Guidelines for prescribers in primary care:

Prescribing infant formula in cows’ milk protein allergy and lactose intolerance

Updated June 2015
Review date June 2017
Summary

1. Cumbria Clinical Commissioning Group (Cumbria CCG) promotes breastfeeding as the best form of nutrition for infants and this should be promoted/ supported wherever possible.

2. Infants with suspected non-IgE mediated cows' milk protein allergy (mild to moderate symptoms with delayed onset) can be managed in primary care.

3. Infants with severe symptoms or acute onset of symptoms should be referred to a paediatrician and dietitian. Prescribing can be initiated in primary care in the short term whilst waiting for specialist referral. If longer term use is required specialist opinion must be sought and there should be a clear plan for weaning and discontinuation included in the care plan from secondary care. Without written guidance to the contrary the recommended maximum ages detailed in this guidance should be applied.

4. In simple cases of secondary lactose intolerance, lactose free formula should be advised and lactose should be reintroduced after an avoidance diet of 4-8 weeks. Lactose intolerance is due to enzyme deficiency; it is not an allergy.

5. Lactose free milks can be bought at a similar cost to standard infant formula and prescribers should not routinely prescribe. Parents can purchase low lactose formula from their chosen retailer, however they are less commonly used and may have to be ordered. Most pharmacies and many supermarkets can obtain stock in a few days

6. Soya products should not be prescribed unless advised by a paediatrician or dietitian due to the high incidence of soya sensitivity in infants intolerant of cows’ milk protein (10-35%) and never under 6 months of age unless on specialist advice e.g. for galactosaemia. Infants of vegan mothers who choose not to breast feed may be given soya milks but not at NHS expense.

7. Powdered milks should be the norm. Liquid feeds are a convenience product and should be purchased if needed.
Introduction

This document is intended to be used in primary care by prescribers and other members of the primary healthcare team with the objective of:

• Aiding diagnosis and improving access to special infant formula where needed, minimising distress of the baby and anxiety to the parents/carers.
• Providing guidance on the nature, prescribing and cost effective supply of milk substitutes for babies by primary care.
• Providing advice on suitable quantities for prescribing, duration of supply and guidance on stopping prescribing.
• Maintaining awareness that breast milk is considered best for babies and not initiating a change from breast to formula milk if the mother is happy to continue breast feeding the infant.

This guidance is for local use in conjunction with NICE Clinical Guideline 116 and the MAP guideline (Milk Allergy in Primary care).

Whilst the public may be given access to this document it is not intended for use by parents or carers.

If an infant has problems with feeding, bowels, vomiting, sleep or settling, a feeding/symptom diary can be very helpful in clarifying symptoms and finding the cause. Parents/carers should be encouraged to photograph skin reactions to help the healthcare professional diagnose and assess severity of reaction.
Cows’ Milk Allergy, CMA

Cows’ milk protein allergy is classified according to the underlying cause:

- Immunoglobulin E (IgE)-mediated reactions are caused by the release of histamine and other mediators. The reactions are acute and frequently have a rapid onset (up to 2 hours after milk ingestion).

- Non-IgE-mediated reactions are thought to be caused by T-cells. The reactions are non-acute and generally delayed (manifest up to 48 hours or even 1 week after milk ingestion).

In all cases of suspected cows’ milk protein allergy an allergy-focused clinical history should be taken.

Mild to moderate non-IgE-mediated ‘delayed’ onset symptoms can be managed in primary care (with referral to a dietician for support) as described in the MAP algorithm below.

Severe non-IgE mediated CMA and IgE mediated CMA should be referred to a paediatrician and dietician. An extensively hydrolysed feed can be prescribed whilst awaiting referral, except in severe non-IgE mediated CMA where an amino-acid based feed should be prescribed.

