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Strategies for Responding Effectively to a Denial of Treatment as Experimental or Investigational

Jennifer Rudenick Ecklund and Andrew Cookingham

**ABSTRACT:** A health plan’s determination that a medical treatment is experimental or investigational can have significant consequences for both the health care provider and the patient. For the health care provider, such a determination can mean denial of reimbursement for medical treatment rendered. For the patient, the determination can represent a lost opportunity to pursue a certain treatment when all other traditional treatment options have been exhausted. This article will explore the application of experimental and investigational exclusions to health care providers’ claims and how a provider can effectively challenge a plan’s determination that a service is experimental or investigational in nature. Many factors must be taken into consideration, including the plan’s language on exclusions, the standard of review, and the degree of acceptance in the medical community. This article also will provide practical advice on effectively challenging experimental or investigational denials or pursuing litigation or arbitration when internal plan appeal processes have been exhausted.

**KEYWORDS:** Reimbursement, ERISA, Experimental/Investigational Denial, Internal Appeal, Managed Care Litigation


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The authors wish to thank Mr. Brett Rector, a third-year law student at the University of Virginia School of Law, for his contributions to this article.
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Introduction

Most, if not all, health benefit plans contain an exclusion for treatment that is considered experimental or investigational. The language of the exclusions varies, as does its location in the plan: Sometimes the language is in the exclusions section, or in the covered services section, or in the definition of medically necessary services. Regardless of its location, the end result is often the same: the health plan denies claims it deems (or, more accurately, its administrator deems) are experimental or investigational in nature.

Customary benefit plan language

The language that a plan uses to exclude payment for treatments deemed experimental or investigational varies widely from benefit plan to benefit plan. Some plans simply exclude coverage for “experimental procedures” without providing any additional definition or information about what qualifies as “experimental,” while other plans provide more detail. For example, a benefit plan may exclude from coverage “[a]ny Experimental/Investigational services and supplies” and then include a detailed definition of Experimental/Investigational.

The plan’s language is often the most crucial factor in determining whether a treatment is properly excluded from coverage as experimental or investigational. A thorough examination of the patient’s benefit plan is the first step to determining whether a provider may be able to challenge a denial based on the treatment’s characterization as experimental or investigational.

2 Exclusions for treatment considered experimental or investigational often appear in benefit plans governed by the Employee Retirement Income Security Act, 29 U.S.C., ch. 18 §§ 1001–1461 (ERISA) (both self-funded and fully insured), as well as in traditional health insurance policies. Many of the rules and cases discussed in this article are specific to the administration of ERISA-governed benefit plans. Although traditional insurance may be subject to similar rules, that will be determined by the applicable state law.
Treatment most often denied as experimental or investigational

The treatment that health plan administrators consider experimental or investigational varies over time. After all, a treatment considered experimental or investigational five years ago may now be the well-established standard of care. Health plan administrators, however, are sometimes several years behind in moving a treatment from the experimental/investigational category into the accepted covered services category.

Unfortunately, treatments denied as experimental or investigational are often developed to treat serious, life-threatening illnesses. In many cases, these treatments are a patient’s last hope. For example, one particular cancer treatment commonly denied as experimental or investigational is high-dose chemotherapy with autologous bone marrow or stem cell transplant. Varying protocols of this treatment can be used to treat patients with various types of cancer, including breast cancer and ovarian cancer. Health plan administrators have been denying claims for high dose chemotherapy and autologous bone marrow transplant since in the late 1980s, and continue to do so.

Another more recent and prominent example of a treatment deemed experimental or investigational is proton therapy, most nota-

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3 Shannon v. Jack Eckerd Corp., 113 F.3d 208, 209 (11th Cir. 1997) (plan determined treatment was no longer experimental while case was pending); Heasley, 2 F.3d at 1260 (“[I]t is difficult to identify precisely when a procedure ceases to be experimental and becomes accepted.”).


5 See Harris v. Mut. of Omaha Cos., 992 F.2d 706, 713 n.4 (7th Cir. 1993) (“[T]here is a growing and confusing body of case law that addresses whether HDC-ABMT is an experimental procedure for purposes of insurance coverage.”).
bly used to treat prostate cancer. In the early 2000s, hospital systems began building proton therapy centers to treat various cancers. Currently, more than a dozen such centers exist in the United States, with a dozen more in development; however, commercial health insurers, including Aetna, Cigna, and BlueShield of California, generally deny reimbursement for this therapy as experimental or investigational. This has resulted in one proton therapy center’s closing and another’s restructuring. One factor cited in closing the center was the lack of randomized clinical trials proving the treatment’s efficacy, a crucial step to gaining acceptance (and reimbursement) from health plans.

Fortunately, most large commercial health plan administrators, including Aetna, certain BlueCross and BlueShield plans, Cigna, and United Healthcare, make their policies regarding treatments they deem to be experimental or investigational publicly available on their websites. Each has set forth, in varying levels of detail, which treatment regimens are considered experimental or investigational for certain diagnoses and which (if any) are not. This enables providers and patients to know in advance whether a certain treatment may be denied coverage and prepare accordingly.

7 Id.
8 Id.
At stake for providers

A plan’s determination that a treatment is experimental or investigational can have significant consequences for providers, especially in regards to reimbursement. For instance, if the plan makes this determination after the provider has rendered treatment and submitted the claim, the plan will not reimburse the provider. Further, if the provider is in the plan administrator’s network, the provider will likely not be allowed to bill the patient, as most managed care agreements preclude a provider from charging the patient for non-covered services absent a pre-treatment agreement to the contrary.

The financial consequences are less dire if the health plan denies the provider’s application for pre-authorization of treatment, as the provider has not yet provided the treatment or service. However, the provider will not be reimbursed by the plan to provide the treatment and has lost the opportunity to provide the treatment (absent an agreement by the patient to pay for it).

The most important consequence, however, may be that the patient is denied potentially life-saving treatment. Many treatments that are denied as experimental or investigational are usually treatments of last resort, offered only after standard treatments have failed.

Challenging Denials in General

All (or nearly all) managed care agreements and health benefit plans require a health care provider or the patient to exhaust all internal appeals of a plan’s denial of benefits. This is true for all benefit denials, and applies whether the denial was prospective (e.g., the plan denied the patient or provider’s request for precertification) or retrospective (most commonly, the plan denied the provider’s claim for reimbursement). Taking advantage of all internal appeal opportuni-

11 At least initially; if the plan overturns the denial through its administrative appeals process, it will be paid.
ties is generally a prerequisite to bringing a lawsuit concerning any plan decision adjudicating benefits.

