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The Social Security Act allows CMS to define services that are appropriate for payment under the Outpatient Prospective Payment System (OPPS). Under this authority, CMS also identifies services that should be performed in the inpatient setting. These services are itemized on the inpatient list, also known as the inpatient-only list. The inpatient list is a litany of services for which Medicare will only reimburse hospitals if the services are provided in the inpatient setting.

Services are included on this list based on the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be discharged safely.

Medicare will not pay the facility for inpatient list services if they are provided outside of the inpatient setting, such as in a hospital outpatient department, an ambulatory surgical center (ASC), or a physician’s office. However, the inpatient list does not affect physician reimbursement. If the medical record documents the medical necessity of a service, taking into consideration any Medicare coverage policy requirements, then the physician will typically receive the Medicare Part B reimbursement for an inpatient list service, regardless of the setting.

The services on the inpatient list are predominately surgical services and are expressed in terms of the American Medical Association’s Current Procedural Terminology (CPT®) codes. CMS maintains and updates the inpatient list as part of the OPPS rulemaking process.

Some hospitals mistakenly assume a procedure’s presence on the inpatient-only list validates medical necessity. However, hospitals must document the procedure’s medical necessity according to local or national coverage determinations (depending on the procedure) before they perform it and have a physician order before it begins or the procedure will be denied.

The inpatient-only list also is coded using CPT codes. This can be a real source of confusion as hospitals have to code inpatient-only procedures in ICD-9 form. Coders with inpatient expertise may have trouble translating the CPT codes, and coders with CPT expertise may struggle with the ICD-9 conversion.

To reduce claim denials, check to see if the procedure is on the inpatient-only list and have an inpatient order on the medical record before the procedure is started.

Passport’s OrderChecker® has the Inpatient-Only procedures check available; please e-mail compliance.support@passporthealth.com if you need additional information on how to use this important feature.
CMS created 23 National Coverage Determinations (NCDs) for specific clinical laboratory tests. Whereas most NCDs describe covered indications and limitations in narrative form, laboratory NCDs list specific ICD-9 codes that fall into 3 categories:

- Covered ICD-9 codes
- Non-covered ICD-9 codes
- Codes that do not support medical necessity

Per Transmittal 2976 CR 8797 dated 6/13/14, the Laboratory NCD Edit Software will be updated to continue the processing of the ICD-9 diagnosis codes.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted, which said that the Secretary of Health and Human Services may not adopt ICD-10 codes prior to October 1, 2015. This requires Health Insurance Portability & Accountability Act of 1996 (HIPAA) covered entities to continue to use ICD-9-CM at least through September 30, 2015.

Also, CR8797 announces there are no updates to the laboratory NCD code lists at this time.

<table>
<thead>
<tr>
<th>Current list of Lab NCDs: Alphabetical</th>
<th>CPT Codes Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCD#</td>
<td>Title</td>
</tr>
<tr>
<td>190.25</td>
<td>Alpha-fetoprotein</td>
</tr>
<tr>
<td>190.15</td>
<td>Blood Counts</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>190.20</td>
<td>Blood Glucose Testing</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>190.26</td>
<td>Carcinoembryonic Antigen</td>
</tr>
<tr>
<td>190.19</td>
<td>Collagen Crosslinks, Any Method</td>
</tr>
<tr>
<td>190.24</td>
<td>Digoxin Therapeutic Drug Assay</td>
</tr>
<tr>
<td>190.34</td>
<td>Fecal Occult Blood Test</td>
</tr>
<tr>
<td>190.32</td>
<td>Gamma Glutamyl Transferase</td>
</tr>
<tr>
<td>190.21</td>
<td>Glycated Hemoglobin/Glycated Protein</td>
</tr>
<tr>
<td>190.33</td>
<td>Hepatitis Panel/Acute Hepatitis Panel</td>
</tr>
<tr>
<td>190.27</td>
<td>Human Chorionic Gonadotropin</td>
</tr>
<tr>
<td>190.14</td>
<td>Human Immunodeficiency Virus (HIV) Testing (Diagnosis)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>190.13</td>
<td>Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)</td>
</tr>
<tr>
<td>190.23</td>
<td>Lipid Testing</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>190.16</td>
<td>Partial Thromboplastin Time (PTT)</td>
</tr>
<tr>
<td>190.31</td>
<td>Prostate Specific Antigen</td>
</tr>
<tr>
<td>190.17</td>
<td>Prothrombin Time (PT)</td>
</tr>
<tr>
<td>190.18</td>
<td>Serum Iron Studies</td>
</tr>
<tr>
<td>190.22</td>
<td>Thyroid Testing</td>
</tr>
<tr>
<td>190.28</td>
<td>Tumor Antigen by Immunoassay (CA 125)</td>
</tr>
<tr>
<td>190.29</td>
<td>Tumor Antigen by Immunoassay (CA 15-3CA 27.29)</td>
</tr>
<tr>
<td>190.30</td>
<td>Tumor Antigen by Immunoassay (CA 19-9)</td>
</tr>
<tr>
<td>190.12</td>
<td>Urine Culture, Bacterial</td>
</tr>
</tbody>
</table>

Compliance Matters
CMS Revisions for FDG PET Scans

CMS has revised the NCD Manual, Section 220.6 to reflect that CMS has ended the coverage with evidence development requirement for subsequent management of anti-tumor treatment strategy for FDG PET, PET/CT, and PET/MRI, after completion of initial anti-cancer therapy.