More detailed information on the MAP guidance, including information about home challenge and reintroducing milk into the diet, can be found here:

http://cowsmilkallergyguidelines.co.uk/home/

Clinical Knowledge Summaries also includes information based on NICE guidance which can be found here:

Mild to Moderate Non-IgE-mediated CMA
- Mostly 2-72 hrs. after ingestion of Cow's Milk Protein
- Formula fed, exclusively breast fed or at onset of mixed feeding
- One, or often, more than one of these signs or symptoms:
  **Gastrointestinal**
  - ‘Colic’
  - Vomiting - ‘Reflux’ - GORD
  - Food refusal or aversion
  - Loose or frequent stools
  - Perianal redness
  - Constipation – especially soft stools, with excessive straining
  - Abdominal discomfort, painful flatus
  - Blood and/or mucus in stools in an otherwise well infant
  **Skin**
  - Pruritus, erythema
  - Significant atopic eczema
  **Respiratory**
  - ‘Catarrhal’ airway signs
  (usually in combination with one or more of the above signs or symptoms)

Extensively Hydrolysed Formula - eHF
Or – Advise exclusively breast feeding mother to exclude all Cow’s Milk Protein (CMP) from her own diet
See Management Algorithm

Severe Non-IgE-mediated CMA
- Mostly 2-72 hrs. after ingestion of Cow’s Milk Protein
- Formula fed, exclusively breast fed or at onset of mixed feeding
- One or more of these **Severe and Persisting** signs or symptoms:
  **Gastrointestinal**
  - Diarrhoea, vomiting, abdominal pain, food refusal or food aversion, significant blood and/or mucus in stools, irregular or uncomfortable stools.
  - +/- Faltering growth
  **Skin**
  - Severe Atopic Eczema +/- Faltering Growth
  **Cow’s Milk Free Diet**
  Amino Acid Formula - AAF
  Or-Advise exclusively breast feeding mother to exclude all Cow’s Milk Protein from her own diet and to take daily Calcium (1000mg) and Vitamin D (10mcg) supplements

Severe IgE CMA
ANAPHYLAXIS
- Immediate reaction with severe respiratory and/or CVS signs and symptoms.
(Rarely a severe gastrointestinal presentation)
- Or-Advise exclusively breast feeding mother to exclude all Cow’s Milk Protein from her own diet and to take daily Calcium (1000mg) and Vitamin D (10mcg) supplements
- IgE testing needed.
  - If diagnosis confirmed (which may require a Supervised Challenge) – Follow-up with serial IgE testing and later planned and Supervised Challenge to test for acquired tolerance
  - Dietetic referral required
  - If competencies to arrange and interpret testing are not in place - early referral to a paediatrician with an interest in allergy - advised

Mild to Moderate IgE-mediated CMA
- Mostly within minutes of ingestion of Cow’s Milk Protein
- Mostly formula fed or at onset of mixed feeding
- One or more of these signs or symptoms:
  **Skin**
  - Acute pruritus, erythema, urticaria, angioedema
  - Acute ‘flaring’ of atopic eczema
  **Gastrointestinal**
  - Vomiting, diarrhoea, abdominal pain/colic
  **Respiratory**
  - Acute rhinitis and/or conjunctivitis

Cow’s Milk Free Diet
Extensively Hydrolysed Formula - eHF
(Initial choice, but some infants may then need an Amino Acid Formula - AAF trial if not settling)
- Urgent referral to a paediatrician with an interest in allergy
- Urgent dietetic referral

Suspected Cow’s Milk Allergy (CMA) in the 1st Year of Life - having taken an Allergy-focused Clinical History

MAP Guideline for Primary and Secondary Care use

March 2015
**Management of Mild to Moderate Non-IgE CMA in Primary and Secondary Care**

**Exclusively Breast-Fed**

- **Strict Exclusion of Cow’s Milk containing foods from Maternal Diet**
  - Maternal supplements of Calcium (1000mg) and Vitamin D (10mcg) daily
  - Refer to dietitian; a maternal substitute milk should be advised, not soya or rice based
  - In cases with eczema or more severe gut symptoms – consider egg avoidance as well
  - If CMA - most symptoms will settle well within the agreed 2-4 week Elimination Diet

**No Improvement**

**Improvement - need to confirm Diagnosis**

- CMA still suspected: Need to consider other maternal foods e.g. egg
  - Refer to a paediatrician with an interest in allergy