**A health care provider must generally appeal all denials**

Generally, the patient or health care provider must appeal the plan administrator’s denial of reimbursement for a particular service. This is true regardless of whether the provider is in-network or out-of-network, and whether the denial is prospective or retrospective.\(^{12}\)

Although benefit plans have their own established deadlines, federal regulations provide minimum required standards for the appeal process for ERISA plans.\(^{13}\) Under these standards, the provider or patient must have at least 180 days to appeal any adverse benefit determination.\(^{14}\) After receiving an appeal, the plan administrator has between 15 and 60 days to respond, depending on the type of claim and number of appeals permitted under the plan.\(^{15}\)

The information submitted by the provider for the internal appeal is critical because the evidence in any subsequent lawsuit to recover benefits will generally be limited to what was submitted with the appeal, as well as any other documents considered by the plan.\(^{16}\) The provider should therefore think proactively about the documentation to be submitted with an appeal (or collaborate with the patient, if the patient is submitting the appeal). The provider should submit any information

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12 See generally 29 C.F.R. § 2560.503-1; Heimeshoff v. Hartford Life & Acc. Ins. Co., 134 S. Ct. 604, 610 (2013) (“The courts of appeals have uniformly required that participants exhaust internal review before bringing a claim for judicial review under [ERISA].”).
13 29 C.F.R. § 2560.503-1(h)(3)(i) (requiring a health benefit plan to “[p]rovide claimants at least 180 days following receipt of a notification of an adverse benefit determination within which to appeal the determination”). For non-ERISA plans, any deadlines will be set by state law.
14 Id.
15 See id. § 2560.503-1(i)(2).
and documentation that supports the provider’s claims that the service or treatment should be covered to disprove the basis on which the claim was denied. Such information may include the patient’s medical records, medical journal articles, results from medical studies, statements from other physicians, and proposed treatment protocols. If possible, the provider should tailor the appeal to the particular plan language on which the plan relied. The provider should always err on the side of inclusiveness with the appeal.

**Taking action to recover incorrectly denied benefits**

If the plan does not reverse its denial of benefits following an internal appeal, the provider can file a lawsuit or proceed to arbitration against the plan and/or the plan administrator.\(^{17}\) If the provider is in-network and the provider agreement requires arbitration, the provider generally must proceed to arbitration.\(^{18}\) The vast majority of managed care agreements (especially those with large health plan administrators) include detailed dispute resolution provisions requiring arbitration. Most dispute resolution provisions in managed care agreements also contain detailed pre-suit notice and mediation requirements before arbitration may be initiated. These provisions specify who will administer the arbitration (often either the American Arbitration Association or the American Health Lawyers Association), the type of relief the arbitrator may (and may not) order, and the type of discovery available in arbitration. Some provisions also contain a limitation period.

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\(^{17}\) In some instances, the plan may be the only proper defendant. See Larson v. United Healthcare Ins. Co., 723 F.3d 905, 913–16 (7th Cir. 2013). In most circuits, however, the plan administrator is a proper defendant so long as it “exercises ‘actual control’ over the administration of the plan.” See Lifecare Mgmt. Servs. LLC v. Ins. Mgmt. Adm’rs Inc., 703 F.3d 835, 844–45 (5th Cir. 2013); see also Spinedex Physical Therapy USA v. United Healthcare of Ariz., Inc., 770 F.3d 1282, 1298 (9th Cir. 2014).

\(^{18}\) In some instances, the arbitration clause may be narrow in scope and may not cover the types of claims the provider is asserting, in which case the provider would be free to choose to bring its claims in a lawsuit as opposed to an arbitration proceeding. See CardioNet, Inc. v. Cigna Health Corp., 751 F.3d 165, 173–74 (3d Cir. 2014).
If the provider is out-of-network, or if the provider’s managed care agreement does not include an arbitration provision, the provider may file suit against the plan and/or the plan administrator. An out-of-network provider may generally only challenge the administrator’s denial of benefits by filing suit as the patient’s assignee under the Employee Retirement Income Security Act (ERISA) if the patient was a member of an ERISA-governed health benefit plan.19 Some courts have permitted an in-network provider to assert certain claims in a lawsuit as assignee of the patient despite the presence of an arbitration clause in the provider’s managed care agreement.20

The character of an in-network provider’s claim is more complicated. Whether an in-network provider may assert claims for breach of its managed care agreement with the administrator depends largely on the nature of the denial. The majority of courts have held that, where the provider’s claims challenge the plan’s determination of the provider’s right to payment, those claims are brought under ERISA, even by an in-network provider (if the patient’s plan is governed by ERISA). When the provider’s claim challenges only the plan’s determination of the correct rate of payment, the claim is brought under the managed care agreement, not ERISA.21 An example of a claim involving the right to payment would be a challenge to the plan’s coverage determination, whereas an example of a claim involving the correct rate of payment would be a claim that the plan did not pay according to the compensation schedule incorporated into the provider’s managed care agreement.

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19 See generally 29 U.S.C. § 1132(a)(1)(B) (permitting plan participant or beneficiary to bring suit to recover improperly denied benefits); e.g., Lone Star OB/GYN Assocs. v. Aetna Health Inc., 579 F.3d 525, 529 n.3 (5th Cir. 2009) (granting standing to providers suing under an assignment of the patient’s benefits). The majority of courts grant a health care provider standing to sue as the patient’s assignee under ERISA. See, e.g., CardioNet, 751 F.3d at 176 n.10 (“We adopt the majority position that health care providers may obtain standing to sue by assignment from a plan participant.”).

20 See CardioNet, 751 F.3d at 176–78 (permitting in-network provider to avoid effect of arbitration provision by asserting derivative claims as its patients’ assignee under ERISA).

21 E.g., id. at 176–78; Lone Star OB/GYN Assocs., 579 F.3d at 530–31; Blue Cross of Cal. v. Anesthesia Care Assocs. Med. Grp., Inc., 187 F.3d 1045, 1051 (9th Cir. 1999).
care agreement, or a claim that the provider is entitled to a late-payment penalty. Thus, claims regarding the administrator’s coverage determinations, even by an in-network provider, frequently will be preempted by and therefore be brought under ERISA.

### Challenging Denials of Treatment Considered Experimental or Investigational

Courts generally consider a number of factors when reviewing a plan’s determination that a treatment is experimental or investigational. Before reaching these factors, however, the court must first determine both the applicable standard of review and which factors apply, if any. This involves evaluating the plan language and the plan’s definition of experimental or investigational. For example, if the plan employs a particular definition of experimental or investigational that does not include these factors, then the court will likely refuse to consider them (even when the plan asks it to). Where the plan language explicitly includes these factors, or fails to define experimental or investigational, courts will then consider these factors in evaluating the correctness of the plan’s adjudication.

### The correct standard of review

The standard of review that a court employs to evaluate a plan’s coverage decision is crucial to all reimbursement litigation, not only to litigation involving experimental or investigational denials. The stan-

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22 See Lone Star OB/GYN Assocs., 579 F.3d at 530–31.
23 Where the patient’s plan is not governed by ERISA, the nature of the provider’s claims will be governed by state law.
24 See, e.g., Adams, 757 F. Supp. at 669–72 (holding that, where the plan defined the terms “Experimental and Investigational” as “the use of any treatment, procedure, facility, equipment, drug, device, or supply not generally acknowledged as accepted medical practice by the suitable medical specialty practicing in Maryland, as decided by us,” the only issue relevant to the determination was whether practicing oncologists in the State of Maryland utilized the cancer treatment at issue as an “accepted medical practice”).
standard of review applied by a court—de novo or discretionary—can often be outcome determinative. The default standard of review is de novo, but if “the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan” by including a discretionary clause, the plan’s decision is reviewed using a more deferential abuse-of-discretion standard.

