



Greater Manchester Joint Commissioning Team

Prescribing infant formula for cow's milk protein allergy in primary care

April 2020

Version 3.0

This supersedes previous versions

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DOCUMENT CONTROL

Document location

Copies of this document can be obtained from:

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Revision history

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
25.02.16	Anna Pracz	Initial draft produced and sent for review by the CCG medicines management leads and the North West Paediatric Allergy Network.	0.0
07.03.16	Anna Pracz	Comments from above and the Medicines Optimisation Team at GM Shared Services incorporated.	0.1
07.03.16	Sarah Jacobs Anna Pracz	Document shared for final comments at the request of Manchester APC and NW Allergy Network representatives.	0.1
09.03.16	Anna Pracz	Subsequent edit. Incorporated comments from colleagues at Manchester APC. Document forwarded for approval by GMMMG.	1.0
06.05.16	Anna Pracz	Consulted with wider audience at GMMMG's request. Incorporated comments from NW Allergy Network, GM's community paediatric dietitians and GM SS Medicines Optimisation colleagues. Compared with available local policies. Sent to GMMMG for final approval on 11.05.16	1.1
20.05.16	Anna Pracz	Final formatting. Approved by GMMMG on 19.05.16	2.0
27.07.16	Anna Pracz	Correction on page 5. Moved Althera from entry listing lactose free formulas to entry listing lactose containing formulas.	2.1
25.10.16	Anna Pracz	Update following comments from Wigan CCG re clarity of prescribing for patients over 2 years old and prescribing recommendations for lactose free formula.	2.2
08.10.19	Karina Osowska	Full technical review of the guidance to incorporate comments from the working group and general update. Initial draft produced and sent for review by Anna Pracz, Senior MO Pharmacist, GMJCT.	2.3
15.10.19	Karina Osowska	Comments from Anna Pracz incorporated.	2.4
24.10.19	Karina Osowska	Comments from the working group incorporated and final draft prepared.	2.5
16.12.19	Karina Osowska	Changes following clinical check by RDTC	2.6
02.03.20	Karina Osowska	Amendments following consultation and comments from Anna Pracz (GMJCT)	2.7
06.04.20	Karina Osowska	Final formatting. Document ready for upload.	3.0

Summary of changes to version 3.0

GUIDELINE SECTION	SUMMARY OF CHANGES
1.Introduction	<ul style="list-style-type: none"> • Addition of information on spend on prescribing in GM
2.Background	<ul style="list-style-type: none"> • Addition of 'red flag symptoms', flowchart on initial differential diagnosis, notes on breastfeeding and links to information leaflets about CMPA for parents and carers
3.Choosing the appropriate type of formula for CMPA	<ul style="list-style-type: none"> • Update on symptoms and referrals to specialist services according to new iMAP guideline recommendations • Update on advice for breastfeeding mothers on over the counter (OTC) calcium and vitamin D3 as per NHS England OTC guidance for CCGs (confirmed with GMMMG's Formulary and Managed Entry Subgroup on 25.02.20)
4.Product choice	<ul style="list-style-type: none"> • Update to formula names, pricing and addition of information on suitability of some brands of formulas for Halal, Kosher and vegetarian diets • Amendment in 'Do not prescribe' section in regards to stopping prescribing formulas for children over 1 year old • Addition of information on not prescribing partially hydrolysed formulas and other mammalian milks
5.Quantities to prescribe	<ul style="list-style-type: none"> • Addition of ounces along with milliliters to the 'Average total volume feed per day'
8.Re-challenging	<ul style="list-style-type: none"> • Addition of information about secondary care led re-challenging of infants with acute CMPA symptoms • Addition of hyperlinks to re-challenging leaflets available on NHS North West Paediatric Allergy Network and iMAP website
9.References	<ul style="list-style-type: none"> • Update to references
10.Appendices	<ul style="list-style-type: none"> • Addition of appendix 1 (Factsheet for parents)

Approvals

This document must be approved by the following before distribution:

NAME	DATE OF ISSUE	VERSION
GMMMG	20.05.16	2
GMMMG	27.07.16	2.1
GMMMG	25.10.16	2.2
GMMMG	April 2020	3.0

Final version available on GMMMG website.

