

Guidelines for the prescribing of specialist infant formula in primary care: Luton and Bedfordshire

December 2019

This document is a revised edition written and agreed by Paediatricians, Paediatric Dietitians, GPs and Medicine Optimisation Teams within Luton and Bedfordshire Clinical Commissioning Groups.

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Introduction

Whilst these guidelines are for specialist infant formula, breast milk is the optimal milk for infants. Breastfeeding should be promoted and encouraged where possible.

This guideline aims to provide information to GP's and Health Visitors on the use of prescribable infant formulae. It provides guidance on initial and on-going prescribing and when to discontinue prescribing.

The guideline covers formula to prescribe from birth to 1 year of age. Some conditions may require formula to be prescribed beyond this age and this will be referenced under 'Review Criteria'.

Specific exceptions: If all nutrition is received by a feeding tube e.g. NG/NJ/PEG for clinical reasons (such as an unsafe swallow), a dietitian will recommend a prescription for the appropriate monthly amount and type of formula. A dietitian may calculate a different volume or suggest the use of a formula outside these guidelines based on individual need. The specific need and clinical rationale will be included with the feed prescription request.

Volumes of feed to prescribe infants

Please use the guide below to estimate quantity of formula to prescribe. Volumes stated are the maximum that are required for an average child (on the 50th percentile for weight); however, those under the care of a dietitian may require more or less formula. Over prescribing can occur if infants are being overfed. If you suspect an infant is being overfed or a parent requires support on responsive feeding refer to the health visiting team for assessment.

Initially prescribe a 1 week trial of 2-3 x 400g or 450g tins or 1 x 800g tin; to see if the infant will accept it

Age of infant	Number of tins for 28 days
Under 6 months	10 x 400g <u>OR</u> 9 x 450g tins <u>OR</u> 6 x 800g tins
Between 6 – 12 months	7 x 400g tins <u>OR</u> 6x 450g tins
Over 1 year	7x 400g <u>OR</u> 6 x 450g tins <u>OR</u> other as stated on prescription request from paediatric dietitian

**Summary Guidelines for the Prescribing of Specialist Infant Formula's in Primary Care
December 2019**

Diagnosis	Guidance	Age range	Formula	Vol. < 6mths for 28 days	Vol. > 6mths for 28 days	Review criteria
Cow's Milk Allergy (CMA) (page 6&7)	First Line Extensively Hydrolysed Formula (EHF) to be used first line if mild to moderate milk allergy suspected.	Birth to 1-2 years	1st line EHF primary care Similac Alimentum (Abbott Nutrition) <i>Casein based</i> <i>Lactose free</i> Other EHF formulas maybe initiated by secondary or specialist care.	10 x 400g	7x 400g	Children prescribed any specialist infant formulae should be reviewed every 6 months . Prescribe up to 2yrs of age or until age-appropriate alternative milk is advised/child tolerates cow's milk. Children with multiple allergies may require prescribed specialist infant formula up to 2 yrs of age .
	Amino Acid based formula Preferably started in secondary care for multiple allergies, severe non IgE mediated allergies or IgE mediated allergy.	Birth to 2 years	1st line primary care Alfamino (SMA Nutrition) (v) Other amino acid based formulas maybe initiated by secondary care. Including: Puramino Neocate LCP Neocate Syneo	10 x 400g	7x 400g	
	Specialist follow on formulas	Over 1 year	Neocate Junior (Nutricia) (h) Nutramigen 3 (Mead and Johnson)	Quantity to be advised following assessment	Quantity to be advised following assessment	These products are only to be issued on written request from a paediatric dietitian.
Pre-term (page 8)	Specialist formula. Only start in secondary care	Birth to 3-6 months corrected age	Nutriprem 2 Powder (Cow & Gate)	6 x 800g	n/a	Do not issue liquid formulations as there is no clinical benefit.
			SMA Gold Prem 2 (SMA Nutrition)	10 x 400g	n/a	
Faltering Growth (page 9)	Specialist High energy formula. Only start in secondary or specialist care	Birth to 1 year Up to 18 months of age or 8kgs body weight.	Infatrini (Nutricia) (h)	Quantity to be advised following assessment	Quantity to be advised following assessment	Review recent assessment report from paediatrician or paediatric Dietitian.
			SMA High Energy (SMA Nutrition)			
			Similac High Energy (Abbott Nutrition) (h) (v)			

Note: The guidelines are intended for use in primary care, if clinically indicated an alternative product may be requested by secondary or specialist care. The clinical rationale will be stated in written correspondence.

