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The Department of Vermont Health Access Clinical Criteria

Subject: Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Diabetic, Venous and/or Pressure Wounds

Last Review: November 8, 2023*

Past Revisions: August 30, 2022; March 26, 2021; May 15, 2019; April 4, 2017; June 6, 2016; June 2, 2015; January 6, 2014

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

Platelet-rich plasma (PRP) is produced by centrifuging autologous or homologous (allogenic) blood to yield a concentrate that is high in platelets and plasma proteins.

From the Centers for Medicaid and Medicare National Coverage Determination (2021):

Platelet-rich plasma (PRP) is produced in an autologous or homologous manner.

Autologous PRP is comprised of blood from the patient who will ultimately receive the PRP. Alternatively, homologous PRP is derived from blood from multiple donors.

Blood is donated by the patient and centrifuged to produce an autologous gel for treatment of chronic, non-healing cutaneous wounds that persist for 30 days or longer and fail to properly complete the healing process. Autologous blood derived products for chronic, non-healing wounds includes both: (1) platelet derived growth factor (PDGF) products (such as Procuren), and (2) PRP (such as AutoloGel).

The PRP is different from other products in that it contains whole cells including white cells, red cells, plasma, platelets, fibrinogen, stem cells, macrophages, and fibrocyte precursors.

The PRP is used by physicians in clinical settings for treating chronic, non-healing wounds, open, cutaneous wounds, soft tissue and bone. Alternatively, PDGF does not contain cells and was previously marketed as a product to be used by patients at home.



Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertain to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

- 7102.2 Prior Authorization Determination
- 4.101 Medical Necessity for Covered Services
- 4.104 Medicaid Non-Covered Services
- 4.106 Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

Autologous PRP for chronic non-healing diabetic, venous and/or pressure wounds may be covered for members:

- When the therapy is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding autologous PRP for chronic non-healing diabetic, venous and/or pressure wounds, and who provides medical care to the member **AND**
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: <https://sos.vermont.gov/opr/>

Coverage Criteria

The DVHA will cover autologous PRP for chronic non-healing diabetic, venous and/or pressure wounds in accordance with Medicare national coverage guidance.

Effective April 13, 2021, the Centers for Medicare and Medicaid Services (CMS) will cover autologous PRP for the treatment of chronic non-healing diabetic wounds 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 (CMS Medicare Coverage Database, 2021).

<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=217>

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

The same criteria will be applied as for initial use.

Type of service or procedure covered

Autologous PRP for the treatment of chronic non-healing diabetic, venous and/or pressure wounds for a duration of 20 weeks when prepared by devices whose Food and Drug Administration (FDA)-cleared indications include the management of exuding cutaneous wounds)

Type of service or procedure not covered (this list may not be all inclusive)

The use of PRP for anything other than chronic non-healing diabetic, venous and/or pressure wounds **or for treatment of chronic non-healing diabetic, venous and/or pressure wounds** longer than 20 weeks.

References

- Centers for Medicare & Medicaid Services. (2021, April 13). *National coverage analysis decision memo autologous blood-derived products for chronic non-healing wounds (CAG-00190R4)*. Medicare coverage database. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=300>
- Centers for Medicare & Medicaid Services. (2021). *National coverage determination (NCD) 270.3 blood-derived products for chronic, non-healing wounds*. Medicare coverage database. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=217>
- Centers for Medicare and Medicaid Services. (2017). *Early and periodic screening, diagnostic, and treatment*. Medicaid.gov. <https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html>
- Conde-Montero, E., de la Cueva Dobao, P., & Martínez González, J. M. (2017). Platelet-rich plasma for the treatment of chronic wounds: Evidence to date. *Chronic Wound Care Management and Research, Volume 4*, 107–120. <https://doi.org/10.2147/cwcmr.s118655>
- Hayes, Inc. Health Technology Assessment. *Platelet-Rich Plasma for Wound Treatment in Diabetic Foot Ulcers*. Lansdal, PA: Hayes, Inc.; April 2023.
- Hayes, Inc. Health Technology Assessment. *Platelet-Rich Plasma for Wound Treatment in Venous Leg Ulcers*. Lansdal, PA: Hayes, Inc.; December 2022.
- Hirase, T., Ruff, E., Surani, S., & Ratnani, I. (2018). Topical application of platelet-rich plasma for diabetic foot ulcers: A systematic review. *World Journal of Diabetes*, 9(10), 172–179. <https://doi.org/10.4239/wjd.v9.i10.172>
- Li, S., Xing, F., Yan, T., Zhang, S., & Chen, F. (2023). The efficiency and safety of platelet-rich plasma dressing in the treatment of chronic wounds: A systematic review and meta-

analysis of randomized controlled trials. *Journal of Personalized Medicine*, 13(3), 430.
<https://doi.org/10.3390/jpm13030430>

Martinez-Zapata, M. J., Martí-Carvajal, A. J., Solà, I., Expósito, J. A., Bolívar, I., Rodríguez, L., García, J., & Zaror, C. (2016). Autologous platelet-rich plasma for treating chronic wounds. *Cochrane Database of Systematic Reviews*, 2016(5), 1–58.
<https://doi.org/10.1002/14651858.cd006899.pub3>

Picard, F., Hersant, B., Bosc, R., & Meningaud, J.P. (2015). The growing evidence for the use of platelet-rich plasma on diabetic chronic wounds: A review and a proposal for a new standard care. *Wound Repair and Regeneration*, 23(5), 638–643.
<https://doi.org/10.1111/wrr.12317>

Weller, C. D., Gardiner, E. E., Arthur, J. F., Southey, M., & Andrews, R. K. (2019). Autologous platelet-rich plasma for healing chronic venous leg ulcers: Clinical efficacy and potential mechanisms. *International Wound Journal*, 16(3), 788–792.
<https://doi.org/10.1111/iwj.13098>

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