

Appropriate Prescribing of Specialist Infant Formulae

Introduction

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.

Purpose of the Guidelines

These guidelines aim to assist GPs and Health Visitors with information on the use of prescribable infant formula. The guidelines are targeted at infants 0-12 months. However, some of the prescribable items mentioned here can be used past this age and advice on this is included in the guidelines.

The guidelines advise on:

- Over-the-counter (OTC) products available where appropriate
- Initiating prescribing
- Quantities to prescribe
- Which products to prescribe for different clinical conditions
- Triggers for reviewing and discontinuing prescriptions
- When onward referral for dietetic advice and/or secondary/specialist care should be considered.

Colour key used on the following pages:

Over the counter products to be purchased
Prescribe as first line
Prescribe as second line
Should not routinely be commenced in primary care
Should not routinely be prescribed

Please refer mothers that require additional support with infant feeding, usually breastfeeding related issues to:

Infant Feeding Co-ordinator City Health Care Partnership CIC Children and Young People Services Clarendon Health Centre, Hull Tel - 01482 617865	Infant Feeding Lead Humber Teaching NHS Foundation Trust Trust Headquarters Willerby Hill, Beverley Road Willerby HU10 6ED Tel – 01482344510
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Breast Feeding Support Office,
Honeysuckle Team,
Diana, Princess of Wales Hospital,
Grimsby DN33 2BA.
Tel. 03033 305822
Mobile. 07850 299641
Nlg-tr.gyinfantfeedingmidwife@nhs.net

Guide on quantities of formulae to prescribe

When any infant formula is prescribed the guide below should be used.

To avoid waste, just 2 weeks supply should be provided until tolerance and compliance is established.

For powdered formula:

Age of Child	Number of tins for 28 days
Under 6 months	10-13 x 400g tins
6-12 months	7-13 x 400g tins
Over 12 months	7 x 400g tins

These amounts are based on:

- Infants under 6 months being exclusively formula fed and drinking 150ml/kg/day of a normal concentration formula.
- Infants 6-12 months requiring less formula as solid food intake increases.
- Children over 12 months drinking the 600mls of milk or milk substitute per day recommended by the Department of Health.

For liquid high energy formula:

The quantity will be recommended by the specialist.

- Review recent correspondence from the paediatrician or paediatric dietitian.

DOS AND DON'TS OF PRESCRIBING SPECIALIST INFANT FORMULAE

DO	Promote and encourage breast-feeding where it is clinically safe and the mother is in agreement.
	Check any formula prescribed is appropriate for the age of the infant.
	Check the amount of formula prescribed is appropriate for the age of the infant (see page 1) and/or refer to the most recent correspondence from the paediatric dietitian.
	Review any prescription where the child is over 2 years old, the formula has been prescribed for more than 1 year, greater amounts of formula are being prescribed than would be expected or stop when able to tolerate OTC products
	Review the prescription if the patient is prescribed a formula for Cows Milk Protein allergy (CMPA) but able to eat any of the following foods – cow’s milk, cheese, yogurt, ice cream, custard, chocolate, cakes, cream, butter, margarine, ghee.
	Prescribe only two weeks initially until compliance/tolerance is established.
	Remind parents to follow the advice given by the formula manufacturer regarding safe storage of the feed once mixed or opened.
	Refer where appropriate to secondary or specialist care - see advice for each condition.
	Refer where appropriate to the paediatric dietitians.
	Seek prescribing advice if needed in primary care from the Medicines Optimisation Team
	Seek prescribing advice if needed in secondary care from the local Hospital Medicines Information Centre.

