INSIDE THIS ISSUE

0308T added to Category III Coverage Article A50740 ............. 4

 Billing for Fracture Care-Emergency Department (ED) vs. Physician/Orthopedic Office ........................................ 4

 Category III CPT Code Covered Article A50740 Update for LCD L31832 ........................................... 4

 CGS Administrators, LLC Contractor Number ......................... 5

 CGS J-15 A/B MAC Investigational Device Exemption Request Form .................................................. 3

 CGS retirement of Local Coverage Determinations and or Articles .................................................. 5

 Collagen Implantation for Urinary Incontinence ...................... 4

 MM6823 - Pulmonary Rehabilitation (PR) Services ................ 8

 MM7806 - Extracorporeal Photopheresis (ICD-10) ............ 16

 MM7856 - October Quarterly Update to 2012 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement ................................ 10

 MM7868 - New Waived Tests ............................................. 14

 Overpayment Letters: Look for Blue Envelopes ..................... 6

 PET Scan for Solitary Pulmonary Nodule .......................... 5

 Podiatry Services and Evaluation & Management Codes .......... 6
SE1226 - Reminder of Importance of Correct Place-of-Service Coding on Medicare Part B Claims ............................................. 11

Revised: MM7499 - Reporting of Recoupment for Overpayment on the Remittance Advice (RA) with Patient Control Number .......................................................... 7

Signatures .................................................................................................................................................. 5

The Difference between Denial Codes and Return/Reject Codes ............................................................................. 5
It Saves Time!
I love that!

my CGS
Now Available!
0308T added to Category III Coverage Article A50740

Payment for CPT Code 0308T is allowed for the insertion of ocular telescope prosthesis including the removal of crystalline lens after cataract extraction when medically necessary effective 07/01/12.

The ICD-9-CM diagnosis codes supporting medical necessity for 0308T are 362.51 with 366.16.

Billing for Fracture Care-Emergency Department (ED) vs. Physician/Orthopedic Office

Recently, provider questions have indicated an area of confusion regarding billing for fracture care “global” services. The CPT (Current Procedural Terminology) manual suggests that the provider who performs “restorative” treatment and is “responsible for the initial cast, follow-up evaluation(s) and the management of the fracture until healed” should use the procedure code for the 90 day global period codes.

The CPT manual continues with definitions of “closed treatment”, “open treatment”, and “percutaneous skeletal fixation.”

- Closed treatment “specifically means that the fracture site is not surgically opened (exposed to the external environment and directly visualized). This terminology is used to describe procedures that treat fractures by three methods; 1) without manipulation, 2) with manipulation, or 3) with or without traction.” (2012 CPT Professional Edition, pg 88)
- Open treatment “is used when the fractured bone is either: 1) surgically opened (exposed to the external environment) and the fracture (bone ends) visualized and internal fixation may be used; or 2) the fractured bone is opened remote from the fracture site in order to insert an intramedullary nail across the fracture site (the fracture site is not opened and visualized).” (2012 CPT Professional Edition, pg 88)
- Percutaneous skeletal fixation: describes fracture treatment which is neither open nor closed. Fracture fragments are not visualized but fixation (eg pins) is placed across the fracture site, usually under X-ray imaging.” (2012 CPT Professional Edition, pg 88).

If manipulative fracture care that meets the definition of “restorative treatment” (the physician has performed a manipulation) is provided by an ED physician and the ED physician also provides a “significant portion of the global fracture care,” the ED physician may use the global code with modifier 54 (surgical care only). However, this treatment must meet the “restorative” care definition and should not be merely splinting a fracture after straightening the limb (manipulation only). Nonphysician practitioners authorized in their state of practice to provide emergency room services should follow the same rules.

According to the American Medical Association CPT manual (2012 Professional Edition, page 142) reporting these services using an E&M code and the appropriate cast/splint application code (as applicable) is supported by the following statement: “If cast application or strapping is provided as an initial service (e.g., casting of a sprained ankle or knee) in which no other procedure or treatment (e.g., surgical repair, reduction of a fracture or joint dislocation) is performed or is expected to be performed by a physician rendering the initial care only, use the casting, strapping and/or supply code (99070) in addition to an evaluation and management code as appropriate.”

Category III CPT Code Covered Article A50740 Update for LCD L31832

Effective August 1, 2012 CPT codes 0245T, 0246T, 0247T, and 0248T are covered for the open treatment and internal fixation of fractured ribs and or flail chest when medically necessary.

The ICD-9-CM diagnosis codes supporting medical necessity for CPT Codes 0245T, 0246T, 0247T, and 0248T are:

- 807.01-807.08
- 807.11-807.18
- 807.4

Collagen Implantation for Urinary Incontinence

Effective January 1, 2012 CGS is retiring the following Coverage Article (A50741) for the states of Kentucky and Ohio. The article was a related document to the Chemotherapy and Biological LCD (L31836). The Drug and Biological Drug chart attached to the LCD has been updated to remove information related to Collagen Implantation for Urinary Incontinence.
CGS retirement of Local Coverage Determinations and or Articles

Effective August 1, 2012 CGS is retiring the following Local Coverage Determination for the states of Kentucky and Ohio. CGS will continue to monitor utilization for medical necessity but based on current utilization data the following Local Coverage Determination is no longer needed at this time.

**LCD# - LCD Title**
L31868 - Esophagogastroduodenoscopy (EGD)

**CGS Administrators, LLC Contractor Number**
When responding to a CERT (Comprehensive Error Rate Testing) request for records please make a notation of the CGS contractor number on the documentation. This will assist the CERT contractor with routing your documentation appropriately.

