



# Prescribing Specialist Infant Formula in Primary Care

## Guidance for use in:

Wakefield

Greater Huddersfield

North Kirklees

Calderdale

***Breast milk is the optimal milk for infants. Breastfeeding should be promoted and encouraged where possible.***

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## QUICK GUIDE TO PRESCRIBING SPECIALIST INFANT FORMULA

**First-line choices are based on COST only. Prescribers must switch to an alternative product if tolerance issues are identified.**

<b>ALL CONDITIONS</b>		
<b>How much should I prescribe?</b>		
28 day supply:	Under 6 months – 8 x 400g OR 4 x 900g tins 6 to 12 months – 7 x 400g OR 3 x 900g tins Over 12 months - 7 x 400g OR 3 x 900g tins	Use these quantities as a guide only.

<b>COW'S MILK PROTEIN ALLERGY (CMPA)</b>		
Symptoms include:	<b>IgE-mediated</b> <ul style="list-style-type: none"> <li>Angioedema of the lips, tongue and palate.</li> <li>Oral pruritis</li> <li>Pruritis, erythema</li> <li>Acute urticaria</li> <li>Acute angiodema</li> <li>Nausea &amp; vomiting</li> <li>Diarrhoea</li> <li>Colicky abdominal pain</li> <li>Nasal itching, sneezing, rhinorrhoea, congestion.</li> <li>Cough, wheezing, shortness of breath</li> <li>Signs or symptoms of anaphylaxis</li> </ul>	<b>Non-IgE-mediated</b> <ul style="list-style-type: none"> <li>Pruritis</li> <li>Erythema</li> <li>Atopic eczema</li> <li>GORD</li> <li>Infantile colic</li> <li>Diarrhoea or constipation</li> <li>Blood and/or mucus in stools</li> <li>Abdominal pain</li> </ul>
Refer to secondary/specialist care if <b>ANY</b> of the following apply:	<ul style="list-style-type: none"> <li>Faltering growth with one or more GI symptoms</li> <li>Acute systemic reactions or severe delayed reactions</li> <li>Significant atopic eczema where multiple or cross-reactive food allergies are suspected by the parent.</li> <li>There is a confirmed IgE-mediated food allergy and concurrent asthma</li> </ul>	<ul style="list-style-type: none"> <li>Possible multiple food allergies</li> <li>Persisting parental suspicion of food allergy (especially where symptoms are difficult or perplexing) despite a lack of supporting history</li> </ul>
Refer to <a href="#">NICE guidelines (Food Allergy in Children and Young People)</a>		
<b>Extensively hydrolysed formula (EHF)</b>	<b>USE FIRST LINE</b> – Use the most cost-effective EHF tolerant for the patient. In cost-effective order these are: Similec Alimentum (birth-2years), Althera (birth-12 months), Aptamil Pepti 1 (birth to 6 months) or Aptamil Pepti 2 (6 months to 2 years), Nutramigen Lipil 1 (birth-6 months) or Nutramigen Lipil 2 (6 months-2 years).	
<b>Amino Acid Formula (AAF)</b>	Nutramigen AA and Neocate LCP should normally be started by secondary/specialist care unless child has a history of anaphylactic reaction to cow's milk. Children with potential anaphylaxis should be treated with AA based feed as <b>initial</b> treatment with immediate referral to secondary care..	

### PRESCRIBE ONLY 1 OR 2 TINS INITIALLY TO ASSESS TOLERANCE AND PALATABILITY

**Review the need for prescribing** if yes to any of the following questions:- Is pt over 2 years of age? Has the formula been prescribed > 1 year? Is pt prescribed more than the suggested quantities of formula for their age? Can pt eat any of the following foods – cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine?

**DO NOT PRESCRIBE SOYA FORMULA – REFER TO FULL GUIDANCE.**

First-line choices are based on COST only. Prescribers must switch to an alternative product if tolerance issues are identified.

### GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

Symptoms include:

- Vomiting (usually in the first 6 months of life)
- Regurgitation of significant volumes of feed
- Reluctance to feed
- Crying a feed times
- Small volumes of feed being taken
- Irritability
- Back arching

**REFER INFANTS WITH FALTERING GROWTH TO PAEDIATRIC SERVICES WITHOUT DELAY**

Rule out overfeeding by establishing the volume and frequency of feeds. Average requirement of formula is 150ml/kg/day for babies up to 6 months and should be spread over 6-7 feeds.

