Easy Choice Health Plan

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Autologous Blood-Derived Growth Factors (Platelet Rich Plasma)

Policy Number: HS-179

Original Effective Date: 7/20/2010

Revised Date(s): 8/2/2011; 7/5/2012; 9/6/2012; 9/5/2013; 9/4/2014; 8/6/2015; 12/8/2016; 8/3/2017; 8/24/2018

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

The use of platelet rich plasma (PRP) (plasma having a platelet concentration above baseline) is an approach being investigated for the treatment of bone healing and other indications. PRP is also referred to as autologous platelet derived growth factor, platelet enriched plasma, platelet-rich concentrate, and autogenous platelet gel or platelet releasate. Due to the paucity of consistent evidence regarding the use of platelet rich plasma, it is considered experimental and investigational in nature. Current studies will continue to be reviewed.[1,2]

POSITION STATEMENT

Applicable To:

- ☑ Medicaid – All Markets
- ☑ Medicare – All Markets

Exclusions

Autologous blood-derived growth factors **are considered experimental and investigational** for:

- Chronic non-healing wounds
- Epicondylitis (e.g., tennis elbow, elbow epicondylar tendinosis)
- Plantar fasciitis
- Dupuytren's contracture
- As an adjunct to spinal fusion
- Sinus surgery
- Periodontal surgery
- Injection of ligament tears with any type of blood-derived growth factor, whether from the patient or another source
- All other conditions not listed above

Coverage

Autologous blood-derived growth factors (i.e. platelet rich plasma) **is a covered benefit** only for patients who have chronic non-healing diabetic, pressure, and/or venous wounds **and** when all the following conditions are met:[2]

1. The patient is enrolled in a clinical research study that addresses the following questions using validated and reliable methods of evaluation. Clinical study applications for coverage pursuant to this National Coverage Determination (NCD) must be received by August 2, 2014.

2. The clinical research study must meet the requirements specified below to assess the effect of PRP for the treatment of chronic non-healing diabetic, pressure, and/or venous wounds. The clinical study must address:

    - Prospectively, do Medicare beneficiaries that have chronic non-healing diabetic, pressure, and/or venous 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, pressure, and/or venous 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; or
        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?

3. The study of PRP must adhere to the following standards of scientific integrity and relevance to the Medicare population:
    a. Principal purpose of the research study is to test whether PRP improves participants' health outcomes.
    b. Research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
    c. Research study does not unjustifiably duplicate existing studies.
    d. Research study design is appropriate to answer the research question being asked in the study.
    e. Research study is sponsored by an organization or individual capable of executing the proposed study successfully.
    f. Research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46.
    g. All aspects of the research study are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors (http://www.icmje.org).
    h. Research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development (CED).
    i. Research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR

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§312.81(a) and the patient has no other viable treatment options.

j. Research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. Research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org). However, a full report of the outcomes must be made public no later than three (3) years after the end of data collection.

l. Research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. Research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

CODING

Non-Covered CPT®* Code
86999 Unlisted transfusion medicine procedure

Non-Covered HCPCS Code
P9020 Platelet rich plasma, each unit

ICD-10-PCS Codes – No applicable codes.

ICD-10-CM Diagnosis Codes – Not covered for all diagnoses.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Platelet-rich plasma (PRP) for ligament and tendon injuries. Hayes Directory Web site. http://www.hayesinc.com. Publish December 24, 2012 (reviewed November 11, 2016). Accessed August 17, 2018.
2. Decision memo for autologous blood-derived products for chronic non-healing wounds (CAG-00190R3). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published August 2, 2012. Accessed August 17, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
8/24/2018, 8/3/2017, 12/8/2016, 8/6/2015, 9/4/2014, 9/5/2013	• Approved by MPC. No changes.
9/6/2012	• Approved by MPC. Coverage now in effect due to CMS Decision Memo (8/2/2012).
7/5/2012	• Approved by MPC. No significant changes.
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.