

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 Orchard Park Health Centre, 210 Orchard Park Road, Hull. HU69BX Tel: 07964 686958	Infant Feeding Lead Humber Teaching NHS Foundation Trust Trust Headquarters Willerby Hill, Beverley Road Willerby HU10 6ED Tel - 01482344510
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Guide on quantities of formulae to prescribe

For powdered formula:

Age of Child	Number of tins for 28 days
Under 6 months	13 x 400g tins or 6 x 900g tins
6-12 months	7-13 x 400g tins or 3-6 x 900g tins
Over 12 months	7 x 400g tins or 3 x 900g 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:

Prescribe an equivalent volume of formula (500mls to 1000mls) to the child's usual intake until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian.

- Some children may require more, e.g. those with faltering growth.
- 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 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 four 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 Management Team.
Seek prescribing advice if needed in secondary care from the local Hospital Medicines Information Centre.	

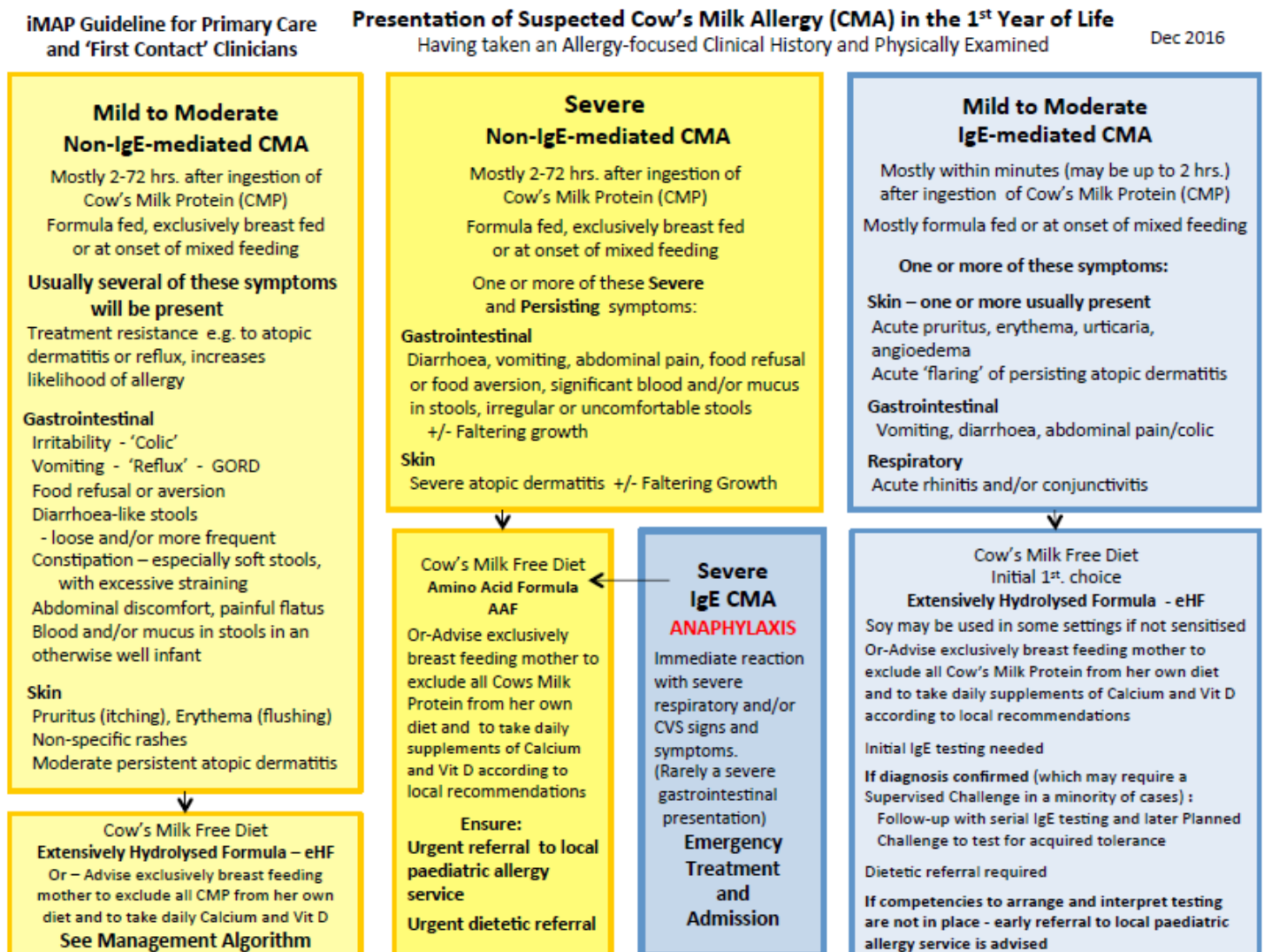
DO NOT	Add infant formulae to the repeat prescribing template in primary care, unless a review process is established to ensure the correct product and quantity is prescribed for the age of the infant.
	Prescribe lactose free formulae (SMA LF®, Enfamil O-Lac®) for infants with CMPA.
	Routinely prescribe 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 and should only be advised in patients who do not tolerate first or second line formula.
	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, ranitidine, 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 (e.g.Lactofree®) from supermarkets.	

