NHS
South West Yorkshire
Area Prescribing Committee

Prescribing Specialist Infant Formula

In Primary Care

Guidance for use in:

NHS Bradford City and NHS Bradford Districts CCGs, NHS Calderdale CCG, NHS Greater Huddersfield CCG, NHS North Kirklees CCG and NHS Wakefield CCG

Breast milk is the optimal milk for infants. Breastfeeding should be promoted and encouraged where possible.

It has been agreed not to prescribe Lactose free infant formula, Anti-Reflux (thickened) infant formula and Soya infant formula which can be purchased over the counter (OTC).

Healthy Start vouchers can be used for Lactose free infant formula and Anti-Reflux (thickened) infant formula.

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Approved by South West Yorkshire Area Prescribing Committee: March 2018
Review Date: March 2020

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PURPOSE

These guidelines are a resource to support the appropriate use of prescribable and over-the-counter (OTC) specialist infant formula in primary care. The guidelines are targeted at infants 0-12 months, however, some prescribable formulas can be used past this age. Where this applies the relevant advice is included.

These guidelines provide information on:

- 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 to refer for dietetic advice and/or secondary/specialist care

Whilst these guidelines advise on appropriate prescribing of specialist infant formula, every effort should be made to encourage the continuation of breast feeding as per current WHO guidelines.

Colour key used on the following pages:

Do not prescribe – OTC – Self purchase / Healthy Start Vouchers
Prescribe as first line
Prescribe as second line
Should not routinely be commenced in primary care

QUICK GUIDE TO PRESCRIBING SPECIALIST INFANT FORMULA

COW'S MILK PROTEIN ALLERGY (CMPA)

Take an allergy-focused clinical history: https://www.allergyuk.org/assets/000/001/293/iMAP-Allergy-focused_History_original.pdf?1502804761

IgE-MEDIATED MILD TO MODERATE. Usually within minutes (up to 2 hrs)

Usually one or more symptoms present
Skin – Acute pruritus, erythema, urticarial, angioedema
Acute flaring of atopic dermatitis (eczema)
Gastrointestinal – Vomiting, diarrhoea, abdominal pain, colic

If SEVERE IgE ANAPHYLAXIS – Immediate reaction with severe respiratory and/or CVS signs and symptoms → Emergency Treatment and Admission

NON-IgE-MEDIATED MILD TO MODERATE. Usually within 2-72 hrs
Most commonly seen type CMPA and can be managed in primary care
Usually several symptoms will be present
Treatment resistance – e.g. to atopic dermatitis (eczema) or reflux, increases likelihood of allergy

Gastrointestinal – Irritability, - 'colic', vomiting – 'Reflux' – 'GORD'
Food refusal or aversion
Diarrhoea-like stools, constipation with excessive straining
Abdominal pain
Blood and/or mucus in stools in otherwise well infant
Skin – Pruritus, erythema, non-specific rashes, moderate persistent atopic dermatitis

For detailed advice see iMAP (International Milk Allergy in Primary Care) Guideline 2017 – Guidance on Managing Cow's Milk Allergy in Primary Care https://www.allergyuk.org/health-professionals/mapguideline

Refer to Secondary/Specialist Care if ANY of the Following apply:

- Faltering growth with one or more GI symptoms
- Acute systemic reactions or severe delayed reactions
- Severe atopic dermatitis (eczema) where multiple or cross-reactive food allergies are suspected by the parent
- There is a confirmed IgE-mediated food allergy and concurrent asthma
- Possible multiple food allergies
- Persisting parental suspicion of food allergy (especially where symptoms are difficult or perplexing) despite a lack of supporting history

First-line choices are based on COST only. Prescribers must switch to an alternative product if tolerance issues are identified. OTC Lactose Free formula are not appropriate for CMPA

Extensively Hydrolysed Formula (EHF)

USE FIRST LINE – Use the most cost-effective EHF tolerant for the patient
In cost-effective order these are: **Similac Alimentum** (birth – 2 yrs), **SMA Althera** (birth –3yrs), **Aptamil Pepti 1** (birth – 6 months), **Aptamil Pepti 2** (6 months to 2 yrs), **Nutramigen 1 with LGG** (birth – 6 months), **Nutramigen 2 with LGG** (6 months – 2 yrs)

Amino Acid Formula (AAF)

AAF should normally be started by secondary/specialist care unless child has a history of anaphylactic reaction to cow's milk. Children with potential anaphylaxis should be treated with an AAF based feed as **initial** treatment with immediate referral to secondary care
In cost-effective order these are **SMA Alfamino, Nutramigen Puramino and Neocate LCP**

Review the need for prescribing if yes to any of the following questions: Is child over 2 years of age? Has the formula been prescribed for more than 1 year? Is child prescribed more than the suggested quantities of formula for their age? Can child eat any of the following foods – cow's milk, cheese, yoghurt, ice-cream, custard?

How much powdered infant formula should I prescribe for 28 days? *(prescribe only 1 or 2 tins initially to assess tolerance and palatability)*		
Under 6 months	**6-12 months**	**Over 12 months**
13 x 400g, 12 x 450g or 6 x 900g tins	7-13 x 400g/450g or 3-6 x 900g tins	7 x 400g, 6 x 450g or 3 x 900g tins

GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

Symptoms include:

- Vomiting (usually in the first 6 months of life)
- Regurgitation of significant volumes of feed
- Reluctance to feed
- Crying at feed times
- Small volumes of feed being taken
- Irritability
- Back arching

REFER INFANTS WITH FALTERING GROWTH TO SECONDARY CARE PAEDIATRIC SERVICES WITHOUT DELAY

Rule out overfeeding by establishing the volume and frequency of feeds. Average requirement of formula is 150ml/kg/day for infants up to 6 months and should be spread over 6-7 feeds.