Home Health & Hospice: Contractor 15004

Part A Kentucky: Contractor 15101
Part A Ohio: Contractor 15201

Part B Kentucky: Contractor 15102
Part B Ohio: Contractor 15202

Thank you for your continued support of the CERT program.

PET Scan for Solitary Pulmonary Nodule

Effective July 1, 2012 CGS will cover PET scan for solitary pulmonary nodule larger than 1.0 cm when highly suspicious of malignancy and prior evaluation has been equivocal. Documentation to support this should be maintained in the patient’s medical record. Providers should bill with PET CPT Code 78811 with ICD-9 Code 793.11.

Signatures

CGS is still seeing a number of denials due to inadequate provider signatures on documentation submitted for medical review. **When documentation is submitted without the proper signature of the rendering/billing provider records cannot be validated and services will be denied.**

To avoid any delay in processing all medical notes should be signed in a timely fashion, however in the event that a signature is inadvertently missing or is illegible you may submit an attestation (an example is on the CGS website, www.cgsmedicare.com, click on the signature icon located at the right of the screen).

Upon review of documentation if a signature is missing or illegible CGS may fax or mail to you a request for an attestation. Should you receive an attestation request please respond in a timely fashion to avoid unnecessary delays in processing your claims.

**REMEMBER: The legible (signature) identifier requirement applies to documentation for ANY service performed and billed to Medicare.**

Reference: CMS Internet Only Manuals (IOM) Publication 100-8, Medicare Program Integrity Manual, Chapter 3, Section 3.3.2.4

The Difference between Denial Codes and Return/Reject Codes

CGS would like to remind providers about the differences between denial codes and return/reject codes.

**Return/reject codes:**
A return/reject code is used when a coverage determination can not be made based on the given information.

Some examples of when providers may receive an RA (Remittance Advice) with return/reject codes:

- **Billing errors**
  - Billing an unlisted code when a CPT/HCPCS code exists for the procedure
  - Billing an unlisted code for a combination of procedures when each procedure has a CPT/HCPCS code

- **Insufficient documentation**
  - Documentation insufficient to make a coverage determination, e.g.; no operative note or Mohs flow sheet for a Mohs procedure, no visual field studies or operative report sent with a blepharoplasty claim, no therapy plan of care or physician certification for a physical/occupational or speech-language pathology claim

This newsletter should be shared with all health care practitioners and managerial members of the provider/supplier staff. Newsletters issued after January 1997 are available at no cost from our website at www.cgsmedicare.com.

Medicare Bulletin – GR 2012-09 - page 5 - September 2012
When you receive a return/reject (not a medical necessity denial) you have an opportunity to resubmit/correct the claim in a timely manner. **Return rejects do not afford appeal rights nor can they be reopened.** So, when a claim is not processed and a return/reject code appears on your RA, you must correct the claim and resubmit.

**Do not appeal the claim or send in a reopening request. The appeal or reopening will be dismissed**

**Denial Reason codes:**
Denial Reason codes are used to deny services that do not meet coverage criteria.

Some examples are:
- NCD denials
- LCD denials
- ICD-9 diagnosis codes to CPT/HCPCS procedure code edits
- Complex medical review of claims involved in Progressive Corrective Action (PCA) cases

Since Denial Reason codes are used after a coverage determination has been made they do afford appeal rights. Providers should NOT resubmit a claim after a medical necessity denial is made-these claims MUST be appealed.

Please review your RA closely to determine the appropriate course of action on a claim-by-claim basis. By responding correctly to return/reject codes and denial codes, claims are processed faster, appeals remain timely, overhead costs are decreased and length of time to payments is minimized.

**Podiatry Services and Evaluation & Management Codes**

Recent data trends indicate a large volume of Podiatrists (specialty code 48) billing Evaluation and Management (E&M) services in nursing homes (place of service 32/33). The Medical Review Department would like to remind Podiatrists of the coverage guidelines for foot care and podiatric services.

- E&M services provided on a repetitive basis to assess a patient's possible need for foot care are considered routine screening exams and are not covered. There must be an underlying systemic condition and/or signs and symptoms warranting the need for an E&M service.
- E&M services provided on the same date of service as covered foot care are considered integral to the foot care and are not separately payable unless the service is separately identifiable from the foot care (CPT modifier -25) and medically necessary.
- Trimming of mycotic nails in a non-ambulatory patient is only covered if there is a secondary infection and/or the patient is experiencing pain caused by the dystrophic nail
- All physician services provided in conjunction with the covered debridement/wound care or foot care CPT Codes are rereimbursed based on the Medicare Physician Fee Schedule (MPFS) for the debridement/foot care/wound care CPT Code

**Overpayment Letters: Look for Blue Envelopes**

Beginning August 13, 2012, CGS began sending all overpayment letters (demand letters) in light blue envelopes. Requests for repayment of Medicare funds are time-sensitive, and we hope that this change in envelope color will help you quickly and easily identify these requests.

