

## **Contract Formula Changes- Connecticut WIC Program**

### **Q & A**

**Effective October 1, 2016 the Connecticut WIC Program, as part of the required rebate contract, will begin issuing *Similac® Advance®* and *Similac® Isomil® Soy* as standard contract formulas.**

See below for questions and answers related to this formula change related to issuance, medical documentation, product availability and calorie density.

**Q: What is the formula contract and why do we get a rebate?**

A: Per federal regulations all WIC State agencies are required to go out to bid for milk/soy based standard formulas. Companies are required to provide a rebate on all of their standard milk/soy based formulas. The state receives a rebate for every can of contract formula redeemed by WIC participants. Currently CT WIC receives a rebate that is 100% of the purchase price.

The NEATO (Northeast States and Tribal Organizations) rebate contract (includes CT, MA, ME, NH RI and the ITOs) with Mead Johnson for Enfamil® products is expiring on September 30, 2016.

Beginning on October 1, 2016 the NEATO contract will be with Abbott Laboratories for *Similac® Advance®* and *Similac® Isomil Soy®*.

**Q: Why is Abbott changing their formulas? What is the research Abbott used as justification?**

A: The change in the standard dilution is being marketed by the company as an “innovation”, to make these formulas “more like breast milk”. They provided some research, which they claim that the energy of breastmilk averages closer to 19 calories/oz. than to 20 calories/oz. In reality, the energy density of breastmilk varies considerably during a feeding and changes in composition as the infant matures and his/her nutritional needs change. Of course, formula does not ‘adapt’ to infants’ needs.

**Q: What is Abbott changing about its formulas?**

A: There are 5 relevant changes:

1. Change in **caloric density from 20 kcal/oz. to 19 kcal/oz.** for *Similac® Sensitive®*, *Total Comfort®* and *Spit Up®*. (Note: *Similac® Advance®*, in container sizes not available through WIC. Will also be changing to 19 kcal/oz.).
2. Label change: The “shield” is being replaced with the “OptiGRO”, reflecting the inclusion of DHA, Lutein and vitamin E.
3. *Similac Sensitive®* concentrate is being discontinued and will no longer be available for purchase.

4. There are now "stages" in the Similac® Advance® line: Stage 1 (0-12 months), will remain at 20 kcal/oz.; Stage 2 (6-12 months); Stage 3 for toddlers (> 12 months); both at 19 kcal/oz. **Only Stage 1 will be available through WIC.**
5. Other changes to *Similac® Sensitive®, Total Comfort®* and *Spit Up®* powdered forms:
  - Scoop size for 19 kcal/oz. formulas will differ from scoop size for the 20 kcal/oz. formulas;
  - Can sizes are decreasing to 12.0 ounces;

Not changing:

- Reconstitution is not changing- all 3 products reconstitute to 90 oz., at standard dilution as do the "original" products.
- Number of cans/month – participants are eligible for the same number of cans per month; however, infants on the 19 kcal/oz. formulas will be receiving fewer calories = 90 kcals less per can.

**Q: Why does it matter that *Similac® Sensitive®, Total Comfort®* and *Spit Up®* formulas are changing to 19 kcal/oz.?**

A: There are three relevant points to understand:

1. Because these formulas provide 19 kcal/oz. they no longer meet the federal WIC regulations mandating that standard infant formulas provide about 20 kcals/oz. Consequently, these products can only be issued if medical documentation is provided.
2. Another potential concern is the lower caloric value of these products. For most healthy infants who are growing well, the reduced energy will likely not adversely affect growth. However, for infants whose growth is a concern, their weight gain should be followed.
3. If the infant was consuming the amount of formula needed to meet energy needs, he/she might increase formula consumption to compensate for the lower calories i.e. the family may need to purchase more formula each month.

**Q: Will Enfamil® Gentlelease® be available anymore?**

A: No. *Enfamil® Gentlelease®* is not an exempt formula and will no longer be available for issuance through Connecticut WIC after October 1, 2016. Participants receiving *Enfamil® Gentlelease®* will need to be transitioned from this product to one of the available alternatives for their October benefit issuance cycle. This means that if a participant has September benefits with a Benefits Start Date (BSD) of 9-18-16 and a Benefits Valid Through (BVT) date of 10-17-16 this is the last month of benefits that Gentlelease® will appear. The October benefits issuance with the BSD of 10-18-16 and a BVT date of 11-17-16, must be for one of the new available formulas. This means the Food Package (on the Food Prescription Screen), for these infants must be ended and changed to a new Food Package with one of the new formulas options, on or after October 1, 2016.

