

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO**

Civil Action No. 16-cv-02353-NYW

ROBERT CUNNINGHAM, on behalf of himself and all others similarly situated,

Plaintiff,

v.

SUSAN E. BIRCH, in her official capacity as Executive Director of the Colorado State
Department of Health Care Policy & Financing,

Defendant.

MEMORANDUM OPINION AND ORDER

Magistrate Judge Nina Y. Wang

This matter is before the court on Defendant's Motion to Dismiss Under Fed. R. Civ. P. 12(b)(1) and 12(b)(6) ("Motion to Dismiss") [#24, filed November 10, 2016]. The court considers this motion pursuant to 28 U.S.C. § 636(c) and the Order of Reference dated October 31, 2016 [#18]. After considering the Parties' briefing, including the Supplemental Authority submitted by Plaintiff on February 14, 2017 [#60-1]; arguments at the December 22, 2016 hearing; and the applicable law, the court **GRANTS** Defendants' Motion to Dismiss for lack of standing.

BACKGROUND

The following facts are drawn from the Complaint, the briefing associated with the instant Motion to Dismiss in this action, and viewed in the light most favorable to Plaintiff for the purposes of considering the instant Motion to Dismiss. The Medicaid program was established by Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.* and is a cooperative federal-state program that provides medical care to income-eligible families and individuals.

Blum v. Yaretsky, 457 U.S. 991, 993–94 (1982). While a state is not required to participate in the Medicaid program, once it does, it must comply with the federal statutes and regulations governing Medicaid. 42 U.S.C. § 1396a(a)(10). Colorado has elected to provide its citizens with a Medicaid Program. Colo. Rev. Stat. § 25.5–4–101 *et seq.* Defendant Susan E. Birch (“Defendant”) is the Executive Director of the Colorado State Department of Health Care Policy and Financing (“HCPF”), the agency responsible for administering the Colorado Medicaid Program. [#1 at ¶ 5]. Plaintiff Robert Cunningham (“Plaintiff” or “Mr. Cunningham”) is a Medicaid enrollee in Colorado who suffers from a chronic infection from HCV, a virus causing Hepatitis C. [*Id.* at ¶¶ 1, 4, 7]. Untreated, chronic Hepatitis C can cause symptoms such as pain, fatigue, depression, and an increased risk of liver failure, as well as fibrosis, cirrhosis, liver cancer, and death. [*Id.*]. The severity of liver damage due to the Hepatitis C virus is measured by a Metavir Fibrosis Score (“MFS”), with a score of F0 or F1 indicating no or minimal liver scarring to F4 indicating cirrhosis. [*Id.* at ¶ 4 & n.1]. Mr. Cunningham has a MFS score of F1. [*Id.* at ¶ 4].

Mr. Cunningham contends that under the HCPF’s criteria, his MFS score categorically disqualifies him from receiving Direct Acting Antiviral medications (“DAAs”), which he describes as “breakthrough medications.” [*Id.*]. Starting in 2013, the Federal Drug Administration (“FDA”) has approved a series of DAAs for the treatment of HCV, which are capable of curing the disease within a relatively short course of once-daily pills over the course of 8-12 weeks, with minimal side effects. [*Id.* at ¶ 19]. The FDA has approved DAAs for use on HCV infected patients regardless of fibrosis score. [*Id.* at ¶ 20]. On November 5, 2015, the federal Centers for Medicare and Medicaid Services (“CMS”) issued Guidance, advising state

Medicaid agencies that the new DAAs should be included in coverage of outpatient prescription drugs. [*Id.* at ¶ 28 (citing CENTERS FOR MEDICARE AND MEDICAID SERVICES, Assuring Medicaid Beneficiaries Access To Hepatitis C (HCV) Drugs (Release No. 172), Nov. 5, 2015)]. In pertinent part, CMS indicated that it was “concerned that some states are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs.” [*Id.* at ¶ 29]. Mr. Cunningham cites to guidelines and studies that indicate that DAAs are recommended for all patients with chronic HCV infections, with a narrow exception for patients with short life expectancies that cannot be remediated by treating HCV, by transplantation or by other directed therapy. [*Id.* at ¶ 23].

