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March 26, 2015

VIA EMAIL

The Honorable Lewis T. Booker, Jr., U.S. Administrative Law Judge c/o Stephanie Shelton
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Midwest Region Field
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Re: Response to Insurer's Position Statement;
ALJ Hearing for Ms. Charlene Rynee Lauderdale,
Appeal Number 1-2814911584

Dear Judge Lewis T. Booker, Jr.,

I am an attorney and authorized representative of Ms. Charlene Rynee Lauderdale **(Member ID: 972146250-1)**, a Medicare Advantage beneficiary enrolled in AARP Medicare Complete HMO, which is administered by United Healthcare ("United"). A hearing has been scheduled before you on Tuesday, March 31, 2015 at 1pm eastern. I am writing to you today to address issues raised by United in its Position Statement.

Ms. Lauderdale's original claim for pre-authorization was denied by United solely on the basis of a transgender services exclusion that it was not permitted to enforce. United has attempted to excuse its error by concocting *post-hoc* justifications for the denial. None of United's excuses are worthy of credence.

This Letter proceeds in two parts. First, it addresses United's proffered basis of denial prior to this hearing. Second, it addresses the new arguments that United has raised in its Position Statement.

I. United's Sole Basis for Denial was the Transgender Exclusion

Prior to the March 23 Position Statement, United's only proffered basis for denying Ms. Lauderdale's pre-authorization was an inoperable transgender services exclusion in the Plan. This is evidenced by the language used in the two written denial letters issued to Ms.

Lauderdale as well as United's representations to MAXIMUS.

First Denial Letter. In the November 25 letter, United stated that Ms. Lauderdale's request for pre-authorization was denied because,

> Based on health plan benefits for surgery done to change sex, coverage is denied. The information shows you currently live as a female. You have had your testicles removed and breasts augmented. You desire to have your genitals surgically modified to female form. You have been taking female hormones and living as a female for 8 years. **Change of genitals to the female form is not a benefit and not covered by your health plan.**

See Exhibit A (emphasis added).

Second Denial Letter. Similarly, in the December 4 letter, United stated that Ms. Lauderdale's request for pre-authorization was denied because,

> The plan benefits say your medical care is generally covered as long as the care you receive is included in the Medical Benefits Chart, is medically necessary and you received your care from a provider who participates in Medicare. **Sex change surgery is not covered under your health plan benefits.** Please encourage the member to speak with her doctor at her earliest convenience for further guidance as needed. **You can find this guidance in the 2014 Evidence of Coverage— AARPMedicareComplete SecureHorizons Value (HMO), Chapter 4, page 4- 36 and 4-37, Section 3.1 "Benefits We do not cover (exclusions)."**
>
> We have determined that our original decision to deny coverage is correct.

See Exhibit B (emphasis added). This letter was signed by Juanita Cortez, a non-physician agent in United's Appeal Grievance.[1]

United's Representation to MAXIMUS. United also argued that the sole basis for its denial was the transgender services exclusion in the Plan when this appeal was before MAXIMUS. As MAXIMUS pointed out,

> United Healthcare must follow Medicare rules. **United Healthcare takes the position that Gender Reassignment Surgery is excluded from Medicare coverage.** That was true until recently when the National Coverage Decision which had excluded surgery was set aside. As a result of that change, after May, 2014 Gender Reassignment Surgery is potentially coverable by Medicare if it is medically necessary and reasonable for the particular patient.

See Exhibit C at 4 (emphasis added).

As the above reveal, United did not look beyond the existence of the inoperable transgender services exclusion when it denied Ms. Lauderdale's pre-authorization request. At

[1] Upon information and belief, Ms. Cortez does not have any demonstrable expertise in transgender medicine.

no time did United contest the medical necessity of this procedure; United simply tried to reap the benefits of a bargain that the Medicare laws no longer permit.

II. Alternative Explanations for Denial

United's March 23 Position Statement presented several suspect *post-hoc* justifications for denying Ms. Lauderdale's November 2014 request for pre-authorization. None of these justifications are worthy of credence.

