Northern Lincolnshire
Area Prescribing Committee

Appropriate Prescribing of Specialist Infant Formulae

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This document has been adapted for Northern Lincolnshire Area Prescribing Committee from the guidance written by Central Eastern Commissioning Support Unit Medicines Management Team and PrescQIPP.

INTRODUCTION

Whilst these guidelines advise on appropriate prescribing of specialist infant formulae, breast milk remains the optimal milk for infants. This should be promoted and encouraged where it is clinically safe to do so and the mother is in agreement.

PURPOSE OF THE GUIDELINES

These guidelines aim to assist clinicians by providing information on the use of infant formula. The guidelines are targeted at infants 0-12 months. However, some of the prescribable items mentioned here can be used past this age and advice on this is included in the guidelines.

 This symbol denotes products that are more cost-effective and should be used in preference to alternatives, when appropriate.

QUANTITIES OF FORMULAE TO PRESCRIBE

When any infant formula is prescribed the guide below should be used

To avoid waste, just 1 week's supply should be provided until tolerance and compliance is established.

Age of child	**Number of tins for 28 days**
Under 6 months	10 x 400g tins
6-12 months	7-13 x 400g tins
Over 12 months	7 x 400g tins or 3 x 900g tins

These amounts are based on:

- Infants under 6 months being exclusively formula fed and drinking 150ml/kg/day of a normal concentration formula.
- Infants 6-12 months requiring less formula as solid food intake increases.
- Children over 12 months drinking the 600mls of milk or milk substitute per day recommended by the Department of Health.

For liquid high energy formula:

- Prescribe an equivalent volume of formula to the child's usual intake until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian.
  - » Some children may require more, e.g. those with faltering growth.
  - » Review recent correspondence from the paediatrician or paediatric dietitian.

DOS AND DON'TS OF PRESCRIBING SPECIALIST INFANT FORMULAE

DO	Promote and encourage breast-feeding where it is clinically safe and the mother is in agreement.
	Check any formula prescribed is appropriate for the age of the infant.
	Check the amount of formula prescribed is appropriate for the age of the infant (see page 2) and/or refer to the most recent correspondence from the paediatric dietitian.
	Review any prescription where the child is over 2 years old, the formula has been prescribed for more than 1 year, or greater amounts of formula are being prescribed than would be expected.
	Review the prescription if the patient is prescribed a formula for CMPA but able to eat any of the following foods – cow's milk, cheese, yogurt, ice cream, custard, chocolate, cakes, cream, butter, margarine, ghee.
	Prescribe sufficient product for 2 weeks initial supply until compliance/tolerance is established.
	Remind parents to follow the advice given by the formula manufacturer regarding safe storage of the feed once mixed or opened.
	Refer where appropriate to secondary or specialist care - see advice for each condition.
	Refer where appropriate to the paediatric dietitians.
	Seek prescribing advice if needed in primary care from the Medicines Optimisation Team.
	Seek prescribing advice if needed in secondary care from the local Hospital Medicines Information Centre.

DO NOT	Add infant formulae to the repeat prescribing template in primary care, unless a review process is established to ensure the correct product and quantity is prescribed for the age of the infant.
	Prescribe lactose free formulae (SMA LF®, Enfamil O-Lac®) for infants with CMPA.
	Routinely prescribe soya formula (SMA Wysoy®) for those with CMPA or secondary lactose intolerance. It should not be prescribed at all in those under 6 months due to high phyto-oestrogen content.
	Suggest milk and formulae made from goat's milk, sheep's milk or mammalian milks for those with CMPA or secondary lactose intolerance.
	Suggest rice milk for those under 5 years due to high arsenic content.
	Prescribe Nutriprem 2 Liquid® or SMA Gold Prem 2 Liquid® unless there is a clinical need.
	Prescribe thickening formulae (SMA Staydown®, Enfamil AR®) with separate thickeners or in conjunction with medication such as antacids, ranitidine, or proton pump inhibitors, since the formulae need stomach acids to thicken and reduce reflux.
	Suggest Infant Gaviscon® more than 6 times in 24 hours or where the infant has diarrhoea or a fever, due to its sodium content.
	Prescribe low lactose/lactose free formulae in children with secondary lactose intolerance over 1 year who previously tolerated cow's milk, since they can use lactose free products (e.g. Lactofree®) from supermarkets.

