



Prescribing of Specialist Infant Formulae in Cow's Milk Allergy (CMA)

Recommendation:

This document is to advise on prescribing of specialist infant formulae in Cow's Milk Allergy (CMA) across Herefordshire and Worcestershire. This guidance covers all infants; including those who breastfeed, who are formula fed or do a combination of both. NHS Herefordshire and Worcestershire CCG Position Statement on the Prescribing of Specialist Infant Formulae as part of the CCG Prescribing Policy should be read in conjunction with this information.

Background

Cow's Milk Allergy (CMA) may be defined as a reproducible adverse reaction of an immunological nature induced by cow's milk protein. Cow's Milk Allergy can be classified into either IgE-mediated immediate-onset (Type1), and non-IgE-mediated delayed-onset according to the timing of symptoms and organ involvement. Estimates vary but incidence of CMA is thought to affect 2-4% of infants. It commonly presents in infancy and most affected children present with symptoms by 6 months of age. Onset is rare after 12 months. Most children will outgrow their allergy by school age.

Indications for Referral to Secondary Care (D=referral to a dietitian)

Immediate reactions (IgE-mediated) (D)	Infant is on an Amino Acid Formula (D)
Diagnostic uncertainty	Food Protein-Induced Enterocolitis Syndrome
Multiple food allergies suspected	Faltering Growth (D)
Concerns about nutritional content of the diet (D)	Does not respond to first line treatment

All infants with confirmed CMA should be referred to Dietitian for milk free weaning advice, to ensure nutritional adequacy of the diet longer term and to provide guidance on re- introduction of cow's milk to diet when/ if appropriate.

Extensively Hydrolysed Formula (EHF) Milks:

- 90% of children will respond to an EHF milk
- Suitable for initiation in primary care
- All are gluten free

EHF Formulary Milks Listed in order of CCG formulary preference for new prescribing

CCG Formulary Products
Aptamil Pepti 1® (<6 months*) 800g or Aptamil Pepti 2® (>6months*) 400g/800g
Alimentum® 400g (suitable from birth)
SMA Althera®** 400g tin (suitable from birth*)
*Contains lactose. Children with CMA will not normally react to lactose. ** awaiting full Halal certification (July20)

It is reasonable to trial a soya milk for children over 6 months of age who are struggling with EHF. 80% will tolerate this but should be reviewed in case of soya allergy developing. Refer to [CCG Position Statement](#).

High Energy Hydrolysed Formula Milk

1kcal/ml extensively hydrolysed whey protein ready-made formula. Indicated for disease-related malnutrition, intractable malabsorption, proven inflammatory bowel disease, short bowel syndrome, bowel fistula, **and**

intolerance to whole protein feeds. Suitable from birth to 18 months or body weight up to 9 kg. This should only be used under upon specialist opinion and can be continued in primary care.

CCG Formulary Products
Infatrini Peptisorb®* 200ml
*Contains lactose. Children with CMA will not normally react to lactose. Certified Kosher. Usual quantity 84 per month

Indications for Amino Acid Formula (AAF) Milks:

- Previous anaphylaxis to cow's milk
- Reactions to one or more EHF milks
- Faltering Growth
- Severe symptoms and multiple food allergies
- Consider using an AAF milk for breast fed infants who react to breast milk when mother is not on a dairy free diet at the time when mother reduces or stops breast feeding. Mother may wish to try further dietary exclusions prior to stopping breast feeding and should be referred for dietetic input

AAF formulae should be initiated in secondary care or upon specialist recommendation but can continue in primary care.

AAF Formulary Milks Listed in order of CCG formulary preference for new prescribing. All are gluten free.

CCG Formulary Products
SMA Alfamino® 400g tin (suitable from birth***)
Nutramigen PurAmino® 400g tin (suitable from birth***)
Neocate LCP® 400g tin (0 – 12 months*** and ****)
*** Halal approved and certified Kosher. **** Vegetarian

Neocate Syneo® is a highly specialised amino acid formula with pre- and probiotics and should only be advised by secondary / tertiary care and used under the direction of a Paediatric Dietitian.

