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IN THE
COURT OF APPEALS OF INDIANA

Ashley Brown,

Appellant-Petitioner,

v.

Indiana Family and Social Services Administration,

Appellee-Respondent

February 16, 2017

Court of Appeals Case No. 82A05-1603-PL-688

Appeal from the Vanderburgh Superior Court

The Honorable Richard G. D'Amour, Judge

Trial Court Cause No. 82D07-1504-PL-1921

Crone, Judge.

Case Summary

[1] Ashley Brown appeals the trial court's denial of her petition for judicial review, in which the trial court sustained the determination of the administrative law judge ("ALJ") that Brown's request for prior authorization of Medicaid coverage for genetic testing was properly denied. The Indiana Family and Social Services Administration ("FSSA") concedes that the ALJ erred in its application of Indiana Medicaid law, and therefore requests that we vacate the trial court's decision and remand with instructions for the trial court to remand the case to FSSA for a rehearing. We agree with FSSA, and therefore we vacate and remand.

Facts and Procedural History

[2] In April 2014, Brown was twenty-nine years old and had three children. Brown received Medicaid coverage from the State of Indiana through the Hoosier Healthwise Program. Brown's insurance coverage was administered by MDWise, a managed care entity administering Medicaid insurance coverage as a state contractor. Brown had surgery to remove a tumor in her abdomen. The tumor was identified as a benign paraganglioma, a type of rare neuroendocrine tumor. Appellant's App. at 50, 52. One-third to one-half of paragangliomas are associated with inherited syndromes, including Hereditary Paraganglioma-Pheochromocytoma ("PGL/PCC") Syndrome. *Id*. at 53. PGL/PCC Syndrome "is a familial cancer syndrome which results in neuroendocrine tumors." *Id*. Genetic testing can identify individuals with PGL/PCC Syndrome, and such identification "may improve patient prognosis

through regular screening and treatment of early-onset malignancies." *Id*. at 54. "Early detection [of tumors] through surveillance and removal of tumors may prevent or minimize complications." *Id*. Brown's doctors recommended that Brown have genetic testing to determine whether she had PGL/PCC Syndrome. If the genetic testing showed that she had PGL/PCC Syndrome, then she would receive monitoring and screenings, and her children would also be tested to determine if they had PGL/PCC Syndrome.

[3] In July 2014, Brown's doctors sought from MDWise prior authorization for approval of the PGL/PCC Syndrome genetic test. MDWise denied authorization, stating that the "genetic lab tests [were] not covered under Indiana Medicaid." *Id*. at 29. Brown pursued MDWise's appeal procedures, which included an external review of the denial by an independent review organization for the Indiana Department of Insurance. The reviewer concluded that the genetic testing was "medically indicated" but that "the genetic testing was correctly denied as it is not a covered benefit under the member's health plan." *Id*. at 45-46.

[4] In October 2014, Brown sought an administrative appeal of MDWise's denial of prior authorization. In February 2015, following a hearing, the ALJ found that PGL/PCC Syndrome genetic testing was not excluded from Medicaid coverage by the Indiana Administrative Code, but the Current Procedural Terminology ("CPT") codes for PGL/PCC Syndrome genetic testing were identified as not covered in the Indiana Health Coverage Programs ("IHCP") manual. The ALJ concluded that Indiana's Medicaid program did not cover

genetic testing for PGL/PCC Syndrome and sustained the denial for prior authorization of the genetic test. *Id*. at 25-26. Brown requested agency review of the ALJ's decision, and in March 2015, the FSSA issued a final determination affirming the ALJ's decision. In April 2015, Brown filed a petition for judicial review of FSSA's determination. In February 2016, the trial court issued an order denying Brown's petition. *Id*. at 6-10. This appeal ensued.

Discussion and Decision

[5] Brown seeks review of an agency action pursuant to the Administrative Orders and Procedures Act ("AOPA"). Under AOPA,

> we are bound by the same standard of review as the trial court. When a court reviews a decision from an administrative agency, the reviewing court may neither try the case de novo nor substitute its judgment for that of the agency. Ind. Code § 4-21.5-5-11. Judicial review of disputed issues of fact must be confined to the agency record for the agency action. *Id*. Further, we will not reweigh the evidence. We give deference to the expertise of the administrative body, and will reverse the agency's decision only if it is
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> > (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
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> > (2) contrary to a constitutional right, power, privilege, or immunity;
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> > (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

> (4) without observance of procedure required by law; or
>
> (5) unsupported by substantial evidence.
>
> Ind. Code § 4-21.5-5-14(d). A decision is arbitrary and capricious when it is made without any consideration of the facts and lacks any basis that may lead a reasonable person to make the same decision made by the administrative agency. The burden of demonstrating the invalidity of an agency action is on the party asserting its invalidity. Ind. Code § 4-21.5-5-14(a).

Dev. Servs. Alternatives, Inc. v. Indiana Family & Soc. Servs. Admin., 915 N.E.2d 169, 176 (Ind. Ct. App. 2009) (citations and quotation marks omitted), *trans. denied* (2010).

[6] Specifically, Brown argues that the ALJ erred in sustaining the denial of her request for prior authorization of Medicaid coverage for PGL/PCC Syndrome genetic testing. The Indiana Medicaid program is governed, in part, by Title 405 of the Indiana Administrative Code.[1] 405 IAC 5-29-1 identifies services that are *not* covered under Medicaid:

> (1) Services that are not medically necessary.
>
> (2) Services provided outside the scope of a provider's license, registration, certification, or other authority to practice under state or federal law.