STEP 1 Give parental reassurance and practical advice on avoidance of over feeding, positioning during and after feeding and activity after feeding before moving to step 2

STEP 2

FIRST LINE (**Formula-fed infants**): 2 week trial (with planned review) of an Anti-Reflux formula (thickened) formula, OTC self-purchased.

Aptamil Anti-Reflux, Cow & Gate Anti-Reflux, HiPP Organic Combiotic Anti-Reflux and **SMA PRO Anti-Reflux** are available to buy from supermarkets. **Enfamil AR** is available to buy over the counter from pharmacies. **Healthy Start vouchers** can be used for these formulas. https://www.healthystart.nhs.uk/healthy-start-vouchers/where-to-use-the-vouchers/

Alternatively, if trial of Anti-Reflux formula not tolerated, **Instant Carobel** thickener can be added to the usual formula

SECOND LINE (**Formula-fed infants**): stop anti-reflux (thickened) formula and trial **Infant Gaviscon** for 2 weeks

FIRST LINE (**Breast fed infants**); trial **Infant Gaviscon** for 2 weeks

DO NOT PRESCRIBE THICKENERS OR ANTACIDS WITH ANTI-REFLUX (THICKENED) FORMULAS

REVIEW AFTER 2 WEEKS IF SYMPTOMS NOT IMPROVED REFER TO SECONDARY CARE PAEDIATRIC SERVICES

SECONDARY LACTOSE INTOLERANCE

Symptoms include:

- Abdominal bloating
- Increased wind
- Loose green stools

Usually occurs following an infectious GI illness but can occur alongside new or undiagnosed coeliac disease

Lactose intolerance should be suspected in infants who have had any of the above symptoms that persist for > 2 weeks
Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis

Low lactose/lactose free formula

Aptamil lactose Free or SMA LF are available to buy from supermarkets, or **Enfamil O-Lac** is available to buy over the counter in pharmacies**. Healthy Start vouchers** can be used for these formulas https://www.healthystart.nhs.uk/healthy-start-vouchers/where-to-use-the-vouchers/
In children over 1 year suggest lactose free full fat cow's milk, yoghurt and other dairy products available in supermarkets (e.g. **Lactofree** brand)

Review after 2 weeks to see if symptoms have improved – consider alternative diagnosis if no improvement in symptoms
Continue lactose free formula for up to 8 weeks to allow resolution of symptoms then advise parent to slowly start to re-introduce standard formula/milk into diet.
Refer to specialist care if symptoms have not resolved on commencement of standard formula/milk

FALTERING GROWTH

Faltering growth cannot be detected without using a growth chart. Diagnosis is made when an infant falls below the 0.4th centile *or* crosses 2 centiles downwards on a growth chart. **REFER TO SECONDARY CARE WITHOUT DELAY**

Symptoms include:

Secondary care will lead in prescribing for this group of infants and generally, all such prescribing should be initiated by a paediatrician/paediatric dietitian.

Prescribing can be initiated in primary care in the short term whilst waiting for specialist referral. Prescribe an equivalent volume of a **high energy feed** to the child's usual intake of regular formula until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian

High Energy Feed

In cost-effective order these are **SMA PRO High Energy, Similac High Energy, Infatrini** (ready to feed products)

Suitable for infants up to 18 months or 8kg. Refer to paediatric dietitian and paediatrician

All infants on a high energy feed will need growth (weight and height/length) monitoring to ensure catch up growth occurs. Once this is achieved the high energy feed should be discontinued to minimise excessive weight gain (usually by the paediatrician/dietitian).

Stop high energy feed at 18months or if patient over 8kg. If concerns with weight remain refer to paediatric dietitian

PRE-TERM INFANTS

Pre-term infant formula **should not** be commenced in primary care – infants will already be on pre-term formula milk on discharge from hospital.

It is started for infants born before 34 week gestation.

STARTED IN SECONDARY CARE	**Nutriprem 2 Powder OR SMA Pro Gold Prem 2 Powder**	Use up to 6 months corrected age (i.e. 6 months EDD + 26 weeks)

Ready-to-feed versions of Nutriprem 2 and SMA Gold Prem 2 should NOT be routinely prescribed unless there is a clinical need

Any infant discharged on these formula should have their growth (this includes weight, length, head circumference) monitored by the health visitor/community nurse. Any concerns with infants growth should be referred to the paediatric dietitian and neonatologist/paediatrician.

These formulas should be discontinued by 6 months corrected age and changed to a standard term formula thereafter if no concerns with growth.

If there are concerns at 6 months corrected age refer back to paediatric services.

PRESCRIBING SPECIALIST INFANT FORMULA – FURTHER INFORMATION

COW'S MILK PROTEIN ALLERGY (CMPA)

Symptoms and Diagnosis

- **CMPA is clinically subdivided** into IgE antibody mediated and Non-IgE-mediated
  Acute IgE-mediated reactions (usually within 2 hours) include rash or urticarial, wheeze or vomiting
  Delayed reactions may be non IgE-mediated or mixed (> 2 hours) including eczema, colic, diarrhoea
- **Useful CMPA diagnosis and management flowcharts are available in iMAP Guideline 2017:** https://www.allergyuk.org/health-professionals/mapguideline includes health professional and patient factsheets
- **Take allergy focused clinical history (appendix 2),** key questions:
  - Any Family history of atopy in parents/siblings?
  - Any personal history of atopic disease as infant/young child?
  - Infant's feeding history and growth?
  - Presenting symptoms and signs, focus on those relating to the gut, skin and respiratory systems?
  - Details previous management, response to any treatment or dietary change?
- **If IgE mediated allergy suspected** NICE recommends further investigations with a skin prick test or specific IgE antibody blood test
- **When Non-IgE-mediated allergy is likely, elimination trial of cow's milk for minimum 2 weeks up to 4 weeks**
- **Planned reintroduction – to confirm or exclude the diagnosis of CMPA**
- Most infants with CMPA develop symptoms within 1 week of introduction of CMPA based formula