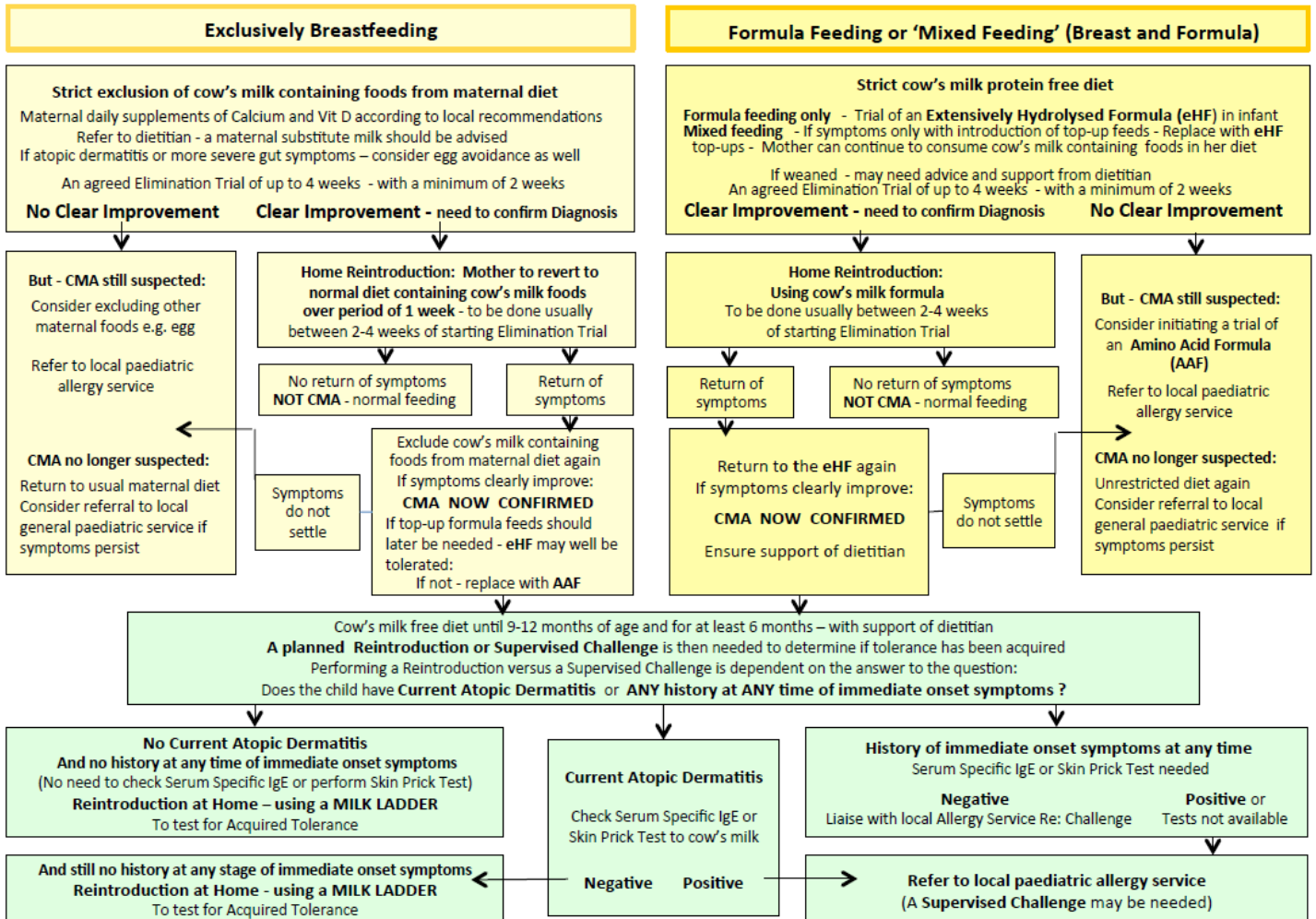
COW'S MILK PROTEIN ALLERGY (CMPA)

Symptoms and diagnosis

Refer to NICE guideline CG116 'Food Allergy in Children and Young People' Feb 2014 for full details. <http://guidance.nice.org.uk/CG116>

Allergy UK; iMAP guidelines 2016 <https://www.allergyuk.org/health-professionals/mapguideline#anchor1>