This revision was requested by the NOPR (National Oncology PET Registry). CMS has ended the prospective data collection requirements across all oncologic indications of FDG PET.

Effective date of service is June 11, 2013 or after.

Initial Anti-Tumor Treatment Strategy

CMS will cover one FDG PET for beneficiaries that are biopsy proven or strongly suggested based on other diagnostic testing when the treating physician is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy.

- Determination whether or not the beneficiary is an appropriate candidate
- Determination of anatomic location for invasive procedure
- Determine anatomic extent of tumor

CMS will now accept and pay for FDG PET for oncological claims, initial or subsequent, without requiring the following:

- Q0 (investigational clinical study)
- Q1 (routine clinical service as part of approved clinical study), or
- V70.7 (clinical research study)
- Condition code 30 (institutional claims only)

Subsequent Anti-Tumor Treatment Strategy

Three FDG PET scans are nationally covered when used to guide subsequent management of anti-tumor strategy after completion of initial anti-cancer therapy for the same cancer diagnosis.

Coverage of any additional FDG PET scans (beyond three) used to guide subsequent management of anti-tumor strategy after completion of initial cancer therapy for the same diagnosis will be determined by the MAC.

When three FDG scans has been exceeded, MACs will reimburse FDG PET claims for subsequent management, (identified by CPT CODES 78608, 78811, 78812, 78813, 78814, 78815 or 78826, modifier –PS, HCPCS A9552) for the same cancer diagnosis, when the –KX modifier is included on the same claim line.

The MACs will not search their files to identify claims for FDG PET scans processed prior to CR 8468, however they will adjust such claims you bring to their attention.

MACs will deny subsequent treatment strategies >3 when a –KX modifier is not included on the claim line using the following:

- Claim adjustment reason code (CARC) 96: “Non-covered charge(s). Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”
- Remittance advice remarks code N435: “Exceeds number/frequency approved/allowed within time period without support documentation.”
- Group code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.
- Group code PR assigning financial liability to the beneficiary if a claim is received with a GA modifier indicating a signed ABN is on file.

For example, each, different cancer diagnosis is allowed one initial treatment strategy PET scan (-PI) and three subsequent treatment strategy (-PS modifier) PET scans without placement of a -KX modifier. The fourth subsequent and beyond for the same cancer diagnosis will always require the –KX modifier.

If a different cancer diagnosis is reported, that cancer diagnosis will be allowed the same as the example above, one initial treatment strategy PET scan (-PI) and three subsequent treatment strategy PET scans (-PS) without placement of the -KX modifier; once there is a fourth subsequent PET scan and above, for that diagnosis, -KX modifier is required.
One initial treatment strategy (PI modifier) FDG PET scan.

- The existence or non-existence of an initial treatment strategy claim has no bearing on the frequency count of subsequent treatment strategy claims.
- Three subsequent treatment strategies (PS modifier) FDG PET scan.
- The fourth FDG PET scan and beyond for subsequent treatment strategy for the same diagnosis will require a PS and KX modifier.

**Note:** The only exception to the above frequency is for diagnosis 185.0, prostate cancer, which is non-covered for initial treatment strategy. Therefore, all -PI modifiers for 185.0 would be denied, and -PS modifiers would allow the same frequency as all other cancer diagnosis codes.

For claims with a date of service on or after July 7, 2014, Medicare contractors shall deny subsequent treatment strategy (-PS) claims for oncologic FDG PET scans when no initial treatment strategy (-PI) is present in history using the following:

MACs shall deny subsequent treatment strategy (-PS) claims for oncologic FDG PET scan claims when no initial treatment strategy (-PI) claim is present in history when appropriate. CWF will begin counting at this point. The prostate cancer exception above applies.

When no initial treatment strategy (-PI) is present in history, the following will be used:

- CARC B5: “Coverage/program guidelines were not met or were exceeded.”
- RARC N640: “Exceeds number/frequency approved/allowed within time period.”
- Group code PR assigning financial liability to the beneficiary, if a claim is received with a GA modifier indicating a signed ABN is on file.
- Group code CO assigning financial liability to the provider, if a claim is received with a GZ modifier indicating no signed ABN is on file.