Onward Referral

- Most infants with CMPA can be managed in primary care until weaned.
- Referral to paediatric dietetics should be made as soon as the infant has started a cow's milk protein free infant formula so that weaning advice is not delayed.
- Breastfeeding mothers following a milk free diet should be referred to a paediatric dietitian who will advise on both the mother's and the infant's diet

Refer to secondary or specialist care if any of the following apply:

1. Faltering growth with one or more gastrointestinal symptoms
2. Acute systemic reactions or severe delayed reactions
3. Significant atopic eczema where multiple or cross-reactive food allergies are suspected by the parent or carer
4. Possible multiple food allergies
5. Persisting parental suspicion of food allergy despite a lack of supporting history (especially where symptoms are difficult or perplexing)

Dietary Management

- **Breast milk is the ideal choice for most infants with CMPA**. If symptoms persist in an exclusively breast fed infant, a maternal milk free diet is indicated for a minimum trial of 2 weeks up to 4 weeks.
- Breastfeeding mothers on a milk free diet **may** require dietary supplementation with 1000mg calcium per day. All breastfeeding mothers should take 10 micrograms of vitamin D daily.
- For Formula feeding only, **extensively hydrolysed formulas (EHF) are the first choice,** unless the infant has a history of anaphylactic symptoms, Heiner Syndrome, eosinophilic oesophagitis, Food Protein-Induce Enterocolitis Syndrome (FPIES) or severe gastro-intestinal and/or skin presentations, particularly in association with faltering growth
- **Amino acid formulas (AAF) should normally be started by secondary or specialist care**
- If a patient has a history of anaphylactic reaction to cow's milk, AAF may be started in primary care, with immediate onward referral to secondary or specialist care.
- For some formula, calcium supplementation may be needed for infants depending on volume and type of formula taken, the paediatric dietitian will advise.

Refer to appendix 1 – comparative costs of specialist infant formulas

COW'S MILK PROTEIN ALLERGY (CMPA)

Review and Discontinuation of Treatment and Challenges with Cow's Milk

- **Review prescriptions regularly** to check that the formula and quantities prescribed are appropriate
- **Avoid adding to the repeat template** for the above reasons, unless a review process is established.
- **Continue cow's milk free diet until 9-12 months age, and for at least 6 months after diagnosis**
- **Challenging with cow's milk – should be reviewed every 6 to 12 months** to assess whether the child has developed a tolerance to cow's milk protein. This can be done at home provided there are no indications for referral to secondary care. See iMAP algorithm (appendix 4) and iMAP milk ladder (appendix 5) https://www.allergyuk.org/assets/000/001/297/iMAP_Final_Ladder-May_2017_original.pdf?1502804928
- **Prescriptions should be stopped** when the child has outgrown the allergy. From around 18 months – 2 yrs age, supermarket calcium enriched soya or oat milk may be suitable as an alternative source of milk where allergy persists. The paediatric dietitian will advise on this.
- **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, yoghurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine, ghee?.
- **Children with multiple allergies may require prescriptions beyond 2 years.** This should always be advised by a paediatric dietitian.

NOTES

- **Do not advise lactose-free formula for infants with CMPA**
- **Soya formula should not** routinely be used for patients with CMPA
- **Soya formula should not be advised at all for those less than 6 months due to high phyto-oestrogen content and** should only be advised in patients over 6 months who do not tolerate the first or second line formula suggested in this guidance
- **EHF and AAF have an unpleasant taste and smell,** which is better tolerated by younger patients. Unless there is anaphylaxis, advise parents to introduce the new formula gradually by mixing with the usual formula used 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.
- **Rice milk** is not suitable for children under 5 years due to its arsenic content
- Infant stools may be strong smelling and have a green colour this is normal with hydrolysed feeds. The formula has a greenish tinge when made up ready for use.

How much powdered infant formula should I prescribe for 28 days?

(Prescribe only 1 or 2 tines initially to assess tolerance and palatability)

Under 6 months	6 – 12 months	Over 12 months
13 x 400g, 12 x 450g or 6 x 900g tins	7-13 x 400g/450g or 3-6 x 900g tins	7 x 400g, 6 x 450g or 2 x 900g tins

GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD)

Symptoms & Diagnosis

- Diagnosis is made from a history of 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 infants 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 infants up to 6 months, and should be offered spread over 6 – 7 feeds. Specific infant formula is not always necessary and resolution of symptoms can occur through giving smaller, more frequent feeds and suitable positioning post-feed
- Symptoms may include regurgitation of a significant volume of feed, reluctance to feed, distress/crying at feed times, small volumes of feed being taken

Onward Referral

- Infants with faltering growth as a result of GORD should be referred to paediatric services without delay.
- If symptoms do not improve 2 weeks after commencing treatment refer to a paediatrician for further investigations

Treatment

Infants with faltering growth should be referred to paediatric services. For other infants the following can be tried:

- If infant is thriving and not distressed, reassure parents and monitor. Provide advice on avoidance of over feeding, positioning during and after feeding, and activity after feeding.
- For formula fed infants consider a 2-week trial (with planned review) with Anti-Reflux (thickened) formula, OTC, e.g. Aptamil Anti- Reflux, Cow & Gate Anti-Reflux, SMA PRO Anti- Reflux or Enfamil AR or thickened feeds using thickening agent (Carobel) added to usual formula.
- Healthy Start vouchers can be used for cows' milk based infant formula suitable from birth; these include Anti-Reflux (thickened) formulas. https://www.healthystart.nhs.uk/healthy-start-vouchers/where-to-use-the-vouchers/
- For Breast fed infants consider a 2 week trial of Infant Gaviscon
- Review after 2 weeks

Anti-Reflux (thickened) formulas must not be used in conjunction with any other thickening agents, (for example Infant Gaviscon), as this can lead to over-thickening of the stomach contents.
In addition these formulas require an acid environment and will not work properly if prescribed with antacid medications such as PPIs or Ranitidine

Review and Discontinuation of Treatment

- Review after 2 weeks
- Infants with GORD will need regular review to check growth and symptoms
- Since GORD will usually resolve spontaneously between 12-15 months, cessation of treatment can be trialled from 12 months
- Once vomiting resolves return to standard formula/breast feeds

NOTES:

- Anti-Reflux (thickened) formulas react with stomach acids, thickening in the stomach rather than the bottle so there is no need to use a large hole teat
- Manufacturer guidelines on how to make up thickened infant formulas are not in line with current recommendations for making up infant formula, since they suggest using cold or hand-hot water rather than water boiled and left to cool to 70C. Where these formulas are recommended, advice should be given by a health professional on how to make them up appropriately.

