



**Greater East Midlands
Commissioning Support Unit**

Greater East Midlands Commissioning Support Unit in association with
Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services,
United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

INFANT FEEDING FORMULARY For Cows Milk Protein Allergy and Lactose Intolerance

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**Compiled by:-
Katy McMillan, Paediatric Dietitian, United Lincolnshire Hospitals Trust
Cathy Johnson, Interface Lead Pharmacist, Greater East Midlands Commissioning
Support Unit**

Executive Summary

1. The NHS promotes breastfeeding as the best form of nutrition for infants and this should be promoted and supported wherever possible.
2. All cases of milk intolerance should usually be referred for specialist advice with the exception of simple cases of secondary lactose intolerance for which a lactose free formula should be advised and the child re-challenged with lactose in 2-3 months.
3. Lactose free milks can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe; however they are less commonly used and may have to be ordered. The CCGs support the position that an initial prescription is appropriate to allow parents time to source further supplies from the retailer of their choice. Most pharmacies and many supermarkets can obtain stock in a few days.
4. Consultants are asked to diagnose and the consultant or dietitian should advise on suitable formula and the length of treatment for all specialist infant formula.
5. Powdered milks should be the norm. Liquid feeds are a convenience product and should be normally purchased if needed.
6. Specialist milks other than those for lactose intolerance should not be initiated in Primary Care. Specialist lactose free formula should only be provided for a short time if initiated in Primary Care. If longer term use is required specialist opinion must be sought and there should be a clear plan for weaning and discontinuation should be included in the care plan. Without written guidance to the contrary the recommended maximum ages detailed in this guidance should be applied.
7. Soya products should never be prescribed for children under six months of age unless on specialist advice e.g. for galactosaemia. Children older than six months of age can be prescribed soya formula for lactose intolerance. Due to the high incidence of soya sensitivity in infants with a cow's milk protein allergy (10-35%) soya products should only be prescribed for these children following advice from a Consultant or Dietitian (infants of vegan mothers who choose not to breast feed may be given soya milks but not at NHS expense).

Introduction

The guideline has been produced at the request of GPs seeking clarity on the prescription of milk substitutes for babies and young children. Such products may only be prescribed in restricted circumstances for ACBS conditions. Prescribing doctors must be satisfied that there is a clear diagnosis and that the child is adequately monitored with support of hospital supervision if necessary.

This document is intended to be used by prescribers with the objectives of:

- Providing guidance on the nature, prescribing and supply of milk substitutes for babies by Primary Care,
- Maintaining an 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.

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

Scope

These guidelines have been produced by the Paediatric Dietetic Team within ULHT and the Prescribing and Medicines Optimisation Service within Greater East Midlands Commissioning Support Unit. The contents reflect the current research evidence available, guidance and good clinical practice. It is not intended to remove or reduce professional accountability, rather to support clinical and financial governance. Please note every effort has been made to ensure the information in this document is correct, however errors may occur and prices for individual products are subject to change between revisions. Where there is any doubt information should be checked with individual manufacturer's recommendations, published literature or other specialist sources. The Prescribing and Medicines Optimisation Service and ULHT Paediatric Dietitians will be happy to offer advice to prescribers if requested.

Paediatric Dietitians,
Nutrition and Dietetic Department,
Lincoln County Hospital,
LN2 5QY
Tel: 01522 573418

Prescribing and Medicines Optimisation Service
Cross o' Cliff Court
Bracebridge Heath
Lincoln LN4 2HN
Tel: 01522 515354

We recognise that infants often present to GP practices with suspected intolerance to their current infant formula and it is not always appropriate to wait for a diagnosis from Secondary Care referral but rather it is necessary to treat empirically.

Lactose intolerance

Primary Lactose Intolerance

Primary lactose intolerance can occur later in life as the ability to produce larger quantities of the enzyme lactase, is lost. Lactose intolerance can be a congenital condition, due to the absence of lactase but this is very rare and diagnosed soon after birth.

Secondary Lactose Intolerance

Secondary lactose intolerance is the most common form of lactose intolerance. There is a temporary deficiency of lactase due to damage caused to the bowel mucosa by an infectious gastrointestinal illness e.g. rotavirus infection.

