DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Departmental Appeals Board, MS 6127
Medicare Appeals Council
330 Independence Avenue
Cohen Building, Room G-644
Washington, DC 20201
(202)565-0100/Toll Free:1-866-365-8204

JAN 21 2016

ALJ Appeal Number: 1-2978123060
Docket Number: M-15-1069

United Healthcare
P.O. Box 6106
MS CA124-0156
Cypress, CA 90630-9948
Attn: Vivian Hermiz

Charlene Lauderdale
[redacted]

NOTICE OF DECISION OF MEDICARE APPEALS COUNCIL

What This Notice Means

Enclosed is a copy of the decision of the Medicare Appeals Council (Council). If you have any questions, you may contact the Centers for Medicare & Medicaid Services (CMS) regional office or the local Medicare contractor.

Your Right to Court Review

If you desire court review of the Council's decision and the amount in controversy is $1500 or more, you may commence a civil action by filing a complaint in the United States District Court for the judicial district in which you reside or have your principal place of business. *See* § 1852(g)(5) of the Social Security Act, 42 U.S.C. § 1395w-22(g)(5). The complaint must be filed within sixty days after the date this letter is received. It will be presumed that this letter is received within five days after the date shown above unless a reasonable showing to the contrary is made.

If you cannot file your complaint within sixty days, you may ask the Council to extend the time in which you may begin a civil action. However, the Council will only extend the time if you provide a good reason for not meeting the deadline. Your reason must be set forth clearly in your request. 42 C.F.R. § 405.1134.

If a civil action is commenced, the complaint should name the Secretary of Health and Human Services as the defendant and should include the ALJ Appeal Number and the Council's Docket Number shown at the top of this notice. 42 C.F.R. § 405.1136(d). The Secretary must be served by sending a copy of the summons and complaint by registered or certified mail to the General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201. In addition, you must serve the United States Attorney for the district in which you file your complaint and the Attorney General of the United States. *See* rules 4(c) and (i) of the Federal Rules of Civil Procedure and 45 C.F.R. § 4.1. You must also notify the other party of your appeal pursuant to section 1852(g)(5) of the Social Security Act.

Enclosure

cc: Ezra Young, Esq.
MAXIMUS Federal Services

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-15-1069

In the case of	**Claim for**
United Healthcare/AARP Medicare Complete (HMO) (Appellant)	Medicare Advantage (MA) Benefits (Part C)
Charlene Lauderdale (Enrollee/Beneficiary)	XXX-XX-3224A (HIC Number)
UnitedHealthcare/AARP Medicare Complete (HMO) (MA Organization (MAO)/MA Plan)	1-2978123060 (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a favorable decision, dated April 24, 2015, concerning the beneficiary enrollee's request for pre-authorization by the appellant Medicare Advantage (MA) Plan (plan) for vaginoplasty, a form of gender reassignment surgery. The ALJ found that the plan was required to cover the vaginoplasty. The plan asked the Medicare Appeals Council (Council) to review the ALJ's decision. The enrollee, through her representative, filed a response to the request for review. The Council admits the plan's request for review and the enrollee's response into the administrative record as Exhibits (Exhs.) MAC-1 and MAC-2, respectively. The Council admits additional submissions and interim correspondence into the record as Exhs. MAC-2A through MAC-4.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). We have carefully considered the record, including the hearing recording, the request for review, and the response. As set forth below, we agree with the ALJ that the Plan is required to cover the vaginoplasty. However, we modify the ALJ's decision to further explain the applicable authorities and the rationale for finding coverage.

BACKGROUND

Procedural History

The record indicates that the enrollee became eligible for healthcare services through the plan on July 1, 2014. Exh. 3, at 26. On November 13, 2014, the enrollee, through her physician, requested that the plan authorize gender reassignment surgery under Current Procedural Terminology (CPT) [1] code 55970, with ICD-9 diagnosis codes 302.50 (transsexualism with unspecified sexual history) and 302.85 (gender identity disorder, adolescents or adults). *Id.* at 33. Both initially and on reconsideration, the plan denied the enrollee's request, concluding that the surgery was "not a benefit and not covered by [the enrollee's] health plan." *Id.* at 34; *see also id.* at 38. The enrollee requested expedited reconsideration by the Independent Review Entity (IRE). *Id.* at 24-26.

The enrollee obtained representation and, through her representative, asked the IRE to close her pending appeal, so it could be "reinitiated" with the plan. *Id.* at 26, 29. Despite the enrollee's request, the IRE issued a reconsideration upholding the denial. The IRE agreed that the plan did "not have to pre-approve Gender Reassignment Surgery at this time." *Id.* at 1. The IRE explained that "after May 30, 2014 Gender Reassignment Surgery is potentially coverable by Medicare if it is medically necessary and reasonable for the particular patient." *Id.* at 3. After obtaining medical review, however, the IRE determined that the surgery was not medically reasonable for the enrollee "because of the patient's psychiatric instability." *Id.*

The enrollee's representative requested an ALJ hearing. Exh. 4, at 1-3, 4-12. The enrollee and plan submitted prehearing briefs and presented testimony and argument at the telephone hearing, which lasted approximately one-hour on March 31, 2015. Hearing CD.