1. Introduction

This document aims at providing an effective clinical outcome and a better patient and family experience along with supporting primary care prescribers in initiation, management and discontinuation of prescribing of specialist formulas for children with cow's milk protein allergy (CMPA) up to 2 years of age.

Most of the cases of CMPA should be treated in primary care. Once a diagnosis of CMPA is suspected, a general practitioner (GP) can manage the condition by prescribing appropriate formula. The infant and mother (if breastfeeding) will need nutritional assessment. In complex cases appropriate support with specialist input may be needed, however, GPs are the mainstay of managing and prescribing for infants with simple CMPA. The infant's growth and need for formula should be monitored regularly by the prescriber. Infants with CMPA should be seen by a paediatric dietitian.

The majority of formulas prescribed in primary care are those to treat CMPA. In Greater Manchester, growth in expenditure and inappropriate prescribing of infant formula used in CMPA became of concern and in 2016 the first version of this guidance was published. Since then, many localities have implemented the guidance and in effect the annual spend for GM plateaued at just over £3m, with a reduction in annual growth in 18/19. Further work and resource is required to ensure that appropriate products are chosen and prescribed only for the recommended period of time.

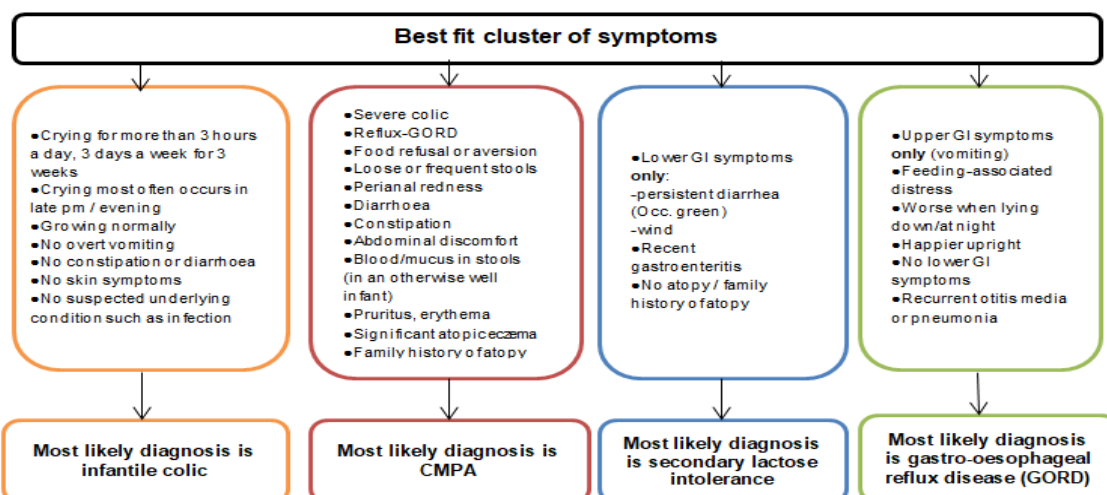
2. Background

CMPA is one of the most clinically complex individual food allergies. Symptoms presenting in infants with feeding difficulties are often not specific and conditions can overlap. However, in infants where these symptoms are multiple, significant, persistent and resistant to medical treatment, CMPA diagnosis should be considered.

Red flag symptoms which require immediate referral to secondary care are¹:

- Anaphylaxis and/or severe symptoms, e.g. wheeze, breathing difficulty, pallor, collapse
- Clinical suspicion of multiple food allergies
- Faltering growth in combination with one or more of the gastrointestinal symptoms above
- Significant atopic eczema

The majority of infants presenting with restlessness, colic and crying do not have CMPA.^{2,3} See diagram below.



According to literature, CMPA occurs in about 2% of UK infants.^{3,4} Most infants with CMPA develop symptoms before 6 months of age, and often within one week of introduction of cow's milk, cow's milk based formula or cow's milk based foods (e.g. porridge). Food allergies, including milk allergy, can have different underlying mechanisms.¹ However, the treatment is based on severity and time of onset of symptoms. Family history of atopy (first degree relatives) should be taken into consideration; see [NICE CG116](#) for full advice on allergy focused history taking.