Symptoms of lactose intolerance include diarrhoea and colic which persists for more than two weeks, abdominal bloating, increased wind, perianal redness and irritation and possibly damage to the perianal tissue. Vomiting and blood or slime in the stools are not a feature of lactose intolerance. Lactose intolerance should be suspected in children who have diarrhoea persisting for more than two weeks. Symptoms usually resolve in 2-3 days when lactose is removed from the diet. Diagnosis can be made if the diarrhoea resolves within two weeks of exclusion of lactose from the diet¹. Secondary lactose intolerance may also develop in some children with gut-related symptoms associated with non-IgE mediated cow's milk protein allergy, which resolves following exclusion of cow's milk protein.

Most children should be able to revert back to normal formula once the GI insult has resolved i.e. within 6- 8 weeks. Lactose free (LF) formula can be purchased at a similar price to standard formula and GPs should consider whether a prescription is actually necessary.

Long term use is not usually necessary for lactose intolerance secondary to infection. Primary lactose intolerance (PLI) can occur less commonly, in older children and adults, as the ability to produce lactase is lost. Long term need for a lactose free diet should require dietetic referral. LF 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.

Treatment

Many GPs will feel confident to manage post-gastroenteritis secondary lactose intolerance (SLI) without referral to secondary or specialist care. Infants should be given a lactose-free formula (listed below). SLI in infants usually lasts 6-8 weeks, so parents of children who have been weaned will also need to understand how to follow a low-lactose diet. A referral to a dietician is recommended if the low-lactose diet is to continue or if the GP feels that the parents will need specialist dietary advice.

Re-challenging for Lactose Intolerance

If infectious gastroenteritis was thought to be the cause of lactose intolerance (i.e. 'Secondary Lactose Intolerance') then the infant should be re-challenged with lactose after 6-8 weeks. This will mean gradually re-introducing their regular formula milk. If already weaned, gradually introduce lactose containing foods, followed by formula milk. Start by replacing one bottle of the lactose free formula with the regular formula and increase this over a number of days until all of the bottles are regular formula again. Advice from a specialist dietician may be required at this time.

Residual Lactose Formula to treat Lactose Intolerance					
Formula	Other information	Energy (kcal/100ml)	ACBS Indications	Size	Cost
Enfamil[®] O-Lac with Lipil	Gluten free Residual lactose	68	Proven lactose intolerance	400g	£4.70
SMA[®] LF	As above	67	As above	430g	£4.81

NB Products recommended for use are in bold
Prices based on October 2013 MIMS

Cow's Milk Protein Allergy (CMPA)

Allergy to Cow's milk protein (CMPA) should be suspected in infants who present with any of the symptoms in **Appendix One** in association with the introduction of cow's milk into their diet.

NICE guidelines² recommend that if food allergy from any cause is suspected, then an allergy focused clinical history should be taken, including family history and a physical examination conducted by a GP or other competent medical personnel. The risk of atopy increases if a parent or sibling has atopic disease (20-40% and 25-35%, respectively), and is higher still if both parents are atopic (40-60%)³.

Diagnosis

Diagnosis of non-IgE mediated CMPA can be made if symptoms resolve after 2-4 weeks on a cow's milk protein elimination diet. However, unless highly confident of the response to the elimination diet (parents often describe them as being a different child), a firm diagnosis can only be made if re-occurrence of symptoms has been demonstrated following a CMP re-challenge. This re-challenge should not be done in children who are thought to have acute IgE mediated allergy. In these children, allergy sensitisation tests should be undertaken to confirm a diagnosis of IgE mediated allergy. Specific IgE antibody testing to CMPA alongside total IgE can be undertaken by GPs who are confident in the interpretation of them. Alternatively, the child will need to be referred to Secondary Care: see NICE guidance² for advice regarding referral to Secondary Care.

Severe CMPA relates to children with anaphylaxis, respiratory difficulties and other systemic reactions to trace amounts of allergen, multiple food allergies, faltering growth, endoscopic / histologically confirmed enteropathy or severe colitis, iron deficiency anaemia due to GI blood loss and severe infantile eczema⁴.

Referral

Referral to a registered dietician with appropriate competencies is essential if a diagnosis of CMPA has been confirmed, to ensure nutritional adequacy, provide practical support and advise on re-challenging.

