Prescribing of Hypoallergenic Formula in South East London

Summary: These guidelines aim to improve the identification, treatment and management of cow's milk allergy (CMA) in infants and children. The guidelines should be implemented to promote and facilitate standardised evidenced-based practice including the appropriate use of hypoallergenic formula (HF).

South East London Integrated Medicines Optimisation Committee (SEL IMOC). A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley/Bromley/Greenwich/ Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS Trust

Abbreviations

Abbreviation used	Meaning
AAF	amino acid formula
ACBS	Advisory Committee on Borderline Substances
BF	breastfeeding
CMA	cow's milk allergy
eHF	extensively hydrolysed formula
GP	general practitioner
HCP	healthcare professional
HF	hypoallergenic formula (includes both AAF and eHF)
IgE	immunoglobulin E
LRT	lower respiratory tract
NEC	necrotising enterocolitis
OTC	over-the-counter
PSD	prescribing support dietitian
RAC	rapid access clinic
SEL	south east London
SOB	shortness of breath
URT	upper respiratory tract

1. Algorithm 1: Diagnosis and Management of Cow's Milk Allergy Quick Reference Guide

Abbreviations:
CMA cow's milk allergy
BF breastfeeding
eHF extensively hydrolysed formula
AAF amino acid formula
HF hypoallergenic formula (includes both eHF and AAF)
IgE immunoglobulin E
LRT lower respiratory tract
OTC over-the-counter
RAC rapid access clinic

Presentation with possible CMA symptoms – Rule out other causes
1. Refer to BF service or health visiting team (see **Referring to Local Services**) for support with feeding if appropriate
2. 2-week trial of 1st-line interventions (NICE Guidance) for **common conditions in infancy (see Section 2.2 in main document)** e.g. colic, reflux, constipation, eczema

[1]Protect, promote and support breastfeeding. Maternal dairy free diet is **not** recommended if no symptoms when exclusively breastfeeding

CMA still suspected

1. Complete **Allergy-focussed clinical history**
2. Refer to symptoms table to determine if **IgE or non-IgE** and **severity** of allergy

Non-IgE CMA suspected

≤12 months

Yes

Mild-moderate

1. Advise 2-4 weeks dairy-free diet. Continue **BF[1]** or prescribe **eHF** (see **Guide 1**)

2. Refer to RAC or similar local service (see **Referring to Local Services**)

3. Discuss dairy challenge. If symptoms return, CMA is confirmed.

Severe CMA or Multiple food allergies

1. Advise 2-4 weeks dairy-free diet. (continue **BF[1]** or prescribe **eHF or AAF, if growth faltering** (see **Guide 1**)

2. Refer to local Allergy Clinic (see **Referring to Local Services**) if multiple food allergies

OR

Urgent referral to paediatrician and local dietetic service (see **Referring to Local Services**) if unsolved growth faltering.

No

1. Advise 2-4 weeks dairy free diet. Continue **BF[1]** or recommend shop bought plant-based milk alternatives (do not initiate HF) – see below.

2. Refer to local dietetic service (see **Referring to Local Services**)

3. Discuss dairy challenge. If symptoms return, CMA confirmed

IgE CMA Suspected

≤12 months

Yes

Mild-moderate

1. Advise dairy free diet. Continue **BF[1]** or prescribe **eHF** (see **Guide 1**) or consider OTC soya formula if > 6 months

2. Refer to local Allergy Clinic (see **Referring to Local Services**)

Severe or Multiple food allergies

1. Advise dairy free diet:

Multiple food allergies - continue **BF[1]** or prescribe **eHF** (see **Guide 1**)

OR

Severe CMA - continue **BF[1]** or prescribe **AAF** (see **Guide 1**)

OR

Consider OTC soya formula if > 6 months

2. Refer to local Allergy Clinic (**urgent referral** if history of severe CMA)

No

1. Advise dairy free diet. Continue **BF[1]** or recommend shop bought plant-based milk alternatives (do not initiate HF) – see below.

2. Refer to local Allergy Clinic (see **Referring to Local Services**) (**urgent referral** if history of severe CMA)

Volume Tables:

1. Volume required if mixed-fed (Based on daily intake of formula as reported by carer)

oz/day	ml/day	g/28 days
10oz	300ml	1600g
14oz	400ml	2000g
17oz	500ml	2400g
20oz	600ml	2800g
24oz	700ml	3200g
27oz	800ml	3600g
30oz	900ml	4000g
33oz	1000ml	4400g
36oz	1100ml	4800g

2. Volume required if exclusively formula fed

Age	g/28 days
0-3 months	4000g
4-6 months	5200g
7-9 months	4000g
10-12 months	3200g

Key points:
1. **[1]Protect, promote and support breastfeeding.** Maternal dairy free diet is **not** recommended if no symptoms when exclusively breastfeeding
2. Non-IgE symptoms can occur from 2 to 72 hours and can be classified as **mild moderate (e.g. pruritus, erythema, atopic eczema, reflux, diarrhoea, blood/mucous in stools, abdominal pain, infantile colic, feeding difficulties, constipation, congestion)** or **severe (faltering growth).**
3. IgE symptoms can occur from few minutes to 2 hours and can be classified as **mild moderate (e.g. pruritus, erythema, urticaria, persistent eczema, angioedema, oral pruritus, nasal itching, sneezing, rhinorrhoea, cough, chest tightness, wheezing)** or **severe (anaphylaxis** and/or **faltering growth).**
4. **Shop bought plant-based milk alternatives suitable for >12 months** include: Soya-, oat-, coconut- and pea-based drinks enriched with calcium. Note that Rice-based milk alternative, organic and low-calorie varieties (e.g. "light") are NOT suitable. **See section 2.5 in main document** for further information.