Parents should be offered reassurance and advice on managing common and natural problems like colic, constipation, reflux, lactose intolerance or overfeeding. Health visitors and infant feeding teams can contribute by advising on feeding techniques including breastfeeding, infant positioning, preparation and appropriate volumes of formula.

Example of CMPA information leaflet for parents and carers available online (and in Appendix 1):

- [The iMAP Milk Allergy Guideline - Initial Fact Sheet for Parents](#)

Note on breastfeeding

CMPA is very rare in breastfed infants. Only about 0.5% of exclusively breastfed infants present with CMPA symptoms and feeding with formula in the first 4-6 months of life increases the risk of CMPA compared to exclusive breastfeeding.⁵ Exclusively breastfed babies develop CMPA as a result of ingestion of milk proteins from products the mother has eaten transferred through breast milk.

The level of cow's milk protein present in breast milk is 100,000 times lower than that in cow's milk. Most reactions to cow's milk protein in exclusively breastfed babies are mild or moderate, and severe forms of CMPA are very rare. It is thought that immunomodulators present in breast milk and differences in the gut flora of breastfed and formula fed infants may contribute to this.⁵

If symptoms of CMPA occur parents should be advised to continue breastfeeding and follow below guidance (see the flowchart on page 6).

Note on lactose intolerance

Secondary lactose intolerance is often confused with CMPA. In infants, it typically follows an acute episode of gastroenteritis which impairs gut functioning and in effect temporarily reduces lactase production. Symptoms include loose acidic stools, abdominal bloating and pain, increased flatus and nappy rash.⁶

Treatment in formula fed infants usually consists of a **temporary** switch to a lactose-free formula which should be reviewed after 2 weeks. If symptoms improve lactose intolerance can be confirmed and lactose free formula continued for a period of up to 6-8 weeks after which regular formula can be slowly reintroduced. If no improvement in symptoms occurs after 2 weeks the appropriately experienced healthcare professional should consider alternative diagnosis, e.g. CMPA.⁷

GPs should not prescribe lactose free formula as it is available at similar cost to regular infant formula from the majority of retailers (see page 7 - do not prescribe advice). Brands include SMA LF and Enfamil O-Lac. These and other lactose free, from birth formulas based on cow's milk can be purchased via the Healthy Start vouchers scheme.

Breastfeeding mothers should be advised to continue breastfeeding and seek advice from a community breastfeeding support worker.

For more information on management of other infant feeding problems refer to local or regional guidelines.

3. Choosing the appropriate type of formula for CMPA^{3,6,8}

Note: A large proportion of infants with CMPA have a mixed - delayed and acute presentation. Treatment should follow the guidance for acute presentation in these cases.



4. Product choice

Extensively hydrolysed formula (EHF)

EHF formula is appropriate for the majority (around 90%) of children with CMPA.⁵

Do not prescribe EHF if there is a history of anaphylaxis or severe symptoms.

Product name	Ages	Approximate cost/tin ¹¹
Aptamil Pepti 1 (400/800g)	From birth	£10/20
Aptamil Pepti 2 (400g/800g)	From 6 months	£9/£19
Nutramigen LGG 1 (400g)	Birth to 6 months	£11
Nutramigen LGG 2 (400g)	From 6 months	£11
Similac Alimentum (400g)	From birth	£9
SMA Althera (450g)	From birth	£11

- If GI symptoms / inflammation in GI tract suspected use a lactose free preparation (Nutramigen LGG, Similac Alimentum).