- CMA no longer suspected: Return to usual maternal diet
  - Consider referral to general paediatricians if symptoms persist

**Formula-Fed or ‘Mixed Feeding’ (Breast and Formula)**

- **Strict Cow’s Milk Protein free Diet**
  - Formula-fed only - Trial of an Extensively Hydrolysed Formula (eHF) in infant
  - Mixed feeding - If symptoms only with introduction of top-up feeds - Replace with eHF top-ups - Mother can continue to consume cow’s milk containing foods in her diet

**No Improvement**

**Improvement - need to confirm Diagnosis**

- Perform Home Challenge using cow’s milk formula (to be done between 2-4 weeks of starting Elimination Diet)
  - Symptoms return
  - No return of Symptoms: NOT CMA

- Return to the eHF again.

- If symptoms settle:
  - CMA NOW CONFIRMED

- CMA still suspected:
  - Refer to a paediatrician with an interest in allergy
  - Consider a trial of AAF

- CMA no longer suspected:
  - Unrestricted diet again
  - Consider referral to general paediatricians if symptoms persist

**Cow’s milk free diet until 9-12 months of age and for at least 6 months – with support of dietitian**

A planned Reintroduction or Supervised Challenge is then needed to determine if tolerance has been achieved.

Performing a Reintroduction vs. a Supervised Challenge is dependent on the answer to the question:

**Does the child have Current Eczema or ANY history at ANY time of immediate onset symptoms?**

**No Current Eczema**

- And no history at any stage of immediate onset symptoms
  - (No need to check Serum Specific IgE or perform Skin Prick Test)
  - Reintroduction at Home – using a MILK LADDER
    - To test for Tolerance

**Current Eczema**

- Check Serum Specific IgE or Skin Prick Test to cow’s milk

**History of immediate onset symptoms at any time**

- Serum Specific IgE or Skin Prick Test needed

  **Negative**
  - Liaise with local Allergy Service Re: Challenge (or tests not available)

  **Positive**
  - Refer to a paediatrician with an interest in allergy
    - (A Supervised Challenge may be needed)
Breast fed infants (all suspected CMA)

Breast fed infants can display symptoms of CMA, though usually less severe, as some cows' milk proteins from the mothers diet may be expressed in breast milk. Mothers should be encouraged to continue feeding whilst following a dairy free diet and given additional calcium 1000mg and vitamin D 10 micrograms daily.

Babies should be weaned onto a cows’ milk free diet.
Referral to a paediatrician is indicated if symptoms are severe or if they do not resolve on a cow's milk free maternal diet.

Formula fed infants

Non-IgE-mediated CMA: ‘Delayed’ onset of symptoms

The symptoms of non-IgE mediated cows’ milk protein allergy are more extensive; see flow chart.
Note this list is not exhaustive – the absence of these symptoms does not exclude food allergy.

Mild to moderate symptoms

Infants should be given a cows’ milk protein free diet for at least six months until at least 9-12 months of age, using a suitable formula (extensively hydrolysed formula initially with consideration of amino acid formula if symptoms do not resolve).
Refer to a dietitian for support and advice on duration of treatment and the need for, and timing of, re-challenge to test if the allergy has resolved. Children are usually challenged at 9 – 12 months of age with varying degrees of success.
Most children grow out of their allergy by 18-24 months of age.

Infants and children should be referred to a paediatrician if symptoms do not resolve on extensively hydrolysed feeds, if symptoms are severe, or there are other medical conditions present.

Suitable products

Used from birth to maximum 24 months (longer only on advice of paediatrician/dietitian)

Requirement 4 - 14 x 400g/month
(wide range dependent upon age and size with highest requirement at 4-6months/before weaning).

Initial product choice should be the lowest cost product from within the appropriate group below at the time of prescribing.

