Circuit Court for Baltimore City
Case No. 24-C-19-002438

UNREPORTED

IN THE APPELLATE COURT

OF MARYLAND*

No. 2039

September Term, 2019

M.M.

v.

UNITED HEALTHCARE INSURANCE CO., et al.

Leahy,
Arthur,
Woodward, Patrick L.
(Senior Judge, Specially Assigned),

JJ.

Opinion by Woodward, J.

Filed: January 5, 2023

* At the November 8, 2022 general election, the voters of Maryland ratified a constitutional amendment changing the name of the Court of Special Appeals of Maryland to the Appellate Court of Maryland. The name change took effect on December 14, 2022.

** This is an unreported opinion, and it may not be cited in any paper, brief, motion, or other document filed in this Court or any other Maryland Court as either precedent within the rule of stare decisis or as persuasive authority. Md. Rule 1-104.

M.M.,[1] appellant, submitted a request for prior authorization to his health insurance company, United Healthcare Insurance Co. ("United Health"), appellee, seeking coverage for an orthotic device to help him regain functional use of his partially paralyzed left arm. United Health denied the request on grounds that the device falls within a policy exclusion for "Experimental Services."

After exhausting United Health's internal grievance process, appellant filed a complaint with the Maryland Insurance Administration ("MIA"). MIA determined that United Health had not violated Maryland insurance law in denying the claim. After an evidentiary hearing, the Maryland Insurance Commissioner ("Commissioner") affirmed MIA's determination. Appellant filed a petition for judicial review of the Commissioner's decision in the Circuit Court for Baltimore City, and the circuit court affirmed.

Appellant filed a timely appeal from the decision of the circuit court, presenting three issues for our review, which we have rephrased as questions and edited for clarity:[2]

[1] We shall identify appellant by his initials to protect his medical privacy.

[2] Appellant presented the following issues in his brief:

A. Whether the MIA's decision, which concluded that [United Health] was entitled to rely exclusively on its poorly research[ed] policy that the MyoPro is unproven is supported by substantial evidence.

B. Whether the MIA's decision is arbitrary and capricious and premised on several erroneous conclusions of law, including incorrect rulings of law regarding IN § 15-10A-04(c), and IN § 15-123(f)(2).

C. Whether the MIA made several erroneous evidentiary rulings, including its penalizing [appellant] for not having his certified prosthetist/orthotist testify, and whether to allow [appellant] to admit documents, in particular supporting articles and studies.

1. Was the Commissioner's decision supported by substantial evidence?

2. Was the Commissioner's decision arbitrary and capricious and premised on erroneous conclusions of law?

3. Did the Commissioner err in excluding evidence?

For the following reasons, we shall affirm.

BACKGROUND

Statutory Framework

In 1998, the General Assembly enacted legislation that created a "comprehensive program establishing standards for health insurers and their agents for reviewing benefit determinations, and providing claimants with an administrative remedy to recover health insurance benefits improperly denied by insurers." *Conn. Gen. Life Ins. Co. v. Ins. Comm'r for the State of Md.*, 371 Md. 455, 458 (2002). Pursuant to Maryland Code (1997, 2017 Repl. Vol.), Insurance Article (IN), § 15-10A-04(c)(1), it is a violation of Maryland law for an insurance carrier "to fail to fulfill the carrier's obligations to provide or reimburse for health care services specified in the carrier's policies or contracts with members."

The legislation also established standards for licensed health insurers to undertake utilization review, which is defined as "a system used by insurers to determine whether a particular health care service is covered under a health insurance contract." *Conn. Gen.*, 371 Md. at 458. Pursuant to IN § 15-10A-04(c)(3):

> [I]t is a violation of this subtitle, if the Commissioner, in consultation with an independent review organization, medical expert, the Department, or other appropriate entity, determines that the criteria and standards used by a health maintenance organization to conduct utilization review are not:
>
> (i) objective;

(ii) clinically valid;

(iii) compatible with established principles of health care; or

(iv) flexible enough to allow deviations from norms when justified on a case by case basis.

The statute is enforced by MIA, "an independent unit of the State government" that is headed by the Commissioner. IN § 2-101. Upon receiving an "adverse decision" from an insurance company, and, after exhausting the insurer's internal grievance process, an insured "may file a complaint with the Commissioner" seeking review of that decision. IN §§ 15-10A-02(c); 15-10A-03(a)(1). The health insurance carrier has the burden of persuading the Commissioner that the carrier's decision to deny coverage was correct. IN § 15-10A-03(e)(1). A final decision of the Commissioner made on a complaint "is subject to a right to file a petition for judicial review under § 2-215 of this article for a carrier or a member." IN § 15-10A-04(e)(ii).