Other things you should know:
- CGS uses the Healthcare Integrated General Ledger Accounting System (HIGLAS). HIGLAS is the standard accounting and payment system for Medicare and Medicaid, and all demand letters from CGS are issued through HIGLAS.
- At this time, HIGLAS demand letters are automatically sent to the physical address on file for the specific provider, based on the completed CMS-855 enrollment form.
- We ask that you alert staff within your facility, practice or place of business to watch for these light blue envelopes so you can take the appropriate action quickly (e.g., refund the requested amount or file an appeal).
Revised: MM7499 - Reporting of Recoupment for Overpayment on the Remittance Advice (RA) with Patient Control Number

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

News Flash – Under the Affordable Care Act, Medicare beneficiaries may now receive coverage for an Annual Wellness Visit (AWV), which is a yearly office visit that focuses on preventive health. In addition, Medicare also provides coverage for the Initial Preventive Physical Examination (IPPE), commonly known as the “Welcome to Medicare” visit. To learn more about the AWV and the IPPE, please refer to the CMS Medicare Learning Network® publication at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/mps_guide_web-061305.pdf on the Centers for Medicare & Medicaid Services (CMS) website.

Note: This article was revised on July 25, 2012, to reflect a revised CR7499 issued on July 19, 2012. The article was revised to show a revised transmittal number, CR release date, and Web address for accessing CR7499. All other information is the same.

Provider Types Affected
This article is for physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, Fiscal Intermediaries (FIs), A/B Medicare Administrative Contractors (A/B MACs), Durable Medical Equipment MACs (DME MACs) and/or Regional Home Health Intermediaries (RHHIs)) for services provided to Medicare beneficiaries.

Provider Action Needed
This article is based on Change Request (CR) 7499 which instructs Medicare’s claims processing systems maintainers to replace the Health Insurance Claim (HIC) number being sent on the ASC X12 Transaction 835) with the Patient Control Number received on the original claim, whenever the electronic remittance advice (ERA) is reporting the recovery of an overpayment.

Background

It has been brought to the attention of CMS that providing the Patient Control Number as received on the original claim rather than the Health Insurance Claim (HIC) number would:

• Enhance provider ability to automate payment posting, and
• Reduce the need for additional communication (via telephone calls, etc.) that would subsequently reduce the costs for providers as well as Medicare.

CR7499 instructs the shared systems to replace the HIC number being sent on the ERA with the Patient Control Number, received on the original claim. The ERA will continue to report the HIC number if the Patient Control Number is not available. This would appear in positions 20-39 of PLB 03-2. A demand letter is also sent to the provider when the Accounts Receivable (A/R) is created. This document contains a claim control number for tracking purposes that is also reported in positions 1-19 of PLB 03-2 on the ERA. (DME ERAs (835’s) will show a Financial Control Number in positions 1-14 of PLB 03-2 and the Adjustment Claim Control Number in positions 15-29 of PLB 03-2.)

Note: Instructions in CR7499 apply to the 005010A1 version of ASC X12 Transaction 835 only and do not apply to the Standard Paper Remit or the 004010A1 version of ASC X12 Transaction 835.

Additional Information
The official instruction, CR7499, issued to your carrier, FI, A/B MAC, DME MAC, or RHHI regarding this change may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1101OTN.pdf on the CMS website.

If you have any questions, please contact your Medicare contractor at their toll-free number, which may be found at http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS website.

This newsletter should be shared with all health care practitioners and managerial members of the provider/supplier staff. Newsletters issued after January 1997 are available at no cost from our website at www.cgsmedicare.com.
MM6823 - Pulmonary Rehabilitation (PR) Services

News Flash – As a result of the Affordable Care Act (ACA), claims with dates of service on or after January 1, 2010, received later than one calendar year beyond the date of service will be denied by Medicare. For full details, see the MLN Matters® article, MM6960, at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6960.pdf on the Centers for Medicare & Medicaid Services website.

Note: This article was revised on July 16, 2012, to add clarifying language, as contained in CR6823, to show that the covered benefit for the comprehensive PR program is for patients with moderate to very severe COPD. All other information is the same.

Provider Types Affected
This article is for physicians and providers submitting claims to Medicare contractors (Medicare Administrative Contractors (A/B MACs), Fiscal Intermediaries (FIs) and/or carriers) for pulmonary rehabilitation (PR) services provided to Medicare beneficiaries.

Provider Action Needed
This article is based on Change Request (CR) 6823 which alerts providers that the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 added payment and coverage improvements for patients with chronic obstructive pulmonary disease (COPD) and other conditions effective January 1, 2010. As a result, Medicare provides a covered benefit for a comprehensive PR program for patients with moderate to very severe COPD under Medicare Part B effective for services on or after January 1, 2010. Be certain your billing staffs are aware of these Medicare changes and of the claims processing system changes to handle claims for PR services that must be implemented no later than October 4, 2010.

Background
Pulmonary Rehabilitation (PR) is a multi-disciplinary program of care for patients with chronic respiratory impairment who are symptomatic and often have decreased daily life activities.

A PR program is individually tailored and designed to optimize physical and social performance and autonomy. The program must provide an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory impairment. In September 2007, the Centers for Medicare & Medicaid Services (CMS), in its final decision memorandum for PR Services, announced there was no basis for a national coverage determination at that time. Specifically, this decision was based on a determination by CMS that the Social Security Act did not expressly define a comprehensive PR program as a Part B benefit, and the evidence was not adequate to draw conclusions on the benefit of the individual components of PR. CMS did (and still does) cover medically reasonable and necessary respiratory treatment services in Comprehensive Outpatient Rehabilitation Facilities (CORFs), as well services to patients with respiratory impairments who are not eligible for PR but for whom local contractors determine respiratory treatment services are covered. MIPPA added payment and coverage improvements for patients with COPD and other conditions, and now provides a covered benefit for a comprehensive PR program for patients with moderate to very severe COPD under Medicare Part B effective January 1, 2010. This law authorizes a PR program, which was codified in the Physician Fee Schedule calendar year 2010 final rule at 42 CFR 410.47.