**STEP 1**

Give parental reassurance and practical advice on before moving to step 2. Provide advice on avoidance of over feeding, positioning during and after feeding, and activity after feeding

**STEP 2**

Consider a 2-week trial (with planned review) of thickened feeds – using a thickening agent added to usual milk **OR** consider a trial with thickening formula. Recommend OTC anti-reflux formula initially: Cow & Gate Anti Reflux or Aptamil Anti Reflux, otherwise:

**USE FIRST LINE – SMA Staydown**

**USE IF FIRST-LINE UNSUCCESSFUL – Enfamil AR**

**PRESCRIBABLE THICKENING FORMULAS – DO NOT PRESCRIBE WITH SEPARATE THICKENERS OR ANTACIDS**

**REVIEW AFTER 1 MONTH. IF SYMPTOMS NOT IMPROVED REFER TO SPECIALIST SERVICES.**

### SECONDARY LACTOSE INTOLERANCE

Symptoms include:

- Abdominal bloating
  - Increased wind
  - Loose green stools
- } Usually occurs following an infectious GI illness but can occur alongside new or undiagnosed coeliac disease

Lactose intolerance should be suspected in infants who have had any of the above symptoms that persist for > 2 weeks. Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis.

**Low lactose/lactose free formula**

SMA LF OR Enfamil O-Lac with Lipil

**NOTE – Lactose free infant formula can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe.**

Prescribe 2 weeks supply initially then review to see if symptoms have improved - consider alternative diagnosis of no improvement in symptoms. Continue lactose free formula for up to 8 weeks to allow resolution of symptoms then advise parent to slowly start to re-introduce standard formula/milk into diet. Refer to specialist care if symptoms have not resolved on commencement of standard formula/milk.

**DO NOT PRESCRIBE FOR > 8 WEEKS WITHOUT REVIEW.**

**DO NOT PRESCRIBE FOR CHILDREN OVER 1 YEAR (SUPERMARKET BRANDS SUITABLE) – REFER TO FULL GUIDANCE**

**First-line choices are based on COST only. Prescribers must switch to an alternative product if tolerance issues are identified.**

<b>FALTERING GROWTH</b>		
<b>Symptoms include:</b>	<p>Faltering growth cannot be detected without using a growth chart. Diagnosis is made when an infant falls below the 0.4<sup>th</sup> centile or crosses 2 centiles downwards on a growth chart. <b>REFER TO SECONDARY CARE WITHOUT DELAY</b></p> <p>Secondary care will lead in prescribing for this group of infants and generally, all such prescribing should be initiated by a paediatrician/paediatric Dietitian.</p> <p>Prescribing can be initiated in primary care in the short term whilst waiting for specialist referral. Prescribe an equivalent volume of <b>high energy formula</b> to the child's usual intake of regular formula until an assessment has been performed and recommendations made by a paediatrician or paediatric Dietitian.</p>	
<b>High Energy Formula</b>	<p><b>USE FIRST LINE – SMA High Energy</b></p>	<p>Suitable for infants up to 18 months or 8kg. Refer to paediatric Dietitian and paediatrician</p>
	<p><b>USE IF FIRST-LINE UNSUCCESSFUL -</b> Infatrini or Similac High Energy</p>	
<p>All infants on high energy formula will need growth (weight and height/length) monitoring to ensure catch up growth occurs. Once this is achieved the formula should be discontinued to minimise excessive weight gain (usually by the paediatrician).</p> <p style="text-align: center;"><b>Stop high energy formula at 18 months of age or if patient over 8kg. If concerns with weight refer to paediatric Dietitian</b></p>		

<b>PRE-TERM INFANTS</b>		
<p>Pre-term infant formula should not be commenced in primary care - infants will already be on pre-term formula milk on discharge from hospital. It is started for babies born before 34 weeks gestation.</p>		
<b>STARTED IN SECONDARY CARE</b>	<p>SMA Gold Prem 2 Powder OR Nutriprem 2 Powder (C&amp;G)</p>	<p>Use up to 6 months corrected age (i.e. 6 months EDD + 26 weeks)</p>
<p><b>Liquid formulations of Nutriprem 2 and SMA Gold Prem 2 should NOT be routinely prescribed unless there is a clinical need.</b></p>		
<p>Any infant discharged on these formula should have their growth (this includes weight, length, head circumference) monitored by the Health Visitor. Any concerns with baby's growth should be referred to the paediatric Dietitian and paediatrician.</p> <p>These products should be discontinued by 6 months corrected age and changed to a standard term formula thereafter if no concerns with growth. If there are concerns at 6 months corrected age refer back to paediatric services.</p>		

Refer to the full guideline "Prescribing Specialist Infant Formula in Primary Care" for more details.

