



# NHS Norfolk and Waveney Policy Statement and Formulary: Infant Formula Milk Products

**Guide 1: Cow's Milk Protein Allergy (CMPA)** 

If you have any queries about prescribing specialist infant formulae related to this guidance, please contact the Medicines Optimisation Dietetic team at N&WICB: <a href="https://nwicb.dieteticqueries@nhs.net">nwicb.dieteticqueries@nhs.net</a>

## Norfolk and Waveney Integrated Care Board

## **Cow's Milk Protein Allergy (CMPA)**

## Presentation: see iMAP Presentation of suspected CMPA in 1st year of life on page 7

- There are 2 types of CMPA: Non-IgE-mediated and IgE-mediated. Mild/moderate non-IgE-mediated allergy can be managed in primary care.
- If CMPA suspected complete allergy focused clinical history (Resource 1 page 4).

## Treatment - see flow charts on page 5 (breastfed infants) & page 6 (formula fed infants)

- Provide advice to parent/carer about CMPA and the treatment process. Provide Resource 2 (page 4) information sheet if possible.
- Advise that most infants with non-IgE mediated CMPA will grow out of the allergy between the ages of 1 and 5 years.
- Breast fed babies can react to milk proteins that are transferred in breast milk from the mother's diet (though not always). If it is suspected that a breastfed baby is reacting to cow's milk protein via breast milk, the mother should be advised to avoid cow's milk and dairy products in their diet while breastfeeding. This involves a cow's milk elimination trial of up to six weeks (give resource 7 on page 4). Support and information should be provided to the mother. Please note mild-to-moderate non-IgE mediated cow's milk allergy in exclusively breastfed babies is rare and is not a reason to stop breastfeeding. Provide Resource 3 (page 4).
- Formula fed infants should be trialled on Extensively Hydrolysed Formulae (EHF), see table below for products. EHFs are suitable for 90% of infants with CMPA. The taste and smell of hydrolysed formulae can be unpleasant. Compliance can be improved by using a bottle, closed cup, or a straw. Younger infants may take them more readily than older infants.
- Lactose-containing EHFs are now first line as evidence suggests lactose is an important
  prebiotic for infants, leading to colonisation of the gut by beneficial bacteria. This is thought
  to improve the gut microbiome and have positive effects on the immune system. If the
  infant does not tolerate lactose-containing EHF after a reasonable trial, then a lactose-free
  EHF should be trialled before stepping up to an amino acid formula (AAF). NB infants who
  have a systemic reaction to EHF are unlikely to tolerate alternative EHF and will need an
  AAF
- Introduction of a new formula to babies who do not have a severe reaction is best done
  by mixing it with their current formula and gradually changing over.
- Only prescribe 3 or 4 tins initially to ensure acceptance of the product.
- For infants who are weaning/weaned a cow's milk free diet should also be followed, see resources 8 (on page 4).
- In order to confirm the diagnosis it is essential to advise a planned home reintroduction during weeks 2-4 of the cow's milk elimination diet for both breast-and formula-fed infants (only in suspected non-lgE mild-moderate allergy). This is now a NICE Food Allergy Quality Standard. Provide Resource 4 (on page 4) to support this.
- The child/infant should follow a cow's milk free diet until 9-12 months of age and for at least 6 months after diagnosis.
- Early introduction of some allergenic foods in infants at high risk of allergies may be advised by the dietitian/paediatrician; there is evidence that this may help to prevent other food allergies.
- Beyond 1 year calcium enriched plant-based milks can be purchased/used as an alternative source of milk (see page 9 for information on suitable milk alternatives).

Ongoing prescription of specialist formulas beyond 1 year may be required in those with severe or multiple allergies (e.g., soya). This should be led by the Paediatrician or allergy dietitian.



### Review and discontinuation:

- Review prescriptions regularly to check that the formula prescribed is appropriate for the child's age.
- Quantities of formula required will change with age. Avoid adding to the repeat template for these reasons unless a review process is established.
- Challenging with cow's milk: Milk tolerance should be evaluated by using the milk ladder (mild/mod non-lgE allergy only) with the recipes (See Resources 5 & 6 on page 4), or a supervised challenge (by specialists for severe non-lgE or lgE-mediated allergy).
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
  - Is the patient over one year of age?
  - Has the formula been prescribed for more than one 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/drink cow's milk containing foods? (E.g., cheese, yoghurt, ice-cream, custard, chocolate, cakes, cream, butter and spreads).