Key Points of CR 6823
Effective January 1, 2010, MIPPA provisions added a physician–supervised, comprehensive PR program for patients with moderate to very severe COPD. Medicare will pay for up to two (2) one-hour sessions per day, for up to 36 lifetime sessions (in some cases, up to 72 lifetime sessions) of PR. The PR program must include the following mandatory components:
1. Physician-prescribed exercise;
2. Education or training;
3. Psychosocial assessment;
4. Outcomes assessment; and
5. An individualized treatment plan.

The following bullet points detail Medicare claims processing requirements for PR services furnished on or after January 1, 2010:
• Effective January 1, 2010, Medicare contractors will pay claims containing Healthcare Common procedure Coding System (HCPCS) code G0424 when billing for PR services, including exercise and monitoring, as described in the Medicare Benefit Policy Manual, Chapter 15, section 231, as revised by CR 6823, and the Medicare Claims Processing Manual, Chapter 32, Section 140, as revised by CR 6823. These revised documents are attached to CR 6823, which is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/
Medicare contractors will pay claims for HCPCS code G0424 (PR) only when services are provided in the following places of service (POS): 11 (physician’s office) or 22 (hospital outpatient). Medicare will deny claims for HCPCS code G0424 performed in other than, and billed without, POS 11 or 22, using the following:
  o Claim Adjustment Reason Code (CARC) 58 – “treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
  o Remittance Advice Remark Code (RARC) N428 – “Service/procedure not covered when performed in this place of service.”
  o Group Code PR (Patient Responsibility) assigning financial liability to the patient if the claim was received with a GA modifier indicating a signed Advance Beneficiary Notice (ABN) is on file or Group Code CO (Contractual Obligation) assigning financial liability to the provider if the claim is received with the GZ modifier indicating no signed ABN on file.

Medicare contractors will pay claims for PR services containing HCPCS code G0424 and revenue code 0948 on Types of Bill (TOB) 13X and 85X under reasonable cost.

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

Contractors will deny claims for PR services provided in other than TOB 13X and 85X using the following:
  o CARC 58 – “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
  o RARC N428 – “Service/procedure not covered when performed in this place of service.”
  o Group Code PR assigning financial liability to the patient if the claim was received with a GA modifier indicating a signed ABN is on file or Group Code CO assigning financial liability to the provider if the claim is received with the GZ modifier indicating no signed ABN on file.

Medicare contractors will also pay for PR services billed with HCPCS code G0424 and revenue code 096X, 097X, or 098X on TOB 85X from Method II critical access hospitals (CAHs).

Medicare will deny PR services that exceed two units on the same date of service and, in doing so, will use the following:
  o CARC 119 – “Benefit maximum for this time period or occurrence has been reached.”
  o RARC N362 – “The number of days or units of service exceeds our acceptable maximum.”
  o Group Code PR assigning financial liability to the patient if the claim was received with a GA modifier indicating a signed ABN is on file or Group Code CO assigning financial liability to the provider if the claim is received with the GZ modifier indicating no signed ABN on file.

Medicare will normally pay for 36 sessions of PR, but may pay up to 72 sessions when the claim(s) for sessions 37-72 includes a KX modifier. Claims for HCPCS code G0424 which exceed 36 sessions without the KX modifier will be denied using the following:
  o CARC 151 – “Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.”
  o Group Code PR assigning financial liability to the patient if the claim was received with a GA modifier indicating a signed ABN is on file or Group Code CO assigning financial liability to the provider if the claim is received with the GZ modifier indicating no signed ABN on file.

Medicare contractors will deny claims for HCPCS code G0424 when submitted for more than 72 sessions even where the KX modifier is present. In the denials, contractors will use the following:
  o CARC B5 - “Coverage/program guidelines were not met or were exceeded.”
  o Group Code PR assigning financial liability to the patient if the claim was received with a GA modifier indicating a signed ABN is on file or Group Code CO assigning financial liability to the provider if the claim is received with the GZ modifier indicating no signed ABN on file.
September 2012
- page 10 -
Medicare Bulletin – GR 2012-09

**Additional Information**

If you have questions, please contact your Medicare MAC, FI, or carrier at their toll-free number which may be found at [http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS website.


**MM7856 - October Quarterly Update to 2012 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

News Flash – Now Available!! The Medicare Billing Certificate Programs for Part A and Part B Providers. Learn about the Medicare Program and the specifics for your provider type with a special focus on Medicare billing, and receive a certificate in Medicare billing from CMS for successful completion of the program. Successful completion consists of completion of all required web-based training courses, required readings, and a 75-percent or higher score on the post-assessment. To participate in either the Part A or Part B provider type program, visit [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/index.html](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/index.html) and click on ‘Web- Based Training Modules’ under ‘Related Links Inside CMS.’

Note: This article was revised on June 29, 2012, to reflect the revised CR7856, issued on June 27.

The CR was revised to show that it also applied to providers/suppliers submitting claims to DME MACs. Also, the CR release date, transmittal number, and the Web address for accessing the CR have been revised. All other information remains the same.

**Provider Types Affected**

This MLN Matters® Article is intended for physicians, providers, and suppliers submitting claims to Medicare contractors (carriers and/or A/B Medicare Administrative Contractors (A/B MACs) and Durable Medical Equipment (DME) MACs) for Skilled Nursing Facility (SNF) services provided to Medicare beneficiaries.

