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July 21, 2016

Via Electronic Mail Only
Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

AdvaMed is writing to express concern over the Medicare Learning Network Matters Advisory (SE 1609) dated April 25, 2016, which addresses CMS' payment policies with respect to external infusion pumps used in connection with prolonged infusions of drugs or biologics that are started in a physician office or outpatient hospital department (Advisory).[1] The billing process outlined in this advisory constitutes a significant change from the process providers and suppliers have used for years. Additionally, the advisory does not clearly state an effective date. As such, AdvaMed requests that providers and suppliers not be required to comply with the policies outlined in the advisory until January 1, 2017. This delay in effective date will provide the time needed to allow providers and suppliers to come into compliance with the Advisory and to educate their patients and customers regarding the changes.

AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. AdvaMed is committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings and supports a system with payment weights and payment rates that include sufficient resources to account for the costs of the medical technologies associated with hospital outpatient and ambulatory surgical center procedures.

[1] Medicare Policy Clarified for Prolonged Drug and Biological Infusions Started Incident to a Physician's Service Using an External Pump, SE1609 (April 25, 2016), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/SE1609.html.

For many years patients have received chemotherapy and/or other highly complex drug or biologic agents in the physician office or outpatient hospital setting via electric intravenous (IV) infusion pumps that regulate the speed and flow of the medication. These pumps are mounted on IV poles that are designed to remain in the physician's office or outpatient department. Certain regimens, however, require that the patient receive an infusion of the chemotherapeutic agent for a period of eight hours or longer. In these instances, the patient is given a portable, battery-operated pump, which permits them to leave the office or outpatient department and to continue the infusion at home. After completing the infusion, the patient may return to the office or outpatient department to have the pump refilled or disconnected.

Prior billing guidance for pumps used for prolonged infusions lead to the practice of having DME suppliers bill the Medicare program directly for the equipment under the DME benefit. This was a standard billing approach used for many cases with prolonged infusions until the recent advisory was issued. However, pursuant to the new guidance CMS will treat prolonged infusion services as incident to the physician's service. The new guidance further states that the pumps and drugs used cannot be billed on DME supplier claims.

Physicians have not historically included the charge for battery-operated pumps in their claims due to the fact that this device cost is not included in the practice expense costs for the associated chemotherapy administration codes. If the cost of the battery-operated pumps is to be considered part of the costs incident to the service, AdvaMed recommends that CMS adopt measures to ensure that physician reimbursement for prolonged chemotherapy administration services account for the use of these pumps.

The new policy constitutes a significant departure from the previous billing method and it will take education and time for stakeholders to understand and accommodate the new requirements. As such, AdvaMed is requesting that CMS grant an extension, through January 1, 2017, for implementing these new changes. This additional time will allow providers and clinics to modify their internal billing systems and to make the necessary adjustments to ensure that the new billing directives are properly implemented. It will also allow time for CMS to modify the costs for the chemotherapy administration codes, through some mechanism, to ensure appropriate reimbursement for physicians using these pumps. Lastly, an extension will provide an opportunity for the A/B MACs to provide uniform guidance to physicians.

AdvaMed appreciates CMS' consideration of our recommendations on this issue. Please feel free to contact me at 202-434-7203 or dmay@advamed.org or DeChane Dorsey at 202-434-7218 or ddorsey@advamed.org if you have any questions regarding these comments.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery