UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

CARL D. MCCUE,	)	
	)	
Plaintiff	)	
	)	
v.	)	1:18-cv-00011-LEW
	)	
SECRETARY OF HEALTH & HUMAN SERVICES,	)	
	)	
Defendant	)	

RECOMMENDED DECISION ON REQUEST FOR JUDGMENT ON ADMINISTRATIVE RECORD

In this action, Plaintiff seeks judicial review of Defendant's decision to deny Plaintiff's request for Medicare Part C coverage of a MRI-guided laser ablation procedure. The matter is before the Court on Plaintiff's motion for judgment on the administrative record[1] (Motion, ECF No. 11), and Defendant's request to affirm the administrative decision.[2] (Response, ECF No. 12.)

Following a review of the administrative record, and after consideration of the parties' arguments, I recommend the Court affirm Defendant's final administrative decision.

[1] In the alternative, Plaintiff asked the Court to remand the matter for further administrative proceedings. (Motion at 18.)

[2] In the response to Plaintiff's motion for judgment, Defendant requested the Court affirm the administrative decision.

BACKGROUND

Plaintiff is a Medicare beneficiary and Part C enrollee. Medicare Part C, also known as Medicare Advantage, enables private insurance companies to provide Medicare benefits. Medicare private health plans are known as Medicare Advantage ("MA") Plans. Plaintiff acquired his MA Plan through Aetna Health Inc., which plan is entitled the Aetna Medicare Select Plan (HMO). (R. 123.) [3]

The Plan provides that, "[a]s a Medicare health plan, [it] must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules." (2015 Evidence of Coverage Document, Ch. 3, § 1, R. 152.) Medical care is covered when it is included in the Plan's benefits chart (chapter 4), is considered medically necessary, and is provided by a network provider. (R. 152 – 53.) "In most cases, care … from an out-of-network provider … will not be covered," subject to three exceptions: (1) emergency care or urgently needed care; (2) necessary care that Medicare requires the Plan to cover, if network providers cannot provide the care; and (3) kidney dialysis at a Medicare-certified

[3] The First Circuit has described the statutory framework as follows:

> Enacted in 1965, Medicare is a federally run health insurance program benefitting primarily those who are 65 years of age and older. Before the recent extension of Medicare to cover a portion of prescription drug costs, Medicare covered only inpatient care through Part A and outpatient care through Part B. Parts A and B are fee-for-service insurance programs operated by the federal government. 42 U.S.C. § 1395c et seq. (Part A); 42 U.S.C. § 1395j et seq. (Part B). In 1997, Congress enacted Medicare Part C to allow Medicare beneficiaries to opt out of traditional fee-for-service coverage under Parts A and B. 42 U.S.C. § 1395w–21 et seq. (Part C). Under Part C, beneficiaries can, inter alia, enroll in "Medicare Advantage" plans, privately-run managed care plans that provide coverage for both inpatient and outpatient services. Id. § 1395w–22(a)(1).

First Med. Health Plan, Inc. v. Vega–Ramos, 479 F.3d 46, 48 (1st Cir. 2007) (internal footnote omitted).

dialysis facility. (R. 153.) Additionally, the Plan does not cover "experimental medical procedures and items," meaning "items and procedures determined by [the] [P]lan and Original Medicare to not be generally accepted by the medical community." (MAC Decision, R. 9 – 10.)

In 2014, Plaintiff sought care from Michael Bedecs, D.O., following a diagnosis of benign prostatic hypertrophy. Dr. Bedecs recommended, and Plaintiff obtained, an MRI-guided biopsy, in November 2014, which biopsy demonstrated "early prostate cancer."[4] (R. 17.) In January 2015, on advice of Dr. Bedecs, Plaintiff received MRI-guided ablation of a precancerous or cancerous lesion on his prostate. (R. 18.) Dan Sperling, M.D., a radiologist in Yonkers, New York, performed the procedure.

In December 2014 or January 2015, Plaintiff submitted the charges for the procedures to Aetna for payment. Plaintiff requested coverage for the laser ablation procedure in advance of the procedure, but on the eve of the scheduled procedure, he was advised that the cost of the procedure would not be covered under the Plan. (R. 21.) Plaintiff nevertheless underwent the procedure.

Although Aetna denied coverage for the laser ablation procedure, Aetna approved coverage for the MRI diagnostic services associated with Dr. Sperling's care in November 2014, because "this procedure is used to diagnose prostate cancer per Centers for Medicare & Medicaid[] Services medical necessity criteria." (R. 109.) In the narrative provided to

[4] The MRI Prostate Study Report dated November 24, 2014, reflects the findings were "moderately suspicious for prostate cancer." (R. 71.)

the independent reviewing entity, MAXIMUS Federal Services, Aetna explained that the ablation services in January 2015 were not covered because the provider was "not enrolled or accredited by a designated CMS accreditation organization." (R. 105.) Aetna further explained that the "focal laser ablation for prostate cancer treatment" was "experimental and investigational because its effectiveness has not been established." (R. 106.)

