Guidelines for Specialist Infant Formula in:

- **Cow's Milk Protein Allergy (CMPA),**
- **Lactose Intolerance,**
- **Gastro-Oesophageal Reflux Disorder (GORD)**
- **Soya-Based Formula**

Cow's Milk Protein Allergy (CMPA)
Quick glance guide and flow chart (see p3-5 for more detail)

If Cow's Milk Protein Allergy (CMPA) is suspected (see p4 for typical symptoms)

All patients should be referred to local Paediatric Dietitian using Referral Management Centre (RMC)

Exclusively breast fed infant

Best practice is cow's milk free diet for the mother for a minimum of 2 weeks. Advise mother to take a multivitamin and mineral preparation e.g. Boots breast feeding support, Vitabiotics pregnacare.

Formula fed infant

Severe symptoms

Require an amino acid formula e.g. SMA Alfamino and **immediate referral to secondary care, HOT clinic.**

Mild to moderate symptoms - Approximately 90% infants improve with an **"Extensively hydrolysed formula"**.

Infants less than 6 months of age initiate with:

- SMA Althera (whey based, contains lactose).
- Similac Alimentum (casein based, no lactose) – preferred choice if concern with lactose in diet.

Infants more than 6 months of age initiate with:

- Milupa Aptamil Pepti 2 (whey based, contains lactose).
- Nutramigen 2 with LGG (casein based, no lactose) - preferred choice if concern with lactose in diet.

Guidance on prescribing quantities

Prescribe 4 tins on a trial basis and continue if symptoms resolve.

Suggested quantities: 0-6 months: 10 x 400g or 450g per month
6-9 months: 8 x 400g or 450g per month
9-12months: 6 x 400g or 450g per month

This is a guide only, based on an average baby's weight and introduction of solids having started around 6 months. Further advice will be provided by the Consultant/Paediatric Dietitian once the patient has been reviewed.

Northamptonshire Healthcare NHS
NHS Foundation Trust

Prescribing Guidance for Cow's Milk Protein Allergy in Infant's (CMPA)

CMPA
Mild to moderate symptoms
Non IgE mediated

One or more of the following symptoms:

- Gastrointestinal:
  Frequent regurgitation, vomiting, diarrhoea, constipation, blood in stool, iron deficiency anaemia.
  Persistent distress or colic (≥ 3 hrs per day – wailing/irritable), for at least 3 days/week over > 3 weeks
- Dermatological:
  Atopic dermatitis, swelling of the lips or eyelids (angio-oedema), urticaria unrelated to acute infections, drug intake or other causes.

Suitable formula / feeding to be initiated on suspicion of CMPA

1. Exclusively breast fed infant:
Suggest Cow's milk free diet for mother for a minimum of 2 weeks. Advise mother to take a multivitamin and mineral preparation e.g. Boots breast feeding support, Vitabiotics pregnacare.

2: Formula fed – Prescribe an Extensively Hydrolysed Formula (EHF).
"Whey Based" EHF formula (contain lactose) are preferred if there are no gastrointestinal symptoms e.g.
Less than 6 months of age
SMA Althera (Nestle) £2.46/100g
Milupa Aptamil Pepti 1 (Nutricia) £2.46/100g
More than 6 months of age
Milupa Aptamil Pepti 2 (Nutricia) £2.35/100g

"Casein Based" EHF (Lactose free) formula e.g.
Less than 6 months of age
Similac Alimentum (Abbott Nutrition) £2.36/100g
Nutramigen1 with LGG (Mead Johnson) £2.80/100g

More than 6 months of age
Nutramigen 2 with LGG (Mead Johnson) £2.80/100 g

CMPA
Severe symptoms only
IgE mediated/non IgE mediated

One or more of the following symptoms:

- Gastrointestinal:
  1. Faltering growth due to chronic diarrhoea and/or regurgitation/ vomiting and/ or refusal to eat.
  2. Iron deficiency anaemia due to occult or macroscopic blood loss.
  3. Protein losing enteropathy (hypoalbuminaemia).
  4. Endoscopic/histologically confirmed enteropathy or severe allergic or eosinophilic colitis.
- Dermatological:
  Exudative or severe atopic dermatitis with hypoalbuminaemia,
- Respiratory:
  Acute laryngoedema or bronchial obstruction with difficulty breathing.
- Systemic reactions:
  Anaphylactic shock – needs immediate referral to hospital for management.
  NB challenge with milk should be under medical supervision

Suitable formula / feeding to be initiated on suspicion of severe CMPA

1. **Exclusively breast fed infant:**
Suggest Cow's milk free diet for mum for a minimum trial of 2 weeks and advise use of multivitamin and mineral for breastfeeding e.g. Boots, Vitabiotics (Containing 700Mg calcium and 10 micrograms Vitamin D)
2. **Formula fed infant-Amino acid based formulas (AAF)**
For a minimum trial of 2 – 4 weeks