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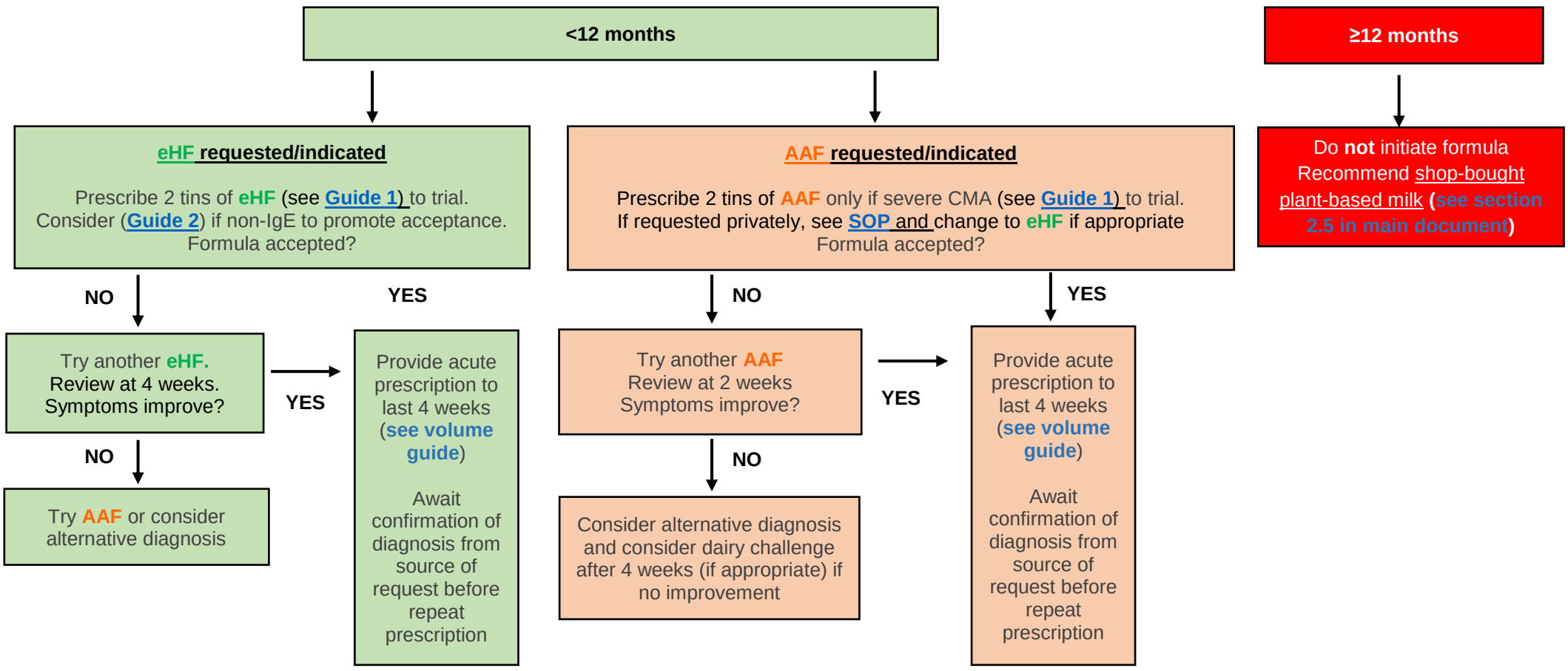
Algorithm 2: Guide for Prescribing Hypoallergenic Formula for GPs and Pharmacists

NEW PRESCRIPTION REQUEST:



Key points:
N.B Maternal dairy free diet is not recommended if no symptoms when exclusively breastfeeding.
OTC products (do not prescribe) – soya formula, lactose-free formula, 'anti-reflux' formula, 'comfort' formula, carobel
Neocate Junior requested – This product MUST not be initiated without dietetic justification (not a follow-on formula)

REPEAT PRESCRIPTION REQUEST:

EMIS prescription template review guide

- Ensure it has been documented on prescription request letter that diagnosis of CMA has been confirmed before providing repeat prescription. If no confirmation of diagnosis has been provided, contact request source.
- Add: next **review date** (review prescription against volume based on age or intake every 3 months) and **prescription end date** within dosage instruction (date when child is 12 months of age)
- Adjust volume:
  1. Volume recommendation from dietitian letter
  2. If not available, use volume recommendation (see **Guide 1**) based on age/intake
- Child should transition from formula to an appropriate shop-bought plant-based milk alternative **(see section 2.5 in main document)** from 12 months of age
- Stop prescription if:
  - tolerating dairy in diet
  - >12 months of age: unless advised by dietitian (check recent dietetic letter)

Neocate Junior: Ensure that dietetic review has been completed within the last 6 months and re-refer if no evidence of dietetic input within the last 6 months.

Ensure all infants with suspected/confirmed CMA receive dietetic support. See **Referring to Local Services**

Contact SEL Prescribing Support Dietitians gst-tr.prescribingsupportdietitians@nhs.net **if:**

- Unsuccessful transition onto shop-bought plant-based milks at 12 months of age despite giving advice on transition
- Child with active HF prescription has been discharged from local dietetics service due to DNA or not making contact
- Any other HF prescription queries

Volume Guide:

1. Volume required if mixed-fed (Based on daily intake of formula as reported by carer)

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17oz	500ml	2400g
20oz	600ml	2800g
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Section 1

1.1 Introduction

Cow's milk allergy (CMA) typically presents in the first year of life and affects approximately 2.4% of infants in the UK[1], with a lower likelihood in exclusively breastfed infants[2]. Most children outgrow non-immunoglobulin E (non-IgE) mediated allergy within 1 year of diagnosis, while IgE-mediated CMA may be outgrown later[3].

