

Congress of the United States
Washington, DC 20515

December 30, 2020

Administrator Seema Verma
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

Chair, Dr. Peter Bach, MD, MAPP
Medicare Evidence Development & Coverage Advisory Committee
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Vice Chair, Dr. Joseph Ross, MD, MHS
Medicare Evidence Development & Coverage Advisory Committee
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Via electronic correspondence.

Dear Administrator Verma, Committee Chair Dr. Bach, and Committee Vice Chair Dr. Ross:

We write to encourage the Centers for Medicare & Medicaid Services' (CMS) Medicare Evidence Development & Coverage Advisory Committee to review and reconsider Medicare's National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy (BRFM). Specifically, we support the inclusion of the *Women's Health and Cancer Rights Act of 1998* (WHCRA) in the BRFM, as well as guaranteed coverage of breast reconstruction procedures and products, such as three-dimensional (3D) nipple-areolar complex (NAC) tattoos, which return the patient's chest to a more natural, symmetrical appearance. Additionally, we call on CMS to encourage state Medicaid Agencies to amend their state Medicaid plans to include the WHCRA and update coverage to reflect the aforementioned breast reconstruction procedures and products, as well as to ensure tattoo artists are eligible providers under Medicaid in order to expand access to NAC tattoo services.

According to CMS, the BRFM NCD has not been updated since 1997. Increased understanding and diagnosis of breast cancer, development of new surgical treatments and skills, advancement in prostheses, and a growth in physician understanding of "the importance of postsurgical psychological adjustment" are specifically acknowledged as crucial to the 1997

revision.¹ One such advancement indicating the necessity for the NCD to be reviewed and revised has been that of 3D NAC tattoos, which closely mimic the color, and create an appearance of texture, of the NAC, particularly when performed by tattoo artists.² A study of patient satisfaction regarding their nipple reconstruction and tattooing found that 77 percent of participants were satisfied with their nipple tattoos, with the most common cause for disappointment being the fading of the tattoo, which is normal for any tattoo.³ These procedures can be performed by licensed medical professionals with the assistance of devices, such as stencils or by tattoo artists, with prescription and referral, to achieve natural results. Further, costs associated with these procedures range from \$640 for a single tattoo up to \$956 for two. This can be cost-prohibitive for many beneficiaries, but may be medically necessary for a comprehensive breast reconstruction, as well as for psychological well-being, which is documented to be higher in post-mastectomy patients that undergo breast reconstruction.⁴ These procedures, when conducted in appropriate settings by professionals and prescribed by a physician, offer a minimally invasive and hyper-realistic option for breast reconstruction patients that is likely to offer satisfactory outcomes and contribute to patient mental health as they adjust to their new anatomy.

As you know, Medicare Administrative Contractors (MACs) Novitas⁵ and Wisconsin Physicians Services Insurance Corporation (WPS)⁶ are the only two MACs explicitly covering NAC tattoos. Medicaid coverage varies state by state based on respective interpretation of “medically reasonable and necessary,” with interpretations resulting in complete denial in West Virginia, constraints in Florida, Iowa, and Vermont, and complete coverage in Louisiana. MACs and state Medicaid Agencies that do not specifically cover this procedure determine whether this procedure qualifies as “medically necessary” a case-by-case basis. Further, neither Medicare nor Medicaid are statutorily required to adhere to the WHCRA, which is why CMS guidance to encourage application is crucial, until Congress acts to resolve this oversight.⁷

While Medicare covers post-mastectomy breast reconstruction based on the WHCRA under the BRFM, such coverage can change at any time, and state Medicaid adherence to any provision under the WHCRA depends on each state agency.⁸ MACs currently consider NAC tattooing to be covered under the BRFM, but this is not guaranteed. The patchwork of differing

¹ [National Coverage Determination \(NCD\) for Breast Reconstruction Following Mastectomy \(140.2\)](#). Medicare Coverage Database. Centers for Medicare and Medicaid Services (CMS).

² [Tattoo Artists Play New Role in Breast Reconstruction](#). American Society of Plastic Surgeons (ASPS). Press Release. May 1, 2014.

