

GUIDELINES ON THE APPROPRIATE USE AND PRESCRIBING OF SPECIALIST INFANT MILK SUBSTITUTES IN ACUTE AND COMMUNITY TRUSTS

This document includes the following:

- Introduction and Background
- Guidelines on quantities to supply
- Guidelines for Prescribing, Reviewing and Stopping Formulae
- References

Document History:

Version	Created by	Date	Main Changes/Comments
1	Jagdeep Minhas/Prina Sahdev	28/07/2020	Taken from Medway/Swale previous documents. The names of specialist infant formulas have been added but will need K&M wide agreement
2	Faria Magre	14/09/2020	Incorporated comments from: <ul style="list-style-type: none"> • KCHT, Medway Swale, DGS Community Paediatrician Dietitian teams • KCHT medicines management teams • Medway Community Trust Medicines team • K&M ICB Medicines Optimisation Teams
3	Faria Magre	23/09/2020	To incorporate comments from meeting held on 23/09/2020
4	Faria Magre	02/11/2020	Incorporated comments from Kent Children's and Maternity Commissioning Team
5	Faria Magre	11/11/2020	Incorporated comments received from JPC
6	Faria Magre	25/11/2020	Incorporated comments received from Consultant Neonatologist at EKFT
7	Amali Gamaarachchi	27/05/2021	Incorporated comments received from Nutricia/Danone
8	Amali Gamaarachchi	27/07/2021	Incorporated comments received from Nestle Health Science, removal of approximate cost/tin
9	Dietitian's review	10/12/2024	Incorporated comments from regional Dietitians

Whilst these guidelines advise on appropriate prescribing of specialist infant formulae, breast milk remains the optimal milk for infants. This should be promoted and encouraged where it is clinically safe to do so and the mother is in agreement.

***Breastfeeding is the healthiest way to feed a baby.
Giving formula milk to a breastfed baby will reduce breastmilk supply***

INTRODUCTION

These guidelines aim to clarify which products and in which circumstances specialist infant formulae can be prescribed for babies and young children in primary care. It also acts as a guide to prescribing quantities and prices. It advises on triggers for reviewing and discontinuing prescriptions and onward referral for dietetic and / or secondary care specialist advice.

Providing infant formulae inappropriately on prescription is considered inequitable prescribing as the prescription is supplied effectively at no charge but no equivalent support is available for breast feeding mothers or parents that purchase their own infant formulae from supermarkets or over the counter at pharmacies. Some patients may be eligible for supply of milk via the Healthy Start Scheme, for more information, refer to [Healthy Start](#).

The majority of specialist formulae prescribed in primary care are those to treat cow's milk allergy (CMA).

BACKGROUND

NICE Clinical Guideline 116 (February 2011) Food Allergy in children and young people covers the diagnosis and assessment of food allergy in children and young people in primary care and community settings. The care pathway from NICE which covers initial recognition to referral to specialist is available via [NICE guidelines on food allergy](#)

A limited range of products (food/milk substitutes) can be prescribed as drugs in line with advice from the Advisory Committee on Borderline Substances (ACBS) and these are defined in borderline substances. Any prescription written needs to be 'ACBS' approved. General Practitioners are reminded that the ACBS recommends products on the basis that they may be regarded as drugs for the management of specified conditions. Doctors should satisfy themselves that the products can safely be prescribed, that patients are adequately monitored and that, where necessary, expert hospital supervision is available. [BNFc Borderline substances](#) 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 CMA. Please refer to MAP Guidelines 2019 (Appendix 1) for guidelines on symptom presentation.

CMA occurs in less than 8% of young infants, however between 5% and 15% of infants present with symptoms suggestive of CMA.

PRODUCT CHOICE

Breastfeeding Mothers:

Kent and Medway NHS promotes breastfeeding as the best form of nutrition for infants and this should be promoted and supported wherever possible. Almost all children with CMA can continue to be successfully breastfed with modification of the mother's diet under the direction of a dietitian. Breastfeeding mothers may require a milk free diet and, in this case Calcium and Vitamin D supplementation will be required and should be purchased Over The Counter. The approach to treatment is detailed in the MAP guideline 2019 included in Appendix 2.

Formula Fed infants:

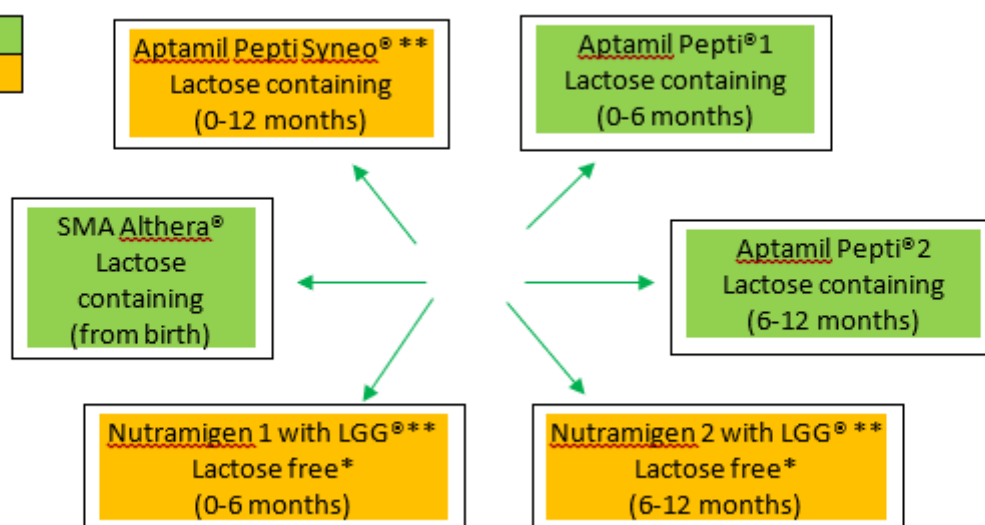
Extensively hydrolysed formula (EHF)

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

DO NOT prescribe EHF if there is a history of anaphylaxis.

