FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA EX REL. STEVEN J. HARTPENCE, Relator, *Plaintiff-Appellant*, v. KINETIC CONCEPTS, INC.; KCI-USA, INC., *Defendants-Appellees.*	No. 19-55823 D.C. No. 2:08-cv-01885-CAS-AGR OPINION

Appeal from the United States District Court
for the Central District of California
Christina A. Snyder, District Judge, Presiding

Argued and Submitted July 10, 2020
Pasadena, California

Filed August 9, 2022

Before: Bobby R. Baldock,[*] Marsha S. Berzon, and Daniel P. Collins, Circuit Judges.

Opinion by Judge Collins

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[*] The Honorable Bobby R. Baldock, United States Circuit Judge for the U.S. Court of Appeals for the Tenth Circuit, sitting by designation.

SUMMARY[**]

False Claims Act

The panel reversed the district court's summary judgment in favor of defendants in a *qui tam* action brought under the False Claims Act, and remanded for further proceedings.

Plaintiff and relator Stephen J. Hartpence alleged that defendants Kinetic Concepts, Inc., and its indirect subsidiary KCI USA, Inc. (collectively, "KCI") submitted claims to Medicare in which KCI falsely certified compliance with certain criteria governing Medicare payment for the use of KCI's medical device for treating wounds. The district court granted summary judgment to KCI, concluding that Hartpence had failed to establish a genuine issue of material fact as to the False Claims Act elements of materiality and scienter.

In the context of a false certification of compliance with a regulatory or statutory requirement for payment, the certification is material if the requirement is so central to the claims that the government would not have paid these claims had it known that the requirement was not satisfied. The panel held that there was a genuine issue of material fact as to whether KCI's use of a "KX" modifier was material to KCI's reimbursement claims submitted to Medicare. This modifier indicated compliance with the requirements of Local Coverage Determinations ("LCD") issued by Durable Medical Equipment Medicare Administrative Contractors,

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

which processed claims on behalf of the Centers for Medicare and Medicaid Services. The panel concluded that the fact that the KX modifier was not accepted at face value in case-specific auditing did not mean that compliance with the LCD criteria (which is what use of the modifier was supposed to signify) was not material to most payment decisions on "stalled-cycle" claims, where KCI's device was used but there was no wound improvement.

The panel agreed that compliance with the specific LCD criterion that there be no stalled cycle would not be material if, upon case-specific review, the Government routinely paid stalled-cycle claims. In other words, if stalled-cycle claims were consistently paid when subject to case-specific scrutiny, then a false statement that avoided that scrutiny and instead resulted in automatic payment would not be material to the payment decision. The panel concluded, however, that the record did not show this to be the case. The panel considered administrative rulings concerning claims that were initially denied, post-payment and pre-payment audits of particular claims, and a 2007 report by the Office of Inspector General of the U.S. Department of Health and Human Services. The panel concluded that none of these forms of evidence supported the district court's summary judgment ruling.

The panel held that the district court further erred in ruling that there was insufficient evidence that KCI acted with the requisite scienter. The district court ruled that, because the use of the KX modifier on stalled-cycle claims was not material, evidence that KCI knew that it was wrongly using the KX modifier was insufficient to establish scienter. Because the district court's premise concerning materiality was wrong, the resulting conclusion that it drew as to scienter was necessarily vitiated. Assuming without

deciding that scienter requires knowledge of materiality as well as knowledge of falsity, the panel concluded that the record in this case established a triable issue regarding KCI's knowledge of the materiality of its misuse of the KX modifier.

The panel further concluded that the remainder of the district court's reasoning concerning scienter rested on a clear failure to view the evidence in the light most favorable to the relator. The panel concluded that there was ample evidence to permit a rational trier of fact to conclude that KCI knew that it was a false statement to attach the KX modifier to a claim that did not satisfy the LCD and that KCI did so knowing that it might thereby escape case-specific scrutiny that, in many cases, it would lose.

COUNSEL

Mark I. Labaton (argued), Glancy Prongay & Murray LLP, Los Angeles, California; Michael A. Hirst, Hirst Law Group, Davis, California; Patrick J. O'Connell, Law Offices of Patrick J. O'Connell, Austin, Texas; Timothy Cornell, Cornell Dolan P.C., Boston, Massachusetts; for Plaintiff-Appellant.

Gregory M. Luce (argued), Bradley A. Klein, Paul A. Solomon, and John A.J. Barkmeyer, Skadden Arps Slate Meagher & Flom LLP, Washington, D.C.; Matthew E. Sloan and Rachael T. Schiffman, Skadden Arps Slate Meagher & Flom LLP, Los Angeles, California; for Defendants-Appellees.

OPINION

COLLINS, Circuit Judge:

In this *qui tam* action brought under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*., Plaintiff and Relator Stephen J. Hartpence alleges that Defendants Kinetic Concepts, Inc. and its indirect subsidiary KCI USA, Inc. (collectively, "KCI") submitted claims to Medicare in which KCI falsely certified compliance with certain criteria governing Medicare payment for the use of KCI's medical device for treating wounds. The district court granted summary judgment to KCI, concluding that Hartpence had failed to establish a genuine issue of material fact as to the FCA elements of materiality and scienter. Because there are triable issues as to both elements, we reverse and remand.