On April 24, 2015, the ALJ issued the favorable decision under review. The ALJ framed the issue as whether the plan "must

---

[1] The CPT is a uniform coding system developed and maintained by the American Medical Association to identify medical services and procedures furnished by physicians and other health care professionals. The Centers for Medicare & Medicaid Services (CMS) has incorporated the CPT coding system into its Healthcare Common Procedure Coding System for processing, screening, identifying, and paying Medicare claims. 42 C.F.R. §§ 414.2, 414.40.

cover the requested gender reassignment surgery, specifically vaginoplasty, to treat the Enrollee's gender identity disorder." ALJ Dec. at 2. First, the ALJ found that the Departmental Appeals Board invalidated National Coverage Determination (NCD), 140.3, Transsexual Surgery, which previously excluded Medicare coverage for all gender reassignment surgery.[2] *Id.* at 4 (citing *In re NCD 140.3, Transsexual Surgery*, DAB Dec. No. 2576, Docket No. A-13-87 (May 30, 2014)). Therefore, the ALJ determined that "neither Medicare nor MA plans, as of May 30, 2014, are able to rely on NCD 140.3 to categorically deny sex reassignment surgery claims." *Id.* The ALJ also noted that "[i]t is no defense for the Plan . . . that CMS approved its [Evidence of Coverage (EOC)] language or that CMS has thus far failed to craft guidance for approving gender-reassignment surgery" because United Healthcare was "obviously aware, based on its issuing the Gender Identity guidance for some of its Plans . . ."[3] *Id.*

Next, based on the hearing testimony and documentary evidence in the administrative record, the ALJ determined that the requested vaginoplasty procedure was reasonable and necessary under section 1862(a)(1)(A) of the Act. The ALJ found that the enrollee had a diagnosis of gender identity disorder and had identified and presented herself as a woman since 2006. *Id.* at 5. The enrollee's treating psychiatrist and consulting surgeon both attested that vaginoplasty was indicated as a treatment for the enrollee's diagnosis and was reasonable and necessary for treating the enrollee's medical condition. *Id.* The enrollee had undergone all necessary steps in preparation for the vaginoplasty (including hormone therapy and other surgical interventions), had satisfied the gender reassignment standards established by the World Professional Association for Transgender Health (WPATH), and "is a qualified candidate per WPATH guidelines for the procedure." *Id.* Although the ALJ

---

[2] An NCD is a determination by the Secretary of the Department of Health and Human Services (HHS) on whether a particular item or service is covered by Medicare on a nationwide basis. 42 C.F.R. § 405.1060(a)(1). NCDs "describe the clinical circumstances and settings under which particular [Medicare items and] services are reasonable and necessary" under section 1862(a)(1) and other applicable provisions of the Act. 67 Fed. Reg.54,534, 54,535 (Aug. 22, 2002); *see also* 42 C.F.R. § 405.1060(a)(3).

[3] On September 1, 2014, United Healthcare, which administers the AARP Medicare Complete (HMO) plan in this case, issued a coverage determination guideline (CDG) captioned "Gender Identity Disorder/Gender Dysphoria Treatment," Guideline Number CDG.011.03, to provide guidelines and standards for treating gender identity disorder/gender dysphoria. *Id.* (referring to Exh. 9). United Healthcare issued a similar document on October 1, 2015, which the Council admits to the record as Exh. MAC-8.

acknowledged that United Healthcare's Gender Identity guidance "does not apply to this specific Plan . . . the [enrollee] would have satisfied the coverage criteria set forth by United Healthcare were she in a different Plan." *Id.* Therefore, under the specific facts of this case, the ALJ concluded that the plan is required to cover the requested procedure. *Id.*

Request for Review

On May 28, 2015, the plan filed a request for review of the ALJ's decision. Exh. MAC-1, at 1. First, the plan argues that the ALJ erred in ordering the plan to cover the vaginoplasty because CMS issued guidance on April 20, 2015, through its Health Plan Management System (HPMS), which states that MA plans are not required to cover transgender surgeries during calendar year 2015, but are to direct enrollees "to Original Medicare" contractors. Exh. MAC-1, at 3. Second, the plan argues that the ALJ erred in making a medical necessity determination that differed from the medical necessity determination of the IRE's consulting physician on reconsideration, which denied coverage based on a finding of psychiatric instability. *Id.* at 4. Third, the plan argues that the ALJ erred in basing his decision on the plan's initial determination and reconsideration, which denied the requested procedure based on an NCD exclusion, although the IRE's reconsideration later determined that the exclusion was no longer in effect. *Id.* at 4-5. Finally, the plan argues that the ALJ erred in basing his determination, in part, on United Healthcare's CDG for subsidiary health plans, which determine coverage "based on numerous factors and those commercial policies may significantly differ from Medicare coverage criteria." *Id.* at 5.