Treatment

EXTENSIVELY HYDROLYSED FORMULAE (lactose free) FIRST LINE	FIRST LINE: Similac Alimentum (Abbott Nutrition)	Birth to 12 months
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EXTENSIVELY HYDROLYSED FORMULAE SECOND LINE (These formulae can be tried if the infant/child is not tolerating the first-line product because of taste. Titrate formulae to facilitate acceptance)	Nutramigen LLG 1 (Mead Johnson) (lactose free)	Birth to 6 months
	Nutramigen LLG 2 (Mead Johnson) (lactose free)	6 months to 1 year
	Nutramigen LLG 3 (Mead Johnson) (lactose free)	1-2 years
	SMA Althera (Nestle) Please note: contains lactose	Birth to 2 years
	Pepti 1® (Milupa Aptamil) Please note: contains lactose	Birth to 6 months
	*Pepti 2® (Milupa Aptamil) Please note: contains lactose	6 months to 2 years

EXTENSIVELY HYDROLYSED FORMULAE WITH MEDIUM CHAIN TRIGLYCERIDES TO BE STARTED BY SECONDARY CARE ONLY	Pregestimil Lipil® (Mead Johnson)	Birth to 2 years
	Aptamil Pepti – Junior® (Nutricia)	Birth to 2 years
	These formulae are used where CMPA is accompanied by malabsorption.	

AMINO ACID FORMULAE	SMA Alfamino (Nestle) Contains MCT	Birth to 2 years
	PurAmino® (Mead Johnson)	Birth to 2 years
	Neocate Syneo® (Nutricia)	Birth to 2 years Do not use for pre term and immunosuppressed patients.
	Neocate LCP® (Nutricia)	Birth to 1 year
	Neocate Junior® (Nutricia)	Over 1 year
	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

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 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 enriched soya or oat milk may be suitable as an alternative if the rest of the diet is adequate. Alpro® Junior 1+ soya milk may be suitable from 1 year. The paediatric dietitian will advise on suitable over-the-counter products for appropriate ages.
2. EHF and 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 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. Care should be taken and ingredients checked in those with multiple allergies.

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.

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 Pro Anti-Reflux® (SMA)	Birth to 18 months
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THICKENING FORMULAE FIRST-LINE	Enfamil AR® (Mead Johnson)	Birth to 18 months
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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 **Pro Anti-Reflux®** and Enfamil AR® 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 **Pro Anti-Reflux®** contains corn-starch.
5. Enfamil AR® contains rice starch.
6. Alert parents/carers to the need to make up thickening formulae with fridge cooled pre-boiled water (see tin for full instructions).
7. 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'.
8. 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, bearing in mind it can take a few months for tolerance to build up.
- 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 4-8 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 (Lactofree® brand).

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 (Milupa)	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.

LOW LACTOSE/ LACTOSE FREE FORMULA FIRST- LINE	Enfamil O-Lac with Lipil® (Mead Johnson)	Birth to 12 months See treatment note above for those over 1 year
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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. Enfamil O-Lac® is lactose, sucrose and fructose free cow's milk formula.
4. SMA and Aptamil LF are lower in calcium than other formula milks, and therefore calcium intake needs to be assessed, and Enfamil O-Lac may need to be prescribed.
5. Soya formula (SMA Wysoy®) should not routinely 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. It should only be advised in patients over 6 months who do not tolerate the first line or second line formula suggested here. Parents should be advised to purchase it as it is a similar cost to cow's milk formula and readily available.

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 length of an infant are measured to properly interpret changes in weight using appropriate growth charts to be able to diagnose.

Onward referral

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

Treatment

- First line:
 - Breast feeding support
 - Formulae fed child – assess volumes/symptoms, manage symptoms
 - Consider a time limited trial of high energy formulae if the previous advice is unsuccessful
- If no progress within 2-4 weeks at >8Kg / 18/12 refer for review to 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 Pro High Energy® 250ml bottle (SMA)	Birth up to 18 months or 8kg
HIGH ENERGY FORMULA SECOND-LINE	Infatrini® 125/200ml bottle (Nutricia)	Birth up to 18 months or 8kg
	Similac High Energy® 120/200ml bottle (Abbott Nutrition)	Birth up to 18 months or 8kg
HIGH ENERGY FORMULA TO BE STARTED IN SECONDARY CARE	Infatrini Peptisorb® 200ml bottle (Nutricia)	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 post-discharge their pre-term formula commenced from the neonatal unit.
- It is started for babies born before 34 weeks gestation, 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 these infants are already under regular review by the paediatrician, the paediatrician will refer directly to secondary care 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 on a monthly basis. Parent's/carer's attend Health Visitor clinics unless other clinical need.
- 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)	

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APPROVAL PROCESS

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