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 5 days of withdrawal of lactose from the diet confirms diagnosis

Onward Referral

- If symptoms do not resolve when standard formula and / or milk products are reintroduced to the diet, refer to secondary or specialist care
- If the child is weaned and a milk free diet is required, offer advice in primary care and refer to paediatric dietitian
- If breastfeeding refer for local breast feeding support before introducing formula milk

Treatment

- Treat with **low lactose/lactose free formula** (self-purchased OTC) for **6-8 weeks** to allow symptoms to resolve, (rarely symptoms may last up to 3 months), then reintroduction to standard formula/milk products slowly into the diet
- Healthy Start vouchers can be used for cow's milk based infant formula suitable from birth; these include lactose free infant formula. https://www.healthystart.nhs.uk/healthy-start-vouchers/where-to-use-the-vouchers/
- In infants who have been weaned, low lactose/lactose free formula should be used in conjunction with a milk free diet
- If an infant presents with suspected lactose intolerance at 1 year or older and is on cow's milk, then a lactose fee full fat cow's milk can be used for the treatment period. This can be purchased form supermarkets (Lactofree® brand)

Review and Discontinuation of Treatment

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

NOTES

- Lactose intolerance is defined as a non-immune mediated adverse reaction to food, i.e. it is not due to allergy but to a lack of the enzyme lactase
- Primary lactose intolerance is rare and does not usually present until later childhood or adulthood
- **Lactose free infant formulas can be bought at a similar cost to standard infant formula**
- **Soya formula** should **not** routinely be used for patients with secondary lactose intolerance. **It should not be advised at all for infants less than 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 formula suggested in this guidance. Parents should be advised to purchase it as it is a similar cost to cow's milk formula and readily available
- Healthy Start vouchers **cannot** be used for soya infant formula

FALTERING GROWTH

Symptoms and Diagnosis

- Faltering growth is indicated when the growth of an infant falls below the 0.4th centile or crosses 2 centiles downwards on a growth chart
- The height/length of an infant needs to be measured to properly interpret changes in weight. It is not possible to detect faltering growth without using appropriate growth charts
- It is important to consider the reason for faltering growth e.g. iron deficiency anaemia, constipation, GORD or a child protection issue and treat accordingly

NB – Family history needs to be noted; some families are constitutionally small

Onward Referral

- **Infants with faltering growth should be referred to paediatric services without delay**
- If a problem appears related to food refusal/fussy eating, consider referral for behavioural intervention.
- If breastfeeding refer to the infant feeding coordinator or IBCLC (Lactation consultant) before introducing infant formula

Treatment

- Secondary care will lead in prescribing for this group of infants and generally, prescribing should be initiated by a paediatrician/paediatric dietitian
- Prescribing can be initiated in primary care in the short term whilst waiting for specialist referral
- Prescribe an equivalent volume of a **high energy ready-to feed** to the child's usual intake of regular formula until an assessment has been performed and recommendations made by a paediatrician or paediatric dietitian.

Refer to appendix 1 – comparative costs of specialist infant formulas

Review and Discontinuation of Treatment

- All infants on a high energy feed will need growth (weight and height/length) monitored to ensure catch up growth occurs. Once this is achieved the high energy feed should be discontinued to minimise excessive weight gain (usually be paediatrician)

NOTES

- Where the majority of nutrition is provided via NG/NJ/PEG tubes, the paediatric dietitian will advise on appropriate monthly amounts of feed required which may exceed the guideline amounts for other infants
- These feeds are not suitable as a sole source of nutrition for infants over 8kg or 18 months of age
- Do not add feed to repeat templates as ongoing need for feed and amount required will need to be checked with each prescription required
- Manufacturer's instructions regarding safe storage once opened and expiry of ready to drink feeds should be adhered to. This may differ from manufacturer to manufacturer.

PRE-TERM INFANTS

Indications

- Preterm formula is used for infants born before 34 weeks gestation, weighing less than 2kg at birth
- These infants will have been started on nutrient enriched preterm formula prior to discharge from hospital

Onward Referral

- These infants must be under regular review by paediatricians
- The paediatrician will refer any infant with faltering growth to the paediatric dietician
- If there are concerns at 6 months corrected age or at a review one month after the formula is stopped, a referral should be made back to paediatric services

Treatment

- Will require prescriptions for **Nutriprem 2 (powder)** or **SMA Pro Gold Prem 2 (powder)** which should have been started in secondary care

These formulas should not be used in primary care to promote weight gain in patients other than infants born prematurely and started on these feeds by secondary care

Review and Discontinuation of Treatment

- Monitoring of growth (weight, length and head circumference) should be carried out by the health visitor while the infant is on these formulas
- **These formulas should be discontinued by 6 months corrected age**
- Not all infants need these formulas 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
- **Ready-to-feed versions of preterm formula should not to be routinely prescribed** unless there is clinical need e.g. immunocompromised infant

COMPARATIVE COSTS OF SPECIALIST INFANT FORMULAS

First-line choices are based on COST only. Prescribers must switch to an alternative product if tolerance issues are identified.