KEY	(v) suitable for vegetarians ((h) halal approved (ve) suitable for vegans.
	Use as first line extensively hydrolysed formula (EHF).
	Preferably started in secondary or specialist services. If started in primary care, refer patient to acute service for assessment with paediatrician and specialist dietetic support
	Over the counter only- parents/carers need to purchase from supermarket or local pharmacy

**Summary of Guidelines for Specialist Infant formula's (TO BE PURCHASED BY PARENT/CARER)
December 2019**

Diagnosis	Guidance	Age range	Formula	Considerations for use
<p align="center">Anti-Reflux</p>	<p>To be used under medical supervision</p> <p>(Food for special medical purposes)</p>	<p>Birth to 1 year</p>	<p align="center">SMA Anti-Reflux (SMA Nutrition)</p> <p align="center">Cow and Gate Anti-Reflux (Cow and Gate) (h)</p> <p align="center">Aptamil Anti-Reflux (Nutricia)</p> <p align="center">HIPP Organic Anti-Reflux (HIPP)</p>	<p>Advise parents to make feeds according to manufacturer instructions (note preparation differs between brands and a fast flow teat may be required)</p> <p>Do not use anti-reflux formula with other thickener products (e.g. carbel) or antacids.</p> <p>If anti-reflux formula is unsuccessful in resolving symptoms stop the formula and consider starting alginate therapy as per NICE guidance.</p>
<p align="center">Lactose free</p>	<p>To be used under medical supervision</p> <p>(Food for special medical purposes)</p>	<p>Birth to 1 year</p>	<p align="center">Aptamil Lactose Free (Nutricia)</p> <p align="center">SMA Lactose Free (SMA Nutrition)</p>	<p><u>Not</u> suitable for infants with suspected cow's milk protein allergy</p> <p>Should only be used for a maximum of 6-8 weeks</p> <p>After 1 year can use shop bought full fat lactose free milk</p>
<p align="center">Soya</p> <p>(May be advised in exceptional cases of cow's milk allergy see page 7)</p>	<p>To be used under medical supervision</p> <p>(Food for special medical purposes)</p>	<p>6 months to 1 year</p>	<p align="center">SMA Wysoy SMA Nutrition)</p>	<p>Soya formula should only be used after 6 months of age if the first line extensively hydrolysed formula is not accepted due to taste.</p> <p>Soya formula may be advised for infants diagnosed with galactosaemia</p> <p>Unsuitable for infants who have reacted to soya traces in food.</p>

