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CMS Announces New Flexibilities For Coverage of Medicare Part B Drugs Administered in a Home Setting

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Healthcare

On March 30, 2020, CMS announced that, in light of the coronavirus pandemic, it would be waiving several Medicare reimbursement regulations to permit reimbursement to providers treating patients remotely, consistent with current social distancing guidelines, and would be allowing providers to receive reimbursement for Medicare Part B drugs that are administered to a patient in his or her home. Although there is no general rule that prohibits Medicare Part B coverage for drugs that are administered in a patient's home, many prescription drugs are typically covered by Part B only when administered in an office or clinic setting.

CMS's coronavirus waivers expand the types of health care personnel that are authorized to administer drugs to a patient, relax physical presence requirements for physicians who must "directly supervise" Medicare-covered services, expand the scope of patients qualifying to receive services in a home setting, and expand the types of practitioners and entities eligible to provide services in a patient's home. These waivers do not, however, relax any requirements that a drug be "reasonable and necessary." Nor do they ease requirements imposed by national or local coverage determinations that a drug's route of administration be limited by FDA-approved labeling. The waivers also do not provide any additional flexibility to allow Medicare Part B drugs to be usually self-administered by the patient in the home setting.

This client alert reviews the various ways in which prescriptions drugs can be covered under Medicare Part B. It further suggests ways that a provider can care for patients in their home such that the provider receives Medicare Part B coverage under CMS's new waivers.

Background

As a general rule, Medicare Part B does not independently cover drugs or biologicals for outpatients. Drugs are covered, however, if they are provided as a part of a separately covered Medicare Part B benefit. For example, drugs are covered if they are administered through a covered item of durable medical equipment (DME) or "incident-to" a physician's services. Medicare Benefit Policy Manual, Ch. 15, §§ 50, 110.3.

In addition, Medicare Part B does not cover drugs or biologics that are "usually self-administered by the patient," unless the drug is one of the six types of drugs specifically exempted from this requirement. 42 C.F.R. §410.26(a)(8); Medicare Benefit Policy Manual, Ch. 15, §50. Drugs that are administered by self-injection, by subcutaneous injection, or in pill form

are presumed to be self-administered, absent evidence to the contrary. Benefit Manual, Ch. 15, §50.

All covered drugs must also be "reasonable and necessary" for the treatment of the illness or injury. Benefit Manual, Ch. 15, § 50.4. At a minimum, coverage is available for drugs that have been approved by FDA, and in instances where administration and use of the drug is consistent with the approved indications for use in the drug's labeling. Id. at §50.4.2. Coverage decisions for an off-label use of a drug are made on a case-by-case basis by the Medicare Administrative Contractor ("MAC"). Id.

Aside from these general rules for drug coverage, Medicare Part B places additional limits on coverage and reimbursement based on the type of benefit under which the drug is covered. These rules are reviewed below.

A. Drugs administered through a covered DME item

Medicare coverage is available where a drug or biological is administered through a covered item of DME, and where the drug is necessary for the effective use of the DME. Benefit Manual, Ch. 15, § 110.3. By definition, DME is covered only when the item is "appropriate for use in the home," and so all drugs covered under the DME benefit must be administered in a patient's home. 42 C.F.R. § 414.202; Benefit Manual, Ch. 15, §110.1. DME provided in an institutional facility such as an assisted living facility or an intermediate care facility for individuals with intellectual disabilities (ICF/IID) is covered, but DME is not covered if it is provided in a hospital or skilled nursing facility. Benefit Manual, Ch.15, § 110.1(D). This means, for example, that a patient living in a nursing home that is dually certified as both a Medicare skilled nursing facility and a Medicaid nursing facility is not eligible to receive a DME benefit, because those facilities primarily provide skilled nursing care and thus do not qualify as a beneficiary's home. Drugs provided to patients in those settings will need to be covered either as "incident-to" a physician's services under Part B or under the Medicare Part D prescription benefit.

Providers or suppliers that dispense prescription drugs through DME are required to furnish the drug directly to the patient for whom a prescription is written. Benefit Manual, Ch. 15, § 110.3. That is to say, the provider or supplier must be licensed by the State to dispense prescription drugs, and must bill and receive payment in its own name. Id.

Examples of drugs covered under the DME benefit include inhalation drugs administered via a nebulizer, heparin used with a home dialysis system, and IV drugs requiring a pump for infusion. Infused drugs include continuous subcutaneous insulin, chemotherapy, morphine, and other drugs administered by a prolonged infusion of at least 8 hours. Drugs covered under the DME benefit are generally paid by Medicare Part B at average sales price (ASP) + 6 percent. DME infusion drugs, however, are paid at 95 percent of average wholesale price (AWP), rather than ASP + 6 percent. SSA, §1842(o)(1)(D)(i).