The majority of infants with non-IgE CMA are managed in primary care, and there is evidence of significant variation in practice (such as over interpretation of symptoms therefore resulting in over diagnosis of CMA[3] and inappropriate prescribing of HF), frequent delays in diagnosis and sub-optimal management of infants with a suspected CMA. This has resulted in poorer quality of life for families, high numbers of GP visits (average of 9 weeks with numerous GP visits before child was diagnosed correctly with CMA) and therefore delay in initiation of appropriate diet[4].

The cost of HF prescribed in 2022/2023 was ≥£1.4 million in South East London (SEL), with 53% of this spend attributed to amino acid-based formula (AAF). Only 69% of all HF prescriptions were for extensively hydrolysed formula (eHF), while NICE recommends that eHF is tolerated by 90% of infants with CMA[5]. The implication of which suggests there is potential to significantly reduce spending on HF with more appropriate prescribing as AAF is twice as expensive as eHF. Also, unnecessary specialised formula use may make a significant contribution to free sugars consumption in young children[6].

1.2 Scope

This guideline aims to support health care professionals (HCPs) in the clinical management of CMA, best practice for prescribing HF and local referral pathways within SEL.

It is designed for use by general practitioners (GPs), medicines optimisation teams, acute and community dietitians, health visitors, pharmacists and other HCPs involved in the care of infants and children who present with CMA.

A Prescribing Support Dietetic (PSD) service has been commissioned across the following SEL boroughs Bexley, Bromley, Lambeth, Lewisham and Southwark. In Greenwich the community dietetic service Oxleas provides a similar service. The service is part of the Medicine Optimisation work stream to support primary care teams. The goal of this service is to ensure appropriate prescribing of HF in line with ACBS prescribing criteria and SEL guidelines so patients are prescribed the most clinically and cost-effective formula with appropriate dietetic support.

Section 2: Clinical guideline

2.1 Breastfeeding and Support

Breastmilk is the ideal source of nutrition for infants. It is rare that breastfeeding would need to stop for infants diagnosed with CMA. Every effort should be made to support and encourage the continuation of breastfeeding where it is clinically safe. Less than 1% of infants react to cow's milk proteins transferred via breastmilk as this rarely triggers an allergy response[2,7].

Mother's do not need to exclude dairy if there are no clinical symptoms of CMA while breastfeeding. It has been suggested that CMA is only likely when exclusively breastfeeding if infant presents with e.g. persistent blood in stool, uncontrolled eczema (despite appropriate topical steroid usage) and/or faltering growth[25].

CMA related symptoms often present at a similar time to common infant conditions such as colic and reflux (usually in the first weeks/months of life). This period also coincides with mothers trying to establish breastfeeding. It is important to refer mothers whose infants have feeding difficulties for support with breastfeeding. This ensures breastfeeding technique is optimised and that common infant conditions are addressed with first line treatments.

Table 1: Contact details for health visiting teams and breastfeeding support across SEL boroughs

	Health Visiting Teams	Breastfeeding Support
Bexley	Bexley 0-4 Children's Public Health Service 0300 330 5777	Refer via email or phone: 0300 330 5777 bromh.bexley0to19@nhs.net Bexley-BF-Info-1016.pdf (kentbabymatters.org)
Bromley	Bromley 0-4 years Public Health Service 0300 330 5777	Refer via email or phone: 0300 330 5777 bromh.bromley0to19@nhs.net Bromley Breastfeeding groups
Greenwich	Greenwich 0 to 4 years Health Visiting service 0300 330 5777	Refer via email or phone: 0300 330 5777 bromh.greenwich0to4@nhs.net Infant feeding clinics: Greenwich 0 to 4
Lambeth	Lambeth & Southwark Health Visitor teams 020 3049 5300 gst-tr.spahealthvisitingservicelambeth@nhs.net	Refer via email: breastfeedingservice@gstt.nhs.uk breast feeding drop-in group
Lewisham	Lewisham Health Visitors 020 3049 1873	Refer via email: lg.breastfeedingvirtualhubs@nhs.net Breastfeeding | Lewisham and Greenwich
Southwark	Lambeth & Southwark Health Visitor teams 020 3049 8166 gst-tr.spahealthvisitingservicesouthwark@nhs.net	Refer via email: breastfeedingservice@gstt.nhs.uk breast feeding drop-in group

Useful resources for parents and health professionals:

- Infants & new mums — First Steps Nutrition Trust
- Breastfeeding resources - Baby Friendly Initiative (unicef.org.uk)

2.2 Treatment of common infant conditions

Key Messages
• At least 40% of infants in the UK have reported reflux[8], 15% reported eczema in England[9], 15% and 20% worldwide have constipation and colic[10]; while 1.7% **of infants in the UK are affected by non-IgE CMA[1]** • Irritability, colic, reflux or constipation symptoms may be due to feeding techniques – assess or refer to health visiting or infant feeding team for support • Infants presenting with the above symptoms, should be advised to **trial 1st line treatment for at least 2 weeks before suspecting CMA** • If symptoms involve multiple systems (e.g. skin, respiratory, gastrointestinal) and/or there is immediate family history of atopy, CMA may be more likely • **Do not** prescribe 'anti-reflux' formula, lactose free formula, soya formula or 'comfort' formula