Formula	Size of tin (g)	Cost per tin	Age Range	Cost per 100ml	Comments	
Similac Alimentum	400g	£9.10	Birth – 2 years	0.29	*Casein based*	*Extensively Hydrolysed Formula*
SMA Althera	450g	£10.68	Birth – 3 years	0.31	*Whey based*	*Extensively Hydrolysed Formula*
Aptimil Pepti 1	400g (& 800g)	£9.87	Birth – 6 months	0.34	*Whey based*	*Extensively Hydrolysed Formula* *Contains Pre-biotics*
Aptamil Pepti 2	400g (& 800g)	£9.41	6 months – 2 years	0.34		
Nutramigen 1 LGG	400g	£11.21	Birth – 6 months	0.38	*Casein based*	*Extensively Hydrolysed Formula* *Contains Pro-biotics*
Nutramigen 2 LGG	400g	£11.21	6 months – 2 years	0.41		
SMA Alfamino	400g	£23.81	Birth until able to tolerate OTC products	0.82	*Amino Acid Formula (AAF) should normally be started by secondary or specialist care unless patient has a history of anaphylactic reaction to cow's milk. For these patients AAF may be started in primary care with immediate onward referral to secondary or specialist care*	
Nutramigen Puramino	400g	£27.63	Birth until able to tolerate OTC products	0.94		
Neocate LCP	400g	£28.70	Birth until able to tolerate OTC products	0.99		
Neocate Junior	400g Strawberry, vanilla, unflavoured	£28.70	Over 1 year	0.99	*Amino Acid Formula for over 1 yr, should only be used by secondary or specialist care*	
Neocate Spoon	15 x 37g sachets unflavoured	£2.66 per sachet	From 6 - months		*Recommended by a paediatric dietitian only*	

Key	USE FIRST LINE	USE SECOND LINE	SHOULD NOT BE ROUTINELY COMMENCED IN PRIMARY CARE

Prices correct as 1st Jan 2018

First-line choices are based on COST only. **Prescribers must switch to an alternative product if tolerance issues are identified.**

FALTERING GROWTH						
Feed	**Size of bottle (ml)**	**Max bottles for 28 days**	**Age Range**	**Price (per bottle)**	**Cost per 100ml**	**Comments**
High Energy Feed						
SMA PRO High Energy	200ml	84 x 200ml	Birth – 18 months (or 8kg)	£1.96 per 200ml	£0.98	*Refer any infant being commenced on a high energy feed to a paediatric dietitian for appropriate monitoring*
Similac High Energy	65ml, 120ml & 200ml	260 x 65ml 140 x 120ml 84 x 200ml	Birth – 18 months (or 8kg)	£2.29 per 200ml	£1.15	
Infatrini	100ml, 200ml & 500ml	168 x 100ml 84 x 200ml 32 x 500ml	Birth – 18 months (or 8kg)	£2.31 per 200ml	£1.16	
KEY:	**USE FIRST LINE**		**USE SECOND LINE**			**SHOULD NOT BE ROUTINELY COMMENCED IN PRIMARY CARE**

PRE-TERM INFANTS						
Formula	**Size of tin (g)**	**Max tins for 28 days**	**Age Range**	**Price(per tin/bottle)**	**Cost per 100ml**	**Comments**
SMA Pro Gold Prem 2 powder	400g	10	Birth up to a max of 6 months corrected age*	£4.92	£0.17	*These infants would have been started on nutrient enriched preterm formula prior to discharge from hospital* *Stop preterm formula at 6 months corrected age and change to standard term formula. Refer to dietitian if concerns regarding weight gain* *NOTE – these formulas should **not** be started in primary care to promote weight gain.* **6 months corrected age = EDD + 26 weeks*
Nutriprem 2 powder	900g	5		£11.67	£0.20	
Nutriprem 2 liquid Ready-to feed	200ml	**Ready-to-feed formulation not to be routinely prescribed** unless there is clinical need e.g. immunocompromised infant		£1.74	£0.87	
SMA Pro Gold Prem 2 liquid Ready-to feed	200ml			£1.64	£0.82	

Prices correct as 1st Jan 2018

Appendix 2

The iMAP Allergy-focused Clinical History for Suspected Cow's Milk Allergy in Infancy

'The Cornerstone of the Diagnosis'

Ask about:

- A family history of atopic disease (atopic dermatitis, asthma, allergic rhinitis or food allergy) in parents or siblings
  - a reported history along with symptoms of suspected cow's milk allergy makes the diagnosis more likely; this applies to both IgE-mediated and non-IgE-mediated
- Sources of cow's milk protein and how much is being or was ingested:

  Exclusive breast feeding - when cow's milk protein from maternal diet comes through in the breast milk (low risk of clinical allergy)

  Mixed feeding - when cow's milk protein is given to the breast feeding infant e.g. top-up formulas, on weaning with solids