Quick reference summary: common feeding concerns in babies

	First line advice for parents/carers (taken from NHS choices website)
Vomiting	<ul style="list-style-type: none"> Carry on breastfeeding/bottle feeding baby. If being sick, try giving small feeds more often than usual Give babies on formula or solid food small sips of water between feeds Do not make baby formula weaker – use it at usual strength <p>Medical review: Signs of dehydration or vomiting occurring longer than 2 days</p>
Regurgitation/ Reflux	<ul style="list-style-type: none"> Get advice re: baby's position during and after breastfeeding or bottle feeding Hold baby upright for as long as possible after feeding Smaller more frequent feeds if formula fed (check not exceeding 150mlskg/day – divide total mls a day by latest weight) Make sure baby sleeps flat on their back (should not sleep on their side or front) <p>Medical review: Not improving after 2 weeks of trying things to ease reflux, gets reflux for the first time after 6 months of age, older than 1 year, not gaining weight, feed refusal</p>
Constipation	<ul style="list-style-type: none"> Can occur when baby starts taking formula or processed foods If baby is formula fed, offer extra drinks of water between feeds – <u>do not</u> add more water to formula feeds. Breastfed babies rarely get constipated, continue to offer breast milk Try gently moving baby's legs in a bicycle motion or careful massaging the tummy to stimulate the bowels Sometimes it can take a few weeks for symptoms to improve. <p>Medical review: Not improving with first line advice, blood in stool, poor weight gain</p>
Diarrhoea	<ul style="list-style-type: none"> Carry on breastfeeding/bottle feeding baby. If also being sick, try giving small feeds more often than usual Give babies on formula or solid food small sips of water between feeds Do not make baby formula weaker – use it at usual strength <p>Medical review: Signs of dehydration or diarrhoea continues longer than 7 days</p>
Colic (Crying more than 3 hours a day, 3 days a week for at least 1 week)	<ul style="list-style-type: none"> Seek advice and support from a health visitor Hold or cuddle baby when they are crying a lot Sit or hold baby upright during feeding to stop them swallowing air Wind baby after feeds Bath baby in a warm bath Have some white noise in the background to distract them Keep feeding baby as usual <p>Note: There is very little evidence for anti-colic drops and probiotic supplements, changes to maternal diet if breastfeeding, spinal manipulation or cranial osteopathy.</p> <p>Medical review: If first line strategies are not improving symptoms, parent/carer finding it hard to cope, baby is older than 4 months of age</p>

Cow's milk allergy (CMA)

DIAGNOSIS:

- Cow's milk allergy (CMA) suspected after taking an allergy focused history as per NICE Food allergy in children. [Find here](#)
- Lactose free formulas are **not suitable** for treating CMA as they contain cow's milk protein (see secondary lactose intolerance on page 10)
- Refer to local cow's milk allergy pathway or iMAP guideline (2019) for clinical advice on diagnosing and managing cow's milk allergy in primary care. [Find here](#)

Mild to Moderate non IgE Mediated Symptoms	Severe non IgE mediated Symptoms	Severe IgE Mediated Symptoms
<p>Mostly 2-72 hours after ingestion of Cow's milk protein.</p> <p>Usually several of these symptoms will be present, symptoms persisting despite first line measures are likely to be allergy related:</p> <ul style="list-style-type: none"> • Gastrointestinal – persistent irritability 'colic' reflux (GORD), vomiting, food refusal or aversion, diarrhoea like stools, constipation especially soft stools with excessive straining, abdominal discomfort, painful flatus blood/mucous in stools otherwise well infant. • Respiratory -“catarrhal airway signs”. • Skin- significant atopic eczema, pruritus (itching) erythema (flushing) non-specific rashes, moderate persistent atopic dermatitis <p>The symptoms above are very common in otherwise well infants so clinical judgement is required. Trial exclusion diets must only be considered if history and examination strongly suggest cow's milk allergy especially in breastfed infants.</p> <p>TREATMENT SUMMARY:</p> <p>Exclusively breastfeeding mother Trial strict exclusion of all cow's milk from her own diet and advise to take calcium and vitamin D for 2-4 weeks. Find diet sheet here</p> <p>Formula-fed or 'mixed feeding' If mother unable to revert to fully breastfeeding, trial extensively hydrolysed formula first line Similac Alimentum for 2-4 weeks.</p> <p>Complete iMAP home challenge to confirm diagnosis after elimination trial Find here then refer to paediatric dietitian</p> <p>Refer to iMAP (2019) for treatment guidelines. Find here</p>	<p>Mostly 2-72 hours after ingestion of Cow's milk protein.</p> <p>One but usually more of these severe, persisting and treatment resistant symptoms:</p> <ul style="list-style-type: none"> • Gastrointestinal – Diarrhoea, vomiting, abdominal pain, food refusal or food aversion, significant blood and/or mucus in stools, irregular or uncomfortable stools with/without faltering growth • Skin – severe atopic dermatitis with/without faltering growth <p>TREATMENT SUMMARY</p> <p>Exclusively breastfeeding mother Trial strict exclusion of all cow's milk from her own diet and advise to take calcium and vitamin D for 2-4 weeks. Find diet sheet here</p> <p>Formula-fed or 'mixed feeding' If mother unable to revert to fully breastfeeding, trial extensively hydrolysed formula first line Similac Alimentum for 2-4 weeks.</p> <p>URGENT REFERRAL TO LOCAL ALLERGY SERVICE (Includes dietitian)</p> <p>Refer to iMAP (2019) for treatment guidelines. Find here</p>	<p>Mostly within minutes of ingestion of Cow's milk protein or up to 2 hours after.</p> <ul style="list-style-type: none"> • Anaphylaxis – immediate reaction with severe respiratory or cardiovascular signs and symptoms (rarely a severe gastrointestinal presentation) <p>One but usually more of these severe, persisting and treatment resistant symptoms:</p> <ul style="list-style-type: none"> • Gastrointestinal - vomiting, diarrhoea, abdominal pain/colic. • Skin- acute pruritus, erythema, urticaria, angioedema or acute “flaring” of persisting atopic dermatitis. • Respiratory- rarely in isolation of other symptoms acute rhinitis and/or conjunctivitis <p>TREATMENT SUMMARY</p> <p>Exclusively breastfeeding mother Trial strict exclusion of all cow's milk from her own diet and advise to take calcium and vitamin D for 2-4 weeks Find diet sheet here</p> <p>Formula-fed or 'mixed feeding' If mother unable to revert to fully breastfeeding, trial extensively hydrolysed formula first line Similac Alimentum for 2-4 weeks</p> <p>URGENT REFERRAL TO LOCAL ALLERGY SERVICE (Includes dietitian)</p> <p>Refer to iMAP (2019) for treatment guidelines. Find here</p>