Treatment

Once the diagnosis has been confirmed they should be given a cow's milk protein-free diet for at least six months, with re-challenging usually undertaken around one year of age. Those children with a suspected or confirmed IgE mediated cow's milk protein allergy should be challenged in hospital. Many children grow out of their cow's milk protein allergy by 18-24 months of age.

Bottle-fed infants

Hypoallergenic formula (HAF) is required alongside referral to a dietician for practical advice on following the dairy-free diet to ensure nutritional adequacy is maintained and to advise on the re-challenging process.

Babies should be weaned at the usual time, 6 months, onto a cow's milk protein free diet and referral to a dietician should be made. They should continue on this until around 12 months of age when they should be re-challenged.

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Hypoallergenic Formula (HAF) to treat CMPA					
Formula	Other information	Energy (kcal/100ml)	ACBS Indications	Size	Cost
Similac Alimentum	Cow's milk protein free, gluten free and lactose free	67.6	Cow's milk allergy or other conditions where extensively hydrolysed formula indicated	400g	£9.10
Pepti[®] 1	Contains lactose and fish oil	67	Established cow's milk protein intolerance, with or without secondary lactose intolerance	400g	£9.54
				900g	£21.46
Pepti[®] 2	Contains lactose and fish oil	68	Established cow's milk protein allergy or intolerance. Not suitable for child under 6 months	900g	£20.48
Althera	Contains lactose	67	Cow's milk protein allergy, multiple food protein allergies	450g	£10.68
Nutramigen[®] Lipil 1	Gluten free Lactose free	68	Disaccharide and/or whole protein intolerance where additional medium chain triglycerides (MCT) not indicated	400g	£10.38
Nutramigen[®] Lipil 2	Gluten free Lactose free	68	Established whole protein sensitivity and/or disaccharide intolerance in patients over 6 months old	400g	£10.38
Pepti-Junior[®]	Residual lactose	66	Disaccharide and/or whole protein intolerance, or	450g	£12.19

	Contains fish oil		where amino acids and peptides are indicated in conjunction with MCT		
Pregestimil® Lipil	Gluten free and lactose free	68	As for Pepti-Junior	400g	£11.51

NB Products recommended for use are in bold
Prices based on October 2013 MIMS

Breast Fed Infants

Breast fed infants can display symptoms, though usually less severe, as some cow's milk proteins from the mother's diet may be expressed in breast milk. For these infants, mothers should be encouraged to continue to breast feed, as there are many benefits to be gained from this, whilst following a strict cow's milk protein free diet with calcium (1000mg elemental calcium) and vitamin D (10mcg vitamin D) supplementation Ref – Vandenplas et al 2007. Referral to a paediatrician is indicated to exclude other conditions. Liaison with a dietician is recommended as advice is likely to be required. If mothers are unable to follow a milk-free diet despite support from their GP and dietician, then careful consideration should be given as to whether breast-feeding should continue and, if not, the infant will require an Amino Acid Formula (AAF). They should not be given extensively hydrolysed formula (eHF) – as infants who react to breast milk are likely to react similarly to eHF.

An emergency back-up supply of formula (AAF if exclusively breastfed) should be considered, in case of sudden breastfeeding failure due to illness etc.

Babies should be weaned at the usual time, 6 months, onto a cow's milk protein free diet and referral to a dietician should be made. They should continue on this until around 12 months of age when they should be re-challenged.

Amino Acid based Formula (AAF) to treat CMPA					
Formula	Other information	Energy (kcal/100ml)	ACBS Indications	Size	Cost
Nutramigen® AA	Gluten free and lactose free	68	Severe cow's milk protein intolerance, multiple food intolerance and other GI disorders where an amino acid based diet is specifically indicated	400g	£25.58
Neocate® LCP	Milk protein free	70	Cow's milk allergy, multiple food protein intolerance and conditions requiring an elemental diet	400g	£27.40

NB Products recommended for use are in bold
Prices based on October 2013 MIMS

Re-challenging for CMPA

Children should be re-challenged after six months of CMP exclusion (usually around 12 months of age to see if they have outgrown CMPA). Whether the food challenge is done in hospital or at home will depend upon the type and severity of the food allergy (see below)