Courts have recognized that a plan administrator who is responsible for both making the coverage determination and paying the benefits (if benefits are payable) suffers from a conflict of interest. In such cases, the standard of review does not change; rather, the conflict of interest is a factor that the court takes into account as it sees fit.

Recently, state laws and regulations have banned or severely limited the operation of discretionary clauses. The National Association of Insurance Commissioners recommended a model law eliminating discretionary clauses, and, so far, at least 20 states have adopted either a ban or limitation on discretionary clauses. This makes it more likely that a plan administrator’s decision will be subject to de novo review.

25 See Lafferty v. Providence Health Plans, 436 F. App’x 780, 781 (9th Cir. 2011) (reversing district court’s de novo analysis and affirming plan administrator’s denial of benefits under the “proper” abuse of discretion standard); see also Healthcare Am. Plans, Inc. v. Bossemeyer, 166 F.3d 347 (10th Cir. 1998) (unpublished table decision) (Henry, J., concurring) (explaining that the court would likely have reached a different result applying de novo review, and citing other cases with similar statements).
26 Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989); see also Glenn, 554 U.S. at 111.
27 Firestone Tire & Rubber Co., 489 U.S. at 115; see also Glenn, 554 U.S. at 111.
28 Glenn, 554 U.S. at 116–19 (“We believe that Firestone means what the word ‘factor’ implies, namely, that when judges review the lawfulness of benefit denials, they will often take account of several different considerations of which a conflict of interest is one.” Id. at 117.).
29 See John Morrison & Jonathan McDonald, Exorcising Discretion: The Death of Caprice in ERISA Claims Handling, 56 S.D. L. Rev. 482, 488 n.44 (2011). The article lists each of the regulations and statutes banning discretionary clauses. A list of the statutes and regulations can also be found at AHIP, LIMITATIONS ON THE USE OF DISCRETIONARY CLAUSES: SUMMARY OF STATE LAWS (as of August 16, 2012), available at www.ahip.org/Discretionary-ClauseChart08162012/.
30 Because of the recency of these state laws and regulations, it is currently unclear the extent to which they are preempted by ERISA.
If an administrator’s decision is subject to discretionary review, overturning the administrator’s denial of coverage may be much more difficult than if the decision were subject to *de novo* review. To prevail when a plan grants the administrator discretionary authority, the provider must establish that the decision was “arbitrary and capricious”; that is, that it was not the result of a “deliberate, principled reasoning process,” and was not supported by substantial evidence. In other words, the administrator’s decision must have been unreasonable.

**The plan language**

The actual language of the benefit plan is critical to any denial of benefits, and a denial based on an experimental or investigational determination is no different. As the Supreme Court recently explained, the ERISA framework “is built around reliance on the face of written plan documents . . . The plan, in short, is at the center of ERISA.”

The terms of a plan determine whether coverage is available and, generally, an administrator must “construe[] the plan according to the plain meaning of the plan language.” Plan language must be interpreted as a whole and according to the plain meaning of the language used. Where language is ambiguous, courts will generally construe

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32 *See generally* Porter *v.* Lowe’s Cos., 731 F.3d 360, 363–64 (5th Cir. 2013).
34 *Lifecare Mgmt. Servs.*, 703 F.3d at 841 (internal quotation marks omitted) (quoting Threadgil *v.* Prudential Sec. Grp., Inc., 145 F.3d 286, 292 (5d Cir. 1998)); *see also* 29 U.S.C. § 1022(a) (requiring ERISA plan to furnish plan descriptions “written in a manner calculated to be understood by the average plan participant”); Koehler *v.* Aetna Health Inc., 683 F.3d 182, 187 (requiring courts to “give [the plan’s] language the ordinary and generally accepted meaning”).
35 *See Lifecare Mgmt. Servs.*, 703 F.3d at 841.
the ambiguity against the plan pursuant to the common law rule that ambiguities in an insurance policy are construed against the insurer.  

Importantly, the terms of the benefit plan determine coverage, not other documents issued by a plan administrator, such as summary plan descriptions. Thus, the summary plan description is not considered the plan and generally cannot be enforced as such.

If a plan provides an explicit definition of experimental or investigational, that definition will control. Indeed, some plans even limit the evidence that the administrator can consider to determine whether the treatment is experimental or investigational. In such cases, a court or arbitrator’s review will be subject to the same limits.

36 See UNUM Life Ins. Co. of Am. v. Ward, 526 U.S. 358, 377–79 (1999) (permitting insurance terms of an ERISA-governed plan to be interpreted in light of state insurance rules), modified on other grounds by Ky. Ass’n of Health Plans v. Miller, 538 U.S. 329, 340 (2003); Koehler, 683 F.3d at 188–89 (requiring that ambiguities be construed in accordance with the terms of the summary plan description and in favor of the insured); but see Bernards v. United of Omaha Life Ins. Co., 987 F.2d 486, 489 n.1 (8th Cir. 1993) (“As we have previously held, the common rule of construction that ambiguous language in an insurance policy is construed against the insurer has no place in the construction of an ERISA plan.”).


38 Id. at 1878 (“[W]e conclude that the summary documents, important as they are, provide communication with beneficiaries about the plan, but that their statements do not themselves constitute the terms of the plan for purposes of [ERISA’s enforcement provision].”).

39 E.g., Martin, 115 F.3d at 1204–05 (quoting detailed plan definition of experimental or investigative procedures); see generally Harris, 992 F.2d at 713–14 (“At bottom, this [claims denial case] is one of contract interpretation . . . controlled by the specific language of the contract . . . .” Id. at 713 n.4.).

40 Fuja v. Benefit Trust Life Ins. Co., 18 F.3d 1405, 1408, 1410–11 (7th Cir. 1994) (limiting admissible evidence to those sources specifically endorsed by the health plan); Harris, 992 F.2d at 713–14 (holding district court correctly ignored new medical research because the health plan specifically identified only three forms of evidence to define experimental treatments).

41 Some plans provide explicit provisions regarding treatments that are routinely the subject of an experimental denial. In those instances, the explicit provisions govern, and obtaining coverage for the treatment for a non-covered diagnosis is near-impossible. See Mire v. Blue Cross/BlueShield of Florida, 43 F.3d 567 (11th Cir. 1994) (quoting health benefit plan provision explicitly authorizing use of high-dose chemotherapy with autologous bone marrow transplant for certain diseases and excluding all others).
In cases where an administrator has ignored a plan’s definition of experimental or investigational, a court often will reverse the administrator’s decision.\textsuperscript{42} For example, in Zervos v. Verizon New York, the plan administrator required the disputed treatment to be “superior” to other existing treatments, even though the plan only required the treatment to be “effective.”\textsuperscript{43} The Second Circuit Court of Appeals reversed the plan’s denial of coverage and explained that, by requiring the treatment to be “superior” instead of “effective,” the plan administrator, “contrary to basic ERISA principles . . . in effect added additional language to the policy.”\textsuperscript{44}

Factors for determining whether a treatment is experimental or investigative

Courts have uniformly agreed that, absent a definition in the plan, the terms “experimental” and “investigational” are ambiguous on their face.\textsuperscript{45} Thus, in the absence of a detailed plan definition of experimental or investigational, a reviewing court will consider some or all of the following factors to define the terms and determine whether the treatment meets that definition:

1. the proven effectiveness of the treatment;

\textsuperscript{42} Zervos v. Verizon N.Y., 277 F.3d 635, 647 (2d Cir. 2002); Kulakowski, 779 F. Supp. at 716 (finding denial arbitrary and capricious where plan excluded only experimental procedures, and plan expert described disputed procedure as investigational, not experimental).
\textsuperscript{43} Zervos, 277 F.3d at 647.
\textsuperscript{44} \textit{Id.}; see also Boldon v. Humana Ins. Co., 466 F. Supp. 2d 1199, 1212–13 (D. Ariz. 2006) (holding plan administrator abused its discretion where it denied coverage on the basis of an outside reviewer’s characterization of the treatment as experimental on the basis of a requirement the plan did not contain).
\textsuperscript{45} Heasley, 2 F.3d at 1260; Dahl-Eimers v. Mut. of Omaha Life Ins. Co., 986 F.2d 1379, 1382–83 (holding the phrase “considered experimental” ambiguous where the plan did not indicate who would decide if treatment was experimental and provided no standards for how that decision would be made); Johnson v. Dist. 2 Marine Eng’rs. Beneficial Ass’n, 857 F.2d 514, 516 (9th Cir. 1988) (“In the context of modern medicine, the term ‘experimental’ seems clearly ambiguous on its face.”), overruled on other grounds by Firestone Tire & Rubber Co., 489 U.S. at 115.
2. whether the treatment has been approved by the Food and Drug Administration (FDA) or is covered by the Centers for Medicare and Medicaid Services (CMS);

3. whether the plan conducted a reasonable administrative review;

4. the treatment protocol; and

5. the success of other, proven treatments.

No one factor is dispositive, except where the plan so provides.

**The proven effectiveness and common use of the treatment**

The proven effectiveness of a treatment is often explicitly referenced in benefit plans and thus, a key factor for the court. Courts are generally skeptical of plan administrators who classify treatments as experimental when medical research shows the treatment to be effective and/or generally accepted by medical professionals. Even though plans differ, some courts have looked to other plans’ or insurers’ coverage of the treatment at issue as evidence that the treatment is no longer classified as experimental or investigational. One court has

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46 See, e.g., Zervos, 277 F.3d at 647 (explaining that benefit plan required the treatment to be “effective”).

47 See, e.g., Pitman v. Blue Cross & Blue Shield of Okla., 24 F.3d 118, 124 (10th Cir. 1994) (reversing dismissal of challenge to benefit denial, noting insurer admitted the proposed treatment could “no longer [be] considered experimental.”); McHenry v. PacificSource Health Plans, 679 F. Supp. 2d 1226, 1237 (D. Or. 2010) (finding plan administrator abused its discretion in denying coverage for autism treatment in the face of “decades of research” supporting the procedure); Adams, 757 F. Supp. at 676 (finding for Plaintiff where procedure was commonly prescribed by the local medical community); Pirozzi v. Blue Cross-Blue Shield, Inc., 741 F. Supp. 586, 594–95 (E.D. Va. 1990) (same); see generally Kulakowski, 779 F. Supp. at 716–17 (reviewing decisions in which courts held benefit denials arbitrary and capricious because plan administrators relied on outdated or erroneous research).

48 See, e.g., Bernards, 987 F.2d at 489 (suggesting that approval by multiple insurance companies makes a treatment generally accepted); Bucci v. Blue Cross-Blue Shield of Conn., Inc., 764 F. Supp. 728, 732–33 (D. Conn. 1991) (holding administrator’s denial of benefits to be arbitrary and capricious when a number of other insurers covered the proposed treatment and research supported its use).
even held that a plan’s denial of a procedure as experimental may be upheld on the basis of what other courts were deciding at the time.49

Alternatively, a court will generally agree with the administrator’s decision to deny benefits where medical research about the treatment is limited, or the available research describes the treatment as experimental.50 Typically, treatment with only a limited impact is insufficient,51 and a pattern of successful treatment by the plaintiff’s doctor may be insufficient if the “medical community” has not yet accepted the treatment.52 On the other hand, a plan cannot require unrealistic research results before approving coverage.53

There is no magic number of peer-reviewed medical studies that must exist before a treatment crosses the line from experimental or investigational to effective or generally accepted.54 Courts are skeptical, however, when either party relies on a single source to support its claims. For example, several courts affirmed benefit denials where the

49 Peruzzi v. Summa Med. Plan, 137 F.3d 431, 435 (6th Cir. 1998) (“That courts were still upholding the denial of coverage for the procedure as experimental at the time SummaCare made its determination supports the conclusion that the decision was not arbitrary and capricious.”).

50 See Ortlieb v. United HealthCare Choice Plans, 387 F.3d 778, 784 (8th Cir. 2004) (noting Plaintiff provided no evidence that treatment was “proven”); Martin, 115 F.3d at 1207 (affirming benefit denial where treatment had yet to become common practice); Chambers v. Family Health Plan Corp., 100 F.3d 818, 827 (10th Cir. 1996) (affirming benefit denial where treatment’s mortality rate remained high, few doctors used it successfully, and other insurers were unfamiliar with the procedure).


52 Ortlieb, 387 F.3d at 782 (affirming benefit denial despite treating physician’s testimony that he had used the disputed treatment on five thousand patients); see also Washington, 736 F. Supp. at 1422 (noting that “Plaintiff’s physician may have had success with such experimental treatment in the past . . . [but] [t]hese possibilities do not, however, render the treatment any less experimental or any more recognized by the medical profession.”).

53 See Zervos, 277 F.3d at 647 (finding abuse of discretion where administrator required treatment to be the “most effective” treatment); Adams, 757 F. Supp. at 675 (holding that treatment need not be “completely curative” for it to be “accepted medical practice”).

54 See Heasley, 2 F.3d at 1260 (“[I]t is difficult to identify precisely when a procedure ceases to be experimental and becomes accepted.”).
plaintiff offered only the testimony of his or her treating physician.\textsuperscript{55} Several courts have also found that a plan administrator abused its discretion by relying on a single expert opinion to classify a treatment as experimental or investigational.\textsuperscript{56}

Further, whether a treatment is experimental or investigational is a diagnosis-specific determination.\textsuperscript{57} In other words, a particular treatment may be generally accepted for the treatment of one illness, but considered experimental or investigational for the treatment of another. Thus, courts typically require a tight “fit” between the patient’s illness, treatment, and available research.\textsuperscript{58} For example, high-dose chemotherapy with autologous bone marrow transplant or peripheral stem cell rescue evolved over the years to treat several different forms of cancer, including certain leukemias, Non-Hodgkin’s Lymphoma, neuroblastomas, breast cancer, and ovarian cancer.\textsuperscript{59}

In the 1990s, courts started treating denials of high-dose chemotherapy with autologous bone marrow transplant differently, even when