Prescribing criteria	Age range	Recommended formula	Clinical Indications
FIRST LINE Extensively hydrolysed formula (EHF)	Birth to 1 - 2 years	<u>1st line primary care</u> Similac Alimentum (Abbott Nutrition) <i>Casein based</i> <i>Lactose free</i> Other EHF formulas maybe initiated by secondary or specialist care.	Suspected or diagnosed cow's milk allergy.
AMINO ACID Formulas Preferably started in specialist or secondary care	Birth to 2 years	<u>1st line secondary care:</u> Alfamino (SMA Nutrition) (v)	Use if symptoms have not resolved on EHF.
		Other amino acid based formulas maybe initiated by secondary care. Including: Puramino Neocate LCP Neocate Syneo	Do not use if extensively hydrolysed formula is not accepted simply based on taste, contact the dietetic team for advice on alternative.
Specialist milk over 1 year	Over 1 year	Neocate Junior (Nutricia) Nutramigen 3 (Mead and Johnson)	These products are <u>only</u> to be issued on written request from a paediatric dietitian.
OVER THE COUNTER - NOT TO BE PRESCRIBED Soya infant formulas only	6 month to 1 year	SMA Wysoy (SMA Nutrition) (v) (h)	Soya formula should only be used <u>after</u> 6 months of age and if the first line EHF is not accepted due to taste. If the child presents with a suspected CMPA over 1 year of age, and there are no growth concerns, Calcium fortified nutrient enriched no added sugar plant based milks can be purchased in most supermarkets. Refer to dietetic team for assessment.

GP REVIEW CRITERIA:

- An extensively hydrolysed formula (EHF) can be prescribed up to the age of 2 years, however, some children may tolerate a plant based milk alternative over 1 year of age and their prescription formula can be stopped. Refer to the latest written correspondence from a Paediatric Dietitian for guidance.
- All patients prescribed these formulas require a regular review by a Paediatric Dietitian for advice on calcium intake, challenging with cow's milk using the milk ladder and other feeding issues relating to a restricted diet.

Pre-term infants

DIAGNOSIS:

Infants born before 34 weeks gestation and weighing less than 2kg at birth are considered pre-term and may be discharged from hospital on a **pre-term nutrient enriched discharge formula**.

