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TO: New York State Academy of Nutrition and Dietetics
FROM: Hinman Straub P.C.
RE: Explanation of the New Law Revising the Enteral Formula Mandate
DATE: January 4, 2019

NATURE OF THIS INFORMATION: This memorandum explains a new law revising the enteral formula mandate.

DATE FOR RESPONSE OR IMPLEMENTATION: The law took effect on January 1, 2019 and applies to policies issued or renewed on and after that date.

HINMAN STRAUB CONTACT PEOPLE: Cheryl Hogan and Sean Doolan

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Category: #10 Miscellaneous/Other Suggested Key Word(s):

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On December 28, 2019, Governor Cuomo signed into law as Chapter 469 of the Laws of 2018 a bill relating to coverage of enteral formulas. As justification for the new law, the Sponsor's Amendment notes that Plans have been denying claims to treat conditions outside of those specifically cited in the law, despite clear language that states the list is not intended to be exhaustive. It also states that Plans have been denying claims for continued use of enteral formulas once a member's condition has stabilized. The amendments to the law are intended to address these concerns. The amendments to the law do not impact the products to which the mandate applies. Thus, the mandate will continue to apply to all policies that include drug coverage, including qualified health plans, the Essential Plan, and Child Health Plus. The mandate does not apply to self-funded business, Medicaid managed care, or Medicare products.

The law became effective on January 1, 2019, and applies to policies issued or renewed on and after that date. The provisions of the law are explained below.

1. Background

Health insurance policies that cover prescription drugs have been required to include coverage of enteral formulas for home use for the treatment of individuals who are or will become malnourished or suffer from disorders, which if left untreated, cause chronic physical disability, mental retardation or death, as well as coverage of modified solid food products for certain conditions, for over 20 years. Over this time period, the mandate has been revised a number of times. Most recently, the law was amended in 2013 to explicitly require coverage of enteral formulas via feeding tube as well as oral enteral formulas.

2. New Revisions to Mandate

The new law makes several changes to the mandate. First, and most significantly, it removes as a condition of coverage the requirement that an individual be or will become malnourished or suffer from disorders, which if left untreated, cause chronic physical disability, mental retardation or death. Under the revised law, enteral formulas for home use must be covered whenever a physician issues a written order stating that the formula is medically necessary and has been proven effective as a disease-specific treatment regimen.

Secondly, the new law makes several changes to the illustrative list of conditions for which enteral formulas have been deemed an effective treatment regimen. With respect to this list, the new law removes the qualification that gastroesophageal reflux be accompanied by "failure to thrive." Also, with respect to multiple, severe food allergies, the new law removes the condition that the allergies be ones "which if left untreated will cause malnourishment, chronic physical disability, mental retardation or death" and replaces it with two examples of such allergies - immunoglobulin E and nonimmunoglobulin E-mediated allergies to multiple food proteins.

The new law also adds the following conditions as examples of those for which enteral formulas have been deemed an effective treatment regimen:

- severe food protein induced enterocolitis syndrome;

- eosinophilic disorders; and
- impaired absorption of nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the gastrointestinal tract

Finally, the new law modifies the requirement to cover modified solid food products that are low protein or which contain modified protein for the treatment of certain inherited diseases of amino acid and organic acid metabolism. The new law also requires such coverage for the treatment of severe protein allergic conditions, and requires coverage of modified solid food products that are amino acid based.

Note that in amending the enteral formula mandate, the Legislature did not eliminate the \$2,500 annual limitation on coverage of modified solid food products, despite the fact that the Affordable Care Act prohibits annual dollar limitations on essential health benefits. Nevertheless, because coverage of modified solid food products is an essential health benefit in New York, federal law supersedes the state mandate and Plans cannot apply the \$2,500 limit.

3. Next Steps

Because the Department of Financial Services model subscriber contract language includes language that is inconsistent with the new law, Plans will be required to amend their contracts. DFS will be issuing revised model language shortly. For policies that have already been issued for 2019, Plans will have to administer the enteral formula mandate consistent with the new law despite the inconsistent contract language.