

Prescribing Guidelines for Specialist Infant Formula Feeds

Midlands and Lancashire CSU.

Contributors to the document:

Carol Pinder, Lancashire Teaching
Hospitals NHS Foundation Trust

(Original version of the document was
contributed to by Julie Lonsdale, Midlands
and Lancashire CSU and Melanie Preston,
Blackpool CCG)

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VERSION CONTROL

Version Number	Date	Amendments made
1	October 2013	
2	October 2014	Amended to be clearer around when formula feeds are okay to be prescribed on FP10. Amendments to the section on pre-term and low weight infants to allow prescribing of PDF in some instances. Corrections to say lactose free. Addition of other formula brands.
2.1	Nov 2014	Removal of LIFIB as contributors
3	December 2017	Guideline updated to reflect new MAP guideline. More information to support prescribing added.
3.1	January 2018	Nutramigen LGG 1 and 2 removed from the table in section 4.1 as reconstitution instructions for these products not consistent with WHO recommendations for the preparation of formula feeds.

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1. INTRODUCTION

The purpose of this guidance is to outline recommendations for the prescribing of specialist infant formula milk within primary care in Lancashire.

Lancashire promotes breastfeeding as the best form of nutrition for infants and this should be promoted, supported and protected wherever possible.

Most of the infant formulas prescribed in primary care are those to treat cow's milk protein allergy (CMA) therefore this document focuses on these infant milks. There is a separate summary table in section 8 for other specialist infant milks.

1.1 Exclusion criteria

Secondary and tertiary care will continue to lead on the prescribing of other specialist infant formulas for the following groups of patients; these are outside the scope of this guideline:

- Preterm and low birth weight infants who may also require iron and vitamin supplementation
- Disease specific conditions e.g. inherited disorders of metabolism, renal disease, liver disease, cardiac disease, cystic fibrosis, oncology
- Complex / multiple food allergies and intolerance
- Faltering growth
- Complex medical cases e.g. infants requiring enteral tube feeding or the ketogenic diet

All such prescribing should be initiated by secondary care. Once stabilised the GP will be informed (and given clear instructions on the indication, goals and length of treatment, as required) 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.

1.2 Background

Cows' milk protein allergy is an immune-mediated allergic response to the proteins in milk. It can be immediate in onset following consumption, referred to as IgE mediated or a non-IgE mediated reaction when the presentation is delayed by hours or even days following exposure.

Food allergy should not be confused with food intolerance, which is a non-immunological reaction that can be caused by enzyme deficiencies, pharmacological agents and naturally occurring substances.

Lactose intolerance occurs when there is reduced or absence of the enzyme lactase. Lactase is present in the lining of the small intestine. Low levels of this enzyme prevent the effective digestion of lactose and results in loose acidic stools. The undigested lactose ferments in the colon to produce gas and mild acid that causes discomfort and flatulence.

Symptoms presenting in infants with feeding difficulties are often non-specific and conditions can overlap. The majority of infants presenting with restlessness, colic and crying do not have CMA. Parents of an infant should be offered reassurance and advice on managing common and natural problems like colic, constipation, reflux, lactose intolerance or overload.

CMA occurs in less than 8% of young infants, however between 5% and 15% of infants present with symptoms suggestive of CMA. Most infants with CMA develop symptoms before 6 months of age, and often within one week of introduction of a whole cow's milk protein infant formula. Approximately 0.5% of exclusively breastfed infants present with CMA symptoms which are usually mild to moderate. If symptoms of CMA occur parents should be advised to continue breastfeeding and follow the advice detailed in the algorithms below.

Allergy focused history taking, considering the severity and time of onset of symptoms, the source and quantity of the cow's milk ingested, along with any family history of atopy is important.

This guidance covers all infants; including those who breastfeed, those who are formula fed or those who do a combination of both. Specialist milks should only be considered when there is truly a clinical need after thorough assessment.

1.3 Guideline objective

The objective of this guidance is to:

- Aid diagnosis and improve rapid access to specialist infant formula where needed, minimising distress of the baby and anxiety to the parents/carers.
- Provide guidance on the nature, prescribing and cost-effective supply of milk substitutes for babies in primary care.
- 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 breast feeding the infant.

