

# Prescribing Guidelines for Specialist Infant Formula Feeds

September 2017

Review Date: September 2020

Version 1.1

## Version Control:

Version No	Type of Change	Date	Description of change

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## **1.0 INTRODUCTION**

The purpose of this guidance is to outline recommendations for the prescribing of infant formula feeds in Worcestershire.

Worcestershire promotes breastfeeding as 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 breastfed babies who present with cow's 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 the guidance are to:

- Aid diagnosis and improve access to special 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 by primary care.
- Providing 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.

## **2.0 Summary**

See tables on page 4 and 5

The Worcestershire CCGs Specialist Infant Formula & Products Commissioning Policy should be read in conjunction with this guideline.

## Prescribing Guidelines for Specialist Infant Formula Feeds Summary

All conditions	Under 6 months	6-12 months	Over 12 months
Amount of formula to prescribe for 28 days	13x 400g, 12 x 450g or 6 x 900g	7-13 x 400g/450g or 3-6 x 900g	7 x 400g, 6 x 450g or 3 x 900g

**Discuss any red flag symptoms with the on call paediatrician:**

Blood stained vomit or stools, melaena, abdominal distension or bile stained vomit or weight loss

<b>COWS MILK PROTEIN ALLERGY (CMPA)</b>	<ul style="list-style-type: none"> <li>Symptoms: skin symptoms, e.g. pruritis, erythema, urticaria, atopic dermatitis, acute angioedema. GI symptoms, e.g. diarrhoea, bloody stools, nausea and vomiting, abdominal distention and/or colicky pain, constipation, GORD, respiratory symptoms, e.g. current wheeze or cough, nasal itching, sneezing, rhinorrhea or congestion, anaphylaxis or faltering growth.</li> <li>Breast milk is the best choice for most infants with CMPA. Mother to be on a milk free diet.</li> </ul>	
	<b>First line formula choices</b>	Aptamil Pepti 1® & Aptamil Pepti 2® Nutramigen with 1 LGG® & Nutramigen with 2 LGG®
	<b>DO NOT PRESCRIBE</b>	Soya based formula (Wysoy®) Lactose free formula (SMA LF®, Enfamil-o-Lac®)
	<b>Second line products e.g. amino acid formula</b>	Should only be started after referral to specialist eg paediatrician, dietician or ANP
	<ul style="list-style-type: none"> <li>Review the need for continued prescribing if the answer is yes to any of the following questions: Can the patient tolerate any dairy foods? Is the patient over two years of age? Has the formula been prescribed for more than one year? Is the quantity prescribed more than the recommended amount?</li> </ul>	
<b>GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)</b>	<ul style="list-style-type: none"> <li>GORD presents with a history of effortless vomiting after feeding (up to two hours), usually in the first six months of life.</li> <li>Over feeding should be ruled out by establishing the volume and frequency of feeds.</li> <li>Give reassurance and advice on positioning post-feed.</li> <li>Infant Gaviscon can be given up to a maximum of six times per day.</li> </ul>	
	<b>DO NOT PRESCRIBE</b>	Cow& Gate® Anti-reflux, Aptamil® Anti-reflux SMA Staydown® Enfamil AR®

<b>INFANT COLIC</b>	<ul style="list-style-type: none"> <li>Symptoms: crying in bouts for no reason, refusing feeds and rumbling tummy, pulling up knees.</li> <li>Reassure and provide leaflet via EMIS or patient <a href="https://patient.info/health/baby-colic-leaflet">https://patient.info/health/baby-colic-leaflet</a></li> </ul>
	<p><b>DO NOT PRESCRIBE</b></p> <p>Colief, Infacol; 'Comfort' milks eg Aptamil Comfort, Cow and Gate Comfort, SMA Comfort</p>
<b>LACTOSE INTOLERANCE</b>	<ul style="list-style-type: none"> <li>Primary lactase deficiency usually occurs after 2 years of age. Secondary lactose intolerance usually occurs after gastrointestinal illness.</li> <li>Symptoms: abdominal bloating, increased (explosive) wind, loose green stools.</li> <li>Resolution of symptoms within 48 hours of withdrawal of lactose from diet confirms diagnosis.</li> </ul>
	<p><b>DO NOT PRESCRIBE</b></p> <p>Lactose free formula (SMA LF<sup>®</sup>, Enfamil-o-Lac<sup>®</sup>) - should be purchased</p>
<b>FALTERING GROWTH</b>	<ul style="list-style-type: none"> <li>Faltering growth cannot be detected without using a growth chart.</li> <li>Diagnosis is made when the growth of an infant falls below the 0.4<sup>th</sup> centile or crosses 2 centiles downwards on a growth chart or weight is 2 centiles below length centile.</li> </ul>
	<p><b>Preferred formula choices</b></p> <p>Similac High Energy<sup>®</sup> SMA High Energy<sup>®</sup></p>
<b>PRE-TERM FORMULA</b>	These infants will have had their pre-term formula commenced on discharge from the neonatal unit and will be undergoing regular review by the paediatricians.
	<p><b>Started in secondary care</b></p> <p>SMA Gold Prem 2<sup>®</sup> Nutriprem 2<sup>®</sup></p>
	<p><b>DO NOT PRESCRIBE</b></p> <p>Liquid formula unless clinically indicated by secondary care e.g immunocompromised infant</p>

