UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

FAMILY FOOT AND LEG CENTER, P.A.,

Plaintiff,

v. Case No.: 2:24-cv-547-SPC-KCD

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services and MEHMET OZ, M.D., Administrator for the Center for Medicare & Medicaid Services,

Defendants.
_____/

OPINION AND ORDER

Plaintiff Family Foot and Leg Center, P.A. seeks judicial review of a denial of Medicare Part B coverage by the Secretary of the United States Department of Health and Human Services ("the Secretary"). The Secretary filed the transcript of the administrative record (Doc. 23),[1] Plaintiff filed an opening brief (Doc. 34), the Secretary responded (Doc. 39), Plaintiff replied (Doc. 42), and the Secretary filed a sur-reply (Doc. 45). For the below reasons, the Court affirms the Secretary's decision.

[1] Cited as "Tr." followed by the appropriate page number.

BACKGROUND

Plaintiff provides podiatric services to Medicare-qualified patients. Between February 9 and June 10, 2022, it injected Procenta (an acellular, human placental-derived allograft) into six different Medicare beneficiaries' foot, ankle, and/or knee for musculoskeletal issues—specifically, osteophytes (bone spurs) or enthesopathy (a condition impacting the connection point between bone and tendons or ligaments). (Tr. 251, 268, 280, 293, 311, 1220). The purpose of these Procenta injections was to increase function, decrease pain, and heal the target tissue. (*Id.*). Plaintiff submitted claims for Medicare Part B coverage for each Procenta injection citing Health Common Procedure Code System ("HCPCS") Q4244 for Procenta (and other codes for the injections). HCPCS code Q4244 identifies Procenta as a wound covering "to treat chronic non-healing wounds" and a "skin substitute." (Tr. 371). As discussed more below, the Secretary ultimately denied coverage, so Plaintiff appeals to this Court. (Doc. 2).

LEGAL STANDARD

Medicare only covers items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Consistent with this statute, the applicable regulations exclude from Medicare all coverage and services that are not reasonable and necessary. *See* 42 C.F.R.

§ 411.15(k)(1). To determine whether a service is "reasonable and necessary," adjudicators must assess whether the "service is safe and effective, not experimental or investigational, and appropriate based on the strongest evidence possible."[2] Medicare Program Integrity Manual ("MPIM"), Ch. 13 §§ 13.3, 13.5.1, 13.7.1. Put simply, an applicant must demonstrate the services for which it seeks coverage are safe and effective, not experimental or investigational, and appropriate. *See* 42 C.F.R. § 424.5(a)(6) ("The provider, supplier, or beneficiary, as appropriate, must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment."); *see also Almy v. Sebelius*, 679 F.3d 297, 305 (4th Cir. 2012) ("It is well established that a claimant has the burden of proving entitlement to Medicare benefits." (cleaned up and citation omitted)).

ADMINISTRATIVE HISTORY

Medicare claims are initially adjudicated by a private contractor. *See* 42 U.S.C. § 1395ff(a)(1). A party who is denied reimbursement may seek redetermination of the contractor's decision. *See id.* § 1395ff(a)(3). If the contractor still denies coverage, a party may seek review from a Qualified

[2] There is no dispute that no national coverage determination or local coverage determination applies. Thus, "contractors may make individual claims determinations." Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations, 68 Fed. Reg. 63692-01; *see also Row 1 Inc. v. Becerra*, 92 F.4th 1138, 1141 (D.C. Cir. 2024) ("Absent a binding national policy or direction from the Secretary, Medicare contractors make the initial coverage decision as to whether an item or service is reasonable and necessary." (citing 42 U.S.C. § 1395kk-1(a)(4)(A))).

Independent Contractor ("QIC"). *See id.* § 1395ff(b)(1), (c). If the QIC's decision is unfavorable, a party may request a hearing before an Administrative Law Judge ("ALJ"). *See id.* § 1395ff(d)(1). If the ALJ also denies coverage, a party may appeal to the Medicare Appeals Council, or the Appeals Council can review the ALJ's decision on its own motion. *See id.* § 1395ff(d)(2); 42 C.F.R. § 405.1110(a). If the party is still unsatisfied, it can seek judicial review in federal court. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 U.S.C. § 405(g).