Enrollee's Response

On June 8, 2015, the enrollee's representative requested an extension of time to respond to the request for review. Exh. MAC-2A. On June 12, 2015, the representative submitted a letter brief, with multiple attachments. Exh. MAC-2. While many of the attached exhibits duplicate documents in the record, others do not. The Council admits all enclosures into the record. 42 C.F.R. § 422.608, *incorporating* 42 C.F.R. § 405.1122(c)(1). Generally, the enrollee argues that the Council should affirm the ALJ's decision because the ALJ committed no error of law. Exh. MAC-2, at 1. After reviewing the procedural background, the enrollee presents three arguments. First, the enrollee argues that the CMS HPMS guidance is inapposite, as the enrollee

seeks surgical services in calendar year 2016, not 2015. *Id.* at 6. Second, the enrollee argues that the ALJ's decision is supported by governing law, as the ALJ considered new written and testimonial evidence of the medical necessity of the vaginoplasty and had a sufficient basis for departing from the IRE's analysis. *Id.* at 7. Third, the enrollee argues that the ALJ did not err in discussing United Healthcare's coverage determination guidelines (CDG) because the ALJ did not base his decision on that policy. *Id.*

APPLICABLE AUTHORITY

MA Plan - Benefits and Coverage

An MA plan must provide an enrollee with coverage for all items and services covered by Medicare Part A and Part B (original Medicare) that are available to Medicare beneficiaries in the plan's service area. Act § 1852(a)(1); 42 C.F.R. § 422.101(a). Medicare provides coverage only for those items or services that are medically reasonable and necessary for the treatment of the beneficiary's illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A); 42 C.F.R. § 411.15 (k)(1). An MA plan must comply with NCDs, local coverage determinations (LCDs), and general coverage guidelines included in original Medicare manuals and instructions. 42 C.F.R. § 422.101(b). At its discretion, an MA plan also may offer certain additional (supplemental) benefits beyond those covered by original Medicare. 42 C.F.R. § 422.102.

An MA plan may specify the networks of providers from whom enrollees receive services, so long as it provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services. Act § 1852(d)(1)(D); *accord* 42 C.F.R. § 422.112(a). The plan must maintain and monitor the network of appropriate providers sufficient to provide adequate access to covered services to meet the needs of the population served. 42 C.F.R. § 422.112(a)(1). Additionally, an MA plan must "[p]rovide or arrange for necessary specialty care . . . . The [plan] arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs." 42 C.F.R. § 422.112(a)(3).

The plan must inform the enrollee of conditions and limitations, premiums and cost-sharing (i.e., copayments, deductibles, and coinsurance), and other conditions associated with receiving or

using benefits. 42 C.F.R. § 422.111(b)(2). This information is typically set forth in the plan's EOC.

DAB Decision No. 2576

On May 30, 2014, pursuant to a challenge by an aggrieved party, the HHS Departmental Appeals Board (Board) determined that NCD 140.3 was invalid. NCD 140.3, Transsexual Surgery; Docket No. A-13-87, Decision No. 2576 (May 30, 2014). (For ease of reference, the Council admits a copy of this DAB decision into the record as Exh. MAC-5.) NCD 140.3 had excluded coverage of transsexual surgery based on information compiled in 1981, which indicated that the surgery was considered experimental and not proven to be safe and effective for treating transsexualism at that time. However, new evidence submitted in the NCD challenge proceeding, which CMS did not dispute, established that "transsexual surgery is a safe and effective treatment option for transsexualism in appropriate cases" and was no longer considered "experimental." *Id.* at 21. Based on the record evidence developed in the proceeding, the Board concluded that the NCD's categorical exclusion of transsexual surgery was no longer reasonable, even if it was reasonable when it was adopted in 1989. *Id.* Therefore, the Board invalidated the NCD.

Since the NCD is no longer valid, the Board held that its provisions are no longer a valid basis for denying claims for Medicare coverage of transsexual surgery, and LCDs used to adjudicate such claims may not rely on the provisions of the NCD. *Id.* The Board directed CMS to implement its decision within 30 days and to apply any resulting policy changes to claims or service requests made by Medicare beneficiaries for any dates of service after implementation. *Id.* at 1.