Nutramigen Puramino (Mead Johnson) £5.75/100g
SMA Alfamino (Nestle) £5.75/100g
Neocate LCP (Nutricia) £7.39/100g

Babies with severe symptoms should be referred to a Consultant Paediatrician with an interest in allergy/HOT clinic for on-going advice with amino acid based formulas

- Please refer infants on cow's milk protein free diets to a Paediatric Dietitian for weaning advice and on-going management
- Prescription for infant formula should not routinely be required after 12-18 months of age (Dietitian will advise)
- Suggested quantities: 0-6 months 10 x 400g or 450g per month
  6-9 months 8 x 400g or 450g per month
  9-12months 6 x 400g or 450g per month
- This is a guide only based on an average baby's weight and introduction solids having started

Contact details for Dietitians:
Highfield Clinical Care Centre, NGH: 01604 745036
Northfield House, KGH: 01536 492317

Guidelines for prescribing infant formula in Cow's Milk Protein Allergy (CMPA)

Background Information

These guidelines have been produced to aid GPs in prescribing appropriate infant formulas for the management of Cows Milk Protein Allergy (CMPA).

Breast feeding is promoted as the best form of nutrition for a good start in life.

Adverse reactions to foods, mainly cow's milk protein is most common in the first year of life.

- Most infants with cow's milk protein allergy CMPA develop symptoms before 1 month age, or within 1 week after the introduction of infant formula.

- CMPA can induce acute IgE- medicated reactions (within 2 hours) e.g. rash or urticaria, wheeze, vomiting and/or delayed reactions that may be either non IgE- medicated or mixed (> 2 hours) e.g. mild-moderate eczema, reflux.

- Severe CMPA symptoms may include anaphylaxis, severe eczema or faltering growth.

- 5 - 15% of infants show symptoms suggestive of adverse reaction to cow's milk protein.

- 16 - 42% of infants with gastro-oesophageal reflux disorder (GORD) have CMPA.

- A remission rate is expected of 45 - 50% of infants at 1 year, 60 - 75% at 2 years and 85 - 90% at 3 years.

Signs and symptoms of possible food allergy

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

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

Management of CMPA

Breast milk is the optimal choice for the CMPA infant.

If CMPA symptoms persist in the breast fed infant, support the mother to continue breastfeeding and suggest a maternal exclusion diet i.e. milk-free diet, for a minimum trial of 2 weeks. The reference nutrient intake for breastfeeding mothers is 1250mg Calcium per day, 10 micrograms Vitamin D. Consider over the counter supplements such as:

- Pregnacare **Breastfeeding**-700mg calcium and 10 micrograms Vitamin D OR
- Boots **Breastfeeding**-700mg and 10 micrograms Vitamin D.

The Dietitian will provide guidance should further supplements be required.

For infants who are not breast fed prescribe an appropriate hypoallergenic infant formula (see flow chart, page 2)

- **An extensively hydrolysed or amino acid formula should be initiated on suspicion of Cow's Milk Protein Allergy without delay.** Prescribe a small amount on a trial basis initially e.g. 4 tins to check for tolerance (quantity suitable for approximately 2 week trial). Continue to prescribe if symptoms resolve. Further guidance to follow from the Consultant/Paediatric Dietitian once a review has been conducted.

- Approximately 90% of the infants will have mild to moderate symptoms and most will resolve on using an extensively hydrolysed formula.

- Severe symptoms require amino based formula e.g. SMA Alfamino and referral to **secondary care, HOT clinic immediately**.

Referral

- All infants on a cow's milk free diet should be referred to a Paediatric Dietitian for further management using Referral Management Centre (RMC)

- Refer to a Paediatric Consultant with an interest in allergy when there is diagnostic uncertainty, poor response, faltering growth or multi-systemic symptoms.

Lactose Intolerance

Symptoms and diagnosis

- Diagnosis of 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.

- Common symptoms are 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.

- Secondary lactose intolerance is the commonest form of lactose intolerance and occurs following an infectious gastrointestinal illness. Damage to the small bowel mucosa causes a temporary deficiency in lactase.

- Primary lactose intolerance can occur later in life as we lose the ability to produce lactase. Lactose intolerance can be a congenital condition, due to absence of the lactase enzyme, but this is very rare.

Treatment

- Breastmilk remains the optimal milk and can assist in gut healing with secondary lactose intolerance.
- Formula fed 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.

- Reintroduction of lactose can be carried out at home

- The cost of “**Over the counter” (OTC)** products for use from birth to maximum 18 months are similar to standard formulas; **therefore prescriptions are not advocated.**

  Products available are:

  - SMA Lactose Free (SMA)
  - Enfamil Lactose Free (Mead Johnson)
  - Aptamil Lactose Free (Aptamil)

Referral

- If the low lactose diet is to continue, refer to the Paediatric Dietitian

- If there are any concerns about significant weight loss or if symptoms do not improve, refer to the Paediatric Consultant.