B. "Incident to" physician services

Prescription drugs can also be covered under Medicare Part B when they are provided "incident to" a physician's services. In order for a drug to be provided "incident to" a physician's service, the cost of the drug must be included as a part of the physician's bill and represent an expense to the physician; the drug must be furnished by a physician; and the drug must be administered by a physician. 42 C.F.R. § 410.26(b); Benefit Manual, Ch. 15. §50.3. Drugs administered

"incident to" a physician's service are reimbursed at ASP + 6 percent, and the physician is paid for administering the drug under the Physician Fee Schedule or the Hospital Outpatient Prospective Payment System.

Drugs can be reimbursed under the "incident to" benefit when administered by auxiliary personnel with whom the physician has an employment or contractual relationship, including non-physician practitioners licensed by the state to administer drugs (e.g. physician assistants, nurse practitioners, and clinical nurse specialists). Drugs administered by non-physician practitioners are covered, however, only if the physician has direct and personal supervision of the administering practitioner. 42 C.F.R. § 410.26(b)(5); Benefit Manual, Ch. 15, §50.3(B).

In order to provide direct personal supervision, a physician must generally be physically present and available to provide assistance, direction, and supervision. In an office setting, this means that the physician must be present in the office suite and be able to immediately provide assistance and direction throughout the time the practitioner is performing services. 42 C.F.R. § 410.26(a)(2); Benefit Manual, Ch. 15, § 50.3(B). This requirement does not preclude coverage for drugs administered in a patient's home, but the administering non-physician practitioner must be physically accompanied by the physician on the house call. Benefit Manual, Ch. 15, §50.3(B).

There is one limited exception to this direct supervision rule: Medicare Part B requires only "general" (as opposed to direct and personal) physician supervision of an appropriately licensed non-physician practitioner for certain types of services (including injections) if provided to "homebound" patients. Benefit Manual, Ch. 15, §60.4. In this case, the physician would not need to be physically present at the patient's place of residence when the service is performed, although the service must still be performed under the physician's overall supervision and control. Id. at §60.4(A). Patients are considered "homebound" if they meet two criteria:

- Criterion 1: patients must either:
  - need the aid of supportive devices to leave their house; or
  - have a condition that would make leaving their home medically contraindicated.
- Criterion 2:
  - patients must normally be unable to leave their home; and
  - if leaving home, the act must require a considerable and taxing effort.

Benefit Manual, Ch. 15, §60.4.1.

For patients that are considered "homebound," Medicare Part B covers the administration of injected drugs in a home setting without direct physician supervision. Id. at §60.4(B). It does not, however, cover drugs administered via infusion, inhalation, or other routes of administration. Id. And even injected drugs are not covered by Part B if the injection could have been provided to the patient by a participating home health agency (HHA) in the area on a timely basis. Id. at §60.4(C).

HHAs can receive reimbursement for skilled nursing services (including injections) provided to "homebound" patients, if the need for the service is intermittent (i.e., is needed fewer than seven days a week). Benefit Manual, Ch. 7, §30. The home health benefit does not, however, cover

the cost of the drug or biologic provided through the injection, except in the case of a statutorily covered osteoporosis drug. SSA, §1861kk; Benefit Manual, Ch.7, §40. For this reason, the home health benefit cannot generally provide an alternative avenue for prescription drug coverage under Medicare Part B. And physicians seeking to take advantage of the "homebound" exception to direct supervision under the "incident to" benefit would receive reimbursement for injectable drugs in only a small subset of circumstances.

C. Statutory coverage of specific drugs

Medicare Part B covers and reimburses certain statutorily identified type of drugs. These drugs are covered even if they are "usually self-administered" and even if they are administered in a home setting without direct personal physician supervision. SSA, § 1861(s)(2); Benefit Manual, Ch. 15, §50.5. These drugs are:

- Immunosuppressive drugs used in therapy for beneficiaries that receive a Medicare-covered transplant;
- Oral anti-cancer drugs that contain the same active ingredient and are used for the same indications as Part B-covered chemotherapy drugs furnished "incident to" a physician's service;
- Oral anti-emetics, if the oral product is used as a full therapeutic replacement for intravenous anti-emetic drugs within 48 hours of IV chemotherapy administration;
- Blood clotting factors approved for hemophilia or Vol Willebrand's disease;
- Erythropoietin, when used for the approved indication to treat anemia in patients with chronic renal failure and undergoing dialysis; and
- Intravenous immune globulin (IVIG), where a physician has determined that administration of IVIG in the patient's home is medically necessary.

Effect of CMS's Coronavirus Waivers

CMS's coronavirus waivers allow for greater Medicare Part B drug coverage by relaxing the direct supervision rules, and broadening the types of practitioners eligible to provide services, under the "incident to" benefit. These waivers can give providers and suppliers a broader set of possibilities for administering drugs in a patient's home, and minimize physical contact consistent with current social distancing recommendations. A full list of CMS's waivers is available here.

