

# DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

# GUIDANCE ON THE APPROPRIATE USE AND PRESCRIBING OF SPECIALIST INFANT FORMULA IN PRIMARY CARE

(Including Lactose Intolerance and Cow's Milk Protein Allergy)

The CCGs promote breastfeeding as the best form of nutrition for a good start in life for every child.

This guidance covers information on the use and prescribing of specialist infant formulas for: faltering growth, premature and low birth weight infants, cow's milk protein allergy, lactose intolerance/galactoasemia.

- All suspected/confirmed cases of non IgE CMPA should be referred to a paediatric dietician (via a paediatrician if necessary) for assessment and dietary advice. Infants should be given a cow's milk protein diet free for at least 6 months. Children can be re-challenged from 12 months of age onwards. Most children will outgrow their allergy by 18 months to 2 years of age.
- Within **Southern Derbyshire**, Non IgE CMPA can be managed using the GP Patient Pathway for Infants under 1 year of age with Cow's Milk Protein Allergy (Non IgE mediated).
- Within **North Derbyshire**, CMPA should be managed following the Milk Allergy in Primary Care (iMAP) Guideline.
- Infants with IgE CMPA should not be challenged with cow's milk in order to confirm their diagnosis. Refer to allergy clinic.
- Extensively hydrolysed infant formula is the first line formula of choice for mild to moderate symptoms of CMPA.
- Secondary lactose intolerance should be treated in primary care with over the counter lactosefree formula and lactose-free diet. Secondary lactose intolerance in infants usually lasts 6-8 weeks but may last as long as 3-6 months. Re-challenge after 3-6 months.
- Soya based formula should not be prescribed unless advised by a consultant paediatrician or paediatric dietician. Only children with specific rare medical conditions require a prescribed soya formula after 1 year of age.
- In premature infants, the specialised infant formula should not be prescribed beyond 6 months corrected age.

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Document update	Date
p.11 further info regarding Halal/ Kosher diet added	January 2019
p.3 SMA pro high energy update as SMA high energy	July 2019
p.6 update PHE advice regarding vitamin D supplementation	October 2019

## 1. Introduction

This guideline has been developed following local concerns about the high expenditure and inequitable prescribing of infant formulae due to lack of guidance, little evidence and limited primary care expertise in this area.

The guideline provides information on some common conditions requiring the use of infant formula. It also sets out circumstances in which prescribing is inappropriate and advises primary care practitioners on products available and management in secondary care.

Infants with severe symptoms, demonstrating faltering growth or with a weight less than the 0.4<sup>th</sup> centile should be referred to a consultant paediatrician urgently.

All suspected cases of non IgE Cow's Milk Protein Allergy (CMPA) should be referred to a paediatric dietitian to ensure appropriate assessment, diagnosis and management of the condition. Once diagnosis of CMPA is confirmed and a management plan put in place, it is recommended that GPs do not initiate changes of formula without consultation with a paediatric dietitian or consultant paediatrician.

Frequent changes of formula are not advised in primary care due to the level of parental support required.

#### 2. Faltering Growth

The term 'failure to thrive' was once used to describe infants and young children who failed to reach their expected growth. The term 'faltering weight' or 'faltering growth' is now the accepted term for infants and children that show a fall in weight or poor weight gain. Under nutrition is recognised as the primary cause of poor weight gain in infancy.

# **Definition** *NICE NG75 (2017):*

Consider using the following as thresholds for concern about faltering growth in infants and children (a centile space being the space between adjacent centile lines on the UK WHO growth charts):

- a fall across 1 or more weight centile spaces, if birthweight was below the 9th centile
- a fall across 2 or more weight centile spaces, if birthweight was between the 9th and 91st centiles
- a fall across 3 or more weight centile spaces, if birthweight was above the 91st centile
- when current weight is below the 2nd centile for age, whatever the birthweight.

#### **Treatment**

Breastfed infants should be referred to the local breastfeeding advisors to ensure that the latch and feeding technique is optimised. Consider: tongue tie, postnatal depression, cow's milk protein allergy and gastroesophageal reflux disease (GORD). Breastfeeding can continue in each of these conditions. They are not grounds for recommending a change to formula.

Formula fed infants should have their feeding volumes monitored at home, to ensure that infants under 6months of age are drinking 150ml/kg per day and infants 6-12months of age are drinking 120ml/kg per day.

Once the above has been considered and offered and the weight gain is not improving within two weeks, refer to a paediatrician and paediatric dietitian. If in South Derbyshire, The Paediatrician will complete the referral through to the Paediatric Dietitian if indicated following assessment.

Prescribable infant formulas for faltering growth: (to be used only under the guidance of a paediatrician and paediatric dietitian)

Formula	Indication	Notes
Infatrini (Nutricia)	Faltering weight	1kcal/ml
SMA High Energy	Faltering Weight	<ul> <li>1kcal/ml, partially hydrolysed milk protein suitable to use in malabsorption</li> </ul>
Infatrini Peptisorb (Nutricia)	Faltering Growth / Malabsorprtion	1kcal/ml, extensively hydrolysed milk protein. Suitable to use in malabsorption and cow's milk protein allergy

## 3. Preterm (<37 weeks gestation) and low birth-weight (<2500g) infants

# **Royal Derby Hospitals**

#### Infant formula

In infants who are not breast-fed, or where supplementation to breast-feeding is required, Nutriprem 1 will be initiated by RDH. This will be continued until the infant reaches 1800g. Infants discharged on Nutriprem 1 will continue to receive supplies from Neonatal Intensive Care Unit.

