after November 9, 2021, PRP, for the treatment of chronic non-healing diabetic wounds must be billed reporting both an ICD-10 diagnosis code for diabetes mellitus and an ICD-10 diagnosis code for chronic ulcers.

Coverage criteria for the treatment of chronic non-health diabetic, venous/and or pressure wounds: Members should meet ALL of the following criteria for treatment of chronic non-healing diabetic neuropathic ulcers:

- Adequate tissue oxygenation, as measured by a transcutaneous partial pressure of oxygen of 30 mm Hg or greater on the foot dorsum or at the margin of the ulcer; AND
- Full-thickness ulcer (i.e., Stage III or IV), extending through dermis into subcutaneous tissues; AND

• Participation in a wound-management program, which includes sharp debridement, pressure relief (i.e., non-weight-bearing), and infection control

Members should meet ALL of the following criteria for treatment of chronic non-healing diabetic pressure ulcers:

- Full-thickness ulcer (i.e., Stage III or IV), extending through dermis into subcutaneous tissues; AND
- Ulcer in an anatomic location that can be off-loaded for the duration of treatment; AND
- Albumin concentration > 2.5 dL: AND
- Total lymphocyte count > 1,000; AND
- Normal values of vitamins A and C

Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined on additional medical review. Claims with approval of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond the initial 20 weeks must include modifier KX.

Effective for claims with dates of service on or after November 9, 2021, POS codes 11, 19, 22, and 49 shall be used for PRP services.

Non-Covered Indications, not an all-inclusive listing:

- Autologous PDGF for the treatment of chronic, non-healing cutaneous wounds, and,
- Becaplermin (recombinant platelet-derived growth factor), a non-autologous growth factor for chronic, non-healing subcutaneous wounds, and,
- Autologous PRP for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision, or for dehiscent wounds.

Definitions

DIABETIC NEUROPATHIC ULCER is a lesion of the skin or mucous membranes marked by inflammation, necrosis, and sloughing of damaged tissue. A diabetic neuropathic ulcer is caused by damage to the autonomic motor and/or sensory nerves that result from metabolic or vascular derangement in patients with longstanding diabetes mellitus.

STAGE III ULCER is full thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.

STAGE IV ULCER is full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supportive structures

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

	701 V1000 1011a010a1		
CPT CODE			
0232T	Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed		
HCPCS CODES			
G0460	Autologous platelet rich plasma for non-diabetic chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment		
G0465	Autologous platelet rich plasma (PRP) for diabetic chronic wounds/ulcers, using an FDA-cleared device (includes administration, dressings, phlebotomy, centrifugation, and all other preparatory procedures, per treatment)		
P9020	Platelet rich plasma, each unit (Billed for coverage of one or more units of PRP transfused in the treatment of the conditions/coagulopathies for which covered is indicated. This code should Not be used to describe the injection of PRP into a specific site.)		
S9055	Procuren or other growth factor preparation to promote wound healing		

DIAGNOSIS		
Diabetes Mellitus		
E08.621	Diabetes mellitus due to underlying condition with foot ulcer	
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer	
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer	
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer	
E10.621	Type 1 diabetes mellitus with foot ulcer	
E10.622	Type 1 diabetes mellitus with other skin ulcer	
E11.621	Type 2 diabetes mellitus with foot ulcer	
E11.622	Type 2 diabetes mellitus with other skin ulcer	
E13.621	Other specified diabetes mellitus with foot ulcer	
E13.622	Other specified diabetes mellitus with other skin ulcer	
Chronic		
L97.111	Non-pressure chronic ulcer of right thigh limited to breakdown of skin	
L97.112	Non-pressure chronic ulcer of right thigh with fat layer exposed	
L97.113	Non-pressure chronic ulcer of right thigh with necrosis of muscle	
L97.115	Non-pressure chronic ulcer of right thigh with muscle involvement without evidence of necrosis	
L97.116	Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis	
L97.118	Non-pressure chronic ulcer of right thigh with other specified severity	
L97.114	Non-pressure chronic ulcer of right thigh with necrosis of bone	
L97.121	Non-pressure chronic ulcer of left thigh limited to breakdown of skin	
L97.122	Non-pressure chronic ulcer of left thigh with fat layer exposed	
L97.123	Non-pressure chronic ulcer of left thigh with necrosis of muscle	
L97.124	Non-pressure chronic ulcer of left thigh with necrosis of bone	
L97.125 L97.126	Non-pressure chronic ulcer of left thigh with muscle involvement without evidence of necrosis Non-pressure chronic ulcer of left thigh with bone involvement without evidence of necrosis	
L97.128	<u> </u>	
L97.128	Non-pressure chronic ulcer of left thigh with other specified severity Non-pressure chronic ulcer of right calf limited to breakdown of skin	
L97.211	Non-pressure chronic ulcer of right call limited to breakdown of skill Non-pressure chronic ulcer of right call with fat layer exposed	
L97.212	Non-pressure chronic ulcer of right call with necrosis of muscle	
L97.214	Non-pressure chronic ulcer of right calf with necrosis of bone	
L97.215	Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis	
L97.216	Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis	
L97.218	Non-pressure chronic ulcer of right calf with other specified severity	
L97.221	Non-pressure chronic ulcer of left calf limited to breakdown of skin	
L97.222	Non-pressure chronic ulcer of left calf with fat layer exposed	
L97.223	Non-pressure chronic ulcer of left calf with necrosis of muscle	
L97.224	Non-pressure chronic ulcer of left calf with necrosis of bone	
L97.225	Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis	
L97.226	Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis	
L97.228	Non-pressure chronic ulcer of left calf with other specified severity	
L97.315	Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis	
L97.316	Non-pressure chronic ulcer of right ankle with bone involvement without evidence of necrosis	
L97.318	Non-pressure chronic ulcer of right ankle with other specified severity	
L97.321	Non-pressure chronic ulcer of left ankle limited to breakdown of skin	
L97.322	Non-pressure chronic ulcer of left ankle with fat layer exposed	
L97.323	Non-pressure chronic ulcer of left ankle with necrosis of muscle	
L97.324	Non-pressure chronic ulcer of left ankle with necrosis of bone	
L97.325	Non-pressure chronic ulcer of left ankle with muscle involvement without evidence of necrosis	
L97.326	Non-pressure chronic ulcer of left ankle with bone involvement without evidence of necrosis	
L97.328	Non-pressure chronic ulcer of left ankle with other specified severity	
L97.411	Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin	