Extensively hydrolysed formula (use first line unless symptoms are severe)

Althera from birth onwards
Aptamil Pepti 1 (Aptamil) up to 6 months of age.
Aptamil Pepti 2 (Aptamil) over 6 months of age.
Pepti Junior (Cow and Gate) birth onwards.
Nutramigen 1 (Mead Johnson) up to 6 months of age.
Nutramigen 2 (Mead Johnson) over 6 months of age.
Similac Alimentum from birth onwards

These guidelines are produced by the Dietetic Department at University Hospitals of Morecambe Bay NHS Foundation Trust, the Dietetic Department at North Cumbria University Hospitals NHS Trust, the Dietetic team at Cumbria Partnership NHS Foundation Trust, and the North of England Commissioning Support Unit Medicines Optimisation Team on behalf of Cumbria Clinical Commissioning Group, with input from NCUHT paediatrics dept.
Amino-acid based formula: Note that amino acid based formula should not be used first-line unless symptoms are severe such as children with enterocolitis/proctitis, food protein-induced enterocolitis syndrome (FPIES), faltering growth, severe atopic dermatitis, anaphylaxis, multiple allergies, exclusively breast fed and reacting or refusing/reacting to EHF.

Amino acid formulas include:

Alfamino (Nestle)
Neocate LCP (Nutricia).
Nutramigen Puramino(Mead Johnson).

These are the most commonly used products but this list is not exhaustive.

Prescriptions should be endorsed ‘ACBS’.

Severe symptoms

Referral to a paediatrician and dietitian is indicated if symptoms of non-IgE mediated CMA are severe, with an amino-acid based feed (see list above) being prescribed whilst waiting for referral appointment.

If symptoms were severe, cows’ milk protein challenges should be carried out under specialist supervision.

IgE mediated Cows Milk Protein Allergy (acute onset of symptoms)

Mild to moderate symptoms

Referral should be made to a paediatrician and dietitian for IgE testing and supervised cows’ milk protein reintroduction.
Products suitable for prescribing in primary care whilst waiting for referral are as listed under mild to moderate symptoms of non-IgE mediated CMA above.

Severe symptoms

Anaphylaxis. Emergency treatment and admission.

Cow’s milk reintroduction should be carried out under specialist supervision.

Stopping prescription formula

Any child still prescribed cows’ milk protein free milk by 2 years of age should be weaned onto supermarket bought milk. Seek dietitian advice about suitable products. **By 2yr prescription formula should no longer be needed.**

If parents/carers ask about the suitability of sheep or goats’ milk, they should be advised to avoid these products as many infants are likely to suffer an adverse reaction to them.
Lactose intolerance

THE PRESCRIBING OF INFANT FORMULA FEED IN SECONDARY LACTOSE INTOLERANCE IN PRIMARY CARE.

SIGNS & SYMPTOMS

- Diarrhoea.
- Colic.
- Transient nature, usually secondary to GI insult.
- Diagnosis confirmed by improvement within 2-3 days of starting lactose-free diet.
- Resolution within two weeks.

ACTION

Breast-fed infants:
Lactase Enzyme Drops (Colief) to be used when feeding.

Formula-fed infants:
Parents to purchase low lactose formula feed from chosen retailer.

TREATMENT

Breast-fed infants:
Lactase enzyme drops (eg Colief)
Dose: 4 drops per feed for 4-8 weeks or until can be gradually withdrawn without return of symptoms.

Formula-fed infants:
Low lactose formula:
- Aptamil Lactose Free
- Enfamil O-Lac
- SMA LF

Weaned infants:
Avoid solids containing lactose.
Offer referral to dietitian for dietary advice.

DURATION

- Lactose should be reintroduced after an avoidance diet of 4-8 weeks: gradually reintroduce usual formula/breast milk.
- May last 3 – 6 months.
- If longer term, use as necessary and refer to paediatric consultant and/or dietitian.

These guidelines are produced by the Dietetic Department at University Hospitals of Morecambe Bay NHS Foundation Trust, the Dietetic Department at North Cumbria University Hospitals NHS Trust, the Dietetic Team at Cumbria Partnership NHS Foundation Trust, and the North of England Commissioning Support Unit Medicines Optimisation Team on behalf of Cumbria Clinical Commissioning Group, with input from NCUHT paediatrics dept.
True lactose intolerance is due to deficiency of the enzyme, lactase; it is not an allergy.