I

A

KCI manufactures and supplies a medical device that helps to heal wounds by means of a method called Vacuum Assisted Closure Therapy, or "VAC Therapy." KCI's device, which requires a prescription, uses "an electric pump connected to specialized wound dressings" to apply "negative pressure" at the site of the wound, thereby drawing the edges of the wound closer together. Payment for such VAC Therapy treatments may be covered by Medicare for patients enrolled in Medicare Part B. When the therapy is prescribed to a Medicare-beneficiary patient, KCI directly bills the Government—on a monthly basis—on that patient's behalf. The dispute in this case centers on whether the claims that KCI submitted for payment falsely certified that the applicable criteria for payment were met.

Under the relevant provision of the Medicare Act, "items and services" otherwise covered by Medicare Part B are generally eligible for reimbursement only if they are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Medicare Act authorizes the Centers for Medicare and Medicaid Services ("CMS") to facilitate the evaluation and reimbursement of claims for covered medical treatment by contracting with private entities, currently known as "medicare administrative contractors," who process those claims on the Government's behalf. *See* 42 U.S.C. § 1395kk-1(a)(1); *see also id*. § 1395u(a). With respect to the sort of durable medical equipment at issue here, CMS has invoked this authority by entering into contracts with four regional Durable Medical Equipment Medicare Administrative Contractors ("DME MACs").[1] CMS delegates the initial determination of which treatments are "reasonable and necessary" to these DME MACs, who are authorized by the Medicare Act to issue Local Coverage Determinations ("LCDs") addressing "whether or not a particular item or service is covered" on a DME MAC-wide basis under that standard. *See* 42 U.S.C. § 1395ff(f)(2)(B) (citing *id*. § 1395y(a)(1)(A)); *see also id*. § 1395kk-1(a)(4).

[1] Prior to the effective date of the relevant provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the statute referred to these contracting private entities as "carriers." *See* 42 U.S.C. § 1395u(a) (2002 ed.). Correspondingly, the predecessors to the four DME MACs were known as "Durable Medical Equipment Regional Carriers." No party contends that this distinction is material to this case, so for the sake of simplicity we will refer to these entities as "DME MACs" without regard to the specific timeframe at issue.

Effective October 1, 2000, all four DME MACs adopted "substantially identical" LCDs to clarify when use of a "negative pressure wound therapy" ("NPWT") pump—such as KCI's VAC Therapy device—would be considered to be "reasonable and necessary" and therefore covered under Medicare Part B.[2] Among other rules, the 2000 LCDs provided that coverage for NPWT pumps ends when "[a]ny measurable degree of wound healing has failed to occur over the prior month." The LCDs required that the requisite "progressive wound healing from month to month" be "documented in the patient's medical records" through "quantitative measurements of wound characteristics" such as "wound length and width (surface area), or depth."[3] To expedite claim processing, the relevant LCDs provided that a supplier could demonstrate that a given claim met all relevant conditions for coverage by adding to the claim a specified two-letter modifier. Here, that modifier was initially "ZX," and then, beginning in July 2002, "KX." Because the parties agree that these two modifiers had the same meaning, we will henceforward refer only to the "KX" modifier. The LCDs expressly stated, in bolded and underscored typeface, that the KX modifier "**must not be used**" if, *inter alia*, the required month-over-month measurable wound healing had failed to occur.

As one of the DME MAC directors explained at his deposition, "if the KX modifier is there" in a submitted

[2] At the time, LCDs such as these were referred to as "Local Medical Review Policies." Because the parties do not contend that the difference in nomenclature has any significance for the issues on appeal, we will refer to them simply as "LCDs," without regard to the timeframe.

[3] In October 2005, the LCDs were revised to specifically define "[w]ound healing" as "improvement occurring in either surface area (length times width) or depth of the wound."

claim, "then the system is set up to pay that claim." Conversely, however, the lack of a KX modifier did not necessarily mean that payment of a claim would ultimately be denied. Although the same director explained that "the system generates an automatic denial" if "the KX modifier is missing," KCI could appeal that denial through a multi-level review and appeal process. *See* 42 C.F.R. § 405.900 *et seq*. That process includes a hearing before an Administrative Law Judge ("ALJ"), *see id*. §§ 405.1000–405.1058, and the ALJ's decision may be appealed to the Medicare Appeals Council, *id*. §§ 405.1100–405.1130. In conducting such review, the ALJ and the Appeals Council "are not bound by LCDs, . . . but will give substantial deference to these policies if they are applicable to a particular case." *Id*. § 405.1062(a). By pursuing this appeals process, KCI could obtain a case-specific review as to whether the particular use of NPWT was "reasonable and necessary" for the treatment of the wound. 42 U.S.C. § 1395y(a)(1)(A).

