Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

NCD 140.3, Transsexual Surgery
Docket No. A-13-47
NCD Ruling No. 2
December 2, 2013

BOARD RULING THAT NCD RECORD IS NOT COMPLETE AND ADEQUATE TO SUPPORT THE VALIDITY OF THE NCD

Based on the current record in this proceeding initiated by an acceptable NCD complaint from an aggrieved party, the Departmental Appeals Board (Board) has determined that the NCD (National Coverage Determination) record in this case "is not complete and adequate to support the validity of the NCD" denying Medicare coverage for transsexual surgery "for sex reassignment of transsexuals." 42 C.F.R. § 426.525(c)(3); NCD 140.3. The submissions of the aggrieved party and the amici curiae, to which the Centers for Medicare & Medicaid Services (CMS) elected not to respond to defend the NCD, demonstrate that the premises for the NCD, which was based on a 1981 review of medical and scientific sources published between 1966 and 1980, are not reasonable in light of subsequent developments. This proceeding will thus move on to discovery and taking of evidence as provided in 42 C.F.R. §§ 426.532 and 426.540. This ruling does not address the ultimate question of whether the NCD as written is valid under the reasonableness standard, but only whether the existing NCD record on which the NCD was based is complete and adequate to support its validity.

Legal Background

An NCD is "a determination by the Secretary [of Health and Human Services] with respect to whether or not a particular item or service is covered nationally under [title XVIII (Medicare)]." Social Security Act (Act) § 1869(f)(1)(B) (42 U.S.C. § 1395ff(f)(1)(B)).[1] NCDs are issued by CMS, apply nationally, and are binding at all levels of administrative review of Medicare claims. 42 C.F.R. § 405.1060. Section 1869(f)(1) of the Act authorizes the Board to review NCDs "[u]pon the filing of a

[1] The table of contents to the current version of the Social Security Act, with references to the corresponding United States Code chapter and sections, can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm.

complaint by an aggrieved party." The applicable regulations governing Board review of NCDs, at 42 C.F.R. Part 426, specify what an NCD complaint must contain in order to be found acceptable and begin the review process. 42 C.F.R. § 426.500(c).

Once the Board finds an NCD complaint is acceptable, the aggrieved party submits a statement "explaining why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard" and CMS may submit a response "in order to defend the NCD." 42 C.F.R. § 426.525(a), (b). The NCD record "consists of any document or material that CMS considered during the development of the NCD" including "medical evidence considered on or before the date the NCD was issued . . . ." 42 C.F.R. § 426.518(a). The Board then "applies the reasonableness standard to determine whether the NCD record is complete and adequate to support the validity of the NCD." 42 C.F.R. § 426.525(c)(1).

If the Board determines that the record is complete and adequate to support the validity of the NCD, the review process ends with the Board's "[i]ssuance of a decision finding the record complete and adequate to support the validity of the NCD . . . ." 42 C.F.R. § 426.525(c)(2). If the Board determines that the record is *not* complete and adequate to support the validity of the NCD, the Board "permits discovery and the taking of evidence . . . and evaluates the NCD" in accordance with the applicable provisions of Part 426, including conducting a hearing, unless the matter can be decided on the written record. 42 C.F.R. §§ 426.525(c)(3), 426.531(a). During an NCD review, the aggrieved party bears the burden of proof and the burden of persuasion for the issues raised in an NCD complaint, and the burden of persuasion is judged by a preponderance of the evidence. 42 C.F.R. § 426.330.

The regulations also provide that a person other that the aggrieved party with an interest in the issues may petition to participate in the review process as an amicus curiae. 42 C.F.R. §§ 426.510(f), 426.513. Additionally, an aggrieved party who has filed an acceptable complaint "may submit additional new evidence without withdrawing the complaint until the Board closes the record." 42 C.F.R. § 426.503.

Case Background

The aggrieved party here filed an initial NCD complaint and supporting materials on March 26, 2013 and a supplement on April 18, 2013, and the Board notified CMS of the filing of an acceptable complaint on April 29, 2013. CMS submitted the NCD record on May 15, 2013, and the aggrieved party submitted, on June 14, 2013, a statement of why the NCD record is not complete or adequate to support the validity of the NCD under the reasonableness standard. In addition, six advocacy organizations petitioned for and were granted permission to participate as amici curiae in the NCD review by filing written briefs, which they submitted between June 20 and July 10, 2013 (with four of the amici submitting a joint brief).