Lactose is a disaccharide sugar found exclusively in milk. Absorption of lactose is dependent upon the enzyme lactase, which is found in the small intestine.

Secondary lactose intolerance follows insult to the intestinal mucosa - eg, acute gastroenteritis. It resolves when the disease process is over and the intestinal mucosa heals. It is more common in children.

Primary lactose intolerance doesn’t usually present until later childhood or adult life and is due to a reduced ability to produce lactase

Other reasons for lactose intolerance include: congenital lactase deficiency, an extremely rare autosomal recessive disorder where there is minimal, or no, lactase activity and symptoms emerge, usually intractable diarrhoea, once milk or lactose formula has been introduced; and developmental lactase deficiency which occurs in premature babies (<34 weeks of gestation) and improves once the intestine matures.

**Signs and Symptoms**

Symptoms of lactose intolerance include diarrhoea (the loose stools may be frothy) and colic which persists for more than 2 weeks, abdominal bloating, excessive flatulence, perianal redness and irritation and possibly damage to the perianal tissue. Vomiting can also occur. The symptoms are transient and usually secondary to a GI insult e.g. rotavirus infection. Blood or slime in the stools is not a feature of lactose intolerance.

**Breast fed infants**

Breast fed babies can sometimes get temporary lactose intolerance in the early days of breast feeding. Breast fed babies with lactose intolerance can be prescribed Colief at a dose of four drops per feed for 4-6 weeks or until symptoms have resolved. This should be added to 1 tsp/5ml of expressed breast milk in a sterile container and given on a sterile plastic spoon before breast feeding as normal.

Exclusion of lactose from the maternal diet is unnecessary as lactose is present in breast milk, independent of diet.

**Formula fed infants**

If symptoms are mild, Comfort lactose-reduced formula could be tried, purchased over-the-counter. The health visitor is likely to have suggested this already before advising GP appointment.

Lactose free formula can be purchased at a similar price to standard formula and the GP should not routinely prescribe; advice to use lactose free formula with appropriate safety netting may be all that is needed and parents should be asked to purchase the quantity required.

Symptoms usually resolve in 2-3 days when lactose is removed from the diet and achievement of this confirms diagnosis. Most children should be able to revert back to normal formula once the gastro-intestinal insult has resolved i.e. within 4-6 weeks. Lactose should be reintroduced after an avoidance diet of 4-8 weeks Challenge should be a very gradual re-introduction to ordinary formula if the child is less than 12 months old or to ordinary cows’ milk products if they are approaching or over 12 months of age. If re-challenge fails refer to a dietitian. Long term use is not usually necessary for lactose intolerance secondary to insult.
Referral should be made to a paediatrician and dietitian for all suspected primary lactose intolerance where there is significant weight loss or no improvement after withdrawal of lactose. Long term need for a lactose free diet requires dietetic referral.

Parents qualifying for Healthy Start vouchers can use their vouchers to purchase lactose-free infant formula milk that is based on cow’s milk and says on the packaging that it can be used from birth. Aptamil Lactose Free, Enfamil O-Lac and SMA-LF can be purchased with vouchers.

Vouchers cannot be used on infant formulas that are not based on cow’s milk, such as soya feeds or follow-on formula milks that say on the packaging that they are for babies aged six months or older.

### Stopping lactose free formula

Lactose free infant formula should not be used beyond 18 months and infants can be weaned onto proprietary lactose free milks purchased at supermarkets from 12 months old.

### Suitable products

Used from birth to maximum 12 months, unless advised by paediatrician or dietitian.

Requirement is 4 - 14 x 400g/month (wide range dependent upon age and size with highest requirement at 4-6 months/before weaning)

- Aptamil Lactose Free
- Enfamil O-Lac (Mead Johnson)
- SMA LF (SMA)

Parents should be asked to purchase the quantity needed.

Can use Lactofree or Alpro Soya 1+ Complete Care from 12 months - purchase from supermarket.