A. Allowing physician supervision without physical presence

CMS's new waivers allow physicians to meet various supervision requirements without having to be physically present. Most importantly, CMS now allows physicians to meet the "direct supervision" requirements using real-time audio/video technology. CMS also waived National Coverage Determination (NCD) and Local Coverage Determination (LCD) requirements requiring a physician's physical presence, including face-to-face visits for evaluations and assessments. Under these waivers, non-physician practitioners are able to travel to a patient's home to administer a prescribed drug, while the physician is available via real-time audio or video technology to supervise. The waiver does not, however, allow non-physician practitioners to administer prescribed drugs under a physician's "general" supervision (i.e. without any real-time supervision) to patients who are not "homebound."

For patients receiving services in a hospital outpatient department or a critical access hospital, CMS waived direct supervision requirements for non-surgical extended duration therapeutic services, and allows physicians to instead provide "general" supervision. This means that the physician does not need to be physically available in the office suite, but the services can instead be performed under the physician's general direction.

Importantly, the coronavirus waivers do not relax CMS's rules prohibiting Medicare coverage for drugs that are "usually self-administered" by the patient. Providers and suppliers that would like to address concerns surrounding patient access to prescribed drugs by allowing patients to self-administer drugs in their home will need to carefully consider how that change may affect the status of the drug as "not usually self-administered." The determination of whether a drug will continue to be covered and reimbursed under the "incident to" benefit is made by the MAC.

In addition, CMS has not waived any rules limiting coverage to only "reasonable and necessary" uses of a drug, as determined by the drug's indication for use in its FDA-approved labeling. For this reason, CMS's waivers would not overcome any FDA requirements (as indicated in the labeling) that the drug be administered at a specific location or by specific types of practitioner, or that administration of the drug be directly supervised by a physician. Decisions about coverage and reimbursement of an off-label use of the drug will be made by the MAC.

B. Expanding the types of personnel and entities that can provide services

Under the new waivers, CMS expanded the definition of "auxiliary personnel" who are able to administer drugs under a physician's direct supervision beyond staff directly employed or contracted by the physician, to also include staff employed by other types of provider or supplier entities, including home health agencies, home infusion therapy suppliers, and entities providing ambulance services. Under this provision, the physician could enter into a contractual arrangement with such entities to allow their staff to function as "auxiliary personnel" and provide services to patients in their home under the "incident to" benefit. The physician would still need to provide direct supervision of these personnel, but that supervision could be provided through real-time audio or video, consistent with other CMS waivers.

Auxiliary personnel providing services under the "incident to" benefit would not directly bill Medicare for their services, and would not be eligible for reimbursement for those services under the home health benefit or other Medicare benefit types. Rather, the provider/supplier employing the auxiliary personnel would seek payment from the billing physician, as governed by the contractual arrangement, and the billing physician would be able to seek payment from Medicare as they normally would. Although CMS guidance does not make it clear, the billing physician would likely be reimbursed for the service and the cost of the drug as they normally would under the "incident to" benefit, and would bear the full cost of the contractual services provided by the auxiliary personnel.

Aside from expanding the types of entities qualifying as "auxiliary personnel," CMS also waived any NCD or LCD requirements that require a specific practitioner type or physician specialty to furnish or supervise a service. CMS similarly waived Medicare requirements that physicians and non-physician practitioners be licensed in the state where they are providing services if those states are experiencing a coronavirus emergency. Practitioners must apply for and obtain licensure waivers from CMS. This does not, however, waive any state or local licensure requirement.

C. Expansion of the "homebound" definition for Home Health Agencies

CMS expanded the definition of a "homebound" individual under the home health benefit to include any beneficiaries that have been advised by their physician not to leave their home because of a confirmed or suspected COVID-19 diagnosis, or because the beneficiaries have a condition that makes them more susceptible to contract COVID-19. The definition does not include individuals who are not at greater risk of infection, but are nonetheless voluntarily "self-isolating" in order to protect themselves or their family from being infected. Although CMS does not state so explicitly, this expanded definition likely also expands the "homebound" exception under the "incident to" benefit, as the two definitions are identical. As a result, in certain limited circumstances, a non-physician practitioner could be authorized to administer an injected drug in a patient's home under a physician's general supervision, without requiring either physical or remote monitoring.

The benefit of this expanded definition is limited, however, for two reasons. First, CMS did not expand the types of services that are covered under the "homebound" exception under the "incident to" benefit. As a result, non-injected drugs administered in the home will still require direct (albeit remote) physician supervision. Nor will this new definition allow coverage for "injected" drugs if the injection could have been administered to the "homebound" patient under the home health benefit.

Second, CMS did not expand coverage and reimbursement for drugs and biologics under the home health benefit, and so while more patients may qualify to receive skilled nursing care in their home as a result of the expanded definition of a "homebound" patient, providers would only be reimbursed for the cost of providing services, and not for the cost of the drug administered.

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