NHS
Gateshead Clinical Commissioning Group

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Guidelines for prescribing in primary care:

Cow's milk allergy in babies and young children

Implementation date: May 2014

Review date: May 2016

This guideline has been prepared and approved for used within Gateshead in consultation with Gateshead CCG and Secondary Care Trusts.

Approved by:

Committee	Date
Gateshead Medicines Management Committee	14th May 2014

This guideline is not exhaustive and does not override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Full details of contra-indications and cautions for individual drugs are available in the BNF or in the Summary of Product Characteristics (available in the Electronic Medicines Compendium) www.emc.medicines.org.uk

Guidelines for Prescribing in Primary Care:

Cow's milk allergy in babies and young children

Aim

To clarify which products and in which circumstances cows milk substitutes can be prescribed for babies and young children in primary care. The prescribing of high energy infant formulas is not covered in this guideline.

Background

NICE produced guideline 116 in February 2011 relating to food allergy in children and young people, it covers the diagnosis and assessment of food allergy in children and young people in primary care and community settings[(1)]. The MAP Guideline (Milk Allergy in Primary Care) for Primary Care Management of mild to moderate non-IgE cow's milk allergy has been approved for implementation by the Northern Region Allergy Network , having being derived from the NICE Guidance.

Summary

- It is important to distinguish between Cow's milk protein allergy (CMPA) and lactose intolerance for effective management.
- A limited range of milk substitute products can be prescribed as drugs, and these are defined in Borderline Substances. Any prescription written needs to be endorsed 'ACBS'.
- It is acknowledged that infants will present to Health Visitors and GP practices with suspected intolerances to infant formula or breast milk and it will not always be appropriate to wait for a diagnosis from secondary care but rather it is necessary to treat empirically.
- Soya based formulas are not recommended for prescribing to infants, especially those under 6 months of age. The reason for this is the risk that the baby may develop a secondary soya allergy. Soya milk also contains phytoestrogens which are an unproven health risk, particularly for male babies [(2)]. (Babies of vegan mothers who choose not to breast feed may be given soya milk but not at the expense of the NHS). In some situations a soya prescription may be requested by a Paediatric Dietitian for clinical reasons.
- Lactose free milks can be bought at a similar cost to standard infant formula and prescribers should consider the need to prescribe at the expense of the NHS. Lactose free milks are available from pharmacies and many supermarkets will stock on demand. Healthy start vouchers can be used towards lactose free infant formula as well as standard formula milk.

Notes:

- Review repeat prescription quantity at 3 month intervals and adjust according to current requirements.
- Prescription for infant formula may be required up until 1 – 1.5 years of age (if allergy persists), and beyond for older patients with severe allergy who are unable to tolerate commercial cow's milk substitutes. This would be at the request of the paediatric dietitian.
- All infants require dietetic input (see algorithm on page 3 for further information).

CMA = cow's milk allergy
CMP = cow's milk protein
AAF = amino acid formula
EHF = extensively hydrolysed formula

Suspected cow's milk allergy (CMA) in the 1st year of life

SIGNS AND SYMPTOMS

Acute onset symptoms

Mild to moderate IgE-mediated CMA

Mostly within minutes of ingestion of CMP
Mostly formula fed or at onset of mixed feeding

One or more of the following symptoms:

Gastrointestinal
- Colic
- Reflux – GORD
- Food refusal or aversion
- Loose or frequent stools
- Perianal redness
- Constipation
- Abdominal discomfort
- Blood and/or mucus in stools in an otherwise well infant

Skin
- Pruritis
- Erythema
- Significant atopic eczema

Respiratory
- Cararrhal airway symptoms (usually in combination with one of more of the above symptoms)

Severe IgE CMA ANAPHYLAXIS

Immediate reaction with severe respiratory and/or CVS signs and symptoms
(rarely a severe GI presentation)

Delayed onset symptoms

Mild to moderate non-IgE mediated CMA

Mostly 2-72 hours after ingestion of CMP
Formula fed, exclusively breast fed or at onset of mixed feeding

One or more of the following symptoms:

Skin
- Acute pruritis
- Erythema
- Urticaria
- Angioedema
- Acute 'flaring'
- Atopic eczema

GI
- Vomiting
- Diarrhoea
- Abdominal pain/ colic

Respiratory
Acute rhinitis +/- conjunctivitis

Severe non-IgE mediated CMA

Mostly 2-72 hours after ingestion of CMP
Formula fed, exclusively breast fed or at onset of mixed feeding