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[1] State Medicaid programs must also comply with 42 U.S.C. § 1396, *et seq*.

> (3) Experimental drugs, treatments, or procedures, and all related services.
>
> (4) Any new product, service, or technology not specifically covered in this article. The product, service, or technology will remain a noncovered product, service, or technology until such time as the office authorizes the coverage of the product, service, or technology. This subdivision does not apply to legend drugs.

This section goes on to list more than thirty specific procedures, services, and drugs that are *not* covered, such as acupuncture, hair transplants, artificial insemination, and amphetamines when prescribed for weight control. Genetic testing is not specifically listed.[2]

[7] In sustaining the denial of Brown's request for prior authorization for PGL/PCC Syndrome genetic testing, the ALJ based its decision on the IAC's exclusion of "[s]ervices that are not medically necessary." 405 IAC 5-29-1(1). Medically necessary services are defined in 405 IAC 5-2-17:

> "Medically necessary service" as used in this title means a covered service (as defined in section 6 of this rule[3]) that is required for the care or well-being of the patient and is provided in accordance with generally accepted standards of medical or professional practice. For a service to be reimbursable by the office, it must:

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[2] We observe that the IAC also provides a list of services for which Medicaid reimbursement may be available with prior authorization. 405 IAC 5-3-13. This list includes "[g]enetic testing for detection of cancer of the breast or breasts or ovaries," but does not specifically include genetic testing for PGL/PCC Syndrome. *Id*.

[3] 405 IAC 5-2-6 provides, "'Covered service' means a service or supply provided by a provider for a member for which payment is available under Medicaid subject to the limitations of this article."

> (1) be medically necessary, as determined by the office, which shall, in making that determination, utilize generally accepted standards of medical or professional practice; and
>
> (2) not be listed in this title as a noncovered service, *or otherwise excluded from coverage.*

(Emphasis added.) The ALJ concluded that because the CPT codes for PGL/PCC Syndrome genetic testing were identified as not covered in the IHCP manual, such testing fell in the category of a service "otherwise excluded from coverage." *Id.*; Appellant's App at 25.

[8] FSSA concedes that the "ALJ erred in her legal reasoning and application of State Medicaid law." Appellee's Br at 12. FSSA states that "the type of genetic testing sought by Brown was not covered under the State Medicaid plan because it was a *new* or *experimental* treatment at the time of the ALJ's decision." *Id.* (citing 405 IAC 5-29-1(3) and -(4)) (emphases added). FSSA urges us to vacate and remand for a new factfinding hearing, explaining as follows:

> the new or experimental provisions of 405 I.A.C. 5-29-1(3) and (4) were not the legal basis for the ALJ's conclusion that the genetic testing was properly considered a noncovered service. And there was no factual finding regarding the genetic testing's status as a new or experimental treatment, e.g., its acceptance in the medical community or general concerns regarding its efficacy or safety. The status of the genetic testing at issue in this case may have now changed from being a new or experimental service, to a medically accepted service, but in order to determine

> the status of the genetic testing at issue in this case, there must be a rehearing of the relevant evidence.

Id.[4] (citations omitted). Indiana Code Section 4-21.5-5-12(b) provides that the court may "remand a matter to the agency before final disposition of a petition for review with directions that the agency conduct further factfinding or that the agency prepare an adequate record, if [] the agency failed to prepare or preserve an adequate record." We agree with the State that under the circumstances of this case remand to FSSA is appropriate.

[9] Brown contends that FSSA is attempting to raise a new issue that it did not properly preserve and that remand is improper, citing Indiana Code Sections 4-21.5-5-10, -11, and -12(a). However, those sections are irrelevant to the propriety of remand to the agency because they address *judicial review* of issues (Section 10) and facts (Section 11) not raised before the agency and when the court may receive evidence in addition to that contained in the agency record (Section 12(a)). The cases relied on by Brown are also inapposite because they address issues pertaining to those sections. Brown also asserts that "even if the Court granted the State's request for a remand instructing [FSSA] to make

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[4] The State notes that a state Medicaid plan may properly limit a new or experimental treatment or service, citing *Miller by Miller v. Whitburn*, 10 F.3d 1315 (7th Cir. 1993). In reference to new or experimental services, the *Whitburn* court observed,

> In making such a decision [whether to provide payment for a particular service], a basic consideration is whether the service has come to be generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used. If it is, Medicare may make payment. On the other hand, if the service is rarely used, novel or relatively unknown, then authoritative evidence must be obtained that it is safe and effective before Medicaid may make payment.

Id. at 1320 (quoting *Rush v. Parham*, 625 F.2d 1150, 1156 (5th Cir. 1980)).

specific findings about the experimental nature of genetic testing, [FSSA] would still need to make an actual determination of medical necessity, which is the crux of Brown's appeal." Appellant's Reply Br. at 6-7. We agree that the FSSA will be required to make an individualized determination as to whether the genetic testing is medically necessary, but that does not persuade us that remand is inappropriate. In fact, Brown asks for us to remand for instructions to the agency to issue a new decision based upon the individual evidence presented regarding medical necessity. Accordingly, we vacate the trial court's denial of Brown's petition for judicial review and remand with instructions for the trial court to remand the case to FSSA for a rehearing.

[10] Vacated and remanded.

Riley, J., and Altice, J., concur.