<b>KEY:</b>	<b>USE FIRST LINE</b>	<b>USE IF FIRST-LINE UNSUCCESSFUL</b>	<b>SHOULD NOT BE ROUTINELY COMMENCED IN PRIMARY CARE</b>	<b>SHOULD NOT BE ROUTINELY PRESCRIBED</b>
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## 1. INTRODUCTION

Whilst these guidelines offer advice on prescribing of specialist infant formula, breast milk remains the optimal food for infants. Therefore breast feeding should be supported and encouraged where it is clinically safe to do so and where the mother is in agreement.

With few exceptions the World Health Organisation and health departments across the world recommend exclusive breast feeding for the first 6 months of an infant's life. Where the mother cannot breastfeed, or chooses not to, then breast milk substitutes, usually infant formula milks, are widely available.

Infant milk formulas are not an exact replication of breast milk. The exact chemical properties of breast milk are unknown and therefore cannot be fully reproduced. Breast milk changes composition in response to the feeding habits of the breastfed infant and adjusts to the infant's individual growth and developmental needs. Infant formula does not promote infant neurological development in the way that breast milk does. Breast milk includes antibodies from the mother and many other factors that help the infant avoid or fight off infections and give the baby the benefit of the mother's mature immune system.

Infant formula feeds require manufacturing, storage, delivery and reconstitution which raise a multitude of quality control problems.

It is essential that alternatives to breast milk are available. Information for parents who are required, or choose to use infant formula must be clear and objective.

## 2. PURPOSE OF THE GUIDELINES

These guidelines aim to assist prescribers with information on the use of prescribable infant formula. The guidelines are targeted at infants 0-12 months, however, some prescribable items discussed can be used past this age. Where this applies the relevant advice is included. These guidelines provide information on:

- Initiating prescribing
- Quantities to prescribe
- Which products to prescribe for different clinical conditions
- Triggers for reviewing and discontinuing prescriptions
- When to refer for dietetic advice and/or secondary/specialist care.

## 3. LOCAL REFERRAL ARRANGEMENTS

Infants needing a referral to either a paediatric dietitian or a paediatrician for feeding problems should be supplied a suitable milk, and regularly monitored, to cover the time until such an appointment takes place so that the infant continues to thrive.

Local referral arrangements are as below:

- North Kirklees - use the yellow community referral forms to refer directly to the paediatric dietitian at Dewsbury and District Hospital.
- Wakefield – to refer by letter to the paediatric dietitians at Pinderfields/Pontefract Hospitals.
- Huddersfield - contact the paediatric dietitian at Huddersfield Royal on 01484 342382
- Calderdale - contact the paediatric dietitian at Calderdale Royal on 01422 224266

## 4. SUMMARY

- a) Breastfeeding is the best form of nutrition for infants and this should be promoted/ supported wherever possible.
- b) NICE produced guideline CG116 in February 2011 relating to food allergy in children and young people. This covers the diagnosis and assessment of food allergy in children and young people in primary and community settings. [Click here for the NICE care pathway.](#)

- c) Soya products should **not** be prescribed 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 unless on specialist advice e.g. for galactosaemia.
- d) Powdered milks should be the norm. In most cases liquid feeds are a convenience product and should be purchased if needed.<sup>1</sup>

### **Quantities to Prescribe**

Use the guide below when prescribing powdered infant formula:

<b>Age of child</b>	<b>Number of tins for 28 days</b>
Under 6 months	8 x 400g tins or 4 x 900g tins
6-12 months	7 x 400g tins or 3 x 900g tins
Over 12 months	7 x 400g tins or 3 x 900g tins

These amounts are based on:

- For infants under 6 months of age the volume prescribed should be roughly the same as the volume of milk they are currently taking. As a guide, for children under the age of 6 months, a 400g tin should last 3.5 days (therefore 8x400g tins a month; 4x900g tins a month).
- 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.