Cow's milk challenge at home

If there is no anticipated risk of an acute reaction i.e. the allergy is thought to be of a non-IgE mediated, with delayed onset pattern of symptoms, the challenge can be done at home. In infants with a strong personal or family history of atopy however, it may be prudent to undertake an IgE sensitisation test to CMP first, to ensure that their allergy has not evolved into IgE mediated allergy associated with a loss of tolerance following an extended period of complete CMP avoidance. It is best to plan the challenge when the child is well and stable. Cow's milk protein should be gradually introduced as tolerated, starting with small amounts of cow's milk for example a small fromage frais. Referral to a dietitian may be needed at this stage for assistance in this process, if the child is not already under the care of a dietician. If the re-challenge around 12 months of age is unsuccessful, then they should return to a cows milk protein free diet and the challenge should be repeated at six monthly intervals. Ingestion of small amounts of cow's milk protein e.g. in baked products, if tolerated should be encouraged, as it is thought to encourage development of future tolerance.

Cow's milk challenge in hospital

If there has been an immediate-type respiratory reaction or anticipated risk of a severe reaction, cow's milk will need to be re-challenged in hospital. As it is not possible to predict the severity of future reactions however, all children with a history of mild or moderate immediate-type reactions indicative of IgE mediated allergy, should be re-challenged in hospital, unless the consultant advises differently.

Many children with non-IgE mediated allergy will have outgrown their allergy by 18-24 months and most by 3-5 years of age⁶, although IgE mediated CMPA can persist into adolescence⁷. The older the child is the less likely it is that they will outgrow the allergy. If they are still allergic at five years of age the child should be given further challenges with CMP every 2 years until 9 years of age with a further challenge at 15 years of age.

Soya-based Formula

In 2004, the Chief Medical Officer issued a statement advising against the use of soya-based formula in infants under six months of age, with cow's milk protein allergy or lactose intolerance due to its phyto-oestrogen content, which could pose a risk to the long-term reproductive health of infants⁸. **The Committee on toxicity of Chemical in food (2009) recommended that soya based formula should only be consumed after six months of age. British Dietetic Association Paediatric group and ESPGHAN 12 recommended that an alternative HAF should be used first line.** Soya formula should not be used in infants during the first six months of life¹⁰.

There is also an increased risk of sensitisation to soya protein. Whilst only a small number of children with IgE mediated CMPA become sensitised to soya (8-14%),¹¹ up to 40% of children with non-IgE mediated CMPA can develop an allergy to soya.

Soya based formula should therefore not be prescribed unless advised by a competent healthcare professional. Parents wishing to feed their infant soya-based formula should be advised of the risks and instructed to buy the formula over the counter rather than have it prescribed. Use of soya formula should be limited to exceptional circumstances, e.g. for treatment of Galactosaemia, or where health professionals consider it to be the most suitable alternative for the management of cow's milk protein allergy or lactose intolerance in infants over six months of age.

Soya based Infant Formula (NB not for use in infants under six months old)					
Formula	Other information	Energy (kcal/100ml)	ACBS Indications	Size	Cost
Infasoy®	Lactose free	66	Proven lactose and associated sucrose intolerance in pre-school children, galactokinase deficiency, galactosaemia and proven whole cow's milk sensitivity	900g	£7.89
Wysoy®	Lactose free	67	As above	430g	£4.80
				860g	£9.14

