

**U.S. Department of Health and Human Services
Departmental Appeals Board
Complaint *In re* NDC 140.3**

Pursuant to 42 C.F.R. § 426.500, *et seq.*, submits the following administrative complaint to initiate a review of National Coverage Determination 140.3 and states as follows:

Beneficiary-identifying information

1. Complainant's name is
2. Complainant's address is
3. Complainant's phone number is
4. Complainant's email address is

Representatives' identifying information

5. Complainant is represented by the following counsel:

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6. A copy of a written authorization to represent the beneficiary is attached as Exhibit A.

Treating physician written statement

7. A copy of the written order for sex-reassignment surgery from Complainant's treating physician, _____ is attached as Exhibit B. The request states that Complainant has a diagnosis of transsexualism (302.50), which is also known as Gender Identity Disorder, and "needs sex reassignment surgery." The data at the bottom of the form indicates that it was sent via facsimile on October 16, 2012.

NCD-identifying information

8. Complainant challenges the National Coverage Determination ("NCD") for Transsexual Surgery (140.3).

9. Complainant challenges NCD 140.3's categorical exclusion of coverage for sex reassignment surgery, which states: "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."

Aggrieved party statement

10. Complainant meets all of the prerequisites for her sex reassignment surgery. Specifically, _____ requires Male to Female Gender Reassignment Surgery (i.e. genital reconstruction surgery) in order to alleviate her Gender Identity Disorder (“GID”). Her primary care physician and two psychologists confirm _____ need for surgery as medically necessary in order to treat her GID.

11. Complainant’s challenge to NCD 140.3 must be evaluated under the “reasonableness standard.” 42 C.F.R. § 426.525(c)(1). *Accord* 42 C.F.R § 426.531; *see* NCD Ruling No. 1 Pancreas Transplants # 35-82. “In determining whether LCDs or NCDs are valid [under the reasonableness standard], the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.” 42 C.F.R. § 426.110. *Accord* 42 C.F.R. § 426.505 (“The Board defers *only* to reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.” (emphasis added)).

12. The categorical exclusion of sex reassignment surgery in NCD 140.3 cannot be reasonably based on any findings of fact, interpretations of law, or applications of fact to law. As demonstrated by the expert declaration of Dr. Ettner and accompanying exhibits, scientific and clinical literature squarely contradicts the assertions in the NCD 140.3 that (a) there are a lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for GID (b) that the treatment is considered experimental and controversial within the medical community (c) that there is a high rate of serious complications

for these surgical procedures. To the contrary, Dr. Ettner's expert declaration demonstrates that sex reassignment surgery is a safe, effective, non-experimental and medically necessary treatment for GID. Indeed, Dr. Ettner explains that surgery is the only effective treatment for persons with severe GID.

13. Because CMS has not yet compiled the administrative record supporting NCD 140.3, it is unclear what evidence it relied upon when it initially published NCD 140.3 in 1989. Once that administrative record is compiled, complainant will demonstrate that the evidence in the record in 1989 could not reasonably support the sweeping and categorical exclusion in NCD 140.3. But even if defendant were ultimately able to convince the Board that NCD 140.3 had a reasonable basis in 1989, the ban on coverage for sex reassignment surgery would still fail the reasonableness test today because CMS has never considered the vast amount of new scientific and clinical evidence that has been developed since 1989, which is discussed in Dr. Ettner's declaration. *Cf.* NCD Ruling No. 1 Pancreas Transplants # 35-82 (concluding that NCD issued in 1995 banning coverage for pancreas transplants was no longer reasonably supported by the administrative record because new evidence was developed in 1999 and CMS has "not yet considered or carefully reviewed that evidence, so that we have no prior agency determination regarding it to which we would defer if reasonable").

14. The unreasonableness of NCD 140.3 is further confirmed by the fact that it conflicts with the overwhelming consensus of the leading medical organizations that sex reassignment surgery is a safe, effective, non-experimental, and medically necessary treatment, including the American Medical Association, the Endocrine Society, the American Psychological Association, and the World Professional Association for Transgender Health. These position statements are included in the Appendix to Dr. Ettner's expert declaration.

15. Indeed, in the context of access to health care for prisoners, federal courts have repeatedly held that categorical bans on sex reassignment surgery to treat GID are so unreasonable that they violate the Eighth Amendment. *See De'lonta v. Johnson*, --- F.3d ---, 2013 WL 310350, at *2 (4th Cir. Jan. 28, 2013) (explaining that under “the generally accepted protocols for the treatment of GID . . . the surgery is not considered experimental or cosmetic; it is an accepted, effective, medically indicated treatment for GID”); *Fields v. Smith*, 653 F.3d 550 (7th Cir. 2011) (holding that categorical ban on surgery to treat GID is facially unconstitutional); *Kosilek v. Spencer*, 889 F.Supp.2d 190 (D. Mass. Sept. 4, 2012) (issuing injunction to provide sex reassignment surgery after determining that surgery was medically necessary); *Soneeya v. Spencer*, 851 F.Supp.2d 228 (D. Mass. 2012) (same); *see also O'Donnabhain v. Comm'r of Internal Rev.*, 134 T.C. 34 (U.S. Tax Ct. 2010) (holding that surgery to treat GID is medically necessary and not cosmetic for purposes of tax deduction).

Clinical or scientific evidence

16. Accompanying this complaint is an expert declaration of Dr. Randi C. Ettner, which summarizes clinical and scientific evidence demonstrating that sex reassignment surgery in general – and genital reconstruction surgery for transsexual women in particular – is safe, effective, non-experimental, and medically necessary to treat Gender Identity Disorder. As discussed above in paragraphs 12-14, Dr. Ettner's expert declaration demonstrates that NCD 140.3 cannot be reasonably based on any findings of fact, interpretations of law, or applications of fact to law.

17. Copies of the clinical and scientific evidence discussed by Dr. Ettner are included as an appendix to her declaration.

Supplemental materials

18. Complainant reserves the right to submit supplemental statements and present supplemental evidence in response to any materials submitted as part of the administrative record to support NCD 140.3. *See* 42 C.F.R. § 426.503 (right to submit additional evidence until Board closes the appeals record); 42 C.F.R. § 426.525(a) (right to submit additional statement upon receipt of NCD record);

Conclusion

For the foregoing reasons, the categorical exclusion of sex reassignment surgery in NCD 140.3 cannot be sustained by the Board under the “reasonableness standard” and must be invalidated.

Dated: March 26, 2013

Respectfully submitted,



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