<table>
<thead>
<tr>
<th>Tumor Type</th>
<th>Initial Treatment Strategy (formerly “diagnosis” &amp; “staging”)</th>
<th>Subsequent Treatment Strategy (formerly “restaging” &amp; “monitoring response to treatment”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorectal</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Esophagus</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Head/Neck</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Non-small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Ovary</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Brain</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Cervix</td>
<td>Cover with exceptions</td>
<td>Cover</td>
</tr>
<tr>
<td>Small cell lung</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Soft tissue sarcoma</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Pancreas</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Testes</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Prostate</td>
<td><strong>Non-covered</strong></td>
<td>Cover</td>
</tr>
<tr>
<td>Thyroid</td>
<td>Cover</td>
<td>Cover</td>
</tr>
<tr>
<td>Breast</td>
<td>Cover with exceptions</td>
<td>Cover</td>
</tr>
<tr>
<td>Melanoma</td>
<td>Cover with exceptions</td>
<td>Cover</td>
</tr>
<tr>
<td>All other cancers not listed</td>
<td>Cover with exceptions</td>
<td>Cover</td>
</tr>
</tbody>
</table>


MLN Matters® Number: MM8468 Related Change Request (CR) #: CR 8468

Related CR Release Date: February 6, 2014

Effective Date: June 11, 2013

Related CR Transmittal #: R2873CP/R162NCD

Implementation Date: March 7, 2014: Non-shared System Edits, July 7, 2014: Shared System Edits

**Modifier 59: CMS MLN Matters Special Edition**

CMS recently released an updated MLN Matters Special Edition article SE1418 reviewing proper use of Modifier 59. This modifier, used to define “separate and distinct” procedures on claims is frequently the focus of various audits conducted by Medicare Administrative Contractors (MAC) and Recovery Auditors (RAC).

The Medicare National Correct Coding Initiative (NCCI) includes Procedure-to-Procedure (PTP) edits that define when two Healthcare Common Procedure Coding System (HCPCS)/Current Procedural Terminology® (CPT®) codes should not be reported together either in all situations or in most situations.

For PTP edits that have a Correct Coding Modifier Indicator (CCMI) of “0,” the codes may be reported together only in defined circumstances which are identified on the claim by the use of specific NCCI-associated modifiers. Appropriate application of an NCCI approved modifier will override the PTP edit and allow separate payment for both services/procedures.

One function of NCCI PTP edits is to prevent payment for codes that report overlapping services except in those instances where the services are “separate and distinct.” Modifier 59 is an important NCCI-associated modifier that is often used incorrectly according to CMS.

Modifier 59 and other NCCI-associated modifiers should NOT be used to bypass a PTP edit unless the proper criteria for use of the modifier are met. Documentation in the medical record must satisfy the criteria required by any NCCI-associated modifier that is used.

Following are some examples from SE 1418 outlining the correct use of Modifier 59.

Modifier 59 is used appropriately:

- for two services described by timed codes (i.e., per 15 minutes, per hour) when they are provided during the same encounter and only when they are performed sequentially (i.e., one service is completed before the subsequent service begins)

- for a diagnostic procedure which precedes a therapeutic procedure only when the diagnostic procedure is the basis for performing the therapeutic procedure

- for a diagnostic procedure which occurs subsequent to a completed therapeutic procedure only when the diagnostic procedure is not a common, expected, or necessary follow-up to the therapeutic procedure


The CMS Modifier 59 Article is also helpful and can be reviewed here: [https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/downloads/modifier59.pdf](https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/downloads/modifier59.pdf)
Proposed Rule Would Strengthen Tie Between Payment and Quality Improvement

On April 30, CMS issued a proposed rule that would update fiscal year (FY) 2015 Medicare payment policies and rates for inpatient stays at general acute care and long-term care hospitals (LTCHs).

This rule builds on the Obama administration’s efforts through the Affordable Care Act to promote improvements in hospital care that will lead to better patient outcomes while slowing the long-term health care cost growth.

CMS projects that the payment rate update to general acute care hospitals will be 1.3 percent in FY 2015. The rate update for long term care hospitals will be 0.8 percent. The difference in the update is accounted for by different statutory and regulatory provisions that apply to each system.

The rule’s most significant changes are payment provisions intended to improve the quality of hospital care that reduce payment for readmissions, and hospital acquired conditions (HACs). The rule also includes proposed changes to the hospital inpatient quality reporting (IQR) program. The rule also describes how hospitals can comply with the Affordable Care Act’s requirements to disclose charges for their services online or in response to a request, supporting price transparency for patients and the public.

The proposed rule asks for public input on an alternative payment methodology for short stay inpatient cases that also may be treated on an outpatient basis, including how to define short stays. In addition, the proposed rule reminds stakeholders of the existing process for requesting additional exceptions to the two-midnight benchmark.