Colour code:

1 st line	Green
2 nd line	Yellow



****‘Lactose free’** should not be confused with ‘cow’s milk free’

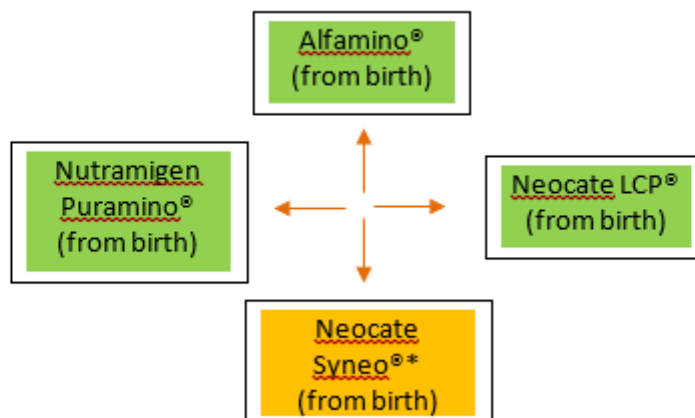
**** Aptamil Pepti Syneo and Nutramigen 1 & 2 with LGG contain pre and/or probiotics and are usually considered for use in managing colic and constipation and if the patient is not improving on Aptamil Pepti 1 or 2. Do not use these products in:** premature infants, low birth-weight term infants, infants who are immunocompromised, in post-pyloric tube feeding, infants with a central venous catheter, infants with short bowel syndrome or at risk of NEC, infants with congenital heart disease, infants on long-term mechanical ventilation, infants in an intensive care / neonatal setting

Amino Acid Formula (AAF)

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.

Colour code:

1 st line	Green
2 nd line	Yellow



* **Neocate Syneo contains pre and probiotics and is usually considered for use in managing colic and constipation and if the patient is not improving on Neocate LCP. Do not use these products in:** premature infants, low birth-weight term infants, infants who are immunocompromised, in post-pyloric tube feeding, infants with a central venous catheter, infants with short bowel syndrome or at risk of NEC, infants with congenital heart disease, infants on long-term mechanical ventilation, infants in an intensive care / neonatal setting.

Do not prescribe/ initiate

- EHF or AAF products for lactose intolerance
- Flavoured products – No clinical advantage
- Formula in children over the age of 12 months unless a clinical need has been established and is under Dietetic review/ or requires re-referral

n.b. Please see long guidance for Halal, Kosher & vegetarian status of all above formulas.

SUPPLY PROCESS

- **Prescribing formulas for lactose intolerance and reflux is not allowed on prescription**
- **Paediatricians/dietitians will request milks on prescription if cow milk allergies are present.**
- **Prescribing for faltering growth should be under the care of a paediatrician to investigate the cause. Referral to paediatrician is necessary unless the GP has specialist knowledge in the area.**

QUANTITIES OF FORMULAE TO PRESCRIBE

The quantities below act as a guide for when any infant formula is prescribed.

To avoid waste, prescribe a minimum of 2 weeks trial (1/2 of quantity prescribed per calendar month, as detailed in table below) until tolerance and compliance is established. Please note all specialist formulas have an unpleasant taste and may take several days and perseverance for an infant to accept them. The iMAP guideline for early home reintroduction provides a useful reintroduction table on page 2, which can also be used as a means to wean a child onto a new product. Please refer to Appendix 4.

Please contact local ICP dietitian if further advice is required.

Infants may require more or less than the recommended average (below) depending upon their age, size and the rest of their diet intake.

FOR POWDERED FORMULA:

Age group	Quantity to prescribe for 28 days complete nutrition		Average Total Volume Feed Per Day (Estimated)
Under 6 months	5200g	13 x 400g	1000mls (~150ml/kg/day)
6 – 9 months	3200g	8 x 400g OR 4 x 800g	800mls
Over 9 months	2800g	7 x 400g	600mls

PRESCRIBING, REVIEWING AND STOPPING FORMULAE

Prescription Management

- Refer to paediatric dietitian to provide support and advice to parent, especially before weaning. Please refer to Appendix 2 and 3 for guidelines on referrals. Refer to latest correspondence before issuing prescriptions.
- Ensure formula prescribing is monitored. If robust monitoring is not in place DO NOT add formula onto a repeat prescription.
- Review regularly (recommended every 6 months), check quantities, type of formula prescribed, child's age and growth.
- EHF is the appropriate choice for vast majority of infants with CMA.
- Review against specialist advice (e.g. children with higher nutritional requirements or multiple allergies may need more formula for a longer period).
- Review all existing patients if they meet one or more of the criteria below:
 - More than 12 months of age
 - Prescribed formula for more than 12 months
 - Quantity prescribed is higher than recommendations

Audit Suggestion

Identify and review all patients prescribed specialist infant formula. Consider switching to a preferred product, rationalising the quantities prescribed or discontinuing the prescription if no longer appropriate.

