



# Louisiana

## Orthopedic Applications of Platelet-Rich Plasma

Policy # 00476

Original Effective Date: 09/23/2015

Current Effective Date: 10/11/2021

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Intra-articular Hyaluronan Injections for Osteoarthritis of the Knee is addressed separately in medical policy 00075.*

*Note: Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions is addressed separately in medical policy 00091.*

*Note: Prolotherapy is addressed separately in medical policy 00106.*

*Note: Orthopedic Applications of Stem Cell Therapy (Including Allograft and Bone Substitute Products Used With Autologous Bone Marrow) is addressed separately in medical policy 00258.*

*Note: Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Non-Orthopedic Conditions is addressed separately in medical policy 00262.*

## Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of platelet-rich plasma (PRP) to be **investigational\*** for all orthopedic indications. This includes but is not limited to, use in the following situations:

- Primary use (injection) for the following conditions:
  - Achilles tendinopathy
  - Lateral epicondylitis
  - Osteochondral lesions
  - Osteoarthritis
  - Plantar fasciitis

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- Adjunctive use in the following surgical procedures:
  - ACL reconstruction
  - Hip fracture
  - Long-bone nonunion
  - Patellar tendon repair
  - Rotator cuff repair
  - Spinal fusion
  - Subacromial decompression surgery
  - Total knee arthroplasty

### **Background/Overview**

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

Autologous platelet concentrate suspended in plasma, also known as platelet-rich plasma, can be prepared from samples of centrifuged autologous blood. Exposure to a solution of thrombin and calcium chloride degranulates platelets, releasing the various growth factors. The polymerization of fibrin from fibrinogen creates a platelet gel, which can then be used as an adjunct to surgery with the intent of promoting hemostasis and accelerating healing. In the operating room setting, platelet-rich plasma has been investigated as an adjunct to various periodontal, reconstructive, and orthopedic procedures. For example, bone morphogenetic proteins are a type of transforming growth factors, and thus platelet-rich plasma has been used in conjunction with bone-replacement grafting (using either autologous grafts or bovine-derived xenograft) in periodontal and maxillofacial surgeries. Alternatively, platelet-rich plasma may be injected directly into various tissues. Platelet-rich plasma injections have been proposed as a primary treatment of miscellaneous conditions, such as epicondylitis, plantar fasciitis, and Dupuytren contracture.

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Injection of platelet-rich plasma for tendon and ligament pain is theoretically related to prolotherapy. However, prolotherapy differs in that it involves the injection of chemical irritants intended to stimulate inflammatory responses and induce the release of endogenous growth factors.

Platelet-rich plasma is distinguished from fibrin glues or sealants, which have been used 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<sup>®</sup> (Baxter) and Hemaseel<sup>®</sup> (Haemacure Corp) are examples of commercially available fibrin sealants. Autologous fibrin sealants can be created from platelet-poor plasma. This evidence review does not address the use of fibrin sealants.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

The U.S. 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 1,270 and 1,271. Blood products such as platelet-rich plasma are included in these regulations. Under these regulations, certain products including blood products such as platelet-rich plasma are exempt and therefore do not follow the traditional FDA regulatory pathway. To date, the FDA has not attempted to regulate activated platelet-rich plasma.

A number of platelet-rich plasma preparation systems are available, many of which were cleared for marketing by the FDA through the 510(k) process for producing platelet-rich preparations intended to be mixed with bone graft materials to enhance the bone grafting properties in orthopedic practices. The use of platelet-rich plasma outside of this setting (eg, an office injection) would be considered off-label. The Aurix System<sup>™</sup> (previously called AutoloGel<sup>™</sup>; Cytomedix) and SafeBlood<sup>®</sup> (SafeBlood Technologies) are 2 related but distinct autologous blood-derived preparations that can be used at the bedside for immediate application. Both AutoloGel<sup>™</sup> and SafeBlood<sup>®</sup> have been specifically marketed for wound healing. Other devices may be used during surgery (eg, Medtronic Electromedics, Elmd-500 Autotransfusion system, the Plasma Saver device, the SmartPREPO [Harvest Technologies] device). The Magellan<sup>™</sup> Autologous Platelet Separator System (Medtronic Sofamor Danek) includes a disposable kit for use with the Magellan<sup>™</sup> Autologous Platelet Separator portable tabletop centrifuge. GPS<sup>®</sup>II (BioMet Biologics), a gravitational platelet separation system, was cleared for marketing by the FDA through the 510(k)

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process for use as disposable separation tube for centrifugation and a dual cannula tip to mix the platelets and thrombin at the surgical site. Filtration or plasmapheresis may also be used to produce platelet-rich concentrates. The use of different devices and procedures can lead to variable concentrations of activated platelets and associated proteins, increasing variability between studies of clinical efficacy.