Improving Patient Care

Hospital value-based purchasing program:
The hospital value-based purchasing (VBP) program, which was established by the Affordable Care Act, adjusts payments to hospitals under the IPPS based on the quality of care they deliver to patients.

For FY 2015, as directed by the law, CMS is increasing the applicable percent reduction, the portion of Medicare payments available to fund the value-based incentive payments under the program, to 1.5 percent of the base operating DRG payment amounts to all participating hospitals.

CMS estimates that the total amount available for value-based incentive payments in FY 2015 will be approximately $1.4 billion, and will update this estimate in the FY 2015 IPPS/LTCH final rule.

Hospital readmissions reduction program:
The maximum reduction in payments under the hospital readmissions reduction program will increase from two to three percent as required by law. For FY 2015, CMS proposes to assess hospitals’ readmissions penalties using five readmissions measures endorsed by the National Quality Forum (NQF). Already, CMS estimates that hospital readmissions in Medicare declined by a total of 150,000 from January 2012 through December 2013.

Hospital-acquired condition reduction program:
CMS proposes to implement the Affordable Care Act’s hospital acquired condition (HAC) reduction program. Beginning in FY 2015, hospitals scoring in the top quartile for the rate of HACs (i.e. those with the poorest performance) will have their Medicare inpatient payments reduced by one percent.

This new program builds on the progress in this area achieved through the existing HAC program, which is currently saving approximately $25 million annually by reducing Medicare payments when certain conditions that are reasonably preventable are acquired in the hospital.

Quality reporting programs:
The proposed rule would revise measures for the hospital inpatient quality reporting, long-term care hospital (LTCH) quality reporting and PPS-exempt cancer hospital quality reporting programs. CMS proposes to align for 2015 and 2016 the reporting and submission timelines for clinical quality measures for the Medicare electronic health record (EHR) incentive program with the reporting and submission timelines of the hospital IQR program.

Wage index – updated labor market areas:
In order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions, we are proposing to use the most recent labor
HHS Announces Auto-Enrollment Plans for Current Marketplace Consumers in 2015

The U.S. Department of Health and Human Services (HHS) expects to announce its plans for helping existing Marketplace consumers get auto-enrolled for next year. These plans would give existing consumers a simple way to remain in the same plan next year unless they want to shop for another plan and choose to make changes.

“As we plan for open enrollment in year two and continue to build a sustainable long-term system, we are committed to simplifying the experience for consumers by allowing auto-enrollment,” said Sylvia Mathews Burwell, Secretary of HHS. “We are working to streamline the process for consumers wishing to remain in their current plan.”

In today’s health insurance market, the vast majority of consumers are generally auto-enrolled in their plan year after year. For example, about 88 percent of employees receiving coverage through the Federal Employee Health Benefits Program don’t choose to change plans and are instead auto-enrolled in their current plan with updated premiums and benefits. These guidelines aim to bring the Marketplace in line with this practice in the existing insurance market.

As with existing open enrollment periods for employer-based coverage, consumers are strongly encouraged to use the open enrollment period as an opportunity to update their information and reevaluate their health coverage needs for the coming year.

Consumers always have the ability to return to the system for shopping, changing plans, or reporting life changes, or a change to their annual income to ensure they are getting the lowest cost possible on their monthly premium. And, to help ensure the program integrity of how taxpayer dollars are spent, while also protecting consumers from having to pay back tax credits they are no longer eligible for, under the approach that the Federally-facilitated Marketplace would use in 2015, the small number of consumers whose updated income information suggests they no longer qualify for a tax credit next year, will still be auto-enrolled in their current plan, but without a tax credit. State-based Marketplaces may take this approach as well, or propose an alternative.

Under the plans that HHS expects to announce, consumers in the Federally-facilitated Marketplace will receive notices from the Marketplace informing them how to update their information to get a tailored and updated tax credit that keeps up with any income changes. Consumers will receive information from their health insurance company about the premium and the amount they are eligible to save on their monthly bill close to the beginning of the open enrollment period, when they will be able to take action should they choose to do so.

“We are continuing to plan for a second open enrollment period, and as we do so, are mindful of our ongoing work to improve the Marketplace for consumers, offering families a way to make the..."
medical records pertaining to approximately 5,000 to 8,000 patients while assisting the retiring physician to transition her patients to new providers, and while considering the possibility of purchasing some of the physician’s practice.

On June 4, 2009, Parkview employees, with notice that the physician was not at home, left 71 cardboard boxes of these medical records unattended and accessible to unauthorized persons on the driveway of the physician’s home, within 20 feet of the public road and a short distance away from a heavily trafficked public shopping venue.