UK Adaptation of iMAP Guideline for Primary Care and 'First Contact' Clinicians

Presentation of Suspected Cow's Milk Allergy (CMA) in the 1st Year of Life

Having taken an Allergy-focused Clinical History and Physically Examined

Oct 2018

Approx. 2% of UK infants have CMA – most children with the symptoms listed below will not have CMA & do not require an elimination diet but there should be an increased index of suspicion in infants with multiple, persistent, significant or treatment-resistant symptoms. Breast milk is the ideal nutrition for infants with CMA. iMAP primarily guides on early recognition of CMA, then confirmation or exclusion, followed by the optimal management of confirmed mild-to-moderate Non-IgE CMA.

Mild to Moderate Non-IgE-mediated CMA

Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP)

Formula fed, exclusively breast fed or at onset of mixed feeding

Usually several of these symptoms will be present

Treatment resistance e.g. to atopic dermatitis or reflux, increase likelihood of allergy

Gastrointestinal

Irritability - 'Colic'
Vomiting - 'Reflux' - GORD
Food refusal or aversion
Diarrhoea-like stools
- loose and/or more frequent
Constipation – especially soft stools, with excessive straining
Abdominal discomfort, painful flatus
Blood and/or mucus in stools in an otherwise well infant

Skin

Pruritus (itching), Erythema (flushing)
Non-specific rashes
Moderate persistent atopic dermatitis

↓

Cow's Milk Free Diet

Exclusively breast feeding mother*

Trial exclusion of all Cow's Milk Protein from her own diet and to take daily Calcium and Vit D

Formula fed or 'Mixed Feeding'*

Trial of Extensively Hydrolysed Formula - eHF

See Management Algorithm

Severe Non-IgE-mediated CMA

Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP)
Formula fed, exclusively breast fed or at onset of mixed feeding

One or more of these **Severe** and **Persisting** 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 dermatitis +/- Faltering Growth

↓

Cow's Milk Free Diet

Exclusively breast feeding mother*

If symptomatic, trial exclusion of all Cow's Milk Protein from her own diet and to take daily Calcium and Vit D

Formula fed or 'Mixed Feeding'*

Trial replacement of Cow's Milk formula with Amino Acid Formula (AAF)

Ensure:

Urgent referral to local paediatric allergy service

Urgent dietetic referral

Severe IgE CMA

ANAPHYLAXIS

Immediate reaction with severe respiratory and/or CVS signs and symptoms.
(Rarely a severe gastrointestinal presentation)

Emergency Treatment and Admission

Mild to Moderate IgE-mediated CMA

Mostly within minutes (may be up to 2 hours) after ingestion of Cow's Milk Protein (CMP)
Mostly occurs in formula fed or at onset of mixed feeding

One or more of these symptoms:

Skin – one or more usually present

Acute pruritus, erythema, urticaria, angioedema
Acute 'flaring' of persisting atopic dermatitis

Gastrointestinal

Vomiting, diarrhoea, abdominal pain/colic

Respiratory

Acute rhinitis and/or conjunctivitis

↓

Cow's Milk Free Diet

Support continued breast feeding where possible.
If infant is symptomatic on breast feeding alone (rare), trial exclusion of all Cow's Milk Protein from maternal diet alongside daily maternal Calcium and Vit D as per local recommendations.

Formula fed or 'Mixed Feeding'*

If mother unable to revert to fully breast feeding
Ist. Choice -Trial of Extensively Hydrolysed Formula – **eHF**
Infant soy formula may be used over 6 months of age if not sensitised

Initial IgE testing needed

If diagnosis confirmed (which may require a Supervised Challenge in a minority of cases) :
Follow-up with serial IgE testing and later Planned Challenge to test for acquired tolerance

Dietetic referral required

UK NICE Guidance - If competencies to arrange and interpret testing are not in place - early referral to local paediatric allergy service

iMAP has been developed completely independent of any industry involvement or funding.