CMS Change Request 8825, effective date May 30, 2014

In accordance with the Board's decision, on June 27, 2014, CMS issued Change Request 8825 (Transmittal 169). The subject of the change request was "Invalidation of National Coverage Determination 140.3 - Transsexual Surgery," and it had an effective date of May 30, 2014. (The Council admits a copy of Change Request 8825 into the record as Exh. MAC-6). According to CMS, the change request implements the Board's decision "by removing section 140.3, Transsexual Surgery, from Pub. 100-03, Medicare National Coverage Determinations Manual." Exh. MAC-6, at 1. Moreover, CMS explained how coverage determinations should be made in light of the policy change:

> Because the NCD is no longer valid as of the effective date, its provisions are no longer a basis for denying claims for Medicare coverage of 'transsexual surgery' under 42 C.F.R § 405.1060. Moreover, any local coverage determinations used to adjudicate such claims may not be based on or rely on the provisions or reasoning from section 140.3 of Pub. 100-03, Medicare NCD Manual. ***In the absence of an NCD, contractors and adjudicators should consider whether any Medicare claims for these services are reasonable and necessary under § 1862(a)(1)(A) of the [Act] consistent with the existing guidance for making such decisions when there is no NCD.***

Id. at 2 (emphasis added).

CMS Health Plan Management System (HPMS) E-Mail

According to CMS' website, the HPMS is a web-enabled information system that serves a critical role in the ongoing operations of the MA program. The claim file contains a document captioned "HPMS E-Mail," dated April 20, 2015, with a cover letter and facsimile cover sheet from the plan's representative to the ALJ, dated April 23, 2015. The cover letter is date-stamped received on May 5, 2015. Although the HPMS E-Mail is in the claim file, it does not appear on the ALJ's Exhibit List and is not discussed in the ALJ's decision. Thus, it is unclear whether the ALJ admitted the document into the record and considered it in his decision. To ensure a complete record in this case, the Council admits this document into the record as Exh. MAC-7. The HPMS E-Mail states as follows:

> As indicated in [Change Request 8825], in the absence of an NCD, contractors and adjudicators should consider whether any Medicare claims for these items and services are reasonable and necessary under § 1862(a)(1)(A) of the Social Security Act consistent with existing guidelines for making such decisions when there is no NCD.
>
> For calendar year 2015, CMS determined that these items and services met the test, as specified in 422.109(a)(2). Therefore, for items and services received in calendar year 2015 only, original fee-for-service Medicare will pay for reasonable and necessary

> items and services obtained by beneficiaries enrolled in MA plans. Plans should account for these items and services in their contract year 2016 bids.
>
> Consistent with § 1862(a)(1)(A) of the Act, Medicare Administrative Contractors will consider whether transgender surgery services are reasonable and necessary and reimbursable by original Medicare for Medicare beneficiaries enrolled in MA plans in CY 2015.

Exh. MAC-7, at 3.

DISCUSSION

The Council has carefully considered the plan's request for review, the enrollee's response, applicable legal authority, and the entire administrative record, including the new evidence. As discussed below, we concur with the ALJ's determination that the plan is required to cover the requested vaginoplasty. However, we modify the ALJ's decision to further explain the applicable authorities and the rationale for coverage. We also address the exceptions raised in the plan's request for review.

The Plan Must Cover the Requested Vaginoplasty Because It Is Reasonable and Necessary to Treat the Enrollee's Transsexualism and Gender Identity Disorder.

On *de novo* review, the Council must determine whether the requested medical services are reasonable and necessary under section 1862(a)(1)(A) of the Act. Exh. MAC-6, at 2. As the ALJ correctly determined below, the NCD that excluded transgender surgery was invalidated on May 30, 2014, nearly six months before the enrollee requested preauthorization for gender reassignment surgery. "Since the NCD is no longer valid, its provisions are no longer a valid basis for denying claims for Medicare coverage of transsexual surgery . . ." Exh. MAC-5 at 1. Therefore, the plan may not exclude coverage of the surgery based on its EOC because the record indicates that the EOC exclusion is based on the NCD provisions that the Board invalidated on May 30, 2014. The plan also stipulated during the hearing that the exclusion no longer applied in this case. Hearing CD at 2:02 p.m. Accordingly, contractors and adjudicators must consider whether the requested vaginoplasty is reasonable and necessary under section 1862(a)(1)(A) of the Act. Exh. MAC-6, at 1.