**Q: Do we need a Medical Documentation Form on file to issue *Similac® Sensitive®*, *Similac® Total Comfort®* or *Similac® for Spit Up®*?**

A: Yes, all three of these formulas will require a completed Medical Documentation Form for issuance. Therefore, as we advised in the July training webinars, it may be a good idea for those participants currently on *Enfamil® Gentlelease®* or *Enfamil® AR®*, to only be issued 1 or 2 month i.e. (through August or September's benefits in order to have a completed Medical Documentation Form in place (reviewed and scanned into CT-WIC) on or after October 1.

An updated, *Guidelines for Clinicians Regarding WIC Standard Contract Formulas and WIC Special Formula Processing* document will be available on-line under the Medical Providers page and the Formula Resources page. We advise that you also provide a copy of this guidance to participants at the same time you are requesting that their health care provider complete the Medical Documentation Form for any of the new 19 kcal/oz., formulas.

**Q: Are *Similac® Sensitive®*, *Similac® Total Comfort®* or *Similac® for Spit Up®* considered exempt or special infant formulas? Are they issued in Food Package III?**

A: No. Not for infants. These three (3) formulas are not exempt formulas, they are standard formulas that can be provided in Food Packages I and II. However, because they are all 19 kcal/oz. they require medical documentation for issuance.

For *Similac® Sensitive®*, *Similac® Total Comfort®* when the provider completes the WIC Medical Documentation Form, they will check a box to acknowledge they are prescribing a 19 kcal/oz. formulas. These two formulas DO NOT require a qualifying medical condition or ICD-10 code for issuance, but a provider can select one if it applies.

*Similac® for Spit Up®*, however will require an acknowledgement on the part of the provider regarding the product is 19 kcal/oz. AND a qualifying medical condition (ICD-10 code) such as Gastrointestinal Reflux or "Other".

In the Food Prescription Screen in CT-WIC, 5 formulas (with various physical forms) will be available for customization when the Core WIC Food Package populates upon clicking the "Add" button to Add a new row to the Food Prescription grid. *Similac® Advance®*, *Similac® Isomil® Soy*, *Similac® Sensitive®*, *Similac® Total Comfort®* and *Similac® for Spit Up®* will be available to select. Additionally, these formulas will also be available to select, when the child is > 1 year of age, when marking the Contract check box, prior to Adding a row to the Food Prescription grid.

Federal Regulations at: ii) *Non-authorized issuance of Food Package III*. This food package is not authorized for: (A) Infants whose only condition is: (1) A diagnosed formula intolerance or food allergy to lactose, sucrose, milk protein or soy protein that does not require the use of an exempt infant formula...

**Q: If an infant can't take food at 6 months, can they be provided *Similac® Sensitive®*, *Similac® Total Comfort®* and *Similac® for Spit Up®* in an increased amount (i.e. 4-5 month amount)?**

A: No. As stated above these 3 formulas are not exempt formulas, they are standard formulas that can be provided in Food Packages I and II. Only participants receiving Food Package III, who have documentation that they cannot take food, may receive increased amounts of formula. Therefore, only formulas that are available when the Prescription check box is marked on the Food Prescription Screen, can also have the 4-5 month check box selected.

**Q: Do infants receiving *Similac® Sensitive®*, *Similac® Total Comfort®* and *Similac® for Spit Up®* require high risk care plans?**

A: No, not necessarily. A high-risk care plan is based on the Nutrition Risk conditions that are assessed at the time of certification. These are standard formulas and infants receiving these formulas may or may not have Nutrition Risk factors assigned that confer high-risk status. In most case, infants receiving exempt or special formulas from WIC do have corresponding Nutrition Risk factors and ICD-10 diagnoses that would require close monitoring and/or developing a high-risk care plan by the Nutritionist.

**Q: What are some proactive steps local agencies can take to manage this transition?**

A: As mentioned above, local agencies may want to consider issuing 2 months of benefits (Aug-Sept; Sept-Oct) and have those participants that would need new WIC Medical Documentation Forms for October 1<sup>st</sup> return to the office with the completed form at their October visit. You may also want to conduct outreach to key pediatric providers about these changes and provide them with copies of the new forms and clinicians' guidance document and WIC outreach brochures.

**Q: How will the state be notifying health care providers?**

A: We have not done so yet, but in the coming weeks we will be working with our partner organizations to reach pediatricians and will have updated the Medical Providers and the Formula Resources page on the WIC website. In the interim, you can use the Guideline for Clinicians document locally to help communicate the changes.