Severe persisting symptoms of one or more of the following:

Gastrointestinal
- Diarrhoea
- Vomiting
- Abdominal pain
- Food refusal or food aversion
- Significant blood loss and/or mucus in stools
- Irregular or uncomfortable stools +/- faltering growth

Skin
- Severe atopic eczema +/- faltering growth

ACTION

Mild to moderate IgE-mediated CMA: **URGENT REFERRAL to paediatric consultant** for secondary care evaluation, diagnosis and support

TREAT infant whilst waiting for referral appointment

Severe IgE CMA anaphylaxis: **EMERGENCY ADMISSION TO HOSPITAL**

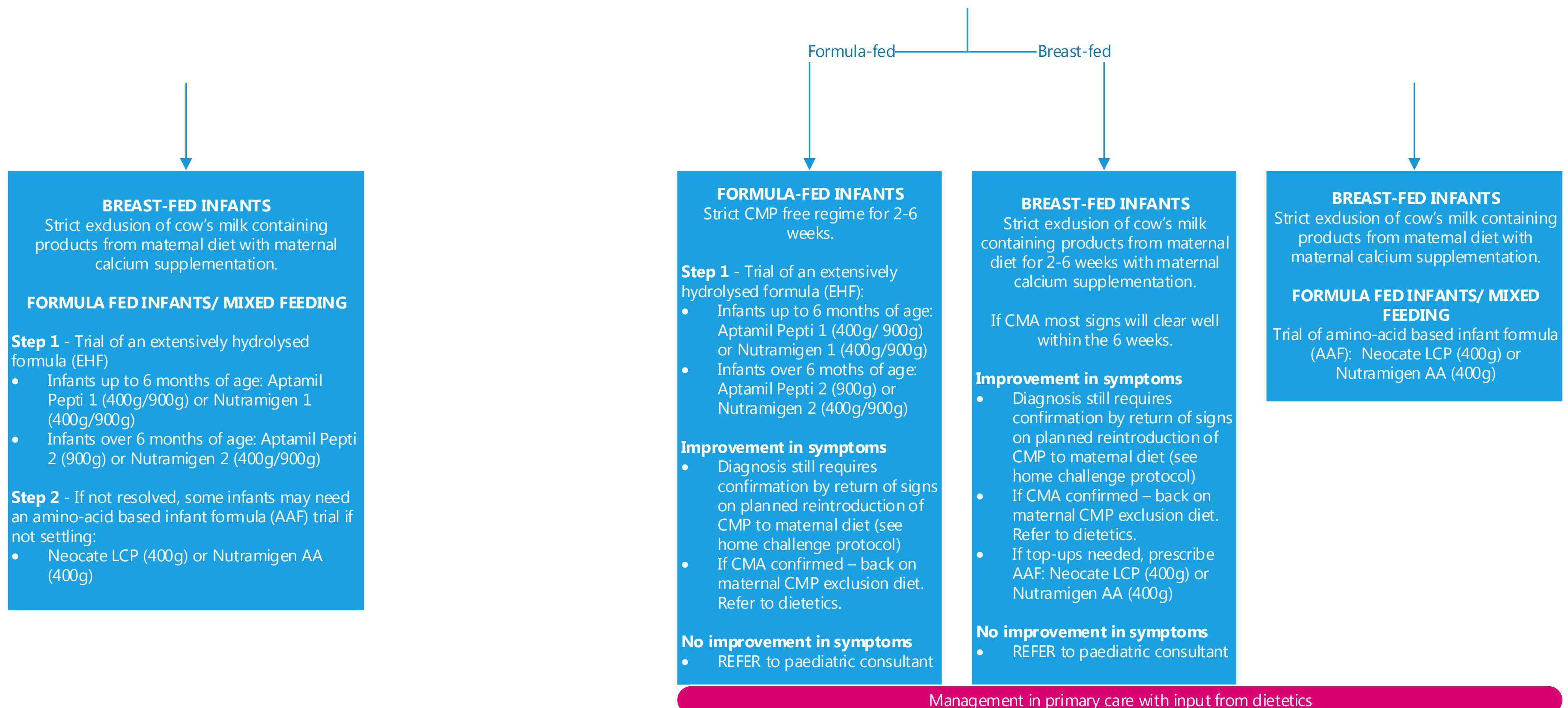
Mild to moderate non-IgE mediated CMA: TREAT infant

REFER to dietetics for support

Formula-fed | Breast-fed

Severe non-IgE mediated CMA: TREAT infant

URGENT REFERRAL to paediatric consultant for secondary care evaluation, diagnosis and support



QUANTITIES OF FORMULA TO PRESCRIBE

Initial prescriptions should be for 1-2 tins to ensure the formulation is acceptable and reduce wastage.