1. Undertake a search for all acute and repeat issues of any specialist infant formula, within the last four months.
2. Review the appropriateness of prescribing in line with Guidelines for the appropriate prescribing of specialist infant formula.
3. Communicate and carry out any necessary changes for all suitable patients, referring back to paediatric dietitian for advice, if necessary.

Cow's Milk Allergy (CMA)			
Diagnosis	Treatment/Review Criteria	Name Of Formula	Criteria For Prescribing Formula
<p>Suspect CMA after careful history taking. Refer to MAP Guidelines 2019 (Appendix 1) for history taking and symptoms.</p> <p>CMA can present as Mild to Moderate Non-IgE mediated CMA, Severe Non-IgE-mediated CMA or Mild to Moderate IgE-mediated CMA. Symptoms can include frequent regurgitation, gastro-oesophageal reflux, vomiting, diarrhoea, and constipation with or without perianal rash, blood in stools, eczema, distress, colic depending on type of CMA. Please refer to Appendix 1 for guidance.</p> <p>Most babies presenting with colic, restlessness and/or crying do not have CMA. Advice should be sought from specialist infant feeding teams to ensure problems with feeding technique and formula reconstitution are addressed.</p>	<p>Breastfeeding mothers should always be encouraged to continue to breast feed their infants. Breastfeeding mothers may require a milk free diet and Calcium and Vitamin D supplementation. The approach to treatment is detailed in the MAP guidelines (Appendix 2).</p> <p>For Formula Fed Infants: First Line: Trial of extensively hydrolysed formula (EHF) for a minimum of 2 weeks for tolerance. It may take up to 4-6 weeks for symptoms to resolve.</p> <p>These infants should be reviewed by/referred to a paediatric dietician. Refer to NICE guidelines for when to refer to paediatric teams.</p> <ul style="list-style-type: none"> The taste of hydrolysed formulae is unpleasant and may take several days for an infant to accept. Younger infants take hydrolysed formulas more ready than older infants. Infants who do not tolerate one formula may tolerate another. Therefore, it is worth prescribing a 2 weeks trial (1/2 of quantity prescribed per calendar month as per table on page 5). 	<p>First Line (listed alphabetically, not in order of preference):</p> <p>Aptamil Pepti[®]1³ / Aptamil Pepti[®]2³ / Aptamil Pepti[®] Syneo³ (lactose containing)</p> <p>Nutramigen 1 with LGG[®] / Nutramigen 2 with LGG[®] (lactose free)</p> <p>SMA Althera[®] (lactose containing)^{1,2,3} (has a plant enzyme as opposed to a protein derivative)</p> <p>Key: 1 Vegetarian 2 Halal 3 Kosher</p>	<p>CONTINUE FORMULA UNTIL INFANT HAS GROWN OUT OF ALLERGY OR THEY ARE 12 MONTHS OLD</p> <ul style="list-style-type: none"> These children should be reviewed every 6 months as paediatric allergy will resolve. Refer to NICE guidelines CG116 and MAP Guidelines 2019 for challenging children with cow's milk in primary care setting. Children over 2 years old with multiple allergies and poor diet, refer to specialist. At 6 months change prescription of Nutramigen 1 with LGG[®] to Nutramigen 2 with LGG[®] unless a dietitian has advised otherwise. The same applies for Aptamil Pepti[®]1[®] and 2[®]
	<p>Second Line: Amino Acid based formulae (AAF):</p> <ul style="list-style-type: none"> Amino acid-based formulae (AAF) are indicated when hydrolysed formulas do not resolve symptoms or when there is evidence of severe or multiple allergies. Where a specialist formula is prescribed, this should be with a care plan and a review date with 	<p>Second Line (listed alphabetically, not in order of preference):</p> <p>Alfamino[®]1,2,3</p> <p>Neocate LCP[®]1,2,3 / Neocate Syneo[®]1,2,3</p> <p>Nutramigen Puramino[®]2,3</p>	

	the paediatric dietitian to which the repeat interval of the prescription is aligned.	Key: 1 Vegetarian 2 Halal 3 Kosher	
	Soya Formula can be considered in infants over 6 months. The chief medical officer advises that soya formula should not be used as the first line treatment for CMPA for children under 6 months. Soya Formula should be considered in infants who will not take a first or second line formula on this list (over 6 months).	OTC	Soya formulas can be bought at a similar cost to standard infant formula. The K&M ICB DOES NOT support the prescribing of these formulations, parents to purchase OTC.

REVIEW AND DISCONTINUATION OF PRESCRIPTIONS:

- Is the patient over 12 months old?
(E.g. Most children over 12 months are able to tolerate over the counter (OTC) fortified milk alternatives such as soya, oat or coconut. However, there may be babies that still need to remain on specialist formula, who should be managed and reviewed by a dietitian/ paediatrician)
- Does the quantity prescribed exceed the recommendations for age? If so, refer to most recent correspondence with managing dietitian
- Any recommendations made by Health Visitors need to be clearly communicated to the patients GP to ensure continuity of care is maintained.
- For some children a number of tins may be required to allow for a transition period onto supermarket calcium fortified plant-based milk (n.b. rice milk is not appropriate for under 5's); This should be a one-off prescription and should not exceed 5 tins unless otherwise advised by a dietitian.
- Refer to this guidance for reviewing prescriptions unless most recent correspondence from the paediatric dietitian provides reasoning to quantities outside of the recommendations, if further dietetic support required please refer to dietitian.
- Children with multiple or severe allergies may require prescriptions up to and beyond 2 years of age if recommended by the paediatric dietitian due to an overly restricted diet. This should be documented in the patient's consultation notes at the GP practice.
- Ensure child's growth is monitored and recorded. Review treatment if child is not thriving.

