

1 U.S.C. § 794(a) (Claim 3). Defendant now moves to dismiss.
2 (Mot. (Docket No. 29).)

3 The parties are familiar with the allegations of the
4 complaint, and the court accordingly will not recite them in
5 detail here. Essentially, it is alleged that plaintiffs are
6 Medicare beneficiaries who received injections of a drug called
7 Stelara in an outpatient clinical setting. The providing of
8 Stelara in that setting was covered by Medicare Part B, which
9 pays for outpatient drugs administered incident to a
10 practitioner's services. In 2021, defendant ended Part B
11 coverage for Stelara by designating it "usually self-
12 administered." However, plaintiffs were not notified of this
13 change by anyone, continued going to the doctor's office to get
14 Stelara injections, and were billed substantial sums for Stelara
15 that they received at the doctor's office.

16 I. Jurisdiction

17 Before addressing the merits of plaintiffs' legal
18 claims, the parties assert a slew of statutory and constitutional
19 jurisdiction arguments. For the reasons discussed below, the
20 court concludes that (1) it has subject matter jurisdiction over
21 Beitzel's December 2019 Medicare claim, but no other Medicare
22 claims; and (2) Beitzel has standing to seek relief for past
23 injuries caused by Stelara's addition to the SAD List, but not to
24 seek relief for any prospective injuries that might be caused by
25 other drugs being listed in the future.

26 A. Subject Matter Jurisdiction Under 42 U.S.C. § 405(g)

27 1. Failure to Exhaust Administrative Remedies

28 Section 405(g) of the Medicare statute vests this court

1 with jurisdiction over claims arising under Medicare^{1 2}, but only
2 after a plaintiff exhausts all available administrative remedies.
3 42 U.S.C. § 405(g); see Odell v. U.S. Dep't of Health & Hum.
4 Servs., 995 F.3d 718, 722 (9th Cir. 2021) ("the Medicare statute
5 requires exhaustion of administrative remedies as a prerequisite
6 to bringing an action in court"). The exhaustion requirement
7 applies on a claim-by-claim basis. See id. at 723 ("[p]roperly
8 channeling one claim -- or even several claims -- [through
9 administrative appeals] does not permit a plaintiff to resolve
10 other claims or causes of action that have not been channeled").

11 Of the eight Medicare claims challenged by the three
12 plaintiffs through the Medicare administrative process, only
13 Beitzel's December 2021 Medicare claim has been properly
14 exhausted. (See FAC ¶ 81-84, 72-83 & n.8, 93-99; see also Opp'n
15 (Docket No. 32) at 15 ("Ms. █████ and Ms. Goldstein have not yet
16 completed Medicare's administrative review process . . .").)

17 2. No Waiver of Exhaustion

18 Plaintiffs argue that the court should waive the
19 exhaustion requirement as to their non-exhausted Medicare claims.
20 A court may do so if a plaintiff can show that the non-exhausted
21 claim is "(1) collateral to a substantive claim of entitlement
22 (collaterality), (2) colorable in its showing that denial of
23 relief will cause irreparable harm (irreparability), and (3) one

24 ¹ Neither party disputes that plaintiffs' claims arise
25 under the Medicare statute. (See Mot. at 18; Opp'n at 13-14.)

26 ² 42 U.S.C. § 405(g) is the Social Security Act's
27 judicial review provision. 42 U.S.C. § 1395ff(b) incorporates
28 this provision into the Medicare statute, 42 U.S.C. § 1395 et
seq.

1 whose resolution would not serve the purposes of exhaustion
2 (futility).” Kaiser v. Blue Cross of California, 347 F.3d 1107,
3 1115 (9th Cir. 2003).

4 The court will not waive the exhaustion requirement
5 because plaintiffs fail to satisfy at least the collaterality
6 prong. While plaintiffs assert that they “do not ask the Court
7 to resolve any issue relating to their individual claims” for
8 benefits (see Opp’n at 16), their complaint and opposition
9 undercut that assertion. (See FAC at 34 (seeking a permanent
10 injunction “[w]aiving the liability of Plaintiffs . . . for Part
11 B medications they received or receive”); Opp’n at 17 (“The
12 requested relief would allow [REDACTED] to seek a refund of the
13 thousands of dollars she paid the hospital”); id. at 22
14 (“[plaintiffs’] due process claim includes waiving the liability
15 of beneficiaries who did not receive adequate notice before
16 receiving a drug that was [removed from Part B coverage]”).)
17 Because plaintiffs’ legal claims are “inextricably intertwined”
18 with their claims for Medicare benefits, they cannot be deemed
19 “collateral.” See Johnson v. Shalala, 2 F.3d 918, 921 (9th Cir.
20 1993); see also Kaiser, 347 F.3d at 1116 n.4 (“all inextricably
21 intertwined claims must first be raised in an administrative
22 process”).

