DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

REVISED product from the Medicare Learning Network® (MLN)

- "Contractor Entities At A Glance: Who May Contact You About Specific Centers for Medicare & Medicaid Services (CMS) Activities" Educational Tool, ICN 906983, downloadable

MLN Matters® Number: MM8567

Related CR Release Date: January 17, 2014

Related CR Transmittal #: R2857CP

Related Change Request (CR) #: CR 8567

Effective Date: January 1, 2014

Implementation Date: April 7, 2014

Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits

Provider Types Affected

This MLN Matters® Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs), including Durable Medical Equipment Medicare Administrative Contractors (DME/MACs), for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8567 which informs MACs about changes to HCPCS codes that are new for 2014 and are subject to CLIA edits. The CLIA regulations require a facility to be appropriately certified for each test performed. Make sure your billing staffs are aware of these changes.

Background

The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for

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laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

The HCPCS codes are considered a laboratory test under CLIA change each year. Contractors need to be informed about the new HCPCS codes that are both subject to CLIA edits and excluded from CLIA edits.

The HCPCS codes listed below are new for 2014 and are subject to CLIA edits. The list does not include new HCPCS codes for waived tests or provider-performed procedures. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests.

- G0461 - Immunohistochemistry or immunocytochemistry, per specimen; first single or multiplex antibody stain;
- G0462 - Immunohistochemistry or immunocytochemistry, per specimen; each additional single or multiplex antibody stain (list separately in addition to code for primary procedure);
- 80155 - Caffeine level;
- 80159 - Clozapine level;
- 80169 - Everolimus level;
- 80171 - Gabapentin level;
- 80175 - Lamotrigine level;
- 80177 - Levetiracetam level;
- 80180 - Mycophenolate (mycophenolic acid) level;
- 80183 - Oxcarbazepine level;
- 80199 - Tiagabine level;
- 80203 - Zonisamide level;
- 81287 - MGMT (O-6-methylguanine-DNA methyltransferase) gene analysis;

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- 81504 - Genetic profiling on oncology biopsy lesions;
- 81507 - DNA analysis using maternal plasma; and
- 87661 - Infectious agent detection by nucleic acid (dna or rna); trichomonas vaginalis, amplified probe technique.

In 2014, there was one new HCPCS code for immunohistochemistry or immunocytochemistry [i.e., 88343 - Immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; each additional separately identifiable antibody per slide (list separately in addition to code for primary procedure)]. The testing described by this code is subject to the CLIA regulations. It is not payable by Medicare in calendar year (CY) 2014. Therefore, this new code was not included in CR 8567.

Additional Information

The official instruction, CR 8567 issued to your MAC regarding this change may be viewed at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2857CP.pdf on the Centers for Medicare & Medicaid Services (CMS) website.

If you have any questions, please contact your 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.

News Flash - Generally, Medicare Part B covers one flu vaccination and its administration per flu season for beneficiaries without co-pay or deductible. Now is the perfect time to vaccinate beneficiaries. Health care providers are encouraged to get a flu vaccine to help protect themselves from the flu and to keep from spreading it to their family, co-workers, and patients. Note: The flu vaccine is not a Part D-covered drug. For more information, visit:

- MLN Matters® Article #MM8433, "Influenza Vaccine Payment Allowances - Annual Update for 2013-2014 Season"
- MLN Matters® Article #SE1336, "2013-2014 Influenza (Flu) Resources for Health Care Professionals"
- HealthMap Vaccine Finder - a free, online service where users can search for locations offering flu and other adult vaccines. While some providers may offer flu vaccines, those that don't can help their patients locate flu vaccines within their local community.
- The CDC website for Free Resources, including prescription-style tear-pads that allow you to give a customized flu shot reminder to patients at high-risk for complications from the flu.

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