

MEDICAL POLICY – 2.01.543


Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions

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Introduction

Special substances that are found in the blood may help cells to grow and divide. Some of these blood-derived growth factors, including some platelet-derived growth factors (PDGFs) and platelet-rich plasma (PRP), have been used to treat wounds and skin ulcers. Some of these growth factors have been made in the lab by manipulating genetic material such as DNA. These are called recombinant blood-derived growth factors. Other growth factors come from your own body. These are called autologous blood-derived growth factors. This policy discusses the use of recombinant and autologous blood-derived growth factors when treating wounds and skin ulcers.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can

be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Treatment	Medical Necessity
<p>Recombinant platelet-derived growth factor (i.e., becaplermin)</p>	<p>Recombinant platelet-derived growth factor (i.e., becaplermin) may be considered medically necessary when used as an adjunct to standard wound management for the following indications (for information on individual selection criteria, see Additional Guidelines section below):</p> <ul style="list-style-type: none"> • Neuropathic diabetic ulcers extending into the subcutaneous tissue • Pressure ulcers extending into the subcutaneous tissue <p>Other applications of recombinant platelet-derived growth factor (i.e., becaplermin) are considered investigational, including but not limited to:</p> <ul style="list-style-type: none"> • Ischemic ulcers • Venous stasis ulcers • Ulcers not extending through the dermis into the subcutaneous tissue

Treatment	Investigational
<p>Use of platelet-rich plasma (i.e., autologous blood-derived preparations)</p>	<p>Use of platelet-rich plasma (i.e., autologous blood-derived preparations) is considered investigational for all non-orthopedic indications, including but not limited to the following:</p> <ul style="list-style-type: none"> • Abnormal uterine bleeding • Acne • Alopecia areata • Androgenetic alopecia (aka androgenic alopecia) • Anal fistula • Anterior pelvic organ prolapse • Assisted reproductive technology <ul style="list-style-type: none"> ○ Intrauterine injection for endometrium thickening



Treatment	Investigational
	<ul style="list-style-type: none"> ○ Poor ovarian response ○ Sperm quality • Atrophic rhinitis • Behçet disease (aka Behçet syndrome/silk road disease, a rare form of systemic vasculitis) • Cardiovascular regeneration • Cerebral palsy • Dry eye • Erectile dysfunction • Fat graft retention • Female stress urinary incontinence • Hair transplantation (including for gender transition/ affirmation) • Inflammatory nail disorders <ul style="list-style-type: none"> ○ Idiopathic trachyonychia ○ Lichen planus-associated nail dystrophy ○ Lichen striatus • Infraorbital neuralgia • Interstitial cystitis/bladder pain • Keloids • Lasik eye surgery • Leprosy peripheral neuropathy • Lymphedema • Macular degeneration • Melasma • Morphea • Oral lichen planus • Olfactory dysfunction (persistent) • Overactive bladder (OAB) • Parosmia • Peyronie’s disease • Psoriasis • Scar healing • Sexual dysfunction • Skin rejuvenation • Stretchmarks • Urethral stricture



Treatment	Investigational
	<ul style="list-style-type: none"> • Uterine adhesions • Vitiligo • Vulvar lichen sclerosis • Vulvovaginal atrophy of menopause (VVA) • Wounds <ul style="list-style-type: none"> ○ Acute ○ Chronic ○ Non-healing ulcers ○ Surgical

Additional Guidelines

Becaplermin

- **Appropriate candidates for becaplermin gel for treatment of neuropathic ulcers should meet ALL of the following criteria:**
 - 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 the 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

- **Appropriate candidates for becaplermin gel for the treatment of pressure ulcers should meet ALL of the following criteria:**
 - Full-thickness ulcer (i.e., stage III or IV), extending through the dermis into subcutaneous tissues

AND

 - Ulcer is in an anatomic location that can be off-loaded for the duration of treatment

AND

 - Albumin concentration is >2.5 dL

AND

 - Total lymphocyte count is >1,000/μL

AND

 - Normal values of vitamins A and C



Additional Guidelines

- Individuals are typically treated once daily for up to 20 weeks or until they are completely healed. Application of the gel may be performed by the individual in the home
- Becaplermin is available in 2-g, 7.5-g, and 15-g tubes and is applied in a thin continuous layer, about 1/16th of an inch thick (i.e., 1.6 mm or the thickness of a dime). The amount of the gel used will depend on the size of the ulcer, measured in square centimeters. However, an average-sized ulcer, measuring 3 cm², treated for an average length of time of 85 days, will require a little more than one 15-g tube. If the ulcer is treated for the maximum length of time of 140 days, 1.75 of the 15-g tubes would be required.

