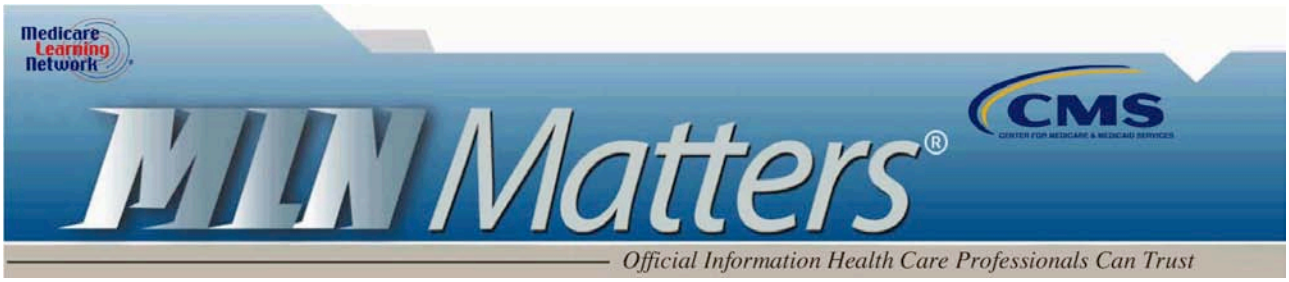
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services



CMS has instructed its contractors to delay turning on Phase 2 denial edits on the following claims to check for a valid individual National Provider Identifier (NPI) and to deny the claim when this information is missing:

- Medicare Part B laboratory and imaging claims and Durable Medical Equipment, Orthotics, and Supplies (DMEPOS) claims that require an ordering or referring physician/non-physician provider; and
- Part A Home Health Agency (HHA) claims that require an attending physician provider.

CMS will advise you of the new implementation date in the near future. In the interim, informational messages will continue to be sent for those claims that would have been denied had the edits been in place. See MLN Matters® Article SE1305 for more information.

MLN Matters® Number: MM8213 Revised

Related Change Request (CR) #: CR 8213

Related CR Release Date: June 10, 2013

Effective Date: August 2, 2012

Related CR Transmittal #: R154NCD, R2720CP

Implementation Date: July 1, 2013

Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds

Note: This article was revised on June 13, 2013, to reflect changes made to CR8213 to delete a reference to "randomized clinical trial". Also, the CR release date, transmittal numbers and the Web address for accessing the CR were also revised. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians and other providers submitting claims to Medicare contractors (fiscal intermediaries (FIs), carriers, and A/B Medicare Administrative Contractors (MACs)) for services to Medicare beneficiaries.

Provider Action Needed

 STOP – Impact to You

If you provide Medicare beneficiaries PRP for the treatment of chronic non-healing wounds, this National Coverage Determination (NCD) could impact your reimbursement.

 CAUTION – What You Need to Know

Effective for claims with dates of service on or after August 2, 2012, CMS will cover PRP for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only when provided under a clinical research study that meets specific requirements to assess the health outcomes of PRP for the treatment of chronic non-healing diabetic, venous and/or pressure wounds.

 GO – What You Need to Do

Please refer to the Background section, below for details.

Background

PRP is produced by centrifuging a patient's own blood to yield a concentrate that is high in both platelets and plasma proteins; and includes whole white and red cells, fibrinogen, stem cells, macrophages, and fibroblasts. Frequently administered as a spray, or a gel; physicians have used it in clinical or surgical settings, for a variety of purposes such as an adhesive in plastic surgery and filler for acute wounds. In addition, it is being used, now, on chronic, non-healing cutaneous wounds that persist for 30 days or longer.