### Soya Based Formula

In 2004 the Chief Medical Officer issued a statement advising against the use of soya-based formula in infants even if they have cows’ milk protein allergy or lactose intolerance. This is due to its phyto-oestrogen content which could give hormonal side effects e.g. fertility problems in adulthood and the increased risk of sensitisation to soya protein which occurs in 3 out of 5 infants with cows’ milk protein allergy. This is especially important in infants under 6 months of age because milk is their only source of nutrition. Soya formula is not hypoallergenic and should not be used in preference to a hypoallergenic formula. They should not be used under 6 months of age unless advised by specialist team.

Use of soya milk should be limited to exceptional circumstances e.g. infants of vegan parents who are not breast feeding or infants that do not tolerate other special infant formulas. These parents should be advised of the risks so they can make an informed choice, and advised to purchase. Wysoy and Infasoy can be used over 6 months of age on specialist advice and can be purchased for the same cost as standard milks and therefore should not be prescribed.

(NB Healthy Start vouchers cannot be used to purchase infant formula based on soya milk)
Other specialist infant formula

Secondary care will lead in prescribing for several special groups of infants such as:

- Pre-term and low birth weight infants (may also require iron and vitamin supplements).
- Disease specific conditions.
- Complex food intolerances and allergies.
- Faltering growth.
- Complex medical cases.
- Cystic Fibrosis.

Dietitians may not be involved in the care of premature and low birth weight infants unless there are problems achieving optimal growth but are involved in the care of all other patients groups above; dietary requirements will be assessed and a formula will be chosen on an individual patient basis. All such prescribing should be initiated by secondary care. Once stabilised the GP will be informed and should take over the prescribing.

The letter from secondary care should include details of prescriptions needed, all planned monitoring and follow up intended and guidance for the GP on when the formula should be stopped.

Children with cystic fibrosis will be on vitamin supplements throughout their lives and on an individual basis determined by their hospital specialists.

Premature and Low Birth Weight Infants

In infants who are not fed on breast milk, or where supplementation of breast milk is required, a first stage preterm formula e.g. Nutriprem 1 will be prescribed whilst the infant is in hospital. This will be continued until the infant reaches 2000g or until 1 week before discharge, when the formula will be switched to second stage preterm formula e.g. Nutriprem 2, which can be prescribed in primary care. This should be discontinued at 6 months corrected age or before if excessive weight is gained or optimal growth and adequate dietary intake is achieved. Prescriptions should be endorsed 'ACBS'.

Once preterm formula is stopped parents/carers should purchase standard or follow-on formula. Infants will be followed up by a paediatrician and if necessary a dietitian until optimal growth is achieved. A dietitian may recommend an additional prescribable product if an infant is not gaining adequate weight.

Appropriate vitamins and iron supplements should also be prescribed after discharge as advised by the hospital until the infant reaches 1 year of age. Iron and folic acid are usually advised for preterm babies on breast milk and vitamins for all babies.

Nutriprem or SMA Gold Prem should not be prescribed in primary care to promote weight gain in term infants.
References


The MAP Guideline. Milk Allergy in Primary care. Available at: http://cowsmilkallergyguidelines.co.uk/home/


Acknowledgements:


The MAP Guideline Expert Group.
Appendix 1: Choosing an infant formula feed for lactose intolerance and cows’ milk protein allergy.

To be used in conjunction with NHS Cumbria guidelines “Prescribing infant formula in cows’ milk protein allergy and lactose intolerance”.