Amino acid formula (AAF)

Note that these products are almost three times more expensive than EHF and only a small number of infants (around 10%) need to be started on AAF in primary care.⁵

Product name	Ages	Approximate cost/tin ¹¹
Neocate LCP (400g)	From birth	£30
Nutramigen Puramino (400g)	From birth	£23
SMA Alfamino (400g)	From birth	£23

- All are lactose free. Appropriate for infants with severe CMPA.
- Nutramigen Puramino is suitable for Halal and Kosher diets
- Neocate LCP is suitable for Halal, Kosher and vegetarian diets¹²
- SMA Alfamino is suitable for vegetarian diet.¹³

Do not prescribe

- EHF or AAF products for lactose intolerance.
- Lactose-free formula – see page 5 for note on treatment of lactose intolerance.
- Soya based formula¹⁴ – not suitable for infants under 6 months old. Can be purchased for older infants if parents choose to. Be aware of risk of cross allergy with cow's milk.¹⁵
- Flavoured products – no clinical advantage.
- Liquid ready to feed products.
- Colief® (lactase), Infacol® (simethicone) – should not be prescribed as per NHS England OTC guidance for CCGs and lack of sufficient evidence to support use in treatment of symptoms of lactose intolerance or CMPA.
- Sheep, goat and other mammalian milks are not suitable for CMPA due to cross sensitivity.^{15,16}
- Do not suggest rice milk for children under 5 due to high arsenic content.¹⁶
- Partially hydrolysed formulas-not suitable for CMPA.¹⁷
- Do not initiate formula in children over 1 year old.
- Infant formula should not be prescribed in children over 2 years old. In general, aim to stop prescribing formula as the child turns 1 year old. Take into account local arrangements for assessment of child with nutritional requirements. Ensure parents receive advice in advance on appropriate cow's milk substitution to ensure optimal nutrition.

5. Quantities to prescribe

To avoid waste prescribe maximum of 1 week supply (2-3 tins) until tolerance and compliance is established.

Age of child	Average total volume feed per day (estimated)	Number of tins required for 28 days complete nutrition	Department of Health ¹⁸ recommendations (based on average weight for age)
Under 6 months	1000mls/35 ounces	10 x 400g (or 450g)	Exclusively formula fed based on 150mls/kg/day of a normal concentrated formula
6-9 months	800mls/28 ounces	8 x 400g (or 450g)	Requiring less formula with increased weaning and solid intake
9-12 months	600mls/21 ounces	6 x 400g (or 450g)	
Over 12 months	600mls/21 ounces	6 x 400g (or 450g)	Requiring 600ml of milk or milk substitute per day

*Note some infants may need greater volumes. Follow advice of specialist or dietitian

6. Practical advice

- It is often difficult to wean babies from breast feeds to formula feeds for various reasons.
- EHF is the appropriate choice for vast majority of infants with CMPA.
- Try a formula for a minimum of two weeks and avoid product switching.
- 2 to 6 weeks without allergen should improve symptoms.
- Both EHF and AAF are less palatable than the standard infant formula bought over the counter and are often initially rejected.
- If an infant does not tolerate taste suggest titrating with regular formula (not for infants with history of anaphylaxis or severe symptoms). However, direct switch to formula will eliminate allergen sooner.
- Infant stools may change and have a green tinge. This is seen with both EHF and AAF.
- If the infant is not thriving review treatment. Only around 10% of infants on EHF will not tolerate this type of formula and subsequently have persistent CMPA symptoms and faltering growth (due to residual allergen contents).⁵ Seek advice of dietitian.
- Immediate need to prescribe AAF happens rarely. Only prescribe AAF when infant has a history of anaphylaxis, and/or has very severe symptoms. Note that majority of these infants can be changed to EHF at a later date with risk assessment/challenge by a specialist. This consideration is an important step as there is emerging evidence suggesting that tolerance to cow's milk occurs sooner on sustained exposure to extensively hydrolysed formulas.^{19,20}
- Parents can be advised to keep a diary inclusive of symptoms and photographs that may aid diagnosis.
- Parents need advice on a cow's milk free weaning diet as appropriate. The process of tolerance development is dynamic and a dietitian should evaluate these infants and direct parents on milk reintroduction on a case by case basis.
- Some formulas have higher sugar content. Ensure dental hygiene advice given.
- Examples of CMPA information leaflets for parents and carers available online:

[The iMAP Milk Allergy Guideline - Initial Fact Sheet for Parents](#)