**Q: What formulas will be available at hospitals?**

A: Abbott representatives have let us know that *Similac® Advance®*, *Similac® Isomil® Soy*, *Similac Sensitive®* will be available in hospitals.

**Q: When will these new products be available in stores?**

A: The new products will become available incrementally. Many of the powder and Ready to Feed versions of several of the products are on store shelves now. Concentrated *Similac® Advance®*, *Similac® Isomil® Soy* will be available by October 1, 2016.

**Q: How is the State agency planning to notify vendors/stores?**

A: We plan to notify vendors of these changes in a direct mailing before the end of August. Additionally we will be highlighting the changes in our next Vendor Bulletin slated for release in September. We are also in communication with representatives of our large chain stores corporate offices. We will update the information on the WIC website, Vendor page.

**Q: What should we tell participants?**

A: Some options or talking points:

- Continue to promote and support breastfeeding as you know, the more moms choose breastfeeding or breastfeed, the less formula may need to be issued.
- For those participants that will be issued the standard contract formula *Similac® Advance®*, *Similac® Isomil® Soy*, make sure they are aware that the WIC-approved *Similac® Advance®*, *Similac® Isomil® Soy* are in a different shape and size container than non-WIC approved *Similac® Advance®*, *Similac® Isomil® Soy*. All staff should have the tear-off pads with the new contract formulas to educate the Authorized Person and/or Caretaker.
- Discuss that for older infants on *Enfamil® Gentlelease®* they may want to transition directly to *Similac® Advance®* since they are older and perhaps now have a varied diet, they may be able to tolerate it.
- If this is not possible, obtain medical documentation required to provide *Similac® Sensitive®*, *Similac® Total Comfort®* 19 kcal/oz. formulas available. As a reminder, *Similac® for Spit Up®* requires both health care provider acknowledgement **AND** a qualifying medical condition on the WIC Medical Documentation Form.

If the Authorized Person wants or needs to have WIC provide these formulas, we suggest keeping it simple. Discussing the calorie content with moms directly may not be meaningful to parents, but they may have questions so be prepared with simple and direct answers.

- Only *Similac® Advance®*, *Similac® Isomil® Soy* will be available beginning on or after October 1<sup>st</sup> as WIC standard contract formulas.
- Although they did not need a completed Medical Documentation Form from their provider to get *Enfamil® Gentlelease®*, because of the new company (brand) and the changes made by the formula company, *Similac® Sensitive®*, *Similac® Total Comfort®* and *Similac®* will only be available with approval from their baby's doctor. As a reminder, *Similac® for Spit Up®* requires both health care provider acknowledgement **AND** a qualifying medical condition on the WIC Medical Documentation Form.
- Discuss the change in the can size and scoop for these formulas. Tell them that when they mix the formula according to the manufacturer's instructions on the can, it will make 90 ounces of formula for the can of powder.
- As before, if a Medical Documentation Form is obtained, it is valid for 6 months or shorter, based on what the health care provider indicates.

**Q: Why is it important to change the End Date of a Food Package on September 30, 2016?**

A: Since Mead Johnson products cannot be issued as benefits in Food Prescriptions (Food Packages) starting October 1, 2016, food packages with these products must be ended on September 30, 2016. Remember, the food packages drive what is issued for benefits.

Consider the following example:

If you have a participant with a current Food Prescription containing Enfamil Products with a Food Prescription End Date AFTER October 1, 2016 and for example, a Benefit Start Date (BSD) of 9/15/16 and they have an Enfamil Infant Food Package valid for that time period – 9/15/16 through 10/14/16, Enfamil Infant will be the benefits they are issued. This is OK, because these are the SEPTEMBER BENEFITS! They were issued in September (or before).

However, any benefits issued on or AFTER October 1, (i.e. the OCTOBER BENEFIT issuance) must be for the new standard contract formulas.

When you end the Enfamil Infant Food Package on September 30 (End Date column on Food Prescription Screen) and start a new row with an Effective Date of 10/1/16 for Similac Advance, the Food Package that will be issued for the BSD of 10/15/16 (OCTOBER BENEFITS) will be for Similac Advance. If you didn't change the End Date of the Enfamil Food Package, (i.e. STOP the Enfamil Infant Food Package) and add a NEW Food Package row starting on 10/1/16 then Enfamil Infant would be issued on the OCTOBER BSD of 10/15/16 and we'd be in breach of our contract.