

Abbott Formula Changes – Overview, Plan, and FAQ's

1/28/2014

Overview:

Abbott Nutrition is changing the caloric density of several of their formulas from 20 kcal/oz standard dilution to 19 kcal/oz. USDA sets standards for infant formulas that WIC can provide. The change in caloric density means they do not meet the standard and we cannot issue these new formulations unless they are both rebated **and** we get special medical documentation for their issuance.

Which formulas are impacted?

The three Abbott formulas impacted by this change include all forms (powder, concentrate and ready to feed/use) of:

- Similac Sensitive for Fussiness and Gas
- Similac Total Comfort
- Similac for Spit Up



What are the minimum requirements or specifications that USDA requires for WIC infant formulas?

Federal WIC regulations give the following minimum requirements and specifications for infant formulas:

- Must provide at least 20 calories per fluid ounce standard dilution
- Must provide at least 10 mg iron per liter standard dilution
- Must not require the addition of any ingredient other than water prior to being served
- Must meet the Food and Drug Administrations definition and requirements for infant formula
- Must be designed for oral or tube feeding use

The Plan:

What is Oregon going to do?

1. Oregon will continue to provide our standard milk-based formula – Similac Advance powder, concentrate or ready-to-feed. Enfamil Prosoabee will remain as Oregon's standard soy-based formula.
2. Since Oregon will likely not be getting a rebate on the 3 formulas that are changing, we will:
 - a. Stop any new assignment of Similac Sensitive for Fussiness and Gas or Similac Total Comfort formulas immediately. These formulas will be end-dated in TWIST February 1, 2014 so they will not be available for assignment after that date.
 - b. Stop assigning or issuing vouchers for Similac Sensitive for Fussiness and Gas or Similac Total Comfort formulas to any participant currently receiving them



beginning May 1, 2014. On 2/1/2014 TWIST will automatically change May and later formula assignments of Similac Sensitive and Similac Total Comfort to Similac Advance. This will prevent vouchers being issued for either of these formulas after April 30, 2014.

- c. Continue to provide Similac for Spit Up as a medical formula with appropriate medical documentation.

Is Similac Advance staying the same 20 kcal/oz?

Yes. By contract, Abbott must provide a milk-based infant formula that meets the required standard. That means there will not be a change in caloric density to the WIC size packaging: 12.4 oz powder, 13 fluid oz concentrate or 32 oz ready to feed.

What can we offer instead?

Most infants will be able to tolerate some form of the standard milk-based formula with guidance on how to change formulas gradually. Those that have a medical diagnosis may get a medical formula with the appropriate medical documentation. Oregon is not adding any other standard infant formulas at this time.

Use the *Baby Behaviors for Formula-fed infants: What is Normal and When to Refer?* tool for ideas of which formulas might be options to offer participants in different situations. Abbott Nutrition designed and marketed Similac Sensitive and Similac Total Comfort for healthy babies. Many caregivers choose Similac Sensitive or Similac Total Comfort because they could, as almost all babies are fussy, gassy, or spitting-up at times. Critical thinking about each family's particular set of circumstances and concerns will be essential. As always, doing a thorough assessment of the caregivers concerns, reviewing baby behaviors, and using participant centered skills such as active listening and reflections will be your primary tools.

Can we get samples of Similac Advance to provide to families that are transitioning?

Our current contract does not provide for distribution of formula samples. If your agency has returned formula available, it can be used to help with the transition. You must follow the guidance for issuing returned formula provided in Policy 735.

Can we assign one of these formulas if we have medical documentation from the health care provider?

No. WIC follows a "no exception" policy and will only issue current rebated standard formulas for healthy infants who are not fully breastfed. Medical documentation can be used to issue special medical formulas (e.g. Nutramigen, Alimentum) for infants with an underlying medical condition. Medical documentation for standard infant formulas will not be allowed.

Why can't we offer Good Start or Gentlease?

Neither of these formulas is rebated, so offering them would incur considerable cost to the program and impact our ability to serve our caseload. We no longer have that option.

How many participants does this change impact?

Approximately 6,500 infants across the state are currently assigned one of the 2 formulas being discontinued. This is approximately 40% of the formula fed infants on WIC.

How will we know who is on this formula?

We will send you a spreadsheet of the participants that had their formula assignment changed. To find out who in your agency is currently assigned one of these formulas, run the “Participant Use of Food Code” TWIST report. See the *TWIST Tips* document for specific instructions.

Which WIC staff can make formula changes?

All WIC staff will be involved in some way. TWIST will make the initial substitution of Similac Advance in the same form (powder, concentrate, or ready-to-feed) being replaced. Any WIC staff person can change forms of formula, e.g. from concentrate to powder. Only a CPA can assign a different formula. Your agency’s WIC nutritionist can help troubleshoot what are the best formula options in different circumstances and can discuss options with health care providers if needed.

How can we ensure that families currently using these formulas are prepared for the change?

Between now and May 2014, all caregivers providing these formulas will likely be seen. When they are in the office, they can be given a heads up about the change and offered guidance on changing formulas. Your agency will need to figure out how each of these families will be identified when they come in for their regular appointments.

- Which group settings are these participants most likely to attend?
- Could front desk staff flag vouchers for these formulas when they are printed?
- What situations would warrant a referral to the WIC nutritionist?

Additional support for you:

What will happen on the Food Package Assignment screen?