**Provider Action Needed**

The changes noted in Change Request (CR) 7856, which apply to the “Medicare Claims Processing Manual,” Chapter 6 (SNF Inpatient Part A Billing and SNF Consolidated Billing), Section 10.1 (Consolidated Billing Requirement for SNFs), allow for correct processing of claims under the Skilled Nursing Facility Consolidated Billing provisions. For the October 2012 update, the only change is the addition of Healthcare Common Procedure Coding System (HCPCS) code J9033 (Injection, bendamustine hcl, 1 mg) to the File 1 Coding List for SNF Consolidated Billing (CB) for dates of service on or after January 1, 2012. Please note that, when brought to their attention, your Medicare contractor will re-open and re-process claims for J9033 with dates of service on or after January 1, 2012, that have been previously denied prior to the implementation of CR7856.

**Background**

Section 1888 of the Social Security Act (see [http://www.ssa.gov/OP_Home/ssact/title18/1888.htm](http://www.ssa.gov/OP_Home/ssact/title18/1888.htm)) codifies the Skilled Nursing Facility Prospective Payment System (SNF PPS) and Consolidated Billing (CB); and the Centers for Medicare & Medicaid Services (CMS) periodically updates the lists of HCPCS codes that are subject to the CB provision of the SNF PPS. These updates (which do not add any additional services) are required by changes to the coding system, not because the services subject to SNF CB are being redefined. Other regulatory changes beyond code list updates will be noted when, and if, they occur.

To assure proper payment in all settings, Medicare systems must edit for services provided to SNF beneficiaries that are both included and excluded from SNF CB. You should be aware that Medicare will not pay any providers (other than SNFs) for services included in SNF CB that appear on claims submitted to Medicare Carriers, A/B MACs, and...
Durable Medical Equipment MACs (DME MACs). However services excluded from SNF PPS and CB may be paid to providers (other than SNFs) for beneficiaries, even when in a SNF stay.

SNF CB applies to physical and occupational therapies and speech-language pathology services whenever they are furnished to a SNF resident, regardless of whether Part A covers the stay; but applies to non-therapy services only when the services are furnished to a SNF resident during a covered Part A stay.

Additional Information
The official instruction, CR7856 issued to your carrier, DME MAC, or A/B MAC regarding this change may be viewed at http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2492CP.pdf on the CMS website.

If you have any questions, please contact your carrier, DME MAC, or A/B MAC at their toll-free number, which may be found at http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS website.

SE1226 - Reminder of Importance of Correct Place-of-Service Coding on Medicare Part B Claims

DEPARTMENT OF health AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

News Flash – Are you billing correctly for ordered/referred services? Will you be impacted when CMS turns on the edits for these services? See the revised MLN Matters® articles #SE1221, #SE1011, and MLN fact sheets “Medicare Enrollment Guidelines for Ordering/Referring Providers” and “The Basics of Medicare Enrollment for Physicians Who Infrequently Receive Medicare Reimbursement” to learn what you need to do.

Provider Types Affected
This MLN Matters® Special Edition Article is intended for physicians and their billing agents who submit claims to Medicare Carriers or Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries.

Provider Action Needed
The Centers for Medicare & Medicaid Services (CMS) is issuing this article to remind providers that accurate place of service coding on claims is essential to avoid improper payments. Make sure that your billing staffs are aware of this article and the need to correctly code the place-of-service on your Medicare claims.

Background
The Medicare Part B Program pays for physician services provided to beneficiaries. Physicians may perform these services in a facility setting, such as a hospital outpatient department or freestanding Ambulatory Surgical Center (ASC), or in a non-facility setting such as a physician’s office, urgent care center, or independent clinic. To account for the increased overhead expenses physicians incur by performing these services in non-facility locations, Medicare reimburses physicians based on a fee schedule that may pay a higher rate for individual services provided in these locations. When physicians perform these services in facility settings, such as hospital outpatient departments or ASCs, Medicare reimburses the overhead expenses to the facility and the physician receives a lower reimbursement rate.

Physicians are required to identify the place-of-service on the health insurance claim forms that they submit to Medicare contractors. The correct place-of-service code ensures that Medicare does not incorrectly reimburse the physician for the overhead portion of the payment if the service was performed in a facility setting.

The Office of Inspector General (OIG) conducted an audit in 2009 that followed up on a similar audit from a 2007 report. The 2009 audit covered 494,129 non-facility-coded physician services valued at $42,245,142. These services were provided in calendar year 2009 and matched hospital outpatient or ASC claims for the same type of service provided to the same beneficiary on the same day.

The OIG conducted the 2009 audit to determine whether physicians correctly coded non-facility place-of-service on selected part B claims submitted to and paid by Medicare contractors. The audit report, titled “Review of Place-of-Service Coding for Physician Services Processed by Medicare Part B Contractors During Calendar Year 2009” is available at http://oig.hhs.gov/oas/reports/region10/11000516.pdf on the OIG website.

Results of Recent OIG Audit
Physicians correctly coded the claims for 17 of the 100 services that the OIG sampled. However, physicians incorrectly coded the claims for 83 sampled services by using non-facility place-of-service codes for services that were actually performed in hospital outpatient departments or ASCs.
Based on the sample results, OIG estimated that nationally, Medicare contractors overpaid Physicians $9.5 million for incorrectly coded services provided during calendar year 2009. These overpayments may be due to internal control weaknesses at the physician billing level. They may also be attributed to insufficient post-payment reviews at the Medicare contractor level to identify potential place-of-service coding errors.