In the absence of an NCD, LCD, or any other CMS policy,[4] the Council finds that the WPATH Standards of Care are reasonable guidelines to determine medical necessity in this case. (The Council admits a copy of the WPATH "Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7," into the record as Exh. MAC-9.) The WPATH Standards of Care provide clinical guidance for health care professionals in treating transsexual, transgender, and gender non-conforming people. Exh. MAC-9, at 165. (The Council paginates Exh. MAC-9 consistent with the page numbering of the original document.) According to the ABSTRACT on the first page of the Standards of Care, the WPATH Standards of Care were first published in 1979 and were last revised in 2011. *Id.* at 165; accord Exh. MAC-5, at 22. As the Board noted in its decision invalidating the prior NCD, the "WPATH Standards of Care have attained widespread acceptance" throughout the world. Exh. MAC-5, at 23. The ABSTRACT represents that the Standards of Care are based on the best available science and expert professional consensus. Exh. MAC-9, at 165. Although much of the recorded clinical experiences and knowledge are from North America and Western Europe, the WPATH Standards of Care are intended to have global application. *Id.* at 167. Additionally, the clinical guidelines contained in the WPATH Standards of Care are intended to be flexible and may be modified based on a patient's unique anatomic, social, or psychological situation. *Id.* at 166.

The Council notes that both parties in this case have recognized the authority of the WPATH Standards of Care. The enrollee's psychiatrists and surgeon, who have prior experience treating transgender patients, applied the WPATH Standards of Care in recommending vaginoplasty to treat the enrollee's medical conditions. Exh. 2, at 32; Exh. 3, at 21; Exh. 4, at 33. The plan referenced the WPATH Standards of Care in its pre-hearing position statement and request for review. Exh. 7 at 9-10; Exh.

---

[4] On December 3, 2015, CMS initiated a National Coverage Analysis to develop an NCD on gender dysphoria and gender reassignment surgery. However, any proposed decision memorandum arising from the proceeding will not be released until June 3, 2016. See National Coverage Analysis (NCA) Tracking Sheet for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N), *available at* https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=282. Although the plan argues in its request for review that the PROPOSED/DRAFT Local Coverage Determination (LCD): Gender Reassignment Surgery (DL35573) prohibits coverage, that draft LCD is "on-hold" and never became effective. *See* "RETIRED Local Coverage Article: Coverage of Gender Reassignment Surgery - Provider Bulletin (A53853)." Accordingly, it has no legal force and does not apply to this case.

MAC-1 at 2. Similarly, United Healthcare considers the WPATH Standards of Care to be authoritative and has incorporated the organization's criteria in its CDG on gender dysphoria treatment. *See, e.g.,* Exh. MAC-8, at 4 (listing among the eligibility criteria for surgery that the "treatment plan must conform to identifiable external sources including the World Professional Association for Transgender Health Association (WPATH) standards, and/or other evidence-based professional society guidance."). Therefore, the Council believes it is reasonable to consider the WPATH Standards of Care to determine whether the requested service is reasonable and necessary in this case in the absence of specific transsexual surgery coverage criteria issued by CMS for Medicare coverage purposes.

The WPATH Standards of Care list the following criteria for vaginoplasty:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent to treatment;
3. Age of majority in a given country;
4. If significant medical or mental health concerns are present, they must be well controlled;
5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are not clinically indicated for the individual);
6. 12 continuous months of living a gender role that is congruent with the patient's identity.

Exh. MAC-9, at 202. Additionally, genital surgery requires two referrals from qualified mental health professionals who have independently assessed the patient. A joint letter signed by both professionals is sufficient if they practice within the same clinic. *Id.* at 183. A letter may not be necessary for providers working within a multidisciplinary specialty team if the assessment and recommendation can be documented in the patient's chart. *Id.* Although it is not an explicit requirement, the WPATH Standards of Care also recommend that gender reassignment patients have regular visits with a mental health or other medical professional. *Id.* at 202.

Applying the criteria for genital surgery in the WPATH Standards of Care, the Council finds that the enrollee meets the clinical requirements for vaginoplasty. Exh. MAC-9, at 202. The record reflects that the enrollee is an adult who has gender dysphoria

and reports feeling female since she was 5 years old. Exh. 4, at 31. She has been receiving psychiatric care since 1997, has taken hormone therapy since 2006, has lived full-time as a woman since 2006, and has the "clinical capacity to understand and appreciate the risks and benefits associated with gender reassignment surgery." Exh. 6, at 2; *see also* Exh. 2, at 31-32; Exh. 3, at 21. Neither the plan, nor the IRE medical consultant disputes these facts. Likewise, they do not suggest that the enrollee has any physical medical conditions that prohibit gender reassignment surgery.

The plan's sole issue of contention concerns whether the enrollee's mental health concerns are well controlled. According to the plan and IRE medical consultant, gender reassignment surgery is "relatively contraindicated at this time due to the patient's current psychiatric instability," as demonstrated by her "emotional outbursts" and four psychiatric hospitalizations in 2014 that involved suicidal ideation, homicidal ideation, and mood lability. Exh. 3, at 9; Exh. 1, at 2.

