New Federal Rule Could Affect Infusion Site of Care Amid COVID-19 Pandemic

Summary

The Centers for Medicare & Medicaid Services (CMS) issued a new Interim Final Rule (IFR) that is intended to allow additional beneficiaries, especially those who are at high-risk, to receive home infusions amid COVID-19 transmission concerns. Specifically, the CMS clarified the definition of “homebound” under the Medicare Home Health Benefit and temporarily suspended enforcement of the National and Local Coverage Determinations (NCD and LCD) related to home infusion services. Uncertainties remain as to how these new flexibilities will be utilized, as well as how these flexibilities could impact treatment outcomes.

Background

Currently, fee-for-service (FFS) Medicare has limited coverage for home infusion therapies and has only recently moved to implement a defined home infusion benefit. While the Home Health
Prospective Payment System (also known as the Home Health Benefit) generally does not include payment for infused therapies, it does cover the costs of drug administration and supplies in an in-home setting when specific conditions are met. Namely, the patient must be deemed “confined to the home” (or “homebound”), require skilled medical care, and be under a physician’s plan of care.

To be considered homebound, an individual must meet defined requirements. Specifically, the individual must be “confined to the home” either (1) need the aid of supportive devices or the assistance of another person in order to leave their place of residence because of an illness or injury; or (2) have a condition such that leaving his or her home is medically contraindicated.

If the patient is deemed homebound, certain infused drugs (along with the external infusion pumps utilized to administer the drugs) may be covered under the Part B Durable Medical Equipment (DME) benefit, while physician or nursing services and supplies provided incident to the infusion are covered under the Medicare Home Health Benefit.

If the beneficiary is not homebound, Medicare covers only the external infusion pump and the eligible infused drug under the DME benefit. Medicare does not pay for the skilled nursing or physician costs necessary to ensure the proper administration of the drug or wellness of the patient post treatment or other equipment costs; FFS beneficiaries must cover these costs out of pocket. In 2016, Congress passed the 21st Century Cures Act, which will create a home infusion therapy benefit to more fully pay for goods and services provided in connection to an infusion for a larger number of Part B drugs and Part B beneficiaries—including those who are not homebound. However, that benefit will not apply until 2021. To bridge the gap before 2021, the Bipartisan Budget Act of 2018 created a temporary home infusion therapy services benefit to pay for goods and services related to the administration of certain Part B covered therapies between 2019 and 2021.

Whether homebound or not, the coverage of the Part B drug under the DME benefit is defined under a Local Coverage Determination (LCD) and National Coverage Determination (NCD) related to the use of infusion pumps. The LCD and NCD, along with Medicare Administrative Contractors (MACs), control and define when a pump would be required to administer the drug and whether the drug can be covered when infused in a home-based setting. Taken together, current statutory and regulatory policies present an often-limiting set of circumstances where FFS Medicare beneficiaries are eligible to receive infused therapies in the home setting.
Changes Related to COVID-19

Quarantines, social distancing, and transportation access challenges are complicating the ability for patients to travel to designated infusion sites of care to receive delivery of infused drugs. However, the current limitations with respect to the coverage of home infusion have limited the ability of providers to transition infusion treatments to other sites of care, including the home.

The CMS noted that some stakeholders had requested the agency extend new flexibilities to allow for the use of the home setting for infusions when deemed necessary by the patient and the provider given COVID-19 concerns. In light of these requests and as part of its broader efforts to expand coverage and reimbursement flexibilities given the public health emergency, the CMS has issued an IFR stating that:

- **It has revised its interpretation of the definition of “homebound” under the Medicare home health benefit.** Specifically, CMS will interpret a patient to be homebound when a physician has determined that a patient has or is suspected of having COVID-19 or where a patient is medically contraindicated from leaving their home due to COVID-19 concerns. The CMS intends this flexibility to be read broadly and to apply to most Medicare beneficiaries. The CMS hopes this will increase access to Medicare home health coverage.

- **It will temporarily not enforce the requirements of the infusion LCD (L33794 External Infusion Pumps) or the NCD (280.14 Infusion Pumps) related to the coverage of infused drugs under Part B.** This may allow other Part B drugs, including those that do not require a pump, to be infused in a beneficiary’s home. Additionally, to the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service or require specific supervision requirements, the CMS will allow the chief medical officer of a facility to choose not to apply those delivery or supervision requirements during the public health emergency.

- **It has revised the definition for “direct supervision” to allow direct supervision to be provided using “real-time interactive audio and video technology.”** The CMS notes that this could include instances where the physician enters into a contractual agreement with third-party entities (e.g., home health agencies) necessary to provide care that would ordinarily be provided incident to the physician’s service. In such instances, the third-party entity would seek payment for their services from the billing provider and not submit a claim to Medicare for such services. The CMS is seeking comment on potential guardrails and potential risks of this policy change. The IFR does not provide direction on the number of real-time direct supervisions through audio or video technology that can occur simultaneously. In addition, state physician licensing and scope-of-practice requirements might impact the authority of providers to supervise or other health care providers to act under supervision.

Even with these key policy revisions, the underlying payment or coverage policies related to Part B drugs would not change. For example, the physician would purchase the drug, contract with a third-party entity (e.g., home health agency, home infusion provider) to conduct the infusion in
the patient’s home, provide the telehealth direct supervision services surrounding the infusion, and bill for the services and drug reimbursement to a Part B MAC. The physician would then provide payment to the third-party entity based on the contractual agreement; the third-party entity would not bill Medicare for the administration services provided on behalf of the physician. Also, any existing NCDs and LCDs (other than those temporarily not enforced via this IFR) would still inform coverage and payment for applicable therapies (e.g., limitations on patient population).

**Implications**

These new flexibilities may impact how Part B covered drugs are delivered during the public health emergency. While they may give providers additional opportunities to decide when a drug administration can be safely performed in a home-based setting, many of the coverage and reimbursement requirements related to Part B drugs remain unchanged.

As healthcare in the US continues to evolve to address patient care challenges brought about by COVID-19, additional factors to consider include:

- The unknown extent to which providers will use these flexibilities to engage in third-party contracting arrangements that allow for the provision of drug administration in the home
- The lack of clarity in the IFR on current DME vendors’ ability to furnish infused therapies to patients that would now be considered homebound
- The need (or lack of need) for an external infusion pump; this is addressed in the suspension of the respective NCDs/LCDs, but the degree to which this occurs and patients receive Part B therapy without ambulating is subject to evaluation
- Uncertainties related to the interpretation and implementation of the IFR; for example, the process of the drug acquisition and shipment to a contracted third-party entity
- The lack of creation by the IFR of greater utilization management for drugs or biologics (based on Avalere’s interpretation); rather the patient access-to-care issue is being addressed with the IFR allowing for telehealth and physician contracting with a home infusion network, allowing patients to receive intravenous administration provided by their physician, an infusion center, or their physician through a contract with a home infusion network

It will be important for the CMS to consider and closely examine how this flexibility could impact treatment outcomes and how effectively care can be delivered in the home setting. In addition, adoption of these flexibilities may vary based on the patient’s condition or diagnosis in addition to the type of provider, supplier, and home health agency. Much of the uptake in these flexibilities will depend on the specific aspects of what did and did not change under these new rules, local coverage and MAC dynamics, and the social determinates of health considerations.
that will affect when and how effectively care can be delivered in the home setting.

Avalere is engaging stakeholders on these considerations and the potential impacts of these changes not only during the public health emergency but also afterward. To learn more about these changes, how we can help with internal and external education efforts, and engagement with regulators and contracted entities around these flexibilities, connect with us.