When the infant reaches 1800g, the formula will be switched to Nutriprem 2. Infants will receive ready-made formula in hospital. However, 900g tins of Nutriprem 2 powder are suitable for prescribing on discharge and in the community.

Appropriate vitamins and iron supplements should also be prescribed, as advised by the hospital - see below.

Infants might be changed to standard infant formula before 6 months if their growth is assessed as optimal. Once Nutriprem 2 is stopped, parents are advised to purchase normal formula.

N.b. Nutriprem 2 should not be prescribed beyond 6 months corrected age.

Infants who are not gaining adequate weight to maintain their centile will be referred to a paediatric dietitian for assessment and advice on appropriate formula. The dietitian might recommend a prescribable product.

# Supplementation (for infants born at <34 weeks gestation)

	Vitamin & iron supplement
Breast-fed infants	14 drops (0.6ml) Abidec daily 1ml sodium feredetate (iron 27.5mg/5ml) oral solution sugar free daily commenced at 4 weeks of age.  Continue until 1 year corrected age (ie 1 year from EDD)
Breast milk supplemented with Nutriprem 2 or Normal infant formula	7 drops (0.3ml) Abidec daily 1ml sodium feredetate (iron 27.5mg/5ml) oral solution sugar free daily commenced at 4 weeks of age.  Continue until 1 year corrected age (ie 1 year from EDD)
Nutriprem 1 or 2 as sole source of nutrition	no supplementation required (intake approximately 120ml/kg/day to 165ml/kg/day)

# Monitoring

Weights are plotted on individual UK WHO growth charts. On discharge, each family will be given written information on feeding their premature baby. A family care co-ordinator will take on the responsibility for supporting the family; advise on frequency of weighing/monitoring and ensuring the infant is gaining weight appropriately. They will liaise with the paediatric dietitian or paediatrician responsible for the infant's care if there are any concerns. They will also liaise with the health visitor and GP.

#### **Notes**

Corrected age = actual age adjusted by number of weeks child was born before 40 weeks gestation (Expected Delivery Date).

## **Chesterfield Royal Hospital Foundation Trust (CRHFT)**

CRHFT follows the feeding guidelines from the North Trent Neonatal Network.

Mothers are encouraged to breastfeed or express breastmilk (EBM) and fortification is used when birthweight is low or growth is poor. EBM may be fortified in hospital with powdered breastmilk fortifiers. Comparable examples are:

Formula	Indication	Notes
SMA Breastmilk Fortifier	Fortification of EBM	<ul> <li>Not available on prescription in primary care</li> <li>In hospital 50 X 2g sachets</li> </ul>
Cow and Gate Nutriprem Breastmilk Fortifier	Fortification of EBM	<ul> <li>Not available on prescription in primary care</li> <li>In hospital 50 X 2.1g sachets</li> </ul>

For mothers who wish to continue breastfeeding or expressing, but their infant's weight gain is poor, every effort will be made to find suitable alternative methods of EBM fortification in the community, the assistance of a paediatric dietitian is recommended.

If mothers are unable to breastfeed or express, a first stage preterm formula is used. Comparable examples are:

Formula	Indication	Notes
SMA Gold Prem Pro	Preterm or low birth weight infants	Ready to use 70ml bottles
Cow and Gate Nutriprem 1 Low Birthweight Formula	Preterm or low birth weight infants until 1800-2000g weight achieved	Ready to use 70ml bottles
Milupa Aptamil Preterm	Preterm or low birth weight infants	Ready to use 70ml bottles

Upon discharge, or once the infant reaches 2000g in weight, they should be changed to a second stage preterm formula:

Formula	Indication	Notes
SMA Gold Prem 2 Catch-up formula	Preterm or low birthweight infants, post discharge until 6months corrected age.	400g tins of powder
Cow and Gate Nutriprem 2	Preterm or low birthweight infants, post discharge until 6months corrected age.	900g tins of powder or 200ml ready to feed cartons

**NOTE:** Liquid feeds should only be used in community when advised by the neonatal unit, e.g. for immunocompromised patients

#### **Supplementation**

Using the table below, commence daily nutrient supplementation as recommended.