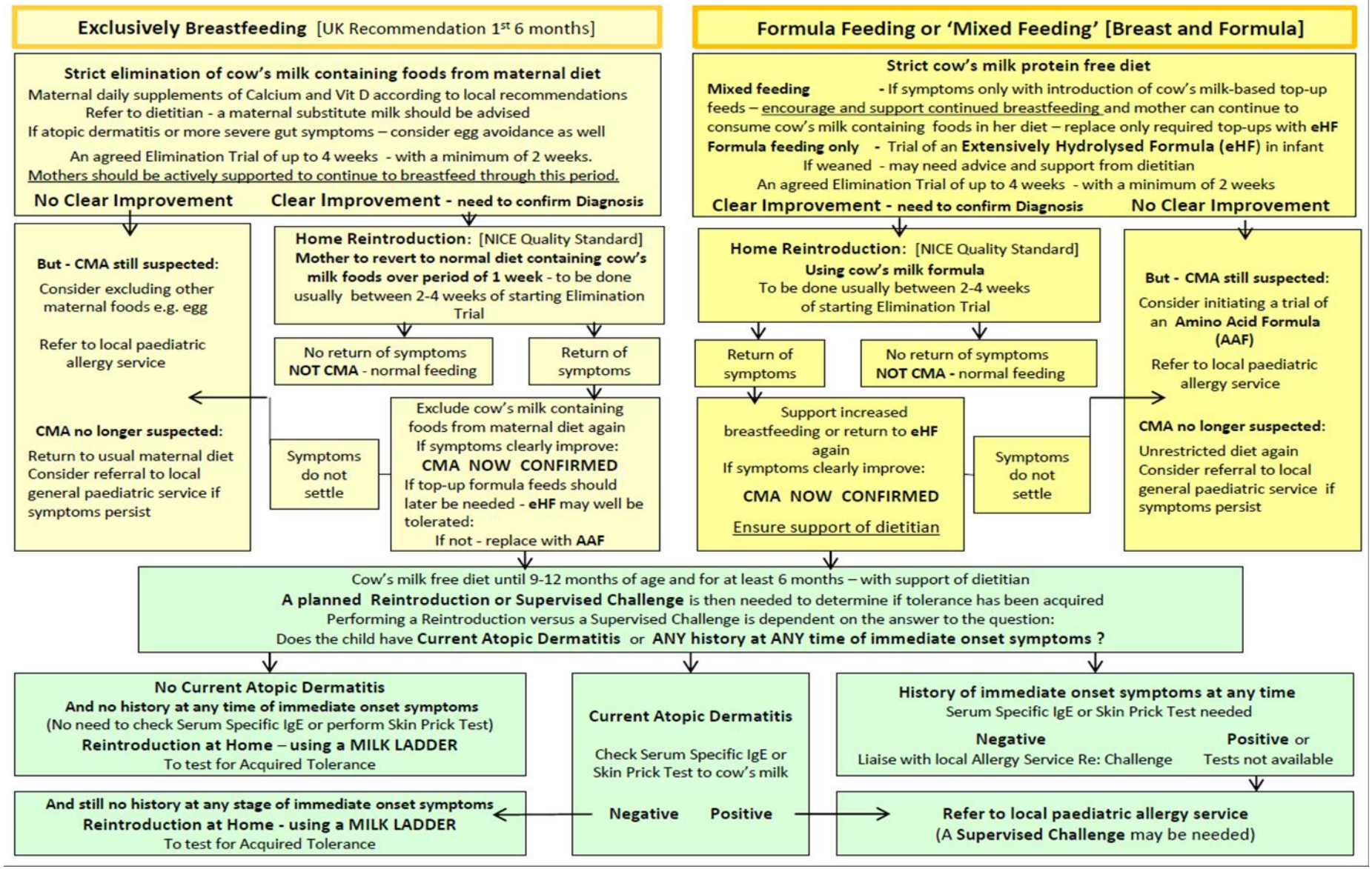
*** Actively support continued breastfeeding**

UK Adaptation of iMAP Guideline for Primary Care and 'First Contact' Clinicians

Management of Mild to Moderate Non-IgE Cow's Milk Allergy (CMA)

Oct 2018

(No initial IgE Skin Prick Tests or Serum Specific IgE Assays necessary)



Clinicians should be cautious in using lactose contain formulae in patients presenting with diarrhoea as the patient may have a secondary lactose intolerance.