Secondary Lactose Intolerance			
NOTE: Primary lactose intolerance is less common than secondary intolerance and does not usually present until later childhood or adulthood			
Diagnosis	Treatment/Review Criteria	Name Of Formula	Criteria For Prescribing Formula
<ul style="list-style-type: none"> Primary lactose intolerance is exceedingly rare in infants. Secondary lactose intolerance can present at any age and is usually reversible with treatment of the underlying cause (typically gastroenteritis). Children with lactose intolerance are not allergic to milk and should not be confused with CMA. Secondary Lactose intolerance usually occurs following an infectious gastrointestinal illness. Symptoms include: abdominal bloating, wind, increased (explosive) and loose, green stools. Lactose Intolerance should be suspected in infants who have had symptoms that persist for more than 2 weeks. Diagnosis is the resolution of symptoms, usually within 48 hours, once lactose is removed from the diet. 	<p>Treatment with lactose free formula for at least 8 weeks to allow symptoms to resolve, then reintroduction to standard formula/milk products slowly into the diet.</p> <p>If symptoms do not resolve on commencing standard infant formula then consider CMA.</p> <p>For treating lactose intolerance in infants who have been introduced to solids, these formulas should be used in conjunction with a Lactose free diet (Allergy UK).</p> <p>If an infant presents with suspected Lactose intolerance at one year or older and is on cow's milk, then a lactose free full fat cow's milk can be used for the treatment period. This is available in supermarkets.</p> <p><i>Note: the use of Lactase drops is not common practice</i></p>	OTC	<p>The K&M ICB DOES NOT support the prescribing of these formulations.</p> <p>Parents/Carers will be required to purchase over the counter (OTC).</p> <p>Lactose free infant formulas can be bought at a similar cost to standard infant formula.</p> <p>The following can be purchased OTC:</p> <ul style="list-style-type: none"> Aptamil Lactose Free® SMA Lactose Free®

Gastro-Oesophageal Reflux (GOR)			
Diagnosis	Treatment/Review Criteria	Name Of Formula	Criteria For Prescribing Formula
<p>A diagnosis of GOR is made clinically from a history of effortless vomiting occurring after meals. Rule out overfeeding by establishing volume of feed as initial treatment.</p> <p>Symptoms of GOR may include:</p> <ul style="list-style-type: none"> • Regurgitation of a significant volume of feed • Reluctance to feed • Distress / crying at feed times • Small volumes of feed being taken 	<p>STEP ONE: 50% of babies have some degree of reflux. If baby is vomiting persistently (not projectile) but the baby is thriving and not distressed, reassure parents and monitor. Provide advice on feeding positioning, avoidance of over feeding and activity following a feed.</p> <p>STEP TWO: If the bottle fed infant is not settled and not gaining weight – trial with thickened formula. Please see list on the right hand column for recommendations for OTC purchase of thickened formulae. Please note thickened formulae should not be used in conjunction with thickeners such as Carobel or antacid medication.</p> <p>Alternatively, a thickening agent such as Carobel can be added to the baby's usual feed for trial period. Please note, feeds thickened with thickening agents should not be used in conjunction with antacid medication. Carobel Thickener is only suitable for full term infants and children. Its' use is not recommended in pre term infants or infants with low birth weight.</p> <p>If the reflux hasn't improved offer an alginate (antacid medication) such as Infant Gaviscon for a trial period. These products can be tried. However, it is important to note that the evidence base to support their use is limited.</p> <p>If using a thickened formula, monitor for constipation and treat appropriately.</p>	<p>OTC</p>	<p>Once vomiting resolves return to standard formula after weaning has commenced.</p> <p>Not to be used for a period of more than 6 months after which a normal formula can be used.</p> <p>Reflux often resolves at 6 months of age or when solids are introduced.</p> <p>These products can be bought at supermarkets and are a similar price to standard formula.</p> <p>The K&M ICB DOES NOT support the prescribing of these formulations.</p> <p>The following can be purchased OTC for GOR: Cow & Gate Anti-reflux® Aptamil Anti-reflux® SMA Anti-reflux®</p>

