DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

The ICD-10-related implementation date is now October 1, 2015. The switch to the new code set will affect every aspect of how your organization provides care, but with adequate planning and preparation, you can ensure a smooth transition for your practice. Keep Up to Date on ICD-10. Please visit the ICD-10 website for the latest news and resources to help you prepare.

MLN Matters® Number: MM7869

Related Change Request (CR) #: CR 7869

Related CR Release Date: November 5, 2012

Effective Date: January 1, 2013

Related CR Transmittal #: R2588CP

Implementation Date: January 7, 2013

Implementation of Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Consolidated Billing Requirements for Daptomycin and a Clarification of Outlier Services for Calendar Year 2013

Provider Types Affected

This MLN Matters® Article for Change Request (CR) 7869 is intended for physicians, other providers, and suppliers who submit claims to Medicare contractors (carriers, Durable Medical Equipment Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), and/or A/B Medicare Administrative Contractors (A/B MACs)) for End-Stage Renal Disease (ESRD) services provided to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 7869 which provides an update to the ESRD PPS for Calendar Year (CY) 2013, including the billing requirements for Daptomycin, and the CR clarifies Outlier Services for Calendar Year 2013.

Background

The Medicare Improvements for Patients and Providers Act (MIPPA; Section 153(b); see **http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf** on the

Internet) amends the Social Security Act (section 1881(b)(12); see **http://www.ssa.gov/OP_Home/ssact/title18/1881.htm** on the Internet) by requiring the implementation of an End Stage Renal Disease (ESRD) bundled Prospective Payment System (PPS) effective January 1, 2011.

The ESRD PPS was implemented by CR7064 (Transmittal 2134, End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services). See the MLN Matters® article, MM7064, corresponding to CR7064 at **https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7064.pdf** on the Centers for Medicare & Medicaid Services (CMS) website.

ESRD Claims Reporting ESRD-Related Drugs and Biologicals

The "Medicare Benefit Policy Manual" (Chapter 11, Section 30.4.1; see **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf** on the CMS website) lists the drugs and fluids that were included under the composite payment system, which are heparin, antiarrythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl, hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, and verapamil.

The manual also explicitly states, "… drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate." Data analysis of 2011 ESRD claims indicate that ESRD facilities are reporting composite rate drugs resulting in duplicate payment to those ESRD facilities that are receiving a blended payment under the transition period and inappropriate inclusion in the outlier calculation (discussed below).

In addition, in the Calendar Year (CY) 2012 ESRD PPS final rule (see **http://www.gpo.gov/fdsys/pkg/FR-2011-11-10/pdf/2011-28606.pdf** on the Internet) and in CR7617 (Transmittal 150,Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year (CY) 2012), CMS discussed alteplase and other thrombolytic drugs. CMS indicated that a clinical review of the 2007 claims used to develop the ESRD PPS revealed that ESRD facilities routinely used alteplase and other thrombolytic drugs for access management purposes. CMS also indicated that because these drugs are used to accomplish the same effect (that is, vascular access management) as a composite rate drug, they are also considered to be composite rate drugs and, therefore, should not be reported on the ESRD claim.

In CR7617, CMS removed alteplase and other thrombolytic drugs from the outlier calculation but CMS did not implement edits to prevent separate payment to the ESRD facilities that are receiving a blended payment during the transition. See the MLN Matters®

article, MM7617, corresponding to CR7617, at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7617.pdf** on the CMS website. For CY 2013, separate payment for alteplase and other thrombolytics will not be paid separately under the composite rate portion of the blended payment for ESRD facilities receiving a blended payment during the transition.

ESRD-Related Drugs and Biologicals that Qualify as Outlier Services

Medicare regulations at 42 CFR §413.237(a)(1)(i) (see **http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr413_main_02.tpl** on the Internet) provide that ESRD outlier services are those ESRD-related services that were or would have been considered separately billable under Medicare Part B for renal dialysis services furnished prior to January 1, 2011. Therefore, items and services that would have been included under the composite rate do not qualify as an outlier services.

ESRD Claims Reporting Daptomycin

CR7064 provided ESRD consolidated billing requirements for certain Part B services included in the ESRD PPS bundled payment.) See the MLN Matters® article, MM7064, corresponding to CR7064 at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7064.pdf** on the CMS website.) All drugs reported on the ESRD facility claim that do not have an AY modifier are considered included in the ESRD PPS. The list of drugs and biologicals for consolidated billing are designated as always ESRD-related and therefore separate payment is not made to ESRD facilities. Daptomycin is included on the consolidated billing list.