# <u>Prescribe supplementation for premature/ low birth weight infants until 1 year of age, and then these can be purchased by parents over-the-counter.</u>

Feed	Birth Weight	Supplements & Vitamins
Breastfed	< 2500g (LBW)	14 drops (0.6 ml) Abidec daily until 5 year of age*
or Expressed Breastmilk (EBM)		1ml sodium feredetate (iron 27.5mg/5ml) oral solution sugar free daily until 6 months corrected age commenced at 28 days of age
Breastfed exclusively	> 2500g	7 drops (0.3 ml) Abidec daily until 18 months of age ( <i>ideally mother should have been taking vitamin D throughout pregnancy</i> )
		Then from this age, all children who are not on 500ml formula require vitamin A and D supplementation until age 5 years* (use Healthy Start, Abidec or Dalivit)
Formula Fed (on standard	< 2500g (LBW)	7 drops (0.3 ml) Abidec od until 1 year of age
OTC formula)		Then from this age, all children who are not on 500ml formula require vitamin A and D supplementation until age 5 years* (use Healthy Start, Abidec or Dalivit)
		1ml sodium feredetate (iron 27.5mg/5ml) oral solution sugar free od until 6 months corrected age commenced at 28 days of age
Preterm Formula >150 ml/kg	<1000g (ELBW)	No supplementation until on term formula (see above)

<sup>\*</sup>It is recommended by Public Health England that all children aged 5 years and above should continue to take 10microg of vitamin D daily. These supplements are available to buy over-the-counter.

For babies receiving combined milk i.e. EBM + pre-term/high calorific formula:

- No Vitamin supplementation is required if the total feed is 1/2 formula or more
- Vitamin supplementation as per above regime is required for infants receiving ¼ of total feed as formula

#### Notes:

- Dalivit contains more vitamin A and not licensed for use in children under 6 weeks, hence Abidec preferred in infancy to avoid Vitamin A toxicity.
- Abidec should be only avoided in cases of confirmed anaphylaxis to peanut.

# 4. Cow's Milk Protein Allergy (CMPA)

CMPA can be classified into IgE mediated and non IgE mediated reactions. IgE mediated reactions are acute and frequently have rapid onset (<2hours) and non IgE mediated reactions tend to be delayed and non-acute. Symptoms of CMPA in infancy are common and include:

Table 1: Signs and symptoms of food allergy (NICE 2011)

IgE-mediated	Non-IgE-mediated
Skin	
<ul> <li>Pruritus</li> <li>Erythema</li> <li>Acute angioedema – most commonly of the lips, face and around the eyes</li> <li>Acute urticaria – localised or generalised</li> </ul>	<ul><li>Pruritus</li><li>Erythema</li><li>Atopic eczema</li></ul>
Gastrointestinal	
<ul> <li>Angioedema of the lips, tongue and palate</li> <li>Oral pruritus</li> <li>Nausea</li> <li>Colicky abdominal pain</li> <li>Vomiting</li> <li>Diarrhoea</li> </ul>	<ul> <li>Gastro-oesophageal reflux disease</li> <li>Loose or frequent stools</li> <li>Blood and/or mucus in stools</li> <li>Abdominal pain</li> <li>Infantile colic, especially after 3mo of age</li> <li>Food refusal or aversion or feeding difficulties</li> <li>Constipation</li> <li>Perianal redness</li> <li>Pallor and fatigue</li> <li>Faltering growth in conjunction with at least one or more gastrointestinal symptoms above (with or without significant atopic eczema)</li> </ul>
Respiratory (usually in combination with one of	or more of the above symptoms and signs)
<ul> <li>Upper respiratory tract symptoms (nasal itching, sneezing, rhinorrhoea or congestion [with or without conjunctivitis])</li> <li>Lower respiratory tract symptoms (cough, chest tightness, wheezing or shortness of breath)</li> </ul>	
Other	
Signs or symptoms of anaphylaxis or other systemic allergic reactions	

Note: this list is not exhaustive. The absence of these symptoms does not exclude food allergy

#### **Diagnosis of Non IgE CMPA**

Non IgE CMPA should be suspected after careful history taking for the above symptoms and their association with the introduction of cow's milk into the diet. NICE (2011) recommend that an allergy focused clinical history should be completed if food allergy from any cause is suspected. Based on the allergy-focussed history, if non IgE CMPA is suspected, cow's milk elimination should be trialled. Diagnosis of non IgE mediated CMPA may be made if symptoms resolve after 2-6 weeks on a cow's milk elimination diet.

A re-challenge may be considered after 8-10 weeks, by gradually reintroducing standard infant formula to make a firm diagnosis. In infants who have presented with severe or distressing symptoms, resolution of symptoms can be accepted as diagnostic. A home challenge to confirm diagnosis should not be done in infants thought to have IgE mediated food allergy.

#### **Treatment of Non IgE CMPA**

Infants should be given a cow's milk protein-free diet for at least 6 months.

In breastfed infants, a complete maternal exclusion of cow's milk and other dairy sources is required, and may require maternal exclusion of soy also. A referral to a paediatric dietitian is required to ensure adequate nutrition.

In formula fed infants, a hypoallergenic formula milk will be prescribed on diagnosis and the child referred to a paediatric dietitian for advice on following a cow's milk-free diet.

Children can be challenged to see if they have outgrown CMPA, 6 months after initiation of cow's milk exclusion, or from 12 months of age onwards. Cow's milk protein is gradually introduced as per the iMAP Milk Ladder (North Derbyshire) or the locally produced Milk Ladder (South Derbyshire). Most infants will be re-challenged at home and advice will be provided by the paediatric dietitian.

The majority of children can be expected to outgrow their non IgE CMPA around 18 months to 3 years of age.