In the alternative, "a member may request a hearing to be held in accordance with § 2-210 of this article of a final decision of the Commissioner made on a complaint under this subtitle." IN § 15-10A-04(e)(2). If a hearing is requested, such hearing shall be conducted in accordance with the Administrative Procedure Act, Contested Cases, State Government Article, §§ 10-201, *et. seq.*[3] IN § 2-210(c)(1). In holding a hearing, "the Commissioner sits in a quasi-judicial capacity" and after a hearing shall issue an order that

[3] A hearing held under IN § 2-210 is not subject to § 10-216 of the State Government Article, which pertains to cases in which the final decision maker in a contested case has not personally presided over the hearing. IN § 2-210(c)(2).

may, among other things, "affirm, modify, or nullify an action already taken." IN § 2-214(a), (b), and (d)(1). An appeal from an order resulting from a hearing may be taken by filing a petition for judicial review with the appropriate circuit court within thirty days after such order was served on the persons entitled to receive it. IN § 2-215(a) and (d)(1).

Appellant's Insurance Plan

At all times relevant to this appeal, appellant was a "covered person" under a health benefits plan ("Plan") that provides medical benefits through United Health. According to the Certificate of Coverage ("Certificate"), which is part of the Plan's policy, United Health is obligated to pay benefits for "Covered Health Services." Covered Health Services is defined in the policy:

> Covered Health Service(s) - those health services, including services, supplies, or Pharmaceutical Products, which we determine to be all of the following:
>
> - Medically Necessary.
> - Described as a Covered Health Service in this *Certificate* under *Section 1: Covered Health Services* and in the *Schedule of Benefits*.
> - **Not otherwise excluded in this *Certificate* under *Section 2: Exclusions and Limitations*.**

(Bold emphasis added).

> "Section 2: Exclusions and Limitations" of the policy provides, in relevant part:
>
> We do not Pay Benefits for Exclusions
>
> We will not pay Benefits for any of the services, treatments, items or supplies described in this section, even if either of the following is true:
>
> - It is recommended or prescribed by a Physician.

- It is the only available treatment for your condition.

The services, treatments, items or supplies listed in this section are not Covered Health Services, except as may be specifically provided for in *Section 1: Covered Health Services* or through a Rider to the Policy.

***

9. Experimental Services. This exclusion does not apply to the off-label use of a Prescription Drug Product if such Prescription Drug Product is recognized for treatment in any of the standard reference compendia or in the medical literature.

***

(Bold emphasis added).

The term "Experimental Services" is defined in the policy, in pertinent part, as "services that are not recognized as efficacious as that term is defined in the edition of the *Institute of Medicine Report on Assessing Medical Technologies* that is current when the care is rendered." To ascertain whether a service is "experimental," United Health undertakes a review of its Omnibus Code Policy ("Omnibus Policy"). The Omnibus Policy is developed by United Health's Medical Policy Team and includes those services that cannot be covered because they are "unproven." An unproven service is one where there is insufficient medical literature to support its efficacy and safety.

MyoPro Recommendation

In September 2016, appellant, then 35 years-old, was diagnosed with cervical myelopathy resulting in left upper extremity weakness. In November 2016, appellant was evaluated at the Kennedy Krieger Institute. The assessment revealed that appellant had "decreased strength in key muscles associated with the level of injury, decreased motor

control and decreased functional skills." It was recommended that appellant participate in a 12-week program of "aggressive activity based restorative therapy" to address "current impairments [and] functional limitations, and [to] maximize functional independence and mobility."

In February 2017, appellant was re-evaluated. At that time, it was noted that there was no official diagnosis to explain the loss of upper extremity function, but that the most likely cause was a spinal cord stroke. A five-month course of occupational therapy had resulted in some functional improvements in appellant's left shoulder and wrist, but his elbow function had not improved. It was noted that appellant had to use his right arm to hold the left arm in any position other than full extension. Appellant was unable to perform tasks such as pushing open a heavy door, placing objects overhead, or carrying his young children. Appellant also required assistance to perform several activities of daily living, which "significantly impacted his quality of life."

The stated focus of the evaluation in February 2017 was to determine if appellant was a candidate for an "upper extremity myoelectric orthosis" that was marketed under the name "MyoPro." MyoPro is described in the record as a wearable, non-invasive device that senses weak muscle signals at the skin's surface, processes the data, and sends the data to a motor on the device that "initiates and enables the desired motion."

The examination revealed that appellant had a "valid myoelectric response on his left upper extremity" with "sufficient strength and graded muscle control" to "properly control and utilize a myoelectrically controlled orthosis." Appellant was determined to be an "excellent candidate" for the MyoPro, which would enable him to have a full range of

elbow flexion that would provide assistance and independence in daily functional tasks. It was recommended that he be fitted for the MyoPro, and a prior authorization request was made to United Health for coverage of the MyoPro.

