



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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