Referral to paediatric dietitian for Non IgE CMPA	Process
Within Southern Derbyshire	Infants with confirmed non IgE CMPA can be referred to the Paediatric Dietitians at Derbyshire Children's Hospital by following the GP Patient pathway for Infants under 1 year of age with Cow's milk Protein Allergy (Non IgE Mediated). See appendix 2.
Within North Derbyshire	Infants with suspected or confirmed non IgE CMPA can be referred to the paediatric dietitians at Chesterfield Royal Hospital as per iMAP guidance (see appendix 3) via a written referral completed by any member of the primary healthcare team, preferably in a letter or on a Nutrition and Dietetic Service Referral Form (appendix 4).

#### Key point:

Infants with suspected milk allergy **and** faltering growth, severe reflux or an unclear presentation should be referred directly to the consultant paediatrician.

#### Diagnosis of IgE CMPA

Infants with suspected IgE mediated reactions to cow's milk should be advised to adopt a strict cow's milk free diet to manage symptoms.

In breastfed infants, a complete maternal exclusion of cow's milk and other dairy sources is required, and may require maternal exclusion of soy also. A referral to a paediatric dietitian is required to ensure adequate nutrition.

In formula fed infants, a hypoallergenic formula milk will be prescribed on diagnosis and the child referred to a paediatric dietitian for advice on following a cow's milk-free diet.

# Unlike non-IgE CMPA, these infants should not be challenged with cow's milk in order to confirm their diagnosis.

In <u>Southern Derbyshire</u>, all infants with suspected IgE CMPA should be referred to the Allergy clinic at Derbyshire Children Hospital for practical advice on allergy management, interpretation of the IgE allergy tests, nutritional advice, future re-challenge advice and long term prescription requirements.

In <u>North Derbyshire</u>, all infants with suspected IgE CMPA should be referred to the allergy clinic at Chesterfield Royal Hospital for practical advice on allergy management, interpretation of the IgE allergy tests, nutritional advice, future re-challenge advice and long term prescription requirements.

#### **Breastfed babies**

Exclusively breast fed infants can develop either IgE or non IgE CMPA, as some cow's milk proteins from their mother's diet pass into the breastmilk. Mothers should be encouraged to continue to breastfeed, whilst following a cow's milk (and sometimes also soya) free diet. Breastfeeding mothers require 1250mg or calcium and 10microgram of vitamin D per day. Mothers may require self-care supplementation depending on vitamin supplements that they may already be taking. See Derbyshire vitamin D position statement.

Breastfeeding mothers should be provided the BDA Milk Allergy fact sheet for interim advice on cow's milk avoidance (<a href="https://www.bda.uk.com/foodfacts/milkallergy.pdf">https://www.bda.uk.com/foodfacts/milkallergy.pdf</a>)
Babies should be weaned onto a cow's milk free diet with a planned controlled cow's milk protein

challenge under supervision of a paediatric dietitian or consultant paediatrician at approximately 12 months of age, or six months after diagnosis

# Hypoallergenic Infant formulas suitable for the management of CMPA

	Treatment
Hypoallergenic Infant Formulas	Formula fed infants with CMPA should be treated with a hypoallergenic infant formula.
(See comparisons of formulas on	Extensively hydrolysed infant formula is the first line formula of choice for mild to moderate symptoms.
next page for details):	An amino acid infant formula is the preferred choice in severe cases of CMPA with faltering growth, severe eczema, multiple food allergies, anaphylaxis, and respiratory difficulties.
	Amino acid formula is also the preferred choice for infants who were symptomatic whilst breastfeeding, if the mother wishes to stop breastfeeding.
Initiation of Hypoallergenic Infant formulas	Initially prescribe 2 x 400g tin of hypoallergenic formula to ensure palatability. If formula well tolerated consider monthly prescriptions. See Table on page 11 for number of tins for monthly prescriptions.
	Advise the mother to try the infant with one bottle of new formula made as the manufacturer recommends. If the infant is reluctant to take new formula, try a 25:75 mix of new formula with existing formula and gradually increase new formula as the taste is accepted.
	Warn parents that hypoallergenic formula may cause green stools and wind.
On-going prescriptions of hypoallergenic	Most infants requiring a hypoallergenic formula will continue to require the formula on a monthly repeat prescription until the age of 1 year of age.
Infant formulas	<ul> <li>If the infant is under the paediatric dietitians at either CRH or Derbyshire Children's Hospital at RDH, the paediatric dietitian will review continued requirement for hypoallergenic formula at approximately 1year of age and update the GP accordingly. At this point a cow's milk-challenge will be considered.</li> </ul>
	If they continue to show symptoms of CMPA during the cow's milk challenge, most infants over the age of 1 year will be weaned onto a calcium-enriched plant-based milk alternative that can be purchased by parents.

# Comparison of formulas for Cow's Milk Protein Allergy

Products are chosen after a thorough assessment of the individual and doses are dependent on age, weight, calculated requirements, condition and intake.