EXTENSIVELY HYDROLYSED FORMULAE FIRSTLINE OPTIONS	**Nutramigen 1 with LGG (Mead Johnson)**	Birth to 6 months
	Apatmil Pepti 1 (Nutricia Ltd)® Contains lactose	Birth to 6 months
	Similac Alimentum (Abbott Nutrition)	Birth to 12 months
	SMA Althera (Nestle Health Science) Contains lactose	Birth to 2 years
	Aptamil Pepti 2 (Nutricia Ltd) LGG Contains lactose	6 months to 2 years
	Nutramigen 2 with LGG (Mead Johnson) 	6 months to 1 year
	Nutramigen 3 with LGG (Mead Johnson)	1-2 years to 2 years
EXTENSIVELY HYDROLYSED FORMULAE WITH MEDIUM CHAIN TRIGLYCERIDES TO BE STARTED IN SECONDARY CARE	**Pregestimil Lipil® (Mead Johnson)**	Birth to 2 years or able to tolerate over the counter products.
	Aptamil Pepti – Junior® (Nutricia Ltd.)	Birth to 2 years or able to tolerate over the counter products.
	These formulae are used where CMPA is accompanied by malabsorption.	
AMINO ACID FORMULAE TO BE STARTED IN PRIMARY CARE IN PATIENTS CLEARLY PRESENTING WITH ANAPHYLACTIC REACTION WITH IMMEDIATE ONWARD REFERRAL TO SECONDARY CARE	**Neocate LCP (Nutricia Ltd)**	Birth to 2 years
	Nutramigen PurAmino (Mead Johnson) 	Birth to 2 years
	Neocate Syneo (Nutricia Ltd.)	Birth to 2 years (liaise with dietetics prior to prescribing)
	SMA Alfamino (Nestle Health Science) 	Birth to 2 years

Review and discontinuation of treatment and challenges with cow's milk

Review prescriptions regularly to check that the formula prescribed is appropriate for the child's age.

- Quantities of formula required will change with age – see guide to quantities required (page 2) and/or refer to the most recent correspondence from the paediatric dietitian.
- Do not add to the repeat template for these reasons, unless a review process is established.
- Challenging with cow's milk - refer to NICE guidelines on which children should be challenged with cow's milk in secondary care setting.
- Prescriptions should be stopped when the child has outgrown the allergy (see notes 1 and 5 below).
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
  - Is the patient over 2 years of age?
  - Has the formula been prescribed for more than 1 year?
  - Is the patient prescribed more than the suggested quantities of formula according to their age?
  - Is the patient prescribed a formula for CMPA but able to eat any of the following foods – cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee?
- Children with multiple or severe allergies may require prescriptions beyond 2 years. This should always be at the suggestion of the paediatric dietitian.

NOTES

1. Soya formula (SMA Wysoy®) should not routinely be used for patients with CMPA. It should not be used at all for those under 6 months due to high phyto-oestrogen content. It should only be advised in patients over 6 months who do not tolerate first line EHF since there is a risk that infants with CMPA may also develop allergy to soya. It is more likely that children will tolerate soya formula from 1 year. Parents should be advised to purchase soya formula as it is a similar cost to cow's milk formula and readily available. From 2 years supermarket calcium enriched soya or oat milk may be suitable as an alternative. Alpro® Junior 1+ psoya milk may be suitable from 1 year. The paediatric dietitian will advise on suitable over-the-counter products for appropriate ages.
2. EHF and AAF have an unpleasant taste and smell, which is better tolerated by younger patients. Unless there is anaphylaxis, advise parents to introduce the new formula gradually by mixing with the usual formula in increasing quantities until the transition is complete. Serving in a closed cup or bottle or with a straw (depending on age) may improve tolerance. In some cases the formula will need to be flavoured e.g. with the minimum amount of milkshake flavouring. Care should be taken and ingredients checked in those with multiple allergies.
3. Outgrowing CMPA – 60-75% of children outgrow CMPA by 2 years of age, rising to 85-90% of children at 3 years of age.
4. Calcium supplementation may be needed for infants depending on volume and type of formula taken. Breast-feeding mothers on a milk free diet may also need a calcium supplement. The dietitian will advise.
5. Lactose free formulae (SMA LF®, Enfamil O-Lac with LIPIL®) are not suitable for those with CMPA.
6. Goats', sheep, and other mammalian milks are also not suitable for those with CMPA.

GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

Symptoms and diagnosis

- GORD is the passage of gastric contents into the oesophagus causing troublesome symptoms and/or complications.
- Symptoms may include regurgitation of a significant volume of feed, reluctance to feed, distress/crying at feed times, small volumes of feed being taken.
- Diagnosis is made from history that may include effortless vomiting (not projectile) after feeding, usually in the first 6 months of life, and usually resolves spontaneously by 12-15months age.
- It should be noted that 50% of babies have some degree of reflux at some time.
- Overfeeding needs to be ruled out by establishing the volume and frequency of feeds. Average requirements of formula are 150mls/kg/day for babies up to 6 months and should be offered spread over 6-7 feeds.