This guidance should be used in conjunction with [NICE Clinical Guideline 116](#) Food allergy in under 19's: assessment and diagnosis. [NICE Clinical Knowledge summaries](#) – Cow's milk protein allergy in children (June 2015)

2. COW'S MILK PROTEIN ALLERGY

2.1 key messages

1. Breastfeeding is the best form of nutrition for infants and this should be promoted, supported and protected wherever possible
2. All infants with suspected IgE-mediated allergy should be referred to a dietitian /paediatric consultant for specialist advice.

3. Prescribing of specialist infant milk can be initiated in primary care in the short-term whilst waiting for specialist referral. If longer-term use is required, the 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.
4. Extensively Hydrolysed Formula (EHF) is the appropriate choice for vast majority of infants with CMA
5. Immediate need to prescribe Amino Acid Formula (AAF) happens rarely. Only prescribe AAF when an infant has a history of anaphylaxis, and/or has very severe symptoms.
6. Soya products should not be recommended for purchase unless advised by a paediatric consultant 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. Soya infant milk may only be prescribed on specialist advice e.g. for galactosaemia. Infants of vegan mothers who choose not to breast feed should not receive soya milks on the NHS in Lancashire as products are available at the same cost as standard milks.
7. Other animal milks (goat, sheep etc.) are not suitable because children who are unable to tolerate cow's milk are at high risk of allergic reactions to other animal milks.
8. The age at which children with CMA tolerate cow's milk is very variable, but the majority do so by age 2 years. Any child still prescribed a specialist infant formula by 2 years of age should be weaned on to a dairy free supermarket bought milk as tolerated e.g. calcium enriched soya, oat or coconut milk. Rice milk is not recommended for children under 4.5 years of age.
9. Powdered milks should be the norm. Liquid feeds are a convenience product and should be purchased if needed, unless they are clinically indicated by a specialist.
10. Do not start formula in children over 1 year old.
11. For infants using formula milk who suffer constipation, clinicians **should not recommend** adding more water to the formula mixture. NHS choices recommends giving infants extra water between their normal feeds if they haven't started to eat solid food yet.

3. DIAGNOSIS of CMA

The Allergy UK IMAP guideline [presentation algorithm](#) provides information on the range of clinical presentations of CMA and guidance on the [management](#) for non IgE mediated CMA

See table below for summarised guidance.

	Mild to moderate non-IgE mediated	Severe non-IgE mediated	Mild to moderate IgE mediated	Severe IgE mediated
Onset of symptoms	Mostly 2-72 hours after ingestion of cow's milk protein. (Can be formula fed, exclusively breast fed or at onset of mixed feeding)	Mostly 2-72hours after ingestion of cow's milk protein.(Can be formula fed, exclusively breast fed or at onset of mixed feeding)	Mostly within minutes of ingestion of cow's milk protein (may be up to 2 hours). Mostly formula fed or at onset of mixed feeding)	Anaphylaxis
Symptoms	One, or often more than one of:- <u>Gastro:</u> Colic, GORD, feed refusal, loose or frequent stools, perianal redness, constipation, abdominal discomfort, blood and or mucous in stools in otherwise well infant. <u>Skin:</u> Pruritus, erythema Non-specific rashes Moderate persistent atopic dermatitis	Severe persisting symptoms of one or more of:- <u>Gastro:</u> Diarrhoea, vomiting, abdominal pain, food refusal or food aversion, significant blood and/or mucus in stools, irregular or uncomfortable stools. +/- Faltering growth <u>Skin:</u> Severe Atopic Dermatitis +/- Faltering Growth	One or more of these symptoms: <u>Gastro:</u> Vomiting, diarrhoea, abdominal pain/colic <u>Skin:</u> one or more usually present Acute pruritus, erythema, urticaria, angioedema Acute 'flaring' of persisting atopic dermatitis <u>Respiratory:</u> Acute rhinitis and/or conjunctivitis	Immediate reaction with significant respiratory and/or Cardiovascular signs and symptoms. (Rarely a severe gastrointestinal presentation) Emergency Treatment and Admission
Management	<u>Breast fed infants:</u> Strict exclusion of cow's milk in maternal diet Maternal supplementation daily of calcium (1000mg) and Vitamin D (10mcg)			
	<u>Formula fed infants:</u> Trial of <i>extensively hydrolysed infant formula</i> + cow's milk free diet.	<u>Formula fed infants:</u> Trial of <i>amino acid infant formula</i> + cow's milk free diet. Refer to secondary care for specialist allergy advice.	<u>Formula fed infants:</u> Initial choice of <i>extensively hydrolysed infant formula</i> + cow's milk free diet Some infants may then need an Amino Acid formula if not settling. IgE testing is required to confirm diagnosis. Refer to secondary care.	<u>Formula fed infants:</u> <i>Amino acid infant formula</i> + cow's milk free diet. Urgent referral to secondary care allergy service.