<u>Name</u>	Tin size	Price per tin	Price/ 100g	Unique Aspects/ Cautions	
Extensively hydrolysed formula (1st line for mild to moderate symptoms)					
Similac Alimentum (Abbott)	400g	£9.10	£2.28	Casein hydrolysate, contains meat derivatives (not suitable for Halal/ Kosher diet*). Lactose Free.	
SMA Althéra (Nestle)	450g	£10.68	£2.37	Whey hydrolysate, contains lactose	
Aptamil Pepti 1 (Milupa/Nutricia) Stocked at CRH	400g	£9.87	£2.47	palatable than amino-acid based formula.  Pepti 2 Suitable for infants from 6 months as part of a	
Aptamil Pepti 2 (Milupa/Nutricia)	400g	£9.41	£2.35	mixed diet and as a principal source of nourishment, with other foods	
Nutramigen with LGG (Mead-Johnson) Stocked at RDH	400g	£11.21	£2.80	Casein hydrolysate, with probiotic. Lactose free. Nutrmigen LGG 2 suitable from 6 months as part of a varied diet.	
				evere cases of CMPA with faltering growth, severe and respiratory difficulties	
Nutramigen Puramino	400g	£23.00	£5.75	Amino acid based, no milk protein and no lactose. Contains MCT, coconut and soya oil, and MSG	
SMA Alfamino (Nestle)	400g	£23.81	£5.95	Amino acid based, no milk protein and no lactose. Contains potato starch.	
Neocate LCP (Nutricia) Stocked at RDH & CRH	400g	£28.70	£7.18	Amino acid based, no milk protein and no lactose. Contains coconut oil. Warn parents that stools will be green and more frequent	
Neocate Syneo	400g	£28.70	£7.18	Amino acid based, no milk protein and no lactose. Contains prebiotics, probiotic and coconut oil. Some small studies show babies have similar gut microbiota to those of breastfed babies. No evidence of clinical outcomes yet	

<sup>\*</sup>information obtained from personal communication with Abbott

# **Unsuitable formulas for CMPA:**

- SMA Staydown
- SMA Comfort
- SMA LF (lactose free)
- Enfamil AR (anti-reflux)
- Enfamil O-lac
- Cow & Gate Anti-Reflux
- Cow & Gate Comfort
- Aptamil Anti-Reflux
- Aptamil Comfort
- Aptamil Lactose Free
- Soya, goat's and sheep's milk formulas

#### 5. Lactose intolerance

Lactose intolerance should not be confused with CMPA. It is intolerance to the lactose (sugar) in cow's milk, not an allergy to the protein. "Lactose free" foods and formulas still contain cow's milk protein.

**Primary lactose intolerance** can occur later in life as we lose the ability to produce lactase. Lactose intolerance can be caused by galactosaemia, a congenital condition, or due to absence of the lactase enzyme, but these are very rare infants and young children.

Secondary lactose intolerance is the most common form of lactose intolerance and occurs following an infectious gastrointestinal illness. Damage to the small bowel mucosa causes a temporary deficiency in lactase enzyme. Some GPs may feel competent to assess and treat simple cases of secondary lactose intolerance, which will resolve before specialist input could be sought.

#### **Symptoms**

Abdominal bloating, increased wind and frothy, loose stools which may in turn cause perianal irritation and redness. Blood or slime in stools is **NOT** a feature of lactose intolerance.

## **Diagnosis**

Lactose intolerance should be suspected in children who have a diarrhoeal illness lasting more than 2 weeks. Resolution of symptoms, usually within 48 hours, when lactose is removed from the diet is the gold standard for diagnosis. Children should be referred if there are any concerns about significant weight loss or if symptoms do not improve.

#### **Treatment**

Infants should be given a lactose-free formula. Secondary lactose intolerance in infants usually lasts 6-8 weeks but may last as long as 3-6 months, so parents will also need to understand how to follow a low-lactose diet. Referral to a dietitian is recommended if the low-lactose diet is to continue past 4 weeks.

#### Formulas available to buy over the counter for lactose intolerance:

- SMA LF
- Enfamil O-Lac

#### 6. Soya-based formula

Soya formula was at one time used for infants with CMPA, however should now be avoided. In 2004 the Chief Medical Officer issued a statement advising against the use of soya-based formula in infants with CMPA or lactose intolerance. Soya formula is no longer indicated for infants who are milk intolerant or allergic under the age of 6 months, due to its phyto-oestrogen content, and the increased risk of sensitisation to soya protein. Approximately 50% of children with CMPA are also intolerant to soya.

The use of soya formula under 6 months of age should be limited to exceptional circumstances to ensure adequate nutrition, for example in children with galactosaemia, or formula fed infants of vegan parents, and in infants who do not tolerate hypoallergenic formulae in the absence of a soya intolerance.

Soya formula can be recommended for formula fed infants over the age of 6 months who do not tolerate hypoallergenic formula in the absence of soya intolerance (Venter et al., 2013).

Parents wishing to feed their infant on soya-based formula should be advised of the potential risks and instructed to buy the formula over the counter. Soya-based formula is prescribable for infants with galactosaemia only, on the advice of a consultant paediatrician.

