Medicare Coverage in Clinical Studies

Developing Evidence to Inform Better Care of Beneficiaries

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“There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare ..., are among the most completely impenetrable texts within human experience...”

“...one approaches [them] with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.”

EXCERPTED FROM REHABILITATION ASSOCIATION OF VIRGINIA, INC. V. KOZLOWSKI, ET AL., 42 F. 3D 1444,1450 (4TH CIR. 1994)
Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,
(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,
1. Coverage with Evidence Development
   - Individual NCD policy
2. Clinical Trial Policy
   - Routine costs in clinical trials
   - NCD Manual, Pub 100-3, Section 310.1
3. IDEs
   - Regulation at 42 CFR 405.201
   - New centralized process
CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data.

In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary.


In CED an item or service is only reasonable and necessary when it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise.

Without CED, the service would not be covered.

CED research may include a broader range of studies than randomized clinical trials – may include observational research and registries.

An NCD requiring CED may be specific about the design, research questions, and outcomes required.
HEALTH OUTCOMES OF INTEREST IN CED STUDIES

- Longer life and improved function/participation
- Longer life with arrested decline
- Significant symptom improvement allowing better function/participation
- Reduced need for burdensome tests and treatments
Medicare National Coverage Process resulting in Coverage with Evidence Development (CED)

6-9 months

NCD opens

CMS Staff Reviews Medical Literature

Proposed Decision Memorandum Posted

Public Comment

Final Decision = CED

CMS Staff Reviews Protocol

Sponsor submits Protocol

CMS Staff Approves Protocol

CMS posts Approved Study on CED Webpage*

Medicare National Coverage Process resulting in Coverage with Evidence Development (CED)

9 months

NCD REopens

CMS Staff Reviews Medical Literature

Proposed Decision Memorandum Posted

Public Comment

Final Decision

Study produces new evidence

Sponsor conducts study
The CTP is under NCD #310.1.

The CTP allows coverage of the routine costs of qualifying clinical trials and reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

All other Medicare rules apply.

The CTP covers Routine Costs of a clinical trial including all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or service itself unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and
- Items and services provided free of charge for any enrollee in the trial.
Routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial.
- Items or services required solely for the provision of the investigational item or service, appropriate monitoring of the effects of the item or service, or prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.
A trial must have the following qualities:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category.
- The trial must have therapeutic intent.
- The trial must enroll patients with a diagnosed disease rather than healthy volunteers.
A trial also must:

- Test whether the intervention potentially improves the participants' health outcomes;
- Be 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;
- Not unjustifiably duplicate existing studies;
- Be appropriate to answer the research question being asked in the trial;
A trial also must:

- Be sponsored by a credible organization or individual capable of executing the proposed trial successfully;
- Be in compliance with Federal regulations relating to the protection of human subjects; and
- Be conducted according to the appropriate standards of scientific integrity.
QUALIFYING FOR THE CTP

- A trial is *automatically* qualified if:
  - It is funded by NIH, CDC, AHRQ, CMS, DOD, and the VA;
  - It is supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
  - Is conducted under an investigational new drug application (IND) reviewed by the FDA; and
  - Is a drug trial that is exempt from having an IND under 21 CFR 312.2(b)(1)
FDA reviews and approves/disapproves an IDE trial/study.

The FDA categorizes IDE’s as ‘A’ (experimental) or ‘B’ (investigational)

CMS may consider a trial/study for coverage

CMS reviews study documentation and approves/disapproves a trial/study for coverage.

Category A – CMS may cover routine services in the trial

Category B – CMS may cover both routine services and the Category A device in the trial
Old process –
- Study sites submit IDE documentation to regional MACs for review and approval
- Continue as instructed by the MAC for trials with FDA approval letter dated before January 1, 2015.

New process –
- Sponsors with an FDA approval letter dated after January 1, 2015 submit the following:
  - Study title
  - Sponsor name
  - NCT number
  - IDE number
  - CMS approval date
Now that there is a new system, will CMS central issue the annual approvals to IDE study sites?

- If the FDA approval letter is dated before January 1, 2015, then MACs continue to issue annual approvals.

If a provider intends to become an IDE study site, should the provider submit a full request to CMS central?

- It is the study sponsor, or the individual named in the FDA letter, who submits the IDE coverage request to CMS.
- MACs may have additional requirements and should continue to interact with the study sites in their region. If the IDE letter is dated before January 1, 2015, then the request should be submitted to the MACs.

How will a study site know if CMS has approved an IDE study?

- CMS will post each approved study on its website.
Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

Instructions: Medicare Coverage Related to Investigational Device Exemption (IDE) Studies

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) allowed Medicare payment of the routine costs of care furnished to Medicare beneficiaries in certain categories of Investigational Device Exemption (IDE) studies. Covering the costs in these IDE studies removes a financial barrier that could otherwise discourage beneficiaries from participating.

In December 2013, CMS finalized changes to the IDE regulations (42 CFR § 405 Subpart B), effective January 1, 2015. CMS added criteria for coverage of IDE studies and changed from local Medicare Administrative Contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies. An approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. An approval for a Category B (Nonexperimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial.