TREATMENT SUMMARY:

- Any infant discharged on these formulas will require growth monitoring (weight, length and head circumference) by the health visiting team.
- Please note pre-term infants can occasionally be discharged on the liquid formulations (Nutriprem 2 or SMA Gold Prem 2) from hospitals out of area. There are no clinical benefits to using liquid formulations.
- **Do not prescribe liquid formulations in the community** due to significant cost implications.

Prescribing criteria	Age range	Recommended formula
SECONDARY CARE Formula that should only be started in secondary care.	Use up to 3 months corrected age* but can be prescribed up to 6 months corrected age*.	Nutriprem 2 Powder (Cow and Gate)
		SMA Gold Prem 2 Powder (SMA Nutrition)
* Corrected age: Corrected age is the actual age minus the number of weeks premature.		

GP REVIEW CRITERIA:

- Pre term formula can be stopped at 3- 6 months corrected age if there is excessive or rapid weight gain. If stopped under 6 months of age, vitamin supplementation will be required in line with local guidelines. [Find east of england neonatal network iron and vitamin guidance here](#)
- All pre-term formulas should be stopped by 6 months corrected age and parents advised to start a standard infant formula.
- If there are concerns regarding an infant's growth on return to standard formula, request review with acute team (including a paediatric dietitian).
- For pre-term starting solids advice refer to the Bliss website. [Find here](#)

Faltering growth

DIAGNOSIS:

NICE Faltering Growth-recognition and management (2017) [Find here](#)

A weight, length and ideally head circumference are required for diagnosis. Faltering growth is defined by one of the following criteria:

- A weight of an infant falls below the bottom centile (0.4th)
- A downward fall through 2 or more centiles for weight or head circumference
- A difference of height and weight of more than two centiles

TREATMENT SUMMARY:

- It is important to consider the reason for faltering growth e.g. iron deficiency anaemia, GORD or a child protection issue and treat accordingly or refer to a paediatrician.
- In breast fed infants consider a referral to a breastfeeding advisor for assessment and support with expressed breast milk top ups.
- Consider a referral to the health visiting team for behaviour management advice if infant is over 6 months old, eating solid food and exhibiting fussy eating behaviour.
- Before commencing a high energy formula ensure parents or carers are offered advice on suitable high calorie foods if the infant is over 6 months old.
- When commencing a high energy formula please ensure the full recommended prescribed dose is issued and consumed every day to maximise energy intake for weight gain.
- All infants on a high energy formula will need regular growth monitoring from the health visiting team (weight, length or height and head circumference) to ensure catch up growth is achieved and appropriate discontinuation of formula to minimise excessive weight gain.

Prescribing criteria	Age range	Recommended formula
SECONDARY CARE High energy formula to be started in secondary or specialist care.	From birth to 18 months or 8 kg body weight.	Infatrini (Nutricia) (h)
		SMA High Energy (SMA Nutrition)
		Similac High Energy (Abbott Nutrition) (h)(v)

GP REVIEW CRITERIA:

- Clinical effectiveness of the supplements should be assessed by regular growth monitoring and assessment.
- Once catch up growth has been achieved the high energy formula should be stopped to prevent excess weight gain.
- If consuming full therapeutic dose and failing to gain or achieve expected growth, consider a referral to a Paediatrician for further investigation.

Gastro-oesophageal reflux

DIAGNOSIS:

Gastro-oesophageal reflux (GOR) is the passage of gastric contents into the oesophagus, with or without vomiting. It is very common (at least 40%) of normal, healthy infants. Infants presenting with GOR usually **do not** require investigation or treatment. Parents and carers should be reassured that this is a common process which becomes less frequent with time. Advise parents to return for a review if there are new concerns. [Find healthcare professional factsheet here](#)

The presence of “red flags” may indicate disorders other than GOR. Refer to NICE GORD in children and young people diagnosis and management (2015) [Find here](#)

TREATMENT SUMMARY:

A diagnosis of gastro-oesophageal reflux disease_(GORD) is warranted when reflux of gastric contents causes complications serious enough to require medical treatment (i.e frequent regurgitation and marked distress)

Initial first line advice for parents:

Breastfed babies: Continue breastfeeding refer baby to health visitor for a breastfeeding assessment and support with positioning before and after feeding. Alginate therapy maybe appropriate if symptoms persist.