MAXIMUS Federal Services agreed that Aetna was not required to pay for the ablation procedure. Noting that under the Plan, Aetna covers items and services in accordance with Medicare rules, MAXIMUS concluded that the ablation procedure was not medically necessary and was experimental/investigational. (R. 78 – 80.) MAXIMUS did not address whether the care should have been excluded as out-of-network care.

Plaintiff appealed from the decision and a hearing on the appeal was scheduled before an administrative law judge (ALJ). The ALJ described the issue as whether Aetna was "obliged to provide coverage for the MRI guided laser prostate ablation." (R. 35.) The ALJ ruled against coverage, relying in part on Dr. Sperling's characterization of the procedure as a "newer thermal ablative technique [that] seems especially suited for prostate cancer." (Id.) The ALJ observed that MRI-guided laser ablation is not a covered service for participants in Medicare Parts A and B, which provide the presumptive scope of coverage for Part C plans. According to the ALJ, although patients might prefer the procedure based on projected recovery time, the effectiveness of the procedure was unknown. The ALJ reasoned:

> While there is sufficient data available to show that the MRI guided method results in less blood loss, less pain, and quicker recovery than either radiation or conventional surgery, the … question is whether the method produces a

> definitive cure and, if so, in what fraction of patients. If, for example, only a minority of all patients treated have to subsequently undergo surgery or radiation, the method may prove cost-effective. If the fraction encompasses either a significant minority – or a majority – of patients, the method may not be cost effective. And, Medicare is not obliged to provide coverage for all therapeutic avenues, and may permissibly base its coverage decisions on whether the procedure in question is cost-effective.

(R. 39.) The ALJ concluded that MRI-guided laser ablation of prostate cells was not "medically reasonable and necessary," as that concept is understood in the context of the Medicare Act, and that the procedure was thus not reimbursable under the Act. (R. 40.)

Plaintiff asked the Medicare Appeals Council (MAC) to review the ALJ's decision. Following a de novo review, the MAC agreed with the ALJ's basic conclusion. (R. 3.) The MAC, however, "modif[ied] the ALJ's decision to address relevant legal authority not discussed in the ALJ's decision and to clarify the basis for the coverage denial." (Id.) The MAC also discussed two letters authored by Dr. Bedecs, dated August 6, 2015, and December 17, 2014, which letters the ALJ had not addressed in his decision. (R. 10.)

Citing section 1862(a)(1)(A) of the Social Security Act, codified at 42 U.S.C. § 1395y(a)(1)(A), MAC observed that coverage under Part C requires that items and services must be within the defined benefit program, and otherwise must be "reasonable and necessary for the diagnosis or treatment of illness or injury" in a particular case. (R. 6 – 7.) Referencing Medicare Program Integrity Manual, Chapter 13, §§ 13.5.1 and 13.7.1, the MAC explained that to qualify as "reasonable and necessary," items and services must be "safe and effective" and "not experimental or investigational," based on "published authoritative evidence" and "general acceptance by the medical community," and not

merely accepted "by individual health care providers, or even a limited group of health care providers." (R. 7.)

The MAC determined that there was insufficient evidence to demonstrate the procedure was not experimental or investigational.[5] (R. 7 – 9.) The MAC explained:

> We recognize that the appellant has researched and weighed the potential risks and benefits in determining how to treat his diagnosis of prostate cancer. However, Medicare is a defined benefit program. Not all items and procedures are covered, and the requirements for coverage include those designed to ensure that relatively new devices, procedures, and treatments will have thoroughly demonstrated their safety and efficacy prior to being covered by Medicare.

(R. 11.)

STANDARD OF REVIEW

A district court has the authority to review the Secretary's final decision under the Medicare Act. 42 U.S.C. § 405(g); 42 U.S.C. § 1395w-22(g)(5) (making 42 U.S.C. § 405(g) applicable to appeals of benefit denials under Medicare Part C); see also 42 C.F.R. § 422.612(b). Judicial review is limited to determining whether the Secretary's decision is supported by substantial evidence and whether the Secretary applied the proper legal standard. 42 U.S.C. § 405(g). Substantial evidence is defined as "relevant evidence a reasonable mind might accept as adequate to support a conclusion." Richard v. Perales, 402 U.S. 389, 401 (1971).

[5] The MAC also concluded that the denial of coverage was appropriate because the record did not establish that "the provider is enrolled as a Medicare provider." (R. 7.) Because the record contains substantial evidence to support the denial of coverage on other grounds, this recommended decision does not address whether the procedure was performed in the Plan's geographic area by an in-network provider.