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\item See Ortlieb, 387 F.3d at 782–84; Mayeaux v. La. Health Serv. & Indem. Co., 376 F.3d 420, 430 (5th Cir. 2004) (“[O]ne concurring medical opinion is inadequate to establish that [a disputed procedure] is standard medical treatment.”).
\item McHenry, 679 F. Supp. 2d at 1237 (holding plan administrator acted unreasonably in classifying proposed treatment as experimental based solely on the opinion of the insurer’s Chief Medical Officer). However, some benefit plans accord sole discretion regarding this determination to the plan administrator, in which case this is less likely to be found arbitrary. See Dahl-Eimers, 986 F.2d at 1383 (“Some courts have found that ambiguity [in the term ‘experimental’] cured when the term . . . is qualified by specifying who will determine the experimental nature of the treatment . . . .”).
\item See Heasley, 2 F.3d at 1259 (“[The plan] contends the term ‘experimental procedure’ must be defined in terms of its particular application, i.e., whether it is an experimental procedure for the type of tumor involved here. We agree.”).
\item See Holder v. Prudential Ins. Co., 951 F.2d 89, 90–91 (5th Cir. 1992) (requiring that research prove the exact treatment effectively treats the exact disease at issue).
\item See generally Mire v. Blue Cross/BlueShield of Florida, 43 F.3d 567 (11th Cir. 1994) (quoting health benefit plan provision authorizing use of treatment for certain diseases and excluding all others); Adams, 757 F. Supp. at 662 n.1 (listing diseases that BlueCross/BlueShield plan at issue authorized use of HDC-ABMT to treat).
\end{enumerate}
\end{footnotesize}
used to treat the same diagnosis. Some courts upheld the denials when the therapy was used to treat small cell lung cancer and epithelial ovarian cancer, but reversed denials of the same treatment for varying stages of breast cancer. More than 20 years have passed since high-dose chemotherapy with autologous bone marrow transplant first became the subject of coverage disputes, but some health plan administrators continue to carefully scrutinize whether the treatment is covered.

In addition to being diagnosis-specific, a determination that a treatment is experimental or investigational can be protocol-specific. In other words, a generally accepted protocol for a particular treatment does not mean that a different protocol for that same treatment will not be classified as experimental or investigational.

Finally, the state of the art of medical research and treatment is generally limited to consideration as it existed at the time the plan administrator denied benefits. Courts recognize that medical research is always advancing, and are wary of holding that an administrator

60 As the Seventh Circuit Court of Appeals wrote, “there is a growing and confusing body of case law that addresses whether HDC-ABMT is an experimental procedure for purposes of insurance coverage.” See Harris, 992 F.2d at 713 n.4.


63 See Holder, 951 F.2d at 90–91 n.5 (noting that the disputed treatment administered under a different protocol was generally accepted before holding that the treatment as applied to the insured was still experimental); Washington, 736 F. Supp. at 1422 (affirming denial of benefits for hyperbaric oxygen treatment for spinal cord injury, in part because treatment would be administered at different stage of the disease).
abused its discretion on the basis of studies that did not exist at the time the plan initially denied coverage. With limited exceptions, most courts also limit review to the administrative record compiled during the plan appeal process. Some courts will accept evidence outside the administrative record, but only if there is good cause to do so.

Some courts have noted that plans and plan administrators have a continuing duty to provide benefits, such that they must consider subsequently available medical research in some situations. In *Shannon*, for example, the patient requested pre-certification of a kidney and pancreas transplant to treat conditions related to his diabetes. The plan denied pre-certification, but the patient underwent the procedure anyway. After surgery, the patient sought reimbursement from the plan and filed suit when the plan denied his claim. The district court held that the plan failed to consider all relevant evidence and remanded to the plan with instructions to consider all available evidence, including evidence that was not available at the time the plan denied pre-certification. The Eleventh Circuit affirmed, explaining that “[s]hould [the patient] wish to present additional information that might affect the determination of eligibility for benefits, the proper course would be to remand to the plan administrator for a new determination.”

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64 See *Holder*, 951 F.2d at 91 (“[l]t is the nature of medical research that what may one day be experimental may be the next state-of-the-art treatment. Had [Plaintiff] undergone a similar treatment more recently ... this case may have turned out differently.”).
65 See, e.g., *LifeCare Mgmt. Servs. LLC v. Ins. Mgmt. Adm’rs Inc.*, 703 F.3d 835, 841 (5th Cir. 2013); *Zervos*, 277 F.3d at 646; see A health care provider must generally appeal all denials, above.
66 See *Zervos*, 277 F.3d at 647 (noting one example of “good cause” is admitting new evidence to provide a “fuller review” of an incomplete record).
67 See *Shannon*, 113 F.3d at 209.
68 *Shannon*, 113 F.3d at 210 (internal quotation and alteration marks omitted); see also *Bernards*, 987 F.2d 486 (remanding case to district court with instructions to consider a number of questions identified at oral argument in light of the current state-of-the-art).
FDA approval and Medicare coverage of the treatment

Unless required by the plan’s language, FDA approval, where relevant, is generally not required in order for a treatment to not be deemed experimental or investigational. Conversely, FDA approval does not, per se, mean that a treatment is no longer considered experimental or investigational.

If a treatment is in Phase II of a clinical trial process, however, that is “strong” evidence that the disputed treatment is either experimental or investigational. A Phase II clinical trial consists of “controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug.” FDA approval (or lack thereof) is further evidence of how common or effective the treatment is.

Plan language appearing to require FDA or a similar level of approval based on completion of certain clinical trials, though difficult to overcome, is not always fatal to a claim for treatment that has not yet completed that level of trial. In Boldon, for example, one of Humana’s medical policies deemed a certain treatment experimental or investigative. Although the plan contained detailed requirements for FDA approval and levels of National Cancer Institute clinical trials,

69 See Wilson, 65 F.3d at 365 (holding clinical approval is not the “critical aspect in determining whether a therapy has become ‘generally accepted’ within the medical community.”); but see Martin, 115 F.3d at 1204–05 (quoting plan language that explicitly required final FDA approval for a treatment to not be considered experimental or investigational); Whitley v. Carolina Care Plan, Inc., C/A No. 3:06-257-CMC (D.S.C. Dec. 28, 2006) (same).
70 Martin, 115 F.3d at 1208 (noting an administrator did not abuse its discretion in classifying treatment as experimental when that treatment was offered pursuant to a Phase II clinical program).
71 21 C.F.R. § 312.21(b).
72 Parsons v. Sisters of Charity of Leavenworth Health Sys., 490 F. App’x 867 (9th Cir. 2012) (affirming proposed treatment was experimental based, in part, on the lack of final approval from the FDA).
73 Boldon, 466 F. Supp. 2d at 1204–05.
the court held that requiring a Phase III clinical trial was arbitrary and capricious because the FDA had permitted the treatment to be marketed without a Phase III trial due to the rareness of the illness it treated.\textsuperscript{74} Another court held that ongoing, not-yet-completed Phase III clinical trials may help establish that a treatment is no longer experimental or investigative and instead, “indicate[] that the treatment is anticipated by an institutional review board to be at least as good as [other accepted treatments], as evidenced by the results from Phase I and Phase II studies.”\textsuperscript{75}

In contrast to FDA approval, numerous courts have treated coverage by Medicare as influential.\textsuperscript{76} Moreover, many plans require coverage by Medicare as part of their experimental/investigative definitions.\textsuperscript{77} Some courts have also considered whether other health plans deem the treatment experimental or investigative.\textsuperscript{78}