Initial Denial

By letter dated May 3, 2017, United Health informed appellant that it had reviewed his request for coverage of the MyoPro and had determined that "[t]he services are not eligible for coverage because your plan does not cover unproven procedures." United Health explained that "[t]o be considered proven, services must be recognized as effective or to have a beneficial effect on the diagnosis or treatment of a specified condition according to clinical evidence published in peer-reviewed medical literature." The denial letter went on to state:

> This decision is based on the following plan language found in the Certificate of Coverage in the section entitled: Exclusions and Limitations: . . . We will not pay Benefits for any of the services, treatments, items or supplies described in this section . . . "Experimental Service(s) – services that are not recognized as efficacious as that term is defined in the edition of the Institute of Medicine Report on Assessing Medical Technologies that is current when the care is rendered."

The denial letter indicated further that the decision was based on United Health's Omnibus Policy, Policy Number 2017T0535OO, Effective Date: March 1, 2017, according to which, "[t]he use of the upper limb orthotic known as the MyoPro™ is unproven and not medically necessary due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature."

The 2017 Omnibus Policy contained a summary of a 2013 pilot trial involving 16 people with moderate upper extremity impairment, in which one subgroup "participated in

repetitive task-specific practice entirely while wearing the portable robotic, while the other [subgroup] performed the same activity regimen manually." According to the summary:

> [T]he finding[s] suggest that therapist supervised task-specific practice with an integrated robotic device could be as efficacious as manual practice in some subjects with moderate upper extremity impairment. Additional studies are needed as there is still insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature.

Internal Grievance

On July 14, 2017, Ability Prosthetics and Orthotics ("Ability"), on behalf of appellant, filed an internal grievance with United Health.[4] In a letter written by Stephanie Morgan Greene, Ability claimed that the 2013 study summarized in United Health's Omnibus Policy was irrelevant to appellant's request because the study involved a different device and was designed to measure only short-term rehabilitation benefit. Ability explained that "[t]he MyoPro's design is primarily intended for permanent wear and use for functional restoration, not merely rehabilitation." Attached to the appeal letter was a reference list of three articles that, according to Ability, demonstrated the "proven clinical efficacy in this kind of technology." Ability claimed that there were numerous other articles demonstrating that patients with varying degrees of upper extremity weakness due to neurological damage benefitted from the use of powered orthoses.

By letter dated August 23, 2017, United Health advised Ability and appellant that it had reviewed the request for grievance and confirmed that the MyoPro was not eligible for coverage based again on the exclusion for "Experimental Services" and the 2017 Omnibus

[4] Pursuant to IN § 15-10A-02(b)(2)(iii), a health care provider may file an internal grievance of behalf of a member of an insurance plan.

Policy. The "specific clinical rationale" provided for the decision was that the MyoPro device "has not been shown to be effective for your condition[,]" and that the Plan "does not cover devices that have not been shown to help."[5]

MIA Complaint

On September 25, 2017, appellant filed a complaint with MIA, asserting that United Health's rationale for denying coverage was based on inadequate research. Attached to the complaint was a list of peer-reviewed studies that purportedly demonstrated the "proven clinical efficacy" of the MyoPro.

MIA sought independent review of the complaint from IPRO, an independent review organization.[6] IPRO was asked to determine (1) whether the MyoPro is medically necessary, (2) whether the MyoPro is unproven, and (3) whether the criteria utilized by United Health in denying coverage were: "(A) [c]orrectly applied by the carrier; (B) [o]bjective; (C) [c]linically valid; (D) [c]ompatible with established principles of health care; and (E) [f]lexible enough to allow deviations from the norms when justified on a case

[5] On October 2, 2017, United Health completed a "re-review" of appellant's grievance. By letter dated October 3, 2017, United Health advised appellant that the denial was upheld for the same reason previously given: "this device has not been shown to be effective for your condition. Your health plan does not cover devices that have not been shown to help."

[6] The Commissioner may consult with an independent review organization in determining whether the criteria and standards used by a health maintenance organization to conduct utilization review violate Maryland law. IN § 15-10A-04(c)(3).

by case basis[.]"[7] The review was conducted by Dr. Monty M. Bodenheimer, a physician who was board certified in physical medicine and rehabilitation with a subspecialty in pain management. Dr. Bodenheimer reviewed appellant's medical records, along with United Health's guidelines and its application of those guidelines, and ultimately concluded that, "[f]rom a physical medicine and rehabilitation/pain management perspective as well as within a reasonable degree of medical certainty," the MyoPro "is best described as unproven and not medically necessary." Dr. Bodenheimer explained the basis for his opinion:

> A medical literature review was performed. The quality and quantity of data in the current peer-reviewed scientific medical literature is inadequate to establish the clinical utility, safety and efficacy of the requested MyoPro, myoelectric prosthesis for the treatment of this patient's clinical condition. There are limited long term rigorous published medical studies to support the clinical efficacy of this particular device.

