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DATE	July 20, 2020		
SUBJECT	Medicare Coverage of the Infusion Drug ONPATTRO® Under the Durable Medical Equipment Benefit Category		

The Centers for Medicare & Medicaid Services (CMS) has clear authority to cover the non-self-administrable infusion drug ONPATTRO® (patisiran) under the Medicare durable medical equipment (DME) benefit category when the drug is administered in the home using a durable external infusion pump. Indeed, the Social Security Act (SSA) clearly evinces Congress's specific *intent* that such a non-self-administrable infusion drug be covered under the DME benefit category: Congress established a home infusion therapy benefit category that *necessarily* presumes that non-self-administrable infusion drugs (and associated pumps), where appropriate for administration by a qualified practitioner in the home setting, are covered under the DME benefit category. In short, Congress has made clear that such non-self-administrable drugs are covered under the DME benefit category when administered using a durable external infusion pump.

I. Background

A. Medicare benefit categories related to home infusion drugs and associated professional services

In 2016, Congress enacted section 5012 of the 21st Century Cures Act, which established a new benefit category for home infusion therapy services. Home infusion therapy involves "the intravenous or subcutaneous administration of drugs or biologicals to an individual at home" through an external infusion pump.[1] The new home infusion therapy benefit category is scheduled to take effect on January 1, 2021, and covers certain professional services (and education) associated with furnishing such home infusion therapy when furnished by a qualified home infusion therapy supplier.[2]

[1] CMS, Home Infusion Therapy Services, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview (last updated June 25, 2020).

[2] *See* SSA § 1861(iii)(1)–(2). In the interim period before the new home infusion therapy benefit takes effect, Congress has also enacted a transitional payment for home infusion therapy, which expires on December 31, 2020.

Although the new home infusion therapy benefit category covers the *professional services* related to providing home infusion therapy, it does not cover the infusion *pump* or infusion *drug* (or other related supplies). Rather, the pump and drug are covered under the DME benefit category, as Congress has expressly confirmed.[3] In other words, the new home infusion therapy benefit category is a *nullity* with regard to a particular drug if that drug and the pump used to administered it are not covered under the DME benefit category, because, if the pump and drug are not covered under the DME benefit category, there are no professional services to cover under the home infusion therapy benefit category.

That the pump and drug are covered under the DME benefit category is consistent with longstanding Medicare coverage policy. Medicare covers durable medical equipment under the DME benefit category.[4] Supplies that are necessary for the effective use of DME are also covered under the DME benefit category.[5] Consistent with this policy, certain infusion drugs are covered under the DME benefit category as supplies necessary for the effective use of an external infusion pump—where the pump used to administer such drugs meets the definition of DME.[6] This policy is implemented through the Local Coverage Determination (LCD) for External Infusion Pumps (LCD L33794), which is a Medicare Administrative Contractor (MAC)-administered coverage policy used to identify whether (and in what circumstances) infusion drugs are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" when administered using an external infusion pump.[7]

B. ONPATTRO and MAC interpretations of the DME benefit category with respect to non-self-administrable infusion drugs

The MACs have taken the position that ONPATTRO *may not* be covered under the DME benefit category because it is a non-self-administered infusion drug. In the MACs' view, non-self-administrable drugs are categorically excluded from coverage under the DME benefit category.

More specifically, in 2019, an LCD reconsideration request was submitted to one of the DME MACs related to the LCD for External Infusion Pumps. The request asked that the MAC add the infusion drug ONPATTRO to the list of infusion drugs covered under the LCD when administered in the home using an external infusion pump that is an item of DME. ONPATTRO is an infusion drug used in the

3 *See id.* § 1861(iii)(c) (a "home infusion drug" is a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual *through a pump that is an item of durable medical equipment*," but that is not an insulin pump system, where the drug is not included on the self-administered drug exclusion list) (emphasis added).

4 *See id.* § 1834(a).

5 *See* CMS, Medicare Part B Home Infusion Therapy Services with the Use of Durable Medical Equipment 2 (2019) (stating that the DME benefit includes the external infusion pump, related supplies, and certain infusion drugs), *available at* https://www.cms.gov/files/document/se19029.pdf.

6 *See, e.g.*, LCD on External Infusion Pumps at 4 ("Payment may be made for supplies that are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment.").

