

Prescribing Guidelines for Specialist Infant Formula Feeds in Cow's Milk Protein Allergy And Lactose Intolerance

Adapted with permission from NHS Pan Mersey Prescribing
Guidelines for Specialist Infant Formula Feeds in Lactose
Intolerance and Cow's Milk Protein Allergy. November 2014

With acknowledgement to NHS Wirral Community Children's Dietetic Service, Wirral University Teaching Hospital NHS Foundation Trust, NHS Pan Mersey Area Prescribing Committee, NHS Wirral CCG, Midlands and Lancashire CSU, NHS Cumbria CCG, NHS Blackpool CCG, Staffordshire and Lancashire CSU, Lancashire Infant Feeding Board, Bridgewater Community Healthcare NHS Foundation Trust, Dietetics Department Alder Hey Children's NHS Foundation Trust

Publication date: April 2016 amended January 2017

Review date: April 2018

Contents

1. INTRODUCTION	3
2. SUMMARY	3
3. LACTOSE INTOLERANCE.....	7
3.1 Signs and Symptoms	7
3.2 Breast-fed infants.....	7
3.3 Formula-fed infants.....	7
3.4 Stopping lactose free formula	8
3.5 Suitable products	8
4. NON-IgE MEDIATED COWS' MILK PROTEIN ALLERGY (COWS' MILK PROTEIN INTOLERANCE)	8
4.1 Breast-fed infants.....	9
4.2 Formula-fed infants.....	9
4.3 Suitable products	9
4.4 Stopping prescription formula	10
5. IgE MEDIATED COWS' MILK PROTEIN ALLERGY	10
6. SOY BASED FORMULA	10
7. OTHER SPECIALIST INFANT FORMULA	10
8. PREMATURE AND LOW BIRTH WEIGHT INFANTS	11
9. QUANTITIES TO PRESCRIBE	12
10. LINK TO CHILDRENS DIETETIC TEAM REFERRAL.....	13
11. LINK TO BRITISH DIETETIC ASSOCIATION INFORMATION ON SPECIALIST MILKS FOR CMPA	13
12. REERENCES	13
13. ACKNOWLEDGEMENTS	13

N.B. OTHER SPECIALIST INFANT FORMULA

Secondary care and/or dietitians 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

These are outside of the scope of this guidance.

1. INTRODUCTION

The purpose of this guidance is to outline recommendations for the prescribing of infant formula feeds in cows' milk protein allergy and lactose intolerance in the Wirral area.

Breastfeeding is the best form of nutrition for infants and this should be promoted, supported and protected wherever possible.

This guidance covers all infants; including those who breastfeed, who are formula-fed or those who do a combination of both. For breast-fed babies who present with cows' milk protein allergy, breastfeeding should be protected as this is usually the best management. Specialist milks should only be considered when there is truly a clinical need after thorough assessment. Assessment should include and consider that formula feed products are being correctly prepared. The objectives of this guidance are to:

- Aid diagnosis and improve access to special infant formula where needed, minimising distress to the baby and anxiety to the parents/carers.
- Provide guidance on the nature, prescribing and cost effective supply of milk substitutes for babies.
- Provide 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 breastfeeding the infant.

This guidance should be used in conjunction with:

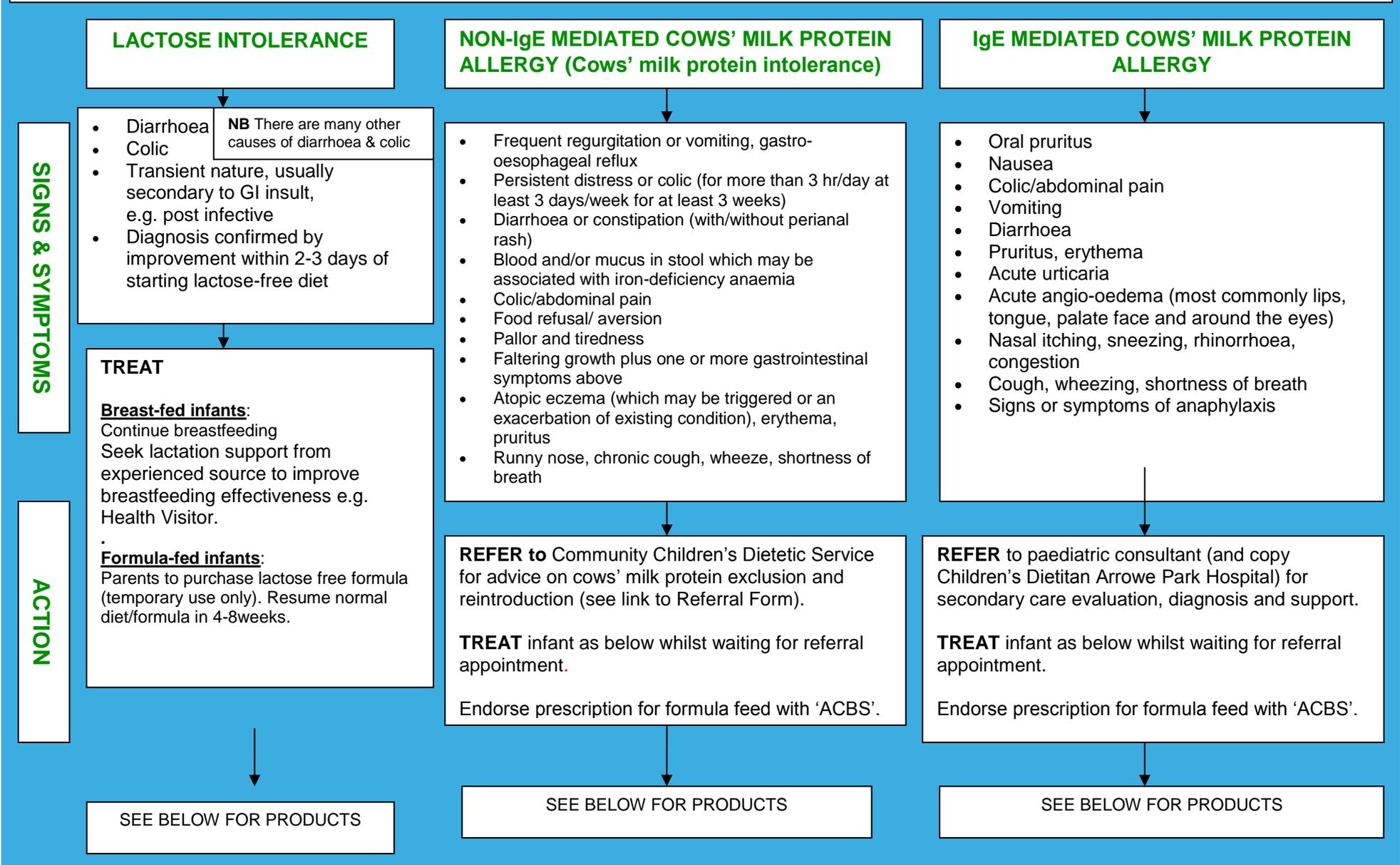
- [NICE Clinical Guideline 116, Food allergy in children and young people: Diagnosis and assessment of food allergy in children and young people in primary care and community settings,](#)
- [NICE Clinical Guideline 37, Postnatal care: Routine postnatal care of women and their babies](#)
- [NICE Quality Standard 37, Postnatal care.](#)
- [MAP Guideline 2013, Diagnosis and management of non-IgE-mediated cow's milk allergy in infancy - a UK primary care practical guide. Venter C et al. Clinical and Translational Allergy 2013; 3 :23. Accessed 27/10/2014. MAP Guideline 2013](#)