Mr. Cunningham’s physician submitted a prior authorization request (“PAR”) for DAAs on or about August 8, 2016. [#24 at 6; #24-3 at ¶¶4–6]. The August 8 PAR was considered under a previous version of HCPF’s Preferred Drug List [#24-2], and Colorado Medicaid denied Mr. Cunningham DAA treatment because his MFS was F1.¹ [#1 at ¶ 4]. He avers that he is “frustrated, irritated, disheartened, and disappointed” because he is unable to receive this breakthrough medication that could cure him of HCV. [*Id.* at ¶¶ 1, 4].

On September 2, 2016, Colorado Medicaid promulgated a new Preferred Drug List and modified the prior authorization criteria for DAA treatment, but did not eliminate the MFS criteria completely. [*Id.* at ¶ 31; #24-1; #24-1 at 22–24]. Rather, it lowered the fibrosis score minimum from F3 to F2 and eliminated the fibrosis score altogether for women planning to

¹ Defendant does not agree that Mr. Cunningham’s prior authorization request was denied due to his fibrosis score, but rather, because he did not submit sufficient information to satisfy the criteria. [#24-2 at ¶ 8]. For the purposes of the Motion to Dismiss, however, this court takes the allegations in Mr. Cunningham’s Complaint as true.

become pregnant the following year. [#1 at ¶ 31; #24-1 at 23]. It also contemplates DAA treatment for individuals “with serious extra-hepatic manifestations of HCV such as leukocytoclastic vasculitis, hepatocellular carcinoma meeting Milan criteria, membranoproliferative glomerulonephritis, or symptomatic cryoglobulinemia despite mild liver disease” or “with fibrosing cholestatic HCV.” [#24-1 at 22]. As of the filing of this action, Mr. Cunningham had not submitted a request for approval for treatment under the treatment criteria effective October 1, 2016.² [#57 at 4].

LEGAL STANDARDS

I. Subject Matter Jurisdiction and Standing

Federal courts are courts of limited jurisdiction. Under Article III of the United States Constitution, federal courts only have jurisdiction to hear certain “cases” and “controversies.” *Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014). As such, courts “are duty bound to examine facts and law in every lawsuit before them to ensure that they possess subject matter jurisdiction.” *The Wilderness Soc. v. Kane Cty., Utah*, 632 F.3d 1162, 1179 n.3 (10th Cir. 2011) (Gorsuch, J., concurring). Indeed, courts have an independent obligation to determine whether subject matter jurisdiction exists, even in the absence of a challenge from any party. *Image Software, Inc. v. Reynolds & Reynolds, Co.*, 459 F.3d 1044, 1048 (10th Cir. 2006) (citing *Arbaugh v. Y & H Corp.*, 546 U.S. 500 (2006)).

A plaintiff must establish Article III standing to bring each of his claims separately. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006); *Bronson v. Swensen*, 500 F.3d 1099,

² In January 2017, Mr. Cunningham’s treating physician submitted a renewed prior authorization request for treatment with DAAs. [#57 at 4]. Mr. Cunningham’s latest request has neither been denied nor approved under the current criteria. *See [id.]*.