DISCUSSION

Plaintiff argues Defendant's final decision is erroneous because Plaintiff demonstrated the procedure was reasonable and necessary, and that MAC did not conduct the required individualized assessment, did not apply the EOC definition of experimental, relied on evidence not of record, and did not appropriately weigh the evidence. (Plaintiff's Appeal Brief and Motion for Judgment Based on the Administrative Record ("Plaintiff's Brief"), ECF No. 11.)

A. Reasonable and Necessary

"Under Medicare Part C, individuals qualified for Medicare enroll in a health plan (MA plan) with a private insurance company. 42 U.S.C. §§ 1395w-21 – 1395w-29. The MA Plan must enter into a contract with the Secretary of Health and Human Services, 42 U.S.C. § 1395w–27, and agree to provide the same benefits an individual is eligible to receive under Medicare, 42 U.S.C. § 1395w–22(a)(1)(A)." Fournier v. Sebelius, 839 F. Supp. 2d 1077, 1081 (D. Ariz. 2012), *aff'*d, 718 F.3d 1110 (9th Cir. 2013). Medicare does not cover services that "are not 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). Accordingly, "the Secretary may not provide reimbursement for services that are 'not reasonable and necessary for diagnosis or treatment of illness or injury.'" Exec. Dir. of Office of Vermont Health Access ex rel. Carey v. Sebelius, 698 F. Supp. 2d 436, 440 (D. Vt. 2010) (quoting New York ex rel Holland v. Sullivan, 927 F.2d 57, 58–59 (2d Cir. 1991)).

> The Secretary of Health and Human Services decides "whether a particular medical service is 'reasonable and necessary' ... by promulgating a generally applicable rule or by allowing individual adjudication." Heckler v. Ringer, 466 U.S. 602, 617 (1984) (emphasis added). The former course involves a "national coverage determination" that announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). In the absence of a national coverage determination, local Medicare contractors may issue a "local coverage determination" that announces "whether or not a particular item or service is covered" by that contractor. Id. § 1395ff(f)(2)(B).
>
> The latter course allows "contractors [to] make individual claim determinations, even in the absence of [a national or local coverage determination], ... based on the individual's particular factual situation." 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). In making an individual claim determination about whether to reimburse a medical provider, "[c]ontractors shall consider a service to be reasonable and necessary if the contractor determines that the service is: [(1)] Safe and effective; [(2)] Not experimental or investigational ...; and [(3)] Appropriate." Centers for Medicare & Medicaid Services ("CMS"), Medicare Program Integrity Manual § 13.5.1 (2015) (describing local coverage determinations); see also id. § 13.3 (incorporating § 13.5.1's standards for individual claim determinations).

United State*s ex rel. Polukoff v. St. Mark'*s Hosp., 895 F.3d 730, 735 (10th Cir. 2018) (emphasis in original).

In this case, Plaintiff's claim is governed by the second course described by the Tenth Circuit. In essence, Plaintiff argues the procedure should be covered because, according to his providers, the treatment was necessary and successful. The mere fact that Plaintiff's physicians determined that the procedure was necessary or successful is not controlling. "A form of treatment may be necessary and completely successful in a particular case yet still be per se unreasonable and unnecessary under 42 U.S.C. § 1395y(a)(1)(A) if the treatment is properly deemed experimental and investigational as a

general rule by someone with the authority to do so." Smith v. Thompson, 210 F. Supp. 2d 994, 1000 (N.D. Ill. 2002).

Here, Defendant's determination that Plaintiff's treatment was experimental and investigational is supported by substantial evidence. In fact, Dr. Sterling's records suggest the procedure was not widely accepted. According to Dr. Sterling's records, Dr. Sterling advised Plaintiff that "the standard treatment for clinically significant cancers is radical prostatectomy or radiation therapy," and that although "[s]everal studies over the years have suggested that focal or targeted ablation of prostate cancer may yield long-term disease-free survival for some 'clinically significant' cancers," laser ablation has not been "FDA approved for the specific indication of focal ablation of prostate cancer." (R. 66.) In addition, the expert opinion generated during the review by MAXIMUS described the "focal laser ablation of the prostate" as "experimental/investigational." (R. 87.) In short, a review of the record reveals substantial evidence to support the conclusion that the laser ablation of cancerous or precancerous prostate cells was still in trial stages and was not yet generally accepted for the treatment of the condition.

B. Individualized Assessment, Administrative Guidance, and EOC Definition

Plaintiff contends that Defendant did not provide an individualized assessment of his claim for coverage and failed to consider regulatory guidance and the Evidence of Coverage definition of "experimental," which definition Plaintiff contends favors coverage. (Plaintiff's Appeal Brief and Motion for Judgment at 7–14.)