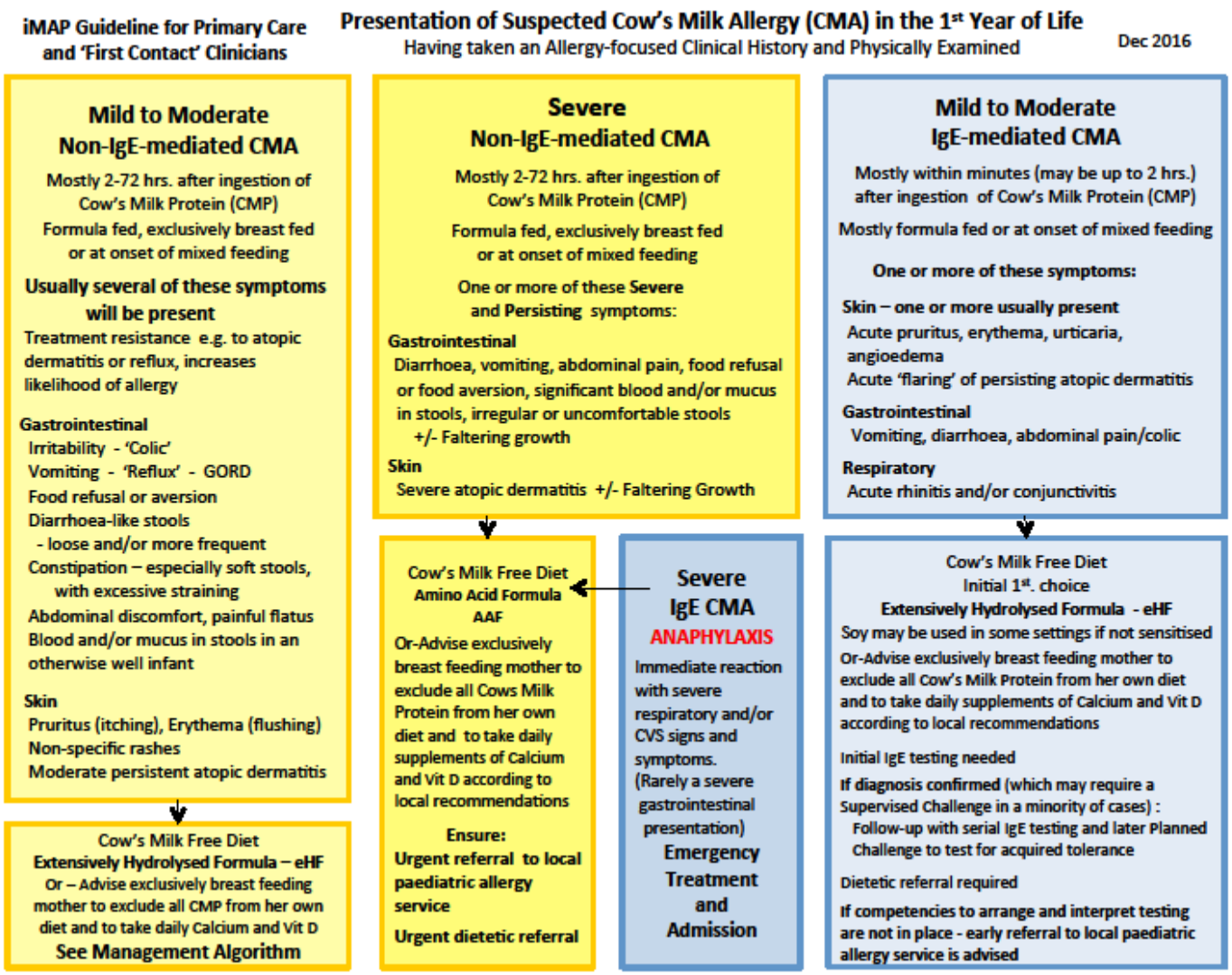
  Formula-feeding infant - the commonest presentation, particularly in countries where there is poor adherence with the WHO guidance of exclusive breastfeeding for 6 months

- Presenting symptoms, to include:
  - if more than one symptom, the sequence of clinical presentation of each one
  - age of first onset
  - timing of onset following ingestion (atopic dermatitis - such 'timing' can be very variable)

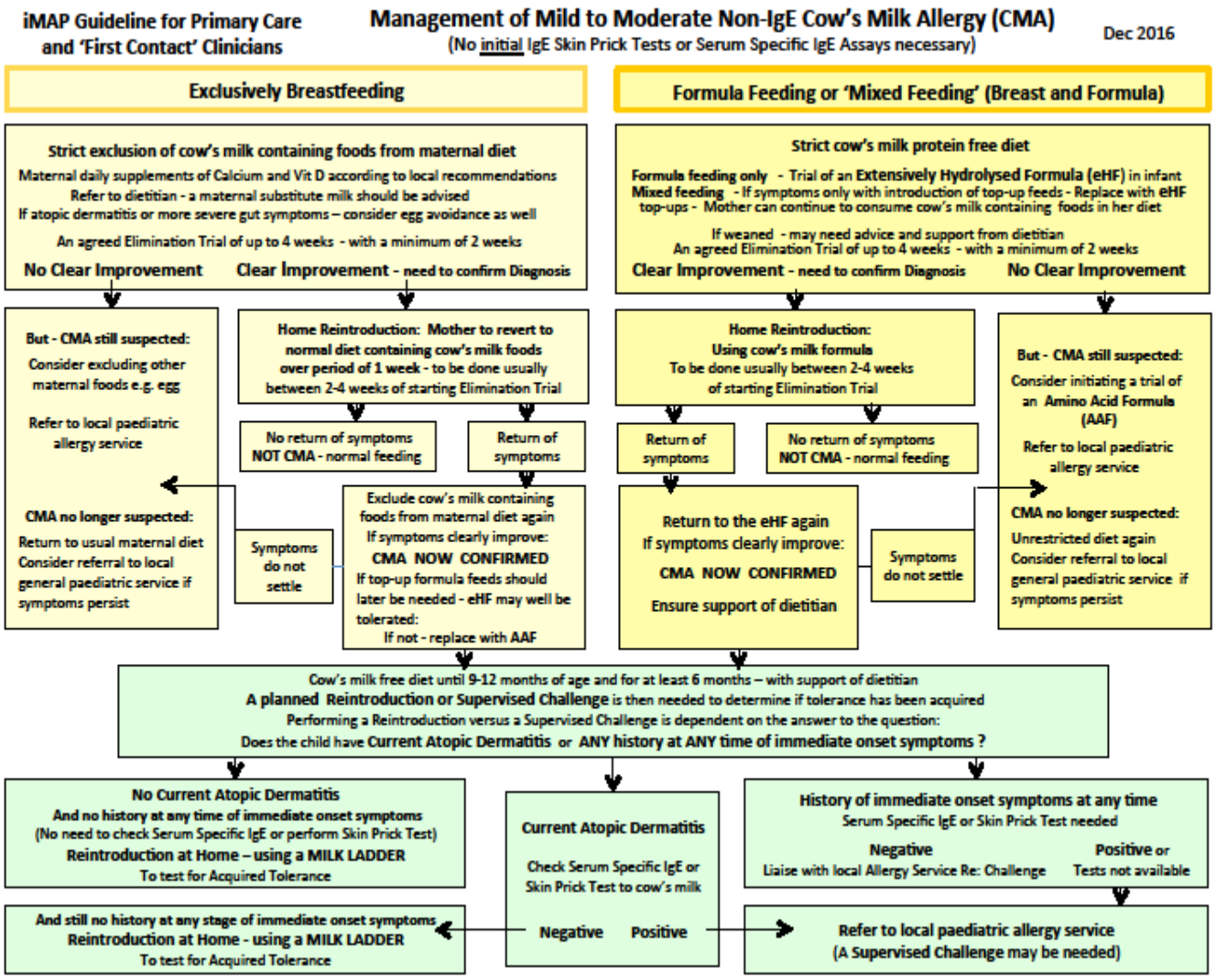
    IgE-mediated - usually within minutes, but can be up to 2 hours