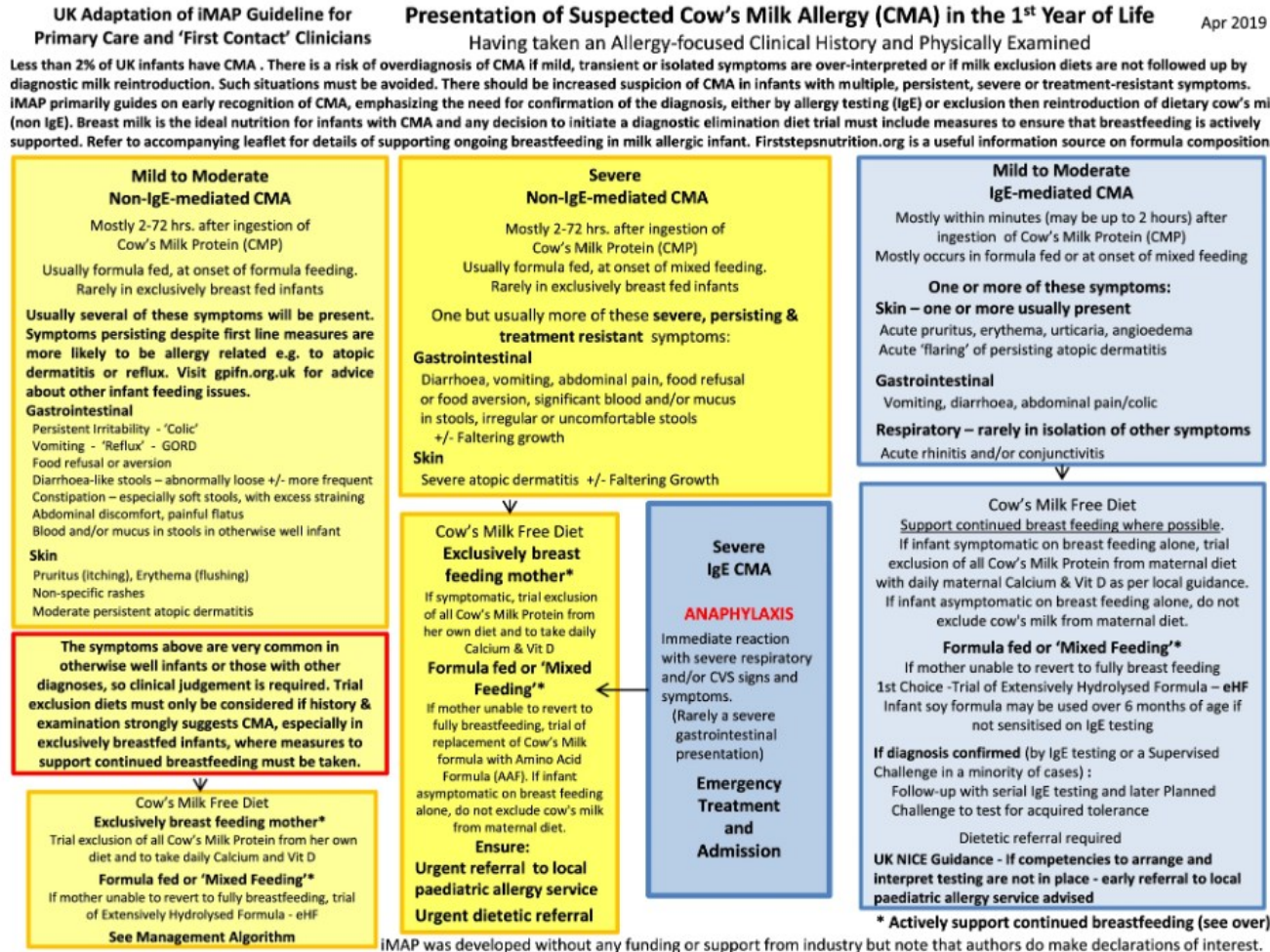
DO NOT	Add infant formulae to the repeat prescribing template in primary care, unless a review process is established within practice to ensure the correct product and quantity is prescribed for the age of the infant.
	Prescribe lactose free formulae (SMA LF®, Enfamil O-Lac®) for infants with CMPA.
	Routinely prescribe soya formula (SMA Wysoy®) for those with CMPA or secondary lactose intolerance. It should not be prescribed at all in those under 6 months due to high phytoestrogen content.
	Suggest milk and formulae made from goat’s milk, sheep’s milk or mammalian milks for those with CMPA or secondary lactose intolerance.
	Suggest rice milk for those under 5 years due to high arsenic content.
	Prescribe Nutriprem 2 Liquid® or SMA Gold Prem 2 Liquid® unless there is a clinical need.
	Prescribe thickening formulae (SMA Pro Anti-Reflux®, Enfamil AR®) with separate thickeners or in conjunction with medication such as antacids, cimetidine, or proton pump inhibitors, since the formulae need stomach acids to thicken and reduce reflux.
	Suggest Infant Gaviscon® more than 6 times in 24 hours or where the infant has diarrhoea or a fever, due to its sodium content.
	Prescribe low lactose/lactose free formulae in children with secondary lactose intolerance over 1 year who previously tolerated cow’s milk, since they can use lactose free products from supermarkets.