N.B. Some children may require more e.g. those with faltering growth.

***Always review recent correspondence from the paediatrician or paediatric dietitian.***

### **What NOT to Prescribe**

There is no supporting evidence for the following products:

- **Readymade milks / tetrapacks**<sup>1</sup> - Liquid feeds are a convenience product and should be purchased if needed (preferred by infants as the sterilisation process makes the formula richer and sweeter) there is no clinical advantage.
- **Colief® or Infacol®** - These are Grey List Products – no evidence to support use for lactase deficiency or excess intestinal gas.
- **Pre-thickened milks AND separate thickener** (this includes pre-thickened milks with Gaviscon Infant)
- **Low lactose/lactose free formulae in children with secondary lactose intolerance over 1 year** who previously tolerated cow's milk, since they can use Lactofree® brand full fat milk, soya milk or oat milk from supermarkets.

<sup>1</sup> High energy formulas only come as ready prepared liquid feeds and may be prescribed, e.g. SMA High Energy, Infatrini, Similac High Energy

## 5. COW'S MILK PROTEIN ALLERGY (CMPA)

### Symptoms and Diagnosis

- CMPA may be caused by two distinct immune pathologies: IgE- and non IgE-mediated. Acute IgE-mediated reactions (usually within 2 hours) include rash or urticaria, wheeze or vomiting. Delayed reactions may be non IgE-mediated or mixed (>2 hours) including eczema, colic, diarrhoea
- Refer to [NICE guideline CG116, "Food Allergy in Children & Young People", Feb 2011](#), for full details of symptoms and diagnosis.

Symptoms include:

1. Skin symptoms (pruritis, erythema, urticaria, atopic dermatitis)
2. Acute angioedema of the lips and face, tongue and palate and around the eyes
3. GI symptoms (diarrhoea, bloody stools, nausea and vomiting, abdominal distension and /or colicky pain, constipation, GORD)
4. Recurrent wheeze or cough, nasal itching, sneezing, rhinorrhea or congestion
5. Anaphylaxis
6. Faltering growth

**Most infants with CMPA develop symptoms within 1 week of introduction of CMP-based formula.**

### Onward Referral

- Most infants with CMPA can be managed in primary care until weaned.
- Parents of all infants requiring a cow's milk free diet should be offered dietary advice in a primary care setting, as should breastfeeding mothers following a milk free diet.

**Refer to secondary or specialist care if any of the following apply:**

1. Faltering growth with one or more gastrointestinal symptoms
2. Acute systemic reactions or severe delayed reactions
3. Significant atopic eczema where multiple or cross-reactive food allergies are suspected by the parent or carer
4. Possible multiple food allergies
5. Persisting parental suspicion of food allergy despite a lack of supporting history (especially where symptoms are difficult or perplexing)

### Treatment

- **Breast milk** is the ideal choice for most infants with CMPA.
- If symptoms persist in an exclusively breast fed infant, a maternal milk free diet is indicated for a minimum trial of 2 weeks.
- Breastfeeding mothers on a milk free diet **may** require dietary supplementation with 1000mg calcium per day.
- If breastfeeding is not occurring, **extensively hydrolysed formulae (EHF) are the first choice**, unless the infant has a history of anaphylactic symptoms.
- **Amino acid formulae (AAF) should normally be started by secondary or specialist care.** They are suitable only when EHF do not resolve symptoms and/or there is evidence of severe symptoms (anaphylaxis, severe persisting GI symptoms, severe atopic eczema, faltering growth) or multiple food allergies. **Only if a patient has a history of anaphylactic reaction to cow's milk should AAF be started in primary care, with immediate onward referral to secondary or specialist care.**
- Lactose free formulae (SMA LF, Enfamil O-Lac) are not suitable for those with CMPA.
- **Calcium supplementation** may be needed for infants on these formulas depending on volumes taken. Advice will be given by the paediatric dietitian.

**Refer to appendix 1 - comparative costs of specialist infant formulas, (pages 15-17), for further information on treatment options.**



## 5. COW'S MILK PROTEIN ALLERGY (CMPA)

### 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 and growth.
- **Quantities of formula** required will change with age and growth – see guide to quantities required (page 2) and/or refer to the most recent correspondence from the paediatric dietitian.
- **Avoid adding 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 note 5 below). From 2 years supermarket calcium enriched soya or oat milk may be suitable as an alternative source of milk. Some supermarkets sell Alpro Junior 1+ soya milk which may be suitable from 1 year. The paediatric dietitian will advise on this.
- **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 allergies may require prescriptions beyond 2 years.** This should always be at the suggestion of the paediatric dietitian.

