August 21, 2012 Emily Pittman Newberry [PHI Redacted]

Tamara Syrek Jensen
Deputy Director, Coverage and Analysis Group
Office of Clinical Standards and Quality, CMS
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms. Jensen,

I am writing to initiate a review of NCD 140.3 Transsexual Surgery (Rev. 1, 10-03-03) CIM 35-61. It states:

"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." It further 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.

[PHI Redacted]

The NCD cited above, 140.3, which Kaiser Permanente Northwest Senior Advantage relied upon to deny [PHI Redacted] transsexual surgery (gender confirming surgery), is directly contradicted by later studies as evidenced in my attachments and the records of [PHI Redacted] appeal. From the statement of the World Professional Association for Transgender Health, the inter-disciplinary body of professionals most directly involved in transsexual health care:

"The current Board of Directors of the WPATH herewith expresses its conviction that sex reassignment, properly indicated and performed as provided by the Standards of Care, has proven beneficial and effective in the treatment of individuals with transsexualism, gender identity disorder and/or gender dysphoria. Sex reassignment plays an undisputed role in contributing toward favorable outcomes,..."

and

"These reconstructive procedures are not optional in any meaningful sense, but are understood to be medically necessary for the treatment of the diagnosed condition."

and

"These medical procedures and treatment protocols are not experimental: decades of both clinical experience and medical research show they are essential to achieving well-being for the transsexual patient."

and

"The WPATH Board of Directors urges health insurance carriers and health care providers in the United States to eliminate transgender or trans-sex exclusions and to provide coverage for transgender patients and the medically prescribed sex reassignment services necessary for their treatment and well being, and to ensure that their on-going health care (both routine and specialized) is readily accessible"

This statement is reiterated and supported by the American Medical Association and the American Psychological Association.

Therefore, [PHI Redacted] since all the major professional associations directly involved with transsexual's health care and research confidently states that these surgeries are medically necessary, safe and effective, I ask the Centers for Medicare and Medicaid Services initiate a review of NCD 140.3, Transsexual Surgery immediately.

Sincerely,

Emily Pittman Newberry

Statement From WPATH Documenting the Necessity of SRS

From: The Standards of Care Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version1, March 2011

http://www.wpath.org/documents/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf

(This is the seventh version of the Standards of Care. The original SOC were published in 1979. Previous revisions were in 1980, 1981, 1990, 1998, and 2001.

The World Professional Association for Transgender Health www.wpath.org

Notation from the SOC, V. 7, p. 54-55

Sex Reassignment Surgery Is Effective and Medically Necessary

Surgery – particularly genital surgery – is often the last and the most considered step in the treatment process for gender dysphoria. While many transsexual, transgender, and gender nonconforming individuals find comfort with their gender identity, role, and expression without surgery, for many others surgery is essential and medically necessary to alleviate their gender dysphoria (Hage & Karim, 2000). For the latter group, relief from gender dysphoria cannot be achieved without modification of their primary and/or secondary sex characteristics to establish greater congruence with their gender identity. Moreover, surgery can help patients feel more at ease in the presence of sex partners or in venues such as physicians' offices, swimming pools, or health clubs. In some settings, surgery might reduce risk of harm in the event of arrest or search by police or other authorities.

Follow-up studies have shown an <u>undeniable beneficial effect of sex reassignment surgery on postoperative outcomes</u> such as subjective well being, cosmesis, and sexual function (De Cuypere et al., 2005; Gijs & Brewaeys, 2007; Klein & Gorzalka, 2009; Pfäfflin & Junge, 1998). Additional information on the outcomes of surgical treatments are summarized in Appendix D.

Excerpt from Appendix D p.107-108

Since the Standards of Care have been in place, there has been a steady increase in patient satisfaction and decrease in dissatisfaction with the outcome of sex reassignment surgery. Studies conducted after 1996 focused on patients who were treated according to the Standards of Care. The findings of Rehman and colleagues (1999) and Krege and colleagues (2001) are typical of this body of work; none of the patients in these studies regretted having had surgery, and most reported being satisfied with the cosmetic and functional results of the surgery. Even patients who develop severe surgical complications seldom regret having undergone surgery. Quality of surgical results is one of the best predictors of the overall outcome of sex reassignment (Lawrence, 2003). The vast majority of follow-up studies have shown an undeniable beneficial effect of sex reassignment surgery on

postoperative outcomes such as subjective well being, cosmesis, and sexual function (De Cuypere et al., 2005; Garaffa, Christopher,& Ralph, 2010; Klein & Gorzalka, 2009), although the specific magnitude of benefit is uncertain from the currently available evidence. One study (Emory, Cole, Avery, Meyer, & Meyer III, 2003) even showed improvement in patient income.

Key References from the above:

De Cuypere, G., T'Sjoen, G., Beerten, R., Selvaggi, G., De Sutter, P., Hoebeke, P., . . . Rubens, R. (2005). Sexual and physical health after sex reassignment surgery. Archives of Sexual Behavior, 34(6), 679-690.

Gijs, L., & Brewaeys, A. (2007). Surgical treatment of gender dysphoria in adults and adolescents: Recent developments, effectiveness, and challenges. Annual Review of Sex Research, 18, 178-224.

Klein, C., & Gorzalka, B. B. (2009). Sexual functioning in transsexuals following hormone therapy and genital surgery: A review (CME). The Journal of Sexual Medicine, 6(11), 2922-2939.