Coding & Billing for Prospective Payment Systems

Autologous Platelet-Rich Plasma for Chronic Non-Healing Wounds

Clinical Laboratory Fee Schedule—Medicare
Travel Allowance

New Waived Tests
Since 1989 HMI Corporation, a Healthcare Management Company, a subsidiary of Healthcare Provider Services, has been assisting acute care, teaching, critical access, long term care, nursing home, home health, and skilled nursing facilities, as well as physician groups, with clinical reimbursement through accurate coding and billing for all financial classes as well as maintaining compliance with Federal payers. HMI’s consultant specialists perform compliance reviews, billing, and coding medical reviews, as well as other revenue improvement services, utilizing the provider’s chargemaster. HMI also provides physician education to strengthen the medical staff’s E/M coding for compliance and to improve reimbursement.

HMI offers a full-service program to assist providers in positioning themselves to meet federal compliance guidelines, with an emphasis on PPS reimbursement. This process also includes inpatient and outpatient record review, on-going chargemaster maintenance, remote chargemaster services, interim chargemaster coordinator coverage, remote contract coding, and on-site education/training of clinical staff and physicians. Our twenty-three year success has been primarily founded on facilitating quality consulting service, on-going accountability through management plan objectives and guaranteed service based on our ability to deliver results.

155 Franklin Road
Suite 100
Brentwood, TN 37027
Phone: 615-661-5145
Fax: 615-661-5147
Email: info@hmi-corp.com
Website: www.hmi-corp.com

Table of Contents:

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Waived Tests</td>
<td>3</td>
</tr>
<tr>
<td>Clinical Laboratory Fee Schedule—Medicare Travel Allowance Fees for Collection of Specimens</td>
<td>4</td>
</tr>
<tr>
<td>Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds</td>
<td>5</td>
</tr>
</tbody>
</table>
Effective July 1, 2013 there will be nine new CLIA waived tests that will require the QW modifier according to Transmittal 2671 issued March 15, 2013.

<table>
<thead>
<tr>
<th>CPT® CODE</th>
<th>Effective Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>82055QW</td>
<td>4/30/2012</td>
<td>Germaine Laboratories Aim Strip Alcohol Saliva</td>
</tr>
<tr>
<td>G0434QW</td>
<td>1/4/2013</td>
<td>American Screening Corporation, Inc., Multi-Drug Testing Cards</td>
</tr>
<tr>
<td>G0434QW</td>
<td>1/4/2013</td>
<td>American Screening Corporation, Inc., Multi-Drug Testing Cups</td>
</tr>
<tr>
<td>G0434QW</td>
<td>1/10/2013</td>
<td>UCP Biosciences, Inc. UCP Compact Drug Test Cards</td>
</tr>
<tr>
<td>G0434QW</td>
<td>1/10/2013</td>
<td>UCP Biosciences, Inc. UCP Compact Drug Test Cups</td>
</tr>
<tr>
<td>85610QW</td>
<td>1/16/2013</td>
<td>Coag-Sense Prothrombin Time (PT/INR) Monitoring System (Professional Use)</td>
</tr>
<tr>
<td>81003QW</td>
<td>1/23/2013</td>
<td>CLIA waved Inc. Automated Urinalysis Test System</td>
</tr>
</tbody>
</table>

Codes 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651, which are listed on page one of Transmittal 2671’s attachment, do not require a QW modifier to be recognized as a waived test.

To read Transmittal 2671 go to:

To read MLN Matters® Number MM8212 go to:
Effective June 17, 2013, CMS will revise the payment of travel allowances when billed on a per mileage using HCPCS code P9603 and when billed on a flat rate basis using HCPCS code P9604.

Where the average trip to a patient’s home exceeds 20 miles round trip (P9603), the rate is $0.565 per mile, plus an additional $0.45 per mile to cover the technician’s time and travel costs, for a total of $1.015 per mile and is then rounded to $1.02. The flat rate fee for P9604 is $10.15.


On March 8, 2013 CMS issued Transmittals 2666 and 152 to indicate that effective for claims with dates of service on or after August 2, 2012, CMS, upon reconsideration, will now cover autologous platelet-rich-plasma (PRP) only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds when PRP is provided under a clinical research study that meets specific requirements to assess the health outcomes of PRP for the treatment of non-healing diabetic, venous and/or pressure wounds. The following conditions must be met in order for the service to be covered.

1. The patient is enrolled in a randomized 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 (NDC) 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 trial.

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 study must meet the requirements 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 received 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 it 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 as 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 the 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 affect enrollment of these populations; and
   3. A plan for the retention and reporting of said populations, the protocol must discuss why these criteria are necessary.

C. Explicitly discusses how the results are, or are not, expected to be generalized 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 and Billing Requirements

Effective for claims with dates of service on or after August 2, 2012, contractors will accept and pay PRP claims using HCPCS code G0460 for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only for approved clinical studies 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 for 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)

Contractors will return to provider/return as unprocessable PRP claims that do not include ALL of the above coding and billing requirements.

The contractors will by PRP services claims in the following settings:

- Hospital outpatient departments
- Skilled Nursing Facilities
- Rural Health Clinics
- Comprehensive Outpatient Rehabilitation Facilities
- Federally Qualified Health Centers
- Critical Access Hospitals