COW'S MILK PROTEIN ALLERGY (CMPA)

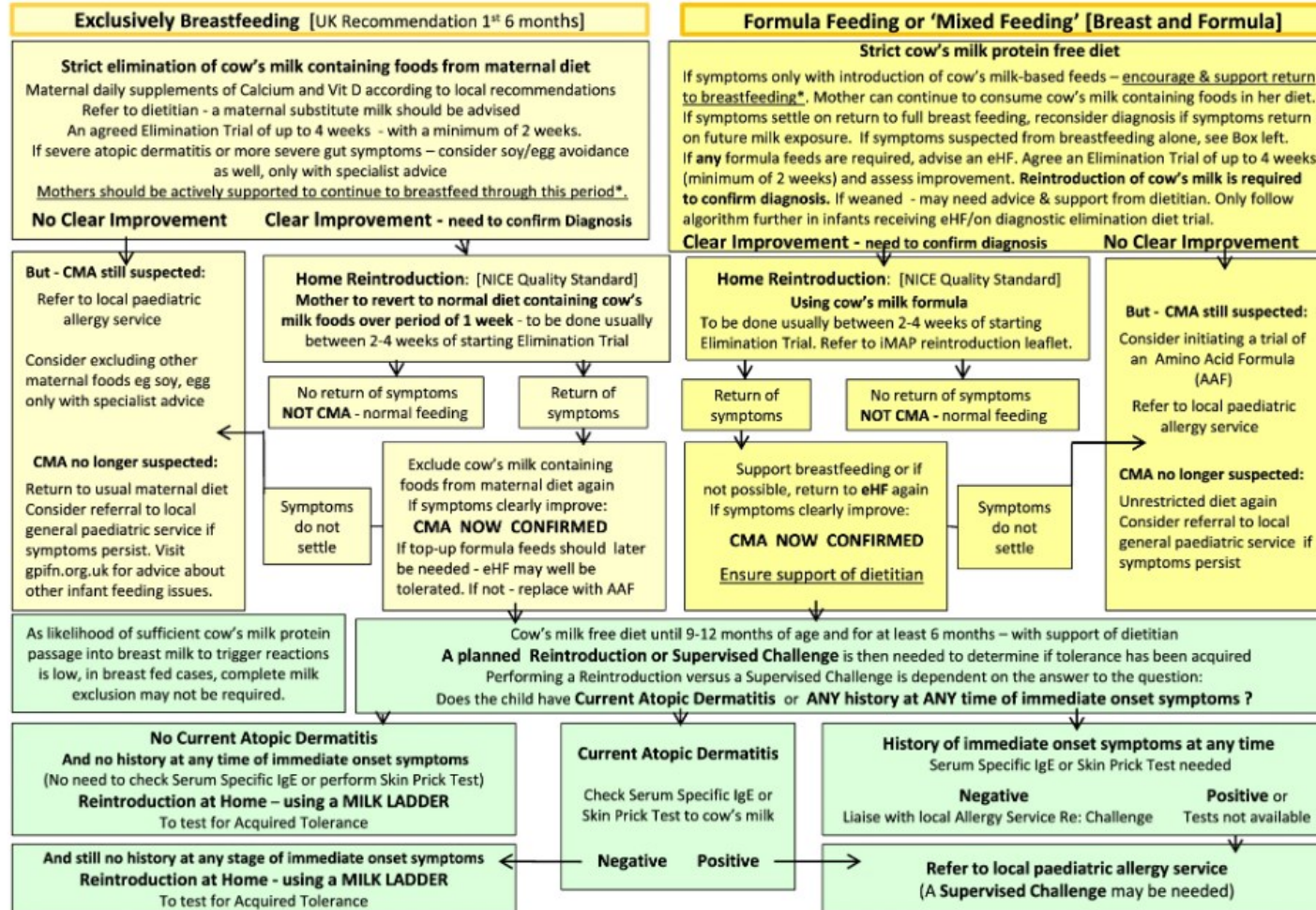
Symptoms and diagnosis

Refer to NICE guideline CG116 'Food allergy in under 19s: assessment and diagnosis full details. <http://guidance.nice.org.uk/CG116>

Allergy UK; iMAP guidelines 2019 <https://ctajournal.biomedcentral.com/articles/10.1186/s13601-019-0281-8>



UK Adaptation of IMAP Guideline for **Management of Mild to Moderate Non-IgE Cow's Milk Allergy (CMA)** May 2019
Primary Care and 'First Contact' Clinicians (No initial IgE Skin Prick Tests or Serum Specific IgE Assays necessary)



*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.