7 SSA § 1862(a)(1)(A); *see also* CGS, *Drugs Used with External Infusion Pumps – Coverage and Billing Reminders* (2011) (explaining that, if a durable pump is used to administer an infusion drug not listed in the LCD, "[t]he pump is eligible for coverage under the DME benefit, but because the drug is not listed in the LCD, all items (the pump, drug, and any associated supplies) will be denied as not reasonable and necessary"), *available at* https://www.cgsmedicare.com/jc/pubs/news/2011/0601/cope15146.html.

treatment of hereditary transthyretin-mediated (hATTR) amyloidosis—a rare but serious (and often fatal) genetic disorder characterized by rapidly-progressive debilitating sensory, motor, autonomic, and cardiac symptoms. When furnished in a home site-of-service using an external infusion pump, ONPATTRO meets the statutory definition of a "home infusion drug" because the drug is a "parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment," and the drug is not included on any self-administered drug exclusion list and the pump is not an insulin pump system.[8]

In response to the ONPATTRO LCD reconsideration request, the MAC denied reconsideration and declined to reopen the LCD. The MAC's denial was *not* based on a determination that ONPATTRO was not reasonable and necessary. Rather, the MAC stated that—because the drug in question was non-self-administrable—the drug was categorically "exclud[ed] . . . from falling under the DME benefit."[9] The practical result of this interpretation is two-fold. In the first instance, it prevents coverage for non-self-administrable home infusion drugs (and the associated pump) under the DME benefit category. As a secondary matter, it also necessarily means that professional services related to furnishing non-self-administrable home infusion drugs are precluded from being covered under the new home infusion therapy benefit category because, as noted, coverage of the pump and drug under the DME benefit category is a necessary predicate to coverage of the professional services under the home infusion therapy benefit category.

II. Analysis

For the reasons discussed below, the SSA does not permit CMS (or its MACs) to categorically exclude non-self-administrable infusion drugs like ONPATTRO from coverage under the DME benefit category. And there is nothing in CMS's regulations that suggests otherwise.

A. The SSA makes clear that a non-self-administrable infusion drug like ONPATTRO is eligible to be covered under the DME benefit category

The SSA clearly contemplates coverage of non-self-administrable infusion drugs like ONPATTRO under the DME benefit category, when such drugs are administered using a (durable) infusion pump as part of home infusion therapy. In particular, the home infusion therapy benefit necessarily indicates that Congress specifically intended non-self-administrable home infusion drugs to be covered under the DME benefit category. After all, without such coverage, the new home infusion therapy benefit category would be a nullity, as there would be no professional services to cover, and as it cannot reasonably be suggested that Congress established the new benefit category to cover professional services to administer only the universe of drugs that can be appropriately self-administered *without* the services of a professional.

[8] SSA § 1861(iii)(3)(C) (ONPATTRO is non-self-administrable and is therefore not a self-administered drug included on any self-administered drug exclusion list. The pump used to furnish ONPATTRO is not an insulin pump system; rather, it is an ambulatory infusion pump billed under Healthcare Common Procedure Coding System (HCPCS) code E0781 (Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient), which is covered as an external infusion pump item of DME when used with other drugs).

[9] Noridian, Re: LCD L33794 (External Infusion Pumps) - Reconsideration Request Denial 3 (Dec. 6, 2019) ("[T]he [label] requirement for clinical supervision during the infusion excludes it from falling under the DME benefit.").

As CMS itself has acknowledged, "Medicare ensures coverage of . . . [home infusion therapy] through a combination of benefit categories,"[10] with the DME benefit category covering the external infusion pump and the infusion drug (and any other associated supplies) and the home infusion therapy benefit covering the "service component, meaning the professional services, training and education."[11] Necessarily implicit in the structure of this statutory scheme, with its interlocking benefit categories, is that non-self-administrable infusion drugs are to be covered under the DME benefit category: The entire statutory purpose of the home infusion therapy benefit category is to provide coverage of "professional services, including nursing services" furnished in association with home infusions.[12] Such professional services are needed only when an infusion *must be furnished by a qualified professional*—i.e., when an infusion drug is non-self-administered. Thus, the structure of the statutory scheme dictates that non-self-administered infusion drugs be covered—because concluding otherwise would obviate Congress's purpose in establishing the home infusion therapy benefit category in the first place.[13]

What is more, Congress has also made *express* that non-self-administrable infusion drugs are to be covered under the DME benefit category. This is so because Congress defined "home infusion drug" to mean a drug or biological (satisfying certain criteria) administered in home "through a pump that is an item of durable medical equipment," so long as the drug is not a "self-administered drug or biological on a self-administered drug exclusion list."[14] In other words, the definition of "home infusion drug" *expressly* contemplates non-self-administered infusion drugs being covered under the DME benefit—both because self-administered infusion drugs are expressly excluded from the statutory definition of a "home infusion drug" and because coverage of home infusion therapy professional services is expressly predicated on coverage of the pump and drug under the DME benefit.