Dr. Bodenheimer also reviewed the three articles referenced by Ability in its July 14, 2017 appeal letter and dismissed all three, noting that:

> [T]he article by Hunsaker does not specifically discuss orthotic devices. The Peters article is limited by its small sample size of 18 and evaluates patients with a different diagnosis (stroke) than that of the patient (myelopathy). The Tyson article actually concludes, "[c]urrent evidence suggests that an upper limb orthosis does not affect upper limb function, range of movement at the wrist, fingers or thumb, nor pain."

Dr. Bodenheimer added that "[o]ther studies are similarly limited by small numbers and differences in methodology and population."

[7] MIA also asked IPRO for its opinion on medical necessity, pursuant to IN § 15-10A-03(d); however, appellant's prior authorization request for coverage was not denied on that basis.

Finally, in addition to concluding that the MyoPro was "considered unproven in the clinical medical literature at this time," Dr. Bodenheimer determined that the criteria utilized to make that decision were correctly applied by the carrier, objective, clinically valid, compatible with established principles of healthcare, and flexible enough to allow deviations from norms when justified on a case-by-case basis.

By letter dated November 15, 2017, MIA advised appellant of Dr. Bodenheimer's review of appellant's complaint with MIA about United Health's denial of coverage. MIA wrote that based on Dr. Bodenheimer's "opinion and our investigation, [MIA] finds no basis on which we can overturn the decision of [United Health] to deny coverage for the MyoPro, myoelectric limb orthosis." In response, appellant filed a request on December 12, 2017, for an administrative hearing pursuant to IN § 2-210. Such request was approved by the MIA on January 2, 2018.

Administrative Hearing

On January 16, 2019, the Commissioner held an evidentiary hearing on appellant's complaint. United Health, as the party with the burden of proving that its adverse decision was correct, presented its case first.

In opening statement, counsel for United Health explained that the claim was denied because the MyoPro was determined to be an "unproven device" and therefore fell within the Plan's exclusion for "Experimental Services." United Health called two witnesses: Dr. Trinh Tran, and Dr. Upasana Bhatnagar.

Dr. Tran, United Health's Medical Director for Appeals and Grievances, testified as to how and why United Health came to its decision. She explained that a "Covered

Service" is defined in Plan documents as a service that is (1) medically necessary, (2) listed as a covered health service in section 1 of the Certificate, and (3) not otherwise excluded under section 2 of the Certificate. When United Health receives a request for prior authorization for a service, the first step is to verify that the service is listed as a covered health service. If the service is listed, the next step is to determine if there are any applicable exclusions. A medical necessity determination is not made unless the service is first found to be listed as a covered health service and is not otherwise excluded.

Dr. Tran stated that the MyoPro is considered durable medical equipment, and that durable medical equipment is a covered service under the Plan. Dr. Tran explained that appellant's prior authorization request was denied, however, because it was excluded. Dr. Tran testified that coverage was denied pursuant to "an exclusion for services that are experimental[.]" She stated that, based on the exclusion for "Experimental Services," "we would then go to . . . our omnibus policy of unproven services and the MyoPro is listed in that policy."

Dr. Tran defined "unproven service" as "a service that has been identified by the medical policy team as not coverable because [] there is insufficient medical literature to support its efficacy and safety." "Unproven" services are catalogued by United Health in the Omnibus Policy, which is a document that "includes services that cannot be covered as they are considered to be unproven." Dr. Tran explained that if the requested service is listed as "unproven," United Health "must follow the [Omnibus Policy] and . . . the benefit document that states that unproven services are excluded from coverage."

Dr. Tran testified that the internal appeal filed on appellant's behalf was denied based on a determination that "the service is unproven and excluded from coverage." In October 2017, the denial was reconsidered but the decision remained unchanged: coverage was denied based on United Health's policy determination that the MyoPro was an unproven device.

Dr. Bhatnagar, the National Medical Director of United Health's Medical Policy Team, was called as a witness to testify about the Omnibus Policy and why the MyoPro was considered "unproven." She explained that the Omnibus Policy is a conglomeration of services that did not "meet the mark of having enough clinical evidence to have coverage, so they're defined as unproven for the most part." She defined "unproven" as "something [that] doesn't work" or that "doesn't have clinical benefit[,]" which, she explained, means that the therapy or service at issue is not more helpful than another therapy or service. She stated that United Health is "rooted in evidence-based medicine and there has to be well substantiated clinical evidence to support use of a particular treatment or service."