2. SUMMARY

- 2.1 In general, all cases of milk intolerance should be referred for specialist dietetic advice with the exception of simple cases of secondary lactose intolerance, for which a lactose free formula should be advised, and a re-challenge carried out in 4-8 weeks. Lactose intolerance is due to enzyme deficiency; it is not an allergy.
- 2.2 Lactose free milks can be bought at a similar cost to standard infant formula, and prescribers should not routinely prescribe. Parents can purchase lactose free formula from their chosen retailer; however they are less commonly used than standard formula and may have to be ordered. Most pharmacies and many supermarkets can obtain stock in a few days.
- 2.3 Soya products should **not** be recommended for purchase unless advised by a paediatric consultant or dietitian due to the high incidence of soya sensitivity (10-35%) in infants intolerant of cows' milk protein, and never for infants under 6 months of age unless on specialist advice e.g. for galactosaemia. Infants of vegan mothers who choose not to breastfeed should not receive soya formula on the NHS as products are available at the same cost as standard formula.
- 2.4 Paediatric consultants and/or dietitians are asked to advise on suitable formula and the length of treatment for specialist infant formula in all cases except secondary lactose intolerance.
- 2.5 Powdered milks should be the norm. Liquid feeds are a convenience product and should be purchased if preferred, unless they are clinically indicated by a dietician or specialist.

- 2.6 Infants requiring specialist milks other than those for lactose intolerance should be referred to a dietitian or paediatric consultant. Prescribing can be initiated in primary care in the short-term whilst waiting for specialist referral. If longer-term use is required dietitian/specialist opinion must be sought and there should be a clear plan for weaning and discontinuation included in the care plan from the dietitian/specialist. In the absence of written guidance to the contrary, the recommended maximum ages detailed in this guidance should be applied.
- 2.7 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.

THE PRESCRIBING OF INFANT FORMULA FEED IN LACTOSE INTOLERANCE and COWS' MILK PROTEIN ALLERGY



THE PRESCRIBING OF INFANT FORMULA FEED IN LACTOSE INTOLERANCE and COWS' MILK PROTEIN ALLERGY

LACTOSE INTOLERANCE

Lactose free formula:

e.g.
Aptamil Lactose Free
Enfamil O-Lac
SMA LF
To be purchased Over the Counter (OTC)

Infants taking solid foods:

Avoid solids containing lactose.
Suitable replacement products are available. Avoid lactose-containing medicines.

NON-IgE MEDIATED COWS' MILK PROTEIN ALLERGY (Cows' milk protein intolerance)

Breast-fed infants:

Continue breastfeeding.
Consider exclusion of cow's milk products from mother's diet (advise a calcium supplement if mother remains on dairy-free diet long term)

Formula-fed infants*:

Trial of extensively hydrolysed feed (hypo-allergenic milk formulas) for 4 weeks.
e.g. Similac Alimentum

If not resolved, or if the reaction is very severe, trial an amino acid formula for further 4 weeks: e.g. Alfamino

***Children with enterocolitis/ proctitis or blood in stools with faltering growth, severe atopic dermatitis and symptoms during exclusive breastfeeding are more likely to require amino acid based formula.**

Following referral a home challenge to confirm or rule out diagnosis of CMPA will be carried out by Community Children's Dietetic Service.

Following specialist confirmed diagnosis, children are usually re-challenged around 12 months of age to determine when tolerance is achieved. Specialist formula may be necessary until 18-24 months of age or longer on advice of dietitian/paediatric consultant.

IgE MEDIATED COWS' MILK PROTEIN ALLERGY

Breast-fed infants:

Continue breastfeeding.
Consider exclusion of cow's milk products from mother's diet (advise a calcium supplement if mother remains on dairy-free diet long term)

Formula-fed infants*:

Trial of extensively hydrolysed feed (hypo-allergenic milk formulas) for 4 weeks.
e.g. Similac Alimentum

If not resolved, or if the reaction is very severe, trial an amino acid formula for further 4 weeks: e.g. Alfamino

***Children with worrying symptoms including potential anaphylaxis, oral angioedema and severe skin reaction should be treated with amino acid based feed as initial treatment.**

Following specialist confirmed diagnosis, children are usually re-challenged around 12 months of age to determine when tolerance is achieved. Specialist formula may be necessary until 18-24 months of age or longer on advice of dietitian/paediatric consultant.