Initially, the Council notes that gender dysphoria often "causes intense emotional pain and suffering" that "if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death." Exh. MAC-5, at 10 (citing a resolution of the American Medical Association); *see also* Exh. 3, at 21 (noting that delaying treatment may cause or aggravate stress-related physical illnesses, as well as mental health and behavioral problems). Additionally, individuals "presenting with gender dysphoria may struggle with a range of mental health concerns . . . whether related or unrelated to what is often a long history of gender dysphoria and/or chronic minority stress." Exh. MAC-9, at 180. For example, "[p]ossible concerns include anxiety, depression, self-harm, a history of abuse and neglect, compulsivity, substance abuse, sexual concerns, personality disorders, and autistic spectrum disorders." *Id.* at 180-181. For these reasons, it is not surprising for individuals with gender dysphoria to have a history of psychiatric problems. Although the WPATH Standards of Care advise that no surgery should be performed while a patient is "actively psychotic," it recognizes that mental health concerns may be present in patients requiring gender reassignment surgery. *Id.* at 203; *see also id.* at 202. In such

circumstances, the mental health concerns must be "well controlled." *Id.* at 202.

Contrary to the plan's assertions, the Council finds that the enrollee is sufficiently stable for gender reassignment surgery. Two mental health professionals at the VA Medical Center with experience treating patients with gender dysphoria (Dr. S.L. and Dr. M.K.) have evaluated the enrollee and referred her for gender reassignment surgery. Exh. 4, at 33; *see also* Exh. 2, at 33; Exh 4, at 10. They state that the enrollee has "completed all the WPATH requirements for gender reassignment surgery," and she "is mentally stable enough to safely tolerate and cooperate with the gender reassignment surgery." Exh. 4, at 33. The record supports the psychiatrists' opinions. Although the enrollee was hospitalized four times in 2014, she was discharged in stable condition each time. *See, e.g.* Exh. 2, at 1 (reflecting a two-day hospital admission), 46 (reflecting a 10-day admission); *see also id.* at 3 (reporting that the enrollee's mood significantly improved throughout her stay and she had no suicidal ideations, homicidal ideations, or hallucinations at discharge). The enrollee takes psychotropic medications to manage her mental health and receives pyschotherapy on a monthly basis with a psychiatrist and on a weekly basis with her social worker. Exh. 2 at 32. She also receives psychotherapy treatment from a second psychiatrist to treat unrelated post-traumatic stress disorder (PTSD). *Id.* The enrollee's "mental health team and [primary care physician] continue to feel this gender confirmation surgery is medically necessary to the [patient's] emotional wellbeing." Exh. 2 at 28.

The Council also notes that the enrollee displays an acute self-awareness of her mental health status and seeks appropriate care, as evidenced by the enrollee's initiation of calls to her mental health professionals and a suicide prevention hotline and her two requests for voluntary admission to inpatient psychiatric care. Exh. 2, at 9, 22-28; Exh. 4, at 31-32. Moreover, the enrollee has been compliant with her medical treatment by taking her medications, attending all psychotherapy sessions, and attending substance abuse meetings. Exh. 4, at 31-32. Her psychiatrists advised the plan on January 5, 2015, that since her second admission on July 18, 2014, the enrollee "has made great improvements in mood stability." *Id.* at 31. Her physicians intend to continue treatment after the surgery, and expect that the enrollee will continue to comply with her treatments. *Id.* at 32-33. In sum, the enrollee's physicians attest, that "despite [her] history of hospitalizations, she was

in November 2014, and remains today, ready and able to undergo genital surgery." Exh. MAC-2, at 2; *see also* Exh. 6, at 1-2. Notably, the record contains no evidence suggesting that the enrollee is actively psychotic. *See, e.g.* Exh. 2 at 1 (discharge summary noting the enrollee's diagnosis as "Major Depressive Disorder, recurrent, moderate, without psychotic symptoms"). Based upon the evidence in the record, the Council finds that the enrollee's mental health concerns are "well controlled."

Having determined that the enrollee's mental health concerns are well controlled, the Council finds that the enrollee satisfies all of the WPATH clinical requirements for gender reassignment surgery. Therefore, the Council concludes that the requested vaginoplasty is medically reasonable and necessary for treatment of this enrollee's gender dysphoria under section 1862(a)(1)(A) of the Act and is covered under existing CMS guidance. Exh. MAC-6, at 2 (Change Request 8825). Further, as explained in the following sections, the exceptions raised in the plan's request for review do not alter this conclusion.

The Plan is Responsible for Transgender Surgeries in 2016.

In its request for review, the plan initially argues that the ALJ erred in ordering it to cover the requested vaginoplasty because the HPMS E-Mail states that original Medicare is financially responsible for transgender surgery services in calendar year 2015. Exh. MAC-1, at 3. However, the Council finds that the HPMS E-Mail does not apply in this case. The HPMS E-Mail states, in pertinent part:

> Therefore, for items and services received in calendar year 2015 only, original fee-for-service Medicare will pay for reasonable and necessary items and services obtained by beneficiaries enrolled in MA plans. Plans should account for these items and services in their contract year 2016 bids.