1st line treatment for common childhood conditions without family atopy	• **Reflux/GORD:** NICE Guidelines (NG1): Gastro-oesophageal reflux disease in children and young people: diagnosis and management[8].
	• **Colic:** NICE Knowledge summary: Colic – infantile[11].
	• **Atopic eczema**: NICE Guidelines (CG57): Atopic eczema in under 12s: diagnosis and management[12].
	• **Constipation:** NICE Knowledge summary: Constipation in children[13]
	• **Lactose intolerance** is not an allergy and occurs as a result of a deficiency of the lactase enzyme in the intestine. Symptoms occur as a result of lactose malabsorption and include abdominal distension, abdominal pain and diarrhoea
	  ○ **Secondary lactose intolerance** most commonly occurs following infectious gastroenteritis causing temporary injury to the gut mucosa. This usually resolves within a 6-8 weeks. Parents can be advised to use lactose-free formula purchased OTC until symptoms resolve. Breast-feeding mothers do not have to exclude lactose (as breastmilk is naturally high in lactose)
	  ○ **Primary lactose deficiency** is very rare in children under age 3 years[14]. It is due to a congenital decline in lactase enzymes over time

Formula available OTC	The following formulas must **NOT be prescribed.** Parents may be advised to purchase OTC for mild reflux, colic or temporary lactose intolerance: 'Anti-reflux' formula Lactose free formula 'Comfort' formula

Resources for parents	• **Reflux:** Living with Reflux | Gastro-oesophageal Reflux Disease - includes a community forum for parent/carer support
	• **Colic:** Support For Crying And Sleepless Babies | Cry-sis **Helpline number: 0800 448 737** (7 days a week 9am-10pm)
	• **Eczema:**
	  • Video Guides - BAD Patient Hub (skinhealthinfo.org.uk)
	  • Allergy Care Pathway Itchy Sneezy Wheezy Project - Eczema Videos
	  • Factsheets | Eczema Information | Eczema.org
	  • Eczema in Children | Allergy UK | National Charity
	  • Eczema Care Online | ECO (eczemacareonline.org.uk)

Referrals required	• Secondary care specialists as per NICE guidelines • Refer to health visiting/infant feeding team for breastfeeding assessment and support • Refer to health visiting/infant feeding team for bottle feeding support See **Referring to Local Services**

2.3 Diagnosis and Management of Cow's Milk Allergy

Step 1: Presentation

Key Messages
• The immune response to cow's milk protein can be subdivided into IgE and non-IgE CMA[15]. • Infants presenting with possible non-IgE CMA symptoms, should be advised to trial 1st line treatment for at least 2 weeks before suspecting CMA • Diagnostic pathway is different for suspected non-IgE (Step 2a) and IgE CMA (Step 2b). An allergy focused clinical history is necessary to ensure correct diagnostic pathway. • Diagnosis for suspected non-IgE CMA is a two-step process: 1. Elimination diet for at least 2-4 weeks. 2. Dairy challenge to confirm or exclude CMA

Allergy Focused Clinical History

Completing an **Allergy-Focused Clinical History** is a key step in appropriately assessing the likelihood of CMA and supports with distinguishing the presentation of CMA as per Table 2.

Table 2: Presenting symptoms that may be associated with CMA, *adapted from NICE*[16]

Presentation	**Non-IgE** (Symptom onset: 2-72 hours)		**IgE** (Symptom onset: minutes – 2 hours)	
	Mild – Moderate	**Severe**	**Mild – Moderate**	**Severe**
Skin	Pruritus Erythema Atopic eczema		Pruritus Erythema Urticaria Angioedema: commonly of the lips, face and around the eyes Flaring of persistent atopic eczema	
Gastrointestinal	Gastro-oesophageal reflux disease (GORD) Loose or frequent stools Blood and/or mucous in stools Abdominal pain Infantile colic Food refusal or aversion Constipation – especially soft stools with excess straining	Faltering growth with at least one or more mild – moderate symptom/s	Angioedema of the lips, tongue and palate Oral pruritus Vomiting Diarrhoea	Faltering growth with at least one or more mild-moderate symptom/s
Respiratory (usually in combination with other symptoms)	Lower respiratory tract (LRT) — cough, congestion		LRT— cough, chest tightness, wheezing, or shortness of breath (SOB) Upper respiratory tract (URT) — nasal itching, sneezing, rhinorrhoea	Anaphylaxis involving respiratory and/or cardiovascular system signs and symptoms

Step 2a: Diagnostic pathway for suspected non-IgE CMA

Key Messages
• Refer all children with suspected non-IgE CMA to dietetics (see **Referring to Local Services**) • Diagnosis is a TWO-STEP process: elimination diet for 2-4 weeks and dairy challenge to confirm or exclude CMA [2,15] • Only advise maternal dairy-free diet if you suspect that child is reacting to cow's milk proteins transferred via breastmilk • Before diagnosis of non-IgE CMA is confirmed, provide an acute prescription only • Severity of symptoms determine type of HF to prescribe (**Algorithm 2**) • Do not initiate HF for children over 12 months