Neocate Junior® is a highly specialised amino acid formula and should only be advised by secondary / tertiary care. It should not be prescribed in infants under the age of 1 year. It is not a 'follow on' from Neocate LCP®. There are different ways to make up Neocate Junior® and therefore all infants prescribed this product should be under the care of a Paediatric Dietitian.

Prescribing Points

For breastfed infants

Formulas may not be required. Continue breast feeding. Exclude dairy and mammalian milks from the mother's diet for 2-4 weeks if an exclusively breastfed infant is symptomatic. If breastfeeding mothers do not wish to or are unable to follow a milk free diet, an AAF may be needed. Breastfeeding mothers who require a milk free diet should have a daily calcium supplement (usually 1000mg) and Vitamin D supplement (10mcg/400iu).

If symptoms persist despite maternal dairy avoidance then discuss with, and refer to, a dietitian. Further dietary exclusions may be trialled, or alternatively an AAF formula may be prescribed after discussion with a dietitian.

For formula fed infants

Initially prescribe 2 tins of 1st choice EHF formula milk as an "ACUTE" prescription in primary care (1 x 400g tin will last ~ 3 days) as a 1st choice formula may not be tolerated. If symptoms do not improve after 2-4 weeks, then prescribe 2 tins 1st choice AAF and review progress.

Number of tins to prescribe per month

N.B. Prescribe 2 tins to confirm acceptability as an "acute" prescription in primary care.

< 6 months	6 -12 months	> 12 months
13 x 400g/450g tins OR 6 x 800g tins	7-13 x 400g/450g tins OR 3-6 x 800g tins	7 x 400g/450g tins OR 3 x 800g tins

General Prescribing Points

- EHF and AAF milks should only be used under medical supervision.
- Review prescriptions regularly to check formula prescribed is appropriate for the child's age. If a child is requiring substantially fewer tins, then refer to dietitian to review the nutritional adequacy of the diet.
- Quantities of formula required will change with age – see guide to quantities required and/or refer to the most recent correspondence from the paediatric dietitian.
- Wastage is reported by community pharmacies so therefore consider quantities required.
- Advise parents to allow 24-48 hours for pharmacies to obtain stock. Repeat dispensing arrangements with pharmacies may be helpful. Allow for Bank Holiday requirements.
- Parents should be made aware that the formulas contain sweeteners that increase the risk of dental decay. Advise to clean baby's teeth 2 times per day i.e. in the morning & after last feed at night.
- Remind parents to follow the advice given by the manufacturer regarding making the feed up and the safe storage of the feed once opened.
- 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. Reintroduction of milk products will need to follow the local guidance provided by secondary care usually using the [iMAP Guideline](#) for most non-IgE CMA.
- Prescriptions should be stopped when the child has outgrown the allergy. European data suggests that 57- 69% of CMA infants can tolerate cow's milk 12 months after initial diagnosis. Prescribing beyond 2 years should be at the recommendation of secondary care or paediatric dietitian.
- Children with multiple or severe allergies may require prescriptions beyond 2 years. This should always be at the recommendation of secondary care or paediatric dietitian.
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
 - Is the patient over 2 years of age?
 - Has the formula been prescribed for more than one year?
 - Is the patient prescribed more than suggested quantities of formula according to their age?
 - Is the patient prescribed a formula for CMA but able to eat/drink foods containing dairy e.g. cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee?

Disclaimer:

Information on formula certification is correct at the time of writing. It should be noted that formula certification can alter when, for example there are changes in ingredients or manufacturing processes. A prescriber will need to check up to date product information if there are specific religious or personal dietary requirements for an individual.

References:

- **NICE** (2014) [Cow's milk protein allergy in children. Clinical Knowledge Summaries](#)
- **NICE** (2011) [Diagnosis and assessment of food allergy in children and young people in primary care and community settings. Clinical Guideline 116.](#)
- **NICE** (2016) [Food Allergy Quality Standard QS118](#)
- **Clinical and Translational Allergy** (2019) [An update to the Milk Allergy in Primary Care guideline](#)
- **Prescqiip** (2016) [Bulletin 146: Infant feeds | PrescQIPP C.I.C](#)
- **iMAP** (2019) [The Milk Allergy in Primary Care Guideline](#)

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