1106 (10th Cir. 2007). The standing inquiry has two components: constitutional and prudential. To establish constitutional standing, a plaintiff must demonstrate “(1) an ‘injury in fact,’ (2) sufficient ‘causal connection between the injury and the conduct complained of,’ and (3) a ‘likel[i]hood’ that the injury ‘will be redressed by a favorable decision.’” *Susan B. Anthony List*, 134 S. Ct. at 2341 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)). A plaintiff must also satisfy the requirements of prudential standing. To establish prudential standing, a plaintiff must (1) assert his own rights, rather than those belonging to third parties; (2) demonstrate that his claim is not simply a “generalized grievance;” and (3) show that plaintiff’s grievance falls within the zone of interests protected or regulated by statutes or constitutional guarantee invoked in the suit. *See Bd. of Cty. Comm’rs of Sweetwater Cty. v. Geringer*, 297 F.3d 1108, 1112 (10th Cir. 2002) (citations omitted). The elements of standing “are not mere pleading requirements but rather an indispensable part of the plaintiff’s case.” *Lujan*, 504 U.S. at 561.

In addition, in order to bring a class action, the named plaintiff must have individual standing, and may not rely upon potential class members’ injuries to establish their standing. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n. 20, (1976) (citing *Warth v. Seldin*, 422 U.S. 490, 502 (1975) (stating that named plaintiffs who seek to represent a class “must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent”)); *Thomas v. Metro. Life Ins. Co.*, 631 F.3d 1153, 1159 (10th Cir. 2011) (“Prior to class certification, the named Plaintiffs’ failure to maintain a live case or controversy is fatal to the case as a whole—that unnamed plaintiffs might have a case or controversy is irrelevant.”). If the

named plaintiff does not have standing, then this court lacks subject matter over the action as a whole. *O’Shea v. Littleton*, 414 U.S. 488, 494 (1974).

II. Rule 12(b)(6)

Under Rule 12(b)(6), a court may dismiss a complaint for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). In deciding a motion under Rule 12(b)(6), the court must “accept as true all well-pleaded factual allegations . . . and view these allegations in the light most favorable to the plaintiff.” *Casanova v. Ulibarri*, 595 F.3d 1120, 1124 (10th Cir. 2010) (quoting *Smith v. United States*, 561 F.3d 1090, 1098 (10th Cir. 2009)). However, a plaintiff may not rely on mere labels or conclusions, “and a formulaic recitation of the elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Plausibility refers “to the scope of the allegations in a complaint: if they are so general that they encompass a wide swath of conduct, much of it innocent, then the plaintiffs ‘have not nudged their claims across the line from conceivable to plausible.’” *Robbins v. Oklahoma*, 519 F.3d 1242, 1247 (10th Cir. 2008) (citation omitted). “The burden is on the plaintiff to frame ‘a complaint with enough factual matter (taken as true) to suggest’ that he or she is entitled to relief.” *Id.* The ultimate duty of the court is to “determine whether the complaint sufficiently alleges facts supporting all the elements necessary to establish an entitlement to relief under the legal theory proposed.” *Forest Guardians v. Forsgren*, 478 F.3d 1149, 1160 (10th Cir. 2007).

ANALYSIS

I. Standing

The court first considers whether Mr. Cunningham has sufficient standing to bring this action. Defendant argues that Mr. Cunningham lacks standing because he is seeking prospective relief only, but the Complaint only alleges a past injury, under a policy that is no longer in force, to support his claim. [#24 at 11]. In support of its Motion to Dismiss, Defendant offers the Affidavit of Brittany Schock, an employee of the HCPF, regarding Mr. Cunningham's prior authorization request. [#24-3 at 1]. Plaintiff urges this court to confine its inquiry only to the allegations as pled in the Complaint, taken as true. [#40 at 10]. Plaintiff contends that he has sufficiently pled standing because: (1) he is an eligible beneficiary under Colorado Medicaid; (2) he has chronic HCV; (3) he has a fibrosis score of F1; and (4) he is therefore ineligible for DAAs under HCPF's current criteria. [*Id.*].