Diagnostic Two-step process	Refer all children with suspected non-IgE CMA to RAC (or similar local service) for diagnosis and management advice: 1. Trial of strict dairy exclusion (2-4 weeks) • Exclusively breastfed fed: maternal dairy-free diet • Mixed-fed*/exclusively formula fed: HF and dairy-free diet for infant • Advise maternal dairy-free diet if exclusively breastfeeding or if mixed fed infants' symptoms do not improve on eHF i.e. you suspect that child is reacting to cow's milk proteins transferred via breastmilk • Children over 12 months: advise dairy-free diet and shop bought plant-based milk alternatives as main drink (**see Section 2.5**) 2. Challenge with dairy after 2-4 weeks e.g. using iMAP Home Challenge[15] • CMA confirmed if symptoms return after challenge with dairy • CMA excluded if no change or no return of symptoms after challenge with dairy *Note that alternative diagnostic tests such as Vega testing, homeopathy, iridology, herbal medicine and faecal calprotectin levels are not proven/reliable tests and are not recommended for the diagnosis of non-IgE CMA*[17] *refers to a combination of breast and formula milk
Prescription (for infants under 12 months of age only)	• Prescribe HF if child is exclusively formula or mixed-fed. ○ Mild-moderate symptoms: eHF ○ Severe symptoms: AAF • See **Guide 1** for product names and refer to Section 3: Prescribing Guideline • Use **Guide 2** for support for transition onto HF • First acute prescription: 2 tins (or 800g) to establish acceptance • If accepted: second acute prescription to last the 2-4 weeks trial
Volume guide	• Exclusively formula fed: use volume guide according to age. Refer **Guide 1** • Mixed fed infants: Ask parent for their total intake per day to determine the volume to prescribe.
Resources for parents	GP Infant Feeding Network - iMAP home reintroduction, CMA information sheet for parents, CMA information sheet for breastfed infant[15]
Referral	• Children under 14 months of age: Telephone Non IgE-mediate CMA RAC (see **Referral Form for Telephone Non IgE-mediated Cow's Milk Allergy Rapid Access Clinic** and **Pathway for Telephone Non IgE-mediated Cow's Milk Allergy Rapid Access Clinic**) • Children over 14 months of age: refer to local dietetic service (see **Referring to Local Services**)

Step 2b: Ongoing management for confirmed Non-IgE CMA

Ongoing management	• SEL CMA RAC will advise on: - Dairy-free complimentary feeding - Gradual dairy reintroduction after 6 months or when infant is 9-12 months whichever is first (iMAP Milk Ladder)[15] - Transition onto shop bought plant-based milk alternative at 12 months • Children with persistent CMA at 12 months should transition onto plant-based milk alternative **(see Section 2.5)** in place of formula provided there are no concerns raised regarding growth or nutritional adequacy of diet.
Prescription	Provide a repeat prescription for HF only if diagnosis is confirmed by positive dairy challenge e.g. using (iMAP Home Challenge)[15]
Referral	Refer to local dietetic team (see **Referring to Local Services**) if concerns raised regarding growth and/or nutritional adequacy of diet beyond 14 months of age

Step 3a: Diagnostic pathway for suspected IgE CMA

Key Messages
1. Refer all children suspected IgE CMA to allergy clinic (see **Referring to Local Services**) for appropriate testing and management 2. Diagnosis does not require home dairy challenge 3. Only advise maternal dairy-free diet if you suspect that child is reacting to cow's milk proteins transferred via breastmilk 4. Severity of symptoms determine type of HF to prescribe 5. Do not initiate HF for children over 12 months

Diagnosis	Appropriate tests in specialist allergy service Suspect IgE CMA when symptoms **(see Table 2)** occur within 0-2 hours of exposure to dairy. Do not advise home dairy challenge to confirm diagnosis
Medical treatment	• Only advise maternal dairy-free diet if you suspect that child is reacting to cow's milk proteins transferred via breastmilk or if mixed fed infants' symptoms do not improve on eHF • Exclusively breastfed: Strict maternal dairy-free diet **(see Section 2.4)** • Mixed fed/exclusively formula fed: prescribe HF and recommend dairy-free diet for infant. • Children over 12 months: advise dairy-free diet and shop bought plant-based milk alternatives in place of formula

Prescription (for infants under 12 months of age only)	Acute prescription: 2 tins (or 800g) to establish acceptance. If accepted: prescribe ongoing until further recommendation from specialist allergy service
	• Prescribe HF if child is exclusively formula or mixed-fed
	  ○ Mild-moderate symptoms: eHF
	  ○ Severe symptoms: AAF
	• See **Guide 1** for product names and refer to Section 3: Prescribing Guideline
	• Use **Guide 2** for support for transition onto HF

Volume guide	• Exclusively formula fed: use volume guide according to age • Mixed fed infants: Ask parent for their total intake per day to determine the volume to prescribe • Refer to **Guide 1** for volume guide according to age/intake
Resources for parents	Allergy UK Anaphylaxis Campaign Provide a management plan to carers. Templates for management plans are available on the British Society for Allergy and Clinical Immunology (BSACI) website
Referral	Specialist Allergy Service to confirm diagnosis with appropriate tests and provide support for ongoing management Please see **Referring to Local Services** for contact details and how to refer to the above services

Step 3b: Ongoing management for confirmed IgE CMA

Ongoing management	• Strict dairy-free diet. Allergy team may provide advice for reintroduction of dairy where appropriate and will advise on dairy-free complimentary feeding • Children with persistent CMA at 12 months should transition onto plant-based milk alternative **(see Section 2.5)** in place of formula provided there are no concerns raised regarding growth or nutritional adequacy of diet
Prescription	Refer to Section 3: Prescribing Guideline and **Guide 1**
Volume guide	• Exclusively formula fed: use volume guide according to age • Mixed fed infants: Ask parent for their total intake per day to determine the volume to prescribe Refer to **Guide 1** for volume guide according to age/intake

2.4 General recommendations for dairy-free diet

The dietary recommendations for children with CMA vary depending on their feeding regime. Breastmilk is the ideal nutrition for infants with CMA and any decision to initiate an elimination diet must include measures to ensure that breastfeeding is actively supported. Infants with CMA with/without eczema are at higher risk of food allergies and may benefit from the introduction of foods such as egg and peanut from 17 weeks (4 months) [24].