In late 2002, KCI sent a formal letter to the DME MACs, seeking clarification of several issues concerning the application of the LCDs. One of these issues concerned the handling of what the parties have referred to as "stalled cycles," *i.e.*, a month in which VAC Therapy was used but there was no wound improvement. Specifically, KCI asked whether, if the month *after* a stalled cycle shows "significant healing, should we submit a claim for both cycles?" In June 2003, the four DME MACs sent a joint responsive letter to KCI. On the issue of stalled cycles, the DME MACs responded in relevant part as follows (emphasis added):

> Lack of improvement in one cycle of use (i.e., a month) would not justify coverage of NPWT for the months following the month in

> which improvement is lacking[]. Even should the carrier make a payment, subsequent post-payment audit could result in an overpayment assessment for that month. Lack of improvement in one cycle of use (i.e., a month) would not justify continued coverage of NPWT for any month after which wound healing progress is lacking, according to the [LCD] coverage criteria. If this cessation of healing occurs within the first 4 months of therapy, then the claim for the month of use after which healing ceased, must be submitted *without the KX modifier*.

The substance of this position was also communicated by memorandum to the DME MACs' personnel handling "Medical Review, Appeals." On September 12, 2003, the DME MAC for "Region D" issued a bulletin confirming that, if there is a stalled cycle, "there will be no further coverage" of NPWT for that wound, even if "subsequent improvement occurs," and "the KX modifier must not be added to claims for any subsequent months for use of the pump on that particular wound."

Within a few days of the issuance of this bulletin, KCI temporarily stopped seeking reimbursement for stalled-cycle claims. In a September 26, 2003 letter to the DME MAC for Region D, KCI took issue with the bulletin's seemingly blanket prohibition on paying any claims after a stalled cycle. KCI explained that, in its view, there were many situations in which use of NPWT would be medically necessary after a stalled cycle and that it believed "that these situations should be reviewed on a case-by-case basis." KCI's letter did not specifically address the bulletin's prohibition on using the KX modifier in such situations. In

a subsequent October 14, 2003 phone call between KCI and the Region D Medical Director, the Director assertedly agreed that "criteria could be established to determine" when use of NPWT would be "medically necessary" after a stalled cycle, and that the recent bulletin should be retracted.

In an October 24, 2003 letter to the DME MACs, KCI provided its formal response to the June 2003 letter. On the issue of stalled cycles, KCI reiterated its objection to the DME MACs' apparent position that, if there is a stalled cycle, "medical necessity could never be established without complete healing." KCI noted that, in a separate LCD governing a different wound therapy (known as "Pressure Reducing Support Surfaces"), there was a recognition that, even if there was an apparent stall in healing, "continued medical necessity can be established as long as there is documentation to show that 'other aspects of the care plan are being modified to promote healing.'" KCI took the position that "the coverage guidelines in the support surface [LCDs] should also be applied to NPWT." The letter did not say anything about the use of the "KX" modifier.

Shortly thereafter, the KCI staff decided to resume billing for stalled-cycle claims under what KCI later termed a "risk sharing" approach: "If one cycle does not improve[,] i.e., wound healing stalled, OK to bill that cycle. If the next cycle does not improve, KCI will NOT bill and VAC will be picked up." As part of this approach, KCI resumed affixing the KX modifiers to its claims where a stalled cycle was followed by a month of wound improvement. In a subsequent, January 30, 2004 letter to the DME MACs, KCI again pointed to the analogy to the "Support Surface" LCD and took the position that, "[i]f healing resumes" after a stalled cycle, KCI "request[ed] that coverage be approved for both cycles." KCI argued, for example, that payment

should be made when a stalled cycle resulted from "debridement"—a medical treatment in which a wound is cleaned and dead or damaged tissue is removed—because debridement may cause a temporary expansion in the size of a wound that is otherwise healing properly and that would benefit from VAC Therapy. This letter likewise did not mention the use of the "KX" modifier.

In early January 2004, a KCI billing employee raised concerns about the stalled-cycle billing practice, asking billing company president Deb Smith in an email whether, in light of a regional DME MAC bulletin comparable to the one discussed above, "it would be fraudulent to submit a bill that is different from what they indicate in this bulletin." Smith forwarded the email to Human Resources Manager Bob Curlee, who echoed the employee's concerns:

> This sounds like an excellent employee has identified the real possibility that Medicare policy is being violated and fraud committed and wants to know if she should continue training her staff to continue doing so. Does challenging the policy actually get us off the hook when crunch time comes? You don't play a game assuming the rules may change the score when you challenge it at the end. You play by the rules you have while trying to get the rules changed for the future. Just my thoughts and I don't know this stuff very well, but I can tell when something is right or wrong.

Nevertheless, KCI continued the practice of billing for stalled-cycle claims, reiterating its "risk-sharing" approach in a February 2004 internal memorandum. Specifically, that

memorandum stated that, in the event of a stalled cycle, the claim would "be held pending [the] outcome of the subsequent cycle," and if that cycle showed significant improvement, "both cycles will be billed." The memorandum, however, did not specifically address whether, in billing such a set of cycles, the KX modifier should be used. KCI's billing department subsequently raised the question whether the KX modifier could be used in such circumstances, and that question was answered in a March 2004 email from KCI's Vice President for Reimbursement Policy and Compliance. Concluding that there were "inconsistencies in the positions taken by the [DME MACs] on this point," she stated that "KCI has made the decision" that, if "the subsequent cycle" after a stalled cycle "shows significant progress, both cycles will be billed using the ZX [*i.e.*, KX] modifier."