Documentation Requirements

For recombinant platelet derived growth factor (i.e., Regranex [becaplermin]) to be used as an added treatment to standard wound management the following supporting documentation is required:

- For neuropathic diabetic ulcers extending into the subcutaneous tissue (diabetic ulcers that reach the innermost layer of skin):
 - Adequate tissue oxygenation as shown by a transcutaneous partial pressure of oxygen of 30 mm Hg or greater on the top of the foot or at the margin of the ulcer

AND

 - Full-thickness ulcer (stage III or IV) ulcer, extending through the dermis and into subcutaneous tissues

AND

 - Participation in a wound management program, which includes the cutting away of tissue, pressure relief (that is, non-weight bearing), and infection control
- For Pressure ulcers extending into the subcutaneous tissue (the innermost layer of skin):
 - Full-thickness ulcer (stage III or IV), extending through the dermis and into subcutaneous tissues

AND

 - The wound is in a location where pressure can be relieved for the duration of treatment

AND

 - Albumin concentration greater than 2.5 dL

AND

 - Total lymphocyte count greater than 1,000/ μ L

AND

 - Normal values of vitamins A and C



Coding

Code	Description
CPT	
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed
HCPCS	
G0460	Autologous platelet rich plasma (PRP) or other blood-derived product for nondiabetic chronic wounds/ulcers, (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)
G0465	Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)
P9020	Platelet rich plasma, each unit
S0157	Becaplermin gel 0.01%, 0.5 gm
S9055	Procuren or other growth factor preparation to promote wound healing (Please note that Procuren may no longer be available, but this code is used to report other growth factor preparations that promote wound healing.)

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

Becaplermin may be used as part of a wound management program, as described in the [Additional Guidelines](#). Use of becaplermin gel is potentially high, particularly if used for off-label indications, or if used outside the setting of adequate and diligent standard wound management.



Description

The use of blood-derived growth factors, including recombinant platelet-derived growth factors (PDGFs) and platelet-rich plasma (PRP), has been suggested as a treatment for wounds or other miscellaneous non-orthopedic conditions, including but not limited to, diabetic ulcers, pressure ulcers, venous stasis ulcers, and surgical and traumatic wounds.

Background

Wound Healing Treatment

A variety of growth factors have been found to play a role in wound healing, including PDGF, epidermal growth factor, fibroblast growth factors, transforming growth factors, and insulin-like growth factors. Autologous platelets are a rich source of PDGF, transforming growth factors (that function as a mitogen for fibroblasts, smooth muscle cells, and osteoblasts), and vascular endothelial growth factors. Recombinant PDGF has also been extensively investigated for clinical use in wound healing.

Autologous platelet concentrate suspended in plasma, also known as platelet-rich plasma (PRP), can be prepared from samples of centrifuged autologous blood. Exposure to a solution of thrombin and calcium chloride degranulates platelets (releasing various growth factors) and results in the polymerization of fibrin from fibrinogen, creating a platelet gel. The platelet gel can then be applied to wounds or may be used as an adjunct to surgery to promote hemostasis and accelerate healing. In the operating room setting, PRP has been investigated as an adjunct to a variety of periodontal, reconstructive, and orthopedic procedures. For example, bone morphogenetic proteins are a transforming growth factor, and thus PRP has been used in conjunction with bone-replacement grafting (using either autologous grafts or bovine-derived xenograft) in periodontal and maxillofacial surgeries.

PRP is distinguished from fibrin glues or sealants, which have been used for many years as a surgical adjunct to promote local hemostasis at incision sites. Fibrin glue is created from platelet-poor plasma and consists primarily of fibrinogen. Commercial fibrin glues are created from pooled homologous human donors; Tisseel (Baxter International) and Hemaseel (Haemacure Corp.) are examples of commercially available fibrin sealants. Autologous fibrin

sealants can also be created from platelet-poor plasma. This policy does not address the use of fibrin sealants.

Wound Closure Outcomes

This policy addresses the use of recombinant PDGF products and PRP for non-orthopedic indications, which include a number of wound closure-related indications.

For this policy, the primary end points of interest for the study of wound closure are as follows, consistent with guidance from the US Food and Drug Administration (FDA) for the industry in developing products for the treatment of chronic cutaneous ulcer and burn wounds¹:

1. Incidence of complete wound closure
2. Time to complete wound closure (reflecting accelerated wound closure)
3. Incidence of complete wound closure following surgical wound closure
4. Pain control

Summary of Evidence

Recombinant Platelet-Derived Growth Factors

For individuals who have diabetic lower-extremity ulcers who receive recombinant PDGFs, the evidence includes randomized controlled trials (RCTs) and systematic reviews. The relevant outcomes are symptoms, change in disease status, morbid events, quality of life (QOL), and treatment-related morbidity. Results have shown improved rates of healing with use of recombinant PDGF for diabetic neuropathic ulcers and pressure ulcers. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have pressure ulcers who receive recombinant PDGF, the evidence includes a single RCT. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Results have shown improved rates of healing with use of recombinant PDGF for pressure ulcers. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have venous stasis leg ulcers or acute surgical or traumatic wounds who receive recombinant PDGF, the evidence includes small RCTs. The relevant outcomes are



symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. The level of evidence does not permit conclusions whether recombinant PDGF is effective in treating other wound types, including chronic venous ulcers or acute traumatic wounds. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Platelet-Rich Plasma