Revision to ESRD Claims Reporting Daptomycin, Effective January 1, 2013

ESRD facilities have the ability to receive separate payment for Healthcare Common Procedure Coding System (HCPCS) code J0878 *Injection, Daptomycin, 1 mg* furnished on or after January 1, 2013, by placing the AY modifier on the 72X claim when Daptomycin is furnished to an ESRD patient that is not for the treatment of ESRD. **The ESRD facility is required to indicate (in accordance with diagnosis coding guidelines) the diagnosis code for which Daptomycin is indicated.**

Revision to ESRD Claims Reporting ESRD-Related Drugs and Biologicals, Effective January 1, 2013

Composite rate items and services should not be reported on the ESRD facility claim. Because ESRD facilities are continuing to inappropriately report composite rate drugs, CMS developed a list of certain drugs and biologicals based on the 2011 claims data that are considered to be composite rate drugs (see attachment A of CR7869, which is at **http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2588CP.pdf** on the CMS website). ESRD facilities that are receiving reimbursement under the transition and have been

inappropriately reporting drugs and biologicals considered to be in the composite rate will no longer be separately paid in the composite rate portion of the blended payment for these drugs effective January 1, 2013. In addition, because these ESRD-related drugs are considered to be in the composite rate they are also considered to be always ESRD-related. Therefore, CMS is updating the list of items and services that, effective January 1, 2013, are subject to consolidated billing requirements which can be found at **http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html** on the CMS website. ESRD-related drugs and biologicals located on this list are not eligible to be paid separately with the AY modifier.

The list of ESRD-related drugs in attachment A of CR7869 is not an all-inclusive list, and ESRD facilities should not be reporting any composite rate items and services on the ESRD claim. ESRD facilities should not change treatment behaviors to receive separate payment. For example drugs and biologicals used for the purpose of access management should not be reported on the claim because, in accordance with the "Medicare Benefit Policy Manual" (Chapter 11, Section 30.4.1; see **http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf** on the CMS website) those drugs are considered to be composite rate drugs. CMS is continuing to monitor the claims data for drug utilization.

The list of ESRD-related drugs and biologicals on attachment B of CR7869 is not an all-inclusive list of the drugs and biologicals that are included in the ESRD PPS. For example, any anti-infective drugs that are used for access management are included in the ESRD PPS. Attachment B has been updated to reflect 2011 claims data. However, any drug or biological (even if not one of the categories in attachment B) that is used for the treatment of ESRD (that is, ESRD-related) is included in the ESRD PPS and is not separately paid.

Clarification of ESRD-Related Drugs and Biologicals that Qualify as Outlier Services, Effective January 1, 2013

Because ESRD facilities are continuing to inappropriately report composite rate drugs, composite rate drugs are incorrectly being included in the outlier calculation. Therefore, we developed a list of drugs and biologicals (attachment A) from the 2011 claims data that are considered to be composite rate drugs. This is not an all-inclusive list and ESRD facilities should not be reporting composite rate items and services on the ESRD claim. The ESRD-related drugs and biologicals listed on attachment A will not qualify as outlier services.

Peginesatide, Effective January 1, 2013

Peginesatide is a new Erythropoiesis-Stimulating Agent (ESA) drug approved for the treatment of anemia in dialysis patients. **Peginesatide has been assigned a permanent HCPCS code of J0890**. This permanent code replaces the temporary code issued Q2047. Peginesatide is subject to ESRD consolidated billing requirements. The drug description indicates use while on dialysis, therefore, it would be inappropriate to bill J0890 with

modifier AY. The consolidated billing requirement may not be overridden with the use of the AY modifier.

Additional Information

The official instruction, CR7869, issued to your carriers, DME MACs, FIs, and A/B MACs regarding this change may be viewed at **http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2588CP.pdf** on the CMS website.

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

MLN Matters® article, MM7064 "End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services" found here **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7064.pdf** on the CMS website**.**

MLN Matters® article, MM7617 "Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year (CY) 2012" found here **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7617.pdf** on the CMS website.

News Flash - Diabetes and the Seasonal Flu - November is National Diabetes Awareness Month. Diabetes can weaken the immune system, which can put seniors and others with diabetes at greater risk for flu-related complications like pneumonia. Medicare provides coverage for one seasonal influenza virus vaccine per influenza season for all Medicare beneficiaries. Medicare generally provides coverage of pneumococcal vaccination and its administration once in a lifetime for all Medicare beneficiaries. Medicare may provide coverage of additional pneumococcal vaccinations based on risk or uncertainty of beneficiary pneumococcal vaccination status. Medicare provides coverage for the seasonal flu and pneumococcal vaccines and their administration for seniors and others with Medicare with no co-pay or deductible. And remember, seasonal flu vaccine is particularly important for health care workers, who may spread the flu to their patients. Don't forget to immunize yourself and your staff. Protect your patients. Protect your family. Protect yourself. *Know what to do about the flu.*

Remember – The influenza vaccine plus its administration and the pneumococcal vaccine plus its administration are covered Part B benefits. The influenza vaccine and pneumococcal vaccine are NOT Part D-covered drugs. CMS has posted the 2012-2013 Seasonal Influenza Vaccines Pricing. You may also refer to the MLN Matters® Article #MM8047, "Influenza Vaccine Payment Allowances - Annual Update for 2012-2013 Season."

For more information on coverage and billing of the flu vaccine and its administration, please visit the CMS Medicare Learning Network® Preventive Services Educational Products and CMS Immunizations web pages. And, while some providers may offer the flu vaccine, others can help their patients locate a vaccine provider within their local community. HealthMap Vaccine Finder is a free, online service where users can search for locations offering flu vaccines.