On June 26, 2013, CMS notified the Board that it declined to submit a response to the aggrieved party's statement of why the NCD record is not complete or adequate to support the validity of the NCD.

The NCD and the NCD record

The challenged NCD, titled "140.3, Transsexual Surgery," states:[2]

> **Item/Service Description**
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> Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses.
>
> **Indications and Limitations of Coverage**
>
> Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

The NCD directly quotes from or paraphrases portions of an 11-page report that the former National Center for Health Care Technology (NCHCT) of the HHS Public Health

[2] NCDs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=ncd.

Service (PHS) issued in 1981, titled "Evaluation of Transsexual Surgery."[3] NCD Record at 13-23. The NCHCT forwarded its 1981 report to officials of the Health Care Financing Administration (HCFA), now called CMS, with a memorandum dated May 6, 1981 recommending "that transsexual surgery not be covered by Medicare at this time." *Id*. at 10-12. HCFA issued the NCD language as part of its Coverage Issues Manual of coverage instructions for Medicare contractors; CMS published the manual in the Federal Register on August 21, 1989.[4] *Id*. at 11; 76-129; 54 Fed. Reg. 34,555, 34,572.

The NCD record also includes three letters that the Transsexual Rights Committee of the American Civil Liberties Union (ACLU) of Southern California sent to HCFA in April 1982 disagreeing with HCFA's non-coverage policy. NCD Record at 24-26, 41-42. The ACLU letters enclose letters and affidavits from physicians and therapists supporting the medical necessity of transsexual surgery and taking issue with the non-coverage determination. *Id*. at 27-76. On May 11, 1982, a HCFA Physicians Panel, which had referred the issue of coverage to the NCHCT in September 1980, recommended against referring the ACLU's submissions to PHS, "on the basis that it does not contain information about new clinical studies or other medical and scientific evidence sufficiently substantive to justify reopening the previous PHS assessment." *Id*. at 1, 4, 7, 9, 10.

The NCHCT's May 6, 1981 memorandum, the 1981 NCHCT report, and the notes of the HCFA Physicians Panel meeting on May 11, 1982, are the materials in the NCD record containing analysis by HCFA or PHS of the issue of Medicare coverage of transsexual

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[3] The concluding summary of the 1981 NCHTC report states:

> Transsexual surgery for sex reassignment of transsexuals is controversial. There is a lack of well controlled, long-term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism. There is evidence of a high rate of serious complications of these surgical procedures. The safety and effectiveness of transsexual surgery as a treatment of transsexualism is not proven and is questioned. Therefore, transsexual surgery must be considered still experimental.

NCD Record at 19.

[4] The HCFA coverage instruction additionally states that transsexual surgery, as well as being "considered experimental," was also "of questionable value," language that does not appear in the 1989 Federal Register notice or in the NCD. NCD Record at 11.

surgery.[5] Although the NCD was not issued until 1989, it is clear that the NCD was based on the NCHCT report and memorandum from 1981.

Analysis

The unrebutted submissions of the aggrieved party and the amici demonstrate that the rationale for the NCD is not adequately supported by the existing NCD record.

1. Summary

The basis for the NCD in 1981, when the NCHCT issued its report containing what became the NCD language, was that transsexual surgery was not safe or effective, due to the high rate of complications and the lack of evidence that it was safe or effective in treating transsexualism. *See* NCD (transsexual surgery "considered experimental" due to "the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism"); NCD Record at 18 (1981 NCHCT report stating that "[t]he procedures cannot be considered safe because of the high complication rates" and noting "the lack of long-term, properly designed studies of the outcome of these procedures demonstrating their efficacy"); *Id*. at 12 (NCTHC May 6, 1981 memorandum stating that "[t]he more controversy exists over the safety and effectiveness of a technology, the better the supporting evidence must be to justify coverage, particularly when there is a body of evidence that questions the effectiveness of the technology."). The NCD record also raises doubts about the reliability and validity of diagnoses of transsexualism, with the NCHCT finding that "[t]he diagnosis of transsexualism is also problematic" and that "[t]he criteria for establishing the diagnosis vary from [university medical] center to center and have changed over time." *Id*. at 14.