### **Rationale/Source**

The use of platelet-rich plasma has been proposed as a treatment for various musculoskeletal conditions and as an adjunctive procedure in orthopedic surgeries. The potential benefit of platelet-rich plasma has received considerable interest due to the appeal of a simple, safe, low-cost, and minimally invasive method of applying growth factors.

### **Summary of Evidence**

#### **Primary Treatment for Tendinopathies**

For individuals with tendinopathy who receive platelet-rich plasma injections, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews with meta-analyses. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Findings from meta-analyses of RCTs have been mixed and have generally found that platelet-rich plasma did not have a statistically and/or clinically significant impact on symptoms (ie, pain) or functional outcomes. Findings from subsequently published RCTs have also been mixed. In RCTs that have found significantly improved pain outcomes for platelet-rich plasma injections, important relevancy gaps and study conduct limitations preclude reaching strong conclusions based on their findings. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### **Primary Treatment for Non-Tendon Soft Tissue Injury or Inflammation**

For individuals with non-tendon soft tissue injury or inflammation (eg, plantar fasciitis) who receive platelet-rich plasma injections, the evidence includes several small RCTs, multiple prospective observational studies, and a systematic review. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The systematic review, which identified 3 RCTs on platelet-rich plasma for plantar fasciitis, did not pool study findings. Results among the remaining RCTs were inconsistent. The largest RCT showed that

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treatment using platelet-rich plasma compared with corticosteroid injection resulted in statistically significant improvement in pain and disability, but not quality of life. Larger RCTs are still needed to address important uncertainties in efficacy and safety. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Primary Treatment for Osteochondral Lesions**

For individuals with osteochondral lesions who receive platelet-rich plasma injections, the evidence includes an open-labeled quasi-randomized study. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. The quasi-randomized study found a statistically significant greater impact on outcomes in the platelet-rich plasma group than in the hyaluronic acid group. Limitations of the evidence base include lack of adequately randomized studies, lack of blinding, lack of sham controls, and comparison only to an intervention of uncertain efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Primary Treatment for Knee or Hip Osteoarthritis**

For individuals with knee or hip osteoarthritis who receive platelet-rich plasma injections, the evidence includes multiple RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related morbidity. Most trials have compared platelet-rich plasma with hyaluronic acid for knee osteoarthritis. Systematic reviews have generally found that platelet-rich plasma was more effective than placebo or hyaluronic acid in reducing pain and improving function. However, systematic review authors have noted that their findings should be interpreted with caution due to important limitations including significant residual statistical heterogeneity, questionable clinical significance, and high risk of bias in study conduct. RCTs with follow-up durations of at least 12 months published subsequent to the systematic reviews found statistically significantly greater 12 month reductions in pain and function scores, but these findings were also limited by important study conduct flaws including potential inadequate control for selection bias and limited or unclear blinding. Also, using hyaluronic acid as a comparator is questionable, because the evidence demonstrating the benefit of hyaluronic acid treatment for osteoarthritis is not robust. The single systematic review evaluating hip osteoarthritis did not report any statistically or clinically significant differences in pain or functional outcomes compared to corticosteroids or placebo. Additional studies comparing platelet-rich plasma with placebo and with alternatives other than hyaluronic acid are needed to determine the efficacy of platelet-rich plasma for knee and hip osteoarthritis. Studies are also needed to determine the optimal protocol for

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delivering platelet-rich plasma. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Adjunct to Surgery**