[The iMAP Milk Allergy Guideline - Initial fact sheet for parents with infants being exclusively or partly breastfed](#)

7. Prescription management

- Endorse prescriptions as ACBS listed.
- Ensure formula prescribing is monitored. If no robust monitoring in place do not prescribe formulas on repeat template. If applicable add review date to prescription.
- Review regularly against quantities and type of formula prescribed and child's increasing age. Ensure infant's growth is monitored and recorded.
- Review against recent correspondence from specialist, if applicable (e.g. children with higher nutritional requirements or multiple allergies may need more formula for a longer period of time).
- Review **all existing patients** if they meet **one or more** of below criteria:
 - More than 2 years old.
 - On formula for more than one year.
 - The quantity of formula prescribed is higher than recommended above (see page 8).
 - Patient can eat cow's milk containing foods (e.g. cows' milk, yoghurt, cream, butter, cheese, ice cream, custard, chocolate, cakes, margarine, ghee).

8. Re-challenging

Note that this is different from the home challenge which is done at 2-4 weeks after introducing specialist formula which aims at confirming CMPA diagnosis (see flowchart on page 6).

Children on long term EHF or AAF should be re-challenged to establish if they have acquired tolerance to cow's milk protein. Around two thirds of children outgrow their CMPA by 2 years of age. By three years of age only 10-15% of diagnosed children remain allergic to cow's milk protein²¹. It is recommended to re-challenge after a symptom free period of 6 months.

Retrial with cow's milk containing food products is suggested in the following time frames:

- For exclusively breastfed infants who have been asymptomatic for last 6 months:
 - Challenge around 9-12 months and every 6 months thereafter.
 - Consider reintroducing milk via maternal diet.
- Formula only and mixed breast and formula fed children who have been asymptomatic for last 6 months:
 - Challenge around 9-12 months and every 6 months thereafter.
 - Initially children should be exposed to low levels of processed milk as it has lower allergic risk (e.g. in baked goods, bread/biscuits/cakes).
 - Gradually increase and then introduce uncooked milk products.

Re-challenge should be led by secondary care in the following scenarios:

- Infants with history of anaphylaxis or severe symptoms.
- Infants with acute onset of mild to moderate onset of symptoms.

Take into account local arrangements and access to specialist services.

For details on re-challenging, milk ladder, etc. refer to resources available from specialists [North West Paediatric Allergy Network](#) , or the [iMAP guidelines \(milk ladder\)](#)

9. References

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Acknowledgements: Louise Calland, NHS Bolton CCG Medicine Optimisation Dietitian-Paediatrics

The iMAP Milk Allergy Guideline

– Initial Fact Sheet for Parents



When Cow's Milk Allergy is being considered as a possible cause of your baby's symptoms

Food Allergy has become more common and happens when a child's Immune System wrongly reacts against some of the proteins in a food, thinking they may be harmful. This will then result in either the onset of an immediate allergic reaction or a more delayed onset allergic reaction.

You have been given this factsheet because your baby may now be showing mild-to-moderate symptoms of a delayed type of allergic reaction to the proteins in cow's milk.

Delayed Onset Cow's Milk Allergy

Correct up-to-date medical term is **Non-IgE Cow's Milk Allergy** (This is still often incorrectly referred to as Cow's Milk Protein Intolerance)

The Immune System gradually builds up this mistaken reaction and as the milk protein continues to be consumed, it may result in a pattern of symptoms developing over hours, days or even weeks. It can occur with breast feeding alone (exclusive breast feeding) due to the small amount of cow's milk protein that passes across into the breast milk when the mother herself consumes cow's milk or dairy products but is more likely to occur later in such a breast fed baby when the time comes for formula, dairy products (e.g. yoghurt) or cow's milk to be added into the baby's own diet (mixed feeding). However, it is much more likely to occur in the baby who is just being bottle-fed.