In addition, nothing in the statute *precludes* non-self-administered infusion drugs from being covered under the DME benefit category. For example, there is no barrier based on the statutory definition of DME. In fact, the statute does not actually contain criteria that meaningfully define the term DME. Rather, the statutory definition of DME simply consists of a non-exhaustive list of certain pieces of equipment that "must" be considered DME, such as iron lungs and hospital beds.[15] Similarly, the statute does not establish any restrictions on coverage of or supplies necessary for the effective use of DME that would prevent coverage of a non-self-administrable home infusion drug, if administered using a durable infusion pump.[16]

[10] CMS, Medicare Part B Home Infusion Therapy Services with the Use of Durable Medical Equipment 2.

[11] *Id.*

[12] SSA § 1861(iii)(2); *see also id.* § 1834(u).

[13] *See Int'l Union of Operating Engineers, Local 627 v. Arthurs*, 355 F. Supp. 7, 9 (W.D. Okla.) ("Where an agency completely ignores the purpose of the controlling statute, . . . there cannot be any rational basis in law to support its decision. A reviewing court would be doing less than its duty if it failed to set aside [such] agency action."), *aff'd*, 480 F.2d 603 (10th Cir. 1973).

[14] SSA § 1861(iii)(3)(C). The drugs on a self-administered drug exclusion list are drugs that are “usually self-administered by the patient, which means “more than 50 percent of the time for all Medicare beneficiaries who use the drug. SSA § 1861(s)(2)(A); Medicare Benefit Policy Manual, ch. 15, § 50.2(C).

[15] *Id.* § 1861(n) (also enumerating certain other specific items, such as blood testing strips and blood glucose monitors).

[16] *See, e.g.*, *id.* § 1834 (no prohibition against self-administrable drugs or other supplies from being covered under the DME benefit category, when necessary for the effective use of an item of DME).

Accordingly, CMS (and its MACs) cannot lawfully interpret the Medicare statute in a manner that renders the home infusion therapy benefit meaningless by categorically excluding non-self-administrable infusion drugs (like ONPATTRO) from coverage under the DME benefit category. "[A] basic tenet of statutory construction, equally applicable to regulatory construction, [is] that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous."[17] Further, there is an obligation for CMS and its contractors to "interpret[] . . . [a] statute to create a symmetrical and coherent regulatory scheme."[18] "'The provisions of a text should be interpreted in a way that renders them compatible, not contradictory. . . . [T]here can be no justification for needlessly rendering provisions in conflict if they can be interpreted harmoniously.'"[19]

In other words, CMS and its contractors are required to interpret the statutory provisions governing the DME and home infusion therapy benefit categories in a harmonious manner that creates a coherent regulatory scheme governing coverage of home infusion drugs and associated home infusion therapy professional services. Doing so requires recognition of the fact that non-self-administrable home infusion therapy drugs may be covered under the DME benefit category as doing so is the only way to rationalize the home infusion therapy benefit category, which covers the professional services associated with administering such drugs, but only when the drug (and associated pump) are covered as DME.

We note that CMS (and its MACs) could not artificially limit the scope of coverage of non-self-administrable infusion drugs by, for example, limiting coverage of infusion drugs under the DME benefit category to drugs that can sometimes be self-administered and are usually administered by a skilled professional (while excluding infusion drugs like ONPATTRO, which must always be non-self-administered).[20] Such a limitation would be inconsistent with the Administrative Procedure Act's (APA's) prohibition against arbitrary or capricious agency action, as there would be no rational justification for such line-drawing.[21] Agencies "must reasonably explain disparate treatment of similarly situated parties."[22] In the absence of a reasoned explanation grounded in statutorily permissible considerations, CMS may not limit the universe of home infusion drugs covered by Medicare to drugs that are sometimes self-administered and sometimes administered by a skilled professional, while excluding drugs that are always administered by a skilled professional—such a distinction would be facially arbitrary and capricious.