A. United Was Required to Give Effect to the May 2014 Board Decision Lifting NCD 140.3

United claims that Medicare's failure to disseminate exacting instructions to Medicare Advantage plans after NCD 140.3 was invalidated excuse its denial of Ms. Lauderdale's request for pre-authorization. Not so.

The May 2014 Board decision unambiguously directed Medicare Advantage plans on how to proceed once the NCD was invalidated.[2] On the first page of the opinion, insurers were instructed that,

> Since the NCD is no longer valid, its provisions are no longer a valid basis for denying claims for Medicare coverage of transsexual surgery . . . . The decision does not require CMS to revise the NCD or issue a new NCD . . . .[3]

This language clearly and unambiguously put insurers on notice that the now invalidated NCD, and any policies that flowed from it, such as United's blanket transgender services exclusion, may no longer be relied upon. Further, the decision expressly acknowledged that the absence of an NCD for Gender Reassignment Surgery is not in itself a reason to deny care.

If United was legitimately confused about how to proceed once the NCD was lifted, it could have looked at relevant CMS regulations and guidance. For instance, CMS has rules in place that provide Medicare Advantage plans clear guidance on modifying plans in the wake of an invalidated NCD. For example, 42 CFR §426.560(b)(2) requires CMS to, within 30 days of a Board decision, change policy to confirm with the Board's decision. It further instructs, "Any change in policy is applied prospectively to requests for service or claims filed with dates of service after the implementation of the Board decision." CMS communicated the change in *two* separate transmittals on June 27, 2014.[4] United was bound to comply with both the May 2014 Board decision invalidating the NCD and the June 2014 transmittals.[5] If, for some reason, United was confused about its obligation to

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[2] Departmental Appeals Board, Dep't of Health & Human Servs., NCD 140.3, Transsexual Surgery, Docket No. A-13-87, Decision No. 2576 at 1 (May 30, 2014), *available at* http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf.

[3] *Id.*

[4] *See* CMS Manual System, Pub. 100-03 Medicare National Coverage Determinations (Transmittal 169, Change Request 8825) https://www.cms.gov/Regulations-and- Guidance/Guidance/Transmittals/Downloads/R169NCD.pdf ; CMS Manual System, Pub. 100-03 Medicare National Coverage Determinations (Transmittal 189, Change Request 8825) https://www.cms.gov/Regulations-and- Guidance/Guidance/Transmittals/Downloads/R189BP.pdf.

[5] *See* 42 CFR § 422.101(b)(1) (mandating Medicare Advantage compliance with CMS's national

comply with the May 2014 decision in light of the Exclusion of Benefits language in either its 2014 or 2015 policies, it was bound by several different regulations in Title 42 to reach out to CMS and request guidance. To my knowledge, this was never done.

B. Dr. Bowers' Medicare Opt-Out Status as of January 1, 2015 is Inapposite

United contends Dr. Bowers became an opt-out physician on January 1, 2015. Ms. Lauderdale does not dispute Dr. Bowers status as of 2015. However, United has not presented evidence that Dr. Bowers had Medicare opt-out status at the time Ms. Lauderdale filed her request for pre-authorization. To my knowledge, Dr. Bowers was prepared to take Medicare patients in 2014 and, under this representation, Ms. Lauderdale filed her request for pre-authorization in November 2014.

Assuming that Dr. Bowers has now opted-out of Medicare participation, Ms. Lauderdale still has a right to be awarded the full value of the service she should have been pre-approved for in November 2014.[6]

C. Novartis' Draft LCD Is Inapposite

By far, United's most creative *post-hoc* excuse for denying Ms. Lauderdale claim is its nod to Novartis' draft LCD.[7] Setting aside the fact that United has never before indicated that it relied upon the Novartis LCD, there are several infirmities with such reliance.