Formula fed babies:

- Check total volume is not exceeding 150mls/kg/day
- Try offering smaller more frequent feeds
- Give advice regarding positional management to treat GOR [Find parent factsheet here](#)
- Refer to health visitor for feeding assessment and support

If all the above strategies have not been effective in treating regurgitation, consider a trial of 1-2 weeks on a thickened formula.

TO BE PURCHASED BY PARENT/CARER	Age range	Recommended formula
Formula to be purchased by family from supermarket or pharmacy To be used under medical supervision (Food for special medical purposes)	Birth to 1 year (Trial stopping formula at regular intervals as 90% of infants will outgrow GORD by 12 months)	SMA Anti-Reflux (SMA Nutrition) Cow and Gate Anti-Reflux (Cow and Gate) (h) Aptamil Anti-Reflux (Nutricia)

GP/Health Visitor Review Criteria

- Refer to paediatrician if reflux continues over 1 year of age
- Review after 1 month, if no improvement in symptoms may need further investigation by a paediatrician.

Secondary lactose intolerance

Diagnosis:

- Usually occurs following an infectious gastrointestinal illness, symptoms include abdominal bloating, increased (explosive) wind and loose green stools for longer than 2 weeks.
- Secondary lactose intolerance should be suspected in infants who have had symptoms that persist for more than 2 weeks.
- Diagnosis is usually the resolution of symptoms within 48 hours once lactose is removed from the diet.
- Primary lactose intolerance is less common than secondary intolerance and does not usually present until later childhood or adulthood
- [Find healthcare professional factsheet here](#)

Treatment Summary (if symptoms have persisted longer than 2 weeks)

- Breastfeeding – continue with usual feeding as no change to maternal diet will be effective, breast feeding remains optimal for the baby.
- Replace standard formula with a Lactose free formula for up to 8 weeks, allow symptoms to resolve then reintroduce standard formula/milk products slowly into the diet. [Find parent factsheet here](#)
- If symptoms persist over 1 year of age then stop the formula, advise on a full fat lactose free supermarket milk and encourage return to a normal diet. Avoiding lactose long term is not recommended.

Note: the use of lactase drops i.e colief is not recommended as there is no evidence base

To be purchased	Age range	Recommended formula
Formula to be purchased by family from supermarket or pharmacy	Birth to 1 year	Aptamil Lactose Free (Nutricia)
To be used under medical supervision (Food for special medical purposes)	(children over 1 year can purchase a shop bought full fat lactose free milk if still indicated)	SMA Lactose Free (SMA Nutrition)

GP/Health Visitor Review Criteria

- If symptoms have not resolved after 8 weeks on lactose free formula/ lactose free diet consider alternative diagnosis e.g cow's milk allergy or refer to paediatrician for assessment

Amendments from 2017 to 2019 version

<u>Amendment</u>	<u>Rationale</u>
Lactose free, soya, anti-reflux formula added back into guidelines	Feedback from primary care for details of over the counter formula as unclear on when these products should be used
Quick reference summary -common feeding concerns in babies	Variation in practice within primary care for common infant feeding concerns e.g constipation. To consider first line advice before starting a specialist formula if diagnosis is unclear.
Summary guide to appropriate prescribing of specialist formulas	Summary of guidance for most common clinical conditions where a specialist formula is being inappropriately prescribed.
Removed supporting documents	New hyperlinks added to document for easier access to supporting documents.
2 nd line EHF removed	Prior to commencing alternative eHf primary care professionals should seek guidance from secondary or specialist service as the majority of infants should tolerate the first line EHF if the underlying diagnosis is non IgE mediated cow's milk protein allergy.

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An assessment framework was used to compile details of infant formulae available at time of review and subsequent recommendations for the prescribing guidelines. This document is available upon request.

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