For those infants prescribed soya formula, most should convert to supermarket-bought calciumenriched soya or other plant-based milk alternatives when they reach 1 year of age if their diet is adequate and they are growing well. Only children with specific rare medical conditions (i.e. galactosaemia) may require a prescribed soya formula after this age.

#### 7. Powders vs liquids

- Powder feeds should be used routinely
- Liquid feeds should only be used when advised by the neonatal unit, e.g. for immunocompromised patients
- Health visitors should give advice about appropriate reconstitution and sterilisation to avoid contamination. See also advice in Birth to Five (DH 2016).

### 8. Approximate quantities to be supplied per month

The table below gives an approximate indication of the number of tins to be supplied per month. This information would usually be included in the letter from the paediatric dietitian to the GP.

Age	No. of tins (using 400g tins)			
0 to 3 months	6 to 11 tins			
4 to 6 months	Up to 14 tins			
7 to 9 months	9 to 11 tins			
10 to 12 months	8 tins			

#### 9. Referrals to secondary care

It is recommended that all infants and children with CMPA see a dietitian for support with cow's milk free weaning.

#### **Royal Derby Hospitals:**

Infants under the age of 1 year with confirmed Non IgE mediated cow's milk allergy can be referred to the Paediatric Dietitian, Derbyshire Children's Hospital via the GP Patient pathway for Infants under 1 year of age with Cow's milk Protein Allergy (Non IgE Mediated).

Infants and children with IgE mediated cow's milk allergy can be referred to Paediatric Allergy Clinic via choose and book

All other referrals can be made to the Consultant Paediatricians, via normal referral process.

#### **Chesterfield Royal Hospital:**

Referral to a Consultant Paediatrician: via normal referral process

Referral to a Paediatric Dietitian: Infants with suspected or confirmed CMPA can be referred to the paediatric dietitians at Chesterfield Royal Hospital as per iMAP guidance (see Appendix 3) via a written referral completed by any member of the primary healthcare team, preferably in a letter or on a Nutrition and Dietetic Service Referral Form (Appendix 4).

### 10. Consultation

- Dr D Traves and Dr L Starkey, Consultant Paediatricians, Royal Derby Hospital
- Allison Mackenzieand Laura Sheldon, Paediatric Dietitians, Royal Derby Hospital
- Rachel Lomax and Sascha Landskron, Paediatric Dietitians, Chesterfield Royal Hospital
- Dr A Foo, Consultant Paediatrician, Chesterfield Royal Hospital

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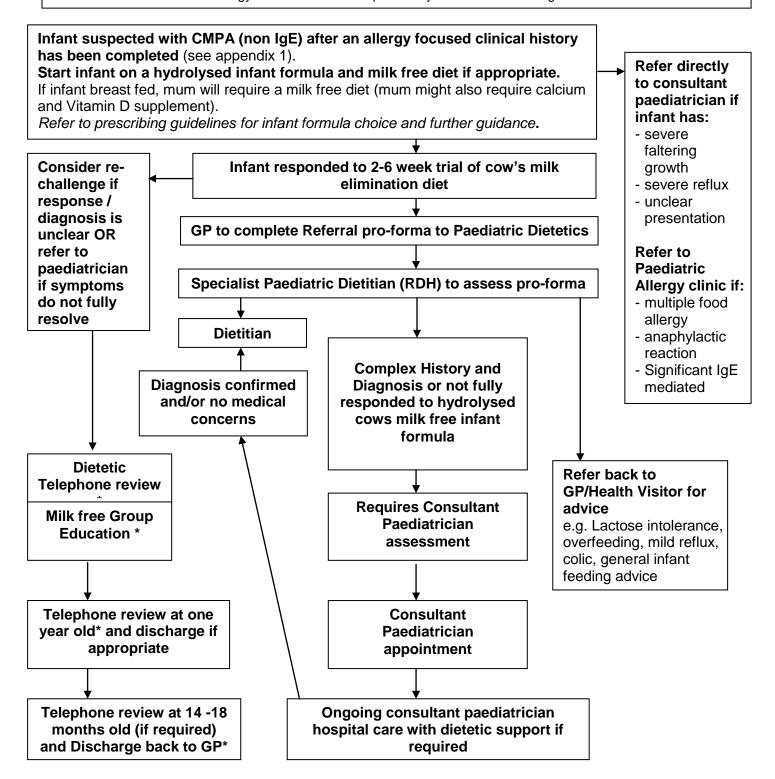
Appendix 1: Summary of Common Conditions requiring the use of infant formula in primary care