B. <u>CMS's regulations also permit coverage of non-self-administrable infusion drug like ONPATTRO under the DME benefit category</u>

17 *Silverman v. Eastrich Multiple Investor Fund*, 51 F.3d 28, 31 (3d Cir.1995).
18 *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121 (2000).
19 *Humane Soc'y of the United States v. McCarthy*, 209 F. Supp. 3d 280, 285 (D.D.C. 2016) (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 180 (2012)).
20 *See* Noridian, Re: LCD L33794 (External Infusion Pumps) - Reconsideration Request Denial 2–3 (an infusion drug that "should be prepared by a healthcare professional" is "exclude[d] . . . from falling under the DME benefit").
21 5 U.S.C. § 706(2).
22 *Baltimore Gas & Elec. Co. v. Fed. Energy Regulatory Comm'n*, 954 F.3d 279, 286 (D.C. Cir. 2020).

Nothing in CMS's regulations purports to prohibit Medicare coverage of non-self-administrable infusion drugs under the DME benefit category.[23] Again, the MACs have asserted that a non-self-administrable home infusion drug like ONPATTRO may not be covered under the DME benefit category because such a drug is never "appropriate for use in the home," as is required by regulation for coverage as DME.[24] But the MACs' interpretation is not required by—or consistent with—CMS's regulations.

CMS has adopted regulations that define DME to mean equipment, furnished by a supplier or a home health agency that (1) can withstand repeated use, (2) has an expected life of at least 3 years (with respect to items classified as DME after January 1, 2012), (3) is primarily and customarily used to service a medical purpose, (4) generally is not useful to an individual in the absence of an illness or injury, and (5) is appropriate for use in the home.[25]

On its face, nothing in CMS's regulatory definition of DME categorically precludes non-self-administered drugs from being covered under the DME benefit, if furnished using a durable infusion pump. In the first place, there is no basis in CMS's regulatory scheme to require an *infusion drug* to satisfy the criteria in CMS's definition of DME. When under the DME benefit category, an infusion drug is a *supply* necessary for the effective use of an item DME (but not, in itself, an item of DME). CMS regulations do not require a *supply* necessary for the effective use of DME to itself meet the definition of DME, and CMS regularly covers supplies necessary for the effective use of DME under the DME benefit category where the supplies themselves do not satisfy the definition of DME.[26] Rather, the test for a supply to be included under the DME benefit is whether it is necessary for the effective use of an item of DME, and infusion drugs satisfy this criterion, if "put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment."[27]

Further, to the extent CMS wishes to adopt a requirement for supplies necessary for the effective use of DME to meet certain criteria included in the definition of DME, CMS is required to promulgate

[23] Of course, CMS's regulations could not provide otherwise, as they may not conflict with the statute. *Ohio v. United States Army Corps of Engineers*, 259 F. Supp. 3d 732, 746 (N.D. Ohio 2017) ("[N]o agency can override statutory requirements by enacting a contradictory agency rule."); *see also Riverkeeper, Inc. v. EPA*, 358 F.3d 174, 181 (2d Cir. 2004) (an agency interpretation cannot "contradict[] Congress's clearly expressed intent").

[24] Noridian, Re: LCD L33794 (External Infusion Pumps) - Reconsideration Request Denial 3.

[25] 42 C.F.R. § 414.202.

[26] *See, e.g.*, 76 Fed. Reg. 70,228, 70,286 ("The lancet itself is disposable and would not be covered as DME, but it is a covered item that falls under the general DME benefit because it is necessary for the effective use of DME—the home blood glucose monitor. Supplies necessary for the effective use of DME also include oxygen and those drugs and biologicals which must be inserted directly into the equipment for the effective use of DME.").

[27] LCD for External Infusion Pumps, L33794 at 4. Separate and apart from the benefit category determination, all items and services must also be reasonable and necessary, but, as noted, the MACs have not ever made such a determination because reconsideration of the LCD was *denied* on benefit category grounds. In order to evaluate whether an item or service is reasonable and necessary (e.g., medically necessary), the MACs would be required to *reopen* the LCD, follow the procedures and evidentiary requirements outlined in CMS rules for LCDs, and only then render a determination of whether the item or service is reasonable and necessary. *See, e.g.*, Medicare Program Integrity Manual, ch. 13 §§ 13.3–13.3.3, 13.5.3–13.5.4 (no basis for the MACs to *deny* an LCD reopening request by announcing a new categorical determination of whether the item or service is reasonable and necessary—because such determination is required to be adopted *after* completing the LCD process, not as a basis for denying reopening an LCD).