³ Goh, S. C. J., Martin, N. A., Pandya, A. N., & Cutress, R. I. (2011). [Patient satisfaction following nipple-areolar complex reconstruction and tattooing](#). Journal of plastic, reconstructive & aesthetic surgery, 64(3), 360-363.

⁴ ['Nipple By Number' Device Helps Plastic Surgeons Perform 3D Nipple Tattoos](#). ASPS. Press Release. December 23, 2019. Chen, W., Lv, X., Xu, X. et al. Meta-analysis for psychological impact of breast reconstruction in patients with breast cancer. Breast Cancer 25, 464–469 (2018).

⁵ [Local Coverage Determination \(LCD\): Cosmetic and Reconstructive Surgery \(L35090\)](#). Medicare Coverage Database. CMS. Original LCD Effective: October 1, 2015. Revised LCD Effective: November 7, 2019.

⁶ [Local Coverage Determination \(LCD\): Cosmetic and Reconstructive Surgery \(L34698\)](#). Medicare Coverage Database. CMS. Original LCD Effective: October 1, 2015. Revised LCD Effective: October 31, 2019.

⁷ [“Finishing Touches: Expanding Access to Nipple-areola Tattooing as a Component of Postmastectomy Breast Reconstruction.”](#) Butler, Paris D., M.D. MPH; Plana, Natalie M., M.D.; and Hastings, Alcee L., Esq. Wolters Kluwer Health, Inc. on behalf of The ASPS. November 7, 2019.

⁸ [Women’s Health and Cancer Rights Act](#). Health Insurance Laws. American Cancer Society (ACS). Last revised: May 13, 2019.

policies, restrictions, and guidelines creates an uncertain and confusing landscape of breast reconstruction procedure availability. Providers and patients may be deterred from prescribing or seeking this or other simple procedures due to coverage uncertainty, and the denial of claims that deserve to be covered is wholly frustrating for claims examiners, especially when other MACs approve the same procedures.

We understand the processes associated with considering and updating the Medicare NCD and that Medicaid coverage is determined by each state. However, we also believe that it is time for CMS to reconsider and encourage nationwide coverage to allow for new technologies, devices, medicines and treatments, therapeutics, and procedures to be easily accessed under the BRFM. Such a course will better serve post-mastectomy breast cancer patients as they seek the reconstruction and path to recovery that is best for them. As you will recall, a letter sent to CMS on October 19, 2019⁹ enumerated requests for adoption of the WHCRA and NAC tattooing coverage when performed by a tattoo artist under Medicare’s Medical BRFM NCD, and called on CMS to collaborate with states in an effort to adopt these provisions at the state-level. Such provisions would expand patients’ access to procedures protected under the WHCRA and to comprehensive, natural results following post-mastectomy breast reconstruction. Additionally, establishing NAC tattoos as a medically reasonable and necessary component of post-mastectomy breast reconstruction, and not merely cosmetic, will provide MACs and state Medicaid programs with clear and consistent guidance to address needs of breast cancer survivors as they heal and resume their lives.

Leaving post-mastectomy care up to interpretation has resulted in denied claims, uncertainty as to what is eligible for coverage, and inability to access comprehensive care. It is incumbent on CMS to protect beneficiaries’ access to care under Medicare and Medicaid and take action to address these shortcomings in post-mastectomy care, which is essential to carrying out this mandate. Thank you for your time and consideration of our request for an NCD reconsideration, in accordance with applicable statutes and regulations. We stand ready to assist in this endeavor.

Sincerely,


Alcee L. Hastings Debbie Wasserman Schultz Vern Buchanan Jackie Walorski
Member of Congress Member of Congress Member of Congress Member of Congress

//s//
Bennie G. Thompson
Member of Congress

//s//
Barbara Lee
Member of Congress

//s//
Jenniffer González Colón
Member of Congress

//s//
Juan Vargas
Member of Congress

⁹ [Hastings Leads Letter Urging CMS to Ensure Full Post-Mastectomy Medicare & Medicaid Coverage for Breast Cancer Patients](#). Press Release. AlceeHastings.house.gov. October 19, 2020.

Cc:

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