First, as United noted, Novartis' draft LCD is not in effect at the time Ms. Lauderdale's pre-authorization was denied nor is it in effect now. Indeed, I personally confirmed the status of this LCD with Novartis representatives earlier this month.[8] Though drafted and opened for comment in 2014, Novartis has declined to adopt this draft LCD and has no plans to adopt it any time soon. As per Novartis' representative, while the LCD is still in the draft stage, "claims received for gender reassignment surgery will be reviewed on an individual consideration [*sic.*]."[9] Frankly, it strains credulity to apply non-binding guidance that even the drafter declines to follow to Ms. Lauderdale's claim.

Second, the reason *why* Novartis did not adopt this draft LCD is important. Since September 2014, a contingent of doctors with expertise in transgender health care as well as community advocates have worked closely with Novartis to redraft the LCD. Those doctors and advocates pointed out to Novartis that several positions the LCD took were unsupportable by the literature. For example, none of the studies Novartis cited support the

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coverage determinations); 42 CFR §422.101(b)(2) (mandating compliance with related instructions from CMS).

[6] *See, e.g.*, Medicare Managed Care Manual, Ch. 13—Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals Applicable to Medicare Advantage Plans, Cost Plans, and Health Care Prepayment Plans (HCPP) § 140.3, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c13.pdf ("If the organization determination is reversed in whole or in part by an ALJ, the MAC, or judicial review, the Medicare health plan must pay for, authorize, or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 60 calendar days from the date it receives notice reversing the initial organization determination.").

[7] Novartis, Proposed LCD DL35573, Gender Reassignment Surgery, *available at* http://www.novitas-solutions.com/LCDSearchResults/faces/spaces/search/page/lcd.jspx?Jurisdiction=JL&medicareType=Part+B&_afrWindowMode=0&lcdID=DL35573&_afrLoop=930059425007000&State=Pennsylvania&_adf.ctrl-state=ta6kvwoa8_4 (last visited March 24, 2015).

[8] *See* Exhibit F.

[9] *Id.*

proposition that "Failure to control and maintain a lifestyle devoid of psychotic behavior and ideations for a period of 24 months prior to planned surgical intervention renders the individual ineligible for surgical gender reassignment . . . ." Moreover, no study or other expert-authored publication supports this position. As addressed in my March 17 letter, many peer review studies say just the opposite. Thus, any reliance on a draft LCD with known infirmities is ill-placed.

Third, even if the draft LCD were in effect, United should not have relied upon it to issue its own assessment of medical necessity. Novartis does have jurisdiction over processing claims for Original Medicare (Parts A and B) in Texas, but does not have jurisdiction over Medicare Part C plans in Texas. As United is well-aware, the point of Part C is to give enrollees the option of turning to trusted, private insurers to administrate their Medicare benefits. This includes entrusting Part C plans to use their wealth of resources and expertise in administrating health benefits to enrollees. For United to argue that it is somehow incapable of devising its own coverage criteria for a Medicare covered procedure is absurd. If United is truly concerned that it does not have the capacity to fully serve its Part C enrollees, it should address this concern directly with CMS, not punish its enrollees.

D. United Had Sufficient Guidance on Processing Claims for Gender Reassignment at the Time Ms. Lauderdale's Claim was Denied

Curiously, United has implied that in the absence of "guidance" from CMS or an LCD, it had no clear guidelines to help it assess medical necessity for Gender Reassignment Surgery. This representation is more than suspect.

First, the World Professional Association for Transgender Health's (WPATH) *Standards of Care*[10] provides exacting guidance on assessing medical necessity for Gender Reassignment Surgery. The *Standards of Care*, a 68-page peer review publication authored by the world's leading experts on transgender care, addresses this exact issue. As per the *Standards of Care*,

> The **presence of coexisting mental health concerns does not necessarily preclude possible changes** in gender role or access to feminizing/masculinizing hormones or surgery; rather, these concerns need to be optimally managed prior to, **or concurrent with**, treatment of gender dysphoria.[11]

The *Standards of Care* go on to advise that though surgery should not be performed when a patient is actively psychotic, the presence of "other serious mental illnesses" does not automatically preclude surgical intervention.[12] No language in the *Standards of Care* supports the notion that there should be a mandatory wait-period after psychotic episodes or psychiatric hospitalizations. Instead of imposing arbitrary wait-periods that are unsupported by literature and clinical expertise, the *Standards of Care* defer to the observations and medical judgment of treating physicians.[13]

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[10] E. Coleman et al., *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7*, 13 INT'L J. TRANSGENDERISM 165 (2011), *available at* http://www.wpath.org/uploaded_files/140/files/IJT%20SOC,%20V7.pdf.