As a covered entity under the HIPAA Privacy Rule, Parkview must appropriately and reasonably safeguard all protected health information in its possession, from the time it is acquired through its disposition.

“All too often we receive complaints of records being discarded or transferred in a manner that puts patient information at risk,” said Christina Heide, acting deputy director of health information privacy at OCR. “It is imperative that HIPAA covered entities and their business associates protect patient information during its transfer and disposal.”

Parkview cooperated with OCR throughout its investigation. In addition to the $800,000 resolution amount, the settlement includes a corrective action plan requiring Parkview to revise their policies and procedures, train staff, and provide an implementation report to OCR.

OCR offers helpful FAQs concerning HIPAA and the disposal of protected health information: http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/disposalfaqs.pdf

To learn more about non-discrimination and health information privacy laws, your civil rights, and privacy rights in health care and human service settings, and to find information on filing a complaint, visit us at http://www.hhs.gov/ocr/office

The Resolution Agreement can be found on the OCR website at: http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/parkview.html
The Office of Inspector General (OIG) issued a proposed rule on May 12 to amend the civil monetary penalty (CMP) rules at 42 CFR (Code of Federal Regulations) parts 1003 and 1005.

This proposed rule would amend the civil monetary penalty (CMP or penalty) rules of OIG to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on civil money penalties, assessments and exclusions to improve readability and clarity.

The Affordable Care Act of 2010 significantly expanded OIG’s authority to protect Federal health care programs from fraud and abuse. OIG proposes to update its regulations to codify the changes made by ACA in the regulations. At the same time, OIG proposes updates to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other statutory authorities, as well as technical changes to clarify and update the regulations.

ACA provides for CMPs, assessments, and exclusion for:
• Failure to grant OIG timely access to records;
• Ordering or prescribing while excluded;
• Making false statements, omissions, or misrepresentations in an enrollment application;
• Failure to report and return an overpayment; and
• Making or using a false record or statement that is material to a false or fraudulent claim.

ACA significantly expanded OIG’s authority over federal healthcare programs, and the agency is proposing to codify these changes.

The OIG is also proposing:
• To reorganize 42 CFR part 1003 to make the regulations more accessible to the public and to add clarity to the regulatory scheme.
• An alternate methodology for calculating penalties and assessments for employing excluded individuals in positions in which the individuals do not directly bill the federal healthcare programs for furnishing items or services.
• To clarify the liability guidelines under OIG authorities.

Comments are being accepted on this proposed rule through July 11, 2014, 5 pm EST.


New Procedure Codes Effective July 2014

The AMA releases Category III CPT® codes in January and July each year. The codes released in January are effective the following July; the codes released in July are effective the following January. As part of the OPPS July 2014 update, CMS is implementing 27 Category III codes that were released in January 2014. Seventeen of the codes are separately payable under APCs.

The new codes involve:
• Radiostereometric analysis services
• Optical coherence tomography of the breast and ancillary lymph nodes
• Intraluminal GI tract imaging (capsule endoscopy)
• Insertion of drug-eluting implant in the lacrimal canaliculus
• Bioelectrical impedance analysis
• Behavioral assessments
• Adaptive behavior treatments
Additionally, there are ten HCPCS codes also effective July 1, 2014:

- C2644  Brachytherapy source, cesium-131 chloride solution, per millicurie
- C9022  Injection, elosulfase alfa, 1mg
- C9134  Factor XIII (antihemophilic factor, recombinant), Tretten, per 10 i. u.
- Q9970  Injection, Ferric Carboxymaltose, 1mg
- Q9974  Injection, Morphine Sulfate, Preservative-Free or Epidural or Intrathecal Use, 10mg
- S0144  Injection, Propofol, 10mg
- S1034  Artificial Pancreas Device System Including Continuous Glucose Monitor
- S1035  Sensor; Invasive (e.g., Subcutaneous), Disposable, For Use with Artificial Pancreas Device System
- S1036  Transmitter; External, For Use With Artificial Pancreas Device System
- S1037  Receiver (Monitor); External, For Use With Artificial Pancreas Device System

More information on the codes and their status indicators is listed in Table 2 in Transmittal 2971 and the payments are listed in Addendum B for July 2014.

Updates from CMS for the HCPCS codes can be found here: http://www.cms.gov/Medicare/Coding/MedHCPCSgeninfo/index.html?redirect=/MedHCPCSgeninfo/

A Milestone in Protection from Influenza

A statement from Biomedical Advanced Research and Development Authority (BARDA) Director and Deputy Assistant Secretary for Preparedness and Response (ASPR) Robin Robinson, Ph.D.

This week, our nation reached a milestone in battling influenza, with the U.S. Food and Drug Administration's first approval to manufacture seasonal influenza vaccine using cell-based technology in a U.S. facility. That facility, owned by Novartis of Basel, Switzerland, and located in Holly Springs, N.C., now can manufacture cell-based vaccine against seasonal as well as pandemic influenza viruses. This new capability demonstrates the effectiveness of a multi-use approach to emergency preparedness.