4. A guide to infant milk formula choice for the management of CMA

4.1 Extensively Hydrolysed Infant Formula (EHF)

EHF formula is appropriate for the majority (approximately 90%) of infants with CMA.
EHF SHOULD NOT be prescribed if there is a history of severe symptoms or anaphylaxis.

Product & Manufacturer	Age range	Presentation	Cost	General comments
Similac Alimentum (Abbott)	From birth	400g	£9.10 / tin	<i>This product is also lactose free so is likely to be beneficial if the child has moderate /severe GI symptoms and inflammation of the GI tract is suspected</i>
Aptamil Pepti 1™(Nutricia)	From birth-6 months	400g 800g	£9.87 £19.73	<i>These products contain lactose and may be more palatable.</i>
Aptamil Pepti 2™ (Nutricia)	From 6 months	400g 800g	£9.41 £18.82	
SMA Althera™ (Nestle)	From birth	450g	£10.68	

Prices - October 2017

Nutramigen LGG 1 & 2 are lactose free products which contain a probiotic which has been reported to accelerate tolerance to cow's milk protein. These products are not recommended for premature or immunocompromised infants. To offer the benefit of the probiotic these formulas are reconstituted differently to standard WHO/DOH guidance, so families should be advised to refer to the products reconstitution details.

4.2 Amino Acid formulas (AAF)

These products are almost 3 times more expensive than EHF.

Only a small proportion of infants with suspected CMA need to be started on an AAF (10%)

AAF formulas are suitable when: -

- There is evidence of severe allergy / anaphylaxis
- An EHF does not resolve symptoms

Product & Manufacturer	Age range	Presentation	Cost	General comments
SMA Alfamino™ (Nestle)	From birth	400g	£23.81	All clinically lactose free
Neocate LCP™ *(Nutricia)	From birth	400g	£28.70	
Nutramigen Puramino* (Mead Johnson)	From birth	400g	£27.63	

Prices - October 2017

*Products are Halal approved

4.3 Practical information on the management of CMA

- It is often difficult to wean babies from breast feeds to formula feeds for various reasons.
- If the Infant feeding care plan involves the introduction of formula milk for a breast fed infant, or if parent/cares would value additional feeding support consideration is to be given to referral to Midwife, Health Visitor or Infant Feeding Specialist
- Try a formula for a minimum of two weeks and avoid product switching
- 2 to 6 weeks without allergen should improve symptoms in infants with non-IgE CMA.
- Both EHF and AAF taste different to standard infant formula bought over the counter and are often initially rejected. If an infant does not tolerate the taste, suggest titrating with regular formula (not for infants with history of anaphylaxis or severe symptoms). However, direct switch to the specialist formula will eliminate the allergen sooner.
- Infant stools may change and have a green tinge. This is seen with both EHF and AAF
- If the infant is not thriving, review treatment. Only around 10% of infants on EHF will not tolerate this type of formula and subsequently have persistent CMA symptoms and faltering growth (due to residual allergen contents). Seek advice of dietitian
- Infants may be changed from an AA to EHF at a later date with risk assessment / challenge by a specialist. This consideration is an important step as there is emerging evidence that tolerance to cows' milk occurs sooner on sustained exposure to extensively hydrolysed formulas
- Parents can be advised to keep a diary inclusive of symptoms and photographs that may aid diagnosis
- Parents need advice on cows' milk free weaning diet as appropriate. The process of tolerance development is dynamic and a dietitian should evaluate these infants and direct parents on milk reintroduction on a case by case basis.
- Some formulas have higher sugar (glucose) content. Ensure dental hygiene advice is given.

5. Re-challenging with milk and dairy products

Children on long term EHF or AAF should be re-challenged to establish if they have acquired tolerance to cow's milk protein. Two thirds of children outgrow their CMA by 2 years of age. By three years of age only 10-15% of diagnosed children remain allergic to cow's milk protein.

5.1 Recommendations for challenging

It is recommended that infants are re-challenged after a symptom free period of 6 months. For those with a history of anaphylaxis or severe symptoms, re-challenging should be directed by a specialist and is usually undertaken in the hospital environment. Reintroduction of cow's milk protein should take place under dietetic guidance.