Dr. Bhatnagar stated that the Medical Policy Team "develop[s] policies to manage services" by looking at current and emerging technologies. She explained the process as follows:

> So we have a robust process of evaluation of services that starts out with looking at evidence-based literature in a variety of manners . . . . [W]e do a simple Google search, we look at PubMed, we look at CMS guidelines. We look at independent review organizations that do technology assessment . . . .
>
> We take the evidence that we have through our medical technology assessment committee and present the level of evidence to come upon

> determinations of whether or not we think something is proven or unproven and whether the evidence meets the mark to substantiate that.
>
> We have dialogue with subject matter experts both within the company and sometimes externally as well. We'll also engage with specialty societies as needed[.]

When the Medical Policy Team reviews scientific studies, "a randomized controlled trial with a substantial number of patients" is given more weight than "a smaller trial which may not have a controlled population[.]" If the evaluation process leads to a determination that there is insufficient clinical evidence to establish a health benefit for the service or device, it is classified as "unproven."

According to Dr. Bhatnagar, services that are considered unproven are reviewed yearly, at a minimum. If there have been any studies since the prior review, those studies are evaluated by a committee for their "level of evidence."

Dr. Bhatnagar explained that the MyoPro is considered "unproven" because there is "very limited clinical evidence" related to its use. Dr. Bhatnagar reviewed the studies cited by appellant during the course of the appeals process. She stated that the additional studies did not change United Health's determination that the MyoPro was unproven. She explained that most of the studies relied on by appellant were not applicable because they either did not apply specifically to the MyoPro or did not measure its benefits.

Dr. Bhatnagar testified that the 2017 Omnibus Policy was updated in 2019, and, at that time, the MyoPro was still considered unproven. As of 2019, there were additional published studies available that were considered, including two reports from ECRI, a health technology assessment company that "review[s] evidence that's available in the literature"

and makes an "independent assessment of whether they see a certain therapy having clinical evidence to support." Dr. Bhatnagar explained that, in a 2017 report, ECRI concluded that there was "limited evidence based on small trials," and that "additional studies are needed to confirm the results, provide longer term results, [and] look at different patient populations[.]" In a 2018 report, ECRI again concluded that "the evidence was insufficient to determine how well the MyoPro works or how it compares to alternative devices intended to improve arm and hand impairment[,]" and that "[c]ontrolled studies with larger sample sizes are needed to assess efficacy, provide longer term results and study the use of the device [] in different patient populations."

Appellant called one witness, Dr. Leo Green, a board-certified prosthetist, and Chief Medical Officer of Myomo, maker of the MyoPro. Dr. Green described how the MyoPro works and explained that the technology was first developed in the 1950s. He testified that other insurance plans provide coverage for the MyoPro and opined that United Health failed to do a comprehensive review of relevant studies and literature in concluding that the MyoPro was "unproven." He questioned the qualifications of the United Health employees who were involved in the decision to deny coverage because they were doctors of internal medicine with no training in prosthetics and orthotics.

Commissioner's Decision

On March 21, 2019, the Commissioner issued a 21-page Memorandum and Final Order, in which the Commissioner concluded by a preponderance of the evidence that United Health did not violate Maryland insurance law when it denied appellant coverage

for the MyoPro, myoelectric limb orthosis, on the basis that it was unproven. Relevant to the instant appeal, the Memorandum and Final Order states:

> **In this case [United Health] need only prove it is more likely so than not so that it correctly determined that the Device is unproven. The evidence presented was not overwhelming by any means, but it did satisfy [United Health]'s burden of proof.**
>
> ***
>
> **Dr. Tran credibly described [United Health]'s process for making a determination after receiving a request for prior authorization. There is no evidence to suggest that [United Health] did not follow the process described by Dr. Tran.** Dr. Tran was not offered as an expert in determining whether the Device is unproven or medically necessary. She did not testify based on knowledge, skill, expertise, or experience with the Device. She did not testify based on knowledge of the research studies or trials, and did not testify based on knowledge of [appellant]'s condition. Dr. Tran's testimony was limited to [United Health]'s process. She was knowledgeable about that process and described it in a clear and concise manner.
>
> **Dr. Green is a licensed physician and a board certified prosthetist.** [] **He is currently the Chief Medical Officer at Myomo, Inc., the manufacturer of the Device, and has been an employee for two years.** [] Dr. Green's employment requires him to clinically evaluate candidacy in patients such as [appellant] and to advocate on behalf of candidates to their insurance companies for approval of the Device. [] Dr. Green testifies on behalf of candidates with a variety of neuromuscular injury illness that leads to chronic arm weakness which is resistant to other treatments. []
>
> Dr. Green was qualified as an expert with respect to the Device, the condition it seeks to treat, how it treats that condition, and that it is the best device for [appellant]'s condition. Dr. Green credibly described the Device, [appellant]'s condition, and why [appellant] was an ideal candidate for the Device. [] There is no doubt that [appellant] is an ideal candidate and would significantly benefit in his daily living activities with the assistance of the Device**. Although Dr. Green sought to testify that many of [United Health]'s insureds who had amputations were approved for myoelectric devices, I was unable to give that testimony much weight without more information.** I did include the cases provided by [appellant] in the facts of this opinion.