    Non-IgE-mediated - usually after ≥2 hours or even days
  - duration, severity and frequency
  - reproducibility on repeated exposure
  - amount and form of milk protein that may be causing symptoms
- Details of any concern with feeding difficulties and/or poor growth
- Details of any changes in diet and any apparent response to such changes
- Details of any other previous management, including medication, for the presenting symptoms and any apparent response to this

Appendix 3


iMAP Guideline for Primary Care and 'First Contact' Clinicians
Presentation of Suspected Cow's Milk Allergy (CMA) in the 1st Year of Life
Having taken an Allergy-focused Clinical History and Physically Examined
Dec 2016
Mild to Moderate Non-IgE-mediated CMA
Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP)
Formula fed, exclusively breast fed or at onset of mixed feeding
Usually several of these symptoms will be present
Treatment resistance e.g. to atopic dermatitis or reflux, increases likelihood of allergy
Gastrointestinal
Irritability - 'Colic'
Vomiting - 'Reflux' - GORD
Food refusal or aversion
Diarrhoea-like stools - loose and/or more frequent
Constipation – especially soft stools, with excessive straining
Abdominal discomfort, painful flatus
Blood and/or mucus in stools in an otherwise well infant
Skin
Pruritus (itching), Erythema (flushing)
Non-specific rashes
Moderate persistent atopic dermatitis
Cow's Milk Free Diet
Extensively Hydrolysed Formula – eHF
Or – Advise exclusively breast feeding mother to exclude all CMP from her own diet and to take daily Calcium and Vit D
See Management Algorithm
Severe Non-IgE-mediated CMA
Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP)
Formula fed, exclusively breast fed or at onset of mixed feeding
One or more of these Severe and Persisting 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
Amino Acid Formula
AAF
Or-Advise exclusively breast feeding mother to exclude all Cows Milk Protein from her own diet and to take daily supplements of Calcium and Vit D according to local recommendations
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 hrs.) after ingestion of Cow's Milk Protein (CMP)
Mostly 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
Acute rhinitis and/or conjunctivitis
Cow's Milk Free Diet
Initial 1st. choice
Extensively Hydrolysed Formula - eHF
Soy may be used in some settings if not sensitised
Or-Advise exclusively breast feeding mother to exclude all Cow's Milk Protein from her own diet and to take daily supplements of Calcium and Vit D according to local recommendations
Initial IgE testing needed
If diagnosis confirmed (which may require 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
If competencies to arrange and interpret testing are not in place - early referral to local paediatric allergy service is advised

Appendix 4


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)
Dec 2016
Exclusively Breastfeeding
Formula Feeding or 'Mixed Feeding' (Breast and Formula)
Strict exclusion 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
If atopic dermatitis or more severe gut symptoms – consider egg avoidance as well
An agreed Elimination Trial of up to 4 weeks - with a minimum of 2 weeks
No Clear Improvement
Clear Improvement - need to confirm Diagnosis
Strict cow's milk protein free diet
Formula feeding only - Trial of an Extensively Hydrolysed Formula (eHF) in infant
Mixed feeding - If symptoms only with introduction of top-up feeds - Replace with eHF top-ups - Mother can continue to consume cow's milk containing foods in her diet
If weaned - may need advice and support from dietitian
An agreed Elimination Trial of up to 4 weeks - with a minimum of 2 weeks
Clear Improvement - need to confirm Diagnosis
No Clear Improvement
But - CMA still suspected:
Consider excluding other maternal foods e.g. egg
Refer to local paediatric allergy service
CMA no longer suspected:
Return to usual maternal diet
Consider referral to local general paediatric service if symptoms persist
Home Reintroduction: 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
Home Reintroduction:
Using cow's milk formula
To be done usually between 2-4 weeks of starting Elimination Trial
Return of symptoms
No return of symptoms NOT CMA - normal feeding
Return to the 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)

Appendix 5

THE iMAP MILK LADDER

To be used only in children with Mild to Moderate Non-IgE Cow's Milk Allergy
Under the supervision of a healthcare professional
PLEASE SEE THE ACCOMPANYING RECIPE INFORMATION

STEP 6 — Pasteurised milk/suitable infant formula
Amount – start with 100ml (3.5 fl oz) of pasteurised milk/infant formula and mix this with current milk replacement. Build up to 200 ml (7 fl oz). If this is tolerated switch all current milk replacements (bottle and in breakfast cereals) to pasteurised milk or suitable infant formula. Discuss what is an appropriate amount of milk/milk products with your healthcare professional. UHT and sterilised milk will be tolerated as well.

Once your child tolerates yoghurt, butter, spread, chocolate buttons, fromage frais, petit filous (be careful of the sugar content), you can introduce softer cheese like cream cheese and camembert/brie – remember to use pasteurised soft cheese for children

STEP 5 — Yoghurt
Amount - 125mls (4.5 fl oz)

STEP 4 — Cheese
Amount 15g (½ fl oz) (hard cheese e.g. cheddar or parmesan) Once your child tolerates cheese, you can introduce 15g baked cheese on a pizza or baked on other food as well.