### NOTES

1. **Soya formula (Infasoy®, SMA Wysoy®)** should not routinely be used for patients with CMPA. **It should not be prescribed at all for those less than 6 months due to high phyto-oestrogen content and** should only be advised in patients over 6 months who do not tolerate the first or second line formula suggested in this guidance. Parents should be advised to purchase it as it is a similar cost to cow's milk formula.
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 used 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 eg. with the minimum amount of milkshake flavouring. Care should be taken and ingredients checked in those with multiple allergies.
3. **Prescribe only 1 or 2 tins initially** until compliance/tolerance is established to avoid waste.
4. **Rice milk** is not suitable for children under 5 years due to its arsenic content.
5. **Outgrowing CMPA** – 60-75% of children outgrow CMPA by 2 years of age, rising to 85-90% of children at 3 years of age.
6. **Calcium supplementation** may be needed for infants depending on volume and type of formula taken. The paediatric dietitian will advise. Breast feeding mothers may also need a calcium and vitamin D supplement daily.
7. Infant stools may be strong smelling and have a green colour this is normal with hydrolysed feeds. The milk has a greenish tinge when made up ready for use

## 6. GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

### Symptoms and Diagnosis

- Diagnosis is made from a history of effortless vomiting (not projectile) after feeding, usually in the first 6 months of life, and usually resolves spontaneously by 12-15 months 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.
- Symptoms may include regurgitation of a significant volume of feed, reluctance to feed, distress/crying at feed times, small volumes of feed being taken.

### Onward Referral

- Advice on positioning and feeding techniques from Health Visitor should be discussed.
- 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.

### Treatment

Infants with faltering growth should be referred to paediatric services. For other infants the following can be tried:

- If infant is thriving and not distressed, reassure parents and monitor. Provide advice on avoidance of over feeding, positioning during and after feeding, and activity after feeding.
- Consider a 2-week trial (with planned review) of thickened feeds – using a thickening agent added to usual milk.
- Consider a trial with thickening formula, e.g. Cow & Gate Anti-Reflux, Aptamil Anti-Reflux (OTC), SMA Stay Down or Enfamil AR.
- Review after one month.

***Thickening formulas must not be used in conjunction with any other thickening agents, (for example Gaviscon), as this can lead to over-thickening of the stomach contents. In addition these formulas require an acid environment and will not work properly if prescribed with antacid medications such as PPIs or ranitidine.***

**Refer to appendix 1 - comparative costs of specialist infant formulas, (pages 15-17), for further information on treatment options.**

### 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 can be trialled from 12 months.
- Once vomiting resolves return to standard formula.

### **NOTES**

1. Thickening formulae react with stomach acids, thickening in the stomach rather than the bottle so there is no need to use a large hole teat.
2. SMA Stay Down® contains corn starch.
3. Enfamil AR® contains rice starch.
4. Alert parents/carers to the need to make up thickening feeds with fridge cooled pre-boiled water (see tin for full instructions).
5. 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.

See appendix 3 (pg 16) for advice on PPI therapy in infants.

## 7. 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 symptoms that persist for more than 2 weeks.
- Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis.

### 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), then reintroduction to standard formula/milk products slowly into the diet.
- In infants who have been weaned, low lactose/lactose free formula should be used in conjunction with a milk free diet.
- If an infant presents with suspected lactose intolerance at 1 year or older and is on cow's milk, then a lactose free full fat cow's milk can be used for the treatment period. This can be purchased from supermarkets (Lactofree® brand).

**Refer to appendix 1 - comparative costs of specialist infant formulas, (pages 15-17), for further information on treatment options.**

### 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.
- If the child is weaned and a milk free diet is required, offer advice in primary care and refer for dietary advice / assessment
- If breastfeeding refer to the infant feeding coordinator or IBCLC (lactation consultant) before introducing artificial milk.