The aggrieved party argues that these bases for the NCD neither "reflect [n]or are supportable by the current state of medical science," and that the NCD "is not reasonable in light of the current state of scientific and clinical evidence and current medical standards of care." Aggrieved Party Statement Why The NCD Record Is Not Complete or Adequate to Support the Validity of NCD 140.3 (AP Statement) at 7. The aggrieved party asserts that "in the intervening 32 years since PHS/NCHCT studied the issue" of coverage:

> (a) dozens of new studies have been conducted that address the methodological limitations of earlier studies and confirm that sex reassignment surgery is a safe and extremely effective treatment for persons

[5] The NCD Record also includes a copy of the 1989 Federal Register notice publishing the NCD language (minus four pages) and an undated page from the HCFA coverage issues manual. 54 Fed. Reg. 34,555-612; NCD Record at 11, 76-129.

> with severe gender dysphoria; (b) advancements in surgical techniques have dramatically reduced the risk of complications from sex reassignment surgery and the rates of serious complications from such surgeries are low, and (c) a robust medical consensus has developed among mainstream medical organizations which endorses the treatment standards established by the WPATH [World Professional Association for Transgender Health] Standards of Care [for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7,13 *Int'l J. Transgenderism* 165 (2011)] and recognizes that sex reassignment surgery is a medically necessary treatment for persons with severe gender dysphoria.

Id.

In support of these arguments, the aggrieved party submitted the declaration testimony of two expert witnesses -- a clinical psychologist and a physician certified by the American Board of Obstetrics and Gynecology -- and copies of two letters from two other physicians to an ALJ in the Department of Health and Human Services Office of Medicare Hearings and Appeals. These documents, which are either sworn to or made under penalty of perjury, indicate that each of these health care professionals has substantial experience in treating persons with gender identity disorder (GID). In the case of the three physicians, this includes many years' experience performing some of the procedures involved in gender reassignment surgery. In addition, the clinical psychologist submitted copies of 32 journal publications and other writings cited in her two declarations.

CMS did not submit a response to the aggrieved party's submissions and thus provided no reason to question the aggrieved party's expert testimony or the experts' descriptions of the medical and scientific literature submitted by the aggrieved party. *Compare Pancreas Transplants # 35-82*, DAB NCD Ruling No. 1 (2005) (*Pancreas Transplants Ruling*) (CMS responded to the aggrieved party's statement and argued that new evidence the aggrieved party submitted did not compel extending coverage to include the disputed procedure).[6] At this stage in the proceeding, however, the Board's role is not to assess the ultimate validity of the NCD based on an evidentiary record but simply to determine whether the information CMS considered *during the development of the NCD*, including medical evidence considered *on or before the date the NCD was issued*, adequately and reasonably supports the validity of the NCD, in light of the materials submitted by the aggrieved party. 42 C.F.R. § 426.518(a). The facts that the NCD here was based on studies published no later than 1980 and that CMS has not responded to the aggrieved

[6] The *Pancreas Transplants Ruling* is available at http://www.hhs.gov/dab/decisions/rul1.htm.

party's arguments and expert statements that developments in the treatment of transsexualism during the intervening 32 years have undermined the rationale for the NCD support our determination that the NCD record is not complete or adequate to support the validity of the NCD.

Having made this determination, the Board is required by regulation to proceed to the taking of evidence, a process that includes discovery by the parties and affording the parties the opportunity for an evidentiary hearing. 42 C.F.R. § 426.525(c)(3); *see, e.g.*, *Pancreas Transplants Ruling* ("We determine only that the evidence proffered suffices to require us to go forward to take evidence from both parties"). During this process, each party will have the opportunity to cross-examine any expert witness who submits a report, and we are required to exclude from the record any reports submitted by experts who are not available for cross-examination. 42 C.F.R. § 426.540(e). CMS will have the opportunity to consider and respond to all new evidence, as well as to present any other evidence that it believes will demonstrate the validity of the NCD.