Table 3: General recommendations for dairy-free diets

Exclusively breastfed	Exclusively formula-fed or mixed-fed	Taking solids
• Recommend exclusive breastfeeding for 26 weeks (6 months), with continued breastfeeding up to 2 years and beyond[19]. • Only recommend maternal dairy-free diet if it is clear that the child is symptomatic following breastmilk ingestion • Milk alternatives for dairy free mothers: soya, oat, coconut, pea, nut-based milks fortified with calcium (and iodine and vitamin B12 if maternal diet is predominantly plant-based) • Consider additional maternal soya exclusion if the infant remains symptomatic (but symptoms have partially improved). Seek advice from a paediatric dietitian (see **Referring to Local Services**)	• Replace cow's milk formula with an appropriate HF (see **Guide 1**). • For mixed-fed infants, if symptoms occurred only with the introduction of top-up formula feeds, replace these with HF top-ups and the mother can continue to consume foods containing cows' milk protein. • For mixed-feeding, refer mother to local specialist/additional breastfeeding support **(see Section 2.1)** for support with return to exclusive breastfeeding or increased breastmilk if this is mother's choice.	• Exclude all dairy and dairy products from the child's diet and recommend a suitable milk alternative. • Soya formula (purchased OTC - do not prescribe) can be recommended for infants between 6-12 months, but if this is not tolerated (suggesting soya allergy) an appropriate HF should be prescribed. Infants who have been tolerating soya formula < 6 months can continue this after 6 months of age. • Introduce dairy-free complimentary foods no earlier than 17 weeks (4 months) but by 26 weeks (6 months). • Consider additional soya exclusion if the child remains symptomatic (but symptoms have partially improved). Seek advice from a paediatric dietitian (see **Referring to Local Services**)

2.5 Shop bought plant-based milk alternatives

At 6-12 months, soya formula is suitable as an alternative formula, provided the child is not allergic to soya[2]. This should be purchased OTC and **not prescribed.**

Plant-based milk alternatives with added calcium should be encouraged to use in foods/cooking from 6 months of age. Most children can safely transition onto these milk alternatives in place of formula from 12 months of age, provided they are eating well and growing well. The transition should only take a few days.

Re-refer to dietetics (see **Referring to Local Services**) or consult with the prescribing support dietetic service if concerns are raised regarding growth and/or nutritional adequacy of the diet for bespoke support for this transition.

Suitable plant-based milk alternatives	Unsuitable plant-based milk alternatives
We recommend products containing a minimum of 40kcal, 1g protein and 120mg calcium per 100ml made from plant-based sources such as (provided not allergic to): Soya Oat Coconut Pea Blends of the above	Organic varieties "Light" varieties Rice milk is not suitable for children under 5 years of age Mammalian milks such as goat or sheep milk

Benefits of transitioning onto plant-based milk alternatives

- Helps to normalise toddler diet as much as possible
- Plant-based milk alternatives are more palatable than HF
- Plant-based milk alternatives are ready to use and readily available in supermarkets
- The majority of these products contain more calcium and protein compared to HF

Useful tips for transitioning

- Prompt introduction of plant-based milk alternatives during the complimentary feeding stage in food and recipes (i.e. adding into cereals, porridge, mashed potatoes and white sauces) is likely to support acceptance of taste when transitioning from formula to plant-based milk at 12 months
- If a straight swap from formula to a plant-based milk alternative is not successful, introduce it gradually over several days as tolerated

From 12 months of age

- Milk is not essential as a drink
- If plant-based milk alternatives are not accepted as a drink, ensure child has other adequate calcium-rich foods in the diet e.g. fortified cereals, tinned fish, tofu, plant-based yoghurt/cheese and/or incorporate plant-based milk alternatives into foods/cereals
- Calcium requirements aged 1-3 years is 350mg/day which is roughly 2-3 portions per day[18]

2.6 Vitamins & Minerals

- The Department of Health and Social Care recommends that babies from birth to 12 months should have a daily supplement containing 8.5 to 10mcg of vitamin D throughout the year if they are breastfed or having less than 500ml formula daily[19]
- Children aged 1-4 years should be given a supplement containing 10mcg/day of vitamin D[19]
- Mothers should be advised to meet daily calcium (1250mg/day) and vitamin D (10mcg/day) requirements, which usually requires additional calcium and vitamin D supplementation
- Mothers and children eligible for NHS Healthy Start scheme can obtain free Healthy Start vitamin drops (these contain vitamin A, C and D)[20]. In Lambeth, Southwark and Lewisham there is no eligibility criteria and Healthy Start vitamins are free to all pregnant/breastfeeding mothers and children under 4 years.

Section 3: Prescribing Guideline

Key Messages
• eHF should be prescribed first-line for mild-moderate CMA for at least 4 weeks before considering AAF (90% CMA infants should tolerate eHF) • Ensure non-IgE CMA diagnosis is confirmed by positive dairy challenge e.g. iMAP Home Challenge before providing a repeat prescription • Soya (unless the child has galactosaema and is under 12 months of age), lactose-free, 'anti-reflux' (pre-thickened) and 'comfort' formulas should be purchased OTC and not prescribed • Review volumes of formula prescribed every 3 months • Stop all HF prescriptions by 12 months unless otherwise recommended by a dietitian • Neocate Junior® is not a follow-on formula for AAF and its prescription requires dietetic justification and minimal 6-monthly review

Please utilise **Quick Reference Algorithm 2** and **Guide 1** for support with appropriate HF prescribing in SEL.