[11] *Id.* at 181 (emphasis added).

[12] *Id.* at 203.

[13] *Id.*

Second, if United was unsatisfied with the *Standards of Care*, it could have also turned to its own internal guidance for assessing medical necessity for Gender Reassignment Surgery. Indeed, if United had consulted its own guidance it would have been forced to authorize care in this case given that its own guidelines do not impose a categorical exclusion where comorbid conditions are present let alone erect a 24-month waiting period.[14]

Third, if United was not satisfied with WPATH's guidance or its own, it could have turned to any number of other guidance documents promulgated by peer insurers. For example, Aetna,[15] Anthem,[16] Health Partners,[17] and Wellmark[18] have all released coverage guidance for Gender Reassignment Surgery. For what its worth, none of these policies advise that care should be denied where comorbid conditions are present. Indeed, it appears that nearly all of these guidelines require only that the referring physician determine that comorbid conditions are "reasonably well controlled."

E. No Peer Review Study, Treatise, or Recognized Standard of Care Supports Denial

As addressed at length in my March 17 letter, no peer review study, treatise, or recognized standard of care supports the contention that a patient with stable, comorbid conditions should be denied Gender Reassignment Surgery.

Moreover, contrary to United's representation, the *Standards of Care* does not preclude treatment in this case. Ms. Lauderdale's condition is stable (and otherwise satisfies the criteria in the *Standards of Care*), as attested to by her treating physician at the time of the request for pre- authorization,[19] again in January 2015,[20] and once again in March 2015[21].

Pursuant to the *Standards of Care*, Ms. Lauderdale's physicians have taken steps to ensure that she is sufficiently stable to undergo surgery. Specifically, the physicians have

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[14] United Healthcare, Coverage Determination Guideline: Gender Identity Disorder/Gender Dysphoria Treatment (Guideline No. CS047.C; Effective Date: Oct. 1, 2014), *available at* https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/C&S/Gender_Identity_Disorder_CDG_CS.pdf.

[15] Aetna, Clinical Policy Bulletin: Gender Reassignment Surgery Policy No. 0615 (last revised Sept. 19, 2014), *available at* http://www.aetna.com/cpb/medical/data/600_699/0615.html (requiring only that comorbid psychological conditions be "reasonably well controlled" prior to surgery);

[16] Anthem, Clinical UM Guideline: Gender Reassignment Surgery, Guideline No. CG-SURG-27 (last reviewed Aug. 14, 2014), *available at* http://www.anthem.com/medicalpolicies/guidelines/gl_pw_a051166.htm (requiring only that comorbid psychological conditions be "reasonably well controlled" and that "an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated).

[17] Health Partners, Gender Reassignment Surgery, Policy No. G008-05 (last reviewed Apr. 2014), *available at* https://www.healthpartners.com/public/coverage-criteria/gender-reassignment/ (requiring only that comorbid conditions be "reasonably well controlled").

[18] Wellmark, Gender Reassignment Surgery, Medical Policy No. 07.01.57 (effective date March 2014), *available at* http://www.wellmark.com/Provider/MedPoliciesAndAuthorizations/MedicalPolicies/policies/Gender_Reassignment.aspx (only requiring disclose of patient's comorbid conditions).

[19] *See* Exhibit G.

[20] *See* Exhibit D.