As a result, Strategic Health Solutions, a CMS contractor, performed a specialty medical review study on Place-of-Service coding for physician services. This study concluded that the most common finding was documentation submitted indicated that the service was incorrectly coded as a non-facility place of service. In addition, a number of providers acknowledged that the claim was coded incorrectly upon receipt of the documentation, or had already initiated the adjustment process.

**Additional Information**
For an overview of place of service coding and a list of the appropriate codes, visit [https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html](https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html) on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS website.
CGS J-15 A/B MAC Investigational Device Exemption Request Form

The following completed form (page 1) should be included when submitting the request to CGS.

REQUESTS CAN BE SUMITTED VIA E-MAIL TO J15IDE@CGSADMIN.COM

1. Point of Contact: ______________________________
2. Address: ______________________________________
3. Phone number: ______________________________
4. Email address: ______________________________
5. IDE number: ______________________________
6. Study Name: __________________________________
7. Trade name (device): ______________________________
8. Device Common name: ____________________________

Facilities where service will be provided:

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Address</th>
<th>NPI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Participating practitioner (s):

<table>
<thead>
<tr>
<th>Name</th>
<th>(MD/DO)</th>
<th>NPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sub</td>
<td></td>
<td></td>
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<td>Sub</td>
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</tr>
<tr>
<td>Sub</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Number of enrollees anticipated at the facility:

Anticipated bill type: (inpatient, outpatient, or both):

CGS is now accepting IDE requests for J-15 Part A and Part B for Kentucky and Ohio and Home Health and Hospice. We look forward to serving you.

The following documentation is required for submission. Please submit all documents at the same time. NOTE: Failure to submit all documentation will result in rejection of your submission and require re-submission of all items.

1. The name of the device (both trade, common or usual and classification name) and a narrative description of the device. Include a statement as to the devices similarities and differences from other products if not explicitly and clearly indicated in submitted documents.
2. An un-redacted copy of FDA approval letters provided to the provider and/or the sponsor or manufacturer of the device.
3. A copy of the approval letter from the provider’s Institutional Review Board (IRB). (A copy of the approval letter for any time extension or other update must also be submitted as the approval occurs.)
4. If necessary a description of action(s) taken to conform to any applicable FDA and/or IRB special controls and/or other requirements.
5. A full copy of the study protocol, including patient inclusion criteria.
6. A copy or description of the provider’s protocol for obtaining informed consent from patients participating in the device trial.
7. A sample of the patient consent form (must clearly describe the patient’s financial responsibility if any).
8. Copies of all agreements between the sponsor and the provider especially, but not limited to, financial agreements.
9. The Principal Investigator’s (PI) budget for the study, showing allocation of all funds from all sources.
10. A description of the facility’s processes/procedures for ensuring that Medicare is not billed for any non-clinical study costs and sponsor or other reimbursed costs.

All IDE approvals will expire after one calendar year or the expiration of the IRB approval whichever is shorter.

Extension or modification requests should include
1. A letter signed by the PI requesting the extension/modification and reason for the extension/modification, any changes to the protocol (if so also need copy of the modifications) and any significant adverse effects;
2. A current IRB showing approval of the extension and any modifications;
3. If adding sub-investigators include name, professional designator (MD/DO) and NPI.

These items shall be submitted at least thirty days prior to expiration of approval or need for the modification. Any time the protocol changes significantly or a major adverse effect occurs CGS expects notification within thirty days of the event. CGS may from time to time request medical records, claims data and other documentation necessary to demonstrate adherence to the protocol and proper billing of Medicare claims related to the IDE request.

Preferably, if possible all items should be e-mailed to J15IDE@cgsadmin.com.

Alternatively, the above documentation may be mailed to:

CGS Administrators, LLC
ATTN: Julene Mull, IDE Request
Two Vantage Way
Nashville, TN 37228

MM7868 - New Waived Tests

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

News Flash – Are you billing correctly for ordered/referred services? Will you be impacted when the Centers for Medicare & Medicaid Services (CMS) turns on the edits for these services? See the revised MLN Matters® articles SE1221, SE1011, and MLN fact sheets “Medicare Enrollment Guidelines for Ordering/Referring Providers” and “The Basics of Medicare Enrollment for Physicians Who Infrequently Receive Medicare Reimbursement” to learn what you need to do.

Provider Types Affected
This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare contractors (carriers and A/B Medicare Administrative Contractors (MACs)) for services to Medicare beneficiaries.

Provider Action Needed

STOP – Impact to You
If you do not have a valid, current, Clinical Laboratory Improvement Amendments of 1998 (CLIA) certificate and submit a claim to your Medicare Carrier or A/B MAC for a Current Procedural Terminology (CPT) code that is considered to be a laboratory test requiring a CLIA certificate, your Medicare payment may be impacted.
**CAUTION – What You Need to Know**

CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. The CPT codes that the Centers for Medicare & Medicaid Services (CMS) considers to be laboratory tests under CLIA (and thus requiring certification) change each year. CR 7868, from which this article is taken, informs carriers and MACs about the latest new CPT codes that are subject to CLIA edits.

**GO – What You Need to Do**

Make sure that your billing staffs are aware of these CLIA-related changes for 2012 and that you remain current with certification requirements.