<table>
<thead>
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<th>Manufacturer</th>
<th>Characteristics</th>
<th>Indications</th>
<th>AgeRange</th>
<th>Available OTC</th>
<th>Size and price*</th>
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<tr>
<td>Comfort milks</td>
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<tr>
<td>Aptamil Comfort</td>
<td>Partially hydrolysed whey, protein, prebiotics, modified fat and thickeners</td>
<td>Birth to 1 year.</td>
<td>Yes</td>
<td>Not in MIMs</td>
<td>Price varies depending on retailer.</td>
</tr>
<tr>
<td>Cow &amp; Gate Comfort</td>
<td>Partially hydrolysed whey, protein, prebiotics, modified fat and thickeners Reduced lactose</td>
<td>Birth to 1 year</td>
<td>Yes</td>
<td>Not in MIMs</td>
<td>Price varies depending on retailer.</td>
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<tr>
<td>SMA Comfort</td>
<td>Partially hydrolysed whey, protein, prebiotics, modified fat and thickeners Reduced lactose</td>
<td>Birth to 1 year</td>
<td>Yes</td>
<td>Not in MIMs</td>
<td>Price varies depending on retailer.</td>
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<tr>
<td>Low lactose</td>
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<tr>
<td>Aptamil Lactose Free</td>
<td>Lactose Free</td>
<td>Lactose Intolerance</td>
<td>Birth to 1 year</td>
<td>Yes **</td>
<td>Not in MIMs Price varies depending on retailer.</td>
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<tr>
<td>SMA LF</td>
<td>Lactose free</td>
<td>Lactose intolerance</td>
<td>Birth to 1 year</td>
<td>Yes **</td>
<td>430g = £5.21 (£1.21/100g)</td>
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<tr>
<td>Enfamil O-Lac</td>
<td>Lactose free</td>
<td>Lactose intolerance</td>
<td>Birth to 1 year</td>
<td>Yes **</td>
<td>400g= £4.83 (£1.21/100g)</td>
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</table>

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<tr>
<td>Extensively Hydrolysed</td>
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<tr>
<td>Althera</td>
<td>Extensively hydrolysed whey</td>
<td>Diagnosis and management of CMPA.</td>
<td>Birth onwards</td>
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<td>Diagnosis and management of CMPA.</td>
<td>Birth to 6 months</td>
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<td>InfatriniPeptisorb</td>
<td>Extensively hydrolysed whey</td>
<td>Malnutrition in infants with whole protein and/or disaccharide intolerance, short bowel syndrome or bowel fistulae</td>
<td>Birth to 18 months (or 9kg)</td>
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<td>Nutramigen Lipil 1</td>
<td>Extensively hydrolysed casein</td>
<td>Diagnosis and management of CMPA.</td>
<td>Birth to 6 months</td>
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<td>Nutramigen Lipil 2</td>
<td>Extensively hydrolysed casein</td>
<td>Diagnosis and management of CMPA.</td>
<td>6 months onwards</td>
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<tr>
<td>Pepti- Junior</td>
<td>Extensively hydrolysed whey</td>
<td>Whole protein and/or disaccharide intolerance, short bowel syndrome or where amino acids/peptides indicated in conjunction with MCT</td>
<td>Birth onwards</td>
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<tr>
<td>Pepdite</td>
<td>Extensively hydrolysed pork collagen and soya</td>
<td>Whole protein and/or disaccharide intolerance, short bowel syndrome, bowel fistulae or protracted diarrhoea</td>
<td>Birth to 12 months</td>
</tr>
<tr>
<td>Pepdite 1+</td>
<td>Extensively hydrolysed pork collagen and soya</td>
<td>Whole protein and/or disaccharide intolerance, short bowel syndrome bowel fistulae or protracted diarrhoea</td>
<td>12 months onwards</td>
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<td><strong>Extensively Hydrolysed continued...</strong></td>
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<tr>
<td>Pregestimil Lipil</td>
<td>Mead Johnson</td>
<td>Extensively hydrolysed casein. 55% MCT</td>
<td>Birth onwards</td>
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<tr>
<td>Similac Alimentum</td>
<td>Abbott Laboratories Ltd</td>
<td>Extensively hydrolysed casein.</td>
<td>Birth onwards</td>
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<td><strong>Amino acid based</strong></td>
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<tr>
<td>Nutramigen Puramino (Nutramigen AA)</td>
<td>Mead Johnson</td>
<td>100% Amino Acid</td>
<td>Under 1 year</td>
</tr>
<tr>
<td>Neocate LCP</td>
<td>SHS</td>
<td>100% Amino Acid</td>
<td>0-12 months</td>
</tr>
<tr>
<td>Neocate Advance</td>
<td>SHS</td>
<td>100% Amino Acid</td>
<td>1 year onwards</td>
</tr>
<tr>
<td>Neocate Active</td>
<td>SHS</td>
<td>100% Amino Acid</td>
<td>1 year onwards</td>
</tr>
<tr>
<td>Neocate Spoon</td>
<td>SHS</td>
<td>100% Amino Acid</td>
<td>6 months onwards</td>
</tr>
<tr>
<td>Alfamino</td>
<td>Nestle</td>
<td>100% Amino Acid</td>
<td>From birth</td>
</tr>
</tbody>
</table>