23 Accordingly, no waiver applies.

24 B. No Alternative Bases for Jurisdiction for Non-Exhausted
25 Claims

26 As a final resort, plaintiffs argue that the court
27 still has jurisdiction over plaintiffs’ non-exhausted Medicare
28 claims under 28 U.S.C. § 1361 (mandamus) and § 1331 (federal

1 question). (See Opp'n at 20-21.)

2 The court disagrees. The text of Section 405(h)
3 plainly makes the court's jurisdiction under Section 405(g)
4 exclusive: it states that no final administrative decision "shall
5 be reviewed by any person, tribunal, or governmental agency
6 except as herein provided." 42 U.S.C. § 405(h). See also
7 Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1,
8 10 (2000) ("Section 405(h) purports to make exclusive the
9 judicial review method set forth in § 405(g)"); Do Sung Uhm v.
10 Humana, Inc., 620 F.3d 1134, 1140 (9th Cir. 2010) (§ 405(g) is
11 "the sole avenue for judicial review for claims arising under the
12 Medicare Act") (citations omitted); Kaiser v. Blue Cross of
13 California, 347 F.3d 1107, 1111 (9th Cir. 2003) ("Jurisdiction
14 over cases 'arising under' Medicare exists only under 42 U.S.C. §
15 405(g), which requires an agency decision in advance of judicial
16 review.").³

17 Accordingly, the court lacks subject matter
18 jurisdiction generally to adjudicate ██████████ and Goldstein's
19 legal claims and will therefore dismiss the claims of ██████████ and

20
21 ³ To the extent that plaintiffs cite binding and contrary
22 cases establishing alternative bases for jurisdiction, the court
23 observes that those cases long predate the Ninth Circuit's more
24 recent and expansive holdings in Do Sung Uhm and Kaiser. To the
25 extent that plaintiffs argue for a narrow exception to Section
26 405(g)'s bar, plaintiffs fail to establish that "application of §
27 405(h) . . . would mean no review at all" because an
28 administrative channel for review and redress clearly exists here
-- one under which plaintiffs have even found some measure of
success. Shalala, 529 U.S. at 19. See Sensory Neurostimulation,
Inc. v. Azar, 977 F.3d 969, 983-84 (9th Cir. 2020) ("no review at
all" exception cannot apply where "an administrative channel for
review exists").

1 Goldstein.⁴ This action will proceed on Beitzel's fully-
2 exhausted December 2021 Medicare claim as the main factual
3 predicate for his legal claims.

4 C. Article III Standing

5 Defendant challenges Beitzel's standing to bring his
6 legal claims to the extent that he requests prospective remedies
7 related to drugs other than Stelara.⁵

8 Federal subject-matter jurisdiction extends only to
9 "Cases" and "Controversies." U.S. Const. art. III, § 2. A
10 plaintiff satisfies this jurisdictional requirement only if he
11 has "(1) suffered an injury in fact, (2) that is fairly traceable
12 to the challenged conduct of the defendant, and (3) that is
13 likely to be redressed by a favorable judicial decision."
14 Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016).

15 Beitzel has not alleged that he suffered an injury in
16 fact as to any other drug than Stelara. His assertions about his
17 "ongoing concerns regarding Medicare's SAD List policies" and
18 "likei[ihood] that [he] will require additional medications that
19 are furnished incident to a practitioner's service" (Opp'n at 24-
20 25) are too remote and speculative to satisfy the constitutional
21 requirement that "threatened injury must be certainly impending."
22 Clapper v. Amnesty Int'l USA, 568 U.S. 398, 409 (2013) (internal
23 quotation marks and alteration omitted). This reasoning applies

24 ⁴ The court accordingl d not address defendant's
25 improper venue argument as to [REDACTED] and Goldstein. (See Mot. at
26 20.)