KCI continued its discussions with the DME MACs over the treatment of stalled cycles, and in April 2004 it forwarded to the DME MACs its February 2004 internal memorandum discussing KCI's approach. That memorandum, as noted earlier, did not explicitly mention the use of the KX modifier, but KCI's subsequent communications with the DME MACs in 2004 did raise that issue and also suggested formal amendment of the LCDs. In particular, a June 23, 2004 KCI email to one of the regional DME MACs stated that, "[m]oving forward," KCI would hold claims for a single stalled cycle and then, "[i]f the subsequent cycle shows significant progress, [KCI] will submit claims for both cycles will [*sic*] the KX modifier."

The DME MACs and KCI appeared close to an agreement in August 2004, when a DME MAC medical director circulated an email stating that the DME MACs were "planning to accept [KCI's] concept of a 'stalled'

healing cycle, paying for the stalled month and the subsequent month only if the subsequent month shows improvement compared to the month before the stalled month." Subsequent discussions between KCI and the DME MACs included proposals to amend or clarify the LCDs to expressly allow use of the KX modifier in the event of a stalled cycle, at least where the stalled cycle was due to debridement. But the negotiations slowed towards the end of 2004, and ultimately no relevant formal amendment was ever made to the LCDs during the pertinent timeframe. As one of the regional DME MAC directors stated at his 2018 deposition, the parties "would get close" in the discussions, but then the DME MACs "would back away." He summarized the overall negotiations by stating that, "after all the years of discussion, we ultimately found all the points unconvincing and made no change in the policy."

In certain internal communications, however, KCI operated on the assumption that it had an agreement "in principle" with the DME MACs, even while acknowledging that the LCDs had not been amended. For example, in one internal email addressed to KCI's General Counsel, the author—who is the relator in this case—explained KCI's professed belief that the DME MACs had "bought into this concept" of billing for stalled cycles that were followed by improvement, but he cautioned that there was "risk" "because our billing practice does not comply with this part of the medical policy and we could be subject to recoupment of very significant amounts of money if the policy were to be strictly interpreted."

In September 2010, the four DME MAC directors held a conference call to discuss KCI's billing practices. The contemporaneous notes of one of the directors described as

follows the directors' then-current understanding of the issues concerning KCI's billing of stalled cycles:

> - Literal reading of policy says not to use KX if wound size increases
>
> - KCI will hold claim for stalled month and if next month improves, will bill stalled month with KX
>
> - KCI does this based on discussions in 2003 and 2004; however, no action was taken by [DME MACs] in policy to memorialize decisions
>
> - Action: Take no action immediately to address KCI's stalled billing. Longer-term action to revise policy once [DME MACs] decide what needs to be done with multiple policy issues . . . .

B

Relator Steven Hartpence worked at KCI from 2001 until 2007, first as Vice President and then as Senior Vice President of Business Systems. On March 20, 2008, Hartpence filed this FCA *qui tam* action on behalf of the United States. In his operative Third Amended Complaint, Hartpence alleges, *inter alia*, that KCI's so-called "risk-sharing" approach to billing stalled-cycle claims violated the FCA because KCI affixed the KX and ZX modifiers to claims that did not actually satisfy all coverage requirements

under the LCDs.[4] On April 27, 2011, the United States declined to intervene.

Hartpence's FCA suit was initially dismissed by the district court on the ground that the FCA's "public disclosure" bar on certain *qui tam* actions deprived the court of subject matter jurisdiction. *See United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, 792 F.3d 1121, 1123 (9th Cir. 2015) (en banc) (explaining that "[t]he public disclosure bar precludes *qui tam* suits where there has been a public disclosure of the fraud, unless the relator qualifies as an 'original source' of the information" (quoting 31 U.S.C. § 3730(e)(4)). Sitting en banc, we overruled the precedent on which the district court had relied in applying the public-disclosure bar, and we remanded the case for reconsideration. *Id*. at 1123, 1129–30 (overruling *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412 (9th Cir. 1992), to the extent that it held that a relator qualifies as an "original source" only if he or she "had a 'hand in the public disclosure' of the fraud" (quoting *Wang*, 975 F.2d at 1418)). On remand, the district court held that the public disclosure bar did not apply to Hartpence's *qui tam* action. No party challenges that ruling on appeal.

After substantial discovery, KCI moved for summary judgment in January 2019 on the ground that Hartpence could not carry his burden of proof with respect to several elements of his FCA claims. Specifically, KCI argued that

[4] Hartpence also asserted below that KCI violated the FCA in several additional respects, but in his opening brief on appeal, he has not challenged the district court's grant of summary judgment rejecting those additional theories. Accordingly, any such further FCA theories have been forfeited, *see EEOC v. Peabody Western Coal Co.*, 773 F.3d 977, 990 (9th Cir. 2014), and the only FCA claims remaining in this case are those arising from KCI's billing of stalled-cycle claims for payment.

Hartpence lacked sufficient evidence as to the materiality and falsity of KCI's claims for payment and as to whether KCI "knew or recklessly disregarded that such claims were false." The district court granted this motion in June 2019, concluding that Hartpence had "failed to create a triable issue as to materiality and scienter with respect to each type of false claim he has identified." The district court held that, as a matter of law, any use by KCI of the KX modifier to falsely certify compliance with LCD criteria that had not actually been met was not material to the Government's ultimate payment decisions. The district court also held that Hartpence had failed to present sufficient evidence that KCI acted with the requisite scienter.

