

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

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Review due in May 2018

## DOCUMENT CONTROL

### Document location

Copies of this document can be obtained from:

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### Revision history

The latest and master version of this document is held on the Medicines Management SharePoint:

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

### 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

### Final version available on GMMMG website.

Editable copy for local adaptation available on request from GM Shared Services.

## 1. Introduction

The majority of formulas prescribed in primary care are those to treat cow's milk protein allergy (CMPA). Recent constant growth in expenditure and inappropriate prescribing became of concern.

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 CMPA up to 2 years of age.

Most of the cases of CMPA should be treated in primary care. Once a diagnosis of CMPA has been suggested a 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. Every effort should be made for infants with milk allergy to be seen by a paediatric dietitian.

## 2. Background

Symptoms presenting in infants with feeding difficulties are often not specific and conditions can overlap. **The majority of infants presenting with restlessness, colic and crying do not have CMPA. Parents of an infant should be offered reassurance and advice on managing common and natural problems like colic, constipation, reflux, lactose intolerance or overload.** Health visitors can contribute by advising on feeding techniques including breastfeeding, infant positioning, preparation and appropriate volumes of formula.

CMPA occurs in less than 8% of young infants, however between 5% and 15% of infants present with symptoms suggestive of CMPA<sup>1</sup>. Most infants with CMPA develop symptoms before 6 months of age, and often within one week of introduction of a whole cow's milk protein infant formula.

Approximately 0.5% of exclusively breastfed infants present with CMPA symptoms which are usually mild to moderate<sup>1</sup>. If symptoms of CMPA occur parents should be advised to continue breastfeeding and follow below guidance.

Food allergies, including milk allergy, can have different underlying mechanisms<sup>2</sup>. However, the treatment is based on severity and time of onset of symptoms. Family history of atopy (1<sup>st</sup> degree relatives) should be taken into consideration; see [NICE CG116](#)<sup>2</sup> for full advice on allergy focused history taking.

### **Note on lactose intolerance**

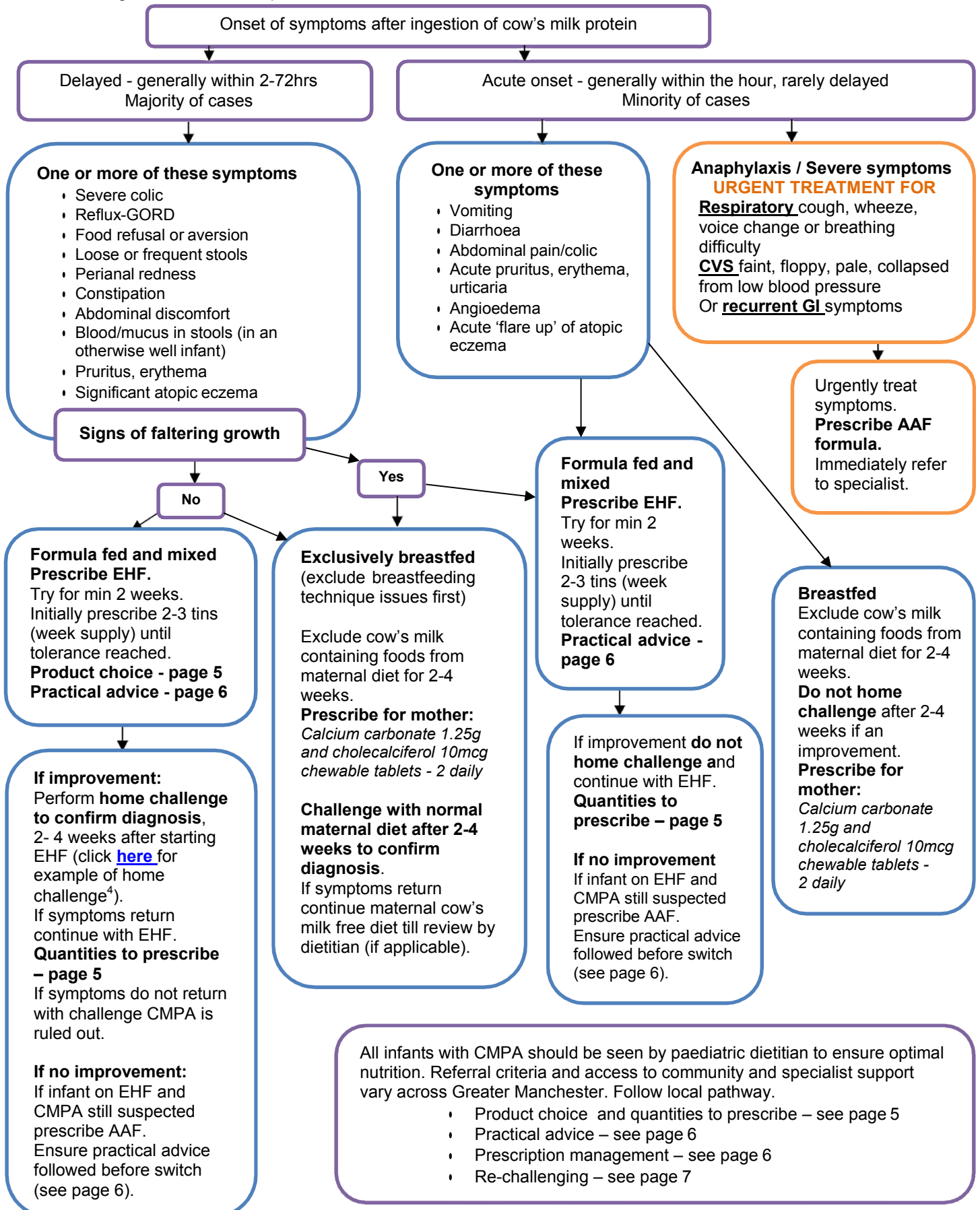
Secondary lactose intolerance is often confused with CMPA. In infants, it typically follows an acute episode of gastroenteritis which impairs gut functioning and in effect temporarily reduces lactase production. Symptoms include loose acidic stools, abdominal bloating and pain, increased flatus and nappy rash<sup>3</sup>.