The Medicare contractor reviewed and denied each of Plaintiff's claims at the initial and redetermination stage, finding that the provided services were not safe and effective and were thus experimental and investigational. (Tr. 1667–71, 1678–82, 1689–93, 1700–03, 1709–12, 1718–22). Reconsideration before a QIC yielded the same result. (Tr. 668–754). Plaintiff then appealed to an ALJ who issued a fully favorable decision. (Tr. 81–99, Doc. 2-5). On its own motion, the Medicare Appeals Council took up review of the ALJ's decision. (Tr. 61–73).

On April 15, 2024, the Medicare Appeals Council reversed the ALJ and issued a final unfavorable decision. (Tr. 4–15, Doc. 2-4). It found that the ALJ did not apply the correct standard when evaluating Plaintiff's claim and thus erred as a matter of law. (Tr. 6–8). The Appeals Council then conducted its

own review and concluded that the record evidence[3] did not support Medicare coverage for the Procenta injections at issue and that Plaintiff was liable for the uncovered costs. (Tr. 8–15).

First, the Appeals Council found Plaintiff's proffered evidence did not show Procenta was a safe and effective treatment for the beneficiaries' conditions—osteophytes and enthesopathy. It explained that the HCPCS Coding Application for Procenta and the Procenta patent application describe Procenta as a wound covering with no suggestion it can be injected to treat musculoskeletal conditions. The Appeals Council also found none of Plaintiff's submitted medical literature supported the safety and efficacy of Procenta as used by Plaintiff. Finally, the Appeals Council dismissed Plaintiff's assertion that Procenta is an FDA-regulated product under § 361 of the Public Health and Safety ("PHS") Act because Plaintiff submitted no evidence to support this assertion and, even if it had, FDA categorization is only one factor in a Medicare coverage determination. (Tr. 10–12).

Next, the Appeals Council determined that the record did not establish Procenta is not experimental or investigational. The Appeals Council acknowledged the ALJ's finding that an August 2020 Tissue Reference Group

[3] The record included the beneficiaries' medical records, Technical Direction Letter ("TDL") 220299, HCPCS Level II Coding Procedures information for Procenta, the Procenta HCPCS application summaries and coding decisions, the Procenta patent application, and nineteen peer-reviewed articles and clinical studies. (Tr. 8).

("TRG") letter stated Procenta meets the criteria for regulation under § 361 of the PHS Act. But it rejected the ALJ's reliance on this TRG letter because the letter applied only when Procenta is intended to serve as a cover to offer protection from the surrounding environment or used as a treating fluid. Further, the letter was not part of the record; no other document in the record established Procenta is FDA-approved; and even if Procenta is FDA-approved, such approval alone does not mean an item is not experimental or investigational for establishing Medicare coverage. Finally, the Appeals Council reiterated that none of the clinical studies Plaintiff provided discuss Procenta's use for treatment of musculoskeletal conditions. (Tr. 12).

For the final coverage element, the Appeals Council concluded Plaintiff failed to establish Procenta was "appropriate" for the beneficiaries' treatment. The Appeals Council explained that no submitted medical literature recommended Procenta as an injectable to increase function or decrease pain as a result of osteophytes or enthesopathy of the knee, ankle, or foot. (*Id.*).

Having concluded Plaintiff failed to show the Procenta injections were medically reasonable and necessary, the Appeals Council addressed whether Plaintiff was liable for the uncovered costs of the Procenta injections. It concluded Plaintiff was not entitled to a limitation of liability under § 1879 of the Social Security Act because Plaintiff failed to show that it did not know or

could not have reasonably been expected to know that amniotic fluid products (like Procenta) were not covered by Medicare. (Tr. 13–14).