We have jurisdiction under 28 U.S.C. § 1291, and we review the district court's grant of summary judgment de novo, *see Protect Our Communities Found. v. LaCounte*, 939 F.3d 1029, 1034 (9th Cir. 2019).

II

To establish a cause of action alleging liability for a false claim under 31 U.S.C. § 3729(a)(1)(A), "the United States or [the] relator must prove the following elements: (1) a false or fraudulent claim (2) that was *material* to the decision-making process (3) which defendant presented, or caused to be presented, to the United States for payment or approval (4) with knowledge that the claim was false or fraudulent." *United States ex rel. Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1047 (9th Cir. 2012) (emphasis added). Thus, although § 3729(a)(1)(A) does not itself use the term "material," its reference to a "false or fraudulent claim" must be understood in light of the common-law understanding of fraud, which included a materiality requirement. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 193 (2016). For similar reasons, it does not matter

whether § 3729(a)(1)(A)'s lack of the word "material" arguably renders the FCA's express definition of "material" inapplicable to that provision. *See* 31 U.S.C. § 3729(b)(4) (defining "material," "[f]or purposes of this section," as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property"). Regardless of "whether § 3729(a)(1)(A)'s materiality requirement is governed by § 3729(b)(4) or derived directly from the common law," the substance of that standard is essentially the same. *Escobar*, 579 U.S. at 193. Materiality "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id*. (simplified).

In the context of a false certification of compliance with a regulatory or statutory requirement for payment, the certification is material if the requirement is "'so central' to the claims that the government 'would not have paid these claims had it known'" that the requirement was not satisfied. *United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1121 (9th Cir. 2020) (quoting *Escobar*, 579 U.S. at 196). Applying that standard, we hold that the district court erred in granting summary judgment. On this record, there was a genuine issue of material fact as to whether the use of the KX modifier—which indicated compliance with the requirements of the LCDs—was material to the reimbursement claims. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

A

As noted earlier, one of the DME MAC directors explained in his deposition that, if the KX modifier is used in a claim when it is submitted, then "the system is set up to pay that claim." A KCI official likewise testified that the general purpose of the KX modifier "was to trigger an automatic payment." That understanding of the KX

modifier is unsurprising, given the place of LCDs in the payment system created by the Medicare Act. As noted earlier, the whole point of the LCD system that Congress authorized is to allow a DME MAC to make payments, on a DME MAC-wide basis and without further consideration of individual circumstances, when certain specific criteria are present. *See supra* at 6. By contrast, omitting the KX modifier would trigger a denial of the claim and the need to pursue a case-specific review of medical necessity on appeal. Given this pivotal practical role played by the use of the KX modifier, a reasonable trier of fact could readily conclude that the presence or absence of that modifier is "material" to the payment decision. That is, given the above-described structure of the coverage determination system, it would be reasonable to conclude that the Government attaches importance, in making a payment decision, to a provider's certification of compliance with the relevant criteria of the applicable LCDs. That inference is further supported by KCI's own practice of persisting in using the KX modifier to ensure prompt payment of stalled-cycle claims despite its knowledge that those claims did not satisfy the literal terms of the LCDs. Accordingly, unless the summary judgment record contains undisputed evidence that would refute such an inference, summary judgment for KCI would be inappropriate because a rational jury could find, consistent with *Escobar*, that the use of the KX modifier was material to the payment of stalled-cycle claims. *See* 579 U.S. at 193.

In rejecting such an inference of materiality, the district court concluded that use of the KX modifier did *not* mean that KCI would be paid automatically, because the audit evidence in the record revealed that some claims submitted with that modifier were ultimately not paid. This reasoning does not support a conclusion that, as a matter of law, the

KX modifier was not material. The vast majority of claims with the KX modifier were not subjected to such audits, and payment of those claims effectively was automatic given KCI's use of the modifier to confirm compliance with the LCDs. The fact that the KX modifier was not accepted at face value in case-specific auditing does not mean that compliance with the LCD criteria (which is what use of the modifier is supposed to signify) was not material to most payment decisions.

B

We agree, however, that compliance with the specific LCD criterion that there be no stalled cycle would not be material if, upon case-specific review, the Government routinely paid stalled-cycle claims. *See Escobar*, 579 U.S. at 195–96. In other words, if stalled-cycle claims were consistently paid when subject to case-specific scrutiny, then a false statement that *avoids* that scrutiny and instead results in automatic payment would not be material to the payment decision. But the record does not show this to be the case, particularly when the record is considered—as it must be—in the light most favorable to the relator. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). The record evidence concerning case-specific review of stalled-cycle claims takes three main forms—administrative rulings concerning claims that were initially denied, post-payment and pre-payment audits of particular claims, and a 2007 report by the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services. None of them supports the district court's summary judgment ruling.