\textit{The reasonableness of the plan’s administrative review}

An important consideration is whether the plan acted reasonably in adjudicating the claim. Courts require that plans sufficiently research the disputed treatment before denying benefits. A plan that conducts an extensive review of medical research across multiple sources is

\begin{footnotesize}
\textsuperscript{74} Id. at 1212–13.
\textsuperscript{75} Adams, 757 F. Supp. at 675.
\textsuperscript{76} See Heasley, 2 F.3d at 1259; Whitley; Shannon, 113 F.3d at 210 (holding plan administrator abused its discretion by denying treatment as experimental in reliance on Medicare’s non-coverage of treatment); Boldon, 446 F. Supp. 2d at 1204 (noting that the treatment is covered by Medicare, Medicaid, and numerous other plan administrators).
\textsuperscript{77} See Fujia, 18 F.3d at 1408 (requiring that the treatment be approved by the Health Care Financing Administration).
\textsuperscript{78} Bernards, 987 F.2d at 489 (remanding for factual development, including whether other health plan administrators cover the treatment); but see Shannon, 113 F.3d at 210 (“Simply accepting the bald assertions of Cost Care and the denial of other insurance companies without examining or evaluating their underlying bases and failing to obtain additional relevant information was arbitrary and capricious.”).
\end{footnotesize}
rarely found to have abused its discretion when it classifies a treatment as experimental.\(^79\)

Courts also approve of plans that request additional medical records from the patient, consult with the patient’s physicians, and seek second opinions from experts before deeming a treatment experimental.\(^80\) Interestingly, while a plan must consider evidence submitted by the treating physician, the plan need not accord special deference to the treating physician’s opinions.\(^81\)

Some courts have insisted that a plan do more than accept the conclusions of other health professionals, however. For example, the Eleventh Circuit Court of Appeals affirmed that it was arbitrary and capricious for a plan to deny coverage for a pancreas transplant after accepting only the “bald assertions” of the plan’s medical consultant and the statements of several other insurance companies that concluded the transplant was investigational.\(^82\) The court noted that relying on the medical conclusions of others without independently “examining or evaluating their underlying bases” and securing “additional relevant information” constituted an abuse of discretion.\(^83\)

Plans generally should seek out independent third-party evaluations, but exclusive reliance on a third-party rating system where the plan fails to disclose that the rating system will be the sole basis for

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\(^{79}\) See Peruzzi, 137 F.3d at 434–45 (affirming benefit denial where plan administrator relied on multiple expert opinions); Martin, 115 F.3d at 1207 (affirming benefit denial where plan’s internal research collated studies from several sources).

\(^{80}\) See Ortlieb, 387 F.3d at 782 (affirming benefit denial where plan administrator requested medical records on two separate occasions, spoke with the insured’s doctors, and sought multiple reviews confirming the denial).

\(^{81}\) Black & Decker Disability Plan v. Nord, 538 U.S. 822, 825 (2003); see also Love v. Dell, Inc., 551 F.3d 333, 337 (5th Cir. 2008) (“ERISA does not require the opinions of treating physicians to be preferred over those of other physicians reviewing a file; ERISA merely requires that the opinions of treating physicians, as with all evidence submitted by the claimant, actually be taken into account in an administrator’s determination.”)

\(^{82}\) See Shannon, 113 F.3d at 209.

\(^{83}\) Id.; see also Boldon, 466 F. Supp. 2d at 1212–13 (noting plan administrator relied on external medical reports without researching their underlying basis).
decision may be an abuse of discretion. In addition, if a plan has not defined the terms experimental or investigational, a court will not permit the plan administrator to bootstrap into its own plan a third-party’s classification of a treatment as experimental or investigational. A plan also may abuse its discretion when it ignores medical research that it erroneously concluded was unreliable.

Conversely, courts rarely overturn benefit denials when the plan administrator has reviewed the patient’s medical records, researched current medical literature on the proposed treatment, and consulted internal anthologies of coverage limits. Even internal documents created by a health plan can be sufficient to declare a treatment experimental if other evidence supports the plan’s internal research. A plan may credit one expert report over others, as long as the plan fairly considered any conflicting opinions.

As mentioned above, courts often note whether the plan retained external, independent experts to review the beneficiary’s file. It is difficult to establish that a plan abused its discretion when it relied on an independent expert report based on a full review of the patient’s

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84 Whitley; see generally Weaver v. Phx. Home Mut. Life Ins. Co., 990 F.2d 154, 158 (4th Cir. 1993) (holding that plan administrator may use a third-party to adjudicate claims, but the third-party service must adhere to the plan).
85 See Heasley, 2 F.3d at 1261 (“[C]ourts have refused to rely exclusively on particular third-party classifications where the plan has not explicitly referenced them in defining its experimental procedure exclusion.”).
86 Zervos, 277 F.3d at 648 (citing administrator’s mistaken belief that expert testimony was faulty before holding the administrator abused its discretion in ignoring that testimony).
87 See, e.g., Murphy, 928 F. Supp. at 706.
88 Id. at 706 (affirming benefit denial where two outside experts concurred with internal plan documents); but see Boldon v. Humana Ins. Co., 466 F. Supp. 2d 1199, 1212–13 (D. Ariz. 2006) (holding plan administrator erred by denying treatment as experimental or investigative despite insurer’s clinical policy stating the treatment was considered experimental and investigative).
89 Peruzzi, 137 F.3d at 434.
90 See Ortlieb, 387 F.3d at 783–84 (affirming benefit denial where two outside doctors agreed that treatment was experimental); Exbom v. Cent. States, Se. & Sw. Areas Health & Welfare Fund, 900 F.2d 1138, 1140 (7th Cir. 1990) (noting with approval that plan administrator sought multiple opinions from outside expert).
medical file, related information, and standards contained within the benefit plan.\textsuperscript{91} Expert opinions based on incomplete information or information "cherry-picked" by the plan cannot be the basis for the denial of benefits.\textsuperscript{92}

In addition to conducting sufficient research, the plan must follow its own internal procedures during the appeal. Such conduct will support a finding that the plan did not abuse its discretion.\textsuperscript{93} In contrast, defects in a plan’s appeals process may bolster claims that the administrator abused its discretion. For example, evidence that a plan denied coverage for experimental treatment over the objections of other internal plan committees could support a finding that the plan abused its discretion.\textsuperscript{94}

Finally, the plan administrator must pay close attention to the language of the plan. Thus, the plan administrator must interpret the benefit plan itself\textsuperscript{95} and may not add unwritten requirements to the plan or deny on a basis not included in the benefit plan.\textsuperscript{96}