### 3.0 Cow's milk protein allergy (CMPA)

#### 3.1 Symptoms and diagnosis

- Refer to NICE Clinical Guideline CG116 'Food Allergy in Children and Young People' Feb 2011 for full details. <https://www.nice.org.uk/guidance/cg116/resources/cg116-food-allergy-in-children-and-young-people-full-guideline3>
- Useful CMPA diagnosis and management flowcharts are available in 'Diagnosis and management of non-immunoglobulin-E (IgE) mediated cow's milk allergy in infancy. <https://ctajournal.biomedcentral.com/articles/10.1186/2045-7022-3-23>
- Symptoms are usually severe and of acute onset if the allergy is IgE-mediated and have a delayed onset if the allergy is non-IgE mediated. Symptoms can include:
  - Skin symptoms (pruritis, erythema, urticaria, atopic dermatitis, acute angioedema of the lips and face, tongue and palate, and around the eyes)
  - GI symptoms (diarrhoea, bloody stools, nausea and vomiting, abdominal distension and /or colicky pain, constipation, GORD)
  - Respiratory symptoms (recurrent wheeze or cough, nasal itching, sneezing, rhinorrhoea or congestion)
  - Anaphylaxis
  - Faltering growth
- Red flag symptoms (blood stained vomit or stools, melaena, abdominal distension or bile stained vomit or weight loss) should be discussed with the on call paediatrician.
- Babies who cry a lot, appear unsettled or have symptoms of possible reflux but are thriving are unlikely to have CMPA.

#### 3.2 Timing of onset of symptoms

NICE recommends further investigation with a skin prick test or specific IgE antibody blood test if IgE-mediated allergy is suspected. When non-IgE mediated allergy is likely, trial elimination for two to six weeks of the suspected allergen is advised with a planned and intentional reintroduction. Most infants with CMPA develop symptoms within one week of re-introduction of cow's milk containing formula.

#### 3.3 Dietary management

- If symptoms persist in exclusively breast-fed infants, a maternal milk free diet is indicated for minimum trial of two weeks.
- Breast milk is the best choice for most infants with CMPA. Breastfeeding mothers on a milk free diet may require supplementation with 1000mg calcium per day.
- If breastfeeding is not occurring, extensively hydrolysed formulae (EHF) are the first choice and should be prescribed, unless the infant has a history of anaphylaxis to cow's milk, Heiner Syndrome, eosinophilic eosophagitis and severe gastro-intestinal and/or skin presentations, particularly in association with faltering growth.
- Amino acid formulae (AAF) should only be started after referral to secondary care. They are suitable when EHF does not resolve symptoms and/or evidence of severe (anaphylactic) allergy.
- If breastfeeding mothers do not wish to or are unable to follow a milk free diet, or are following a milk free diet and symptoms persist, an EHF will be needed if top-ups are required and can be prescribed in primary care.
- If a patient has a history of anaphylactic reaction to cow's milk, AAF may be started in primary care, with immediate onward referral to secondary or specialist care.