1

The record includes a substantial number of administrative decisions in which KCI appealed denials of

payments for claims that included stalled cycles.[5] The picture that emerges from a consideration of these administrative rulings is that there was no per se rule one way or the other as to payment of stalled-cycle claims. Such claims were paid only if case-specific circumstances demonstrated that the treatment was reasonable and necessary in a particular instance. Thus, although the record contains several instances in which, upon further case-specific review, an ALJ authorized payment of particular claims involving a stalled cycle, the Government did *not* follow KCI's risk-sharing approach either. Rather than follow KCI's preferred bright-line rule, the agency took a closer look at the totality of the circumstances in determining medical necessity and deciding whether or not to pay stalled-cycle claims. As a result, case-specific review of stalled-

[5] The evidence indicates that there were at least two ways in which such an appeal involving a stalled-cycle claim might occur. First, as one KCI employee explained in an email, a "major driver" of stalled-cycle denials occurred when a claim was examined by the DME MAC on *other* grounds—such as failure to comply with the LCDs' separate rule against paying for more than four cycles of NPWT treatment—and the stalled cycle would then be discovered in the resulting review. Although the record is not entirely clear on the point, it may well be that, in such cases, the KX modifier was *not* used in submitting such claims due to the failure to meet the generally applicable four-cycle cap. Indeed, the submission of a *fifth* claim for the same patient is presumably readily detectable by the DME MAC and it is therefore unsurprising that a KCI billing employee explained that, rather than use the normal electronic system of claims submission, KCI submitted "paper bills to Medicare for claims for patients whose treatment progressed to a fifth cycle or more." Second, the record indicates that some stalled-cycle claims submitted *with* the KX modifier were included among KCI claims that were selected for a pre-payment review or audit. As a result, the pool of administrative decisions presumably contains some claims in which the KX modifier was used and some in which it was not. The administrative decisions themselves, however, are generally silent as to whether the KX modifier was used in any given case.

cycle claims was a hit-or-miss proposition—meaning that KCI's false use of the KX modifier to obtain automatic payment avoided a scrutiny that it sometimes lost.

In 2009, the Medicare Appeals Council—"which is the highest level of agency adjudication" on these matters, *see Int'l Rehab. Sciences Inc. v. Sebelius*, 688 F.3d 994, 996 (9th Cir. 2012)—reviewed KCI's appeals of 64 VAC Therapy claims from all four regions and rejected payment for all of them. In that decision, the Appeals Council squarely addressed KCI's argument that "Medicare should cover cases where there has been no measurable wound healing"—*i.e.*, a stalled-cycle—"because the wound has undergone debridement." The Appeals Council rejected that argument and instead upheld the ALJ's "strict adherence to the terms" of the LCDs. The Appeals Council acknowledged that medical necessity for use of the VAC Therapy might nonetheless be shown even when debridement caused a stalled-cycle that resulted in a failure to satisfy the LCDs. But the Council held that that would be true "[o]nly if facts established through documentation show that a debridement is of such an unusual and unpredictable nature or generates unanticipated medical complications." Because KCI failed to establish such facts, the Appeals Council denied all 64 of these claims.

Although the record contains a few favorable case-specific determinations in cases in which KCI challenged initial denials of payment before ALJs, these rulings do not establish that the presence of a stalled cycle is immaterial, but only that it is not always dispositive. At best, these decisions—which, being from the "low levels of the agency adjudication process," are less significant, *see Int'l Rehab. Sciences*, 688 F.3d at 996—show only that ALJs *sometimes*

authorized payment based on particular case-specific factors that justified payment despite the presence of a stalled cycle.

For example, a June 2011 ALJ decision allowed payment of several claims involving allegedly stalled cycles. After first concluding that some of the cases *did* comply with the LCDs (because there was in fact a "reduction in the wound surface area"), the ALJ found that medical necessity had been established in the remaining cases based on "sufficient documentation" in the respective case files, either in the form of physician prescriptions or a "Letter of Medical Necessity." A November 2010 ALJ decision comparably allowed payment only because the "medical record" for the particular patient "show[ed] sufficient documentation" from the treating physician "to support medical need" for the VAC Therapy. Notably, this decision states that the "mere occurrence of a debridement does *not* excuse" compliance with the LCD's "progressive healing" requirement (emphasis added). Two April 2005 decisions (both from the same ALJ) made the converse point that the mere occurrence of debridement does not necessarily mean that "the wound *failed* to show improvement" (emphasis added).[6] Rather, the ALJ concluded, whether the wound has improved requires "consideration of the clinical evidence in the case record for each beneficiary." Likewise, a September 2005 ALJ ruling recognized that payment might be warranted, upon individualized consideration, if a case involved a "brief 'stall' within the context of good overall improvement."

[6] Other decisions, such as ALJ decisions from August 2006, April 2008, and May 2008, similarly made the point that a debridement that temporarily increased wound size would promote wound healing and did not necessarily mean that further use of VAC Therapy was unwarranted.

Taken together, these various decisions reaffirm the LCD requirements, while recognizing that, under the circumstances of a given case, medical necessity *might or might not* still be shown. But KCI's success in prevailing in particular instances of case-specific review does not show that failure to comply with the LCD—or using the KX modifier to falsely state such compliance and thereby avoid individualized review—was immaterial.