Treatment

Clinicians should be cautious using lactose-containing formulae in patients presenting with diarrhoea as the patient may have a secondary lactose intolerance

If breast-feeding preferred option consider referring mum to dietitian for milk free diet.

EXTENSIVELY HYDROLYSED FORMULAE FIRST LINE	Nutramigen 1 with LGG (Mead Johnson) (lactose free)	Birth to 6 months
	Nutramigen 2 with LGG (Mead Johnson) (lactose free)	6 months to 1 year
	Nutramigen 3 with LGG (Mead Johnson) (lactose free)	1-2 years
	SMA Althera (Nestle Health Science) Please note: contains lactose, whey protein based, Halal and vegetarian	Birth to 2 years
	Aptamil Pepti 1® (Nutricia Ltd) Please note: contains lactose, whey protein based	Birth to 6 months
	Aptamil Pepti 2® (Nutricia Ltd) Please note: contains lactose, whey protein based	6 months to 2 years
	Aptamil Pepti-Syneo (Nutricia Ltd) Please note: contains lactose, whey protein based	Birth to 2 years

EXTENSIVELY HYDROLYSED FORMULAE WITH MEDIUM CHAIN TRIGLYCERIDES TO BE STARTED BY SECONDARY CARE ONLY	Aptamil Pepti - junior® (Nutricia Ltd)	Birth to 2 years or able to tolerate over the counter products
	These formulae are used where CMPA is accompanied by malabsorption.	

AMINO ACID FORMULAE	SMA Alfamino (Nestle Health Science) Contains MCT and whey based	Birth to 2 years
	Nutramigen PurAmino® (Mead Johnson)	Birth to 2 years
	Neocate Syneo® (Nutricia)	Birth to 2 years (please liaise with dietetics before prescribing)
	Neocate Junior® (Nutricia)	Over 1 year
	Neocate LCP® (Nutricia Ltd)	Birth to 2 years
	If a patient presents with clear anaphylactic reaction to cow's milk these formula should be commenced in primary care, with immediate onward referral to secondary or specialist care	

Review and discontinuation of treatment and challenges with cow's milk

Review prescriptions regularly to check that the formula prescribed is appropriate for the child's age.

- Quantities of formula required will change with age – see guide to quantities on page 2 required and/or refer to the most recent correspondence from the paediatric dietitian.
- Some formula have different numbers for different ages e.g. Nutramigen LGG 1 and Aptamel Pepti 1, these can be continued at weaning at 6 months or changed to next age range. This does not require a referral to the paediatric dietetic service to do this.
- Challenging with cow's milk – refer to NICE and IMAP guidance on which children should be challenged with cow's milk in a secondary care setting
- Prescriptions should be stopped when the child has outgrown the allergy or diet is deemed adequate on review by paediatric dietitian.
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
 - Is the patient over 2 years of age?
 - Has the formula been prescribed for more than 1 year?
 - Is the patient prescribed more than the suggested quantities of formula according to their age?
 - Is the patient prescribed a formula for CMPA but able to eat any of the following foods – cow's milk, cheese, yogurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee?
- Children with multiple or severe allergies may require prescriptions beyond 2 years. This should always be at the suggestion of the paediatric dietitian.

NOTES

1. Soya formula (SMA Wysoy®) should not routinely be used for patients with CMPA. It should not be used at all for those under 6 months due to high phyto-oestrogen content. It should only be advised in patients over 6 months who do not tolerate first line or second line Extensively Hydrolysed Formulae (EHF) since there is a risk that infants with CMPA may also develop allergy to soya. It is more likely that children will tolerate soya formula from 1 year. Parents should be advised to purchase soya formula as it is a similar cost to cow's milk formula and readily available. From 1 year supermarket

calcium, iodine and protein enriched soya or oat milk may be suitable as an alternative if the rest of the diet is adequate. The paediatric dietitian will advise on suitable over-the-counter products for appropriate ages.

2. EHF and Amino Acid Formulae (AAF) have an unpleasant taste and smell, which is better tolerated by younger patients. Unless there is anaphylaxis, advice parents to introduce the new formula gradually by mixing with the usual formula (or breast milk) in increasing quantities until the transition is complete. Serving in a closed cup or bottle or with a straw (depending on age) may improve tolerance. In some cases the formula will need to be flavoured e.g. with the minimum amount of milk free milkshake flavouring or alcohol free vanilla essence. Care should be taken and ingredients checked in those with multiple allergies.
3. Outgrowing CMPA – Most children will grow out of their cow's milk allergy in early childhood
4. Calcium supplementation may be needed for infants depending on volume and type of formula taken. Breast-feeding mothers on a milk free diet may also need a calcium supplement. The dietitian will advise.
5. Lactose free formulae (SMA LF, Aptamil LF) are not suitable for those with CPMA
6. Goats', sheep and other mammalian milks are not suitable for those with CPMA.

GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

Refer to NICE NG 1 Gastro-oesophageal reflux disease in children and young people: diagnosis and management, January 2015 <https://www.nice.org.uk/guidance/ng1>

Symptoms and diagnosis

- GORD is the passage of gastric contents into the oesophagus causing troublesome symptoms and/or complications.
- Symptoms may include regurgitation of a significant volume of feed, reluctance to feed, distress/crying at feed times, small volumes of feed being taken.
- Diagnosis is made from history that may include effortless vomiting (not projectile) after feeding, usually in the first 6 months of life, and usually resolves spontaneously by 12-15 months age.
- It should be noted that 50% of babies have some degree of reflux at some time.
- Overfeeding needs to be ruled out by establishing the volume and frequency of feeds. Average requirements of formula are 150mls/kg/day for babies up to 6 months, and should be offered spread over 6-7 feeds.
- Symptoms of GORD and CPMA have overlap, full history of both symptoms and feeding history is required before starting treatment.

Onward referral

- Infants with faltering growth as a result of GORD should be referred to paediatric services without delay.
- If symptoms do not improve one month after commencing treatment, try EHF formulae to rule out CMPA prior to referring to a paediatrician for further investigations since CMPA can co-exist with GORD.
- If infant regurgitates after all food as well as liquid, then to refer onto secondary care.

Treatment

- If the infant is thriving and not distressed reassure parents and monitor.
- Provide advice on avoidance of overfeeding, positioning during and after feeding, and activity after feeding. If bottle-fed suggest over-the-counter (OTC) products listed below.
- The first line of advice is small frequent feeds and then thickened formulae prior to prescription of alginate (Infant Gaviscon®).
- If the breast-fed infant is not gaining weight and/or not settled – trial with alginate (Infant Gaviscon®) offered on a spoon before feeds. Advice for those with faltering growth will be given by secondary/specialist care.

- Prescribable thickening formulae should not be used in conjunction with separate thickeners or with medication such as ranitidine, or with proton pump inhibitors.

Review and discontinuation of treatment

- Review after one month.
- Infants with GORD will need regular review to check growth and symptoms. Re-assess need for medication every 4-8 weeks.
- Since GORD will usually resolve spontaneously between 12-15 months, cessation of treatment can be trialled from 12 months.

OVER THE COUNTER THICKENED FORMULAE TO BE PURCHASED FIRST-LINE	Cow & Gate® Anti-reflux (Cow & Gate)	Birth to 1 year
	Aptamil® Anti-reflux (Milupa)	Birth to 1 year
OVER THE COUNTER THICKENING FORMULAE TO BE PURCHASED FIRST-LINE	SMA Anti-Reflux® (SMA)	Birth to 18 months

Notes

1. Over the counter (OTC) thickened formulae such as Cow& Gate® Anti-reflux and Aptamil® Anti-reflux contain carob gum. This produces a thickened formula and will require the use of a large hole (fast-flow) teat.
2. Thickening formulae such as SMA **Anti-Reflux®** react with stomach acids, thickening in the stomach rather than the bottle so there is no need to use a large hole (fast flow) teat.
3. All of the above milks contain Cow's Milk Protein & Lactose so are not suitable for infants with CMPA or a Lactose Intolerance. However Carobel® (Cow&Gate) can be used to thicken appropriate formula milks used to treat CMPA. Carobel® contains carob gum: it should not be used with Gaviscon but can be used with other anti reflux medicines.
4. SMA **Anti-Reflux®** contains corn-starch so alert parents/carers to the need to make up thickening formulae with fridge cooled pre-boiled water (see tin for full instructions).
5. Infant Gaviscon® contains sodium, and should not be given more than 6 times in 24 hours or where the infant has diarrhoea or a fever. N.B. Each half of the dual sachet of Infant Gaviscon® is identified as 'one dose'. To avoid errors, prescribe with directions in terms of 'dose'. Dispensing Pharmacists should advise about appropriate doses of OTC products.
6. If thickened formulae and pharmacological therapy fails, refer to secondary care.