L97.412	Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
L97.413	Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle
L97.414	Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
L97.415	Non-pressure chronic ulcer of right heel and midfoot with muscle involvement without evidence of necrosis
L97.416	Non-pressure chronic ulcer of right heel and midfoot with bone involvement without evidence of necrosis
L97.418	Non-pressure chronic ulcer of right heel and midfoot with other specified severity
L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
L97.423	Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
L97.424	Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone
L97.425	Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis
L97.426	Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of
	necrosis
L97.428	Non-pressure chronic ulcer of left heel and midfoot with other specified severity
L98.411	Non-pressure chronic ulcer of buttock limited to breakdown of skin
L98.412	Non-pressure chronic ulcer of buttock with fat layer exposed
L98.413	Non-pressure chronic ulcer of buttock with necrosis of muscle
L98.414	Non-pressure chronic ulcer of buttock with necrosis of bone
L98.415	Non-pressure chronic ulcer of buttock with muscle involvement without evidence of necrosis
L98.416	Non-pressure chronic ulcer of buttock with bone involvement without evidence of necrosis
L98.418	Non-pressure chronic ulcer of buttock with other specified severity
L98.421	Non-pressure chronic ulcer of back limited to breakdown of skin
L98.422	Non-pressure chronic ulcer of back with fat layer exposed
L98.423	Non-pressure chronic ulcer of back with necrosis of muscle
L98.424	Non-pressure chronic ulcer of back with necrosis of bone
L98.425	Non-pressure chronic ulcer of back with muscle involvement without evidence of necrosis
L98.426	Non-pressure chronic ulcer of back with bone involvement without evidence of necrosis
L98.428	Non-pressure chronic ulcer of back with other specified severity
L98.491	Non-pressure chronic ulcer of skin of other sites limited to breakdown of skin
L98.492	Non-pressure chronic ulcer of skin of other sites with fat layer exposed
L98.493	Non-pressure chronic ulcer of skin of other sites with necrosis of muscle
L98.494	Non-pressure chronic ulcer of skin of other sites with necrosis of bone
MODIFIE	
KX	Requirements specified in the medical policy have been met
LOCATIO	
11	Office Office Office
19	Off Campus-Outpatient Hospital
22	On Campus-Outpatient Hospital
49	Independent Clinic

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 09/01/2010

Date	Explanation & Changes
02/01/10	Effective February 2010, per contractual agreement, a PRP pilot program was
02/01/10	established allowing reimbursement for providers participating in program
	 Updated coverage - Per review by TAWG on 2/18/12 and 03/21/12, determination was
06/01/12	made to terminate coverage for this procedure for all providers
06/01/12	A letter was sent to providers participating in the PRP pilot program notifying them of the
	termination effective 06/01/12

08/02/12	 Effective for claims with dates of service on or after August 2, 2012, CMS will cover PRP for the treatment of chronic non-healing diabetic venous and/or pressure wounds only, when provided under a clinical research study that meets specific requirements to assess the health outcomes of PRP for the treatment of chronic non-healing diabetic venous and/or pressure wounds
04/10/13	 TAWG reviewed & it was determined that Platelet Rich Plasma Injection will continue to be non-covered for all product lines as there is no proven beneficial impact on health outcomes
05/24/13	 Code update - CMS has created a specific HCPCS code for PRP (G0460) with an active date of 7/01/13
04/18/14	 Policy reviewed and updated to reflect most current clinical evidence per TAWG
09/17/15	Added code S9055
09/17/13	 Policy reviewed and updated to reflect most current clinical evidence per TAWG
09/23/16	 Policy reviewed and updated to reflect most current clinical evidence per TAWG
12/19/2020	 Medical policy placed on the new Paramount Medical Policy Format
03/22/2021	 Policy reviewed and updated to reflect most current clinical evidence
	Maintain non-coverage determination
11/01/2021	 Medicare coverage criterial implemented effective 11/9/2021, CMS Transmittal: 10981
	 Revised procedure code G0460 documentation Effective 1/1/2022 procedure G0460 is now also not covered for the Elite/ProMedica Medicare Plan
05/02/2022	 Added new 2022 procedure code G0465 Effective 1/1/2022 procedure G0465 is only covered for the Elite/ProMedica Medicare Plan and requires a prior authorization No change in coverage criteria
02/17/2023	Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
03/07/2024	Medical policy placed on the new Paramount Medical Policy Format

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to

https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Guidance/Manuals-Index https://www.cms.gov/Regulations-and-Index https://www.cms.gov/Regulations-and-Index https://www.cms.gov/Regulations-and-Index https://www.cms.gov/Regulations-and-Index <a href="https://www.

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/ Industry Standard Review

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review