### 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.

### **NOTES**

1. Lactose intolerance is defined as a non-immune mediated adverse reaction to food, i.e. it is not due to allergy but to a lack of the enzyme lactase.
2. Primary lactose intolerance is rare and does not usually present until later childhood or adulthood.
3. Lactose free infant formulas can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe. An initial prescription may be appropriate to allow parents time to source further supplies from the retailer of their choice. Most pharmacies and supermarkets can obtain stock in a few days.
4. First line lactose/lactose free formulae are SMA LF® and Enfamil O-Lac®
5. SMA LF® is a low lactose, whole protein cow's milk formula.
6. Enfamil O-Lac® is a lactose, sucrose and fructose free cow's milk formula.
7. **Soya formula (Infasoy®, SMA Wysoy®)** should **not** routinely be used for patients with secondary lactose intolerance. **It should not be prescribed 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 the first line formula suggested in this guidance. Parents should be advised to purchase it as it is a similar cost to cow's milk formula and readily available.

## 8. FALTERING GROWTH

### Symptoms and Diagnosis

- Faltering growth is indicated when the growth of an infant falls below the 0.4th centile or crosses 2 centiles downwards on a growth chart.
- The height/length of an infant needs to be measured to properly interpret changes in weight. It is not possible to detect faltering growth without using appropriate growth charts.
- It is important to consider the reason for faltering growth e.g. iron deficiency anaemia, constipation, GORD or a child protection issue and treat accordingly.

*\*NB- Family history needs to be noted; some families are constitutionally small*

### Onward Referral

- **Infants with faltering growth should be referred to paediatric services without delay.**
- If problem appears related to food refusal/fussy eating, consider referral for behavioural intervention.
- If breastfeeding refer to the infant feeding coordinator or IBCLC (lactation consultant) before introducing artificial milk.

### Treatment

- Secondary care will lead in prescribing for this group of infants and generally, all such prescribing should be initiated by a paediatrician/paediatric dietitian.
- Prescribing can be initiated in primary care in the short term whilst waiting for specialist referral.
- 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.

**Refer to appendix 1 - comparative costs of specialist infant formulas, (pages 15-17), for further information on treatment options.**

### Review and Discontinuation of Treatment

- 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 (usually by the paediatrician).

### **NOTES**

1. 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.
2. These formulae are not suitable as a sole source of nutrition for infants over 8kg or 18months of age.
3. Do not add formula to repeat templates as ongoing need for formula and amount needed will need to be checked with each prescription request.
4. Manufacturers instructions regarding safe storage once opened and expiry of ready to drink formulae should be adhered to. This may differ from manufacturer to manufacturer.

## 9. PRE-TERM INFANTS

### Indications

- Preterm formula is used for babies born before 34 weeks gestation, weighing less than 2kg at birth.
- These babies will have been started on nutrient enriched preterm formula prior to discharge from hospital.

### Onward Referral

- These infants must be under regular review by paediatricians
- The paediatrician will refer any baby with faltering growth to the paediatric dietician
- If there are concerns at 6 months corrected age or at a review one month after the formula is stopped, a referral should be made back to paediatric services

**Treatment** – will require prescriptions for Nutriprem 2 (powder) or SMA Gold Prem 2 (powder) which should have been started in secondary care.

***These formulas should not be used in primary care to promote weight gain in patients other than babies born prematurely and started on these feeds by secondary care.***

**Refer to appendix 1 - comparative costs of specialist infant formulas, (pages 15-17), for further information on treatment options.**

### Review and Discontinuation of Treatment

- Monitoring of growth (weight, length and head circumference) should be carried out by the Health Visitor 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.

## 10. DO'S 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.
- Initiate treatment but at initiation refer the infant for dietician review.
- Check the amount of formula prescribed is appropriate for the age of the infant (see page 4) 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 only 1 or 2 tins/bottles initially until compliance/tolerance is established.
- Remind parents that ready to drink formula and powdered formula, once mixed, are safe for 4 hours in the bottle at room temperature or 24 hours in the fridge.
- Refer where appropriate to secondary or specialist care - see advice for each condition.

### Do NOT:

- Add infant formulae to the repeat prescribing template in primary care.
- Prescribe lactose free formulae (SMA LF®, Enfamil O-Lac®) for infants with CMPA.
- Routinely prescribe soya formula (Infasoy®, 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 goat's milk and formulae made from it, sheep's milk or other mammalian milks for those with CMPA or secondary lactose intolerance.**
- Do not suggest rice milk for those under 5 years due to high arsenic content.
- Prescribe Nutriprem2® liquid unless there is a clinical need.
- Prescribe thickening formulae (SMA Staydown®, Enfamil AR®) with separate thickeners, Gaviscon, or in conjunction with medication such as 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 Lactofree® brand full fat milk, soya milk or oat milk from supermarkets.