These guidelines are produced by the Dietetic Department at University Hospitals of Morecambe Bay NHS Foundation Trust, the Dietetic Department at North Cumbria University Hospitals NHS Trust, the Dietetic team at Cumbria Partnership NHS Foundation Trust, and the North of England Commissioning Support Unit Medicines Optimisation Team on behalf of Cumbria Clinical Commissioning Group, with input from NCUHT paediatrics dept.
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Characteristics</th>
<th>Indications</th>
<th>Age Range</th>
<th>Available OTC</th>
<th>Size and price*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Soya-based</strong></td>
<td>Cow &amp; Gate</td>
<td>Galactosaemia Galactokinase deficiency. Not to be prescribed except on specialist advice</td>
<td>See notes below◊</td>
<td>Yes</td>
<td>900g = £8.14</td>
</tr>
<tr>
<td>Infasoy (Being discontinued July 2015)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wysoy</td>
<td>SMA</td>
<td>Galactosaemia Galactokinase deficiency. Not to be prescribed except on specialist advice</td>
<td>See notes below◊</td>
<td>Yes</td>
<td>430g = £5.20 860g = £9.91</td>
</tr>
</tbody>
</table>

List inclusive of products on the market at the time of writing.

* Prices taken from Monthly Index of Medical Specialities (MIMS) December 2014. Where infant formula can be bought OTC, prices may vary between different retailers. For up to date prices see latest edition of MIMs.

** Healthy Start vouchers can be used to purchase lactose-free infant formula milk that is based on cow’s milk and says on the packaging that it can be used from birth. SMA-LF and Enfamil O-Lac can be purchased with vouchers. Vouchers cannot be used on infant formulas that are not based on cow’s milk – such as soya formulas or follow-on formula milks that say on the packaging that they are for babies aged six months or older.

◊ Use of soya milk should be limited to exceptional circumstances e.g. infants of vegan parents who are not breast feeding or infants that do not tolerate other special infant formulas. These parents should be advised of the risks (See guidance) so they can make an informed choice. Wysoy and Infasoy can be used over 6 months of age on specialist advice and can be purchased for the same cost as standard milks and therefore should not be prescribed.
Detailed guidance about prescribing of formula in pre-term infants is not covered in this guidance. However, it should be noted that Nutriprem 1, Aptamil Preterm and SMA Gold Prem 1 should not be prescribed in primary care. Nutriprem 2 and SMA Gold Prem 2 can be continued in primary care (following moving to this second stage pre-term formula in hospital). This should be discontinued at 6 months corrected age or before if excessive weight is gained or optimal growth and adequate dietary intake is achieved.

<table>
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<tbody>
<tr>
<td>Aptamil Preterm</td>
<td>Milupa</td>
<td>Preterm/low birth weight infants in hospital</td>
<td>From birth until hospital discharge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutriprem 1</td>
<td>Cow &amp; Gate</td>
<td>Preterm/low birth weight infants in hospital</td>
<td>From birth until hospital discharge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMA Gold Prem 1</td>
<td>SMA Nutrition</td>
<td>Preterm/low birth weight infants in hospital</td>
<td>From birth until hospital discharge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nutriprem 2</td>
<td>Cow &amp; Gate</td>
<td>Preterm infants following discharge</td>
<td>Until 6 months corrected age. See above #</td>
<td></td>
<td>900g = £11.24</td>
</tr>
<tr>
<td>SMA Gold Prem 2</td>
<td>SMA Nutrition</td>
<td>Preterm infants following discharge</td>
<td>Until 6 months corrected age. See above #</td>
<td></td>
<td>400g = £5.18</td>
</tr>
</tbody>
</table>

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