1. MPIM guidance

A Medicare contractor may use Medicare manuals for guidance to make a coverage determination. Plaintiff argues Defendant failed to apply the Medicare Program Integrity Manual ("MPIM"), which provides guidance in the determination of whether items or services are "reasonable and necessary for the diagnosis or treatment of illness." MPIM, CMS Pub. No. 100–08, Ch.13.[6]

Federal regulations specify that ALJs and the MAC are not "bound" by these guidance manuals, but must give "substantial deference" to them "if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). The MPIM provides in relevant part:

> Contractors may review claims on either a prepayment or postpayment basis regardless of whether a [national coverage determination], coverage provision in an interpretive manual, or [local coverage provision] exists for that item or service. . . . . An item or service may be covered . . . if it meets all of the conditions listed in § 13.5.1, Reasonable and Necessary Provisions in LCDs.

MPIM § 13.3. The MPIM states that an item or service is covered by Medicare only if it comports with the statutory requirements of 42 U.S.C. § 1395y(a)(1)(A). MPIM § 13.5.1. Most significantly, the item or service must be "reasonable and necessary":

> Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
>
> - Safe and effective;
> - Not experimental or investigational ...; and

[6]Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html (last visited on January 2, 2019).

• Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:

○ Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;

○ Furnished in a setting appropriate to the patient's medical needs and condition;

○ Ordered and furnished by qualified personnel;

○ One that meets, but does not exceed, the patient's medical need; and

○ At least as beneficial as an existing and available medically appropriate alternative.

Id.

The MPIM also instructs contractors to use the "strongest evidence available" and provides a list of evidence in order of preference:

• Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and

• General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:

○ Scientific data or research studies published in peer-reviewed medical journals;

○ Consensus of expert medical opinion (i.e., recognized authorities in the field); or

○ Medical opinion derived from consultations with medical associations or other health care experts.

MPIM § 13.7.1. The MPIM further provides:

> Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

The MPIM cautions that determinations that "challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage." Id. Finally, the MPIM states: "Less stringent evidence is needed when allowing for individual consideration." Id.

Plaintiff relies upon the "less stringent evidence" language to support his contention that Defendant did not appropriately consider Plaintiff's individual claim. The language of the regulation does not compel a different result. Instead, the language is consistent with the entire regulation, which is designed to allow the adjudicator some discretion to assess, in accordance with 42 C.F.R. § 405.1062(a), how various factors inform the coverage determination, such as the general acceptance of a procedure within a particular coverage area, even in the absence of authoritative studies and publications.[7] In this case, Defendant noted the absence of both definitive studies and evidence of general acceptance. To apply the "less stringent evidence" language of the MPIM as Plaintiff urges would ignore the MPIM's caution that "[a]cceptance by individual health care providers, or even a limited group of health care providers normally does not indicate general acceptance by the medical community."

[7] The regulations do not mandate that the ALJ or the MAC quote or discuss the "less stringent evidence" provision in a written decision.

2. Evidence of Coverage definition of experimental

Plaintiff also contends the Evidence of Coverage definition of experimental items and services as "those items and procedures determined by our plan and Original Medicare to not be generally accepted by the medical community" (R. 9–10) requires a different result. Contrary to Plaintiff's argument, the definition is consistent with the requirements of the applicable Medicare statute, regulations, and guidance.

C. Scope and Weight of the Evidence

Plaintiff contends that the reference by the ALJ and the MAC in their decisions of a "review" of the MRI-guided ablation procedure by the Plan demonstrates that they relied on information that was not part of the record evidence. (Plaintiff's Brief at 14–15.) Regardless of whether Plaintiff was aware of the Plan's review or the ALJ's reference to the review, the record evidence, without reference to or reliance on the Plan's review, constitutes substantial evidence to support the determination. As referenced above, the evidence presented by Plaintiff's own physicians sufficiently supports the determination.

Finally, Plaintiff asserts that the MAC improperly required him to present "scientific data or research studies published in peer-reviewed medical journals" to sustain his claim. (Id. at 17, citing R. 10.) An objective review of the MAC's decision reveals that the MAC did not consider scientific data or research to be essential. Rather, the MAC referenced the lack of scientific data and research as one reason it did not find the letters submitted by Plaintiff's physicians to be persuasive. In that context, the MAC's reference was understandable and reasonable. The MAC did not, as Plaintiff contends, apply an improper standard of proof.

CONCLUSION

Plaintiff's investigation of treatment options is understandable. As the MAC explained, however, "Medicare is a defined benefit program" and "[n]ot all items and procedures are covered." (R. 11.) A review of the record reveals that the administrative decision is supported by substantial evidence and that Defendant did not otherwise err in the decision-making process. Accordingly, based on the foregoing analysis, I recommend the Court affirm Defendant's final administrative decision.

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which de novo review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within fourteen (14) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within fourteen (14) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court's order.

/s/ John C. Nivison
U.S. Magistrate Judge

Dated this 4th day of January, 2019.