	<p>Review after one month. If no improvement in symptoms, may need further investigation by a Paediatrician. These infants require regular review. Breastfed babies with GOR may continue to be breastfed; further guidance on supporting a breastfed baby with GOR is available via a health visitor.</p> <p>Infants with reflux suffering from faltering growth should be referred to Specialist Infant Feeding Teams to check feeding techniques /adequate volumes being taken. If no improvement then referral to dietitian should be considered</p>		<p>The following can be purchased OTC as thickening agents:</p> <p>Cow & Gate Instant Carobel</p>
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Pre-Term Infants – TO BE STARTED IN SECONDARY CARE ONLY			
Diagnosis	Treatment/Review Criteria	Name Of Formula	Criteria For Prescribing Formula
<p>These children will have had their formula commenced in hospital. It is started for babies born before 34 weeks gestation.</p> <p>NOTE: This formula should not be used in primary care to promote weight gain in term infants.</p>	<p>Any infant discharged on these formulae should have their growth (this includes weight, length and head circumference) monitored by the health visitor. Ensure the neonatal and infant close monitoring (NICM) growth chart is used for plotting. Frequency of monitoring depends on individual clinical circumstances. Please refer to Neonatal/Paediatric team for more advice.</p>	<p>SMA Gold Prem 2 Powder^{®/2}</p> <p>Nutriprem 2 Powder^{®2,3}</p> <p>Key: 1 Vegetarian 2 Halal 3 Kosher</p>	<ul style="list-style-type: none"> Up to 6 months corrected age (i.e. six months plus the number of weeks premature added on). Review use of pre-term formulae if upward crossing through centiles is identified. If there are concerns regarding growth, refer to the paediatric dietitian. Standard formula or follow on formula would be the appropriate step. Do not prescribe liquid formulae unless clinically indicated. Exclusively Breast Fed Infants generally exhibit a different pattern of growth. If there are concerns regarding growth, initial referral to specialist breastfeeding support services should be sought. In cases where there is a clinical indication for a modified approach to responsive feeding such as preterm or small for gestational age babies, babies who have not regained their birthweight or are gaining weight slowly individual guidance is given. All preterm babies are under care of paediatric/neonatal consultants. If there are any concerns in early discharge to community services then advice would be sought from the paediatric/ neonatal consultant/ neonatal outreach programme teams.

Faltering Growth			
Diagnosis	Treatment/Review Criteria	Name Of Formula	Criteria For Prescribing Formula
<p>Faltering growth is indicated when the weight of an infant :</p> <ul style="list-style-type: none"> Falls across 1 or more weight centile spaces, if birthweight was below the 9th centile Falls across 2 or more weight centile spaces, if birthweight was between 9th and 91st centiles Falls across 3 or more weight centile spaces, if birthweight was above the 91st centile or; When current weight is below the 2nd centile for age, whatever the birthweight. <p>The height and head circumference, as well as weight, of a child needs to be measured in order to properly interpret changes in the latter. It is not possible to detect growth faltering without using appropriate growth charts.</p>	<p>It is important to consider the reason for faltering growth e.g. iron deficiency anaemia, constipation, GOR or a child protection issue and treat accordingly.</p> <p>Before commencing a high energy, formula ensure parents/carers are offered food first advice on suitable high calorie foods if the infant is introduced to solids.</p> <p>Refer any infant being commenced on a high calorie formula to the Health Visitor Infant Feeding Lead.</p> <p>Note: All infants on a high energy formula will need growth (weight, head circumference and length/height) monitoring to ensure catch up growth and appropriate discontinuation of formula to minimise excessive weight gain.</p> <p>It is important to rule out possible disease-related/medical causes for the faltering growth.</p> <p>If faltering growth detected, referral to secondary care should not be delayed.</p>	<p>(listed alphabetically, not in order of preference):</p> <p>Infatrini Liquid[®]SMA</p> <p>High Energy Liquid^{®2,3}/</p> <p>Similac High Energy Liquid^{®1,2,3}</p> <p>Key:</p> <p>1 Vegetarian</p> <p>2 Halal</p> <p>3 Kosher</p>	<p>These formulas should be used until 18 months. After this time, if the child is growing well, the prescription should be discontinued. The feed should be stopped at any time if weight gain is excessive.</p> <p>These formulas should be used until 18 months and/ 8kg (unless under specialist request)</p> <p>If on-going concerns about weight gain refer for a dietetic assessment.</p> <p>Should be under the care of a paediatrician to investigate cause of faltering growth.</p>

OTHER POINTS TO CONSIDER

- Infants with CMA may need Calcium supplementation.
- All infants on a specialised formula should be reviewed regularly by the dietitian and / or doctor in line with NICE guidelines – CG116, and if appointments are missed, repeat prescriptions should not be given.
- From 2 years of age, children with CMA, who are eating a varied diet, can switch from a hypoallergenic formula to ready-made milks, e.g. fortified soya (if appropriate), pea, or oat milk.
- Rice milk is not recommended until at least 4 ½ years of age because of the high levels of arsenic contamination found in this milk. [Statement on arsenic levels in rice milk](#). Food Standard Agency (2018).
- Review repeat prescription quantity at 3 month intervals and adjust according to current requirements.
- Any recommendations made by Health Visitors need to be clearly communicated to the patients GP to ensure continuity of care is maintained.**

USEFUL CONTACTS

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REFERENCES:

1. [BNFC \(British National Formulary for Children\) | NICE](#)
2. Guidelines for the diagnosis and management of cow's milk protein allergy in infants. Vandenplas Y et al, Arch Dis child October 2007, 92: 902-90
3. National Institute of Clinical Excellence (NICE) Clinical Guidance 116, Food allergy in children and young people: Diagnosis and assessment of food allergy in children and young people in primary care and community settings, February 2011 <http://publications.nice.org.uk/food-allergy-in-children-and-young-people-cg116>
4. NICE Guideline [NG75], Faltering growth: recognition and management of faltering growth in children, September 2017 <https://www.nice.org.uk/guidance/ng75>
5. The Milk Allergy in Primary Care (MAP) Guideline 2019 <https://gpifn.org.uk/imap/>
6. NICE Guideline [NG1] Gastro-oesophageal reflux disease in children and young people: diagnosis and management (October 2019) <https://www.nice.org.uk/guidance/ng1>
7. [imap-home-reintroduction-guide-for-parents.pdf](#)
8. [Statement on arsenic levels in rice milk](#). Food Standard Agency (2018).

