CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

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New CMS Proposals Streamline Medicare Coverage, Payment, and Coding for Innovative New Technologies and Provide Beneficiaries with Diabetes Access to More Therapy Choices

Durable Medical Equipment (DME) proposed rule would reduce administrative burden for new innovative technologies

On October 27, under the leadership of President Trump, CMS proposed new changes to Medicare Durable Medical Equipment, Prosthetics, Orthotic Devices, and Supplies (DMEPOS) coverage and payment policies. This rule would provide more choices for beneficiaries with diabetes, while streamlining the process for innovators in getting their technologies approved for coverage, payment, and coding by Medicare.

The proposed rule would expand the interpretation regarding when external infusion pumps are appropriate for use in the home and can be covered as DME under Medicare Part B, increasing access to drug infusion therapy services in the home. The proposed rule also drastically reduces administrative burdens – such as complicated government coverage, payment, and coding processes – that block innovators from getting their products to Medicare beneficiaries in a timely manner. This action aligns with President Trump's Executive Order on Protecting and Improving Medicare for Our Nation's Seniors.

"With the policies outlined in this proposed rule, innovators have a much more predictable path to understanding the kinds of products that Medicare will pay for," said CMS Administrator Seema Verma. "For manufacturers, bringing a new product to market will mean they can get a Medicare payment amount and billing code right off the bat, resulting in quicker access for Medicare beneficiaries to the latest technological advances and the most, cutting-edge devices available. It's clearly a win-win for patients and innovators alike."

Due to administrative constraints, the process for making Medicare benefit classifications, pricing determinations, and creating billing codes for DMEPOS used to routinely take up to 18 months to complete. Last year, CMS changed this process through sub-regulatory guidance to reduce that timeframe to six months in many cases, and is now proposing to establish a streamlined process for coding, coverage, and payment in regulation. Under this accelerated process, benefit classification and pricing decisions could happen on the same day the billing codes used for payment of new items take effect, which would facilitate seamless coverage and payment for new DMEPOS and services. If finalized, this proposed rule would allow innovators to bring their products to Medicare beneficiaries quicker giving them more choices and increased access to the latest, cutting-edge devices.

If finalized, this proposed rule will also expand Medicare coverage and payment for Continuous Glucose Monitors (CGMs) that provide critical information on blood glucose levels to help patients with diabetes manage their disease. Currently, CMS only covers therapeutic CGMs or those approved by the FDA for use in making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM.

CMS is proposing to classify all CGMs (not just limited to therapeutic CGMs) as DME and establish payment amounts for these items and related supplies and accessories. CGMs that are not approved for use in making diabetes treatment decisions can be used to alert beneficiaries about potentially dangerous glucose levels while they sleep and that they should further test their glucose levels using a blood glucose monitor. With one

in every three Medicare beneficiaries having diabetes, this proposal would give Medicare beneficiaries and their physicians a wider range of technology and devices to choose from in managing diabetes. This proposal will improve access to these medical technologies and empower patients to make the best health care decisions for themselves.

In addition, the proposed rule would expand classification of external infusion pumps under the DME benefit making home infusion of more drugs possible for beneficiaries. An external infusion pump is a medical device used to deliver fluids such as nutrients or medications into a patient's body in a controlled manner. The proposal would expand classification of external infusion pumps as DME in cases where assistance from a skilled home infusion therapy supplier is necessary for safe infusion in the home, allowing beneficiaries more choices to get therapies at home instead of traveling to a health care facility.

Lastly, in the proposed rule, CMS proposes to continue to pay higher amounts to suppliers for DMEPOS items and services furnished in rural and non-contiguous areas to encourage suppliers to provide access and choices for beneficiaries living in those areas. CMS is making this proposal based on previous stakeholder feedback that indicate unique challenges and higher costs for providing for DMEPOS items for beneficiaries in rural and remote areas.

For More Information:

- Proposed Rule
- Fact Sheet

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