SECONDARY LACTOSE INTOLERANCE

Symptoms and diagnosis

- Usually occurs following an infectious gastrointestinal illness but may be present alongside newly or undiagnosed coeliac disease.
- Symptoms include abdominal bloating, increased (explosive) wind, loose green stools.
- Lactose intolerance should be suspected in infants who have had any of the above symptoms that persist for more than 2 weeks.
- Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis.

Onward referral

- If symptoms resume when standard formula and/or milk products are reintroduced to the diet or if symptoms do not resolve on a lactose-free diet refer to secondary or specialist care.
- Refer to the paediatric dietitian if the child is weaned and a lactose free diet is required.

Treatment

- For breast feeding mothers Colief® drops can be purchased and given with a feed on a spoon mixed with a little expressed milk.
- Treat with low lactose/lactose free formula for 6-8 weeks to allow symptoms to resolve. Rarely symptoms may last up to 3 months.
- If symptoms do not improve on a lactose free diet, then other allergies/intolerances should be considered.
- In infants who have been weaned, low lactose/lactose free formula should be used in conjunction with a lactose free diet.
- Lactose should be re-introduced gradually in to the diet and/or as standard formula, to allow the production of lactase to resume.
- In children over 1 year who previously tolerated cow's milk, do not prescribe low lactose/lactose free formulae. Suggest use of lactose free full fat cow's milk, yoghurt and other dairy products which can be purchased from supermarkets.

Review and discontinuation of treatment

OVER THE COUNTER LOW LACTOSE/ LACTOSE FREE FORMULA TO BE PURCHASED FIRST-LINE	SMA LF® (SMA)	Birth to 12 months, See treatment note above for those over 1 year
	Aptamil LF (Nutricia)	Birth to 12 months, See treatment note above for those over 1 year

Low lactose/lactose free formula should not be prescribed for longer than 8 weeks without review and trial of discontinuation of treatment.

Notes

1. Primary lactose intolerance is less common than secondary lactose intolerance and does not usually present until later childhood or adulthood.
2. SMA LF® is low lactose, whole protein cow's milk formula.
3. Soya formula (SMA Wysoy®) should not be used for patients with secondary lactose intolerance. It should not be prescribed at all for those under 6 months due to high phyto-oestrogen content.

FALTERING GROWTH

Refer to NICE NG 75 Faltering growth: recognition and management of faltering growth in children, September 2017 <https://www.nice.org.uk/guidance/ng75>

Symptoms and diagnosis

- Refer to section NICE NG 75, [1.2 Faltering growth after the early days of life: thresholds](#)
- The height/length of a child is measured to properly interpret changes in weight using appropriate growth charts to be able to diagnose.
- It is essential to rule out possible disease related/medical causes for the faltering growth e.g. iron deficiency anaemia, constipation, GORD or a child protection issue. If identified appropriate action should be taken.

Onward referral

If faltering growth is diagnosed refer to NICE NG 75 regarding management and onward referral.

Treatment

- First line:
 - Refer to breast feeding support if child is breast fed
 - Formulae fed child – assess volumes/symptoms, manage symptoms
- Prescribe an equivalent volume of high energy formula to the child's usual intake of regular formula until an assessment has been performed and recommendations made by paediatrician or paediatric dietitian.

Review and discontinuation of treatment

- The team to whom the infant is referred should indicate who is responsible for review and discontinuation. If the team hand responsibility back to the GP this should be with an indication of what the goal is at which point discontinuation can occur.
- All infants on high energy formula will need growth (weight and height/length) monitored to ensure catch up growth occurs.
- Once this is achieved the formula should be discontinued to minimise excessive weight gain.

HIGH ENERGY FORMULA FIRST-LINE	SMA High Energy® 200ml carton (SMA)	Birth up to 18 months or 8kg
	Infatrini® 125/200ml bottle (Nutricia Ltd)	Birth up to 18 months or 8kg
	Similac High Energy® 200ml bottle (Abbott Nutrition)	Birth up to 18 months or 8kg

HIGH ENERGY FORMULA TO BE STARTED IN SECONDARY CARE	Infatrini Peptisorb® 200ml bottle (Nutricia Ltd)	Birth up to 18 months or 8kg
	N.B. This formula is suitable for infants with faltering growth and intolerance to whole protein feeds e.g. short bowel syndrome, intractable malabsorption, inflammatory bowel disease, bowel fistulae.	