STEP 3 — Pancake
Amount - ½ and build up to 1 (see Recipe)

STEP 2 — Muffin
Amount - ½ and build up to 1 (see Recipe)

STEP 1 — Cookie/Biscuit
Amount - 1 and build up to 3 (see Recipe)

AT EACH OF THE FOLLOWING STEPS
Cookie, muffin, pancake, cheese and yoghurt
It may be advisable in some cases to start with a ¼ or a ½ of that particular food and then over a few days to gradually build up to a whole portion - Please ask your healthcare professional for guidance on this

THE LOWER STEPS ARE DESIGNED TO BE USED WITH HOME MADE RECIPES. THIS IS TO ENSURE THAT EACH STEP HAS THE APPROPRIATE MILK INTAKE. THE RECIPES WILL BE PROVIDED BY YOUR HEALTHCARE PROFESSIONAL
Should you wish to consider locally available store-bought alternatives - seek the advice of your healthcare professional Re: availability

October 2016

Practical Pointers for Parents/Carers on using at home the iMAP Milk Ladder

ONLY FOR CHILDREN WHO ARE BEING MANAGED AS MILD-TO-MODERATE NON-IgE COW'S MILK ALLERGY

The practical concept of this Ladder is the recognised fact that the more 'baked' cow's milk protein is, usually the less allergenic it is. Therefore you will see that Step 1 begins with a form of very well baked milk protein and then the further Steps give examples of gradually less well baked milk protein products.

The following 'Pointers' should make it easier for you to understand how best to use this Ladder. We advise that you are supported by a Healthcare Professional (HCP) until the Ladder has been successfully climbed. This may be your doctor, nurse but ideally your dietitian.

- Before starting the Ladder and progressing to each further Step, please ensure that your child is well at the time and also that any tummy symptoms, bowel symptoms or eczema are settled.
- Most children will start on Step 1. However some may be already eating one or more foods on the Ladder. If that is the case, you need to be advised which Step you should start on.
- The Ladder has 6 Steps, but your HCP may adjust the number of Steps to suit your child best.
- The time spent on each Step will vary from one child to another depending on their individual expression of milk allergy. This should also be discussed and agreed with you.
- The amounts in the Ladder are given as a guide – occasionally smaller or larger amounts may be recommended.
- Each of the early Steps of the Ladder importantly is accompanied by the appropriate recipe (see recipes).
- Each of the recipes has an egg and wheat free option (they are all soya free) to make the Ladder suitable for children who may have other co-existing food allergies.
- If the food on any Step of the Ladder is tolerated, your child should continue to consume this (as well as all the foods in the previous Steps) and then try the food on the next agreed Step.
- If your child does not tolerate the food in a particular Step, simply go back to the previous Step. You should then be advised when that further Step can be tried again.

October 2016

REFERENCES/FURTHER READING

Cow's Milk Protein Allergy

NICE Clinical Guideline 116 Food Allergy in Children and Young People.
https://www.nice.org.uk/guidance/CG116

The iMAP Guideline 2017 – Guidance on Managing Cow's Milk Allergy in Primary Care
https://www.allergyuk.org/health-professionals/mapguideline

Milk allergy: MAP publishes international update https://www.guidelinesinpractice.co.uk/allergy/milk-allergy-map-publishes-international-update-/453526.article

Venter et al.Better recognition, diagnosis and management of non-IgE-mediated cow's milk allergy in infancy: iMAP-an international interpretation of the MAP guideline. Clinical and Translational Allergy 2017; 7: 26. https://ctajournal.biomedcentral.com/articles/10.1186/s13601-017-0162-y

Schoemaker AA et al. Incidence and natural history of challenge-proven cow's milk allergy in European children – EuroPrevall birth cohort. Allergy 2015; 70(8): 963-72

Dietary products used in infants for treatment and prevention of food allergy. Joint statement of the European Society for Paediatric Allergology and Clinical Immunology (ESPACI) Committee on Hypoallergenic Formulas and the European Society for Paediatric Gastroenterology, Hepatolgy and Nutrition (ESPGHAN) Committee on Nutrition. *Arch Dis Child 1990; 81:80-84.*

Soya Formula
Department of Health: CMO's Update 37 (2004). *Advice issued on soya based infant formula.*
Paediatric group Position Statement on Use of Soya Protein for Infants. *British Dietetic Association: February 2004.*

Rice Milk
Food Standard Agency, Arsenic in rice last updated 2016 https://www.food.gov.uk/science/arsenic-in-rice

Gastro-Oesophageal Reflux Disease
Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society of Pediatric Gastroenterolgy, Hepatology and Nutrition (NASPGHAN) and the European Society of Pediatric Gastroenterology, Hepatology and Nutrition. (ESPGHAN) *Journal of Ped Gastroenterology and Nutrition 2009 49: 498-547.*

Secondary Lactose Intolerance
Buller HA, Rings EH, Montgomery RK,Grand RJ. Clinical aspects of lactose intolerance in children and adults. *Scand J Gastroenterolgy Suppl 1991;188:73-80*

General
Clinical Paediatric Dietetics 4th Edition (2014). Edited by Vanessa Shaw and Margaret Lawson. Published by Blackwell Publishing.

First Steps Nutrition – specialised infant milks in the UK: 0-6 months Information for health professionals
http://www.firststepsnutrition.org/pdfs/Specialised_infant_milks_January_2018b.pdf

Making the most of Healthy Start – A practical guide:
http://www.firststepsnutrition.org/pdfs/Making_the_Most_of_Healthy_Start_Sep_2017.pdf

Infant Feeding Guidelines. Health and Social Care Board. January 2013 Version 0.2 Final Draft.

PrescQIPP, Appropriate prescribing of specialist infant formulae Bulletin146 November 2016

NICE guidance on faltering growth in references (Sept 2017) https://www.nice.org.uk/guidance/ng75

https://www.nice.org.uk/guidance/ng75