Since its establishment in 2006, the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR), has sponsored the development of new technologies for use in emergencies, including the cell-based technology at Holly Springs. These new technologies are flexible enough to produce vaccines and other medical products for a variety of public health emergencies.

In pursuing new technology, BARDA leverages public-private partnerships. We also support development of medical countermeasures – drugs, vaccines, diagnostics and devices – that can be used to diagnose or treat illness or injury in public health emergencies like pandemics or following acts of bioterrorism, as well as day-to-day medical conditions. This multi-use approach strengthens everyday systems and increases our resilience in emergencies.

The Holly Springs facility was built through a partnership established in 2009 between BARDA and Novartis to increase the domestic production capacity of pandemic influenza vaccine and quickly provide additional influenza vaccines to combat public health threats.

In 2012, BARDA broadened this partnership with Novartis and expanded the Holly Springs facility's role in emergency preparedness as one of three national Centers for Innovation in Advanced Development and Manufacturing. These centers provide support for the development and manufacturing of medical countermeasures and can transition efficiently to manufacture pandemic influenza vaccines or other medical products for public health emergencies. The centers also
aid in bringing new medical countermeasures to the market and help train the biopharmaceutical workforce needed in the future.

As a center, the Holly Springs facility can produce up to 200 million doses of pandemic influenza vaccine within six months of the declaration of a pandemic.

In 2012, the Holly Springs facility opened to produce cell-based influenza vaccine that could be authorized by the FDA for use during the emergency. That same year cell-based influenza vaccine called Flucelvax, made by Novartis in Germany, became the first approved by FDA for use in the United States. Now, with the approval of manufacturing the Holly Springs facility, the capacity for seasonal influenza vaccine production in the United States has increase by at least 50 million doses.

This latest FDA approval affirms the value and success possible through public-private partnerships as we move forward bringing our nation the medical countermeasures needed to protect health and save lives every day.

CMS: Prior Authorization to Ensure Beneficiary Access and Help Reduce Improper Payments

CMS announced plans to expand a successful demonstration for prior authorization for power mobility devices, test prior authorization in additional services in two new demonstration programs, and propose regulation for prior authorization for certain durable medical equipment, prosthetics, orthotics, and supplies.

Prior authorization supports the administration’s ongoing efforts to safeguard beneficiaries’ access to medically necessary items and services, while reducing improper Medicare billing and payments. The proposed rule is estimated to reduce Medicare spending by $100 to $740 million over the next ten years.

“With prior authorization, Medicare beneficiaries will have greater confidence that their medical items and services are covered before services and supplies are rendered. This will improve access to services and quality of care,” said CMS Administrator Marilyn Tavenner.

The announcement builds upon lessons learned from the Medicare Prior Authorization of Power Mobility Device Demonstration. Launched in 2012, the demonstration established a prior authorization process for certain power mobility devices.

Based on September 2013 claims data, monthly expenditures for certain power mobility devices decreased from $12 million in September 2012 to $4 million in August 2013 across the seven demonstration states (California, Florida, Illinois, Michigan, New York, North Carolina, and Texas) with no reduction in beneficiary access to medically necessary items.

CMS seeks to leverage this success by extending the demonstration to an additional 12 states. These states include:

- Arizona
- Georgia
- Indiana
- Kentucky
- Louisiana
- Maryland
- Missouri
- New Jersey
- Ohio
- Pennsylvania
- Tennessee
- Washington

This will bring the total number of states participating in the demonstration to 19.

CMS also proposes to establish a prior authorization process for certain durable medical equipment, prosthetics, orthotics, and supplies items that are frequently subject to unnecessary
utilization. Through a proposed rule, CMS will solicit public comments on this prior authorization process, as well as criteria for establishing a list of durable medical items that are frequently subject to unnecessary utilization that may be subject to the new prior authorization process.

The proposed rule was published on May 28, 2014. It is currently on display and can be reviewed at: https://www.federalregister.gov/articles/2014/05/28/2014-12245/medicare-program-prior-authorization-process-for-certain-durable-medical-equipment-prosthetics

The deadline to submit comments is July 28, 2014. CMS will also launch two payment model demonstrations to test prior authorization for certain non-emergent services under Medicare. These services include hyperbaric oxygen therapy and repetitive scheduled non-emergent ambulance transport. Information from these models will inform future policy decisions on the use of prior authorization.

Prior authorization does not create additional documentation requirements or delay medical service. It requires the same information that is currently necessary to support Medicare payment, but earlier in the process. CMS believes prior authorization is an effective way to ensure compliance with Medicare rules for some items and services.