Notes

- Where all nutrition is provided via NG/NJ/PEG tubes, the paediatric dietitian will advise on appropriate monthly amounts of formula required which may exceed the guideline amounts for other infants. These formulae are not suitable as a sole source of nutrition for infants over 8kg or 18 months of age.
- Manufacturer's instructions regarding safe storage once opened and expiry of ready to drink formulae should be adhered to – this may differ from manufacturer to manufacturer.

PRE-TERM INFANTS

Indications

- These infants will have had their pre-term formula commenced on the neonatal unit to ensure tolerance, and supplied at discharge as per local procedure.
- It is started for babies born before 34 weeks gestation and/or weighing less than 2kg at birth.
- These formulae should not be used in primary care to promote weight gain in patients other than babies born prematurely.

Onward referral

- These infants should already be under regular review by the paediatricians.
- If there are concerns regarding growth whilst the infant is on these formulae, refer to the paediatric dietitian.
- If there are concerns regarding growth at 6 months corrected age or at review one month after these formulae are stopped, refer to the paediatric dietitian.

Review and discontinuation of treatment

- The Health Visitor will monitor growth (weight, length and head circumference) while the baby is on these formulae at a frequency determined by the appropriate health care professional.
- These products should be discontinued by 6 months corrected age.
- Not all babies need these formulae for the full 26 weeks from expected date of delivery (EDD).
- If there is excessive weight gain at any stage up to 6 months corrected age, stop the formula.

PRE-TERM INFANT FORMULA TO BE STARTED IN SECONDARY CARE	SMA Gold Prem 2® powder (SMA)	Birth up to a maximum of 6 months corrected age
	Nutriprem 2® powder (Cow and Gate)	Birth up to a maximum of 6 months corrected age
	6 months corrected age = EDD + 26 weeks	

PRE-TERM INFANT FORMULA WHICH SHOULD NOT ROUTINELY BE PRESCRIBED <small>Unless there is a clinical need e.g. immunocompromised infant</small>	SMA Gold Prem 2® liquid (SMA)	
	Nutriprem 2® liquid (Cow and Gate)	

NICE Clinical Guideline 116 Food Allergy in Children and Young People: assessment and diagnosis <https://www.nice.org.uk/Guidance/CG116>

Allergy UK. iMAP guidelines 2019
<https://ctajournal.biomedcentral.com/articles/10.1186/s13601-019-0281-8>

Food Hypersensitivity. Diagnosing and managing food allergy and intolerance. (2009). Edited by Isabel Skypala and Carina Venter. Published by Wiley- Blackwell.

World Allergy Organisation DRACMA guidelines 2010 (Diagnosis and Rationale Against Cow's Milk Allergy)
https://www.worldallergy.org/UserFiles/file/world_allergy_organization_wao_diagnosis_and_1.pdf

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Paediatric group Position Statement on Use of Soya Protein for Infants. British Dietetic Association: October 2010, update 24 April 2019
<https://www.bda.uk.com/uploads/assets/fa3d24ca-ab35-4a73-80db37116a4db24f/soyafomulapositionstatement.pdf>

Department of Health: CMO messaging DH advice for toddlers and young children (1 – 5 years) to avoid rice drinks due to risk of exposure to inorganic arsenic 21st May 2009
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=101208>

NICE NG 1 Gastro-oesophageal reflux disease in children and young people: diagnosis and management, January 2015, last updated: 9 October 2018
<https://www.nice.org.uk/guidance/ng1>

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NICE NG 75 Faltering growth: recognition and management of faltering growth in children, September 2017 <https://www.nice.org.uk/guidance/ng75>

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<http://www.publichealth.hscni.net/publications/birth-five>

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Document and version control	This information is not inclusive of all prescribing information and potential adverse effects. Please refer to the SPC (data sheet) or BNF for further prescribing information.		
	Version number:	1	
	Date approved by Guidelines and SCF Group:	20/09/23	
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1	Jane Morgan	Principal pharmacist	HERPC and NLAPC versions merged and reviewed with Andrew Karvot, Vanessa Smith, Sally Aitkin, Cheryl Baig, Noelle Hynes, Michelle Pudsey and Sally Uren