For individuals with chronic wounds who receive PRP, the evidence includes meta-analyses of a number of small, controlled trials. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. In meta-analyses of individuals with lower extremity diabetic ulcers, PRP demonstrated an improvement over the control groups in complete wound closure, recurrence rate, and healing time, but moderate to high risk of bias and imprecision preclude drawing conclusions on other important outcomes such as recurrence, infection, amputation, and quality of life. In individuals with venous ulcers, PRP did not demonstrate an improvement over the control groups in complete wound closure, recurrence, wound infection, or quality of life, although imprecision likely precluded identifying differences on these outcomes. In individuals with pressure ulcers, although PRP reduced wound size, other important outcomes such as complete wound closure were not measured. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have acute surgical or traumatic wounds who receive PRP, the evidence includes systematic reviews and a number of small, controlled trials. The relevant outcomes are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity. Current results of trials using PRP are mixed, and the studies are limited in both size and quality. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals where platelet rich plasma has been used for fat graft retention (aka fat graft take) there is limited evidence that supports this use. Published trials regarding the use of platelet rich plasma combined with fat grafting address different clinical scenarios such as facial liposuction for cheek contouring and split treatments to the face and hand with autologous fat grafting and PRP. One histological review of fat grafting and PRP in wound healing from animal studies concluded, “the fundamental issue of low fat graft survival hinders its clinical use in all settings.” The review acknowledges that PRP may increase the viability of fat grafts but states that well-designed studies in humans are needed to establish its clinical usefulness. Another article discussing the use of PRP for facial rejuvenation and hair restoration in combination with



fat grafting describes the lack of standardized protocols for the platelet rich plasma preparation. Limitations of these studies include small sample sizes and lack of long-term follow-up which is needed to determine the sustainability of the response of this treatment. These limited clinical scenarios prohibit the ability to extrapolate their findings to other clinical scenarios. Thus, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Platelet-Rich Plasma for Non-Orthopedic Indications

Platelet-rich plasma (PRP) has been proposed for a wide variety of medical conditions and has been in use for several decades. A myriad of studies in the medical literature discuss PRP use for many indications including but not limited to alopecia, erectile dysfunction, Peyronie's disease, assisted reproductive technology, stress urinary incontinence, facial and vaginal rejuvenation, cardiovascular regeneration and others. Almost all of the studies to date have a small sample size, lack a control, lack a reference protocol describing the PRP applications, and the frequency and the amount of PRP used. The studies are also missing data on subject's characteristics and statistical methods used, and studies are retrospective, and/or have a short follow-up. These methodological flaws result in the limited utility of studies to evaluate the benefits of PRP use in the proposed non-orthopedic applications. There is widespread variability in PRP preparation and contents. This results in inconsistencies in bioavailability of PRP delivered growth factors, as well as platelet concentrations, leucocyte and red blood cell counts, and activation method. PRP to date is therefore viewed as individual and quite variable.¹⁰⁶

Alopecia

For individuals who receive PRP for alopecia, the evidence includes systematic reviews, meta-analyses, a number of randomized controlled trials (RCTs) and a prospective controlled study. A systematic review by Sindhusen, Tawanwongsri, and Eden (2025) included two RCTs and one prospective study with a total of 217 subjects with androgenetic alopecia (AGA) using PRP as an adjunct to hair transplantation. There was substantial heterogeneity between the PRP preparation methods, the treatment protocols, as well as the reported outcome measures assessment. There was a lack of standardized evaluation tools as well as trichoscopic analysis (examination of the scalp and hair). This resulted in a limited consistency and comparability of the author's findings. Additional RCTs with standardized protocols as well as long-term follow-up are required to conclude if PRP provides effective outcomes with AGA.¹⁰⁷ A systematic review by Mao, Zhang and Fan (2019) included 11 studies with 262 AGA subjects using PRP for hair



restoration by increasing hair density and diameter while reducing hair loss, Most of the studies suggested that subcutaneous injection of PRP may decrease hair loss, while increasing hair diameter and density in subjects with AGA. However, the studies were assessed as low quality and had small sample sizes. Each study had different treatment protocols as well as publication bias. Due to the low quality of the studies, small sample sizes, different treatment regimens and possible publication bias, the results are inconclusive and require additional RCTs to rigorously assess the outcome of PRP on AGA.¹⁰⁸ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

A systematic review and meta-analysis by Kieling, et al. (2024) included 431 AGA subjects from 14 studies. The studies suggest that PRP effectively increases hair density in AGA, However, the studies were quite variable, assessed as low quality and included publication bias. The authors concluded that further RCTs are required to strengthen the evidence to conclude if PRP has a positive outcome for hair growth in AGA subjects.¹⁰⁹ A systematic review and meta-analysis by Evans et al. (2020) included 30 studies with a total of 687 subjects. Of these, ten studies were included in the review and analysis. The evaluation showed that hair density and thickness improved in both men and women with AGA. However, the studies had a high risk of bias, and heterogeneous treatment protocols. The authors conclude that further RCTs are needed to optimize treatment protocols and reduce variability between studies to reach an evidence based conclusion on effectiveness of PRP on hair density and thickness for AGA subjects.¹¹⁰ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Assisted Reproductive Technology

For individuals who receive PRP for assisted reproductive technology (ART), the evidence includes systematic reviews, meta-analysis, before-after trial designs, and a small controlled observational study. A systematic review and meta-analysis by Wang et al. (2024) examined the utility of PRP to improve pregnancy outcomes in women with intrauterine adhesions (IUAs). IUAs may result in infertility and recurrent pregnancy loss which may significantly impact women's reproductive health. This systematic review and meta-analysis examined 8 RCTs and 4 non-RCTs including 874 subjects with 425 subjects receiving PRP and 449 subjects in the control group. Although PRP decreased IUA recurrence, there was no significant change seen in the live birth rate, miscarriage rate or biochemical pregnancy rate. (very early pregnancy loss occurring shortly after the implantation of the embryo into the uterus).¹¹¹ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