Condition	Information	Signs/symptoms	Diagnosis and Referral	Usual Treatment
Primary lactose intolerance	Doesn't usually present until later childhood or adult life due to losing the ability to produce lactase.	Abdominal bloating Increased (explosive) wind Frothy, loose stools (perianal soreness)	Lactose intolerance should be suspected in children who have had symptoms that persist for more than 2 weeks. (Infectious diarrhoea in children can persist for up to 2 weeks.)	Lactose-free formula Advice on dailry-free diet Re-challenge in 3-6
Secondary lactose intolerance	More common than primary lactose intolerance and occurs following an infectious gastrointestinal illness. Lactose intolerance can also co-exist with other conditions that damage the small bowel mucosa, like coeliac disease.		The <b>criterion for diagnosis</b> is the resolution of symptoms, usually within 48 hours, when lactose is removed from the diet.  Refer all suspected Primary Lactose Intolerance cases and any cases of Secondary Lactose Intolerance where there is significant weight loss or no improvement after withdrawal of lactose.	months
Cow's milk protein allergy	Standard infant formula milks are made from cow's milk. Symptoms of cow's milk protein allergy in infancy are common (estimated incidence: 5 - 15% of infants).  Breast fed babies  Exclusively breast fed infants can have CMPA, due to proteins passing through the breast milk. Exclusive breast feeding for at least 4 months may be protective, as far fewer infants in this group will go on to get CMA.	<ul> <li>Frequent regurgitation, gastro-oesophageal reflux</li> <li>Vomiting</li> <li>Diarrhoea</li> <li>Constipation (with / without perianal rash)</li> <li>Blood in stool</li> <li>Iron deficiency anaemia</li> <li>Atopic dermatitis</li> <li>Urticaria unrelated to acute infections, drug intake or other causes.</li> <li>Runny nose, chronic cough or wheezing unrelated to infection</li> <li>Persistent distress or colic (wailing/irritable for &gt; 3 hrs per day) at least 3 days per week over &gt; 3 weeks</li> </ul>	Suspect after careful history taking of symptoms and their association with the introduction of cow's milk into the diet.  The criteria for the diagnosis of Cow's Milk Protein Allergy is the resolution of symptoms after 2- 6 weeks on a cow's milk protein elimination diet, with re-occurrence of symptoms on re-exposure.  In practice, for most patients, a re-challenge is not done to confirm the diagnosis if there has been a clear resolution of symptoms.  Children can be re-challenged to see if they've recovered from 9-12 months of age onwards. Most children will grow out of their intolerance by 18mths to 2 years of age.  In practice many children are informally challenged at home. Successful informal challenges do not need to be repeated in hospital.  Infants presenting with immediate hypersensitivity symptoms ie. Urticaria, angio-oedema, acute flare of atopic dermatitis and vomiting are more likely to have IgE mediated CMPI. In these infants, cow's milk protein challenges should be done under specialist supervision.  Refer all cases of Cow's Milk Allergy.  Southern Derbyshire- infants with Non IgE milk allergy can be managed using the GP Patient Pathway for Infants under 1 year of age with Cow's milk protein allergy (Non IgE mediated).  North Derbyshire- infants with suspected or confirmed non IgE CMPA can be referred to the paediatric dietitians at Chesterfield Royal Hospital as per iMAP guidance. It is recommended that infants and children with cow's milk allergy see a paediatric dietitian for support with milk free weaning/diet.	CMP-free specialist formula Advice on CMP-free diet Re-challenge after at least 6 months as advised by consultant/paediatric dietitian  Breast fed babies - Mothers should be encouraged to continue to breast feed whilst following a cow's milk free diet with calcium and vitamin D supplementation. Babies should be weaned onto a cow's milk free diet with controlled cow's milk protein challenge as advised by consultant.



# GP Patient Pathway for Infants under 1 year of age with Cows Milk Protein Allergy (Non IgE Mediated)

Note: Cows Milk Protein Allergy now includes those previously described as having Cows Milk Protein Intolerance



Note\* Dietitian can refer back to consultant paediatrician at any point in pathway
THIS PATHWAY SHOULD BE USED IN CONJUNCTION WITH THE GUIDANCE ON THE
APPROPRIATE USE AND PRESCRIBING OF SPECIALIST INFANT FORMULA IN PRIMARY CARE

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

Dec 2016

#### 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, increases likelihood of allergy

#### Gastrointestinal

Irritability - 'Colic'

Vomiting - 'Reflux' - GORD

Food refusal or aversion

Diarrhoea-like stools

- loose and/or more frequent

Constitution – especially soft stools, with excessive straining Abdominal discomfort, painful flatus

Abdominal discomfort, painful flatu 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 Extensively Hydrolysed Formula – eHF

And still no history at any stage of immediate onset symptoms

Reintroduction at Home - using a MILK LADDER

To test for Acquired Tolerand

Or – Advise exclusively breast feeding mother to exclude all CMP from her own diet and to take daily Calcium and Vit D 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

# \_ Severe

(Rarely a severe

gastrointestinal

presentation)

**Emergency** 

Treatment

and

Admission

Or-Advise exclusively breast feeding mother to exclude all Cows Milk Protein from her own diet and to take daily supplements of calcium

ANAPHYLAXIS Immediate reaction with severe respiratory and/or CVS signs and symptoms.