Soya-based formula

In 2004 the Chief Medical Officer issued a statement advising against the use of soya-based formula in infants with cow's milk protein sensitivity or lactose intolerance. Soya formula is no longer indicated for infants who are milk intolerant or allergic, due to its phyto-oestrogen content, and the increased risk of sensitisation to soya protein. This is especially important for infants under 6 months of age. 10 to 35% of children with CMPA are also sensitive to soya.

Use of soya formula should be limited to exceptional circumstances to ensure adequate nutrition, for example, infants of vegan parents who are not breastfeeding, or infants who find alternatives unacceptable. Parents wishing to feed their infant on soya-based formula should be advised of the risks and instructed to buy the formula over the counter.

Soya-based formula is prescribable for galactosaemia only, on the advice of a Consultant.

For those infants prescribed soya formula, most should convert to supermarket bought soya or oat calcium-enriched milk when they reach 1 year of age if their diet is adequate and they are growing well. Only children with specific rare medical conditions require a prescribed soya formula after this age.

Gastro-Oesophageal Reflux Disorder (GORD)

Adapted from PrescQIPP B146- specialist infant formula

Symptoms and diagnosis

- GORD is the passage of gastric contents into the oesophagus causing troublesome symptoms and/or complications, 50% of babies have some degree of reflux at some time.
- Symptoms may include regurgitation of a significant volume of feed, reluctance to feed, distress/ crying at feed times, small volumes of feed being taken.
- Diagnosis is made from the 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.

Treatment

- If the infant is thriving and not distressed, reassure the parents and monitor. Infants with faltering growth as a result of GORD should be referred to paediatric services without delay.
- All breastfed infants should have their feeding assessed as correcting breastfeeding technique (encouraging mothers to feed responsively and in suitable upright position after feeds) may eliminate symptoms.(NICE Quality Standard QS112)
- Provide advice on avoidance of overfeeding (average requirements of formula are 150mls/kg/day for babies up to six months, aim to spread over six to seven feeds), positioning during and after feeding, and activity after feeding.
- If above suggestions do not improve symptoms Carobel® can be used to thicken standard formulae **OR** suggest one of the over-the-counter (OTC) infant formula products listed below.
  Note - Over the counter pre-thickened formulae contain carob gum. This produces a thickened formula and will require the use of a large hole (fast-flow) teat.

Aptamil® Anti-reflux (Milupa)	Birth to one year (pre-thickened)
Cow & Gate® Anti-reflux (Cow & Gate)	Birth to one year (pre-thickened)
Enfamil AR® (Mead Johnson)	Birth to 18 months (thickens in the stomach - contains rice starch)
SMA PRO Anti Reflux® (SMA)	Birth to 18 months (thickens in the stomach - contains cornstarch)

- If a bottle fed infant is not gaining weight and/or not settled after introducing over-the-counter (OTC) infant formula products listed above prescribe an **antacid, e.g. Infant Gaviscon®** and **return to previous formula**. If a breast-fed infant is not gaining weight and/or not settled prescribe an antacid, e.g. Infant Gaviscon® offered on a spoon before feeds.
- Pre-thickened formulas should not be used along with other thickening agents, e.g. Gaviscon®, Carobel® to avoid over thickening of the stomach contents.
- 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'. Dispensing pharmacists should advise about appropriate doses of OTC products.

Review and discontinuation of treatment

- Review after one month. If symptoms do not resolve after commencing treatment refer to a paediatrician for further investigations since CMPA can co-exist with GORD and treatment for CMPA may be required
- 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.

References

AAAI: Guidelines for the Diagnosis and Management of Food Allergy (1047kb)

CKS: Suspected cows milk protein allergy: NICE guideline on how to manage a child with suspected IgE-mediated cow's milk protein allergy (0 months - 5 years)

CKS: Confirmed cows milk protein allergy: NICE guideline on how to manage a child with confirmed cow's milk protein allergy (0 months - 5 years)

ESPGHAN GI committee practical guidelines: Diagnostic Approach and Management of Cow's Milk Protein Allergy in Infants and Children 2012 (384kb)

iMAP- Guidelines for Primary Care and 'First Contact' Clinicians- Presentation of Suspected Cow's Milk Allergy (CMA) in the 1st year of Life. December 2016

NICE Food Allergy for children and young people 2011

NICE Guidance NG1 Gastro-oesophageal reflux disease in children and young people: diagnosis and management January 2015

NICE Quality Standard QS112: Gastro-oesophageal reflux in children and young people January 2016WAO: Diagnosis and Rationale for Action against Cow's Milk Allergy (DRACMA) Guidelines (2676kb)

Paediatric Group Position Statement, Use of Infant Formulas based on Soy Protein for infants OCT 2010 British Dietetic Association

The Breastfeeding Network: Gastro Oesophageal Reflux (GOR) and GORD in infants May 2015

https://gpifn.org.uk/

https://gpifn.org.uk/reflux-and-gord/

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