Prescribing of HF is governed by the ACBS. ACBS advice takes the form of its 'recommended list' which is published as Part XV of the Drug Tariff. It is essential that all prescriptions for HF meet specific ACBS criteria, are clinically- and cost-effective according to local guidance, and that appropriate first-line management for presenting symptoms has been trialled if non-IgE CMA is suspected.

3.1 HCPs involved in the prescribing of HF

Prescriptions for HF must be **started**, **reviewed** and **stopped** appropriately in order to provide best clinical practice, reduce the potential risk of compromising the nutritional status of the child and avoid unnecessary cost.

The following HCPs may be involved in the prescribing of HF:

- GP
- Pharmacists
- Acute or community paediatric dietitian
- Acute or community paediatrician
- Health visitor
- Consultant paediatrician or dietitian in private practice
- Prescribing support dietitian

All HCPs involved in HF prescribing are accountable for ensuring that the prescription is both cost-effective and clinically indicated, and that it is reviewed and stopped when appropriate. A HCP requesting an NHS prescription for HF from the child's GP must provide an end and/or review date for the prescription. Please refer to Letter 1 for a recommended letter template for dietitians initiating prescriptions for HF.

3.2 Private prescription requests

Please refer to the Standard Operating Procedure for **SEL GPs/Pharmacists Receiving Hypoallergenic Formula Prescription Requests from Private Healthcare Professionals** and **South East London NHS and Private Interface Prescribing Guide**[21] for prescription requests received from private HCPs.

Any request for an NHS prescription for HF must be reviewed in accordance with these guidelines. If the request is not in accordance with guidelines, the GP should recommend the child acquires a private prescription, change to an appropriate prescription, or refer for review from the PSD or local dietetic service.

3.3 Starting a prescription for HF

3.3.1 Initial acute prescription (trial)

Please see **Guide 1** for HF which can be prescribed.

HF prescriptions must not be initiated if the child is older than 12 months, unless clear justification has been provided by a dietitian. Recommend an appropriate plant-based milk alternative (see section 2.5) and ensure child receives dietetic support.

- **eHF** is **first-line** for mild-moderate CMA, as **90% of infants with CMA should tolerate eHF**[4]
- **AAF** is only first line if the child presents with **severe** CMA symptoms such as anaphylaxis, FPIES or faltering growth (with other symptoms of CMA)
- To avoid waste, **1 x 800g tin/2 x 400g tins** should be provided initially using either prescription or nutritional company sample services until accepted
- To promote acceptance, advise parent/carer to mix HF with their usual formula/ expressed breastmilk initially to introduce the taste **(do not recommend mixing with cow's milk formula for suspected IgE-mediated CMA).** Please refer to **Guide 2**

For Suspected Non-IgE CMA:

Review 1-2 weeks later:

- If the HF provided is accepted and tolerated, provide a second **acute** prescription to last **4 weeks**, and refer to either the SEL CMA RAC if criteria met (see **Referral Form** and/or **Pathway for RAC**) or similar local service (see **Referring to Local Services**) for support with confirming the diagnosis by dairy challenge
- If there is poor acceptance or response to the eHF provided, trial an alternative eHF, then follow the steps above
- Refer to **Guide 1** for recommended volumes to prescribe as a **4 week trial**

For Suspected IgE-mediated CMA:

- Provide a **repeat** prescription once child is showing a response to prescribed HF. There is no need to complete a dairy challenge
- Refer to the local Allergy Clinic for appropriate tests (see **Referring to Local Services**)

Partial Response to eHF After at Least 4 Weeks

- **Second line option:** Consider prescribing AAF for mild-moderate CMA *only* if there is partial response to a trial of eHF/s after **at least 4 weeks**. Only 10% of infants with CMA should require AAF, if formula-fed[4]
- The dietitian should consider a step down to eHF from AAF when clinically appropriate as evidence suggests this may promote cow's milk tolerance acquisition [22,23]

3.3.2 Repeat prescriptions

A **repeat** prescription for HF for suspected non-IgE CMA should only be provided once the diagnosis has been confirmed by a positive dairy challenge. A letter should be provided by the dietetic service to request this. Please see **Letter 1** for the recommended letter template

If IgE-mediated CMA is suspected, a repeat prescription for HF should be prescribed once accepted and symptoms improve. There is no need to complete a dairy challenge

Recommended age-related volumes for repeat prescriptions are outlined in **Guide 1**. This information is also included in the recommended letter template for dietitians (**Letter 1**)

Some children may require larger quantities e.g. faltering growing. Review recent correspondence from the paediatric dietitian.

3.4 Reviewing prescriptions for HF

- Volumes of HF prescribed should be reviewed by the GP/pharmacist **every 3 months** in order to ensure that the prescription meets the needs of the child. See **Guide 1** for recommended volumes
- The HCP requesting the prescription (e.g. paediatric dietitian) should provide an **end date** on their correspondence. See **Letter 1** for recommended letter template
- The GP/pharmacist should also record the end date and review date on their electronic record system, and request a prescription end date from the requesting HCP if this was not provided
- Unless otherwise advised by a dietitian, the end date for the prescription should be the date at which the child is **12 months old**
- In rare cases, where a dietitian has recommended continuing the prescription beyond 12 months, clear justification must be provided, and the dietitian should review at least every 6 months. If there is no review within 6 months of the initial request to continue, the prescription should be stopped
- The parent/carer should be provided with support for transitioning to an appropriate shop-bought plant-based milk alternative from 12 months of age, until cow's milk is tolerated. See **section 2.5**.