\textsuperscript{91} See Klein v. Cent. State, Se. & Sw. Areas Health & Welfare Plan, No. 09-3275 (6th Cir. 2009) (reversing district court order in favor of Plaintiff where lower court improperly rejected expert’s opinion).
\textsuperscript{92} See Spangler v. Lockheed Martin Energy Sys., 313 F.3d 356, 362 (6th Cir. 2002) (finding benefit denial arbitrary and capricious where plan administrator relied on an expert report based on selective information provided by the plan).
\textsuperscript{93} See Murphy, 928 F. Supp. at 706 (affirming benefit denial based, in part, on plan promptly following appeal procedures initiated by insured); Jacobs v. Guardian Life Ins. Co. of Am., 730 F. Supp. 2d 830, 855–56 (N.D. Ill. 2010) (reviewing plan’s internal appeals policy before affirming benefit denial).
\textsuperscript{94} Bechtold v. Physicians Health Plan of N. Ind., Inc., 19 F.3d 322, 327–28 (7th Cir. 1994) (citing possibility that plan administrator could abuse its discretion in ignoring other internal guidance on experimental treatment before holding that no such abuse occurred).
\textsuperscript{95} See Weaver, 990 F.2d at 158 (holding plan fiduciary abused its discretion by denying claim where it relied entirely on a subcontractor to determine whether the stay should be covered, and did not even know what standards had been applied to reach that decision).
\textsuperscript{96} Zervos, 277 F.3d at 647 (holding that plan administrator abused its discretion by denying claim because the treatment would not be “superior” to other treatments when the plan only required that the treatment be “effective”); Boldon, 466 F. Supp. 2d at 1212–13 (plan administrator abused its discretion where it denied coverage on the basis of an outside reviewer’s characterization of treatment as experimental because it had not reached the Phase III clinical trial stage where the plan contained no such requirement).
The provider or protocol’s description of the treatment

Courts consider how the health care provider has described the disputed treatment to patients prior to initiating treatment and whether the treatment protocol describes the proposed procedure as such.\(^97\) If a provider’s own consent forms describe a treatment as investigational or experimental, courts are less likely to find that a plan abused its discretion in classifying the same treatment as experimental or investigational.\(^98\)

The language in the provider’s consent form or protocol description is important regardless of whether the plaintiff is the insured or the health care provider. Courts have held that both parties should know that a treatment is experimental if they provide or sign forms describing the treatment as such.\(^99\)

The success of other accepted treatments

Often, a patient will not have begun their treatment of their particular illness with a treatment that is subject to denial as experimental or investigational. Generally, the patient will have started off with a well-accepted treatment and moved to a treatment that a health plan may consider as experimental or investigative only after the traditional treatment was ineffective.\(^100\) In many cases of experimental or investigational denials, the treatment at issue represents the patient’s only

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97 See Fuja, 18 F.3d at 1408, 1410–11 (holding that both the consent form and treatment protocol for insured’s treatment offered “overwhelming” evidence that proposed procedure was experimental); Hendricks, 39 F.3d at 513–14 (same); Schnitker v. Blue Cross-Blue Shield of Neb., 787 F. Supp. 903, 905–06 (D. Neb. 1991) (same).

98 See, e.g., Martin, 115 F.3d at 1208 (citing health provider’s consent form, which stated that treatment was “investigational” and “entirely for research,” as evidence supporting plan’s denial).

99 Martin, 115 F.3d at 1209; Hendricks, 39 F.3d at 513–14 (upholding administrator’s denial of benefits where consent forms described, in detail, the experimental nature of the disputed treatment); see also Parsons, 490 F. App’x at 869 (noting that treating physician described procedure as a “pilot study”).

100 E.g., Heasley, 2 F.3d at 1252; Adams, 757 F. Supp. at 664–66.
realistic chance at long-term survival (sometimes referred to as the treatment of last resort).\textsuperscript{101}

While the patient’s circumstance (i.e., having to pursue a treatment of last resort) is not a factor courts have applied when reviewing an experimental or investigational denial (except in the rare circumstance where the plan provided different coverage for potentially life-saving treatment),\textsuperscript{102} the fact that a treatment may make the difference between life and death is plainly visible in the background of some court decisions, and is something that may, in close cases, tip the scales in favor of coverage.\textsuperscript{103}

**Characteristics of a successful claim**

No single factor described above guarantees success in suits challenging the denial of benefits for a treatment that a plan has deemed investigational or experimental. The standard of review affects the weight afforded other factors, but plaintiffs have succeeded even when courts apply deferential standards of review. Successful suits demonstrate some combination of the following facts:

1. the disputed treatment is effective and/or commonly prescribed to treat the specific disease at issue;
2. the plan relied on insufficient or outdated research to define the treatment as experimental or investigational;
3. there exists some other deficit in the plan’s decisionmaking process;

\textsuperscript{101} Fujia, 18 F.3d at 1407 (explaining that patient’s chance of long-term survival without treatment was negligible); Bernard, 987 F.2d at 487 (expediting appeal due to patient’s rapidly deteriorating condition).

\textsuperscript{102} See Ortlieb, 387 F.3d at 784 (discussing plan’s explicit exception to experimental or investigative treatment exclusion for life-threatening conditions).

\textsuperscript{103} See Fujia, 18 F.3d at 1407, 1412 (lamenting that a decision on whether a patient is provided treatment her physician believes is the difference between life and death came down to a battle of the experts).
4. the treatment is FDA approved (if applicable) or is covered by Medicare; or
5. the disputed treatment falls outside any definition of experimental or investigational included in the plan.

For example, the court in *Adams v. Blue Cross-Blue Shield of Maryland* held that the plan abused its discretion by denying coverage for high-dose chemotherapy with autologous bone marrow transplant to treat two patients in different stages of breast cancer. The plan’s language excluded treatment “not generally acknowledged as accepted medical practice,” but the court cited multiple treatment centers in Maryland that provided the disputed treatment. Moreover, the patients had submitted letters from numerous physicians with their respective appeals to the plan, and listed other area oncologists as references; the plan never contacted any of them, however. Thus, even though the court acknowledged that questions remained about the procedure’s effectiveness, the broad research support and number of area oncologists using the treatment were sufficient to make the procedure generally accepted and covered under the terms of the plan.

In *Whitley v. Carolina Care Plan*, the court found an abuse of discretion where the plan relied on outdated medical standards, failed to consider several research studies that approved use of the disputed treatment, and failed to follow proper internal appeal procedures.

Finally, the court in *McHenry v. Pacific Source Health Plans* found that a plan improperly denied coverage where years of research studies approved the procedure and the plan offered only one opinion supporting its denial.

In contrast, a patient or provider has an uphill battle in challenging an experimental or investigational denial if the FDA has not approved

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104 *Adams*, 757 F. Supp. at 664, 672.
105 *Id.* at 669, 671–72.
106 *Whitley*.
the proposed treatment (if necessary); Medicare does not cover the treatment; no medical literature shows the treatment to be generally accepted; and the consent form signed by the patient describes the treatment as experimental.108

**Practical Advice on Defeating Experimental or Investigational Denials**

If a health care provider’s claim is denied because the plan determined the treatment to be experimental or investigational, the best course of action often will depend on several facts, including whether the denial was pre-treatment (denial of the provider’s request for pre-certification) or post-treatment (denial of a claim for payment); the relevant plan language, standard of review, and medical literature supporting the treatment; and where the dispute can be brought.