Exh. MAC-7, at 3. As expressly stated therein, the HPMS E-mail only applies to items and services that are **received** in calendar year 2015. By its own terms, the HPMS E-Mail does not apply to items and services provided in 2014 (when the Board invalidated the NCD) or in 2016 (when the enrollee's covered surgery likely will occur); nor does it apply to services that were requested or pending administrative adjudication in 2014 and 2015, as is the case here. Rather, it only applies to services that are

actually received in 2015. Because the enrollee did not receive transgender surgery in 2015 and most likely will receive it in 2016, the Council assumes that the plan has made an accounting for 2016, as instructed by the HPMS E-Mail. In any event, the plan is responsible for the cost of the surgery in 2016 and beyond under current provisions.

The ALJ Did Not Err in Determining the Medical Necessity of the Requested Vaginoplasty Without Seeking an Independent Medical Expert or Deferring to the IRE's Medical Consultant.

The plan next argues that the ALJ erred in not obtaining independent medical expert testimony and making a finding on medical necessity that differed from the finding of the IRE's consulting psychiatrist. Exh. MAC-1, at 4. The plan also suggests that the ALJ should have deferred to the IRE's consulting physician's determination that the enrollee's psychiatric condition indicated that the requested surgery was not reasonable and necessary at the time the enrollee requested preauthorization. *Id.* The Council finds no merit in these arguments.

First, the ALJ is not bound by any prior adjudicator's determination, but "conducts a *de novo* review and issues a decision based on the hearing record." 42 C.F.R. § 405.1000(d). The ALJ is required to develop the administrative record for decision, making "a complete record of the evidence, including the hearing proceedings, if any." 42 C.F.R. § 405.1042(a)(1). The ALJ then issues a decision with findings of fact, conclusions of law, and reasons for the decision. 42 C.F.R. § 405.1046(a). "The decision must be based on evidence offered at the hearing or otherwise admitted into the record." *Id.*

Second, contrary to the plan's suggestion, the ALJ is not restricted to the record before the IRE's consultant. The ALJ (and the Council) may admit and consider any additional evidence that is relevant and material to the issues before him. *See* 70 Fed. Reg. 4,740, 4,676 (Jan. 28, 2005) (noting that the provisions of 42 C.F.R. Part 405 that are dependent upon qualified independent contractors do not apply to MA plan appeals, such as the limitation on the submission of new evidence in 42 C.F.R. §§ 405.108, 405.1122). New evidence may include information reflecting a change in the enrollee's condition since the initial determination or any additional

evidence relevant to whether the plan made a correct initial determination with regard to the enrollee's condition.

Third, there is no requirement that an ALJ obtain independent medical expert testimony in making a decision on the medical necessity of an item or service requested by an MA plan enrollee. The ALJ's departure from the analysis of the IRE consultant is the result of his *de novo* review of the administrative record before him, as required by regulation.

To the extent the plan disagrees with the ALJ's weighing of the evidence, it had an opportunity to present additional evidence and argument at the hearing. Likewise, the plan could have addressed these concerns in its request for review. On review, a party must identify with specificity those portions of an ALJ's decision with which it disagrees and point, also with specificity, to evidence in the record which supports its arguments. 42 C.F.R. §§ 405.1100(c), 405.1112(b). However, the plan points to no specific clinical finding by the ALJ as erroneous and identifies no clinical evidence in the record that would weigh against the ALJ's findings. The fact that the plan based its initial and redetermination denials on an NCD exclusion, without evaluating medical necessity, does not relieve it of the responsibility to address medical necessity at subsequent levels of appeal when it becomes a direct issue.

Even if the plan had based its arguments on specific clinical information in the record, the Council finds no error in the ALJ assigning more evidentiary weight to the opinions of the enrollee's treating psychiatrists and consulting surgeon than to the IRE's consulting physician. To be clear, the Council is not applying the treating physician rule.[5] However, in this particular case, the Council notes that the pool of experienced medical professionals who have expertise in gender reassignment surgery is relatively small. Exh. 2, at 6.

---

[5] The treating physician rule requires adjudicators to defer to the opinion of a treating physician. It was originally developed by the Courts of Appeals as a means to control disability determinations made by Social Security ALJs. *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, No. 02-469 slip op. at 5 (2003). However, the rule had not attracted universal adherence outside the Social Security disability context, even in other public and private benefit contexts. *Id.* at 6, n.3. CMS Ruling 93-1 (*eff.* May 18, 1993) provides that no presumptive weight should be assigned to a treating physician's medical opinion in determining the medical necessity of inpatient hospital or skilled nursing facility services. Rather, "[a] physician's opinion will be evaluated in the context of the evidence in the complete administrative record." The Council is bound by CMS Rulings. 42 C.F.R. § 405.1063(b).