[21] *See* Exhibit E.

prescribed a regimen of drugs which they believe have rendered her sufficiently stable to undergo surgery, they have continued to reevaluate her over time to ensure that her condition has not deteriorated, and they have promised to continue to evaluate her leading up to and immediately after surgery. Lastly, Ms. Lauderdale's physicians have sufficiently explained that her prior hospitalizations do not, in their learned medical judgment, evidence instability. Rather, Dr. LoboPrabhu contends that Ms. Lauderdale's hospitalizations evidence her compliance with medical care and a strong commitment to practicing self-care.[22]

F. Other Factors that Evidence Ms. Lauderdale's Stability

Despite United's accusation that Ms. Lauderdale is too unstable to undergo Gender Reassignment Surgery, Ms. Lauderdale's recent surgical history suggests just the opposite. As noted by Dr. LoboPrabhu, Ms. Lauderdale has already undergone breast augmentation and removal of the scrotum and testicles, treatments prescribed as part of Ms. Lauderdale's gender transition treatment.[23] Though Ms. Lauderdale continued to receive treatment for her comorbid conditions throughout the recovery process, her recovery was not negatively impacted. Given Ms. Lauderdale's past compliance with medical care during other Gender Reassignment procedures, any supposed concerns about her stability to undergo genital surgery are unwarranted. Indeed, it makes little sense to impose an arbitrary 24-month wait period since Ms. Lauderdale has already proven that she can undergo surgery and remain compliant with care.

In addition, I believe that Ms. Lauderdale's comportment throughout the appeals process itself evidences that she is sufficiently stable at this time. As the record reflects, Ms. Lauderdale has been actively pursuing coverage of genital reassignment surgery (the last step in her medical transition) since Fall 2014. She worked closely with her physicians at the Michael E. DeBakey VA Medical Center in Houston, Texas to identify a surgeon and put together the necessary materials to submit to United for pre-authorization. After United issued its first denial in late November 2014, Ms. Lauderdale took it upon herself to seek out legal counsel to assist her in the appeals process. For my part, I can attest to the fact that Ms. Lauderdale has never acted erratically or made me question her mental stability. Since starting this representation on December 1, 2014 we have exchanged dozens of emails, talked on the phone on a weekly basis, and closely coordinated our appeal efforts with Ms. Lauderdale's physicians. Ms. Lauderdale has always promptly replied to my emails and phone calls, she has scrupulously updated me on her health status and remained compliant with all instructions from her physicians and me. Ms. Lauderdale's capacity to endure several months of appeals with all the up's and down's concomitant to it evidence that she is prepared to cope with the comparatively short recovery period associated with genital surgery.

Lastly, Ms. Lauderdale's resilience in dealing with other major life events throughout the appeals process further evidence her capacity to safely navigate the rigors of surgery and recovery. For example, Ms. Lauderdale has maintained her sobriety throughout this process, and has just recently celebrated her 8-month sober anniversary. In mid-February, Ms. Lauderdale spent several days volunteering with Patriot Paws, a non-profit organization in Rockwall, Texas that trains service dogs for veterans. Earlier this month, Ms. Lauderdale and her wife moved to a new home and, despite the stress attendant to any change in residence, Ms.

[22] *See* Exhibit D.
[23] *See* Exhibit D at 3; Exhibit E at 2.

Lauderdale remained compliant with her medical care. On March 23rd, Ms. Lauderdale's wife of nearly two decades underwent a major in-patient surgery. Once released from the hospital, Ms. Lauderdale will serve as her wife's primary caretaker. Clearly, if Ms. Lauderdale can successfully navigate these life events, she most certainly has the resilience to navigate genital surgery.

Conclusion

As the foregoing reveals, there is no reasoned basis in law or medical judgment to deny Ms. Lauderdale's appeal.

Sincerely,

Ezra Young, Esq.
NY Bar No. 5283114

Encl.

Exhibit A: First Denial Letter (Nov. 25, 2014)
Exhibit B: Second Denial Letter (Dec. 4, 2014)
Exhibit C: Maximus Determination (Dec. 24, 2014)
Exhibit D: Letter from Dr. LoboPrabhu & Dr. Kauth (Jan. 5, 2015)
Exhibit E: Letter from Dr. LoboPrabhu (Mar. 19, 2015)
Exhibit F: Email with Vicki Kurland, Novartis (Mar. 5, 2015)
Exhibit G: Letter Requesting Preauthorization (Nov. 4, 2014)