Age of child	Number of tins for 28 days
<6 months	10 x 400g tins or 5 x 900g tins
6-9 months	8 x 400g tins or 4 x 900g tins
9-12 months	6 x 400g tins or 3 x 900g
>12 months*	6 x 400g tins or 3 x 900g tins

*dietetics review required for continued need for formula

Key points for cow's milk protein allergy

- Adverse reactions to foods, mainly cow's milk protein are most common in the first year of life[3]. In infancy the main atopic symptoms are atopic dermatitis, gastrointestinal (GI) symptoms (diarrhoea, blood in stools, vomiting, abdominal distension, colic and constipation) and recurrent wheeze.
- CMPA may be caused by two distinct immune pathologies: IgE and non IgE-mediated. Acute IgE-mediated reactions (usually within 2 hours) include rash or urticaria, wheeze or vomiting. Delayed reactions may be non-IgE-mediated or mixed (>2 hours) including eczema, colic, diarrhoea.
- Suspect CMPA when: a child has one or more signs or symptoms, especially if persistent symptoms affecting different organ systems; when a child has not responded to treatment for atopic eczema reflux or chronic GI symptoms including constipation [2].
- Breast fed infants can display symptoms, as some cow's milk proteins from the mothers diet may be expressed in breast milk.
- Infants with mild to moderate non-IgE mediated CMPA 'delayed' onset symptoms should be managed in Primary Care (see MAP Guidance)
- All children following a CMPA free diet should be referred to a Paediatric Dietitian.
- Infants with severe Non-IgE-mediated CMPA 'Delayed' onset symptoms should be referred to a consultant paediatrician and paediatric dietitian with an interest in allergy for support and advice (see MAP Guidance)
- Most children grow out of their allergy by 18-24 months of age.

Managing cow's milk protein allergy

Breast milk is the ideal choice for the infant with CMPA with maternal exclusion of cow's milk and supplementation with calcium (to provide 1000mg calcium daily) for a minimum trial of two weeks.

For bottle fed infants an appropriate hydrolysed formula is required. These formulas vary in palatability and should be introduced as soon as possible. If not accepted initially introduce with incremental mixing with the standard formula. Give a minimum trial of two weeks. It is advisable to inform parents/guardians that these formulas contain glucose, so that they may pay special attention to dental hygiene as new teeth appear.

The Paediatric Dietitian will review and inform the GP of all planned monitoring, the follow up intended and guidance given to parents on weaning and the plan to stop formula milk. Typically the paediatric dietitians will usually recommend challenging with small amounts of cow's milk from the age of 12-18 months. In cases of IgE mediated allergy the challenge needs to be under medical supervision.

From the age of 12 months and by the age of 18 months most infants will have been weaned onto normal cow's milk or if this is not tolerated, a commercially available liquid milk substitute using varieties fortified with calcium. A prescription for a child older than 18m should only be issued if requested by a paediatric dietitian for specified reasons.

The Paediatric Dietitian will regularly assess the infant's nutritional intake to promote a balanced diet. Infants on a CMP free diet may require a calcium and/or vitamin D supplement to achieve this.

Guidance for concerns about colic

- In most cases of colic, no underlying cause can be found.
- Addressing parental concerns is often the best way to cope with colic. Reassure parents that colic will resolve.
- Parents may wish to purchase colic remedies such as Dentinox, Infacol or Gripe Mixture. Although there is no good evidence of effectiveness, parents may perceive this to be beneficial.
- Lactase enzymes (e.g. Colief) are **not prescribable** for colic as there is limited evidence of effectiveness and their use contraindicates DH guidance on the preparation of infant formula.
- For unresolved severe colic, consider CMPA.

Guidance for concerns about gastro-oesophageal reflux (GOR)

- In most cases of GOR, no underlying cause can be found, although GOR may be associated with cow's milk protein allergy.
- If reflux is suspected consider an anti-regurgitation formula.
    - Anti-regurgitation infant formulas such as Aptamil Anti Reflux®, Enfamil AR® or SMA Staydown® should **not** be prescribed along with other thickening agents such as Carobel® or Gaviscon® infant sachets. In addition, these anti-regurgitation infant formulas require an acid environment in order to thicken and therefore will not work properly when prescribed along with antacid medications such as omeprazole or ranitidine.
    - Gaviscon® infant sachets should **not** be used with thickening agents or infant milk preparations containing a thickening agent, as this could lead to over-thickening of the stomach contents. They should therefore not be prescribed along with Carobel®.
- If an anti-regurgitation formula is ineffective please seek further advice from dietetics.