STANDARD OF REVIEW

Judicial review of the Secretary's decision regarding a claim for Medicare benefits "is limited to whether there is substantial evidence to support the findings of the Secretary, and whether the correct legal standards were applied." *Gulfcoast Med. Supply, Inc. v. Sec'y, Dep't of Health & Hum. Servs.*, 468 F.3d 1347, 1350 n.3 (11th Cir. 2006) (cleaned up) (citing 42 U.S.C. § 405(g) and 42 U.S.C. § 1395ff(b)(1)(A)); *Wilson v. Barnhart*, 284 F.3d 1219, 1221 (11th Cir. 2002). "Substantial evidence is more than a scintilla and is such relevant evidence as a reasonable person would accept as adequate to support a conclusion." *Crawford v. Comm'r of Soc. Sec.*, 363 F.3d 1155, 1158 (11th Cir. 2004). The Court cannot substitute its judgment for that of the agency "concerning the wisdom or prudence of the proposed action." *Vitreo Retinal Consultants of the Palm Beaches, P.A. v. U.S. Dep't of Health & Hum. Servs.*, 649 F. App'x 684, 689 (11th Cir. 2016) (citation omitted). Indeed, deference to the Secretary's judgment is especially warranted in the Medicare context "[b]ecause Medicare is a complex and highly technical regulatory program." *Gulfcoast Med. Supply*, 468 F.3d at 1353 (citation omitted).

ANALYSIS

Plaintiff's appeal is two-fold. It argues the Secretary's decision that Medicare Part B does not cover the administered Procenta injections was improper. And, alternatively, it argues it is entitled to limitation of liability under § 1879 of the Social Security Act (42 U.S.C. § 1395pp). The Court addresses each in turn.

I. Substantial evidence supports the Appeals Council's finding that Plaintiff failed to show entitlement to Medicare Part B coverage.

Plaintiff allocates a great deal of its opening brief to its belief that the ALJ's decision was supported by substantial evidence. (Doc. 34 at 11–16). In fact, it ultimately asks the Court to "reinstate" the ALJ's decision. (*Id.* at 25). But "in cases where the Appeals Council reverses an ALJ's decision on its own motion, judicial review is limited to determining whether the Appeals Council's decision is supported by substantial evidence." *Parker v. Bowen*, 788 F.2d 1512, 1519–20 (11th Cir. 1986). In other words, it is the Appeals Council's decision that is on review here; whether substantial evidence supports the ALJ's decision is irrelevant. *See id.; see also Int'l Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1002 (9th Cir. 2012) (explaining the "substantial evidence" standard of review "does not give the district court license to compare the agency decision on direct review with other agency decisions not on review and determine which is supported by more substantial evidence"). So, much of

Plaintiff's briefing is moot from the get-go, and the Court addresses only Plaintiff's arguments pertaining to the Appeals Council's decision.

Plaintiff raises only a few unpersuasive arguments against the Appeals Council's decision. It begins by citing the following portion of the decision:

> Notably, the HCPCS level II code application includes no information about treatment of musculoskeletal conditions, but rather states that Procenta "is indicated to treat chronic non-healing wounds, such as venous stasis and diabetic foot ulcers for the purpose of providing an extracellular matrix (ECM) scaffold and soluble proteins to assist in the wound healing process." Likewise, while the patent application states that the product "*may* be used to treat joint or bone ailments, and *may* be useful in treatment of arthritic conditions, fractures, or other ailments," the application clearly dictates that "the clinical indications for the scaffold product is the treatment of chronic or non-healing wounds." In this case, the appellant administered Procenta for the treatment of osteophytes of the knee and foot and enthesopathy of the knee, ankle, and foot, none of which are clinically indicated conditions according to the materials submitted by the appellant.

(Doc. 34 at 18 (citing Tr. 10)). Plaintiff takes issue with this passage, arguing the Appeals Council refers solely to Plaintiff's use of Procenta for treatment of osteophytes and enthesopathy while ignoring the fact it was also used to decrease pain. (Doc. 34 at 18). This argument makes little sense though considering the pain Plaintiff was treating was a result of the osteophytes and/or enthesopathy. What's more, the Appeals Council did address Plaintiff's use of Procenta to decrease pain elsewhere in its decision. (*See* Tr. 12 (concluding Plaintiff failed to show Procenta injections were "appropriate" because "no evidence, medical literature, or clinical studies in the record document or recommend the use of Procenta as an injectable to increase

function *and decrease pain*[.]" (emphasis added))). And ultimately, the Appeals Council's decision is clear that Plaintiff failed to show injecting Procenta into the foot, knee, or ankle was medically reasonable and necessary, regardless of the treatment's purpose.