A systematic review and meta-analysis by Wu et al., (2024) examined the utility of PRP to treat poor ovarian responders who had in vitro fertilization (IVF). There were 10 trials with a total of 876 subjects studies treated with PRP to increase ovarian response in conjunction with IVF. One study had a control group, and the other 9 studies were before-after studies with no control group. The study limitations included different diagnostic criteria for poor ovarian responders which generates high heterogeneity, non-standard PRP preparation, non-standard injection of PRP, and variability in postoperative treatment and follow-up. The 9 out of 10 before-after trials had study design limitations which produced potential bias. Although there was inherent bias and poor trial design including only one controlled trial out of 10, the authors claimed that PRP showed promising results in IVF with poor ovarian responders upon examination of pregnancy rate of 25.4% (no control), 7.3% increase in MII oocytes (mature oocytes which are ideal for IVF), and 11.7% higher antral follicle count (measure of number of eggs available for fertilization). Limitations of the study included heterogeneity in PRP preparation and protocol used, No information was given in any of the studies regarding platelet concentrations, white blood cell counts, or growth factor concentrations. Lack of standardized PRP across studies makes it difficult to form a consensus conclusion. There were variations in the diagnostic criteria among studies for poor ovarian responders, PRP preparation was nonstandard, as well as injection technique, amount of PRP injected, and post operative treatment and follow up. The data is interpreted cautiously per the authors due to the relatively low quality of the evidence. Additionally large RCTs are recommended to overcome these methodological flaws.¹¹² The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

A systematic review and meta-analysis by Maleki-Hajiagha et al. (2019) examined 7 studies with 625 subjects (311 subjects treated with PRP and 314 control subjects). These were analyzed for the utility of PRP to improve favorability in IVF success by improving endometrium thickness. Two studies included subjects with a thin endometrium, and 5 studies included those with recurrent implantation failure who were undergoing a frozen-thawed embryo transfer (ET) cycle. The authors state that there was a higher probability of chemical pregnancy, (1%) (chemical pregnancy defined as an early pregnancy lost shortly after implantation), clinical pregnancy (2%) (confirmed by human gonadotropin hormone and ultrasound), and implantation rate (1%) compared to the control group. There was no difference seen in the miscarriage rate between the PRP and control groups. Thickness of the endometrium increased after treatment with PRP compared to the control group. The sample sizes were too low to draw confident conclusions. The authors state that additional prospective RCTs with larger sample sizes are needed.¹¹³ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



A small observational controlled study by Hosseini et al. (2024) studied PRP application to sperm processing to increase sperm quality for infertile men using assisted reproductive technology (ART). The study used 80 semen samples with 40 samples collected from men with asthenoteratozoospermia (impaired motility and abnormal morphology), and 40 samples collected from men with normal sperm. Each sample portion was divided equally with one receiving an addition of 2% concentration of PRP and the control was not treated with PRP. The two groups were processed identically for incubation and swim up processes. The PRP treated asthenoteratozoospermia had a 45% increase in progressive sperm motility and a 51% increase in non-progressive sperm motility. There was no change in sperm viability between PRP treated and non-treated sperm (viability is percentage of live sperm in semen, 50% is usually needed for conception). The authors state that although some sperm parameters showed improvements, the long-term effects of PRP treatment on male fertility outcomes are unknown and require further investigation with multiple large RCTs.¹¹⁴ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Erectile Dysfunction

For males who receive PRP injections for erectile dysfunction (ED), the evidence includes two systematic reviews and meta-analyses, RCTs and observational studies. A systematic review by Mao et al., (2024) examined the efficacy of treatment of ED with PRP penile injections. Four double blinded RCTs were chosen with 413 subjects. Minimal clinically important difference (MCID) and International Index of Erectile Function (IIEF) validated standardized questionnaires were both analyzed at follow ups at 1, 3, and 6 months. The study reported a statistically significant increase in MCID and IIEF scores both at 1 and 6 months, but not at 3 months. The research was limited by non-standard preparation of PRP, non-unified formulation and components of the injected PRP, variations in platelet separation devices employed, consistency of PRP that was injected, dosing and interval timing, proportions and concentration of platelets, growth factors and cytokines. Flaws in subject characteristics made it unable to determine if the subjects had organic ED or psychogenic ED. The study cited the impact of loss to follow-up as a factor in data evaluation but did not quantify the number of subjects lost to follow-up.¹¹⁵ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

A systematic review and meta-analysis by Falcone et al., (2025) reviewed the efficacy of treatment of ED with PRP penile injections. A total of 5 studies were reviewed including 3 prospective double-masked RCTs and 2 observational comparative studies with a total of 220 subjects with vasculogenic ED, with 107 subjects in the PRP treatment group and 113 subjects in the placebo group. Primary outcomes were change in erectile function from baseline using 5



validated questionnaires including the IIEF. Secondary outcomes were variations in vascular parameters using penile duplex ultrasound, There was improvement in erectile function compared to placebo in all 3 RCTs, as well as the pre and post treatment questionnaire scores. The improved results were durable through the 6 month follow ups. Two studies reported a significant increase in the caliber of the cavernous artery per the reported vascular data obtained from dynamic penile Doppler ultrasound pre and post PRP treatment. However, study limitations included variability in PRP preparation and composition, timing, number, and volume of injections. Larger RCTs are needed to validate the data and determine injected dose, injection interval preparation techniques, and clinical utility.¹¹⁶ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Facial Rejuvenation