#### Ensure: Urgent referral to local paediatric allergy

and Vit D according to

local recommendations

Cow's Milk Free Diet

Amino Acid Formula <

Urgent dietetic referral

#### Mild to Moderate IgE-mediated CMA

Mostly within minutes (may be up to 2 hrs.) after ingestion of Cow's Milk Protein (CMP)

Mostly 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 Initial 1st, choice

#### Extensively Hydrolysed Formula - eHF

Soy may be used in some settings if not sensitised Or-Advise exclusively breast feeding mother to exclude all Cow's Milk Protein from her own diet and to take daily supplements of calcium and Vit D according to local recommendations

#### 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

If competencies to arrange and interpret testing are not in place - early referral to local paediatric allergy service is advised

Refer to local paediatric allergy service

(A Supervised Challenge may be needed)

#### iMAP Guideline for Primary Care and 'First Contact' Clinicians

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

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

Dec 2016

#### **Exclusively Breastfeeding** Formula Feeding or 'Mixed Feeding' (Breast and Formula) Strict cow's milk protein free diet Strict exclusion of cow's milk containing foods from maternal diet Formula feeding only - Trial of an Extensively Hydrolysed Formula (eHF) in infant Maternal daily supplements of calcium and Vit D according to local recommendations Refer to dietitian - a maternal substitute milk should be advised Mixed feeding - If symptoms only with introduction of top-up feeds - Replace with eHF top-ups - Mother can continue to consume cow's milk containing foods in her diet. If atopic dermatitis or more severe gut symptoms – consider egg avoidance as well If weaned - may need advice and support from dietitian An agreed Elimination Trial of up to 4 weeks - with a minimum of 2 weeks An agreed Elimination Trial of up to 4 weeks - with a minimum of 2 weeks No Clear Improvement Clear Improvement - need to confirm Diagnosis Clear Improvement - need to confirm Diagnosis No Clear Improvement Ψ Home Reintroduction: Mother to revert to Home Reintroduction: But - CMA still suspected: Using cow's milk formula normal diet containing cow's milk foods But - CMA still suspected: Consider excluding other over period of 1 week - to be done usually To be done usually between 2-4 weeks Consider initiating a trial of maternal foods e.g. egg between 2-4 weeks of starting Elimination Trial of starting Elimination Tria an Amino Acid Formula (AAF) Refer to local paediatric No return of symptoms Return of No return of symptoms NOT CMA - normal feeding Return of allergy service Refer to local paediatric NOT CMA - normal feeding symptoms symptoms allergy service V Exclude cow's milk conta CMA no longer suspected: CMA no longer suspected: foods from maternal diet again Return to the eHF again Unrestricted diet again Return to usual maternal diet If symptoms clearly improve: Symptoms Symptoms CMA NOW CONFIRMED Consider referral to local Consider referral to local CMA NOW CONFIRMED do not general paediatric service if general paediatric service if If top-up formula feeds should settle later be needed - eHF may well be symptoms persist symptoms persist Ensure support of dietitian tolerated: If not - replace with AAF Cow's milk free diet until 9-12 months of age and for at least 6 months – with support of dietitian A planned Reintroduction or Supervised Challenge is then needed to determine if tolerance has been acquired Performing a Reintroduction versus a Supervised Challenge is dependent on the answer to the question Does the child have Current Atopic Dermatitis or ANY history at ANY time of immediate onset symptoms? **No Current Atopic Dermatitis** History of immediate onset symptoms at any time And no history at any time of immediate onset symptoms (No need to check Serum Specific IgE or perform Skin Prick Test) Serum Specific IgE or Skin Prick Test needs **Current Atopic Dermatitis** Positive or Negative Reintroduction at Home - using a MILK LADDER Check Serum Specific IgE or Liaise with local Allergy Service Re: Challenge Tests not available To test for Acquired Tolerance

Negative

Skin Prick Test to cow's milk

Positive

# Appendix 4: CHESTERFIELD ROYAL HOSPITAL AND DERBYSHIRE COMMUNITY HEALTH SERVICES - NORTH DERBYSHIRE

Nutrition and Dietetic Service Referral Form

Patient Det	ails:								
Surname:		Address:	Address:						
Forename(s	s):								
DOB:		Postcode:							
NHS No:		Tel no:	Tel no:						
Reason For Refe	erral (Please tick reason for referra	al):							
Nutrition Support	Type 1 Diabetes	Obesity		Eating Disorder *					
Coeliac Disease	Type 2 Diabetes	IBS		Other Gastro *					
Food Allergy / Intolerance *	Type 2 Diabetes on Insulin	Vitamin/ Mineral Advice *		Faltering Growth					
Other *	* Please give diagnosis/further information:								
Diagnosis & Pas	t Medical History:								
Relevant Social History:  Details of other health professionals/family involved:  Weight: BMI: MUST Score:									
Unable to weigh:	•	e to weigh:							
	UST score details not completed v	-			ort patients				
PLEASE INDICA	ATE WHERE YOU WOULD LIKE TH Hospital / Outpatient	HE PATIENT TO BE SEEN (PI / Care Home / Own Home (if h							
If patient is in h	ospital, please indicate which hospi			,					
If patient is to be seen at home, please indicate additional information which may be required (e.g. house entry key code number, need to have family member / carer present, family contact number):									
GP DETAILS	Name:		ONSULTANT DETAILS: Name: appropriate)						
	Surgery:								
	Tel No:	В	Base:						
REFERRERS DI Name - printed:	ETAILS (Please Print)	Signature:	Signature:						
Job Title:		Date:	Date:						
Base:		Tel No:	Tel No:						