Related CMS Fact Sheets for review:

### CMS Releases Final Rule Concerning Direct Supervision

Reforms to Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and other health care providers will save nearly $660 million annually, and $3.2 billion over five years.

On May 7, 2014, CMS released the Final Rule for Part II Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction. This new rule finalized the previously proposed change of removing the term “direct” from the current requirement at § 482.53(b)(1).

“We received several comments on our proposed change to § 482.53, primarily from professional organizations, hospitals and hospital systems, and individual nuclear medicine technologists. All commenters were supportive of the proposed change with no commenters opposed. In accordance with the comments discussed above, we are finalizing the changes to § 482.53(b)(1) as proposed.”

Together with another rule finalized in 2012, this rule is estimated to save health care providers more than $8 billion over the next five years. This final rule supports President Obama’s unprecedented regulatory retrospective review—or “regulatory lookback”—initiative, where federal agencies are modifying, streamlining or eliminating excessively burdensome and unnecessary regulations on business.

“By eliminating stumbling blocks and red tape we can assure that the health care that reaches patients is more timely, that it’s the right treatment for the right patient, and greater efficiency improves patient care across the board,” said CMS Administrator Marilyn Tavenner.

This rule helps health care providers to operate more efficiently by getting rid of regulations that are out of date or no longer needed. Many of the rule’s provisions streamline health and safety
standards health care providers must meet in order to participate in Medicare and Medicaid.

For example, a key provision reduces the burden on very small critical access hospitals, as well as rural health clinics and federally qualified health centers, by eliminating the requirement that a physician be held to a prescriptive schedule for being onsite. This provision seeks to address the geographic barriers and remoteness of many rural facilities, and recognizes telemedicine improvements and expansions that allow physicians to provide many types of care at lower costs, while maintaining high-quality care.

The rule will also save hospitals resources by permitting registered dietitians and qualified nutritionists to order patient diets directly, which they are trained to do, without requiring the preapproval of a physician or other practitioner. This frees up time for physicians and other practitioners to care for patients.

Major provisions of the rule are:

- Eliminates unnecessary requirements that ambulatory surgical centers must meet in order to provide radiological services that are an integral part of their surgical procedures, permitting them greater flexibility for physician supervision requirements.

- Permits trained nuclear medicine technicians in hospitals to prepare radiopharmaceuticals for nuclear medicine without the supervising physician or pharmacist constantly being present, which will help speed services to patients, particularly during off hours.

- Eliminates a redundant data submission requirement and an unnecessary survey process for transplant centers while maintaining strong federal oversight.

As part of the President’s regulatory lookback initiative, CMS issued a final rule in May, 2012, that also reduces burdensome or unnecessary regulations for hospitals and additional health care providers. Those rules are saving nearly $1.1 billion across the health care system in the first year and more than $5 billion over five years.


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**National Coordinator for Health IT Names Winners of Code-a-Palooza Challenge**

*Digital privacy notice challenge winners also announced*

A new electronic tool designed to help patients and their families use Medicare claims data to make health care choices won the second annual Code-a-Palooza challenge according to announcement today by Karen DeSalvo, M.D., national coordinator for Health Information Technology, at the 2014 Health Datapalooza. The winner is Smart Health Hero by [LyfeChannel](http://www.lyfechannel.com) of San Carlos, California.

In addition, the Office of the National Coordinator for Health Information Technology (ONC) is announcing the winner of the Digital Privacy Notice Challenge: [PatientPrivilege](http://www.patientprivilege.com) of Portland Oregon. This tool will help consumers integrate notices of privacy practices from their healthcare providers and health plans directly into their personal health records or into their providers’ portals. ONC and the Office for Civil Rights collaborated on the Digital Privacy Notice Challenge.

“"The challenge winners and finalists demonstrate how innovation can bring the value of data and information to help patients make smarter choices about their health and care,” said Dr. DeSalvo."
Coalition Calls For Action Against EHRS That Block Interoperability

The Health IT Now Coalition is calling on HHS to decertify electronic health record systems that require extra modules or additional costs to share data, Politico’s “Morning eHealth” reports. The group also is calling on HHS and lawmakers to investigate firms that obstruct data sharing while participating in federal incentive programs (Gold, “Morning eHealth,” Politico, 6/16).

Background

The calls come after a recent RAND Corporation report found that a lack of interoperability hinders technologies that otherwise could lower costs and improve care quality (Health IT Now Coalition release, 6/13). Specifically, the report found that Epic, an EHR vendor, was operating a “closed platform” that limited interoperability.

In response, an Epic spokesperson noted that the report was authored by two Department of Veterans Affairs researchers who suggested the VA health system’s platform as an alternative to Epic’s system (“Morning eHealth,” Politico, 6/16).