Extensively hydrolysed Formula (EHF)							
Product	Pack size	Cost per 100kcals	Indicated Age Range				
First line (lactose-containing)							
SMA Althera® (Contains lactose) SMA Nutrition/Nestle	400g	£0.55	Birth until infant has grown out of allergy (up to 12m as per policy).				
Aptamil-Pepti 1® (Contains lactose) Nutricia	400g or 800g	£0.57	Birth to 6 months.				
Aptamil-Pepti 2® (Contains lactose) Nutricia	400g or 800g	£0.58	6 months until infant has grown out of allergy (up to 12m as per policy).				
Second line (lactose-free)							
Nutramigen 1 LGG® (Clinically lactose-free) Mead-Johnson	400g	£0.64	Birth to 6 months. May be prescribed up to 12 months if Nutramigen 2 is unavailable.				
Nutramigen 2 LGG® (Clinically lactose-free) Mead-Johnson	400g	£0.64	6 months until 1 year. (Nutramigen 3 LGG available for >1 year in exceptional clinical need)				



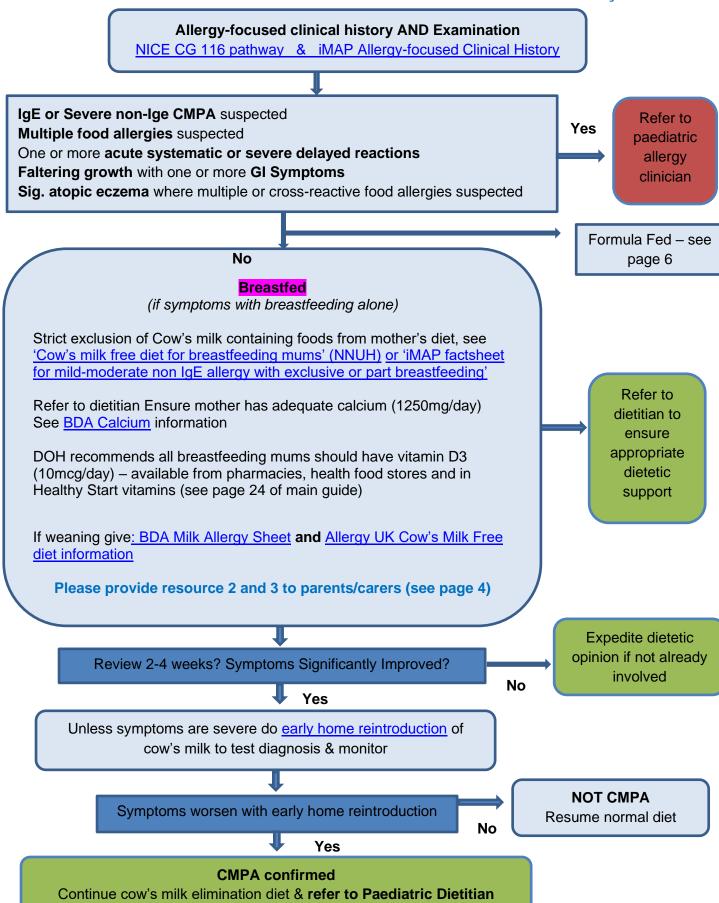
Amino Acid Formula –GPs may only initiate if EHF not tolerated after reasonable trial and if they have made a formal referral to a paediatrician or paediatric allergy dietitian, and it is not clinically appropriate to wait for a specialist recommendation							
Nutramigen Puramino®	400g	£1.13	Birth until infant has				
Mead Johnson			grown out of allergy (up to				
			12m as per policy)				
Neocate LCP®	400g	£1.26	Birth until infant has				
Nutricia			grown out of allergy (up to				
			12m as per policy)				
SMA Alfamino	400g	£1.29	Birth until infant has				
SMA Nutrition/Nestle			grown out of allergy (up to				
			12m as per policy)				