TREATMENT

DURATION

- Most infants should be able to revert to a normal diet in 4-8 weeks: gradually reintroduce usual formula/breast milk.

- If longer term dietary restriction is necessary refer to dietitian and/or paediatric consultant.

3. LACTOSE INTOLERANCE

True lactose intolerance is due to deficiency of the enzyme lactase; it is not an allergy. Primary lactase deficiency is genetic and doesn't usually present until later childhood or adult life and is due to a reduced ability to produce lactase; it is the most common cause of lactose intolerance. Infants are more likely to have one of the following:

- Secondary, acquired, or transient lactase deficiency which is caused by an injury to the small intestine, from acute gastroenteritis, diarrhoea, chemotherapy, intestinal parasites or other environmental causes.
- Congenital lactase deficiency, which is a very rare, autosomal recessive genetic disorder that prevents lactase expression from birth. People with congenital lactase deficiency are unable to digest lactose from birth, and they are unable to digest breast milk.

3.1 Signs and Symptoms

Symptoms of lactose intolerance include diarrhoea (the loose stools may be frothy), 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 gastrointestinal (GI) insult e.g. rotavirus infection. Blood or slime in the stools is not a feature of lactose intolerance.

3.2 Breast-fed infants

Breast-fed babies can sometimes get temporary lactose intolerance. Breast-fed babies with lactose intolerance can be given lactase enzyme drops (e.g. *Colief*). Wirral does not recommend prescribing lactase enzyme drops on the NHS but they may be purchased. Lactase enzyme drops should be added at a dose of four drops per feed to 1 tsp/5ml of expressed breast milk in a sterile container, and given to the infant for 4-6 weeks or until symptoms have resolved. In individual patients where lactose intolerance is a longer-term condition and it has been confirmed by testing, it may be considered for prescribing on the NHS (prescription endorsed "ACBS"). Such prescribing should be reviewed for continued clinical need at regular intervals.

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

Continuation of breastfeeding, to speed the healing of the gut, should be encouraged.

More severe symptoms which do not resolve with the first line management described require specialist review. Seek specialist advice e.g. dietitian, health visitor or breastfeeding adviser.

3.3 Formula-fed infants

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

Lactose free formula can be purchased at a similar price to standard formula and the GP should not prescribe; where parents wish to trial lactose free formula then advice on how to use it, information about possible risks (e.g. to dental health due to exposure to glucose) and appropriate checking for other complicating factors may be all that is needed.

Residual lactose infant formula (e.g. comfort formula milk) has not been proven to be effective in managing temporary lactose intolerance, and so should not be recommended.

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 gastrointestinal insult has resolved i.e. within 6-8 weeks. The child should be re-challenged with dairy 2-4 months later. 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, revisit the diagnosis and if necessary refer to a dietitian explaining reasons. Long-term use is not usually necessary for lactose intolerance secondary to insult.

Referral should be made to a paediatric consultant 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 cows' milk and says on the packaging that it can be used from birth. For example, SMA-LF and Enfamil O-Lac can be purchased with vouchers.

Vouchers cannot be used to purchase infant formulas that are not based on cows' 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.

3.4 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.

3.5 Suitable products

Used from birth to maximum 12 months, unless advised by paediatric consultant or dietitian. Parents should be asked to purchase the quantity needed.

Requirement is 4-14 x 400g/month (wide range dependent upon age and size with highest requirement at 4-6months/before weaning) – see section 9.

Examples of lactose free formula:

Aptamil Lactose Free
Enfamil O-Lac
SMA LF

Full cream equivalent lactose-free milk, can be used from 12 months of age. This is to be purchased from a supermarket. Ensure good calcium intake if cows' milk and milk products are excluded.

4. NON-IgE MEDIATED COWS' MILK PROTEIN ALLERGY (COWS' MILK PROTEIN INTOLERANCE)

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.