- For exclusively breastfed infants who have been asymptomatic for last 6 months, consider reintroducing milk via maternal diet.

- For formula only and mixed breast and formula fed children (who have been asymptomatic for last 6 months) challenge should be around age 9-12 months once established on milk free weaning diet.
- Initially children should be exposed to low levels of processed milk as it has lower allergic risk (e.g. in baked goods, bread/biscuits/cakes). Milk products are then gradually introduced and increased in a staged way depending on tolerance.

6. LACTOSE INTOLERANCE

6.1 Key points

- Secondary lactose intolerance is often confused with CMA. In infants, it typically follows an acute episode of gastroenteritis which impairs gut functioning and in effect temporarily reduces lactase production. Symptoms include loose acidic stools, abdominal bloating and pain, increased flatus and nappy rash.
- Diagnosis can be confirmed by improvement within 2-3 days of commencing a lactose free diet.
- Most children should be able to revert to a normal formula once the gastro-intestinal insult has resolved. Typically, within 6-8 weeks.
- Families should be encouraged to gradually reintroduce breast milk / standard infant formula and milk containing solid food gradually after a period of 6-8 weeks
- Primary lactose intolerance is due to lactase enzyme deficiency. It is a genetic disorder and usually presents in later childhood or adult life.
- Referral should be made to a paediatrician and dietitian for all suspected primary lactose intolerance, in patients with secondary intolerance where there is significant weight loss or no improvement after withdrawal of lactose or if symptoms persist for longer than 3 months.
- Lactose free infant formulas should not be used beyond 18 months of age. Infants can be weaned on to proprietary lactose free milks purchased at the supermarket from age 12 months.

6.2 Management of lactose intolerance

Breast fed infants	Formula fed infants	Infants taking mixed diet (milk and solids)
<p>Exclude breast feeding technique issues. A lactose free maternal diet is unnecessary as lactose is naturally present in breast milk</p> <p>Mild symptoms: Encourage mothers to persevere with breast feeding to promote gut healing.</p> <p>There is lack of sufficient evidence to support the prescription of Colief™ (lactase enzyme) to improve symptoms but parents may choose to purchase this.</p> <p>Severe symptoms: Consider alternative feeding options temporarily whilst encouraging the mother</p>	<p>Recommend a temporary switch to a lactose free formula for a 6-8 week period after which a standard infant milk formula can be reintroduced.</p> <p>Lactose free formulas e.g. SMA LF™, Enfamil – O-Lac™, Aptamil Lactose free™</p> <p>These formulas can be purchased over the counter at a similar price to standard formula, so should not be prescribed.</p>	<p>Advise to avoid all solids containing lactose (all milk and dairy products)</p> <p>Consider the impact of lactose containing medicines</p>

to express breast milk to maintain her supply. Consider advising the parents to purchase a lactose free formula feed in the short term. Seek specialist advice e.g. health visitor, breast feeding advisor		
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7. PRESCRIBING GUIDELINES

- When prescribing specialist infant formula use the table below. This offers a guide only based on average feed volumes. Some infants may require more, in these cases you will be guided by the paediatrician or dietitian.
- To avoid waste, initially prescribe a 2-week supply of formula until tolerance and compliance is established. If clinical improvement is noted provide ongoing monthly prescriptions.

7.1 Quantities to prescribe:

Age of child	Number of tins required for 28 days complete nutrition	Comments
Under 6 months	10 - 12 x 400g/450g tins	Exclusively formula fed based on 150mls/kg/day of a normal concentration formula
6 – 9 months	8 -10 x 400g/450g tins	Less formula required as quantity of weaning diet increases
9 – 12 months	6-8 x 400g/450g tins	
Over 12 months	6 x 400g/450g tins	Requiring 600ml of milk substitute per day

7.2 Prescription management

- Endorse prescriptions as ACBS listed.
- Do not start formula in children aged over 1 year
- Ensure formula prescribing is monitored. If no robust monitoring in place do not prescribe formulas on repeat template. If applicable, add review date to prescription.
- Review regularly against quantities and type of formula prescribed and child's increasing age. Ensure infant's growth is monitored and recorded.
- Review against recent correspondence from specialist, if applicable (e.g. children with higher nutritional requirements or multiple allergies may need more formula for a longer period).

7.3 Review and discontinuation of specialist formulas

Review all existing patients if they meet one or more of the below criteria:

- More than 2 years old.
- On formula for more than one year.