**Background**

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the attached list (i.e., CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Effective Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0434QW</td>
<td>March 14, 2012</td>
<td>Wondfo Oxycodone Urine Test {Dip card format}</td>
</tr>
<tr>
<td>G0434QW</td>
<td>March 14, 2012</td>
<td>Wondfo Oxycodone Urine Test {Cup format}</td>
</tr>
<tr>
<td>87880QW</td>
<td>March 23, 2012</td>
<td>McKesson Strep A Test - Dipstick</td>
</tr>
<tr>
<td>87880QW</td>
<td>March 23, 2012</td>
<td>McKesson Strep A Test - Twist</td>
</tr>
<tr>
<td>86318QW</td>
<td>April 3, 2012</td>
<td>McKesson H. pylori Test (Whole Blood)</td>
</tr>
<tr>
<td>87804QW</td>
<td>April 20, 2012</td>
<td>Sofia Analyzer and Influenza A+B FIA (for user with nasal swabs and nasopharyngeal swabs)</td>
</tr>
<tr>
<td>85610QW</td>
<td>May 8, 2012</td>
<td>AlereINRatio®2 PT/INR Home Monitoring System {Prescription Home Use}</td>
</tr>
<tr>
<td>83986QW</td>
<td>May 8, 2012</td>
<td>Dale Medical Products, Inc. RightLevel pH</td>
</tr>
<tr>
<td>83986QW</td>
<td>May 8, 2012</td>
<td>Dale Medical Products, Inc. RightSpot pH</td>
</tr>
</tbody>
</table>

**Additional Information**


If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS website.
MM7806 - Extracorporeal Photopheresis (ICD-10)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

News Flash – In response to shortage of liposomal doxorubicin (Doxil), the Food and Drug Administration is permitting the temporary importation of Lipodox, a brand of liposomal doxorubicin hydrochloride. Visit http://www.FDA.gov/NewsEvents/Newsroom/PressAnnouncements/ucm292658.htm for additional information. The Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Quarterly Update includes two new codes (Q2048 and Q2049) for liposomal doxorubicin that will become effective Sunday, July 1, 2012. The code descriptors are worded in a manner that distinguishes Lipodox and Doxil. As of Sunday, July 1, 2012, HCPCS code J9001 will not be used for Medicare billing. CMS will release a Change Request (CR) with additional instructions in the near future.

Note: This article was revised on July 11, 2012, to reflect the revised CR7806 issued on July 10. The CR release date, transmittal number, and the Web address for accessing CR7806 were revised. All other information is the same.

Provider Types Affected
This MLN Matters® Article is intended for physicians and other providers who bill Medicare Carriers, Fiscal Intermediaries (FIs), or Medicare Administrative Contractors (A/B MACs) for providing extracorporeal photopheresis procedures for the treatment of Bronchiolitis Obliterans Syndrome (BOS) following lung allograft transplantation.

Provider Action Needed
Effective for claims with dates of service on and after April 30, 2012, Medicare will cover extracorporeal photopheresis for the treatment of Bronchiolitis Obliterans Syndrome (BOS) following lung allograft transplantation, but only when provided under an approved clinical research study that meets specific requirements to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation. You should make sure that your billing staffs are aware of the expanded coverage provided in this NCD.

Background
Extracorporeal photopheresis is a second-line treatment for a variety of oncological and autoimmune disorders that is performed in the hospital inpatient, hospital outpatient, and Critical Access Hospital (CAH) settings. In the procedure, some of a patient’s removed white blood cells are exposed first to the drug 8-methoxypsoralen (8-MOP) and then to ultraviolet A (UVA) light. After UVA light exposure, the treated white blood cells are re-infused into the patient, stimulating their immune system in a series of cascading reactions. This activation of the immune system then impacts the illness being treated.

Currently, Medicare covers extracorporeal photopheresis for the following indications:
- Palliative treatment of skin manifestations of CTCL that has not responded to other therapy;
- Patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment; and
- Patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment.

On August 4, 2011, the Centers for Medicare & Medicaid Services (CMS) accepted a formal request for a reconsideration to add coverage for extracorporeal photopheresis treatment for patients who have received lung allografts and then developed progressive Bronchiolitis Obliterans Syndrome (BOS) refractory to immunosuppressive drug treatment.

As a result of the reconsideration, effective for claims with dates of service on and after April 30, 2012, Medicare will begin to cover extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation; but only when provided under a clinical research study that meets specific requirements to assess its effect in the treatment of BOS following lung allograft transplantation.
**NCD Clinical Research Study Requirements**

This is a National Coverage Determination (NCD). In keeping with this NCD, any clinical research study that includes Medicare coverage of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation must be approved by meeting the requirements listed below. Additionally, consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet these standards and address the research questions.

An approved clinical research study:

1. Must address one or more aspects of the following question:
   - Prospectively, do Medicare beneficiaries who have received lung allografts, developed BOS refractory to standard immunosuppressive therapy, and received extracorporeal photopheresis, experience improved patient-centered health outcomes as indicated by:
     a. Improved Forced Expiratory Volume in One Second (FEV1);
     b. Improved survival after transplant; and/or
     c. Improved quality of life?

2. Must adhere to the following standards of scientific integrity and relevance to the Medicare population:
   a. Its principal purpose is to test whether extracorporeal photopheresis potentially improves the participants’ health outcomes;
   b. 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;
   c. It does not unjustifiably duplicate existing studies;
   d. Its design is appropriate to answer the research question being asked in the study;
   e. It is sponsored by an organization or individual capable of successfully executing the proposed study;
   f. It is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 Code of Federal Regulations CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must also be in compliance with 21 CFR parts 50 and 56;
   g. All of its aspects are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org);
   h. 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) coverage;
   i. 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 Section 312.81(a) and the patient has no other viable treatment options;
   j. It is registered on the ClinicalTrials.gov website (http://clinicaltrials.gov) by the principal sponsor/investigator prior to the enrollment of the first study subject;
   k. Its protocol specifies the method and timing of public release of all prespecified 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);
   l. It explicitly discusses subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect 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. Its 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.
Note: Any clinical study in which there is coverage of extracorporeal photopheresis for this indication under this NCD must be approved by April 30, 2014 (two years from the effective date of this NCD). If there are no approved clinical studies by this date, this NCD will expire and coverage of extracorporeal photopheresis for BOS will revert to the coverage policy in effect prior to the issuance of its Final Decision Memorandum (DM) on April 30, 2012.