Appendix 1 <https://gpifn.files.wordpress.com/2019/10/imap-presentation-algorithm-1.pdf>

UK Adaptation of iMAP Guideline for Primary Care and 'First Contact' Clinicians

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

Apr 2019

Having taken an Allergy-focused Clinical History and Physically Examined

Less than 2% of UK infants have CMA. There is a risk of overdiagnosis of CMA if mild, transient or isolated symptoms are over-interpreted or if milk exclusion diets are not followed up by diagnostic milk reintroduction. Such situations must be avoided. There should be increased suspicion of CMA in infants with multiple, persistent, severe or treatment-resistant symptoms. iMAP primarily guides on early recognition of CMA, emphasizing the need for confirmation of the diagnosis, either by allergy testing (IgE) or exclusion then reintroduction of dietary cow's milk (non IgE). Breast milk is the ideal nutrition for infants with CMA and any decision to initiate a diagnostic elimination diet trial must include measures to ensure that breastfeeding is actively supported. Refer to accompanying leaflet for details of supporting ongoing breastfeeding in milk allergic infant. Firststepsnutrition.org is a useful information source on formula composition.

Mild to Moderate Non-IgE-mediated CMA

Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP)

Usually formula fed, at onset of formula feeding.
Rarely in exclusively breast fed infants

Usually several of these symptoms will be present. Symptoms persisting despite first line measures are more likely to be allergy related e.g. to atopic dermatitis or reflux. Visit gpifn.org.uk for advice about other infant feeding issues.

Gastrointestinal

Persistent Irritability - 'Colic'
Vomiting - 'Reflux' - GORD
Food refusal or aversion
Diarrhoea-like stools – abnormally loose +/- more frequent
Constipation – especially soft stools, with excess straining
Abdominal discomfort, painful flatus
Blood and/or mucus in stools in otherwise well infant

Skin

Pruritus (itching), Erythema (flushing)
Non-specific rashes
Moderate persistent atopic dermatitis

The symptoms above are very common in otherwise well infants or those with other diagnoses, so clinical judgement is required. Trial exclusion diets must only be considered if history & examination strongly suggests CMA, especially in exclusively breastfed infants, where measures to support continued breastfeeding must be taken.

Cow's Milk Free Diet

Exclusively breast feeding mother*

Trial exclusion of all Cow's Milk Protein from her own diet and to take daily Calcium and Vit D

Formula fed or 'Mixed Feeding'*

If mother unable to revert to fully breastfeeding, trial of Extensively Hydrolysed Formula - eHF

See Management Algorithm

Severe Non-IgE-mediated CMA

Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP)

Usually formula fed, at onset of mixed feeding.
Rarely in exclusively breast fed infants

One but usually more of these severe, persisting & treatment resistant symptoms:

Gastrointestinal

Diarrhoea, vomiting, abdominal pain, food refusal or food aversion, significant blood and/or mucus in stools, irregular or uncomfortable stools
+/- Faltering growth

Skin

Severe atopic dermatitis +/- Faltering Growth

Cow's Milk Free Diet Exclusively breast feeding mother*

If symptomatic, trial exclusion of all Cow's Milk Protein from her own diet and to take daily Calcium & Vit D

Formula fed or 'Mixed Feeding'*

If mother unable to revert to fully breastfeeding, trial of replacement of Cow's Milk formula with Amino Acid Formula (AAF). If infant asymptomatic on breast feeding alone, do not exclude cow's milk from maternal diet.

Ensure:

Urgent referral to local paediatric allergy service
Urgent dietetic referral

Severe IgE CMA

ANAPHYLAXIS

Immediate reaction with severe respiratory and/or CVS signs and symptoms.
(Rarely a severe gastrointestinal presentation)

Emergency Treatment and Admission

Mild to Moderate IgE-mediated CMA

Mostly within minutes (may be up to 2 hours) after ingestion of Cow's Milk Protein (CMP)
Mostly occurs in formula fed or at onset of mixed feeding

One or more of these symptoms:

Skin – one or more usually present

Acute pruritus, erythema, urticaria, angioedema
Acute 'flaring' of persisting atopic dermatitis

Gastrointestinal

Vomiting, diarrhoea, abdominal pain/colic

Respiratory – rarely in isolation of other symptoms

Acute rhinitis and/or conjunctivitis

Cow's Milk Free Diet

Support continued breast feeding where possible.

If infant symptomatic on breast feeding alone, trial exclusion of all Cow's Milk Protein from maternal diet with daily maternal Calcium & Vit D as per local guidance.
If infant asymptomatic on breast feeding alone, do not exclude cow's milk from maternal diet.

Formula fed or 'Mixed Feeding'*

If mother unable to revert to fully breast feeding 1st Choice - Trial of Extensively Hydrolysed Formula – eHF
Infant soy formula may be used over 6 months of age if not sensitised on IgE testing

If diagnosis confirmed (by IgE testing or a Supervised Challenge in a minority of cases):

Follow-up with serial IgE testing and later Planned Challenge to test for acquired tolerance

Dietetic referral required

UK NICE Guidance - If competencies to arrange and interpret testing are not in place - early referral to local paediatric allergy service advised

* Actively support continued breastfeeding (see over)

iMAP was developed without any funding or support from industry but note that authors do make declarations of interest.