Dr. Bhatnagar's testimony was offered to explain why [United Health] considered the Device to be unproven for any condition. [] Dr. Bhatnagar's background included a residency in obstetrics and gynecology. After medical school she was in private practice for 12 years, the last two years also working for the Food and Drug Administration providing, among other things, clinical review of new drug applications and pregnancy registry protocols. Upon joining [United Health], Dr. Bhatnagar was part of the Medicare and Retirement and Special Plans Team. Thereafter, **Dr. Bhatnagar joined [United Health]'s Medical Policy Team ("MPT"). In this position, Dr. Bhatnagar works with the MPT developing policies, reviewing policies, coding updates, and maintaining policies for all lines of business.** []

Dr. Bhatnagar credibly described how a policy is created, including how the Omnibus Policy is created. [] **According to Dr. Bhatnagar, the Omnibus Policy is a policy designed to "conglomerate services that we've evaluated that didn't meet the mark of having enough clinical evidence to have coverage, so they're defined as unproven for the most part."** [] **Dr. Bhatnagar credibly testified that the services contained in the Omnibus Codes do not have enough clinical evidence to support their use and that every clinical service contained in the Omnibus Policy has its own clinical review at least annually.**

Dr. Bhatnagar was asked "how United came up with the conclusion that . . . the MyoPro device was unproven." [] **Dr. Bhatnagar explained in detail "how" a service is reviewed. [United Health] makes this determination based on the studies, the type of study, who conducted the study, what the studies showed. [United Health] looks for a body of evidence with reproducibility.**

With respect to the Device, Dr. Bhatnagar explained that between 2017 when [appellant]'s request was received and denied, and 2019 there were more published studies. There was also an ECRI technology assessment in 2017 and again in 2018. ECRI is an independent health technology assessment company that reviews evidence in the literature and makes a determination concerning whether there is clinical evidence to support the therapy. [] According to the Omnibus Policy, effective January 1, 2019, a 2017 ECRI health Technology Assessment concluded that "MyoPro alone improved activities of daily living as much as supervised therapy alone in the short term for some stroke patients." [] Further, "[a]dding MyoPro to supervised therapy provided little to no additional benefit." [] Finally, "[t]hese conclusions are based on limited evidence from 4 very small published studies and 1 conference abstract reporting on 91

> stroke patients." [] The same Omnibus Policy also described a 2018 ECRI Custom Product Brief which concluded "that the evidence is insufficient to determine how well the MyoPro works or how it compares with alternative devices intended to improve arm and hand impairment." [] Both the 2017 and 2018 ECRI reports concluded that "controlled studies with larger sample sizes are needed to assess efficacy, provide longer-term results, and study use of the device in different patient populations." []
>
> **Dr. Bhatnagar testified that she had reviewed the materials submitted by [appellant], including various studies, and did not find a basis on which to change [United Health]'s determination that the Device is unproven. Dr. Bhatnagar's testimony together with IPRO's determination, and the findings of the MPT provided the bare minimum for my determination that [United Health]'s evidence proved by a preponderance that it did not fail to fulfill its obligations to provide or reimburse for health care services specified in its policies or contracts with members.**

(Emphasis added).

Petition for Judicial Review

Appellant filed a timely petition for judicial review of the Commissioner's decision with the circuit court. Following a hearing, the circuit court affirmed, concluding that the Commissioner's findings were based on substantial evidence, specifically, the testimony of Dr. Tran regarding the process for making a coverage determination, the testimony of Dr. Bhatnagar regarding the basis for the decision that the MyoPro was an unproven device, and the findings of the independent review organization. The court further found that the Commissioner's decision was not premised on an incorrect conclusion of law, and that the Commissioner did not erroneously exclude evidence. This timely appeal followed.

STANDARD OF REVIEW

In an appeal of a final administrative order of the Commissioner, we "directly evaluate the Commissioner's administrative determination, not the decision of the Circuit

Court." *Md. Ins. Comm'r v. Kaplan*, 434 Md. 280, 297 (2013). "Our role is 'limited to determining if there is substantial evidence in the record as a whole to support the [Commissioner's] findings and conclusions, and to determine if the administrative decision is premised upon an erroneous conclusion of law.'" *Richardson v. Md. Dep't of Health*, 247 Md. App. 563, 569 (2020) (quoting *Milliman, Inc. v. Md. State Ret. and Pension Sys*., 421 Md. 130, 151 (2011), *cert. denied*, 472 Md. 17 (2021)). "[B]ecause agency decisions are presumed *prima facie* correct, we review the evidence in a light most favorable to the agency." *Md. State Highway Admin. v. Brawner Builders, Inc.*, 248 Md. App. 646, 657 (2020), *aff'd sub nom*. 476 Md. 15 (2021).