A. Appropriate Standard of Review

As an initial matter, the court addresses the applicable standard of review. Standing is adjudicated under Rule 12(b)(1) of the Federal Rules of Civil Procedure, because it is a challenge to a court's jurisdiction, under Article III of the Constitution, to adjudicate the action. Plaintiff cites to no authority, and this court found none, that allows this court to simply decide to "apply the Rule 12(b)(6) standard of review to Defendant's standing challenge." [#40 at 9]. Instead, the court converts a motion brought under Rule 12(b)(1) to one under Rule 12(b)(6) or Rule 56 when the jurisdictional question requires the resolution of an aspect of the substantive claim. *See Holt v. United States*, 46 F.3d 1000, 1003 (10th Cir. 1995). Plaintiff does not argue, nor does this court find, that the issue of standing is intertwined with the merits of this action. Nor does this

court agree that Defendant is making a facial challenge to Plaintiff's standing; rather, Defendant's standing arguments implicate the factual underpinnings of the alleged injury to Plaintiff. *See generally* [#24, #48].

Nevertheless, “[w]hen evaluating a plaintiff’s standing at the stage of a motion to dismiss on the pleadings, ‘both the trial and reviewing courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party.’” *S. Utah Wilderness All. v. Palma*, 707 F.3d 1143, 1152 (10th Cir. 2013) (quoting *Warth*, 422 U.S. at 501). But it is equally clear that it is appropriate for this court to look beyond the four corners of the Complaint, including affidavits submitted by the Parties, in resolving the issue of standing, though those are also construed in the light most favorable to the plaintiff. *Id.* And even in adjudicating a motion to dismiss under Rule 12(b)(6), this court would be permitted to consider documentation (or lack thereof) of Plaintiff’s prior authorization requests related to DAAs as well as the prior authorization criteria for DAAs without converting this instant motion to one for summary judgment, as both are central to the claims raised in this suit and there is no dispute as to its authenticity. *See Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002) (discussing when a court may look beyond the four corners of a complaint on a Rule 12(b)(6) motion). Indeed, to hold otherwise would be to permit a plaintiff to simply ignore the facts associated with his case, for a potentially more favorable pleading. *Cf. GFF Corp. v. Associated Wholesale Grocers, Inc.*, 130 F.3d 1381, 1385 (10th Cir. 1997).

B. Concrete and Particularized Injury

The court now turns to whether Mr. Cunningham has constitutional standing to bring this action. To establish the existence of an “injury in fact,” “a plaintiff must offer something more

than the hypothetical possibility of injury.” *Colorado Outfitters Ass’n v. Hickenlooper* (“*Colorado Outfitters II*”), 823 F.3d 537, 544 (10th Cir. 2016). Instead, the alleged injury must be “concrete, particularized, and actual or imminent.” *Id.* (citing *Lujan*, 504 U.S. at 560). Where a plaintiff seeks prospective relief like an injunction, the plaintiff must be suffering a continuing injury or be under a real and immediate threat of being injured in the future. *See Colorado Cross Disability Coal. v. Abercrombie & Fitch Co.*, 765 F.3d 1205, 1211 (10th Cir. 2014).

In this case, there is no dispute that at the time of the inception of this litigation, Mr. Cunningham had not submitted a PAR under the currently effective guidelines. [#1; #19-16 at ¶ 5]. Thus, the operative inquiry is whether Mr. Cunningham is under a real and immediate threat of being injured in the future. During oral argument, Mr. Cunningham contended that no such PAR was necessary, because given the effective criteria, he would not be eligible for treatment. In support of this position, Mr. Cunningham points to his own Declarations and that of his treating physician, Alvaro F. Martinez-Camacho, who indicated that Mr. Cunningham’s medical conditions do not meet any of the prior authorization criteria for treatment. [#19-16; #40-2; #40-1]. Defendant argued that Dr. Martinez-Camacho’s opinion that a subsequent PAR would be futile could not confer standing, as there was no actual injury to Mr. Cunningham and his request for prospective relief could not be premised on a past denial under criteria that were no longer effective. Mr. Cunningham contends that he need not show that he has applied for coverage and had been denied when it is clear an application would be rejected, as such a requirement would be “silly.” [#40 at 12]. This court respectfully disagrees.