- The quantity of formula prescribed is higher than that recommended above.
- Patient are eating and tolerating cow's milk containing foods (e.g. cows' milk, yoghurt, cream, butter, cheese, ice cream, custard, chocolate, cakes, margarine, ghee).
- Children with multiple or severe allergies may require prescriptions beyond the age of two years. This should always be at the suggestion of the paediatric dietitian.

8. OTHER SPECIALIST INFANT FORMULA

Use the table below for information and advice on other specialist infant milk formula and when it is appropriate to prescribe.

Product Type	Name / manufacturer	General comments	Provision
Soya Infant milk formulas	Wysoy* - SMA	Not suitable as a first-line alternative for the management of cow's milk allergy in infants under six months of age. Can be used from birth for the management of the inborn error of metabolism galactosaemia.	If parents choose this formula for their infant it should be purchased over the counter. Formula should be prescribed and endorsed ACBS for the management of galactosaemia.
High Energy Infant milk formulas	Similac High Energy* (Abbott) SMA PRO High Energy * (SMA) Infatrini (Nutricia) Infatrini Peptisorb (Nutricia)	Suitable from birth. Used in the management of infants who have faltering growth or who have their nutrition provided via an enteral tube feeding device. These formulae are not suitable as a sole source of nutrition for infants over 8kg or 18 months of age.	Prescribe as directed by secondary and tertiary care.
Lactose free infant milk formulas	SMA LF* (SMA Nutrition) Enfamil – O-Lac (Mead Johnson) Aptamil Lactose free (Nutricia)	Suitable from birth. Low lactose/lactose free formula should not be used for longer than eight weeks without review and trial of discontinuation of treatment. Further investigation should be undertaken if no clinical improvement. These formulas should not be used beyond 18 months of age. Infants can be weaned on to proprietary lactose free milks purchased at the supermarket from age 12 months.	These formulas can be purchased over the counter at a similar price to standard formula, so should not be prescribed.
Anti-reflux formulas	Aptamil Anti-reflux (Nutricia)	Refer to NICE Guideline NG1 Jan 2015 Gastro-oesophageal reflux disease:	These formulas can be

	<p>Cow & Gate Anti-reflux (Cow & Gate) Enfamil AR (Mead Johnson) SMA Stay Down* (SMA)</p>	<p>recognition, diagnosis and management in children and young people https://www.nice.org.uk/guidance/ng1 <u>1</u> These infant milks are suitable from birth for the management of GORD. The Milupa and Cow & Gate brands are pre-thickened and are likely to require the use of a fast flow teat. The Mead Johnson and SMA brands rely on the stomach acid for thickening so should not be used in conjunction with ranitidine or omeprazole.</p> <p>Anti-reflux milks should not be used in conjunction with other thickening agents or Gaviscon Infant.</p>	<p>purchased over the counter at a similar price to standard formula, so should not be prescribed. The Enfamil AR is only available through pharmacies.</p>
<p>Post discharge nutrient enriched formulas for preterm infants</p>	<p>Nutriprem 2 (Cow & Gate) SMA Pro Gold Prem 2 (SMA)</p>	<p>These formulas should only be prescribed on request from secondary or tertiary care for those preterm infants who have been identified as being at 'high nutritional risk' on discharge from the NNU. They are only suitable for infants born before 34 weeks gestation, weighing less than 2kg at birth who are not breast fed and should not be used to promote weight gain in other infants.</p> <p>Infants will have regular review and the product should be stopped as soon as catch up growth is achieved.</p> <p>These formulas should not be prescribed beyond the age of 6 months corrected (EDD + 6 months) unless an infant has ongoing nutritional concerns as advised by secondary or tertiary care where the child remains under specialist care.</p>	<p>Prescribe as directed by secondary and tertiary care.</p> <p>Only prescribe the powdered varieties.</p>

*Products are halal approved.

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10. ACKNOWLEDGEMENTS

Pan-Mersey Prescribing Guidelines for Specialist Infant Formula Feeds in Lactose Intolerance and Cows' Milk Protein Allergy (2016)

PrescQIPP bulletin Nov 2016 – Appropriate prescribing of specialist infant formulae (foods for special medical purpose)

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Midlands and Lancashire Commissioning Support Unit,
Jubilee House, Lancashire Business Park, Leyland, PR26 6TR
Tel: 01772 644 400 | www.midlandsandlancashirecsu.nhs.uk