Moreover, the record contains additional ALJ decisions which further support an inference that compliance with the LCDs was material. For example, in a January 2007 decision, an ALJ upheld and applied the general rule that when multiple claims are considered at once, "the absence of measurable healing during the first cycle precludes coverage for *any* of the subsequent months" (emphasis in original). Using reasoning similar to the earlier-described Appeals Council ruling, the ALJ stated that, when the failure to satisfy the LCD was due to debridement, continued use of the VAC Therapy might be medically reasonable and necessary if the debridement was "of such an unusual and unpredictable nature, or generate[d] such unanticipated medical complications, as to justify the continuation of NPWT despite the lack of measurable healing." However, the ALJ found that in the record before it, no such extraordinary circumstances had been shown, and KCI's requests for payment were denied.

In short, there is no basis for concluding that the subset of ALJ decisions that were favorable are representative of the "mine run" of cases. *Escobar*, 579 U.S. at 195. Indeed, an ALJ decision would only be rendered in those cases that KCI specifically *chose* to appeal—which were likely closer cases or claims with extenuating factors weighing in favor of reimbursement. A KCI senior manager stated in a 2009

email that, at least as of September 2007, "the directive [KCI employees] got was don't take anything [to appeal] we know we can't win." Because KCI was being selective in choosing which claims to appeal, it is reasonable to infer that it had a greater success rate in those appeals than it would have had if it had appealed all denials in cases involving stalled-cycle claims.

2

A post-payment audit conducted in Region D supports the same conclusion that emerges from the administrative rulings—*viz*., that case-specific reviews sometimes did, and sometimes did not, reveal sufficient justification for payment of claims that did not strictly meet the LCD criteria.

In 2007, one of the DME MACs—known as Region D—conducted a post-payment audit of VAC Therapy claims. According to the declaration of a KCI employee, the audit revealed that, of 241 claims submitted and reviewed, there were 19 "instances in which KCI submitted claims to the Region D [DME MAC] using the KX modifier where the wound's healing stalled for a cycle followed by a cycle of resumed improvement." Of those 19 claims, auditors approved 14 for payment and denied the remaining five "because the auditors found insufficient medical records supporting continued VAC Therapy." The declaration indicates, however, that the five denials were not based simply on a failure to comply with the LCD but on a consideration of "all of the medical records KCI submitted for [each] patient." Once again, the hit-or-miss nature of case-specific review supports an inference that falsely using the KX modifier to avoid such a review, and to instead be paid automatically, is material to the Government's payment decision. Indeed, an audit in which five of 19 stalled-cycle claims are denied—more than 25 percent—confirms the

materiality of using a code that typically would evade such a case-specific review.

KCI also points to a pre-payment audit of VAC Therapy claims that was conducted by the DME MAC for Region B from 2007 until 2008. A KCI manager's declaration subsequently stated, in conclusory fashion, that she believed there were no claims denied in this audit on the basis of a stalled cycle. But even if some stalled-cycle claims were upheld when specifically examined in this audit, that does not establish, as a matter of law, that all such claims were paid or even that the mine run of such claims were paid.

3

Finally, the OIG's 2007 audit report also supports an inference that the false use of the KX modifier was material. The OIG report noted that nearly 21 percent of wound-therapy-pump claims lacked sufficient—or any—supporting documentation and that an additional three percent were "not medically necessary," mostly because they "did not have a measurable degree of healing over the past month." These results affirmatively support the view that falsely using the KX modifier to escape case-specific review was material. Indeed, the OIG report specifically noted that "[c]laims that do *not* have the KX modifier are automatically flagged for possible review" (emphasis added).

* * *

Accordingly, we conclude that the district court erred in holding that, as a matter of law, KCI's false certification of compliance with the LCDs was not material.[7]

III

The district court further erred in holding that there was insufficient evidence that KCI acted with the requisite scienter.[8]

A

As an initial matter, the district court held that, because the use of the KX modifier on stalled-cycle claims was not material, evidence that KCI knew that it was wrongly using the KX modifier is insufficient to establish scienter. Because the district court's premise concerning materiality was wrong, the resulting conclusion that it drew as to scienter is necessarily vitiated.

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[7] In addition to the prohibition on presentation of false claims in § 3729(a)(1)(A), the FCA contains an alternative prohibition on knowingly making "a false record or statement material to a false or fraudulent claim." *See* 31 U.S.C. § 3729(a)(1)(B). To the extent that the relator here also relies on that provision, the analysis as to materiality under that clause in this case is, so to speak, not materially different.

[8] We reject KCI's contention that Hartpence forfeited this issue by supposedly failing to raise it adequately in the opening brief. Although the brief would have benefited from a distinct subsection expressly devoted to this issue, the brief as a whole makes sufficiently clear that Hartpence contends, contrary to the district court's ruling, that KCI well knew that it was making false statements about facts material to payment. That is especially true given that, as we explain, *see infra* at 26–28, the district court's erroneous scienter ruling was largely predicated on its erroneous materiality ruling.

The district court quoted *Escobar*, 579 U.S. at 181, for the proposition that the FCA's scienter requirement turns on "whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." Although *Escobar* was concerned primarily with materiality and addressed scienter only in passing, the district court apparently construed the quoted language as suggesting that liability requires not only knowledge that a representation was false but also knowledge that the representation was *material*. *See id*. We need not decide whether this assumption was correct. Even assuming that *Escobar* requires knowledge of materiality as well as knowledge of falsity, the record in this case establishes a triable issue regarding KCI's knowledge of the materiality of its misuse of the KX modifier.

