Prescribing Guidance for Specialist Infant Formula Feeds in mild to moderate Non-IgE Cow's Milk Allergy (CMA) and Lactose Intolerance

The purpose of this guidance is to outline recommendations for the prescribing of infant formula feeds in mild to moderate non-IgE mediated cow's milk allergy (CMA) and lactose intolerance. This guidance supersedes the previous HSCB infant feeding guidance (2017) which has been stood down. This guidance is intended for healthcare professionals including doctors, dietitians and health visitors. For suspected IgE mediated CMA refer to a specialist allergy paediatrician.

1. Background and Context

The diagnosis of CMA can be challenging. This has resulted in the over diagnosis of CMA, as well as inappropriate and over prescribing of specialist infant formula feeds in Northern Ireland (NI). NI spends more than twice as much per infant in comparison to the rest of the UK on prescribing specialised milks for CMA (£88 per infant in NI compared to £40/£49/£44 per infant in England/Wales /Scotland). **In 20/21 £4.68 million was spent on CMA milks in NI**.

This guidance covers all infants i.e. those who are breastfed, formula fed or combination fed.

Breastfeeding is the best form of nutrition for infants and this should be promoted, actively supported and protected wherever possible.

2. Assessment of infants

Assessment should cover the following points:

- Consider if powdered formula feed products are being correctly prepared.
- Consider diary keeping. If an infant has problems with feeding, bowels, vomiting, sleep or settling, a feeding or symptom diary can be very helpful in clarifying symptoms and finding the cause.
- Parents and carers should be encouraged to photograph skin reactions to help healthcare professionals with diagnosis.

More detailed information on the diagnosis of CMA and other infant feeding presentations can be found on The GP Infant Feeding Network (UK) (GPIFN) website and specifically:

- Presentation of Suspected Cow's Milk Allergy (CMA) in the 1st Year of Life iMAP presentation algorithm

3. **Prescribing of extensively hydrolysed (eHF) or amino acid-based (AAF) formula in infants presenting with mild-moderate non-IgE mediated CMA symptoms**

More detailed information on the treatment of CMA and other infant feeding presentations can be found on The GP Infant Feeding Network (UK) (GPIFN) and specifically:

- Management of mild-moderate non-IgE cow's milk allergy (CMA) **iMAP treatment algorithm**

Prescriptions for such products should be endorsed 'ACBS'.

(i) Prescribing eHF for infants

- For formula fed infants the first step is to undertake an elimination trial with eHF, ***including*** where symptoms suggest severe allergy or suspected IgE allergy. HSCB no longer recommend a cost-effective choice formula as there is little price difference between brands. If the infant is breastfed do not prescribe formula - the mother should remove all cow's milk containing foods from her own diet for the duration of 2-4 week elimination trial.

- A maximum of 6-8 tins of eHF should be prescribed to allow the elimination trial to take place.

- If an improvement in patient symptoms is seen after this trial no further prescriptions for eHF should be issued and a home challenge with cow's milk containing formula should take place. In the case of breastfed (or combination fed) infants, the mother should revert to normal diet containing cow's milk foods over the course of one week. This reintroduction should take place approximately 4 weeks after commencing trial of eHF or maternal exclusion of cow's milk containing foods.

- ***Details of this home challenge should be highlighted to parents at the outset of treatment. iMAP Home Reintroduction to Confirm or Exclude diagnosis*** provides the practical details for the family of how to carry out the reintroduction at home.

- If after the home challenge symptoms do not return then CMA is not suspected and no further formula should be prescribed.

- If after the home challenge symptoms return, then in the case of formula fed infants further eHF can be prescribed and if symptoms again improve then CMA is confirmed. Only then should long term prescribing with regular review proceed.

- Following a diagnosis of CMA, refer to specialist dietitian or paediatric consultant following local processes and access criteria. The dietitian or specialist should draw up a care plan for weaning and discontinuation.

- If after the initial 2-4 week elimination trial using eHF, no clear improvement in symptoms is seen but CMA is still suspected prescribers should consider a trial of an amino acid-based formula (AAF) as detailed below; and refer patient to paediatrics or secondary care allergy clinic.

(ii) Prescribing AAF for infants

AAF should ***only*** be initiated following an initial trial of eHF for at least 2-4 weeks.

Children with faltering growth due to enterocolitis or proctitis, severe atopic dermatitis and symptoms during exclusive breastfeeding are more likely to require AAF.