For individuals who receive PRP for facial rejuvenation dysfunction, the evidence includes systematic reviews which included a number of small, uncontrolled trials. A systematic review of PRP and platelet-rich fibrin (PRF) by Qin et al., (2025) reviewed the efficacy of PRP or PRF as a single therapy by reviewing 20 articles with 514 subjects. Improvements were reported in 80% of studies on skin thickness, 75% of studies on elasticity, 40% of studies on wrinkles, 33% of studies on texture, 17% of studies on dyschromia and no studies reported improvement in hydration.¹¹⁷

A systematic review of PRP by Cruciani et al., (2025) reviewed the efficacy of PRP as a monotherapy reviewing 20 articles along with 8 articles which included PRP as an adjunct treatment with other treatments (laser therapy, fat grafting, hyaluronic acid, basic fibroblast growth factor). Most of the primary studies (71%) lacked a control. Four systematic reviews, described in a narrative manner, indicate that PRP combined with laser therapy enhances patient satisfaction and skin elasticity while reducing the erythema index, though the certainty of evidence is very low due to imprecision, non-systematic observations, and risk of bias. The confidence in the results of the systematic reviews in 12 of 13 studies was graded as low or critically low. Almost all of the systematic reviews showed poor compliance by evaluation with AMSTAR 2 criteria. (AMSTAR 2 is a critical appraisal tool designed to evaluate the methodological quality and trustworthiness of systematic reviews that include randomized or non-randomized studies). The limitations included no standardized PRP preparation methods, administration schedules, or duration of follow-up. PRP was administered topically in one study and was administered as an injection in the other studies.¹¹⁸ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



Peyronie's Disease

For males who receive PRP for Peyronie's disease (PD), the evidence includes a prospective cohort study, a pilot study and a clinical trial update. A prospective cohort study by Dachille et al., (2025) investigated efficacy of PRP intra-plaque injections in subjects with PD. The study included 72 subjects with PD who received 3 PRP injections at two week intervals and evaluated erect penis curvature angle, plaque size, and sexual function questionnaires including the IIEF. The study found that plaque size decreased 35%, and median curvature decreased by 10°. The authors noted that increased subject BMI was associated with a lower outcome benefit with PRP treatment for PD. Further large scale RCTs with longer follow-up are needed to establish efficacy of PRP treatment for PD.¹¹⁹ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Stress Urinary Incontinence

For females who receive PRP for stress urinary incontinence (SUI), the evidence includes systematic reviews, RCTs, and prospective studies. A systematic review of PRP by Dankova et al., (2023) reviewed the efficacy of PRP for female SUI by analyzing one RCT and six prospective studies with a total of 155 women in the SUI group who were evaluated, yet only 145 received PRP. Post PRP treatment, female SUI was evaluated by standardized questionnaires and clinical outcome measures. The RCT had 10 subjects in the PRP arm and 10 subjects who received the standard of care midurethral sling procedure. The sling group reported a higher mean score for the standardized SUI questionnaire compared to the PRP group. However, all 7 SUI studies reviewed reported improvements post PRP injections. The outcome measures were evaluated with questionnaires, mean urinary leakage in one hour, and in a cough stress test. However, the studies lacked standardization of PRP dosing frequency, duration, and site of injection, as well as lack of standardization for PRP preparation. The quality of the outcome findings were reported as low due to the noted methodology concerns.¹²⁰ The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Vulvovaginal Atrophy of Menopause (VVA)

For females who receive PRP for stress vulvovaginal atrophy of menopause (VVA) also known as genitourinary syndrome of menopause (GSM), the evidence includes an RCT, a small controlled trial, and a pilot study. A comparative RCT by Scarin et al., (2025) with 90 postmenopausal women ages 50 to 65 years with VVA treated by either PRP or estrogen therapy. The study measured outcomes using validated questionnaires and clinical outcomes evaluating lubrication,



elasticity, and dyspareunia. Both groups showed significant improvements with the validated questionnaires as well as clinical outcome measures. Patient satisfaction was high in both groups and was slightly higher in the PRP group. The PRP group had fewer side effects and lacked systemic symptoms compared to the estrogen group.¹²¹ Due to the small study size and lack of other data, the efficacy of PRP for VVA is inconclusive. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some larger studies that might influence this review are listed in [Table 1](#).

Table 1. Summary of Key Clinical Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT07117955	Treatment of Peyronie's Disease With Platelet-Rich Plasma: A Randomized, Double-blind, Placebo-controlled Clinical Trial	84	Sep 2028
NCT06645379	Application of Platelet-rich Plasma (PRP) in Reproductive Medicine	300	Sep 2027
NCT03474718	Evaluating the Efficacy of Platelet-rich Plasma Therapy in the Treatment of Androgenic Alopecia	16	Jun 2027
NCT05850611	The Effect of Combination Therapy of Oral Methylene Blue and Platelet-rich Plasma-fibrin Glue in Patients With Non-healing Diabetic Foot Ulcer: a Pilot Study	20	Sep 2024 (unknown status)
NCT05996614	Evaluation of Platelet Rich Plasma in Skin Graft Take for Patients With Post Burn Raw Areas	40	Feb 2025 (unknown status)
NCT06281483	Efficacy of Platelet-rich Plasma Versus Platelet-rich Fibrin Versus Conventional Treatment in Chronic Non-healing Skin Ulcers: A Comparative Study	36	Jan 2026
NCT05181748	Investigating the Efficiency of Autologous Platelet Rich Plasma Intraovarian Infusion on Improving Ovarian Functionality in Poor Ovarian Response Patients	100	Jan 2026



NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT01372566	Effect of Autologous Platelet-rich Plasma on Photoaged Skin: A Prospective Randomized Controlled Trial (Phases A and B)	23	Dec 2025
NCT05790655	Ovarian Platelet-Rich Plasma Injections for Diminished Ovarian Reserve Patients: A Double-Blinded Placebo-Control Trial	230	Dec 2025
NCT05479474	Platelet Rich Plasma Testis Treatment for Infertile Men	10	Dec 2026
NCT06028009	Vaginal Injection of Platelet Rich Plasma (PRP) for the Genitourinary Syndrome of Menopause (GSM)	30	Dec 2026
NCT06264635	Pilot Randomized Controlled Trial Evaluating the Efficacy of Platelet-Rich-Plasma (PRP) for Erectile Dysfunction	60	Mar 2025
NCT06298110	The Effect of PRP on Wound Healing in High Risk Patients Undergoing Abdominal Hysterectomy	80	Sep 2024
NCT06264635	Pilot Randomized Controlled Trial Evaluating the Efficacy of Platelet-Rich-Plasma (PRP) for Erectile Dysfunction	60	Mar 2025
Unpublished			
NCT05979584	Platelet Rich Plasma VS Platelet Fibrin Plasma in Treatment of Diabetes Foot Ulcer: a Randomized Controlled Trial	56	Mar 2025
NCT06440655	A Randomized, Split-head Comparison Study of the Efficacy and Safety of Platelet-Rich Fibrin and Platelet Rich Plasma in Female Pattern Hair Loss Patients : A Pilot Study	10	Sep 2024 (recruiting)
NCT05348343	A Pilot Clinical 'Proof of Concept' Study of Activated Platelet-rich Plasma (PRP) in Subjects With Androgenetic Alopecia (AGA)	17	Sep 2023 (completed)
NCT02071979^a	Registry Trial of the Effectiveness of Platelet Rich Plasma for Chronic Non-Healing Wounds (CMS)	1500	Jan 2018(terminated ; updated 01/16/18)
NCT02312596^a	A Prospective, Randomized Clinical Trial of PRP Concepts Fibrin Bio-Matrix in Chronic Non-Healing Pressure Ulcers	200	Dec 2021 (unknown)
NCT02312570^a	A Prospective, Randomized Clinical Trial of PRP Concepts Fibrin Bio-Matrix in Chronic Non-Healing Pressure Ulcers	200	Dec 2021 (unknown)
NCT02307448^a	Effectiveness of Autologous Platelet Rich Plasma in the Treatment of Chronic Non-Healing Wounds	80	Dec 2022 (terminated)



NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02402374 ^a	Randomized, Placebo-controlled, Blind-assessor Study to Evaluate the Safety and Efficacy of Autologous Platelet Rich Plasma Gel Prepared With the RegenKit-BCT Plus Family of Kits for the Treatment of Diabetic Foot Ulcer	192	Dec 2020 (unknown)

NCT: national clinical trial; PRP: autologous platelet-rich plasma

^a Denotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Physicians

In 2015 the American College of Physicians (ACP) published guidelines on treatment of pressure ulcers.⁹⁴ The guidelines noted that “although low quality evidence suggests that dressings containing PDGF [platelet-derived growth factors] promote healing, ACP supports the use of other dressings such as hydrocolloid and foam dressings, which are effective at promoting healing and cost less than PDGF dressings.” A search of the ACP website on December 1, 2020, found that this 2015 guideline is now listed as inactive.

Association for the Advancement of Wound Care

The Association for the Advancement of Wound Care developed guideline recommendations for the management of pressure ulcers (2010)⁹⁵ and venous ulcers (2015)⁹⁶.

- Pressure ulcer: “Growth factors are not indicated for PU [pressure ulcers] at this time” (level C evidence – no RCTs available comparing growth factors with A-level dressings)⁹⁵



- Venous ulcer: "Platelet derived growth factor has shown no significant effects on VU [venous ulcer] healing or recurrence" (level A evidence)⁹⁶

Wound Healing Society

The 2023 Wound Healing Society (WHS) guideline for the treatment of pressure ulcers makes the following recommendations:⁹⁷

"Consider the use of growth factor therapy for pressure ulcers that are not responsive to initial comprehensive therapy and/or before surgical repair...Platelet rich plasma (PRP) gel consists of cytokines, growth factors, chemokines, and a fibrin scaffold derived from a patient's blood. The mechanism of action of PRP gel is thought to be inducing and stimulating cellular and molecular processes enhancing wound healing."

The 2024 WHS guideline for the treatment of diabetic foot ulcers makes the following recommendations:⁹⁸

"Topical growth factors such as platelet-derived and recombinant human epidermal growth factor have been shown to increase the incidence of ulcer healing and reduce the time to heal."