Appendix 2 – Management of Mild to Moderate Non-IgE Cow's Milk Allergy (CMA) iMAP

UK Adaptation of iMAP Guideline for Primary Care and 'First Contact' Clinicians

Management of Mild to Moderate Non-IgE Cow's Milk Allergy (CMA)

(No initial IgE Skin Prick Tests or Serum Specific IgE Assays necessary)

May 2019

Exclusively Breastfeeding [UK Recommendation 1st 6 months]

Strict elimination of cow's milk containing foods from maternal diet

Maternal daily supplements of Calcium and Vit D according to local recommendations
Refer to dietitian - a maternal substitute milk should be advised
An agreed Elimination Trial of up to 4 weeks - with a minimum of 2 weeks.
If severe atopic dermatitis or more severe gut symptoms - consider soy/egg avoidance as well, only with specialist advice

Mothers should be actively supported to continue to breastfeed through this period*.

No Clear Improvement

Clear Improvement - need to confirm Diagnosis

But - CMA still suspected:

Refer to local paediatric allergy service

Consider excluding other maternal foods eg soy, egg only with specialist advice

CMA no longer suspected:

Return to usual maternal diet
Consider referral to local general paediatric service if symptoms persist. Visit gpifn.org.uk for advice about other infant feeding issues.

As likelihood of sufficient cow's milk protein passage into breast milk to trigger reactions is low, in breast fed cases, complete milk exclusion may not be required.

Home Reintroduction: [NICE Quality Standard]
Mother to revert to normal diet containing cow's milk foods over period of 1 week - to be done usually between 2-4 weeks of starting Elimination Trial

No return of symptoms
NOT CMA - normal feeding

Return of symptoms

Symptoms do not settle

Exclude cow's milk containing foods from maternal diet again
If symptoms clearly improve:
CMA NOW CONFIRMED
If top-up formula feeds should later be needed - eHF may well be tolerated. If not - replace with AAF

Formula Feeding or 'Mixed Feeding' [Breast and Formula]

Strict cow's milk protein free diet

If symptoms only with introduction of cow's milk-based feeds - encourage & support return to breastfeeding*. Mother can continue to consume cow's milk containing foods in her diet. If symptoms settle on return to full breast feeding, reconsider diagnosis if symptoms return on future milk exposure. If symptoms suspected from breastfeeding alone, see Box left. If **any** formula feeds are required, advise an eHF. Agree an Elimination Trial of up to 4 weeks (minimum of 2 weeks) and assess improvement. **Reintroduction of cow's milk is required to confirm diagnosis.** If weaned - may need advice & support from dietitian. Only follow algorithm further in infants receiving eHF/on diagnostic elimination diet trial.

Clear Improvement - need to confirm diagnosis

No Clear Improvement

Home Reintroduction: [NICE Quality Standard]
Using cow's milk formula
To be done usually between 2-4 weeks of starting Elimination Trial. Refer to iMAP reintroduction leaflet.

Return of symptoms

No return of symptoms
NOT CMA - normal feeding

Support breastfeeding or if not possible, return to eHF again
If symptoms clearly improve:

CMA NOW CONFIRMED

Ensure support of dietitian

Symptoms do not settle

But - CMA still suspected:

Consider initiating a trial of an Amino Acid Formula (AAF)
Refer to local paediatric allergy service

CMA no longer suspected:

Unrestricted diet again
Consider referral to local general paediatric service if symptoms persist

Cow's milk free diet until 9-12 months of age and for at least 6 months - with support of dietitian
A planned Reintroduction or Supervised Challenge is then needed to determine if tolerance has been acquired
Performing a Reintroduction versus a Supervised Challenge is dependent on the answer to the question:
Does the child have **Current Atopic Dermatitis** or **ANY history at ANY time of immediate onset symptoms**?

No Current Atopic Dermatitis
And no history at any time of immediate onset symptoms
(No need to check Serum Specific IgE or perform Skin Prick Test)

Reintroduction at Home - using a MILK LADDER
To test for Acquired Tolerance

And still no history at any stage of immediate onset symptoms
Reintroduction at Home - using a MILK LADDER
To test for Acquired Tolerance

Current Atopic Dermatitis

Check Serum Specific IgE or Skin Prick Test to cow's milk

Negative Positive

History of immediate onset symptoms at any time
Serum Specific IgE or Skin Prick Test needed