Here, the surgeon who is most familiar with the enrollee's medical condition and needs, and who originally agreed to perform the surgery (but who is no longer a plan provider), Dr. M.B., has extensive experience treating patients with gender dysphoria. Indeed, this surgeon attested that she had performed over 1,200 vaginoplasty surgeries. Exh. 3, at 21. Similarly, the enrollee's psychiatrist has experience treating four other patients with gender dysphoria and previously led a major academic center on human sexuality, which was responsible for teaching medical students about transgender issues, for 10 years. Exh. 2, at 33. Even the IRE's medical consultant recognized the expertise of the enrollee's physicians within this medical field. Exh. 3 at 9. The plan did not challenge the credentials of the enrollee's medical experts or provide any specific reason to question their clinical opinions. Instead, the plan merely defers to the contrary opinion of the IRE's medical consultant. Although the IRE's medical expert is Board Certified in psychiatry and psychosomatic medicine and he attests that he has "expertise in the field of medicine that is appropriate for the services at issue" and is "knowledgeable in the treatment of the enrollee's condition," there are no details in the record about the nature or extent of his experience concerning gender dysphoria and sex reassignment surgery. Exh. 3, at 8.

The ALJ Did Not Limit His Review to the Plan's Initial Determination and Reconsideration.

The plan argues that the ALJ erred in basing his decision on the plan's initial determination and reconsideration, which denied the requested procedure based on an NCD exclusion that was no longer in effect. Exh. MAC-1, at 4-5. The plan's exact objection with regard to this matter is not entirely clear.

The Council recognizes that the plan's initial determination and reconsideration denying coverage were based on the NCD exclusion, and thus no further analysis of medical reasonableness and necessity was undertaken. However, as the plan acknowledged, the issues before an ALJ include all the issues brought out in the initial determination, plan reconsideration or IRE reconsideration that were not decided entirely in a party's favor. 42 C.F.R. § 405.1032(a). Furthermore, as discussed above, the ALJ is not bound by any prior adjudicator's determinations, but "conducts a *de novo*

review and issues a decision based on the hearing record." 42 C.F.R. § 405.1000(d).

Here, the Council finds that the ALJ conducted a *de novo* review of the record, as required by the regulations. The ALJ did not base his decision solely on the plan's initial and reconsideration determinations. Rather, he considered "the testimony presented and the documentary evidence" in the record. ALJ Dec. at 5. The Council notes that determining the applicable coverage authorities was a genuine issue that the ALJ needed to resolve in order to conduct a *de novo* review in this case. The Council concurs with the ALJ's determination that NCD 140.3 was invalid and could not serve as a basis for denying coverage. Thus, the ALJ properly rejected a categorical exclusion and considered whether the requested services were reasonable and necessary under section 1862(a)(1)(A) of the Act.

The ALJ Did Not Apply United Healthcare's Coverage Determination Guidelines.

Finally, the plan argues that the ALJ erred in "relying upon a [United Healthcare] commercial coverage guideline document" that did not specifically apply to the plan. Exh. MAC-1, at 5. This argument lacks merit. The ALJ's decision expressly stated that the United Healthcare CDG did not apply to the plan, and the ALJ did not rely on it in reaching his decision. Dec. at 5. The ALJ merely noted that the CDG demonstrated that United Healthcare was aware of the advances in medical knowledge and surgical technique over the last several decades. *Id.* at 4. Thus, the plan's initial reliance on the invalid NCD was not reasonable, even though CMS had not issued guidance listing specific coverage criteria for approving gender reassignment surgery. The ALJ also noted that the enrollee would have satisfied the coverage criteria in United Healthcare's CDG if she were in a different plan. *Id.* at 5. However, the ALJ did not grant coverage on that ground. The Council finds that the ALJ's references to United Healthcare's CDG were merely dicta and did not serve as a basis for his determination that the plan is required to cover the requested procedure. Therefore, the Council finds no basis for changing the ALJ's decision in this respect.

CONCLUSION

The Council's analysis is limited to the facts presented and the record evidence in this case. Absent further coverage guidance from CMS on gender reassignment surgery, the Council adjudicates claims for gender reassignment surgery on a case-by-case basis.

The Council has considered the record, the contentions in the request for review, and the enrollee's response. The Council finds that the vaginoplasty surgery requested in this case is covered and is the responsibility of the Plan. The Council modifies the ALJ's decision as discussed above.

MEDICARE APPEALS COUNCIL

Gilde Morrisson
Gilde Morrisson
Administrative Appeals Judge

K. Robinson
Karen R. Robinson
Administrative Appeals Judge

Date: JAN 21 2016