## Resources list - please provide suitable information to parents/carers

- 1) Allergy Focused Clinical History (iMAP)
- 2) Initial Fact Sheet for Parents (iMAP) (suitable for breastfeeding and formula feeding)
- 3) <u>Initial fact sheet for infants with symptoms of mild to moderate non-lgE mediated allergy</u> whilst being exclusively or partly breastfed (iMAP)
- 4) The Early Home Reintroduction to Confirm the Diagnosis of Cow's Milk Allergy (iMAP)
- 5) The iMAP Milk Ladder
- 6) iMAP Milk Ladder recipes
- 7) Cow's Milk free diet for breastfeeding mums
- 8) BDA Milk Allergy and/or Allergy UK Cow's Milk Free Diet for babies and children

## Flowchart for treatment of CMPA in primary care - Breastfed





## Flowchart for treatment of CMPA in primary care - Formula Fed



Yes

## Allergy-focused clinical history AND Examination

NICE CG 116 pathway & iMAP Allergy-focused Clinical History

IgE or Severe non-IgE CMPA suspected

Multiple food allergies suspected

One or more acute systematic or severe delayed reactions

Faltering growth with one or more GI Symptoms

Sig. atopic eczema where multiple or cross-reactive food allergies suspected

Refer to paediatric allergy clinician

Breastfed – see page 5

## Formula-fed

Trial of 1<sup>st</sup> line hydrolysed formula (EHF): Prescribe as ACUTE 3-4 tins initially to assess tolerance (See page 3).

**Mixed feeding:** If symptoms only with introduction of top-up feeds replace with breastfeeding (with maternal milk-free diet) or EHF top-ups.

**If weaning give**: 'BDA Milk Allergy Sheet' and 'Allergy UK Cow's Milk Free diet information'.

Please provide resource 2 and 4 to parents/carers (see page 4).

Advise parents/carers to complete <u>early home reintroduction</u> (resource 4, page 4) to confirm diagnosis of CMPA IF symptoms significantly improved after 2-4 weeks of EHF. Advise parents/carers to inform GP of outcome of retrial or arrange follow up if no improvement in symptoms.

Symptoms worsen with early home reintroduction of cow's milk

Symptoms NOT improved with 1st line EHF

Yes

Trial lactose-free 2<sup>nd</sup> line alternative EHF if appropriate (see page 3).

NB – if severe systematic reaction to EHF then an AA trial is required + referral to dietitian.

No

**NOT CMPA** 

Resume normal diet

**CMPA** confirmed

Re-start EHF

Review 2-4 weeks Symptoms significantly improved?

Simple mild/moderate non-IgE CMPA can be managed in primary care, please ensure:

- Parents/Carers are given the correct resources and information (see page 4).

Yes

- Parents/Carers are aware that 80% infants grow out of CMPA by the time they're 2 so it's important to reintroduce milk gradually with the milk ladder at approx. 9-12months old (or 6 months from diagnosis) to avoid restricting foods unnecessarily.
- Formula milk prescription is reviewed regularly to ensure age-appropriate amounts.
- GP/Primary care clinician to review at 1 year to advise on weaning off formula and onto alternative plant-based milk if the milk allergy is still present. See page 9 for suitable milks.
- Ensure a plan for reviewing and stopping formula.
- Refer to paediatric dietitians to ensure dietetic support is available when weaning.

Prescribe AA formula AND refer to paediatric allergy clinician if CMPA still suspected.

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

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

Apr 2019

Having taken an Allergy-focused Clinical History and Physically Examined

Less than 2% of UK infants have CMA. There is a risk of overdiagnosis of CMA if mild, transient or isolated symptoms are over-interpreted or if milk exclusion diets are not followed up by diagnostic milk reintroduction. Such situations must be avoided. There should be increased suspicion of CMA in infants with multiple, persistent, severe or treatment-resistant symptoms. iMAP primarily guides on early recognition of CMA, emphasizing the need for confirmation of the diagnosis, either by allergy testing (IgE) or exclusion then reintroduction of dietary cow's milk (non IgE). Breast milk is the ideal nutrition for infants with CMA and any decision to initiate a diagnostic elimination diet trial must include measures to ensure that breastfeeding is actively supported. Refer to accompanying leaflet for details of supporting ongoing breastfeeding in milk allergic infant. Firststepsnutrition.org is a useful information source on formula composition.

## Mild to Moderate Non-IgE-mediated CMA

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

Usually formula fed, at onset of formula feeding. Rarely in exclusively breast fed infants

Usually several of these symptoms will be present. Symptoms persisting despite first line measures are more likely to be allergy related e.g. to atopic dermatitis or reflux. Visit gpifn.org.uk for advice about other infant feeding issues.