### 3.4 Review and discontinuation of dietary management and challenges with cow's milk

- Review prescriptions regularly to check formula prescribed is appropriate for the child's age.
- Quantities of formula required will change with age – see guide to quantities required (page 4) and/or refer to the most recent correspondence from the paediatric dietitian.
- Avoid adding to repeat template for these reasons, unless a review process is established.
- Challenging with cow's milk – children should have a cow's milk free diet until 9-12 months of age and for at least 6 months.
- The child should be evaluated every three months to assess development of tolerance to cow's milk protein. This can be done at home if there are no indications for referral to secondary care, for example one or more acute systemic reactions.
- Reintroduction of milk products using the milk ladder recommended by the Milk Allergy in Primary Care (MAP) guidance (<http://cowsmilkallergyguidelines.co.uk/interactive-algorithm/#div12>). If a child reacts then wait three months before re-trying
- Prescriptions should be stopped when the child has outgrown the allergy. European data suggests that 57- 69% of CMPA infants can tolerate cow's milk 12 months after initial diagnosis.
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
  - Is the patient over two years of age?
  - Has the formula been prescribed for more than one year?
  - Is the patient prescribed more than suggested quantities of formula according to their age?
  - Is the patient prescribed a formula for CMPA but able to eat/drink any of the following foods cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee? (Cooked milk products are usually better tolerated).
  - Children with multiple or severe allergies may require prescriptions beyond two years. This should always be at the recommendation of the paediatric dietitian.

### 3.5 CMPA first line options

Lactose containing products	Lactose free products
Aptamil Pepti 1® 400g/ 800g	Nutramigen 1 with LGG® 400g
Aptamil Pepti 2® 400g/800g	Nutramigen 2 with LGG® 400g

### 3.6 CMPA secondary line options

- Prescribing of these second line options should be started after referral to a specialist e.g. paediatrician, ANP or dietitian.

Extensively hydrolysed formula with medium chain triglyceride Used where CMPA is accompanied by malabsorption	Amino Acid formula (AAF) suitable only where an EHF does not resolve the symptoms and/or there is evidence of severe (anaphylactic) allergy	High calorie formulae- not automatically required by all infants over 1 year. See also section on faltering growth
Pepti Junior® (contains lactose)	Alfamino® 400g	Neocate Junior® 400g
Pregestimil Lipil® (lactose free)	Nutramigen Puramino® 400g	Neocate Spoon® 15 x 37g
	Neocate LCP® 400g	

### **3.7 Soya and other milks**

- Soya formula should not routinely be used for patients with CMPA or lactose intolerance.
- They have a high phyto-oestrogen content and other more appropriate hydrolysed protein formulas are available.
- It should only be advised in patients over six months who do not tolerate first line extensively hydrolysed formula (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 one year. Note that it is advertised as suitable from birth.
- In line with the CCGs Commissioning Policy these products should be purchased. Parents/carers should be advised to purchase soya formula as it is a similar cost to cow's milk formula and readily available. See Worcestershire CCGs Specialist Infant Formula & Products Commissioning Policy.

## **4.0 Gastro-oesophageal reflux disease (GORD)**

### **4.1 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.
- Refer to NICE NG 1: Gastro-oesophageal reflux disease in children and young people: diagnosis and management for full details. <https://www.nice.org.uk/guidance/ng1/chapter/1-Recommendations>
- Diagnosis is made from history that may include effortless vomiting (not projectile) after feeding (up to two hours), usually in the first six 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.
- Resolution of symptoms can occur through reducing the quantity of feed and suitable positioning post-feed. 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 six months, and should be offered spread over six to seven feeds.
- Red flag symptoms should be discussed with the on call paediatrician. These include recurrent, forceful (projectile vomiting) which might suggest pyloric stenosis, blood stained vomit or stools, melaena, abdominal distension or bile stained vomit or weight loss.

### **4.2 Treatment**

- If the infant is thriving and not distressed reassure the parents/ carers 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 can be tried. Examples:
  - Aptamil® anti-reflux; pre-thickened
  - Cow & Gate anti-reflux®; pre-thickened
  - Enfamil AR®; thickens in stomach and contains rice starch
  - SMA Stay Down; thickens in stomach and contains cornstarch

- In line with the Worcestershire CCGs Specialist Infant Formula & Products Commissioning Policy these products should be purchased.
- If the bottle fed infant is not gaining weight and/or not settled consider trial with thickening formula or antacid, e.g. Infant Gaviscon®. Advice for those with faltering growth will be given by secondary/specialist care.
- If breast-fed infant is not gaining weight and/or not settled consider trial with Infant Gaviscon® offered on a spoon before feeds. Advice for those with faltering growth will be given by secondary/specialist care.
- Pre-thickened formulas should not be used along with other thickening agents, e.g. Gaviscon®, Carobel® to avoid over thickening of the stomach contents. Pre-thickened formula requires the use of a large hole (fast-flow) teat.
- Formulae that thicken in the stomach react with stomach acids to thicken and should not be used in conjunction with separate thickeners or with medication such as ranitidine, or proton pump inhibitors. As they thicken in the stomach rather than the bottle there is no need to use a large hole (fast flow) teat.
- Thickeners such as Infant Gaviscon® are preferred for babies who vomit immediately post-feed. Infant Gaviscon® contains sodium, and should not be given more than six 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'.

