



January 26, 2015

David Moroney, MD
Chief Medical Officer
BlueCare Tennessee
1 Cameron Hill Circle
Chattanooga, TN 37402-0001

Dear Dr. Moroney,

As a collective voice of multidisciplinary practitioners, we have previously reached out to you concerned about the impact of insurer use of step therapy. Requiring patients to try and fail on one or more medications not indicated for their medical condition may jeopardize patient health and prolong suffering when access to care is delayed. Further, it subjects patients to unintended consequences associated with exposure to medications that may not have been well studied for use in treating a particular medical condition.

We have learned that there has been no change in your company's policy to delay or block appropriate access to the only FDA-approved therapy for nausea and vomiting of pregnancy (NVP), by requiring pregnant women to first fail on other medicines – none of which are indicated for the treatment of NVP.

We would like to point you to several reputable sources that address the safety risks associated with products used off-label to treat NVP. These are professional governing societies providing recommendations for pregnant women to use FDA-approved medications for NVP.

- The **Association for Women's Health Obstetric and Neonatal Nurses (AWHONN)** February/March 2014 edition of *Nursing for Women's Health* article, *A New Pharmacologic Treatment for Nausea and Vomiting of Pregnancy*¹

¹ <http://onlinelibrary.wiley.com/enhanced/doi/10.1111/1751-486X.12096/>

- The **Association of Professors of Gynecology and Obstetrics (APGO)**, *Educational Series on Women's Health Issues*, focusing on Nausea and Vomiting of Pregnancy²
- The **New England Journal of Medicine** March 20, 2014 perspective *FDA Approval of Doxylamine–Pyridoxine Therapy for Use in Pregnancy*³
- The **Journal of Family Practice** February 2014 article, *Pharmacologic Management of Nausea and Vomiting of Pregnancy*⁴

We believe insurers should not require patients to fail on medications that are not FDA-approved for use in treating their health conditions when FDA-approved options are readily available.

Respectfully Submitted,

National Perinatal Association

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National Healthy Mothers, Healthy Babies Coalition

Janice Frey-Angel, CEO

Center for Medicine in the Public Interest

Peter Pitts, President

American Sexual Health Association

Deborah Arrindell, Vice President, Health Policy

² <https://www.apgo.org/education/women/nausea-and-vomiting-of-pregnancy.html>

³ <http://www.nejm.org/doi/full/10.1056/NEJMp1316042>

⁴ <http://www.jfponline.com/index.php?id=21913>