Lactose intolerance

- Lactose intolerance is defined as a non-immune mediated adverse reaction to food i.e. it is not due to allergy but to a lack of the enzyme lactase.
- Primary lactose intolerance is rare; generally lactose intolerance is secondary to gastroenteritis and is transient, usually lasting around 4 to 6 weeks.
- Lactose free formula can be purchased at a similar price to standard formula and the GP should consider whether a prescription is actually necessary; advice to use a lactose free infant formula may be all that is required.
- Symptoms usually resolve in 2-3 days when lactose is removed from the diet and achievement of this confirms the diagnosis.
- From the age of one year infants continuing to require lactose free milk should be weaned onto proprietary lactose free milks purchased at supermarkets. (Lactose free infant formula should not be required beyond 18 months.)
- Lactose free milk is more cariogenic than standard formula as it contains glucose in place of lactose.

REFERENCES

1. NICE Clinical Guideline 116 Food Allergy in children and young people
2. BDA Paediatric Group (2008) Paediatric Group Position Statement on the use of soya protein for infants. British Dietetic Association; London
3. Vandenplas Y et al: Guidelines for the diagnosis and management of cow's milk allergy in infants. Arch Dis Child 2007; **92**:902-8.
4. Venter et al. Diagnosis and management of non-IgE-mediated cow's milk allergy in infancy – a UK primary care practical guide (The MAP Guidelines) Clinical and Translational Allergy 2013; **3**: 23

Gateshead Health NHS Foundation Trust
Infant Formula Formulary

Please note quantities of formula prescribed will need to be adjusted according to the infant's age, growth, stage of weaning and severity of allergy.

Product	Indication	Age suitability	Additional Information	Re-challenge with cow's milk
Extensively Hydrolysed Infant Formula (EHF)				IgE mediated allergy will be challenged under the medical supervision. Please refer to MAPP milk ladder for further information. From 12-18 months commercially available oat, soya and rice milk is available in most supermarkets and can be used to replace any formula for drinking. From 6m – 12m these milks can be introduced in small amounts in foods e.g. to make up cereals.
Aptamil Pepti 1 (400g = £8.62/ 900g = £19.39)	CMPA (mild-moderate)	From birth	Contains lactose	
Aptamil Pepti 2 (900g = £19.39)		From 6 months	Contains lactose	
Nutramigen 1 (400g = £10.38)		From birth	Lactose free	
Nutramigen 2 (400g = £10.38)		From 6 months	Lactose free	
Amino-Acid Based Infant Formula (AAF)				
Neocate LCP (400g = £23.83)	CMPA (severe)	From birth	Prescribe if above not tolerated after a trial of a minimum of two weeks, or if symptoms severe.	
Nutramigen AA (400g = £22.89)		From birth		
Soya Based Infant Formula				
Infasoy (900g = £7.47)	Infants with CMPA that are unable to tolerate other formula. **Only prescribe at paediatric dietitians request with clinical reasoning.**	From 6 months	Only prescribe if other milks are not tolerated as potential health risk of phytoestrogens for babies fed predominantly on soya milk, also high incidence of soya allergy in children with CMPA. Do not prescribe for infants of vegan parents at the cost of the NHS. Health Start vouchers cannot be used to purchase soya milk. Occasionally the dietitian will request a prescription for clinical reasons or if an older child cannot tolerate the taste of EHF or AAF.	
Wysoy (430g = £4.59/ 860g = £8.75)				

*Prices from BNF for Children October 2013

Appendix 3

Information sheet for parents

Gateshead Clinical Commissioning Group

IMPORTANT INFORMATION FOR PARENTS:

YOUR BABY HAS BEEN PRESCRIBED A SPECIALIST MILK.

Many babies need to have a trial of alternative milk. The hospital will when possible provide some of this milk to begin with. If the new milk is working then you will need to get a further supply form your GP and local chemist. This will need to be done in good time and your chemist will need at least 48 hours' notice.

PLEASE GET THE PRESCRIPTION BEFORE YOUR CURRENT SUPPLY RUNS OUT SO THAT YOU HAVE SUPPLIES!

We hope that this helps to avoid running out of milk.

Childrens Unit
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