For individuals with anterior cruciate ligament reconstruction who receive platelet-rich plasma injections plus orthopedic surgery, the evidence includes several systematic reviews of multiple RCTs and prospective studies. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. In 2 systematic reviews that conducted a meta-analysis, adjunctive platelet-rich plasma treatment did not result in a significant effect on International Knee Documentation Committee scores, a patient-reported, knee-specific outcome measure that assesses pain and functional activity. Individual trials have shown mixed results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with hip fracture who receive platelet-rich plasma injections plus orthopedic surgery, the evidence includes an open-labeled RCT. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. The single open-labeled RCT failed to show a statistically significant reduction in the need for surgical revision with the addition of platelet-rich plasma treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with long bone nonunion who receive platelet-rich plasma injections plus orthopedic surgery, the evidence includes 3 RCTs. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. One trial with a substantial risk of bias failed to show significant differences in patient-reported or clinician-assessed functional outcome scores between those who received platelet-rich plasma plus allogenic bone graft and those who received only allogenic bone graft. While the trial showed a statistically significant increase in the proportion of bones that healed in patients receiving platelet-rich plasma in a modified intention-to-treat analysis, the results did not differ in the intention-to-treat analysis. The second RCT, which compared platelet-rich plasma with recombinant human bone morphogenetic protein-7, also failed to show any clinical or radiologic benefits of platelet-rich plasma over morphogenetic protein. The third RCT reported no difference in the number of unions or time to union in patients receiving platelet-rich plasma injections versus no

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treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with rotator cuff repair who receive platelet-rich plasma injections plus orthopedic surgery, the evidence includes multiple RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. Although systematic reviews consistently found significant reductions in pain with platelet-rich plasma at 12 months, important study conduct and relevance weaknesses limit interpretation of these findings. Additionally, the pain reductions with platelet-rich plasma were not maintained in longer-term studies. Further, the systematic reviews and meta-analyses failed to show a statistically and/or clinically significant impact on other outcomes. Findings of subsequently published small, single-center RCTs were consistent with the systematic reviews. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals undergoing spinal fusion who receive platelet-rich plasma injections plus orthopedic surgery, the evidence includes a single small RCT and a few observational studies. Relevant outcomes include symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. Studies have generally failed to show a statistically and/or clinically significant impact on symptoms (ie, pain). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with subacromial decompression surgery who receive platelet-rich plasma injections plus orthopedic surgery, the evidence includes a small RCT. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. A single small RCT failed to show a reduction in self-assessed or physician-assessed spinal instability scores with platelet-rich plasma injections. However, subjective pain, use of pain medications, and objective measures of range of motion showed clinically significant improvements with platelet-rich plasma. Larger trials are required to confirm these benefits. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with total knee arthroplasty who receive platelet-rich plasma injections plus orthopedic surgery, the evidence includes a systematic review. Relevant outcomes are symptoms,

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functional outcomes, health status measures, quality of life, morbid events, resource utilization, and treatment-related morbidity. The review showed no significant differences between the platelet-rich plasma and untreated control groups in range of motion, functional outcomes, and long-term pain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **Supplemental Information**

#### **Practice Guidelines and Position Statements**

##### **American Academy of Orthopaedic Surgeons**

In 2013, the American Academy of Orthopaedic Surgeons (AAOS) guidelines did not recommend for or against growth factor injections and/or platelet-rich plasma for patients with symptomatic osteoarthritis of the knee. A recommendation of inconclusive was based on a single low-quality study and conflicting findings. The AAOS recommendation was based on 3 studies published before May 2012.

In 2017, the AAOS issued evidence-based guidelines on the management of osteoarthritis of the hip. In the section on intra-articular injectables, the guidelines stated there is strong evidence supporting the use of intra-articular corticosteroids to improve function and reduce pain in the short term for patients with osteoarthritis of the hip. There was also strong evidence that the use of intra-articular hyaluronic acid does not perform better than placebo in improving function, stiffness, and pain in patients with hip osteoarthritis. The guidelines also noted that there were no high-quality studies comparing platelet-rich plasma with placebo for the treatment of osteoarthritis of the hip.

##### **National Institute for Health and Care Excellence**

In 2013, the National Institute for Health and Care Excellence (NICE) issued guidance on the use of autologous blood injection for tendinopathy. The NICE concluded that the current evidence on the safety and efficacy of autologous blood injection for tendinopathy was “inadequate” in quantity and quality.