new regulations adopting such a requirement. CMS (and its contractors) may not establish such a policy through sub-regulatory guidance because CMS is not permitted to adopt rules "that establish[] or change[] a substantive legal standard governing the scope of benefits," without promulgating a regulation after undergoing notice-and-comment rulemaking.[28]

In addition, even if CMS could properly impose the "appropriate for use in the home" DME criterion on supplies used in conjunction with DME, nothing about this criterion is inconsistent with coverage of a non-self-administrable drug. CMS's regulations do not define "appropriate for use in the home,"[29] and therefore in no way indicate that an infusion drug can never be appropriate for use in the home, if it is non-self-administered. Further, for CMS to be able to conclude that non-self-administrable infusion drugs are categorically inappropriate for use in the home, CMS would need to supply a reasoned and non-arbitrary explanation of *why* such drugs can never be appropriate for use in the home.[30] CMS could not articulate such a rationale: There is no reasoned explanation for why a non-self-administrable infusion drug categorically cannot be appropriate for use in the home *if the drug is administered by a qualified home infusion therapy supplier operating in that home setting*.[31]

C. The LCD for External Infusion Pumps itself is inconsistent with the MACs' stated policy of excluding coverage of non-self-administrable infusion drugs

Finally, we note that the MACs' stated rationale for declining to include ONPATTRO in the LCD for External Infusion Pumps is inconsistent with the actual content of the MACs' own LCD. Even though the MACs have stated that ONPATTRO may not be included in the LCD because it is non-self-administrable, the LCD for External Infusion Pumps has historically included drugs in the LCD that are not typically non-self-administered.

For example, the LCD for External Infusion Pumps authorizes coverage for blinatumomab, which is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). The labeling for blinatumomab expressly recommends "supervision by a healthcare professional or hospitalization" for certain parts of cycles of the treatment regimen.[32] As a consequence, it is our understanding that blinatumomab (much like ONPATTRO) is not usually self-administered.

[28] SSA § 1871(a)(2); *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1809 (2019) ("The [] statute require[s] the government to provide public notice and a 60-day comment period (twice the APA minimum of 30 days) for any 'rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare].'") (internal citations omitted).

[29] 42 C.F.R. § 414.202. CMS manual guidance also does not define "appropriate for use in the home." Medicare Claims Processing Manual, ch. 20, § 10.1.1. And we are not aware any CMS sub-regulatory (and sub-manual) guidance interpreting "appropriate for use in the home" in the context of infusion drugs.

[30] *See, e.g.*, *Northpoint Tech. Ltd. v. FCC*, 412 F.3d 145, 151 (D.C. Cir. 2005) (courts do not give deference to an agency interpretation unless there is a "reasoned explanation" for the interpretation; "a 'reasonable' explanation of how an agency's interpretation serves the statute's objectives is the stuff of which a 'permissible' construction is made . . . ; an explanation that is 'arbitrary, capricious, or manifestly contrary to the statute,' however, is not").

[31] *See Nat'l Shooting Sports Found., Inc. v. Jones,* 716 F.3d 200, 215 (D.C. Cir. 2013) (agencies must consider and explain its 'rejection of 'reasonably obvious alternative[s]'") (internal citations omitted).

[32] FDA Label for BLINATUMOMAB at 2, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125557lbl.pdf.

The MACs may not rely on a policy justification inconsistent with their own historical practices, absent a reasoned explanation for a change in policy. What is more, CMS may not countenance such inconsistent administration of the Medicare program. "[A]n "[u]nexplained inconsistency" in agency policy is "a reason for holding an interpretation to be an arbitrary and capricious change from agency practice."[33] By allowing its contractors to adopt a self-contradictory and internally inconsistent policy regarding coverage of infusion drugs, CMS acts unlawfully because inconsistencies in the agency's (and its contractors') policies are resulting in the arbitrary and capricious implementation of the Medicare program.

III. CONCLUSION

For the above reasons, there is clear legal authority for CMS to cover a non-self-administrable infusion drug like ONPATTRO under the DME benefit category when administered in the home by a qualified home infusion therapy supplier using an external infusion pump that is an item of DME. The Medicare statute clearly evinces Congress's intent that such non-self-administrable infusion drugs be covered under the DME benefit category, and there is nothing in statutory or regulatory scheme that prohibits coverage of such a drug under the DME benefit category. Indeed expanding such coverage to Medicare beneficiaries is precisely what Congress intended in enacting the Medicare program's home infusion therapy benefit.

[33] *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117 (2016).