In applying the substantial evidence test, we must decide, "'after reviewing the evidence in a light most favorable to the administrative agency, whether a reasoning mind reasonably could have reached the factual conclusion the agency reached.'" *Richardson*, 247 Md. App. at 570 (quoting *Colburn v. Dep't of Pub. Safety & Corr. Serv.*, 403 Md. 115, 128 (2008)) (additional citation and some internal quotation marks omitted). "We defer to the agency's (i) assessment of witness credibility, (ii) resolution of conflicting evidence, and (iii) inferences drawn from the evidence." *Id.*

Further, "purely legal questions are reviewed *de novo* with considerable 'weight afforded to an agency's experience in interpretation of a statute that it administers.'" *Comm'r of Lab. & Indus. v. Whiting-Turner Contracting Co.*, 462 Md. 479, 490 (2019) (quoting *Schwartz v. Md. Dep't of Nat. Res.*, 385 Md. 534, 554 (2005)). We are, however, "under no constraint to affirm an agency decision premised solely upon an erroneous conclusion of law." *Md. Ins. Comm'r*, 434 Md. at 297.

DISCUSSION

Was the Commissioner's Decision Supported by Substantial Evidence?

Appellant's first argument on appeal is that there was a lack of substantial evidence before the Commissioner to support a conclusion that the MyoPro was unproven and therefore excluded from coverage as an "experimental service." In support of this contention, appellant asserts that United Health inappropriately relied on a single study and "failed to consider any of the many other articles dealing with myoelectric devices and the MyoPro in formulating its policy." Appellant further claims that the Commissioner's reliance on the report of the IPRO was "misplaced" because the report was based on "the same faulty reasoning" employed by United Health in denying coverage. Finally, appellant contends that the Commissioner incorrectly relied on the testimony of Dr. Bhatnagar that a review of the additional studies appellant cited during the internal grievance process did not alter United Health's decision to deny appellant's claim because she "has no qualifications or ability to assess any of the studies referenced by [appellant]."[8]

Viewing the evidence in the light most favorable to agency, as we must, we conclude that there was substantial evidence to support the Commissioner's findings and

[8] Appellant also argues that, because United Health "had no justification for its determination that the MyoPro was 'otherwise excluded' as experimental[,] it was required to determine whether the MyoPro was Medically Necessary." Under appellant's Plan, however, for services such as MyoPro to be covered, all of the following elements must be met: (1) medically necessary, (2) a Covered Health Service, and (3) not otherwise excluded. Because we conclude, *infra*, that there was substantial evidence to support the Commissioner's decision that the MyoPro was excluded from coverage as an "experimental service," United Health was not required to review the MyoPro's "medical necessity."

conclusions. Dr. Tran explained that, in determining whether the exclusion for "experimental services" applies to a request for prior authorization, United Health turns to its Omnibus Policy, which lists services that are considered to be unproven.[9] Dr. Bhatnagar testified that a service is considered unproven if there is insufficient clinical evidence to establish a health benefit for the service. According to Dr. Bhatnagar, United Health's Omnibus Policy classified the MyoPro as an unproven service because of a lack of well-substantiated clinical evidence to support its use. Dr. Bhatnagar also indicated that the Omnibus Policy on the MyoPro relied on a technology assessment by ECRI, an independent health technology assessment company, that "the evidence was insufficient to determine how well MyoPro works or how it compares with alternate devices intended to improve arm and hand impairment." Finally, Dr. Bhatnagar testified that she had reviewed the materials submitted by appellant, including various studies, and found no basis on which to change the determination that the MyoPro was unproven. The Commissioner expressly credited the testimony of both Drs. Tran and Bhatnagar.

In reaching a determination in favor of United Health, the Commissioner also relied on the IPRO report from Dr. Bodenheimer, who conducted an independent review of

[9] Appellant contends that United Health could not rely solely on the Omnibus Policy to determine that the MyoPro was unproven and thus "otherwise excluded" from coverage. Pointing to language in appellant's Plan that the Omnibus Policy "provides assistance in interpreting [United Health]'s benefit plans," appellant claims that the Omnibus Policy is only "a starting point" and that United Health needed to "conduct an updated review of the medical literature supporting use of the MyoPro." Appellant, however, fails to cite to any language in appellant's Plan that precludes United Health from relying solely on the Omnibus Policy in determining whether a service is "otherwise excluded," nor does appellant identify any Plan language requiring an updated review of medical literature supporting the MyoPro.

medical literature related to the MyoPro. Dr. Bodenheimer concluded that the "quality and quantity of data in the peer-reviewed scientific medical literature is inadequate to establish the clinical utility, safety and efficacy of the requested MyoPro[.]"