4.1 Breast-fed infants

Breast-fed infants can display symptoms, though usually less severe, as some cows' milk proteins from the mothers diet may be found in breast milk. Mothers should be encouraged to continue feeding and may need to follow a dairy-free diet (ensure good calcium intake). Mothers should be advised to use a calcium supplement if they remain on a dairy-free diet long term. Babies should be weaned onto a cows' milk-free diet. Infants should be referred for diagnosis, dietitian support and advice on duration of treatment and the need for and timing of re-challenge to test if the intolerance has resolved. With a specialist confirmed diagnosis, children are usually challenged from 12 months of age with varying degrees of success. Many children grow out of their intolerance by 18-24 months of age.

4.2 Formula-fed infants

Infants should be given a cows' milk protein-free diet until at least 12 months of age, supplemented with a suitable infant formula until 18-24 months of age. Infants should be referred for diagnosis, dietitian support and advice on duration of treatment and the need for and timing of re-challenge to test if the intolerance has resolved. With a specialist confirmed diagnosis, children are usually challenged around 12 months of age with varying degrees of success. Many children grow out of their intolerance by 18-24 months of age.

Infants and children should also be referred to a paediatric consultant if growth/weight gain is not satisfactory on the special diet, if symptoms are severe or there are other medical conditions present.

If symptoms of non IgE-mediated CMA are severe cows' milk protein challenges should be done under specialist supervision.

4.3 Suitable products

Used from birth to usual maximum of 2 years (longer only on advice of paediatric consultant/dietitian).

Requirement 4-14 x 400g/month

(wide range dependent upon age and size with highest requirement at 4-6 months/before weaning).

Examples of extensively hydrolysed formula include:

Althera

Aptamil Pepti 1 up to 6 months of age*

Aptamil Pepti 2 over 6 months of age*

*Aptamil Pepti contains some lactose and may not be suitable for infants with secondary lactose intolerance

Nutramigen LGG 1 up to 6 months of age

Nutramigen LGG 2 over 6 months of age

Similac Alimentum

Examples of amino acid formula include:

Alfamino

Neocate LCP

Nutramigen PurAmino

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

Children with enterocolitis/proctitis with faltering growth, severe atopic dermatitis and symptoms during exclusive breastfeeding are more likely to require amino acid based formula.

Prescriptions should be endorsed 'ACBS'.

4.4 Stopping prescription formula

Any child still prescribed specialist formula by 2-3 years of age should be weaned onto supermarket bought milk e.g. calcium enriched soya milk. **By 2-3 years of age prescription formula should no longer be needed in the majority of children; however in some circumstances it may still be necessary beyond this age if advised by a dietitian.**

As the proteins in sheep, goats and other mammalian milk are similar to cows' milk, most infants will also react to these and so they are not normally recommended.

5. IgE MEDIATED COWS' MILK PROTEIN ALLERGY

Much of the information for non-IgE mediated cows' milk protein allergy applies, however cows' milk protein reintroduction should be managed by secondary care, possibly with allergy testing and admission to hospital day care for oral challenge.

6. SOY BASED FORMULA

In 2004 the Chief Medical Officer issued a statement advising against the use of soy 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 soy 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. Soy 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 soy milk should be limited to exceptional circumstances e.g. infants of vegan parents who are not breastfeeding 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.

Products such as SMA Wysoy can be used over 6 months of age on specialist advice and can be purchased for the same cost as standard formula and therefore should not be prescribed on the NHS.

7. OTHER SPECIALIST INFANT FORMULA

Dieticians/specialists 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

Dieticians 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 a dietitian/specialist. Once stabilised the GP will be informed and should take over the prescribing.

The letter from dietitian/specialist 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.

8. 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.

A Cochrane review has found no substantiation for the use of 'post-discharge' formula, such as Nutriprem 2 (74kcal/100ml) over normal proprietary brand 'first stage' infant formulae. Therefore they should not normally be prescribed post discharge on the NHS, although some very premature babies will not thrive on standard formula and, where they provide demonstrable benefit, post-discharge formula may be prescribed.

Once preterm formula is stopped, parents/carers should purchase standard 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 should not be prescribed in primary care to promote weight gain in term infants.