In 2013, the NICE also issued guidance on the use of autologous blood injection (with or without techniques for producing platelet-rich plasma) for plantar fasciitis. The NICE concluded that the evidence on autologous blood injection for plantar fasciitis raised no major safety concerns but that the evidence on efficacy was “inadequate in quantity and quality.”

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In 2019, the NICE issued guidance on the use of platelet-rich plasma for osteoarthritis of the knee. The NICE concluded that current evidence on platelet-rich plasma injections for osteoarthritis of the knee raised “no major safety concerns”; however, the “evidence on efficacy is limited in quality.” Therefore, NICE recommended that “this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.”

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02923700	Leukocyte-rich platelet-rich plasma (PRP) vs. Leukocyte-poor platelet-rich plasma (PRP) for the Treatment of Knee Cartilage Degeneration: a Randomized Controlled Trial	192	Dec 2020 (unknown)
NCT02872753	Intra-operative Platelet-rich Plasma (PRP) Injection Following Partial Meniscectomy	90	Mar 2021 (unknown)
NCT03734900	Comparison of Effectiveness Between PL and PRP on Knee Osteoarthritis: a Prospective, Randomized, Placebo-controlled Trial	150	Jul 2021 (recruiting)

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<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
NCT01668953 <sup>a</sup>	Impact of Platelet Rich Plasma Over Alternative Therapies in Patients With Lateral Epicondylitis (IMPROVE)	100	Dec 2021 (ongoing)
NCT03300531	Autologous Pure Platelet-rich Plasma in the Treatment of Tendon Disease: A Randomized Controlled Trial	540	Dec 2021
NCT04241354	A Comparison of Platelet-rich Plasma Treatment to the Intra-articular vs. Intra- and Extra-articular Environments in Patients Diagnosed With Hip Osteoarthritis	84	Dec 2021 (recruiting)
NCT04521387	Evaluation of Clinical Efficacy of Different Injection Therapies for Treating Humeral Epicondylopathy	200	May 2022 (recruiting)
NCT04703998	Arthroscopic Rotator Cuff Repair Augmented With Platelet Rich Plasma	100	Sep 2022 (recruiting)
NCT04697667	Exercise and PRP vs. Exercise Alone in Patients With Knee Osteoarthritis	75	Dec 2022 (recruiting)
NCT03136965	Platelet-Rich Plasma Therapy for Patellar Tendinopathy: A Randomized Controlled Trial Correlating Clinical, Biomechanical and Novel Imaging Biomarkers	76	Aug 2023 (recruiting)
NCT03984955	A Prospective, Double Blind, Single Centre, RCT, Comparing the Effectiveness of Physiotherapy in Addition to One of 3 Types of Image Guided Injection of the Common Extensor Tendon, on Pain and Function in Patients With Tennis Elbow	123	Apr 2023 (recruiting)
NCT01843504	Platelet-Rich Plasma (PRP) Injection for the Treatment of Chronic Patellar Tendinopathy	44	Dec 2023

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NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT03138317	Evaluation of Platelet Rich Plasma (PRP) for Knee Osteoarthritis	60	May 2018 (unknown)
NCT03129971	Platelet-Rich Plasma Combined with Conventional Surgery in the Treatment of Atrophic Nonunion of Femoral Shaft Fractures	92	Dec 2018 (unknown)
NCT01915979	Role of Biological Therapy in Rotator Cuff Tendinopathy. Effectiveness of Plasma Rich in Growth Factors Regarding Functional Capacity and Pain Compared With the Conventional Treatment Using Steroids	92	Dec 2018 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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### **Policy History**

Original Effective Date: 09/23/2015

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09/03/2015 Medical Policy Committee review

09/23/2015 Medical Policy Implementation Committee approval. New Policy.

09/08/2016 Medical Policy Committee review

09/21/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

09/07/2017 Medical Policy Committee review

09/20/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/06/2018 Medical Policy Committee review

09/19/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/05/2019 Medical Policy Committee review

09/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/03/2020 Medical Policy Committee review

09/09/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/02/2021 Medical Policy Committee review

09/08/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2022

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### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2020 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0232T, 36513, 86999
HCPCS	C1734, P9020
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

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standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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