#### Gastrointestinal

Persistent Irritability - 'Colic' Vomiting - 'Reflux' - GORD

Food refusal or aversion

Diarrhoea-like stools - abnormally loose +/- more frequent Constipation – especially soft stools, with excess straining Abdominal discomfort, painful flatus

Blood and/or mucus in stools in otherwise well infant

#### Skin

Pruritus (itching), Erythema (flushing) Non-specific rashes

Moderate persistent atopic dermatitis

The symptoms above are very common in otherwise well infants or those with other diagnoses, so clinical judgement is required. Trial exclusion diets must only be considered if history & examination strongly suggests CMA, especially in exclusively breastfed infants, where measures to support continued breastfeeding must be taken.

Cow's Milk Free Diet

#### Exclusively breast feeding mother\*

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

#### Formula fed or 'Mixed Feeding'\*

If mother unable to revert to fully breastfeeding, trial of Extensively Hydrolysed Formula - eHF

See Management Algorithm

## Severe Non-IgE-mediated CMA

Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP) Usually formula fed, at onset of mixed feeding. Rarely in exclusively breast fed infants

One but usually more of these severe, persisting & treatment resistant symptoms:

#### Gastrointestinal

Diarrhoea, vomiting, abdominal pain, food refusal or food aversion, significant blood and/or mucus in stools, irregular or uncomfortable stools +/- Faltering growth

#### Skin

Severe atopic dermatitis +/- Faltering Growth

## Cow's Milk Free Diet

## **Exclusively breast** feeding mother\*

Ψ

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

## Formula fed or 'Mixed Feeding'\*

If mother unable to revert to fully breastfeeding, trial of replacement of Cow's Milk formula with Amino Acid Formula (AAF). If infant asymptomatic on breast feeding alone, do not exclude cow's milk from maternal diet.

#### **Ensure:**

Urgent referral to local paediatric allergy service **Urgent dietetic referral** 

## Severe IgE CMA

#### **ANAPHYLAXIS**

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

(Rarely a severe gastrointestinal presentation)

> **Emergency** Treatment and Admission

iMAP was developed without any funding or support from industry but note that authors do make declarations of interest.

## Mild to Moderate **IgE-mediated CMA**

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

## One or more of these symptoms: Skin – one or more usually present

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

#### Gastrointestinal

Vomiting, diarrhoea, abdominal pain/colic

### Respiratory – rarely in isolation of other symptoms

Acute rhinitis and/or conjunctivitis

#### Cow's Milk Free Diet

Support continued breast feeding where possible. If infant symptomatic on breast feeding alone, trial exclusion of all Cow's Milk Protein from maternal diet with daily maternal Calcium & Vit D as per local guidance. If infant asymptomatic on breast feeding alone, do not exclude cow's milk from maternal diet.

#### Formula fed or 'Mixed Feeding'\*

If mother unable to revert to fully breast feeding 1st Choice -Trial of Extensively Hydrolysed Formula – eHF Infant soy formula may be used over 6 months of age if not sensitised on IgE testing

If diagnosis confirmed (by IgE testing or a Supervised Challenge in a minority of cases):

Follow-up with serial IgE testing and later Planned Challenge to test for acquired tolerance

#### Dietetic referral required

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

\* Actively support continued breastfeeding (see over)



## Frequently asked questions about CMPA

## Q. Can goat's milk formula be used as a treatment for CMPA?

 No: Goat's milk and sheep's milk are not advised due to the cross reactivity with cow's milk.

## Q. What happens when an infant reaches 1 year of age and is still allergic to cow's milk?

- Children over 1 year can use unsweetened and fortified soya-based or pea-based milk alternative which have suitable amounts of micronutrients, energy and protein and are widely available in supermarkets (see page 9 or <u>Suitable plant-based milk alternatives for</u> age 1+ with CMPA).
- In multiple/complex allergy continue prescription of specialist formula as recommended by allergy/paediatric dietitian.

## Q. What happens when an infant reaches 2 years of age and still has multiple allergies and is prescribed specialist formula?

- The formula milk should no longer be required and the child can go onto an unsweetened and fortified plant-based milk alternative which has suitable amounts of micronutrients, energy and protein (see page 9 or <u>Suitable plant-based milk alternatives for age 1+ with</u> <u>CMPA</u>).
- Rice milk is not suitable for children under the age of 4½ years.

