NHS
Norfolk and Waveney
Integrated Care Board

NHS Norfolk and Waveney ICB
Policy Statement and Formulary

Infant Formula Milk products

Improving lives **together**
Norfolk and Waveney Integrated Care System

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Norfolk and Waveney
Integrated Care Board

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Summary and policy statement on Prescribing of Infant Formula Milks

Breastfeeding should be strongly encouraged as providing the safest, most nutritionally adequate form of feeding for most infants. Mothers should be supported to continue breast feeding if they are happy to continue, a change from breast milk to formula milk is not necessary to address feeing issues, however supplementary feeding may sometimes be advised. NHS Norfolk and Waveney CCG only commission primary care prescribing of infant formula milks on a restricted basis in accordance with the following policy.

Where breast feeding is not in place, appropriate infant formula milks should be purchased. For those qualifying for 'Healthy Start', the Healthy Start card can be used to purchase cow's milk based infant formula which states on the packaging that it can be used from birth. This therefore includes lactose-free milks which are derived from cow's milk (see page 23 for further information).
For infants who appear unsettled, colicky etc. there are a range of commercially available milks designed to be easier to digest which parents are able to purchase. Similarly, infants presenting with reflux symptoms should be advised that there are commercial products to purchase. However special formula milks are often not necessary to treat these common conditions.
Prescribing of milk for gastro-oesophageal reflux by GPs is not supported for all ages.

Soya-based infant formula was originally developed for babies who can't have infant formula based on cows' milk because, for example, they have a milk allergy. Other types of formula that are more suitable for these babies are now available. Soya-based infant formula must not be given to infants under 6 months of age due to the phytoestrogen content. It may also contain glucose which is more harmful to babies' and small children's teeth than the lactose in infant formula made with cows' milk.
Prescribing of soya milk formulas by GPs is not supported for all ages.

Infants may develop short-term **lactose intolerance** secondary to damage to the intestinal epithelium, e.g., an infectious gastrointestinal illness. Primary lactose intolerance is extremely rare in infants. Symptoms of lactose intolerance include, abdominal bloating, wind, increased (explosive) and loose, green stools. Lactose intolerance should be suspected in infants who have had symptoms that persist for more than 2 weeks. Diagnosis is the resolution of symptoms, usually within 48 hours once lactose is removed from the diet. Lactose free infant formulas can be bought at a similar cost to standard infant formula.
Prescribing of lactose free infant formulas by GPs is not supported for all ages.

Pre-term infants will have had their formula commenced in hospital. It is started for babies born before 34 weeks gestation and is continued until the child reaches 6 months corrected age. At this age infants can be moved onto standard infant formula.
Prescribing of special formula milks for pre-term infants over the age of 6 months corrected age by GPs is not supported.

In certain conditions some foods have characteristics of drugs and the Advisory Committee on Borderline Substances (ACBS) advises as to the circumstances in which such substances may be regarded as drugs. The ACBS recommendations are listed in the Drug Tariff. Prescriptions, where issued, must be in accordance with the Committee's advice and endorsed "ACBS".

Prescribing of all infant feeds in children meeting the ACBS criteria will only be supported until the infant is 1 year of age, unless a shorter or longer period is indicated within the policy or there are exceptional clinical circumstances.

Cow's Milk Protein Allergy (CMPA) - Extensively Hydrolysed formula (EHF) for infants with a suspected cows' milk protein allergy (CMPA) will be used first line. ***Prescription of hydrolysed formula milks may be initiated by GPs but should only be continued if there is resolution or improvement in symptoms after 2-4 weeks.*** Prescriptions will initially be for a 2 week trial period (for tolerance). Infants who do not tolerate one formula may tolerate another. Therefore it is worth prescribing only 3 or 4 tins initially and if not tolerated after perseverance, try another comparable formula. Once symptoms have resolved an early home milk reintroduction should be advised to confirm the diagnosis. Non-IgE CMPA that improves with EHF and the allergy is confirmed with early home milk reintroduction can be managed in primary care without input from specialists. However a planned milk reintroduction (The Milk Ladder) should be advised.