2. Discussion

Regarding the safety and rates of complications of transsexual surgery, the aggrieved party and amicus submissions assert that surgeries for transgender persons are safe and have a low rate of complications; that most complications that occur are minor; that recipients of sex reassignment surgery do not have the same level of serious complications as occurs with kidney, pancreas, liver, cardiac, vascular, esophageal and other surgeries that Medicare may cover; and, that there is currently no scientific or medical basis for the statement in the NCD that sex reassignment surgery has not been proven safe and has a high rate of serious complications. *See generally* AP Statement, Apps., Decls. Declaration testimony further states that almost all of the complications reported in five studies published between 1997 and 2013, which the aggrieved party submitted with her NCD complaint, "are not specific to sex reassignment surgeries, but rather are known potential side effects of any type of urogenital surgery which are covered by Medicare." Decl. of Katherine Hsiao, M.D. at ¶ 15. These materials indicate that the record on which the safety concerns expressed in the NCD were based is not complete and adequate.

The incomplete and inadequate state of the NCD record with respect to the safety concerns cited in the NCD appears to stem, in part, from the substantial passage of time since publication of the sources on which the NCHCT relied in recommending the exclusion of transsexual surgery. We note, for example, that the psychologist who submitted a declaration in support of the complaint cited a 1997 study as showing that "after 1985, surgical outcomes were far superior, owing to improvements in technique, shortened hospital stays and improvements in postoperative care." Supp. Decl. of Randi Ettner, Ph.D. at ¶ 12, citing Eldh *et al.* (1997) (Decl. App. Ex. 9); *see also* Hsiao Decl. at ¶ 18 (citing the same study as showing that "surgical complication rates decreased

significantly over time"). In *Pancreas Transplants Ruling*, the Board concluded that the NCD record was not complete and adequate where CMS "does not directly deny the aggrieved party's contention that the state of practice relating to [the disputed surgical procedure] has changed in the intervening [five] years" since the NCD was last revised.

The declarations and supporting materials also show that the record on which the NCD was based is not complete or adequate to support the NCD's determination that transsexual surgery has not been shown to be effective (i.e., that the surgery is experimental). According to these materials, the medical community has reached consensus that transsexual or gender reassignment surgery is an effective treatment for persons with a sufficiently severe degree of GID or gender dysphoria. They and the aggrieved party's other submissions also indicate that these surgeries have been performed for many decades and are part of the WPATH-established standards of care for patients with gender dysphoria, which have been endorsed by the American Medical Association, the Endocrine Society, the American Psychological Association, and the American College of Obstetricians and Gynecologists. Ettner Decl. at ¶ 14, citing Decl. App. Exs. 3, 5; Hsiao Decl. at ¶ 22. The psychologist also cites studies published from 1998 and 2010 — including what she describes as a 1998 "meta-analysis" of data from 80 studies spanning 30 years and a 2007 analysis of 18 studies published between 1990 and 2007 encompassing 807 patients — as finding that gender reassignment procedures were "effective in relieving gender dysphoria," and that sex reassignment surgery is "the most appropriate treatment to alleviate the suffering of extremely gender dysphoric individuals." Ettner Decl. at ¶¶ 20-22, citing Gijs and Brewaeys (2007), Pfäfflin & Junge (1998), Smith *et al*. (2005) (Decl. App. Exs. 10, 25, 27).

In addition, in response to the NCD's statement that surgical procedures and attendant therapies for transsexualism are considered experimental due to "the lack of well controlled, long term studies" of their safety and effectiveness, the clinical psychologist cites six "long-term" follow-up studies published from 2002 to 2010 as finding surgeries effective and with low complication rates based on assessing transsexual persons over periods of time up to 20 years. *Id*. at ¶¶ 26, 27, citing Hepp *et al*. (2002), Imbimbo *et al*. (2009), Johansson *et al*. (2010), Lobato *et al*. (2006), Vujovic *et al*. (2009), Weyers (2009) (Decl. App. Exs. 12, 13, 15, 22, 29, 30). She further cites two studies published in 1987 and 1990 as having compared patients who received the surgery to control groups of patients who did not and finding improved psychosocial outcomes in surgery patients. *Id*. at ¶¶ 28-30, citing Kockott & Fahrner (1987), Mate-Kole *et al*. (1990) (Decl. App. Exs. 17, 23). CMS has not responded to any of this evidence.