IDE studies approved by MACs prior to January 1, 2015 will continue to be administered by the MAC. Study sponsors do not have to submit the protocol to CMS if the participating study investigator sites have already received approval from their MAC. Study sponsors should continue to follow the process established by the MAC for any site additions or protocol changes.
Coding for Clinical Trials
NCD for Platelet Rich Plasma
Decision Memo for Autologous Blood-Derived Products for Chronic Non-Healing Wounds (CAG-00190R3)

Decision Summary

CMS covers autologous platelet-rich plasma (PRP) only for patients who have chronic non-healing diabetic, pressure, and/or venous wounds and when all 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. Clinical study applications for coverage pursuant to this National Coverage Determination (NCD) must be received by August 2, 2014.

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?
Autologous Platelet-rich Plasma (PRP)

CMS covers autologous platelet-rich plasma (PRP) only for patients who have chronic non-healing diabetic, pressure, and/or venous wounds and when all the following conditions are met:

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

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?

CMS issued a Medicare National Coverage Determination on August 2, 2012 which allows coverage of autologous PRP under coverage with Evidence Development (CED) with certain conditions. The complete determination is available on our website.
Transmittals for Chapter 32

10 - Diagnostic Blood Pressure Monitoring
   10.1 - Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements

11 - Wound Treatments
   11.1 – Electrical Stimulation
   11.2 – Electromagnetic Therapy
   11.3 – Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds
      11.3.1 – Policy
      11.3.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding
      11.3.3 – Types of Bill (TOB)
      11.3.5 – Place of Service (POS) for Professional Claims
11.3 – Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds
(Rev. 2720, Issued: 06-10-2013, Effective: 08-02-12, Implementation: 07-01-13)

11.3.1 – Policy
(Rev. 2720, Issued: 06-10-2013, Effective: 08-02-12, Implementation: 07-01-13)

Effective for claims with dates of service on or after August 2, 2012, contractors shall accept and pay for autologous platelet-rich plasma (PRP) only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only in the context of an approved clinical study in accordance with the coverage criteria outlined in Pub. 100-03, chapter 1, section 270.3, of the NCD Manual.

11.3.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding
(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

HCPCS Code

Effective for claims with dates of service on or after August 2, 2012 Medicare providers shall report HCPCS code G0460 for PRP services.
If ICD-9 Diagnosis coding is applicable

For claims with dates of service on or after August 2, 2012, PRP, for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only in the context of an approved clinical study must be billed using the following ICD codes:

- V70.7
- ICD-9 code from the approved list of diagnosis codes maintained by the Medicare contractor.

If ICD-10 Diagnosis coding is applicable

For claims with dates of service on or after the implementation of ICD-10, ICD-10 CM diagnosis coding is applicable.

- Z00.6
- ICD-10 code from the approved list of diagnosis codes maintained by the Medicare contractor.
Additional billing requirement:

The following modifier and condition code shall be reported when billing for PRP services only in the context of an approved clinical study:

- Q0 modifier
- Condition code 30 (for institutional claims only)
- Value Code D4 with an 8-digit clinical trial number. NOTE: This is optional and only applies to Institutional claims.
NEW products from the Medicare Learning Network® (MLN)

“Annual Wellness Visit,” Podcast, ICN 908726, Downloadable only.

MLN Matters® Number: MM8401 Revised
Related Change Request (CR) #: CR 8401
Related CR Release Date: May 13, 2014
Effective Date: January 1, 2014
Related CR Transmittal #: R2955CP
Implementation Date: January 6, 2014

Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims
Approved CED Studies for PRP NCD (excerpt)

Study Title: Effectiveness of Autologous Platelet Rich Plasma in the Treatment of Chronic Non-Healing Wounds  
Sponsor: ACR Biologics, LLC  
ClinicalTrials.gov Number: NCT02307448 - http://clinicaltrials.gov/ct2/show/NCT02307448  
CMS Approval Date: 10/31/2014

Study Title: A Prospective, Randomized Clinical Trial of ECLIPSE PRP™ Wound Biomatrix in Non-Healing Diabetic Foot Ulcers  
Sponsor: PRP Concepts, LLC  
ClinicalTrials.gov Number: NCT02312596 - http://clinicaltrials.gov/ct2/show/NCT02312596  
CMS Approval Date: 09/25/2014

Study Title: Leucopatch® System in the Management of Hard-To-Heal Diabetic Foot Ulcers  
Sponsor: Nottingham University Hospitals NHS Trust (Reapplix Aps)  
ClinicalTrials.gov Number: NCT02224742 - http://clinicaltrials.gov/ct2/show/NCT02224742  
CMS Approval Date: 08/14/2014

Study Title: A Multi-Center, Randomized Trial Comparing the Effectiveness of APIC-PRP to Control, when added to Standard of Care in the Treatment of Non-healing Diabetic Foot Ulcers  
Sponsor: Cytonics Corporation  
ClinicalTrials.gov Number: NCT02209662 - http://clinicaltrials.gov/ct2/show/NCT02209662  
CMS Approval Date: 07/30/2014
Thank you