Negative

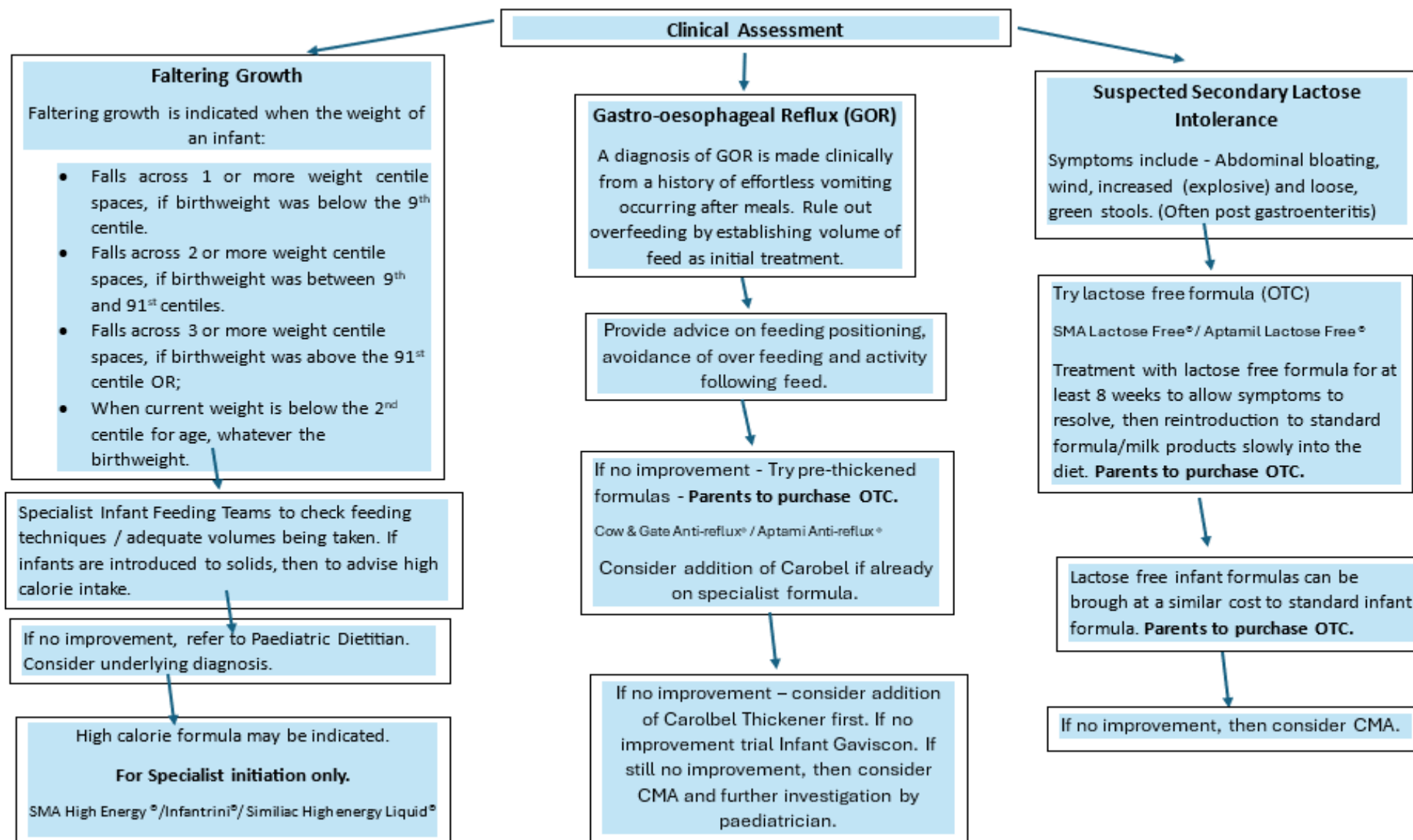
Liaise with local Allergy Service Re: Challenge

Positive or
Tests not available

Refer to local paediatric allergy service
(A Supervised Challenge may be needed)

*Breast milk is the ideal nutrition for infants & hence continued breastfeeding should be actively encouraged as far as is possible. WHO recommends breastfeeding until 2 years and beyond. Mothers should be offered support of local NHS breastfeeding support services & signposted to further support. Please refer to iMAP patient information leaflet on supporting breast feeding.

Appendix 3 – Recommendations for Management of Faltering Growth, Gastro-oesophageal reflux and Suspected Lactose Intolerance



Appendix 4 - The Early Home Reintroduction to Confirm the Diagnosis of Cow's Milk Allergy [-home-reintroduction-guide-for-parents.pdf](#)

Practical Example of a Reintroduction in a Formula Fed Child

The Days	Volume of Boiled Water mls. (fl. oz.)	Hypoallergenic Formula mls. (fl. oz.)	Cow's Milk Formula mls. (fl. oz.)
Day 1	210 mls. (7 fl.oz.)	180 mls. (6 fl.oz.) in 1st bottle only	30 mls. (1 fl.oz.) in 1st bottle only
Day 2	210 mls. (7 fl.oz.)	150 mls. (5 fl.oz.) in 1st bottle	60 mls. (2 fl.oz.) in 1st bottle
Day 3	210 mls. (7 fl.oz.)	120 mls. (4 fl.oz.) in 1st bottle	90 mls. (3 fl.oz.) in 1st bottle
Day 4	210 mls. (7 fl.oz.)	90 mls. (3 fl.oz.) in 1st bottle.	120 mls. (4 fl.oz.) in 1st bottle
Day 5	210 mls. (7 fl.oz.)	60 mls. (2 fl.oz.) in 1st bottle	150 mls. (5 fl.oz.) in 1st bottle
Day 6	210 mls. (7 fl.oz.)	30 mls. (1 fl.oz.) in 1st bottle	180 mls. (6 fl.oz.) in 1st bottle
Day 7	210 mls. (7 fl.oz.)	0	210 mls. (7 fl.oz.) in 1st bottle
If no symptoms occur after Day 7, when you have replaced the 1st bottle of the day completely with cow's milk formula, give your child cow's mik formula in all bottles.			