Onward referral

- Infants with faltering growth as a result of GORD should be referred to paediatric services without delay.
- If symptoms do not improve one month after commencing treatment refer to a paediatrician for further investigations since CMPA can co-exist with GORD and treatment as for CMPA may be required.

Treatment

- If the infant is thriving and not distressed reassure parents and monitor.
- Provide advice on avoidance of overfeeding, positioning during and after feeding, and activity after feeding. If bottle-fed suggest over-the-counter (OTC) products listed below.
- If the bottle fed infant is not gaining weight and/or not settled – trial with thickening formula or antacid e.g. Infant Gaviscon®. Advice for those with faltering growth will be given by secondary/ specialist care.
- If the breast-fed infant is not gaining weight and/or not settled – trial with Infant Gaviscon® offered on a spoon before feeds. Advice for those with faltering growth will be given by secondary/specialist care.
- Prescribable thickening formulae should not be used in conjunction with separate thickeners or with medication such as ranitidine, or with proton pump inhibitors.

Review and discontinuation of treatment

- Review after one month.
- Infants with GORD will need regular review to check growth and symptoms.
- Since GORD will usually resolve spontaneously between 12-15 months, cessation of treatment may be trialled from 12 months.

OVER THE COUNTER THICKENED FORMULAE	**Cow& Gate® Anti-reflux(Cow &Gate)**	Birth to 1year
	Aptamil® Anti-reflux (Milupa)	Birth to 1years
	SMA Anti-Reflux (SMA)	Birth to 18 months
	Enfamil AR (Mead Johnson)	Birth to 18 months

Notes

1. Over the counter (OTC) thickened formulae contain carob gum. This produces a thickenedformula and will require the use of a large hole (fast-flow) teat.
2. Thickening formulae react with stomach acids, thickening in the stomach rather than thebottle so there is no need to use a large hole (fast flow) teat.
3. SMA Anti-Reflux® contains corn-starch.
4. Enfamil AR® contains rice starch.
5. Alert parents/carers to the need to make up thickening formulae with fridge cooled pre-boiled water (see tin for full instructions).
6. Infant Gaviscon® contains sodium and should not be given more than 6 times in 24 hours or where the infant has diarrhoea or a fever. N.B. Each half of the dual sachet of Infant Gaviscon® is identified as 'one dose'. To avoid errors, prescribe with directions in terms of 'dose'. Dispensing pharmacists should advise about appropriate doses of OTC products.

SECONDARY LACTOSE INTOLERANCE

Symptoms and diagnosis

- Usually occurs following an infectious gastrointestinal illness but may be present alongside newly or undiagnosed coeliac disease.
- Symptoms include abdominal bloating, increased (explosive) wind, loose green stools.
- Lactose intolerance should be suspected in infants who have had any of the above symptomsthat persist for more than 2 weeks.
- Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis.

Onward referral

- If symptoms do not resolve when standard formula and/or milk products are reintroduced to the diet, refer to secondary or specialist care.
- Refer to the paediatric dietitian if the child is weaned and a milk free diet is required.

Treatment

- Treat with low lactose/lactose free formula for 4-8 weeks to allow symptoms to resolve. Rarely symptoms may last up to 3 months.

- In infants who have been weaned, low lactose/lactose free formula should be used in conjunction with a milk free diet.
- Standard formula and/or milk products should then be slowly reintroduced to the diet
- In children over 1 year who previously tolerated cow's milk, do not prescribe low lactose/lactose free formulae. Suggest use of lactose free full fat cow's milk, yoghurt and other dairy products which can be purchased from supermarkets (Lactofree® brand).

Review and discontinuation of treatment

- Low lactose/lactose free formula should not be prescribed for longer than 8 weeks without review and trial of discontinuation of treatment.

LOW LACTOSE/ LACTOSE FREE FORMULA FIRST-LINE–TO BE PURCHASED OVER THE COUNTER	**SMA LF® (SMA)**	Birth to 2 years but see treatment note above for those over 1 year
	Enfamil O-Lac with Lipil® (Mead Johnson)	Birth to 2 years but see treatment note above for those over 1 year
	Apatamil LF (Nutricia Ltd.)	Birth to 2 years but see treatment note above for those over 1 year

Notes

1. Primary lactose intolerance is less common than secondary lactose intolerance and does not usually present until later childhood or adulthood.
2. SMA LF® is a low lactose, whole protein cow's milk formula.
3. Enfamil O-Lac® is a lactose, sucrose and fructose free cow's milk formula.