27 ⁵ Neither party disputes that Beitzel has standing to
28 seek relief for Stelara injections that were denied coverage.
(See Opp'n at 23-24; Reply (Docket No. 33) at 8.)

1 with special force when plaintiffs' complaint does not identify a
2 single other drug currently covered by Part B that they currently
3 need or anticipate needing in the very near future.

4 Accordingly, the court will consider Beitzel's legal
5 claims only to the extent that they seek relief for past injuries
6 caused by Stelara being added to the SAD List without adequate
7 notice.

8 II. Rule 12(b)(6)

9 Finally, the court examines the underlying merits of
10 Beitzel's legal claims. In so doing, the court construes all
11 factual allegations as true and grants Beitzel every reasonable
12 factual inference. See Ashcroft v. Iqbal, 556 U.S. 662, 678
13 (2009).

14 A. Due Process (Claim 1)

15 In order to state a due process claim, a plaintiff must
16 allege a deprivation of a constitutionally protected property
17 interest and a denial of adequate procedural protections.
18 Kildare v. Saenz, 325 F.3d 1078, 1085 (9th Cir. 2003); see Bd. of
19 Regents v. Roth, 408 U.S. 564, 569-70 (1972).

20 Regarding adequacy, the Ninth Circuit has specifically
21 rejected the idea that the Due Process Clause requires prior
22 notice before enacting and enforcing laws of general
23 applicability. See, e.g., Halverson v. Skagit County, 42 F.3d
24 1257, 1260 (9th Cir. 1994) ("[G]overnmental decisions . . . not
25 directed at one or a few individuals do not give rise to the
26 constitutional procedural due process requirements of individual
27 notice and hearing; general notice as provided by law is
28 sufficient."); Gallo v. U.S. Dist. Ct. For Dist. of Arizona, 349

1 F.3d 1169, 1182-83 (9th Cir. 2003) ("Since the amended rule
2 affects a large number of people, as opposed to targeting a small
3 number of individuals based on individual factual determinations,
4 Gallo's claim that he is entitled to individual notice and an
5 opportunity to be heard fails because the amended legislative
6 rule does not 'give rise to constitutional procedural due process
7 requirements.'" (citing Christensen v. Yolo County Bd. of
8 Supervisors, 995 F.2d 161, 166 (9th Cir. 1993))). See generally
9 Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 441,
10 445 (1915) ("Where a rule of conduct applies to more than a few
11 people, it is impracticable that everyone should have a direct
12 voice in its adoption.") (Holmes, J.).

13 The addition of Stelara to the SAD List clearly is a
14 decision of general applicability, which was accompanied by
15 accordingly appropriate general notice to the public. Beitzel
16 alleges that Stelara was added to the SAD List in at least two
17 out of twelve nationwide MAC jurisdictions. (FAC ¶¶ 37, 63, 91,
18 106.) Beitzel also describes in great detail a nationwide,
19 years-long advocacy campaign to stop Stelara and other drugs from
20 being added to the SAD Lists. (Id. ¶¶ 123-31.) Finally, the SAD
21 Lists including Stelara were made public back in 2020 before
22 taking full effect in 2021. (Id. ¶ 127 & Local Coverage Articles
23 A53032, A53021.)

24 While it does appear unfair to expect Beitzel, or any
25 Medicare beneficiary generally, to keep abreast of such complex
26 regulatory developments in order to avoid astronomical medical
27 bills, not every unfairness rises to the level of a
28 constitutional violation. Beitzel can point to no authority

1 other than the Due Process Clause for his proposition that
2 individualized notice was due. And for the reasons discussed
3 above, the Due Process Clause alone cannot vindicate him here.

4 Accordingly, the court is constrained to dismiss the
5 due process claim.

6 B. Failure to Waive Liability Under Medicare Statute
7 (Claim 2)

8 The Medicare statute directs defendant to waive
9 beneficiaries' liability incurred due to a denial of coverage in
10 certain circumstances. See 42 U.S.C. § 1395pp(a)-(b) (requiring
11 waiver of liability or indemnity where both individual and
12 healthcare provider did not and could not have known that Part B
13 would not cover given expense). However, this authority is
14 expressly limited to certain enumerated categories of denied
15 claims. Id. § 1395pp(a) (services that are not reasonable and
16 necessary, 42 U.S.C. § 1395y(a)(1); custodial care, id. §
17 1395y(a)(9); and certain home-health and hospice services, id. §
18 1395pp(g)).