1. Similac Sensitive (SSF) or Similac Total Comfort (STC) will not appear on the formula drop down after February 1. This will keep staff from accidentally assigning these formulas to participants.
2. TWIST will find any participant assigned either Similac Sensitive for Fussiness and Gas (SSF) or Similac Total Comfort (STC) in May or later and will substitute Similac Advance. This gives participants currently using these formulas 3 months to transition to another formula and gives a firm end point for issuance. See the *TWIST Tips* document for more information.

What staff training materials are available?

1. Existing online training modules:
 - a. *PCS – Setting the Stage* (we highly recommend all staff review this new course as it reviews the basics of customer service)
 - b. *Baby Behaviors* (this course might help certifying staff work with caregivers to explore the reasons an infant may be fussy)

2. Sent along with this document:
 - a. *Baby Behaviors for Formula-fed infants: What is Normal and When to Refer?* (reviews which formulas might be offered in different situations)
 - b. *Using PCS During Formula Changes* (suggestions and sample wording to use when talking with parents and caregivers)
 - c. *TWIST Tips: Formula Changes for February - May 2014* (provides instructions for TWIST during the transition)
3. Coming in February
 - a. Discussion guide for staff (scenarios/case studies, participant handouts)

What participant education materials are available?

1. Baby Behaviors handouts from the [WIC website](#)
 - a. *Understanding Your Baby's Cues*
 - b. *Why Do Babies Cry?*
 - c. *Healthy Sleep: For You and Your Baby*
2. *Infant Formula changes in WIC* (describes how to “trial back” to a different formula)

How are health care providers going to learn about this change?

The State WIC office will send pediatricians and family practitioners a letter in February informing them of this change. You are the most important link with your local health care providers, so we will provide a sample letter for you to use with your local health care providers, community health nurses, and medical officer if needed.

What is a “warm line” and when would I use it?

The “warm line” is a phone line that will be staffed by state Nutrition Consultants during normal business hours during the months of the transition. We are confident that you can handle most questions locally and want to support your efforts. You can refer health care providers or participants with questions you don't feel prepared to answer to the “warm line” at 503-866-5106. Nutrition Consultants will be available to answer questions about formulas, USDA requirements or regulations, and help brainstorm options or solutions.

How are vendors handling this change?

The state Vendor Team is notifying vendors of what is changing and asking them to remove the affected pages from the *Formula Reference Guide* and adjust their stocking of Similac Advance. Vendors can only provide what is listed on the vouchers and these formulas will not appear after April.

Why are we choosing to make this change now?

The main reason is because Abbott has set a time frame when the formulation will change and the rebate will stop for these formulas. We need to make the transition as close to that time as possible.

The Science:

What are the reasons Similac Sensitive for Fussiness and Gas or Similac Total Comfort are being used?

Many infants go through periods of fussiness as a normal part of development. In some cases the fussiness may also be accompanied by brief periods of constipation, gas, or spitting up. Most grow out of these periods fairly quickly. Some health care providers react to a parent's concerns by suggesting they try a different formula. These two formulas are currently being offered as options.

I have heard that the decreased lactose in these formulas may help with these issues. Is that true?

According to the American Academy of Pediatrics (AAP), "In developed countries, even in the case of acute gastroenteritis, enough lactose digestion and absorption are preserved so that low-lactose and lactose-free formulas have no clinical advantages compared with standard lactose-containing formulas except in severely undernourished children, in whom lactose-containing formulas may worsen the diarrhea and lactose-free formulas may be advantageous. ... Although lactose-free cow milk-based formulas are readily available and popular, no studies have documented that these formulas have any clinical impact on infant outcome measures including colic, growth, or development."¹

What age would an infant likely develop lactose intolerance?

According to AAP "Lactose intolerance is a common cause of abdominal pain in older children and teenagers. Lactose intolerance attributable to primary lactose deficiency is uncommon before 2 to 3 years of age in all populations; when lactose malabsorption becomes apparent before 2 to 3 years of age, other etiologies must be sought."²

If not lactose reduced formula, is there a formula solution for fussy babies?

Generally, most of these behaviors are developmentally normal and babies will grow out of them in time. *Baby Behaviors for Formula-fed infants: What is Normal and When to Refer?* offers other evidence based solutions to consider in individual situations.

Background:

Why did Abbott make these changes?

According to marketing information from Abbott, the changes to their formulas are based on recent research regarding the caloric density of breast milk.

¹ Lactose Intolerance in Infants, Children, and Adolescents, Heyman, M. for the Committee on Nutrition, *Pediatrics*, 2006;118; 1279-1286

² Ibid.

Why is the rebate so important?

Besides being mandated by USDA, our program relies on the revenue we receive from the rebates to serve more WIC participants. Use of bid formulas supports approximately one quarter of the WIC caseload in Oregon. Continued use of the impacted formulas would cost Oregon approximately \$700,000 per month and greatly impact our ability to serve our caseload.

Will this change just impact Oregon families?

No, this change is happening across the country. Any WIC program using Abbott products will have the same issues. Oregon belongs to a large buying consortium, Western States Contracting Alliance (WSCA), which includes over 25 states across the country. Belonging to WSCA allows us greater flexibility and greater buying power than if we entered into a contract with Abbott by ourselves. The bid formula companies (Abbott for milk based formulas) and Mead Johnson (for the soy based formula) provides WIC with rebates from the revenue generated by the sale of these infant formulas.

What if I have other questions?

Talk with your WIC Coordinator or WIC nutritionist or call your agency's state Nutrition Consultant if you have questions.