Infants should be recommenced on an eHF after 6 months of using an AAF unless advised otherwise by paediatric consultant or dietitian (however prescribing may revert back to AAF if eHF not tolerated).

(iii) Ongoing prescribing and review of patients

After confirmation of CMA, a cow's milk free diet should be followed until 9-12 months of age and for at least 6 months. A planned reintroduction of cow's milk is then needed to determine if tolerance has been achieved. Further information on planned reintroduction can be found in the GPIFN treatment guidance iMAP Milk Ladder

Many children grow out of their allergy by 24 months. Children should be referred to a paediatric consultant if weight gain is not satisfactory, symptoms are severe or if there are other medical conditions present. If suspected IgE CMA or anaphylaxis to cow's milk then refer to allergy service for further assessment and management.

Children may remain on eHF and AAF for longer than 24 months **only** on the advice of paediatric consultant or dietitian. However, when dietary intake is adequate children may use plant based milk substitutes from the age of 12 months. Check for letters on

GP system from paediatricians or dietitians to identify any children continuing to require prescribed formula over the age of 12 months. In the absence of secondary care recommendation to prescribe beyond 24 months no further prescriptions should be issued and those children should be weaned onto supermarket bought milk. British Dietetic Association has information on cow's milk alternatives.

4. Breastfed infants

For breastfed babies who present with CMA, breastfeeding should be protected as this is usually the best management, mothers should be actively supported to continue breastfeeding during this period. Refer baby to the Paediatric Dietetic Service for advice for the mother to follow a cow's milk free diet for4 weeks; they will be seen as urgent referrals. Mothers should be advised to use a calcium and vitamin D supplement if they remain on a cow's milk free diet. Specialist milks should only be considered when there is truly a clinical need after thorough assessment.

5. Quantities to Prescribe (Powdered formula)

Following diagnosis, on initiation of any new formula, it is advisable to **prescribe 1-2 tins maximum initially** to assess tolerance and palatability. After tolerance has been confirmed the number of tins prescribed for 28 days should be based on age.

Age of child	**Number of tins for 28 days**
Under 6 months	4 -14 x 400g tins or 2-7 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 tins
Over 12 months – dietitian review for continued need for formula	6 x 400g tins or 3 x 900g tins
24 months +	Supermarket bought milks (except exceptional circumstances)

Some children may require larger quantities e.g. those with faltering growth. This table provides guidance only.

Powdered milks should be the first line option. Liquid formulation should not be prescribed where a powder formulation is available, unless they are clinically indicated by a dietitian or specialist.

6. Lactose intolerance

Primary lactose intolerance is rare. Lactose-free infant milks can be bought at a similar cost to standard infant formula and should not be prescribed. Lactose-free infant

formula should not be used beyond 18-24 months and children can be weaned onto full cream equivalent lactose-free milks purchased at supermarkets from 12 months old. Ensure good calcium intake if cow's milk and milk products are excluded.

7. Soy-based formula

Soy-based formula should not be prescribed or recommended for purchase unless advised by a paediatric consultant or dietitian. This is due to the high incidence of soya sensitivity in infants intolerant of cow's milk protein (10-35%). Soy-based formula should not be used in infants under 6 months. Infants of vegan mothers who choose not to breastfeed should not receive soy - based formula on prescription as products are available at the same cost as standard formula.

Summary of actions for those recommending or prescribing formula:
• Follow the steps above in the management of suspected CMA. Discuss the challenge with cow's milk protein at outset of treatment • Discourage parents from frequently changing milks • During review of older babies, establish if the child is able to tolerate cheese, ice-cream or other dairy products • Review infants 18 months and over who are prescribed formula with a view to de-prescribing • GPs should refer to COMPASS for analysis of their CMA prescribing patterns • Add review dates to prescriptions • Do not initiate formula in children over one year • Direct parents and carers to Patient Zone for further information and resources

This guidance should be used in conjunction with: -

1. The Milk Allergy in Primary Care (MAP) Guideline 2019 | The GP Infant Feeding Network (UK) (gpifn.org.uk)

2. British Dietetic Association Information on specialist milks for CMA Milk allergy: Food Fact Sheet

3. NICE Clinical Guideline 116, Food allergy in under 19s: Assessment and Diagnosis.

4. NICE pathway Postnatal care: Planning and supporting babies' feeding.

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