19 Beitzel's Stelara injection was denied coverage under
20 Part B because Stelara is now deemed "usually self-administered."
21 See 42 U.S.C. §§ 1395k(a)(1), 1395x(s). (See also FAC ¶¶ 3, 32,
22 63.) This is not one of the enumerated categories, and defendant
23 accordingly has no statutory authorization to waive liability for
24 claims denied under that basis.⁶

25 ⁶ The court is not persuaded by Beitzel's attempt to
26 couch "usually self-administered" denials as medical necessity
27 determinations, 42 U.S.C. § 1395y(a)(1). MACs rely on empirical
28 statistical information, certain presumptions based on a drug's
delivery mechanism, and conditions related to the drug to
determine whether a drug is usually self-administered. (FAC ¶¶

1 Accordingly, the court must also dismiss this claim.

2 C. Rehabilitation Act § 504 (Claim 3)

3 Section 504 of the Rehabilitation Act, 29 U.S.C. § 701
4 et seq., provides that “[n]o otherwise qualified individual with
5 a disability . . . shall, solely by reason of her or his
6 disability, be excluded from the participation in, be denied the
7 benefits of, or be subjected to discrimination . . . under any
8 program or activity conducted by any Executive agency.” 29
9 U.S.C. § 794(a). A defendant may violate Section 504 if it
10 “denies a qualified individual with a disability a reasonable
11 accommodation that the individual needs in order to enjoy
12 meaningful access to the benefits of public services.” Mark H.
13 v. Hamamoto, 620 F.3d 1090, 1097 (9th Cir. 2010).

14 Beitzel argues that defendant’s recharacterization of
15 Stelara as a usually self-administered drug deprived him of
16 “meaningful access to [his] Medicare benefits.” (See FAC ¶ 150;
17 Opp’n at 32-33.) Accordingly, he requests a reasonable
18 modification for “Medicare-covered administration of [Stelara] by
19 a qualified health care professional.” (FAC ¶ 150.)

20 Because Beitzel has not alleged that he was deprived of
21 Medicare-covered administration of Stelara, the court concludes
22 he has failed to allege sufficient facts that show a deprivation
23 of meaningful access to Medicare benefits. At oral argument, the
24 parties clarified that the Part B coverage of Stelara

25 33-35.) MACs also make this determination on a drug-by-drug
26 basis, not a beneficiary-by-beneficiary basis. (Id. ¶ 35.) See
27 also Glassman v. Azar, No. 1:18-CV-00945LJO BAM, 2019 WL 2917990,
28 at *4 (E.D. Cal. July 8, 2019) (“Section 1395pp does not apply
every time a service is not medically necessary.”).


1 administration was not at issue, but rather that Part B coverage
2 for obtaining Stelara was. (See also FAC ¶ 29 (“Part B pays for
3 drugs and biologicals furnished incident to the service of a
4 physician (or other practitioner).”) (emphasis added); Docket No.
5 27-3 at 7 (partial Part B coverage for \$252 charged for Stelara
6 administration, but no Part B coverage for \$43,543.47 charged for
7 1mg of Stelara).)

8 Beitzel acknowledges that he, like other patients
9 dependent on Stelara, has continued coverage for obtaining
10 Stelara under Part D. (See Opp’n at 32 (“Mr. Beitzel and other
11 disabled beneficiaries obtain coverage from Part D at least
12 theoretically”).) Absent any additional allegations that
13 Beitzel is precluded from obtaining Stelara on his own through
14 Part D, as he presently does (see FAC ¶ 86), and then getting
15 Stelara administered at a doctor’s office through Part B, the
16 court cannot conclude that Beitzel has lost meaningful access to
17 his Medicare benefits.

18 Accordingly, the court will also dismiss this claim.
19 Beitzel will be given leave to amend this claim if he can allege
20 additional facts showing that he was meaningfully deprived of
21 Medicare-covered administration of Stelara.

22 IT IS THEREFORE ORDERED that defendant’s motion to
23 dismiss (Docket No. 29) be, and the same hereby is, GRANTED.
24 Plaintiffs are given 20 days from the date of this Order to file
25 an amended complaint if they can do consistent with this Order.

26 Dated: April 19, 2024

27 
28 **WILLIAM B. SHUBB**
UNITED STATES DISTRICT JUDGE