Plaintiff then cites to nine of the nineteen journal articles it submitted into the record, arguing they support Plaintiff's use of Procenta for pain relief. But the Appeals Council thoroughly analyzed the medical literature Plaintiff submitted and found none conclusively supported Procenta's medical reasonableness or necessity for the six beneficiaries' conditions. (Tr. 10–11). For instance, it observed that some clinical studies were performed on rats and thus did not establish safety and efficacy for Medicare beneficiaries. (Tr. 10). Another study found similar injections "may" be safe but noted that further testing is needed. (*Id.*). And a National Institute of Health article set out the parameters for a potential clinical trial evaluating amnion injections to treat shoulder osteoarthritis but never reported any outcomes. (*Id.*).

The Court finds reasonable the Appeals Council's review and discount of Plaintiff's medical literature. "It is not our office to tender an independent judgment on the value and validity of the various scientific studies submitted. We ask only whether the Secretary's assessment was a reasonable one[.]" *Almy v. Sebelius*, 679 F.3d 297, 305–06 (4th Cir. 2012). Indeed, so long as substantial evidence supports the decision, "it is not for this Court to reweigh

the evidence or supplant its judgment for that of the Appeals Council." *Gordon v. Azar*, No. 19-CV-63041, 2021 WL 1520695, at *10 (S.D. Fla. Feb. 12, 2021), *report and recommendation adopted sub nom.*, 2021 WL 1099367 (Mar. 23, 2021). Such is the case here.

Substantial evidence supports the Appeals Council's decision. As the Appeals Council observed, the Procenta patent application designates its purpose as treatment of chronic or non-healing wounds. (Tr. 416). Similarly, the HCPCS application for Procenta identifies it as a wound covering "to treat chronic non-healing wounds." (Tr. 371). Even the TRG letter the ALJ relied on (which was not part of the administrative record) explains Procenta met the criteria for regulation under § 361 of the PHS Act "when intended to serve as a cover, to offer protection from the surrounding environment, or to retain fluid[.]" Tissue Reference Group Letter, Food and Drug Admin. (August 19, 2020). In other words, the uncontroverted evidence establishes Procenta's use as a wound covering, not as an injection for orthopedic purposes. And, as noted above, the Appeals Council reasonably determined Plaintiff's medical literature did little to move the needle. Considering the foregoing, substantial evidence supports the Appeals Council's decision.

Finally, Plaintiff argues the Appeals Council should have reviewed Procenta's use individually for each beneficiary rather than rejecting them all in one fell swoop. Plaintiff cites no supporting authority. In any event, the

Court sees no problem here. Plaintiff injected Procenta into each beneficiary for a similar purpose: treating osteophytes or enthesopathy. Because Plaintiff failed to show its use of Procenta injections generally was medically reasonable and necessary, the underlying symptoms of each beneficiary are irrelevant.

In sum, substantial evidence supports the Appeals Council's finding that Medicare B coverage did not extend to Plaintiff's administration of Procenta injections. Plaintiff's arguments to the contrary are unavailing.

II. Substantial evidence supports the Appeals Council's finding that Plaintiff is not entitled to a limitation of liability.

Even if Medicare denies coverage because the administered services were not reasonable and necessary, Medicare may reimburse the provider if the provider "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services." 42 U.S.C. § 1395pp(a). The Appeals Council determined that Plaintiff could have reasonably been expected to know that Medicare would not cover the provided services. (Tr. 14). Plaintiff disagrees.

Substantial evidence supports the Appeals Council's determination. Although it conceded there is no pertinent guidance concerning the non-coverage of amniotic fluid products for orthopedic joint pain,[4] it correctly

[4] It is curious that the Appeals Council conceded this point. In February 2022, CMS issued a TDL declaring certain "manipulated amniotic and/or other placental tissue biologics for injections" were experimental exosome biologic products that have not been proven to be safe and directed Medicare Administrative Contractors to apply automatic claim denials for such

explained that the Secretary's silence on a particular service does not suggest coverage. Regardless, enough information was available such that Plaintiff should have known Medicare would not cover the Procenta injections.