**Obtain the plan and all clinical policies**

Generally, an analysis of the plan language should be performed first upon receipt of a denial of a claim, if not sooner. This will allow the provider to (i) judge whether an experimental or investigational exclusion applies and (ii) tailor its internal appeal of the denial to the precise language of the plan. Ideally, a patient will have access to the plan and plan language so that he or she can provide them to the provider. In reality, however, most patients have only the summary plan description, not the plan itself, and the two can sometimes differ, as explained above.

An out-of-network provider who is acting pursuant to an assignment of the patient’s rights and benefits is entitled to request the plan from the plan administrator, who must, under ERISA, provide it within 30

108 See, e.g., Parsons, 490 F. App’x at 869 (affirming plan administrator’s denial of autologous bone marrow transplant to treat Crohn’s Disease as experimental and investigational); Fuja, 18 F.3d at 1408, 1410–11.
days of receiving the request.\textsuperscript{109} A network representative or provider hotline representative may be able to provide a copy of the relevant portions more quickly.

In addition to obtaining a copy of the benefit plan (or at least the provision defining the scope of an experimental or investigational treatment exclusion), the provider should obtain any clinical policies that the plan administrator has concerning the treatment. Many large third-party administrators will post these clinical policies on their provider websites. If those policies are not publicly available, the provider should request them in addition to the benefit plan.

**Provide all relevant documents as part of the internal appeal**

Once the provider has received a copy of the benefit plan and any applicable clinical policies, the provider should determine what documents it will submit to the plan as part of its internal appeal.\textsuperscript{110} This decision should be made carefully, because in a subsequent litigation or arbitration, the evidence will generally be limited to the evidence before the plan when the plan made its decision, as discussed above.

Supporting documentation should be tailored to the specific definition contained in the benefit plan, if one is included. For example, where the plan defines the experimental exclusion solely by reference to its acceptance in the medical community, the provider should submit (if possible) declarations and other evidence showing that peers in the medical community also utilize the treatment for the same or similar

\textsuperscript{109} See 29 U.S.C. §1132(c); see also id. §§ 1133(1)–(2) (requiring the plan to provide a beneficiary with both written notice “setting forth the specific reasons for . . . denial” and a reasonable opportunity to pursue a “full and fair review” of the denial).

\textsuperscript{110} A provider should always appeal the denial of its claims, even if success is doubtful. The federal government has reported that between 39% and 59% of internal appeals result in the plan administrator reversing its initial denial. See U.S. GOV'T ACCOUNTABILITY OFFICE, PRIVATE HEALTH INSURANCE: DATA ON APPLICATIONS AND COVERAGE DENIALS 1, Pub. No. GAO-11-268 (March 2011), available at www.gao.gov/products/GAO-11-268 [hereinafter PRIVATE HEALTH INSURANCE].
While peer-reviewed medical studies and other information should also be submitted in this situation, evidence showing the level to which the treatment is accepted by the relevant medical community usually carries greater weight.

If the plan does not contain a particular definition of experimental or investigational, the provider should submit evidence regarding each of the factors identified above, including: peer-reviewed medical studies about the treatment; statements from peer physicians in the same specialty regarding their use of the treatment; documents showing FDA approval and/or Medicare coverage; the treatment protocol; the patient’s complete medical records (especially if those records show an ineffective prior treatment of the same disease); and any other document showing the degree to which the treatment is accepted to treat that particular disease (which may include documents showing the number of centers providing that treatment, the number of times the treatment has been prescribed, and studies or journal articles regarding the treatment’s efficacy in fighting a particular disease). Commercially available ratings services, such as the Hayes Ratings, may also be useful to show the degree to which the particular treatment has been generally accepted for treating the disease at issue.

Importantly, the provider need not compile all of this on his or her own. Where possible, he or she should collaborate with peer physicians in the same specialty and with others, such as medical device manufacturers and academic medical centers. For example, if the treatment involves a particular drug or medical device, the manufacturer or the manufacturer’s sales representative may have evidence showing acceptance by the medical community, including peer-reviewed studies.

111 See Adams, 757 F. Supp. at 663 (where the plan defined “experimental or investigative” as “any treatment . . . not generally acknowledged as accepted medical practice by the suitable medical specialty practicing in Maryland, as decided by us,” plan administrator erred by denying treatment as experimental without contacting any Maryland oncologists, even though the providers had submitted statements from and contact information for several Maryland oncologists with their appeals).
volume of use nationwide, and contact information of other physicians prescribing the treatment in the same way. Other good sources of information may include research hospitals and university medical centers that utilize the treatment.

**Pursue external review**

In addition to submitting an internal appeal with the plan administrator, state law may entitle the provider (acting as the patient’s representative) to pursue an external review with an independent review organization. For example, in Texas, a patient who has been denied treatment on the basis of an experimental or investigative exclusion, or his or her health care provider, may seek an independent review following an adverse decision on appeal. The plan is then required to adhere to the independent review organization’s determination. Other states have similar external review mechanisms.

The benefit of an external review is that review is conducted by a neutral third-party, which eliminates the potential conflict of interest inherent in review by the plan administrator. Statistics have also shown that the external review process results in reversal of the coverage denial approximately 40% of the time. External review is also relatively quick and inexpensive compared to litigation or arbitration.

**Filing a claim in litigation or arbitration**

After all internal appeals have been exhausted, the provider’s last option is to file a lawsuit or pursue arbitration challenging the denial. Venue for the dispute will be determined by reference to the provid-

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113 Tex. Ins. Code § 4201.401(c).
115 Private Health Insurance, at 1.
er’s network agreement, if the provider is in the plan administrator’s network. Generally, these agreements include detailed dispute resolution clauses requiring arbitration and, on occasion, pre-arbitration mediation.

The type of relief that the provider requests will depend on whether the denial was prospective or retrospective. If the denial was prospective, the provider generally should seek declaratory relief—a declaration that the treatment is not experimental or investigational and is therefore covered—as well as injunctive relief requiring the plan administrator to approve the treatment.\textsuperscript{116} If the denial was retrospective, the provider generally is limited to monetary relief—the amount that the plan would have paid for performing the treatment.\textsuperscript{117}

Regardless of the relief sought, the provider also may be entitled to reasonable attorney’s fees. If the provider is out-of-network and suing exclusively under ERISA, ERISA entitles the claimant to attorney’s fees in most circumstances.\textsuperscript{118} If the provider is in-network, however, the provider’s network contract may impose a limit on the provider’s ability to recover attorney’s fees (and other costs).

\section*{Conclusion}

Overturning a plan’s denial of coverage for a treatment because the plan has deemed the treatment experimental or investigational can be a complicated process. To properly challenge a plan’s denial, the provider must act quickly and deliberately because failing to include pertinent information and documentation during the internal appeal process could prevent the provider from relying on that information.

\begin{footnotes}
\item[116] In-network providers should be aware, however, that some managed care agreements explicitly preclude an arbitrator from awarding declaratory relief.
\item[117] See Aetna Health Inc. v. Davila, 542 U.S. 200 (2004) (holding that an ERISA plan member is generally limited to the value of the benefit denied); \textit{id}. at 222–24 (Ginsburg, J., concurring).
\end{footnotes}
and documentation in later litigation. By considering the factors and guidelines outlined in this article, a provider can proactively approach the appeal, external review, and litigation or arbitration if necessary, to maximize its chance for success.