Billing Requirements
Effective for claims with dates of service on and after April 30, 2012, your carrier, FI, or A/B MAC will accept and pay for hospital outpatient and physician claims containing Healthcare Common Procedure Coding System (HCPCS) procedure code 36522 along with one of the International Classification of Diseases (ICD-9-CM or ICD-10) diagnosis codes displayed in the following table.

<table>
<thead>
<tr>
<th>ICD 9 CM</th>
<th>ICD 9 CM Description</th>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>491.20</td>
<td>Obstructive chronic bronchitis without exacerbation</td>
<td>J44.9</td>
<td>Chronic obstructive pulmonary disease, unspecified</td>
</tr>
<tr>
<td>491.21</td>
<td>Obstructive chronic bronchitis with (acute) exacerbation</td>
<td>J44.1</td>
<td>Chronic obstructive pulmonary disease with (acute) exacerbation</td>
</tr>
<tr>
<td>491.9</td>
<td>Unspecified chronic bronchitis</td>
<td>J42</td>
<td>Unspecified chronic bronchitis</td>
</tr>
<tr>
<td>496</td>
<td>Chronic airway obstruction, not elsewhere classified</td>
<td>J44.9</td>
<td>Chronic obstructive pulmonary disease, unspecified</td>
</tr>
<tr>
<td>996.84</td>
<td>Complications of transplanted lung</td>
<td>T86.810</td>
<td>Lung transplant rejection</td>
</tr>
<tr>
<td>996.84</td>
<td>Complications of transplanted lung</td>
<td>T86.811</td>
<td>Lung transplant failure</td>
</tr>
<tr>
<td>996.84</td>
<td>Complications of transplanted lung</td>
<td>T86.812</td>
<td>Lung transplant infection (not recommended for ECP coverage)</td>
</tr>
<tr>
<td>996.84</td>
<td>Complications of transplanted lung</td>
<td>T86.818</td>
<td>Other complications of lung transplant</td>
</tr>
<tr>
<td>V70.7</td>
<td>Examination of participant in clinical trial</td>
<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program (needed for CED)</td>
</tr>
</tbody>
</table>

Please note that your claims will only be paid when they also contain all of the following:
- Diagnosis code V70.7 (as secondary diagnosis);
- 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); and
- Value Code D4 with an 8-digit clinical trial number (optional)(FIs only).

Additionally, should your Medicare contractor return your claims as unprocessable because they are missing: 1) Diagnosis code V70.7 (as secondary diagnosis), 2) Condition code 30 (Institutional claims only), 3) Clinical trial modifier Q0 (Institutional claims only), and 4) Value Code D4 with an 8-digit clinical trial number (optional) (FIs only); they will use the following messages:
- CARC 4 – The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC MA 130 – 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.
- RARC M16 – Alert: Please see our web site, mailings, or bulletins for more details concerning this policy/procedure/decision.
Please keep in mind that your contractor will not retroactively adjust claims from April 30, 2012, processed prior to implementation of CR7806. However, they may adjust claims that you bring to their attention.

**Additional Information**


If you have any questions, please contact your carrier, FI, or A/B MAC at their toll-free number, which may be found at [http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip](http://www.cms.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip) on the CMS website.
Join the CGS ListServ

By joining the CGS electronic mailing list, you can get immediate updates on Medicare information, including:

- Medicare publications
- Important updates
- Workshops
- Medical Review information

To join the ListServ follow this link: https://www.cgsmedicare.com/medicare_dynamic/ls/001.asp
Overpayment Refunds

Personal provider checks sent to us for any reason should be sent to the following address (if you are submitting a refund due to Medicare Secondary Payer, include “MSP” on the envelope or correspondence):

Kentucky and Ohio Providers
CGS – J15 Part B Kentucky and Ohio
PO Box 957065
St. Louis, MO 63195-7065

Personal provider checks should never be sent to our Nashville operations as this will create processing delays. For example, in situations where you have received a letter of notification regarding a Medicare overpayment, these delays can result in payment offset and/or interest accrual.

Checks issued by CGS that need to be returned to us should be sent to the following address:

Kentucky and Ohio Providers
CGS – J15 Part B Kentucky and Ohio
PO Box 957065
St. Louis, MO 63195-7065

Medicare Bulletin

... a service of CGS
Two Vantage Way
Nashville, TN 37228

The CGS website (www.cgsmedicare.com) provides formal notification for all notices developed and distributed by CGS, including the Part B Medicare Bulletin. Providers/suppliers are obligated and responsible for remaining updated on current Medicare issues and legislation as it is posted to the website.

Please note that for LCDs listed on the website, the start of the notice period may be different than the date it is posted to the website. Please abide by the notice period dates on the document, not the posting date.

A quarterly CD-ROM, which includes the Medicare Bulletin and other additional resources, is mailed to the same location as Medicare checks. Provider groups will receive one copy of the CD-ROM. Each individual provider in that group will not receive their own copy for his/her individual provider identification number (PIN).
It's Convenient!
I love that!

my CGS
Now Available!