"The evidence is uncertain for the efficacy of therapy with platelet-rich plasma as studies report mixed results regarding the benefits of this therapy."

National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence updated its guidance on the prevention and management of diabetic foot problems.⁹⁹ The guidance stated that neither autologous platelet-rich plasma (PRP) gel nor platelet-derived growth factors should be offered in the treatment of diabetic foot ulcers.

Medicare National Coverage

In 2012, the Centers for Medicare & Medicaid Services (CMS) revised its national coverage decision on autologous blood-derived products for chronic non-healing wounds.^{100,101} This revision replaces prior noncoverage decisions.^{102,103}



The Centers for Medicare & Medicaid Services covers autologous PRP only for individuals who have chronic non-healing diabetic, pressure, and/or venous wounds and when all of the following conditions are met:

- The patient is enrolled in a clinical research study that addresses the following questions using validated and reliable methods of evaluation...
- The clinical research study must meet the requirements specified below to assess the effect of PRP for the treatment of chronic non-healing diabetic, venous, and/or pressure wounds. The clinical study must address:
 - Prospectively, do Medicare beneficiaries that have chronic non-healing diabetic, venous, and/or pressure wounds who receive well-defined optimal usual care, along with PRP therapy, experience clinically significant health outcomes compared to patients who receive well-defined optimal usual care for chronic non-healing diabetic, venous, and/or pressure wounds as indicated by addressing at least one of the following:
 - a. Complete wound healing?
 - b. Ability to return to previous function and resumption of normal activities?
 - c. Reduction of wound size or healing trajectory, which results in the patient's ability to return to previous function and resumption of normal activities?

In response to a formal request from Nuo Therapeutics on May 9, 2019, CMS began a fourth reconsideration of its national coverage decision.⁷³ To inform this reconsideration, the Mayo Evidence-based Practice Center performed a technology assessment that was published by Qu et al (2020) and its results are described in the Rationale section.¹⁰⁴ Following their review of this evidence, on December 21, 2020, CMS posted a Proposed Decision Memorandum that proposes to expand its 2012 Coverage with Evidence Development decision to cover any use of autologous PRP "...for the treatment of chronic non-healing diabetic wounds under section 1862(a)(1)(A) of the Social Security Act (the Act)."¹⁰³ This decision is based on the evidence described above that is sufficient "...to demonstrate that patients with diabetic ulcers who are treated with autologous PRP have better outcomes (complete wound healing) when compared to patients who receive standard care." CMS additionally noted that a limitation of the evidence is that "None of these studies addressed whether or not PRP affected a patient's ability to return to previous function and resumption of normal activities or resulted in reduction of wound size or healing trajectory as an intermediary towards a formal endpoint of a patient's ability to return to previous function and resumption of normal activities."



For other chronic non-healing wounds, "CMS proposes that coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by local Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Act."

In April 2021, CMS published an updated decision memo following the fourth reconsideration of the national coverage analysis stating that CMS will "cover autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic wounds under section 1862(a)(1)(A) of the Social Security Act (the Act) for a duration of 20 weeks, when prepared by devices whose FDA cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers. Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by local Medicare Administrative Contractors (MACs).

Coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by local Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Act."¹⁰⁵

Regulatory Status

Becaplermin

In 1997, becaplermin gel (Regranex; Smith & Nephew), a recombinant PDGF product, was approved by the FDA for the following labeled indication:

- Regranex Gel is indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply. When used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief, and infection control, Regranex Gel increases the complete healing of diabetic ulcers.
- The efficacy of Regranex Gel for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue or ischemic diabetic ulcers ... has not been evaluated...Regranex is not intended to be used in wounds that close by primary intention.

In 2008, the manufacturer added the following black box warning to the labeling for Regranex:

- An increased rate of mortality secondary to malignancy was observed in patients treated with three or more tubes of Regranex Gel in a post marketing retrospective cohort study.



Regranex Gel should only be used when the benefits can be expected to outweigh the risks. Regranex Gel should be used with caution in patients with known malignancy.

In 2018, the "Boxed Warning" and "Warnings and Precautions" were changed to remove "increased rate of cancer mortality" and "cancer mortality," respectively.

Platelet-Rich Plasma

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Blood products such as PRP are included in these regulations.

Under these regulations, certain products including blood products such as PRP are exempt and therefore do not follow the traditional FDA regulatory pathway. To date, the FDA has not attempted to regulate activated PRP.²

Numerous PRP preparation systems have been cleared for marketing by the FDA through the 510(k) process. These devices are intended to concentrate patient plasma at the point of care during bone grafting procedures. The use of different devices and procedures can lead to variable concentrations of active platelets and associated proteins, increasing variability between studies of clinical efficacy.