The aggrieved party and the amici curiae also cite decisions by United States courts of appeals in seven circuits recognizing that GID or gender dysphoria is a serious medical condition. Most of these cases involve actions by prison inmates challenging the denial of medically-indicated treatment for GID or gender dysphoria (through hormone treatments and surgery) as cruel and unusual punishment under the Eighth Amendment to

the United States Constitution. AP Statement at 13; WPATH Amicus Br. at 12; Joint Amicus Br. at 2, 12; HRC Amicus Br. at 10 n.7; and cases cited therein. In 2010, the U.S. Tax Court held that the plaintiff's hormone therapy and sex reassignment surgery to treat gender dysphoria were "medical care" and not cosmetic surgery. *O'Donnabhain v. Comm'r of Internal Revenue*, 134 T.C. 34, 70, 77 (2010). In doing so, the court cited decisions from the seven circuits concluding that severe GID or transsexualism constitutes a serious medical need for purposes of the Eighth Amendment and observed that no U.S. Court of Appeals had held otherwise. 134 T.C. at 62. Decisions of the seven circuits include a decision from the Fourth Circuit stating that sex or gender reassignment surgery is an accepted, effective, medically-indicated treatment for GID. *De'lonta v. Johnson*, 708 F.3d 520, 522-23 (4th Cir. 2013) (also stating that the surgery is not experimental or cosmetic and that the WPATH Standards of Care "are the generally accepted protocols for the treatment of GID"). In *Meriwether v. Faulkner*, 821 F.2d 408, 412 (7th Cir. 1987), the Seventh Circuit noted with approval other court decisions that "expressly rejected the notion that transsexual surgery is properly characterized as cosmetic surgery, concluding instead that such surgery is medically necessary for the treatment of transsexualism." The Eighth Circuit held that Medicaid benefits may not be denied for sex reassignment surgery when it is a medical necessity for the treatment of transsexualism. *Pinneke v. Pressier*, 623 F.2d 546 (8th Cir. 1980). In *Fields v. Smith*, 653 F.3d 550 (7th Cir. 2011), the Seventh Circuit held that enforcement of a statute preventing corrections medical personnel from providing hormone therapy or sexual reassignment surgery to prison inmates with GID constituted deliberate indifference to those inmates' serious medical needs.

While these decisions are not necessarily dispositive of the issue before us, they appear to be consistent with the position of the aggrieved party and the amici curiae that given the WPATH standards, the reliability and validity of a diagnosis of transsexualism are not "problematic," and the surgical procedures the NCD excludes from coverage are not considered experimental and, indeed, constitute medically-indicated treatment in appropriate cases.

The aggrieved party also argues that the NCD when issued was invalid and unsupported by the NCD record. The aggrieved party argues that the 1981 NCHCT report acknowledged the effectiveness of transsexual surgery in stating that "eight of the nine studies" that "represent[ed] the major clinical reports thus far published" between 1969 and 1980 on the outcome of the surgery "reported that most transsexuals show improved adjustment on a variety of criteria after sex reassignment surgery."[7] NCD Record at 17-18. The aggrieved party also argues that the ninth, unfavorable, study on which the

[7] The NCHCT discounted these findings on the ground that the eight favorable studies did not meet "the ideal criteria of a valid scientific evaluation of a clinical procedure." NCD Record at 18.

NCHCT relied was "severely flawed and ideologically biased," and criticizes two of the sources cited in the 1981 NCHT report as ideologically biased against transgender individuals, based on their published writings. AP Statement at 5. We need not and do not address these arguments since we need not decide here whether the NCD record was complete and adequate to support the NCD at the time the NCD record was tttdeveloped. In any event, our determination that the NCD record fails to account for developments in the care and treatment of persons with GID during the more than 30 years that have passed since the NCHCT issued its report containing the findings that HCFA adopted in issuing the NCD is, without more, a sufficient basis for our determination that the NCD record is not complete and adequate to support the validity of NCD 140.3.

Conclusion

For the reasons explained above, we conclude that the NCD record is not complete and adequate to support the validity of NCD 140.3, "Transsexual Surgery." Therefore, as required by the statute and regulations, we will proceed to discovery and the taking of evidence. As stated above, our ruling here does not address the ultimate question of whether the NCD as written is valid under the reasonableness standard in the statute and regulations.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member