## Q. Are vitamin and mineral supplements required?

- Department of Health recommends that all children aged 6 months to 5 years are given vitamin supplements containing vitamins A, C and D every day.
- All infants from birth to 1 year of age who are being exclusively or partially breastfed should be given a daily supplement containing 8.5 to 10µg of vitamin D (340-400 IU/d).
- The government recommends that children from the age of 6 months to 5 years are given a daily supplement of vitamin A (233µg) unless they are consuming over 500ml of infant formula a day.
- Babies who are having more than 500ml (about a pint) of infant formula a day should not be given vitamin supplements. This is because formula is fortified with vitamins.
- Vitamin supplements can be obtained through the Healthy Start scheme if eligible (see page 24 of main guide).
- Children on a cow's milk free diet may require a calcium supplement. This will be advised by the Paediatric Dietitian.

## Q. Why is soya formula not advised?

- Soya infant formula is not recommended to be given to babies under six months of age, due to the phytoestrogen content.
- Some infants with CMPA will also react to soya protein.
- Soya formula contains added sugars instead of the milk sugar lactose which are more likely to harm babies' teeth.
- Parents wishing to feed their infant on a soya-based formula should be advised to purchase the formula over the counter.

## Q. Can lactose free products be used in cow's milk protein allergy?

• No. These products contain cow's milk protein and are therefore not suitable.

Review date: Oct 2025

## Suitable plant-based milk alternatives for age 1+ with Cow's Milk Protein Allergy (CMPA)



## Plant-based milks

- Global and UK dietary guidelines recommend that children who are not being breastfed after the **age of 1**, drink animal milk as the main milk drink. This is normally cows' milk.
- Cow's milk contains high quality protein, all essential amino acids, and is a good source of vitamins and minerals including calcium, vitamins A and B, zinc, and iodine.
- Plant-based milk alternatives vary, and are often lower in energy, protein and micronutrients when compared to animal milks.
- It is important to try to reintroduce animal/ cow's milk products (if following an omnivorous diet) as soon as it's appropriate to ensure 'tolerance' of cow's milk in foods and drinks (discuss this process with your healthcare professional).
- In the UK, public health guidance suggests that unsweetened, fortified milk alternatives can be included instead of animal milks as the main milk drinks from the **age of 1** (except for rice-based milks which are high in arsenic).

## Types of plant-based milk alternatives that are suitable:

- **Unsweetened** and **fortified soya-based** and **pea-based** products should be **first choice** as they contain suitable amounts of micronutrients, energy, and protein.
- Unsweetened, fortified oat-based milk alternatives are second choice as they have a lower protein content and contain free sugars from the processing of oats.
- Choose **full fat/whole** versions to improve the energy content.
- Choose milks which are fortified with calcium, iodine, Vitamin D and Vitamin B.
- Nut-based and coconut-based products are very low in energy and protein.
- Please note: Unsweetened, full-fat plant-based alternative milks can be used in cooking and in weaning foods from 6 months.

Examples of some widely available suitable milks to be used as a drink for infants 1+ (this list is not exhaustive): Correct at the time of writing Sept 2024

Soya-based	<ul> <li>Tesco Soya Drink Unsweetened</li> <li>Alpro Growing Up Drink Soya 1-3+ Years</li> <li>M&amp;S Plant Kitchen Unsweetened Soya Drink</li> <li>Morrison's Long Life Unsweetened Soya Drink</li> </ul>	£1.35 per L £2.00 per L £1.70 per L £1.25 per L
Pea-based	Mighty Pea M.Lk Unsweetened	£1.90 per L
Oat-based (ensure protein content is approx. 1g/100ml or more)	<ul> <li>Oatly Oat Drink Barista/whole</li> <li>Oddlygood Barista Oat Drink</li> <li>Asda Oat Barista</li> <li>MOMA Oat Drink Whole</li> <li>Mighty Milkology Whole Dairy Free Oat Milk</li> <li>Alpro Growing Up Oat Drink 1-3+ Years</li> </ul>	£2.10/£2.20 per L £1.99 per L £1.45 per L £2.00 per L £1.90 per L £2.00 per L

### Sources:

<u>Plant-based milk alternatives in the diets of 1–4-year-olds</u>. First Steps Nutrition Trust [accessed September 2024] Cow's Milk Free Diet Information For Babies and Children. Allergy UK [accessed September 2024]