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History

Date	Comments
05/05/97	Add to Medicine Section - New Policy
08/17/99	Replace Policy - Revised policy; addresses becaplermin gel.
10/08/02	Replace Policy - Policy reviewed with changes: new policy statement on becaplermin gel for treatment of pressure ulcers.
10/16/03	Replace Policy - Policy updated; no change in policy statement. Information regarding Autologel and SafeBlood provided. Title updated by removing Platelet and adding Blood.
01/11/05	Replace Policy - Policy updated focusing on autologous blood derived wound healing products; reference added; no change in policy statement.
01/10/06	Presented at January MPC - Policy revised; policy statement added regarding miscellaneous use of platelet-rich plasma as a primary procedure. Description and rationale now include discussion of platelet-rich plasma. MPC requested further research before adopting.
02/14/06	Replace Policy - Policy revised per MPC request of removing description regarding fibrin sealant and surgical indications (primary wound closure).
06/16/06	Update Scope and Disclaimer - No other changes
07/10/07	Replace Policy - Policy updated with literature search; references added; policy statement unchanged.
08/12/08	Replace Policy - Policy updated with literature search; no change to the policy statement.
01/13/09	Code Updates - Codes Q4102 and Q4103 added, effective 1/1/09.
10/13/09	Replace Policy - Policy updated with literature search; policy statement updated to include "acute" wounds for PRP. References added.



Date	Comments
12/27/10	Codes Updated - CPT code 0232T added to policy; no other changes.
06/13/11	Replace Policy - Policy updated with literature search, reference numbers 11-14, 18, 19, 23, 24 added, policy statements unchanged. ICD-10 codes added to policy. CPT coding related to platelet-rich plasma also updated. Title changed to "Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions."
03/22/12	Minor update, Related Policies updated with 7.01.113 and 1.01.16.
06/26/12	Replace policy. Policy updated with literature search through February 2012, references added and reordered; some references removed; policy statements unchanged. Codes Q4102 and Q4103 removed; these do not apply to this policy and appear on 7.01.113.
07/25/12	Related Policies Update: 8.01.52 and 8.01.55 have been added.
08/24/12	Update Related Policies – Remove 1.01.16 as it was archived. Update coding section – ICD-10 codes are now effective 10/01/2014.
07/23/13	Replace policy. Policy updated with literature search through March 8, 2013; references added and reordered; policy statements unchanged.
03/17/14	Update Related Policies. Remove 7.01.100 as it was archived.
07/31/14	Annual Review. Policy updated with literature review through March, 2014. References 6, 19, 22-23, 26, 31, 36, and 48 added; others renumbered/removed. Policy statements unchanged. HCPCS code G0460 added to the policy.
09/23/14	Update Related Policies. Add 7.01.142.
07/14/15	Annual Review. Policy title changed to "Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Non-Orthopedic Conditions." Orthopedic applications of platelet-rich plasma (PRP) policy statements removed from this policy and placed in new Policy No. 2.01.98. Coding table in Policy Guidelines updated to match Coding section of policy. Policy updated with literature review through April 15, 2015; references 1 and 3 added. Policy statements removed as noted, others remain unchanged. CPT code 20926 removed; platelet-rich plasma is not considered a tissue graft. ICD-9 and ICD-10 codes removed; these were for informational purposes only.
09/01/15	Update Related Policies. Add 7.01.149
10/16/15	Update Related Policies. Remove 7.01.142.
04/01/16	Annual Review, approved March 8, 2016. Policy updated with literature review through October 29, 2015; references 16 and 18-19 added. Policy statements unchanged.
04/01/17	Annual Review, approved March 14, 2017. Policy updated with literature review through November 8, 2016; references 1, 16, 20, 23, and 27-31 added. Policy statements unchanged.
09/22/17	Policy moved to new format. No changes to policy statements.



Date	Comments
04/01/18	Annual Review, approved March 20, 2018. Policy updated with literature review through November 2017; no new references added; notes 1-2, 29-30, and 32-34 updated. Policy statements unchanged.
03/01/19	Annual Review, approved February 25, 2019. Policy updated with literature review through October 2018; 12, 27, and 30 references added. Policy statements unchanged.
04/01/20	Annual Review, approved March 19, 2020. Policy updated with literature review through November 2019; references added. Policy statements unchanged.
08/01/20	Update related policies. 7.01.149 is now 7.01.583.
04/01/21	Annual Review, approved March 2, 2021. Policy updated with literature review through December 1, 2020; references added. Policy statements unchanged.
04/01/22	Annual Review, approved March 7, 2022. Policy updated with literature review through December 13, 2021; references added. Policy statements unchanged. Added HCPCS code G0465. Removed CPT code 86999.
04/01/23	Annual Review, approved March 6, 2023. Policy updated with literature review through December 13, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization. Updated code description for HCPC code G0460.
03/01/24	Annual Review, approved February 26, 2024. Policy updated with literature review through November 14, 2023; references added. Policy statements unchanged.
01/01/25	Policy renumbered from 2.01.16 Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions to 2.01.543, approved December 10, 2024. Added to the policy statement that "for fat graft retention (aka fat graft take)" the use of PRP is considered investigational. References added.
04/01/25	Annual Review, approved March 10, 2025. Policy updated with literature review through November 22, 2024; references added. Policy statements unchanged.
07/03/25	Minor update made to Related Policy section. Policy 7.01.113 Bioengineered Skin and Soft Tissue Substitutes is deleted and replaced with 7.01.582 Bioengineered Skin and Soft Tissue Substitutes.
12/01/25	Interim Review, approved November 11, 2025. Policy reviewed with literature update. References added. Added additional conditions for which the use of PRP is considered investigational, otherwise policy statements are unchanged.
04/01/26	Annual Review, approved March 9, 2026. Policy updated with literature review through November 24, 2025; references added. Policy statements unchanged. Code descriptors updated for G0460 and G0465.



Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2026 Premera All Rights Reserved.

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