9. QUANTITIES TO PRESCRIBE

When any infant formula is prescribed the guide below can be used:

For powdered formula: Age of child	Number of tins for 28 days	
Under 6 months	4-14 x 400g tins or 2-7 x 900g tins	
6-9 months	8 x 400g tins or 4 x 900g tins	
9-12 months	6 x 400g tins or 3 x 900g tins	
Over 12 months – dietitian review for continued need for formula	6 x 400g tins or 3 x 900g tins	

At initial prescription prescribe a smaller quantity in case there are palatability issues, to reduce potential wastage

NB some children may require more e.g. those with faltering growth. This table provides **guidance** only.

10. Link to Community Children's Dietetic Team Referral:

http://www.wirralct.nhs.uk/images/Paediatric_Dietetics_referral_form_Nov_2014.doc

11. Link to British Dietetic Association Information on specialist milks for CMPA (Patient Information Leaflet):

<http://www.dba.uk.com/foodfacts/CowsMilkAllergy/Children.pdf>

12. REFERENCES

1. National Institute for Health and Clinical Excellence. Postnatal care: Routine postnatal care of women and their babies. NICE Clinical Guideline 37, July 2006. Accessed 27/10/2014. [Postnatal care: Routine postnatal care of women and their babies.](#)
2. National Institute for Health and Clinical Excellence. Postnatal Care. NICE Quality Standards 37, July 2013. Accessed 27/10/2014. [Postnatal Care](#)
3. First Steps Nutrition Trust. Infant Milks in the UK, A practical guide for health professionals, June 2013. Accessed 27/10/2014. [Infant Milks in the UK, A practical guide for health professionals](#)
4. First Steps Nutrition Trust. Specialised infant formula in the UK: Additional information for health professionals, Draft March 2013. Accessed 27/10/2014. [Specialised infant formula in the UK: Additional information for health professionals](#)
5. Young L, et al. Nutrient-enriched formula versus standard term formula for preterm infants following hospital discharge (Review). The Cochrane Library 2012, Issue 3. Accessed 27/10/2014. [Nutrient-enriched formula versus standard term formula for preterm infants following hospital discharge \(Review\)](#)
6. World Health Organisation. International Code of Marketing of Breast-milk Substitutes. 1981 Accessed 27/10/2014 [International Code of Marketing of Breast-milk Substitutes.](#)
7. National Institute of Health and Clinical Excellence. Food allergy in children and young people. Diagnosis and assessment of food allergy in children and young people in primary care and community setting. NICE Clinical Guideline 116, February 2011. Accessed 27/10/2014. <https://www.nice.org.uk/Guidance/CG116>.
8. Department of Health 2009. Birth to Five. Accessed 27/10/2014 [Birth to Five](#)
9. British Dietetic Association. Paediatric Group Position Statement on the use of Soya Protein for Infants, February 2004. J Fam Health Care. 2003;13(4):93. Accessed 27/10/2014. [BDA Soya Protein Infants](#)
10. Department of Health. Advice on preparation of formula milks restated. January 2013. Accessed 27/10/2013 [Advice on preparation of formula milks restated](#)
11. Department of Health. Healthy Start Vouchers. Accessed 27/10/2014: [Healthy Start](#)
12. Department of Health. [Chief Medical Officers Update 37. January 2004](#). Advice issued on soya-based infant formulas.
13. MAP Guideline 2013, Diagnosis and management of non-IgE-mediated cow's milk allergy in infancy - a UK primary care practical guide. Venter C et al. Clinical and Translational Allergy 2013; 3:23. Accessed 27/10/2014. [MAP Guidelines](#)

13. ACKNOWLEDGEMENTS

NHS Wirral Community Children's Dietetic Service, Wirral University Teaching Hospital NHS Foundation Trust, NHS Wirral CCG, Midlands and Lancashire CSU, NHS Cumbria CCG, NHS Blackpool CCG, Staffordshire and Lancashire CSU, Lancashire Infant Feeding Board, Bridgewater Community Healthcare NHS Foundation Trust, Dietetics Department Alder Hey Children's NHS Foundation Trust