The **typical mild-to-moderate** symptoms include one or usually more than one of the following:

- **Irritability (colic), reflux, vomiting, refusing or disliking being fed, loose or frequent stools, constipation (especially straining to pass even a soft stool), pain in the tummy, a little blood or slime in the stools**
- **Itching of the skin, redness of the skin, a tendency to 'rashes', eczema (dry inflamed itchy patches of skin)**

Cow's milk allergy is more likely to be the cause of these symptoms if there is a history of eczema, asthma, hay fever or food allergy in any close family members: mother, father, brothers or sisters. However such a history does not have to be present.

There are no skin or blood tests for delayed onset cow's milk allergy (Non-IgE allergy). The only reliable test is to take all the cow's milk protein out of the diet of the exclusively breast feeding mother or out of the diet of the bottle fed infant and then to later reintroduce it in a planned way.

It can be difficult to identify when some of these symptoms (e.g. irritability/colic, reflux/vomiting, and feeding difficulties), which so often occur in babies, are actually due to cow's milk allergy. In most cases allergy will not be the cause and each of the symptoms will settle in time, most needing minimal if any treatment. The **iMAP guideline** is designed to initially help your healthcare professional identify which babies should be suspected of having cow's milk allergy by listing these possible symptoms. The guideline then goes on to show how the diagnosis can be confirmed and then how to manage those babies with mild-to-moderate delayed onset cow's milk allergy (Non-IgE allergy).

All cow's milk and cow's milk containing foods must be removed from your diet if exclusively breast feeding or from your baby's diet **for a period of up to 4 weeks (minimum 2 weeks)**, as this is the time it may take for the symptoms to improve. Your healthcare professional will advise how your diet will need to change if you are exclusively breast feeding or will prescribe a special low allergy formula for your baby if he/she is being bottle fed. During the trial, the symptoms will either begin to clearly improve, suggesting the presence of cow's milk allergy, or there will be no significant change, which usually excludes the diagnosis of allergy.

At the end of this agreed trial it is really important to reintroduce the cow's milk protein.

If exclusively breast feeding you can simply start eating dairy products again or if your baby is bottle fed the previous cow's milk based formula can be reintroduced. A further **iMAP Parents Guide** will provide you with details of how to do this gradually, safely and easily at home. This will show whether any clear improvement seen in symptoms during the trial was actually due to cow's milk allergy and not just to your baby improving naturally. If allergy is the cause, the symptoms can be expected to return within the first few days of reintroducing the milk protein, but will usually settle well again as the milk free diet is restarted.

By following this guide, **the diagnosis of cow's milk allergy can then be properly confirmed or excluded.** If the diagnosis is confirmed, the next steps in management will be explained to you and they should importantly include the on-going support of a dietitian.

There are other types of adverse reactions to milk

Immediate Onset Cow's Milk Allergy and Lactose Intolerance

There is often confusion around how these two conditions differ from Delayed Onset Milk Allergy.

Immediate Onset Cow's Milk Allergy

(Correct medical term is IgE Cow's Milk Allergy)

This immediate onset type of food allergy usually affects slightly older children and is often due to other foods such as egg, peanut, tree nuts or sea food. It can however occur with cow's milk, most commonly when cow's milk based formula feeds are used as 'top-ups' in the breast fed baby or later when weaning with solids begins and dairy products (e.g. yoghurt) or even cow's milk are added into the diet of these babies. **Symptoms usually develop within minutes following ingestion.** They may be mild, such as reddening of the skin, hives, and puffiness around the mouth or eyes. Rarely much more serious 'internal' symptoms can develop; especially breathing difficulties (this is called Anaphylaxis).

Lactose Intolerance

The sugar in cow's milk and in breast milk is called lactose. An enzyme called lactase, present in the gut is needed to break this complicated sugar into smaller sugars that the body can then absorb and use. As young children grow up and drink less milk, the amount of this enzyme gradually and naturally falls. For some children, especially those from an Asian or African ethnic background, this may mean that over time not all the lactose they consume is broken down. Very gradually gut symptoms begin to develop. These symptoms may include bloating, tummy pains, wind and very loose stools – it does not include constipation or reflux/vomiting. **However this does not usually happen until later in childhood and certainly it very rarely occurs in young babies.**