## **5.0 Infant Colic**

### **5.1 Signs and Symptoms**

- Crying in bouts for no apparent reason. Can go on and off for hours. Cry might be higher pitched than normal.
- Refusing feeds and rumbling tummy.
- Pulling up the knees.
- Red flag symptoms should be discussed with the on call paediatrician. These include features of sepsis, features of intussusception/bloody stools or weight loss.

### **5.2 Treatment**

- Give advice / reassure and provide leaflet via EMIS web or <https://patient.info/health/baby-colic-leaflet>
- Reassure that colic occurs in up to 3 out of 10 babies and tends to stop by age 3-4 months.
- Discuss the need for 'time-out' from a crying baby and reassure this acceptable.
- Direct care giver to CRY-SIS website: <http://www.cry-sis.org.uk/>
- The prescribing of products for colic including lactase enzyme drops (Colief®) is not supported in Worcestershire. See Worcestershire CCGs Specialist Infant Formula & Products Commissioning Policy.
- The prescribing of 'comfort' milks is not supported in Worcestershire. Examples include Aptamil Comfort, Cow & Gate Comfort, SMA Comfort. See Worcestershire CCGs Specialist Infant Formula & Products Commissioning Policy.
- Clinical Knowledge summaries do not recommend the use of these products because there is insufficient good quality evidence to support their use.

## **6.0 Lactose Intolerance**

### **6.1 Symptoms and diagnosis**

- Primary lactase deficiency is less common than secondary lactose intolerance and does not usually present until after two years of age and may not fully manifest itself until adulthood. Secondary lactose intolerance usually occurs following an infectious gastrointestinal illness but may be present alongside newly coeliac disease. It may also be a sign of 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 two weeks.
- Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis.
- Red flag symptoms which include blood stained vomit or stools, melaena, abdominal distension or bile stained vomit or weight loss should all be discussed with the on call paediatrician.

### **6.2 Treatment**

- Give advice and reassure.
- Treatment of secondary lactose intolerance should be with purchased lactose free formula for six to eight weeks to allow symptoms to resolve. Most cases resolve within 8 weeks. If still not tolerated consider discussion with paediatrician. Standard formula and/or milk should then be slowly reintroduced to the diet.
- Lactose free formula should be purchased over the counter. See Worcestershire CCGs Specialist Infant Formula & Products Commissioning Policy.
- In infants who have been weaned, lactose free formula should be used in conjunction with a milk free diet.
- Lactose free formula should be stopped at 12 months. For infants over 12 months full cream equivalent lactose free milks available from supermarkets should be used.

## **7.0 Faltering Growth**

### **7.1 Symptoms and diagnosis**

- Diagnosis is made when the growth of an infant falls below the 0.4<sup>th</sup> centile or crosses 2 centiles downwards on a growth chart or weight is 2 centiles below length centile.
- The height/length of an infant are measured to properly interpret changes in weight using appropriate growth charts to be able to diagnose.
- Need to rule out any disease related/ medical cause e.g. iron deficiency anaemia, constipation, GORD, cow's milk allergy, other food allergies or child protection issues.

### **7.2 Treatment**

- 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 paediatrician or paediatric dietitian.
- Do not add formula to the repeat templates as ongoing need for formula and amount required will need to be checked with each prescription request.
  - Infantrini®

- SMA High Energy®
- Neocate Junior®
- Neocate Spoon®

## **8.0 Post discharge nutrition for pre-term infants**

### **8.1 Indications**

- These infants should have their prescribed 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 other than babies born prematurely.

### **8.2 Products**

- Nutriprem 2® (900g)
- SMA Gold Prem 2® (400g)
- The ready to drink liquids are not supported for use in Worcestershire unless there is specific clinical need e.g. immunocompromised infant. See Worcestershire CCGs Specialist Infant Formula & Products Commissioning Policy.

### **8.3 Review and Discontinuation**

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

## **9.0 References**

Prescqiipp Bulletin 146. Appropriate prescribing of specialist infant formulae (foods for special medical purposes) November 2016. <https://www.prescqiipp.info/infant-feeds/send/93-infant-feeds/3141-bulletin-146-infant-feeds> Accessed on 17/8/17

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## **10.0 Acknowledgements**

Midlands and Lancashire CSU