Details of Call for Investigation

In a release, Health IT Now Executive Director Joel White said,

“The RAND report reiterates what those in the health IT industry know well: Interoperability must be a priority if we truly want to improve patient outcomes, decrease costs and achieve a technology enabled system.”

The coalition calls for HHS to:

• Work with lawmakers to investigate firms that could be inhibiting data sharing while being involved in federal incentive programs; and
• Revoke certification of EHR systems that require extra modules, expenses or other customization for data sharing.

White said that $24 billion in taxpayer money has been paid over the past three years to health IT systems that do not easily share data (Health IT Now Coalition release, 6/13).

Read the article here: http://www.ihealthbeat.org/articles/2014/6/17/coalition-calls-for-action-against-ehrs-that-block-interoperability
Update to Partial Code Freeze for ICD-9-CM and ICD-10

The ICD-10 Coordination and Maintenance Committee (formerly the ICD-9-CM Coordination and Maintenance Committee) implemented a partial freeze of the ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) codes prior to the implementation of ICD-10 which would end one year after the implementation of ICD-10. There was considerable support for this partial freeze.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93) was enacted, which said that the Secretary may not adopt ICD-10 prior to October 1, 2015.

Accordingly, the U.S. Department of Health and Human Services expects to release an interim final rule in the near future that will include a new compliance date that would require the use of ICD-10 beginning October 1, 2015. The rule will also require HIPAA covered entities* to continue to use ICD-9-CM through September 30, 2015. When published, links will be provided to this interim final rule at: http://www.cms.gov/Medicare/Coding/ICD10/Statute_Regulations.html.

The partial freeze will be implemented as follows:

- The last regular, annual updates to both ICD-9-CM and ICD-10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014 there will be only limited code updates to both the ICD-9-CM and ICD-10 code sets to capture new technologies and diseases as required by section 503(a) of Pub. L. 108-173.
- On October 1, 2015, there will be only limited code updates to ICD-10 code sets to capture new technologies and diagnoses as required by section 503(a) of Pub. L. 108-173. There will be no updates to ICD-9-CM, as it will no longer be used for reporting.
- On October 1, 2016 (one year after implementation of ICD-10), regular updates to ICD-10 will begin.

The ICD-10 Coordination and Maintenance Committee will continue to meet twice a year during the partial freeze. At these meetings, the public will be asked to comment on whether or not requests for new diagnosis or procedure codes should be created based on the criteria of the need to capture a new technology or disease. Any code requests that do not meet the criteria will be evaluated for implementation within ICD-10 on and after October 1, 2016 once the partial freeze has ended.

There are no new ICD-9-CM code updates effective October 1, 2014.


Million Hearts and Eating-Well Magazine Launch Heart-Healthy Nutrition Resource

The Million Hearts initiative announces the launch of a new Healthy Eating and Lifestyle Resource Center, developed in partnership with the Centers for Disease Control and Prevention and Eating-Well magazine. The resource center features lower-sodium, heart-healthy recipes and family-friendly meal plans, with an emphasis on managing sodium intake, a major contributor to high blood pressure and heart disease.

By helping individuals and families access content and recipes to promote consumption of healthier foods, this consumer-friendly addition to existing Million Hearts tools supports the initiative’s goal of preventing one million heart attacks and strokes.

“Because sodium is a major contributor to high blood pressure, it is important to help people understand how they can manage sodium intake at home,” said Janet S. Wright, MD, FACC, Executive Director of Million Hearts. “This online resource offers practical, accessible eating and lifestyle-based solutions for people looking for ways to reduce sodium in their diet and create heart-healthy, tasty meals for themselves and their families.”

All the recipes featured in the resource center include nutritional facts and use everyday ingredients found at local supermarkets and have been tested by Eating Well’s test kitchen. Search and filter options make it easier to quickly find the right meal based on prep time, cuisine, course, and number of servings. The meal plans are flexible, easy to use, convenient, and can be customized to an individual’s dietary needs.

“This resource helps people see that it’s not about giving up the food you love, but choosing lower sodium options that taste great,” said Dr. Tom Frieden, Director of the CDC. “Small changes can make a big difference. We can prevent 11 million cases of high blood pressure each year if everyone reduced their daily sodium intake to 2,300 mg.”

To learn more about the Million Hearts Healthy Eating and Lifestyle Resource Center, visit http://recipes.millionhearts.hhs.gov/. Million Hearts is a joint initiative of the Centers for Disease Control and Prevention and the Centers for Medicare & Medicaid Services. For more information about the initiative and to access resources, visit http://millionhearts.hhs.gov.

About Million Hearts

Million Hearts is a national initiative to prevent 1 million heart attacks and strokes by 2017. Million Hearts brings together communities, health systems, nonprofit organizations, federal agencies, and private-sector partners from across the country to fight heart disease and stroke.