Appellant's arguments focus on the credibility and weight of the evidence. Appellant first attacks United Health's reliance on the 2017 Omnibus Policy by pointing to the critique of that policy contained in Ability's July 14, 2017 appeal letter. Second, appellant claims that the Commissioner's reliance on IPRO's determination was misplaced, because "IPRO merely rubber stamped the previous [United Health] denials, using the same faulty reasoning." Lastly, appellant asserts that Dr. Bhatnagar was not qualified "to assess any of the studies referenced by [appellant]." As we have explained, however, "[if] there was evidence of the fact in the record before the agency, no matter how conflicting, or how questionable the credibility of the source of the evidence, the court has no power to substitute its assessment of credibility for that made by the agency, and by doing so, reject the fact." *Travers v. Balt. Police Dep't,* 115 Md. App. 395, 421 (1997) (quoting *Comm'r, Balt. City Police Dep't v. Cason*, 34 Md. App. 487, 508 (1977)). "If the facts in the record allow reasoning minds to reach the same determination as the agency, 'then [the determination] is based on substantial evidence, and the court has no power to reject that conclusion.'" *Md. Real Est. Comm. v. Garceau,* 234 Md. App. 324, 349 (2017) (citations omitted). Here, the facts in the record would allow a reasoning mind to conclude that United Health did not violate Maryland law in denying appellant's prior authorization request for coverage of the MyoPro.

Was the Commissioner's Decision Arbitrary and Capricious and Premised on Erroneous Conclusions of Law?

Appellant argues that United Health's denial of coverage violated IN § 15-10A-04(c)(1), which states that it is a violation of the law "for a carrier to fail to fulfill the carrier's obligations to provide or reimburse for health care services specified in the carrier's policies or contracts with members." Appellant also contends that the criteria and standards used by United Health did not comply with IN § 15-10A-04(c)(3), because such criteria and standards were not "(1) objective; (2) clinically valid; (3) compatible with established principles of health care; or (4) flexible enough to allow deviations from norms when justified on a case by case basis."

In our view, appellant's argument on this question does not involve any misinterpretation or misapplication of the law upon which the Commissioner's decision was based. Rather, appellant is claiming that the Commissioner's ultimate determination that United Health did not violate the law by denying coverage was incorrect. As we have already concluded, there was substantial evidence in the record to support the Commissioner's decision.[10]

[10] Appellant also contends that United Health violated IN § 15-123(f)(2), because United Health admitted that only United Health employees were involved in developing the Omnibus Policies. According to appellant, IN § 15-123(f)(2) "requires that such policies [] be developed with input from physicians and other recognized experts who are not employed by the insurance company doing the evaluation." Appellant mischaracterizes the record evidence. Although Dr. Bhatnagar did testify that the committee developing the Omnibus Policy consists only of United Health employees, he also stated that United Health consults with internal and external subject matter experts and specialty societies. Accordingly, appellant's claim of error is without merit.

Did the Commissioner Err in Excluding Evidence?

Appellant's third and final contention is that the Commissioner improperly excluded eighteen journal articles and a video that he offered into evidence at the conclusion of trial.[11] Regarding the eighteen journal articles, appellant argues, without explanation or elaboration, that "[t]hese articles, however, were directly relevant to whether the MyoPro was 'otherwise excluded' from coverage as unproven as well as to whether [United Health]'s Omnibus Policy was adequately supported." United Health responds that the articles were not related to the MyoPro device, were not clinical studies on such device, or involved the issue of medical necessity, which was not the basis for denial of coverage. Without further identification by appellant of the allegedly relevant articles and specific argument on such articles' relevance, this Court is unable to conclude that any reversible error was committed by the Commissioner. *See* Md. Rule 8-504(a)(4) ("Reference shall be made to the pages of the record extract or appendix supporting [appellant's] assertions."); *Rollins v. Cap. Assocs., L.P.*, 181 Md. App. 188, 201 (2008) ("[W]e cannot be expected to delve through the record to unearth factual support favorable to the appellant.").

Turning now to the video, appellant argues that the Commissioner erroneously excluded the video that appellant intended to submit as part of the testimony of Tyler Cook, an employee of Ability. United Health responds that the video was irrelevant to United Health's denial of coverage or to whether United Health violated Maryland insurance law.

[11] Appellant appears to suggest the Commissioner also excluded one of his witnesses, Tyler Cook, from testifying. The record, however, does not support such claim.

In light of appellant's failure to provide further argument on why the video was relevant, we are again unable to conclude that any reversible error was committed by the Commissioner.[12] *See id.*

JUDGMENT AFFIRMED. APPELLANT TO PAY COSTS.

[12] Appellant also asserts error by the Commissioner for failure to mention any of the documents submitted as a part of Cook's proffered testimony. Appellant's claim of error fails for lack of a factual predicate. At the hearing, when the Commissioner asked appellant what "paperwork" he had submitted from Cook regarding the latter's proffered testimony, appellant responded "[t]he video."