Topic Disposition Summary: Breast Implant Illness

Date: 6/10/2024
Nomination Number: 1093

Purpose: This document summarizes the information addressing a nomination submitted on February 21, 2024, (link to EHC posted topic nomination) through the Effective Health Care Website. This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: The nominator of this topic is an individual who requesting a guideline or more primary research that would explore the diagnosis and harms of breast implant illness (BII), a constellation of symptoms that has been identified as a potential adverse effect of breast augmentation.

Findings: The EPC program does not conduct primary research and ascertained that the primary evidence available on this topic is too limited to justify a new systematic review. Therefore, the EPC program will not consider this topic further.

Background:

Breast augmentation is one of the most popular cosmetic surgeries in the United States, accounting for nearly 300,000 procedures done in 2022 according to the American Society of Plastic Surgeons.[1] While current evidence supports the safety of breast implantation,[2] the procedure does come with risks, including but not limited to breast pain and changes in sensation, the need for implant removal, breast-implant-associated anaplastic large cell lymphoma, and systemic symptoms.[3] Breast implant illness (BII) is one such systemic issue, and consists of a collection of symptoms thought to be related to breast implants, including fatigue, headache, chest pain, hair loss, chills, rash, and chronic pain, among others.[2] The incidence and cause of BII are not yet well understood; however, it is thought that implant removal (also called "explantation") may be an effective approach to resolving BII for some patients.[4, 5]

Although BII is one potential side effect of breast augmentation that impacts patient quality of life and warrants further study, the available primary literature is currently too limited to justify a new EPC evidence product.

Related Resources:

We identified additional information during our assessment that might be useful:

- The United States Food and Drug Administration (FDA) acknowledges that BII is one potential complication of breast augmentation. The FDA encourages patients to report any injury, adverse events, or symptom related to a medical device, including those attributed to BII, to the FDA by phone at 1-800-FDA-1088 or online at MedWatch.[3]

- A 2022 overview of current regulations and screening guidelines for breast implant safety is available, and provides information about the landscape of current BII research.[4]
- A recent conference abstract from the 2024 Aesthetic Society Meeting outlines an upcoming systematic review titled Breast Implant Illness (BII) As a Clinical Entity: A Systematic Review of the Literature, which will explore existing literature about BII. A publication date for this review is not yet available.[6]

References

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6. Hemal KK, R.; Stanton, E.; Sorenson, T.; Boyd, C.; Karp, N.; Choi, M. Breast Implant Illness (BII) As a Clinical Entity: A Systematic Review of the Literature. Aesthet Surg J Open Forum. 2024 MayApr 12;6(Suppl 1):ojae007.73. doi: https://dx.doi.org/10.1093/asjof/ojae007.073. eCollection 2024 May.

Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this brief.

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