Patients discharged from dietetic services due to non-attendance/cancellation:

- **GP/pharmacists:** Review and stop or change prescription according to these guidelines.
- **Dietitians**: Letter to GP should advise stopping the prescription for HF if non-IgE CMA has not been confirmed and/or the child is older than 12 months of age. Please see **Letter 2** for recommended discharge letter template, which includes options for non-response to opt-in letter.

3.5 Stopping Prescriptions for HF:

Prescription for HF should be stopped when:

- Diagnosis of non-IgE CMA has been excluded following dairy challenge supported by dietitian/HCP
- The child tolerates dairy (cow's milk and/or dairy products)
- Non-IgE CMA is suspected but parent/carer has failed to engage with dietetics to have diagnosis confirmed e.g. parent/carer does not attend dietetic appointment or fails to make contact
- The child is **12 months** of age or older and there has been no correspondence from a paediatric dietitian with instructions to continue the prescription in the last 6 months e.g. growth faltering or concerns regarding nutritional intake.
- ***Please note that Neocate Junior® is not a follow-on formula for AAF and should only be prescribed if a paediatric dietitian has provided written justification. Again, this needs to be reviewed at least every 6 months by a paediatric dietitian in order to continue the prescription. Children should not be discharged from dietetic services until Neocate Junior® is no longer required.***
- Other products indicated for children older than 12 months e.g. Nutramigen 3 with LGG® are not recommended. Children older than 12 months should transition onto plant-based milk alternatives or continue with their formula (e.g. Nutramigen 2 with LGG®) if there is a clinical justification.

3.6 Formulas not to be prescribed

The following products can be purchased OTC at a similar price to that of standard formula therefore the SEL ICB does **not** support prescribing of these products. The GP, pharmacist or PSD reserves the right to stop these prescriptions and advise the parent/carer to purchase them OTC.

- Soya formula (suitable for CMA from 6 months only, if soya is tolerated) *
- Lactose-free formula **
- 'Anti-reflux' (pre-thickened) formula **
- 'Comfort' formula **

* Exception should be made if the child has a diagnosis of galactosaemia and is under 12 months of age
** **Not** suitable for infants with CMA

3.7 Inappropriate prescribing of HF

Table 4: Inappropriate prescribing of HF and actions to take

Scenario	Action	Justification
Any HF prescribed for unconfirmed non-IgE CMA i.e. no evidence of positive dairy challenge	Refer to Telephone non-IgE mediated CMA RAC if criteria are met (see **Referral Form for Telephone Non IgE-mediated Cow's Milk Allergy Rapid Access Clinic** and/or **Pathway for Telephone Non IgE-mediated Cow's Milk Allergy Rapid Access Clinic**)/ local dietetic service (see **Referring to Local Services**). Stop prescription if appointment is not attended or parent/carer declines input.	Prescription cannot be considered clinically appropriate.
AAF prescribed for mild-moderate CMA without 4-week trial of eHF	Change to eHF and refer to Telephone non-IgE mediated cow's milk allergy rapid access clinic if criteria are met or local dietetic service. Refer to 3.2 if requested privately	Prescription cannot be considered clinically appropriate.
Volume for HF exceeds what is recommended for age.	Reduce prescription to age-appropriate volume or review volume required with parent/carer. Refer to volume guide in **Guide 1**.	Excessive volumes incur unnecessary cost and may lead to waste. Child's intake may exceed what is recommended for age and may compromise nutritional intake e.g. from solid food.
Soya, lactose-free, "anti-reflux" or "comfort" formula is prescribed	Unless soya formula is prescribed for galactosaema and child is under 12 months of age, stop prescription. Parent/carer is advised to purchase product OTC from supermarket or pharmacy.	These products are available commercially at a similar cost to that of standard formula. SEL ICB does not support their prescription.
Any HF prescribed for child is older than 12 months and there is no correspondence from a paediatric dietitian justifying a need to continue HF beyond 12 months	Stop prescription for HF and recommend transition to a shop bought plant-based milk alternative Refer to **section 2.5** for recommended products. Refer to the local dietetic service (see **Referring to Local Services**) if there are any nutritional concerns e.g. growth concerns or restricted diet.	Children with CMA can transition to a plant-based milk alternative with added calcium, provided they are growing well and their nutritional intake is otherwise sufficient i.e. cow's milk is the only food requiring substitution.
Neocate Junior® is prescribed without clear justification from a paediatric dietitian.	Stop prescription and recommend transition to a shop bought plant-based milk alternative. Refer to **section 2.5** for recommended products. If there are nutritional concerns and child is 12-24 months old, change to previously prescribed HF and refer to local dietetic service (see **Referring to Local Services**) for review.	Neocate Junior® is not a follow-on formula for AAF. It requires dietetic justification and review.

Neocate Junior® is prescribed and was requested by a paediatric dietitian but there has been no dietetic review for more than 6 months.	Refer to local dietetic service for review. Do not issue prescription until the need for the prescription has been reviewed.	Prescription cannot be considered clinically appropriate.
HF prescribed due history of necrotising enterocolitis (NEC) with subsequent malabsorption. Child is now older than 6 months.	Refer to local dietetic service (see **Referring to Local Services**) for advice on appropriate reintroduction of cow's milk protein. If child is older than 12 months corrected and growing and eating well, stop prescription for HF and recommend transition to a shop bought plant-based milk alternative. Refer to **section 2.5** for recommended products.	Children with a history of NEC requiring HF are often managed as having presumed non-IgE CMA. They are likely to acquire tolerance to cow's milk proteins from 6 months after commencing HF or from complementary feed age.

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