## COMPARATIVE COSTS OF SPECIALIST INFANT FORMULAE<sup>2</sup>

Recommended volumes to prescribe listed below are for infants over 6 months of age.

First-line choices are based on COST only. Prescribers must switch to an alternative product if tolerance issues are identified.

Cow's Milk Protein Allergy (CMPA)						
Formula	Size of tin (g)	Age Range	Max tins per month	Price (per tin)	Cost per 100ml	Comments
<b>Extensively Hydrolysed Formula (EHF)</b>						
Similec Alimentum	400g	Birth – 2 years	7	£9.10	0.29p	Lactose free
Aptamil Pepti 1	400g & 900g	Birth – 6 months	7 x 400g 3 x 900g	400g = £9.54 900g = £21.46	0.32p	Contain lactose
Aptamil Pepti 2	900g	6 months – 2 years	3	£20.48	0.32p	
Althera (SMA)	450g	Birth – 12 months	6	£10.68	0.31p	
Nutramigen Lipil 1	400g	Birth – 6 months	7	£10.38	0.35p	Lactose free
Nutramigen Lipil 2	400g	6 months – 2 years	7	£10.38	0.38p	
<b>Amino Acid Formula (AAF)</b>						
Nutramigen AA	400g	Birth until able to tolerate OTC products	7	£25.58	0.87p	Should normally be started by secondary or specialist care unless patient has a history of anaphylactic reaction to cow's milk. For these patients AAF may be started in primary care with immediate onward referral to secondary or specialist care.
Neocate LCP	400g	Birth until able to tolerate OTC products	7	£28.30	0.98p	
Neocate Active	15x63g (unflavoured or blackcurrant)	Over 1 year	3	£66.60	£1.48	Neocate Active & Neocate Advance are highly specialised products and therefore should only be used by secondary or specialist care.
Neocate Advance	10 x 100g sachets (unflavoured) 15 x 50g sachets (banana/vanilla flavour)	Over 1 year	3 4	£58.60 £46.35	£1.47 £1.54	

KEY:	USE FIRST LINE	USE IF FIRST-LINE UNSUCCESSFUL	SHOULD NOT BE ROUTINELY COMMENCED IN PRIMARY CARE	SHOULD NOT BE ROUTINELY PRESCRIBED
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<sup>2</sup> Prices obtained from NHS Dictionary of Medicines and Devices and Chemist and Druggist. Accessed at 24 February 2014 and maybe subject to change



First-line choices are based on COST only. Prescribers must switch to an alternative product if tolerance issues are identified.

GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)						
Formula	Size of tin (g)	Max tins per month	Age Range	Price (per tin)	Cost per 100ml	Comments
<b>Thickened Formula</b>						
SMA Stay Down	900g	3	Up to 18 months	£7.29	0.10p	Symptoms usually resolve between 12-15 months of age. Once vomiting resolves return to standard formula  Consider advising on OTC products initially. Both C&G Anti-Reflux and Aptamil Anti-Reflux are available OTC
Enfamil AR	400g	7	Up to 18 months	£3.52	0.12p	

SECONDARY LACTOSE INTOLERANCE						
Formula	Size of tin (g)	Max tins per month	Age Range	Price (per tin)	Cost per 100ml	Comments
<b>Low Lactose/Lactose Free Formula</b>						
SMA LF	430	7	Birth – 2 years	£5.06	0.15p	Treat for 4-8 weeks to allow symptoms to resolve, then reintroduction to standard formula/milk products slowly into the diet.  For children > 1 year who previously tolerated cow's milk, do not prescribe. Suggest use of lactose free full fat cow's milk which can be purchased from supermarkets (Lactofree brand). <b>NOTE – Lactose free infant formula can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe.</b>
Enfamil O-Lac	400	7		£4.70	0.15p	