Since 1992, the Centers for Medicare & Medicaid Services (CMS) has issued national non-coverage determinations for platelet-derived wound healing formulas intended to treat patients with chronic, non-healing wounds. In December 2003, CMS issued a national non-coverage determination specifically for the use of autologous PRP in treating chronic non-healing cutaneous wounds except for routine costs when used in accordance with the clinical trial policy defined in section 310.1 (Routine Costs in Clinical Trials (Effective July 9, 2007)) of the "National Coverage Determinations (NCD) Manual". Currently, as of March 2008, CMS has non-coverage determinations for the use of autologous blood-derived products for the treatment of acute wounds where PRP is applied directly to the closed incision site, and for dehiscent wounds, as well as non-coverage for chronic, non-healing cutaneous wounds.

On October 4, 2011, CMS accepted a formal request to reopen and revise Section 270.3 of the "Medicare NCD Manual", which addresses Autologous Blood-Derived Products for Chronic Non-Healing Wounds. The request was for a reconsideration of the coverage of autologous PRP for the treatment of the following chronic wounds: diabetic, venous, and/or pressure ulcers. It was requested

that CMS cover PRP through an NCD with data collection as a condition of coverage; and requested that this would provide a practical means by which CMS could obtain the necessary data to evaluate the performance of PRP and to confirm the outcomes presented in their request.

Effective August 2, 2012, upon reconsideration, CMS determined that PRP is covered for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only when the following conditions are met:

1. The patient is enrolled in a clinical trial that addresses the questions listed below using validated and reliable methods of evaluation. Clinical study applications for coverage pursuant to this National Coverage Determination (NCD) must be approved by August 2, 2014. Any clinical study approved by August 2, 2014, will adhere to the timeframe designated in the approved clinical study protocol.

   If there are no approved clinical studies on or before August 2, 2014, CED for PRP only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds will expire.

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

   The clinical study must address:
   - Prospectively, do Medicare beneficiaries, with 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 only well-defined optimal usual care for such 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?

3. The required PRP clinical trial must adhere to the following standards of scientific integrity and relevance to the Medicare population:
   - Its principal purpose is to test whether PRP improves the participants' health outcomes;
   - It 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;
   - It does not unjustifiably duplicate existing studies;
   - Its design is appropriate to answer the research question being asked in the study;
   - It is sponsored by an organization or individual capable of executing the proposed study successfully;
   - It is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46;

- All of its aspects are conducted according to appropriate standards of scientific integrity set by the International Committee of Medical Journal Editors (http://www.icmje.org);
- It has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development (CED);
- It 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 §312.81(a) and the patient has no other viable treatment options;
- It is registered on the ClinicalTrials.gov website (http://www.clinicaltrials.gov/) by the principal sponsor/investigator prior to the enrollment of the first study subject;
- Its study protocol:
  a. Specifies the method and timing of public release of all pre-specified outcomes to be measured, including the release of outcomes that are negative or that the 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;

  b. Must explicitly discuss: 1) Subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies; 2) How the inclusion and exclusion criteria effect enrollment of these populations, and 3) 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.

  c. 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.

Note: Consistent with Section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Coding and Payment Details

Healthcare Common Procedure Coding System (HCPCS) Codes

Effective for claims with dates of service on or after August 2, 2012, contractors will accept and pay PRP claims, HCPCS code G0460 (Autologous PRP for ulcers), for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only in the context of an approved clinical study, when all of the following are present:

- ICD-9/ICD-10 CM Diagnosis code from the list of diagnosis codes to be maintained by the contractors
- Diagnosis code V70.7 (secondary dx) (ICD-10 Z00.6)
- Condition code 30 (institutional claims only)
- Clinical trial modifier Q0 (Investigational clinical service provided in a clinical research study that is in an approved research study)
- Value Code D4 with an 8-digit clinical trial number (optional, institutional claims only)

Medicare contractors will return to provider/return as unprocessable your PRP claims that do not include ALL these diagnosis coding and additional billing requirements:

Should they return your PRP claims for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only in the context of an approved clinical study, they will use the following messages:

- CARC 16 - "Claim/service lacks information which is needed for adjudication."
- RARC M16 - "Alert: See our Web site, mailings, or bulletins for more details concerning this policy/procedure/decision." and
- RARC MA130 – "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Type of Bill