Treatment usually consists of a **temporary** switch to a lactose-free formula for a period of 6-8 weeks after which regular formula can be reintroduced. GPs should not prescribe lactose free formula as it is available at cost similar to regular infant formula from the majority of retailers (see page 5 - 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 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<sup>3</sup>

Note: A large fraction 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%<sup>1</sup>) of children with CMPA.

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

Product name	Ages	Approximate cost <sup>5</sup> /tin
Althera (450g)	From birth	£11
Aptamil Pepti 1 (400/800g)	Birth to 6 months	£10/19
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

- Althera, Aptamil Pepti 1 & 2 contain lactose and may be more palatable.
- 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%<sup>1</sup>) need to be started on AAF in primary care.

Product name	Ages	Approximate cost <sup>5</sup> /tin
Alfamino (400g)	From birth	£23
Neocate LCP (400g)	From birth	£28
Nutramigen Puramino (400g)	From birth	£27

- All are lactose free. Appropriate for infants with severe CMPA.

### **Do not prescribe**

- EHF or AAF products for lactose intolerance.
- Lactose-free formula – see page 3 for note on treatment of lactose intolerance.
- Soya based formula<sup>6</sup> – 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.
- Flavoured products – no clinical advantage.
- Liquid ready to feed products –no clinical advantage, may be more palatable and useful if concerns over making up powdered formula.
- Colief® (lactase), Infacol® (simethicone) – lack of sufficient evidence to support use in treatment of symptoms of lactose intolerance or CMPA.
- Do not initiate formula in children over 1 year old.
- Do not prescribe formula in children over 2 years old and aim to stop prescribing of formula as the child turns 1 year old. Ensure parents receive advice 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 <sup>7</sup> recommendations (based on average weight for age)
Under 6 months	1000mls	10 x 400g (or 450g)	Exclusively formula fed based on 150mls/kg/day of a normal concentrated formula
6-9 months	800mls	8 x 400g (or 450g)	Requiring less formula with increased weaning and solid intake
9-12 months	600mls	6 x 400g (or 450g)	
Over 12 months	600mls	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 dietician.

## 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%<sup>1</sup> 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). 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 that tolerance to cow's milk occurs sooner on sustained exposure to extensively hydrolysed formulas<sup>8,9</sup>.
- Parents can be advised to keep a diary inclusive of symptoms and photographs that may aid diagnosis.
- Parents need advice on 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.

## 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 5).
  - 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 4).

Children on long term EHF or AAF should be re-challenged to establish if they have acquired tolerance to cow's milk protein. 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 protein<sup>10</sup>. It is recommended to re-challenge after a symptom free period of 6 months. For those with a history of anaphylaxis or severe symptoms re-challenging should be directed by a specialist.

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.

For details on re-challenging, milk ladder, etc. refer to resources available from specialists [North West Allergy guidelines<sup>11</sup>](#), or the [MAP guidelines<sup>4</sup>](#).

## 9. References

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