FALTERING GROWTH						
Formula	Size of bottle (ml)	Max bottles per month	Age Range	Price (per bottle)	Cost per 100ml	Comments
<b>High Energy Formula</b>						
SMA High Energy	250ml	68	Birth – 18 months (or 8kg)	£2.29	0.92p	Refer any infant being commenced on a high energy formula to a Dietitian for appropriate monitoring.
Infatrini	100ml, 200ml & 500ml	168 x 100ml 84 x 200ml 34 x 500ml	Birth – 18 months (or 8kg)	£1.12 £2.17 £5.89	£1.12 £1.08 £1.18	
Similac High Energy	65ml, 120ml & 200ml	260 x 65ml 140 x 120ml 84 x 200ml	Birth – 18 months (or 8kg)	£0.65 £1.30 £2.10	£1.00 £1.08 £1.05	
<b>KEY:</b>	<b>USE FIRST LINE</b>	<b>USE IF FIRST-LINE UNSUCCESSFUL</b>	<b>SHOULD NOT BE ROUTINELY COMMENCED IN PRIMARY CARE</b>		<b>SHOULD NOT BE ROUTINELY PRESCRIBED</b>	



PRE-TERM INFANTS						
Formula	Size of tin (g)	Max tins per month	Age Range	Price	Cost per 100ml	Comments
SMA Gold Prem 2 powder	400g	8	Birth up to a max of 6 months corrected age*	£5.03	0.18p	These babies would have been started on nutrient enriched preterm formula prior to discharge from hospital.
Nutriprem 2 powder	900g	4		£11.24	0.19p	
SMA Gold Prem 2 liquid	250ml bottle	Not to be routinely prescribed unless there is clinical need e.g. immunocompromised infant.		£2.10	0.84p	Stop pre-term formula at 6 months corrected age and change to standard term formula. Refer to dietitian if concerns regarding weight gain.  NOTE – these formulas should not be started in primary care to promote weight gain.  *6 months corrected age = EDD + 26 weeks
Nutriprem 2 liquid	200ml bottle			£1.68	0.84p	

KEY:	USE FIRST LINE	USE IF FIRST-LINE UNSUCCESSFUL	SHOULD NOT BE ROUTINELY COMMENCED IN PRIMARY CARE	SHOULD NOT BE ROUTINELY PRESCRIBED
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## PPI THERAPY IN INFANTS

### (LOCAL ADVICE)

The following advice has been issued by Mid Yorks NHS Trust for the use of PPI agents in infants

#### Rationalisation of Proton Pump Inhibitors in Children

Following discussions with paediatric consultants with regards to standardising Proton Pump Inhibitors in children, it has been agreed to use Lansoprazole orodispersible tablets (*Zoton FasTabs*) in children over 5kg. Although lansoprazole is not licensed for use in children, there is peer support for its use (BNFc). Lansoprazole orodispersible tablets offer a more practical alternative for administration. It is also significantly less expensive than omeprazole (*Losec*) MUPS or 'special' liquid formulations.

The FasTabs are licensed for administration via nasogastric feeding tubes.

Weight (Kg)	DOSE RANGE		Suggested Dose	Portion of Lansoprazole 15mg Fastab
	0.5mg/kg	1mg/kg		
5kg	2.5mg	5mg	3.75mg	A quarter
10kg	5mg	10mg	7.5mg	Half a tablet
15kg	7.5mg	15mg	7.5mg to 15mg	Half a tablet to one tablet
20kg	10mg	20mg	15mg	One tablet
25kg	12.5mg	25mg	15mg	One tablet

For children under 5kg - use Omeprazole MUPS.

For Omeprazole MUPS, disperse 10mg with 10ml water. This results in a 1mg/1ml suspension. Shake well and immediately give the appropriate dose and discard any remainder.

Lansoprazole should be given on an empty stomach, so feeds should be withheld for one hour prior and post administration of lansoprazole.

Calderdale and Huddersfield NHS Foundation Trust follow Mid Yorks advice except Lansoprazole can be used from 3.5kg:

Weight (Kg)	DOSE RANGE		Suggested Dose	Portion of Lansoprazole 15mg Fastab
	0.5mg/kg	1mg/kg		
3.5 - 5kg	2.5mg	5mg	3.75mg	A quarter
10kg	5mg	10mg	7.5mg	Half a tablet
15kg	7.5mg	15mg	7.5mg to 15mg	Half a tablet to one tablet
20kg	10mg	20mg	15mg	One tablet
25kg	12.5mg	25mg	15mg	One tablet

Lansoprazole FasTabs are strawberry flavoured and contain aspartamine and lactose.

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