Your contractor will pay claims for PRP services in the following settings:

- Hospital outpatient departments Type of Bills (TOB) 12X and 13X based on OPPS;
- Skilled Nursing Facilities (SNF) TOBs 22X and 23X based on MPFS;
- Rural Health Clinics (RHC) TOB 71X based on all inclusive;
- Comprehensive Outpatient Rehabilitation Facilities (CORF) TOB 75X based on MPFS;
- Federally Qualified Health Centers (FQHC) TOB 77X based on all-inclusive,
- Critical Access Hospitals (CAH) TOB 85X based on reasonable cost, and
- CAHs TOB 85X and revenue codes 096X, 097X, or 098X based on MPFS.

They will pay for PRP services in Maryland hospitals under the jurisdiction of the Health Services Cost Review Commission (HSCRC) on an outpatient basis, TOB 13X, in accordance with the terms of the Maryland waiver.

Contractors will deny claims for PRP services (HCPCS code G0460) when provided on other than TOBs 12X, 13X, 22X, 23X, 71X, 75X, 77X, and 85X using:

- CARC 58 – "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. NOTE: Refer to the 832 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present";
- RARC N428 – "Service/procedure not covered when performed in this place of service"; and
- Group Code: CO

Place of Service (POS) Professional Claims

Effective for claims with dates of service on or after August 2, 2012, you should use place of service (POS) codes 11 (Office), 22 (Outpatient Hospital), and 49 (Independent Clinic) for PRP services. Your contractor will deny all other POS codes using the following messages:

- CARC 58 – "Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service";
- RARC N428 – "Service/procedure not covered when performed in this place of service"; and
- Group Code: CO.

Note: Contractors will not retroactively adjust claims from August 2, 2012, through the implementation of this CR. However, contractors may adjust claims that are brought to their attention.

Additional Information

CR 8213 is being released in two transmittals which may be found at:

- http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R154NCD.pdf and
- http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2720CP.pdf on the CMS website.

Both transmittals (R152NCD and R2666CP) contain a listing of relevant ICD-9 and ICD-10 diagnostic codes.

You can find information regarding clinical trials in the Claims Processing Manual, Chapter 32, Section 69 (Qualifying Clinical Trails), for information regarding clinical trials, at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c32.pdf on the CMS website.

If you have any questions, please contact your FI, carrier or A/B MAC at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.

Flu Activity Continues: Prompt Antiviral Treatment is Crucial for Seniors Sick with Flu

This season, flu activity started early and has placed a significant burden on people 65 years of age and older. In fact, so far this season, CDC has reported nearly four times more hospitalizations among people 65 and older than occurred during the entire 2011-2012 season. The CDC recommends that vaccination efforts continue as long as influenza viruses are circulating. People 65 years of age and older, as well as their close contacts and caregivers, should be vaccinated; and should seek medical treatment with antiviral drugs as soon as symptoms appear in order to reduce serious complications from flu infection, including hospitalizations, intensive care unit (ICU) admissions and deaths.

Note: Influenza vaccine and its administration is a Medicare Part B covered benefit. Influenza vaccines are NOT Part D-covered drugs.

For More Information:

- 2012-2013 Seasonal Influenza Vaccines Pricing list.
- MLN Matters® Article #MM8047, "Influenza Vaccine Payment Allowances - Annual Update for 2012-2013 Season".
- Visit the CMS Medicare Learning Network® 2012-2013 Seasonal Influenza Virus Educational Products and Resources and CMS Immunizations web pages for information on coverage and billing of the flu vaccines and their administration fees.
- HealthMap Vaccine Finder is a free, online service where users can find locations offering flu vaccines as well as other vaccines for adults.
- CDC website offers a variety of provider resources for the 2012-2013 flu season.
- CDC article Seniors among *Seniors among Groups Hardest Hit by Flu this Season*