Plaintiff is correct that standing does not necessarily require a plaintiff to “await the consummation of threatened injury to obtain preventive relief.” *Blum*, 457 U.S. at 1000.

Standing requires only that a plaintiff be immediately harmed or immediately threatened with harm. *Id.* The concept of “imminence” is concededly “elastic,” and is put in place to ensure that the alleged injury is not too speculative for Article III purposes. *Clapper v. Amnesty Int’l USA*, 133 S. Ct. 1138, 1147 (2013). Yet allegations of *possible* future injury are generally not sufficient to satisfy the requirements of constitutional standing. *Id.* Nor can this court simply presume that standing is satisfied in order to reach the merits of this action, no matter the importance of such claim. *See Colorado Outfitters II*, 823 F.3d at 543. Rather, the Supreme Court has described “imminence” as “certainly impending.” *Clapper*, 133 S. Ct at 1147.

This court is persuaded under the cases cited by Defendant in this matter that Mr. Cunningham’s prior denial of DAAs under a now-obsolete policy is insufficient to confer standing to challenge a policy under which he had not applied until after the oral argument on the Motion to Dismiss. *See Buchwald v. Univ. of N.M. Sch. of Med.*, 159 F.3d 487, 491 (10th Cir. 1998); *Schutz v. Thorne*, 415 F.3d 1128, 1134–35 (10th Cir. 2005). The court also find this conclusion supported by the Tenth Circuit’s determination in *Smith v. United States Court of Appeals for the Tenth Circuit*, 484 F.3d 1281 (10th Cir. 2007). In that case, the plaintiff sought to challenge the adequacy of state appellate review culminating in unpublished opinions, because he had just taken his state appeal when he filed the action, and the state appellate court had taken no action as to his appeal yet. In so ruling, the Tenth Circuit observed:

Mr. Smith had just taken his state appeal when he filed this action. He was in no position to challenge the adequacy of state appellate review in cases culminating in unpublished opinions unless he could show that he would in fact receive such review from the state court of appeals (and from the state supreme court as well, if it took the case on certiorari). As we have explained,

an injury in fact must be actual or imminent, not conjectural or hypothetical. Allegations of possible future injury do not satisfy

the requirements of Art[icle] III. A threatened injury must be certainly impending to constitute injury in fact. An Article III injury must be more than a possibility. The threat of injury must be both real and immediate.

Id. at 1155 (quotation marks, ellipses and citations omitted). *Mr. Smith cannot make this required showing because the manner of resolution of his future appeals is entirely speculative.*

Smith, 484 F.3d at 1285 (emphasis added).

Like in *Smith*, the manner of resolution of Mr. Cunningham's PAR is still speculative at this point, and was also speculative at the inception of this action as his physician had not submitted a PAR under the currently effective criteria at that time. *Cf. Barryman–Turner v. D.C.*, 115 F. Supp. 3d 126, 136 (D.D.C. 2015) (finding no standing to seek prospective relief when plaintiff had not sought relief under the existing statute that had been amended since plaintiff's denial of benefits). The self-determination, by Mr. Cunningham and his doctor, that he will necessarily be denied, submitted after the inception of this action, is insufficient to change this court's conclusion. Standing is determined at the time the action is first brought; it generally cannot be based on subsequent events. *See Mink v. Suthers*, 482 F.3d 1244, 1254 (10th Cir. 2007). "Accordingly, the initial standing of the original plaintiff is assessed at the time of the original complaint, even if the complaint is later amended." *S. Utah Wilderness All.*, 707 F.3d at 1153. At the inception of the action, Mr. Cunningham had not yet been subject to the now effective criteria. Taken to its logical end, Plaintiff's argument appears to be that a plaintiff need not have suffered an actual injury or be imminently threatened with such injury to have standing to challenge the Preferred Drug List criteria, but rather, have simply determined, unilaterally, that his PAR will likely be denied. In this court's view, such a unilateral

determination is insufficient to confer constitutional standing. Nor can the potential Intervenors [#61] save this action from dismissal, even if they have standing in their own right.