The Procenta patent application and HCPCS code Q4244 should have signaled to Plaintiff that the Procenta injections were not medically reasonable and necessary. They make clear that Procenta is intended to treat non-healing wounds, even describing Procenta as a skin substitute. Plaintiff had no reason to believe administering Procenta for a treatment beyond the prescribed purpose—*i.e.*, injection into the foot, ankle, and knee for orthopedic treatment—would be approved. *Cf. Vitreo Retinal*, 649 F. App'x at 697 (finding the plaintiff-provider was not entitled to a limitation under § 1395pp(a) after administering a drug beyond the prescribed dosage on the drug's label). Plaintiff's reliance on the medical literature to bolster its position is unavailing because, as discussed above, none supported its belief that Procenta injections were medically reasonable and necessary.[5] Thus, substantial evidence

services. TDL-220221, February 2, 2022. This TDL should have notified Plaintiff that at least one of its claims would be denied given Plaintiff administered Procenta injections as early as February 9, 2022—while this TDL was in effect. That said, CMS rescinded this TDL in March 2022, instead requiring a case-by-case analysis for such claims but noting that "[t]he recission of the subject TDLs is not intended by CMS, and shall not be construed, as a finding that any products are eligible for coverage or payment." TDL-220299, March 25, 2022. Even so, one could argue these TDLs provided Plaintiff with some notice that it might not receive reimbursement for the Procenta injections.

[5] Plaintiff objects to the Appeals Council placing the burden of proof on Plaintiff, arguing that doing so "turns the statute on its head[.]" (Doc. 34 at 22). But it cites no authority to support its argument. And, as noted above, it is ultimately the applicant's burden to show entitlement to Medicare payment.

supports the Appeals Council's determination that Plaintiff is not entitled to a limitation of liability under § 1395pp(a).[6]

In its reply brief, Plaintiff argues that it reasonably expected reimbursement for the Procenta injections because Medicare previously paid Plaintiff for such injections for several years. (Doc. 42 at 9). There are two problems with this argument. First, Plaintiff cites nothing in the record to support its assertion. Second, the Court does not address arguments raised for the first time in a reply. *See Kellner v. NCL (Bahamas), LTD.*, 753 F. App'x 662, 667 (11th Cir. 2018) ("[I]t is by now clear that we cannot consider arguments raised for the first time in a reply brief." (collecting cases)). So Plaintiff's argument is unpersuasive.

Accordingly, it is now

ORDERED:

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[6] Even assuming substantial evidence did not support the Appeals Council's finding, remand is unnecessary because it is well documented that amniotic fluid injections (like Procenta) were subject to a great deal of federal scrutiny during this time frame (and continuing to this date). *See supra* note 4; *see also* Amniotic Fluid Injections Are at the Center of the Federal Government's New Enforcement Effort, Dr. Nick Oberheiden, THE NATIONAL LAW REVIEW, January 14, 2022, https://natlawreview.com/article/amniotic-fluid-injections-are-center-federal-government-s-new-enforcement-effort (advising that "[p]roviders who administer amniotic fluid injections should familiarize themselves with the possible healthcare fraud charges they could face as a result of improperly billing Medicare"). A court need not remand when doing so would be a useless exercise. *See NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969) (noting that where "remand would be an idle and useless formality," a reviewing court is not required to "convert judicial review of agency action into a ping-pong game").

1. The decision of the Secretary is **AFFIRMED** under sentence four of 42 U.S.C. § 405(g).
2. The Clerk is **DIRECTED** to enter judgment for Defendants and against Plaintiff, terminate any deadlines, and close the case.

DONE and **ORDERED** in Fort Myers, Florida on September 4, 2025.

SHERI POLSTER CHAPPELL
UNITED STATES DISTRICT JUDGE

Copies: All Parties of Record