FALTERING GROWTH

Refer to NICE NG 75 Faltering growth: recognition and management of faltering growth in children, September 2017 https://www.nice.org.uk/guidance/ng75

Symptoms and diagnosis

- Refer to section NICE NG 75, 1.2 Faltering growth after the early days of life, thresholds for diagnostic criteria
- The height/length of an infant are measured to properly interpret changes in weight using appropriate growth charts to be able to diagnose.
- It is essential to rule out possible disease related/medical causes for the faltering growth e.g. iron deficiency anaemia, constipation, GORD or a child protection issue. If identified appropriate action should be taken.

Onward referral

- If faltering growth is diagnosed refer to NICE NG 75 regarding management and onward referral.

Treatment

- Refer to breast feeding support if child is breast fed.
- Formula fed child – assess volumes of formula taken and any symptoms exhibited and manage symptoms
- Prescribe an equivalent volume of high energy formula to the child's usual intake of regular formula until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian.

Review and discontinuation of treatment

- The team to whom the infant is referred should indicate who is responsible for review and discontinuation. If the team hand responsibility back to the GP this should be with an indication of what the goal is at which point discontinuation can occur.
- All infants on high energy formula will need growth (weight and height/length) monitored to ensure catch up growth occurs.
- Once this is achieved the formula should be discontinued to minimise excessive weight gain.

HIGH ENERGY FORMULA FIRST-LINE	**SMA High Energy® 200ml Carton (SMA)**	Birth up to 18 months or 8kg
	Infatrini® 200ml bottle (Nutricia Ltd.)	Birth up to 18 months or 8kg
	Similac High Energy® /200ml bottle (Abbott Nutrition)	Birth up to 18 months or 8kg
HIGH ENERGY FORMULA TO BE STARTED IN SECONDARY CARE	**Infatrini Peptisorb® 200ml bottle (Nutricia)**	Birth up to 18 months or 8kg
	N.B. This formula is suitable for infants with faltering growth and intolerance to whole protein feeds e.g. short bowel syndrome, intractable malabsorption, inflammatory bowel disease, bowel fistulae.	

Notes

- Where all nutrition is provided via NG/NJ/PEG tubes, the paediatric dietitian will advise on appropriate monthly amounts of formula required which may exceed the guideline amounts for other infants. These formulae are not suitable as a sole source of nutrition for infants over 8kg or 18 months of age.
- Manufacturer's instructions regarding safe storage once opened and expiry of ready to drink formulae should be adhered to – this may differ from manufacturer to manufacturer.

PRE-TERM INFANTS

Indications

- These infants will have had their pre-term formula commenced on discharge from the neonatal unit.
- It is started for babies born before 34 weeks gestation, weighing less than 2kg at birth.
- These formulae should not be used in primary care to promote weight gain in patients otherthan babies born prematurely.

Onward referral

- These infants should already be under regular review by the paediatricians.
- If there are concerns regarding growth whilst the infant is on these formulae, refer to the paediatric dietitian.
- If there are concerns regarding growth at 6 months corrected age or at review one month after these formulae are stopped, refer to the paediatric dietitian.

Review and discontinuation oftreatment

- The Health Visitor should monitor growth (weight, length and head circumference) while the baby is on these formulae.
- These products should be discontinued by 6 months corrected age.
- Not all babies need these formulae for the full 26 weeks from expected date of delivery (EDD).
- If there is excessive weight gain at any stage up to 6 months corrected age, stop the formula.

PRE-TERM INFANT FORMULA TO BESTARTED INSECONDARY CARE	**SMA Gold Prem 2® powder (SMA)**	Birth up to a maximum of 6 months correctedage
	Nutriprem 2® powder (Cow and Gate)	Birth up to a maximum of 6 months correctedage
	6 months corrected age = EDD + 26 weeks	

PRE-TERM INFANT FORMULA WHICH SHOULD NOT ROUTINELY BE PRESCRIBED unless there is a clinical need e.g. immunocompromised infant.	**SMA Gold Prem 2® liquid (SMA)**
	Nutriprem 2® liquid (Cow and Gate)
	Cost per 100kcals is £1.12 - £1.15 for liquid compared with 23p-25p for powders.

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Additional PrescQIPP Resources

Briefing

Data pack

Available here: https://www.prescqipp.info/our-resources/bulletins/bulletin-146-infant-feeds/