KCI was plainly aware that using the KX modifier avoided a costly review and appeals process that it would sometimes win and sometimes lose. In particular, emails from a KCI senior manager confirm KCI's awareness of the risks of losing stalled-cycle claims in a case-specific review. For example, noting that the LCDs generally limited NPWT treatment to four monthly cycles, this senior manager explained that KCI "[h]istorically" did not appeal denials of a "fifth cycle" if KCI's review disclosed that there was also a stalled-cycle in one of the first four months. As she explained, "[w]e have found that if we were to have pursued cycle 5 in appeal and there was a stalled cycle previously, Medicare would recoup their money up to and including the stalled cycle." In another email, she also explained that KCI's "mindset at that time (2006) was that we were pushing the envelope with policy," and that, after several years of appealing reimbursement denials, KCI was "able to see what really was going to be paid and what would be denied. Stalled cycles . . . were [a] large denial area[]."

More generally, a reasonable jury could conclude that KCI's deliberate insistence on using the KX modifier when it knew that the LCD was not met was driven precisely by its desire to be paid promptly and without the hassle and risks of case-specific review. That further confirms that a rational trier of fact could find that KCI knew that its misuse of the KX modifier was material to payment.

B

Beyond its threshold error in predicating its scienter analysis on its erroneous materiality ruling, the remainder of the district court's reasoning concerning scienter rests on a clear failure to view the evidence in the light most favorable to the relator. To satisfy the scienter requirement, relators must allege "a false statement or course of conduct made knowingly and intentionally." *United States ex rel. Campie v. Gilead Sciences, Inc.*, 862 F.3d 890, 904 (9th Cir. 2017). "Innocent mistakes, mere negligent misrepresentations and differences in interpretations are not false certifications under the Act." *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996). Under the statute, a false statement or false claim is knowingly made by a person if that person has actual knowledge of the falsity or if that person acts in deliberate ignorance or reckless disregard of its truth or falsity. *See* 31 U.S.C. § 3729(b)(1)(A). "[P]roof of specific intent to defraud" is *not* required. *Id*. § 3729(b)(1)(B). Here, there is ample evidence to permit a rational trier of fact to conclude that KCI knew that it was a false statement to attach the KX modifier to a claim that did not satisfy the LCD and that KCI did so knowing that it might thereby escape case-specific scrutiny that, in many cases, it would lose.

For example, the record contains an email from a billing employee who, after reading the relevant DME MAC

guidance, expressed serious concerns to higher management that the "policy instructions" she had been given concerning the use of the KX modifier in billing for stalled cycles "contradict" that guidance. *See supra* at 11. She specifically raised the question whether "it would be fraudulent to submit a bill" that does not follow the DME MAC's instructions concerning the use of the KX modifier. The record also contains an email from a KCI employee who worked on appeals of denied claims, and she explained that, after experiencing adverse rulings on many claims, KCI had become more cautious about what it did and did not appeal. As noted earlier, she specifically identified "[s]talled cycles" as one of the "large denial areas." Together with the other abundant evidence in the record that KCI followed an intentional policy to use the KX modifier on claims that did not meet the LCDs' requirements, such evidence supports a reasonable inference that KCI did so to avoid case-specific scrutiny that, often enough, it would lose.

In discounting this evidence, the district court relied on either (1) its view that knowledge of the "technical[]" falsity of KCI's use of the KX modifier was immaterial and therefore "insufficient to establish scienter"; or (2) record evidence concerning KCI's extensive discussions with the DME MACs concerning KCI's objections to the LCDs and its intention to follow a "risk-sharing approach" to billing. *See supra* at 8–14. As to the first point, we have already explained that this reasoning rests on the district court's flawed materiality ruling and falls with it. *See supra* at 26–28. As to the second, KCI certainly has a strong case to make to jurors as to why they should not draw the inferences that we have sketched out above. But KCI's showing does not negate those reasonable inferences so as to establish that KCI is "entitled to judgment as a matter of law." *See* FED. R. CIV. P. 56(a). In particular, even assuming that KCI

communicated to the DME MACs its decision to adopt an *overall* approach to billing that did not follow the LCDs, that does not negate the reasonable inference that KCI knew that, in practice, its blanket misuse of the KX modifier effectively ensured near-automatic payment of claims that otherwise might not survive individualized scrutiny. And, in light of the internal communications discussed earlier, a reasonable jury could find that KCI knew that it did not actually have the DME MACs' endorsement of its billing practices and that it decided to take a calculated risk that it could get away with bending the rules.

IV

KCI asks us to affirm the grant of summary judgment on the alternative ground that Hartpence's theory of liability is contrary to *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). In *Allina*, the Court vacated a Medicare policy that altered hospital reimbursement rates, holding that the Government was required to provide opportunity for notice and comment before adopting that policy. *Id*. at 1810–12. KCI argues that, under *Allina*, the LCDs at issue here may not validly serve as the basis for an FCA claim. We decline to reach this issue in the first instance on appeal. We leave it to the district court to address this issue if it is raised again on remand.

V

For the foregoing reasons, we reverse the district court's grant of summary judgment and remand for further proceedings consistent with this opinion, including consideration of any remaining alternative arguments that KCI raised in its summary judgment motion.

REVERSED and REMANDED.