Mr. Cunningham's arguments to the contrary do not persuade this court. As an initial matter, unlike *Early v. Bankers Life and Cas. Co.*, 959 F.2d 75, 79 (7th Cir. 1992) cited by Plaintiff, the law of this District does not permit a plaintiff to amend his complaint through responding to a motion to dismiss. See *In re Qwest Communications Int'l., Inc.*, 396 F. Supp. 2d 1178, 1203 (D. Colo. 2004). Second, Plaintiff cites no law, and this court could not find any, that supported the proposition that a plaintiff's unilateral determination of futility was sufficient to confer constitutional standing. [#40 at 4–10]. Third, Mr. Cunningham's request to defer ruling on standing for an evidentiary hearing is unnecessary. This court does not base its determination on Defendant's characterization of its consideration on Plaintiff's prior PAR under no longer effective criteria; it reaches this conclusion based on the fact that Mr. Cunningham, at the inception of this action, has failed to even seek review under the existing criteria. There is no dispute as to that fact and, therefore, no need for an evidentiary hearing—particularly when Plaintiff has already availed himself of the opportunity to submit additional evidence.

In reaching this conclusion, this court is particularly mindful that the Supreme Court has repeatedly observed, “[n]o principle is more fundamental to the judiciary’s proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.” *Clapper*, 133 S. Ct. at 1146 (citations omitted). Grounded in principles of separation of powers, standing “serves to prevent the judicial process from being used to usurp the powers of the political branches.” *Id.* (citations omitted). Even as in this case, where there is no requirement for exhaustion of administrative remedies, this court concludes that standing

requires a plaintiff to do something more than simply predict that the actions of the executive will harm him. This is particularly true when nothing about the circumstances prevent a plaintiff from actually suffering the injury-in-fact; as Plaintiff himself observes, “thousands” of Coloradans have been denied DAAs, presumably under the existing criteria. This is simply not a case where the concept of “imminence” needs or should be stretched to ensure review of the challenged criteria.

When a court dismisses a case for lack of subject matter jurisdiction, this is not a determination on the merits of the case, but only a decision that the court lacks the authority to adjudicate the action. *See Castaneda v. INS*, 23 F.3d 1576, 1580 (10th Cir. 1994) (recognizing federal courts are courts of limited jurisdiction and may only exercise jurisdiction when specifically authorized to do so). If the court determines that it lacks subject matter jurisdiction over a claim, it may not consider any other issue. *See Cunningham v. BHP Petroleum Great Britain PLC*, 427 F.3d 1238, 1245 (10th Cir. 2005) (holding that once a federal court determines that it is without subject matter jurisdiction, it must not proceed to consider any other issue).

For the foregoing reasons, **IT IS ORDERED** that:

- (1) Defendants’ Motion to Dismiss [#24] is **GRANTED**;
- (2) Plaintiff’s Motion for Certification of Class, Approval of Class Representatives, and Approval and Appointment of Class Counsel [#19] is **DENIED without prejudice**;
- (3) Motion for Leave to Intervene on Behalf of Samuel Wilson and Earby Moxon [#61] is **DENIED without prejudice**;
- (4) Defendant’s Motion to Continue Hearing on Class Certification [#62] is **DENIED as MOOT** and the hearing and status conference currently set for February 22, 2017, at 2:00 p.m. is **VACATED**;
- (5) This case is **DISMISSED without prejudice** due to lack of subject matter jurisdiction; and

(6) Each party will bear its own costs and fees associated with this action.

DATED: February 17, 2017

BY THE COURT:

s/Nina Y. Wang
Nina Y. Wang
United States Magistrate Judge