NB Products recommended for use are in bold
Prices based on October 2013 MIMS

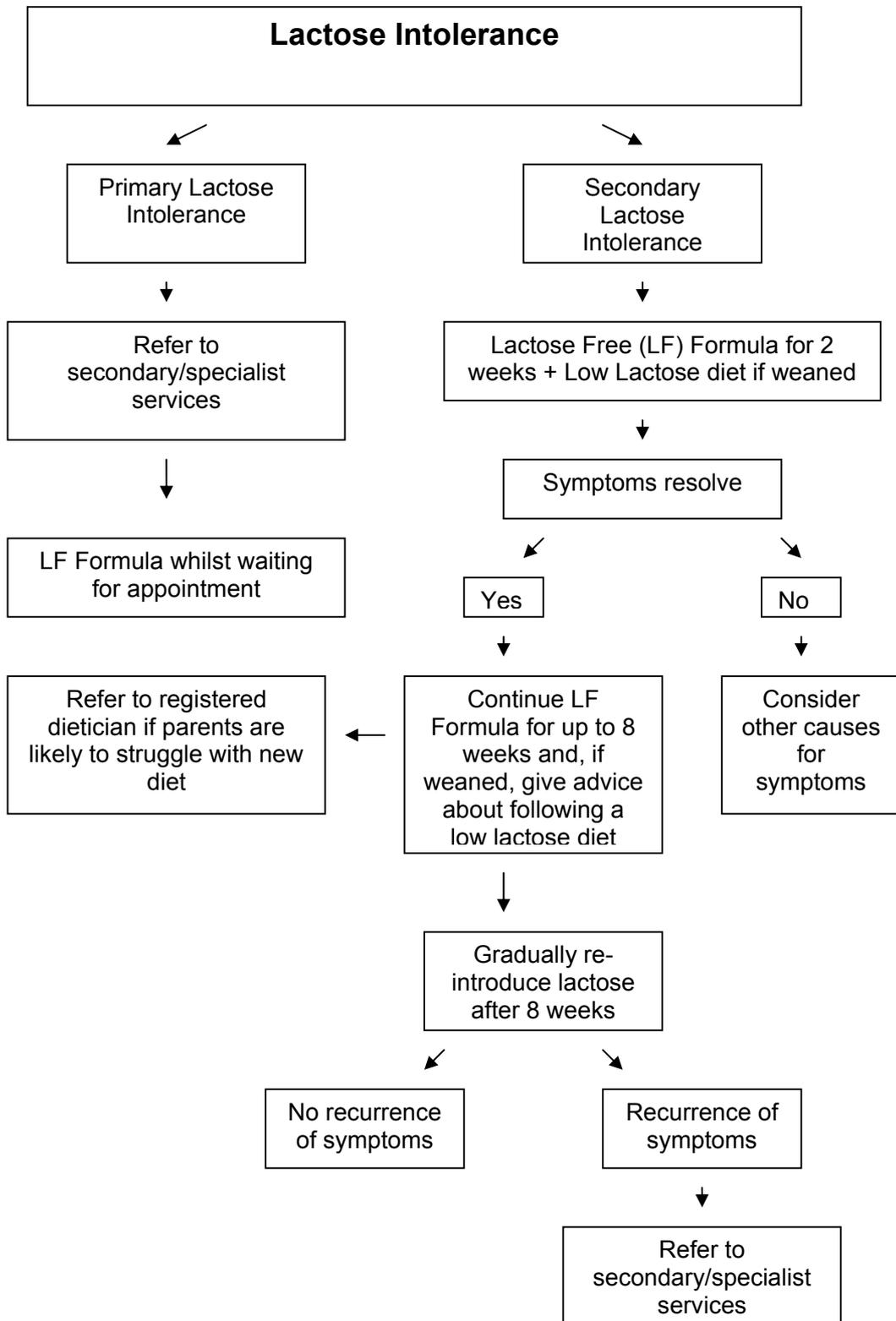
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10. ESPGHAN Committee on Nutrition, 2006. Soy protein formulae and follow on formulae: A commentary by the ESPGHAN Committee on Nutrition. *J Ped Gastroenterol Nutr*; **42 (4)**: 352-361.
11. Skapala and Venter 2009.

Appendix One

IgE- mediated	Non-IgE-mediated
<i>The Skin</i>	
Pruritus Erythema Acute urticaria (localised/ generalised) Acute angioedema (commonly lips, face & eyes)	Pruritus Erythema
Atopic eczema	
<i>The Gastrointestinal system</i>	
Angioedema of lips, tongue & palate Oral pruritus Nausea Colicky abdominal pain Vomiting Diarrhoea	Gastro-oesophageal reflux disease Loose or frequent stools Blood and/or mucus in stools Abdominal pain Infantile colic Food refusal or aversion Constipation Perianal redness Pallor and tiredness Faltering growth plus one or more gastrointestinal symptoms (with/ without significant atopic eczema)
<i>The Respiratory System (usually in combination with one or more of the above symptoms and signs)</i>	
Upper respiratory tract symptoms – nasal itching, sneezing, rhinorrhoea or congestion (with/ without conjunctivitis)	
Lower respiratory tract symptoms (cough, chest tightness, wheezing or shortness of breath)	
<i>Other</i>	
Signs or symptoms of anaphylaxis or other systemic allergic reactions	

Appendix Two



Appendix Three