Amino Acid Formula (AAF) should only be prescribed when hydrolysed formulas do not resolve symptoms or when there is evidence of severe/multiple allergy. ***These are highly specialised products which should only be initiated by secondary/tertiary care. GPs should only initiate if EHF has not been tolerated after a reasonable trial (advisable to try more than one EHF product) and if they have made a formal referral to a paediatrician or dietitian and it is not clinically appropriate to wait for a specialist recommendation. GPs should only accept continued prescribing of these products after benefit has been demonstrated with an Early Home Reintroduction (See resource 4 on page 10) and in line with an agreed treatment plan from a Paediatrician or Dietitian.***

Faltering Growth - should be considered in infants when:

- They lose more than 10% of their birthweight in the early days of life
- They do not return to their birthweight by 3 weeks of age
- There is a fall across 1 or more weight centile spaces, if birthweight was below the 9th centile
- There is a fall across 2 or more weight centile spaces, if birthweight was between the 9th and 91st centiles
- There is a fall across 3 or more weight centile spaces, if birthweight was above the 91st centile
- When current weight is below the 2nd centile for age, whatever the birthweight (NICE 2017 NG75)

It is important to rule out possible disease-related/medical and social causes. **High energy formula milks** must only be initiated in secondary care after assessment by a paediatrician. Before referral to secondary care ensure parents/carers are offered food first advice on suitable high calorie foods if the infant is weaned.

All infants on a high energy formula must have growth (weight and length/height) monitoring to ensure catch up growth and appropriate discontinuation of formula to minimise excessive weight gain.

Recommendations

- Promote and encourage breast-feeding where it is clinically safe and the mother is in agreement. Provide information on local services available to support this.
- Advise about a maternal milk free diet for infants with cow's milk protein allergy (CMPA) who are exclusively breast fed and refer infant to a dietitian.
- 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 and/or refer to the most recent correspondence from the paediatric dietitian.
- Review any prescription where the child is over one year old, the formula has been prescribed for more than one year, or greater amounts of formula are being prescribed than would be expected.
- Review the prescription if the patient is prescribed a formula for CMPA but able to eat or drink any cow's milk containing foods such as cow's milk, cheese, yogurt, ice cream, custard, chocolate, cakes, cream, butter, margarine (list is non-exhaustive).
- Prescribe only three or four 400g tins initially until compliance/patient acceptability is established to avoid waste.
- Remind parents to follow the advice given by the formula manufacturer regarding safe storage of the feed once mixed or opened.
- **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.
- **Do not** prescribe lactose free formulae (SMA LF®, Aptamil LF®, Enfamil O-Lac®) for infants with CMPA as this still contains cow's milk protein.
- **Do not** prescribe soya formula (SMA Soya®) for those with CMPA or secondary lactose intolerance. It should not be recommended at all in those under six months due to high phytoestrogen content.
- **Do not** suggest formulae made from goat's milk, sheep's milk, or other mammalian milks for those with CMPA or secondary lactose intolerance.
- **Do not** suggest rice milk for those under five years due to high arsenic content.
- **Do not** prescribe High energy formula milks unless they have been requested by a dietitian or paediatrician.
- Pre-thickened formulae should not be used along with other thickening agents, e.g. Gaviscon Infant®, Carobel® to avoid over thickening of the stomach contents.
- **Do not** suggest Gaviscon Infant® more than six times in 24 hours or where the infant has diarrhoea or a fever, due to its sodium content.

The volumes of feed to prescribe for infants

For infants under 6 months of age the volume prescribed should be the same as the volume of milk they are currently taking (NOTE: most commonly used shop bought formulas are in 900g tins). As a rough guide, for a child taking 150ml/kg/day a 400g tin should last 3.5 days. Therefore 7-10 x 400g tins per month; 4-5 x 800g tins per month or 3-5 x 900g tins per month.

For infants over 6 months of age individual requirements may vary and GPs should prescribe sufficient to meet the dietary needs of the child. Requirements will gradually reduce after weaning depending on intake of solid food. By 1 year due consideration should be given to reducing the quantities prescribed and stopping the milk prescription when appropriate.

Key to recommendations

	1st line
	2nd line
	Specialist initiated
	Available to purchase OTC (not for prescribing)

Cow's Milk Protein Allergy (CMPA): Treatment flow chart for CMPA in primary care

Norfolk and Waveney Integrated Care Board

Allergy Focused Clinical history AND Examination
NICE CG 116 pathway & iMAP Allergy-focused Clinical History

IgE or ***severe* non-IgE CMPA** suspected
Multiple food allergies suspected
One or more **acute systemic or severe delayed reactions**
Faltering growth with one or more **GI symptoms**
Sig. atopic eczema where multiple or cross-reactive food allergies suspected

Yes → **Refer to specialist clinician**

No

Breastfed infant

(if symptoms with breastfeeding alone)

Strict exclusion of Cow's milk containing foods from mother's diet, see 'NNUH cow's milk free diet for breastfeeding mums' or 'iMAP factsheet for mild-moderate non-IgE allergy with exclusive or part breastfeeding'

Refer to dietitian to ensure appropriate dietetic support

Ensure mother has adequate **calcium** (1250mg/day) See BDA Calcium information

DOH recommends *all* breastfeeding mums should have **vitamin D3 (*10mcg*/day)-** available from pharmacies, health food stores and in healthystart vitamins

If weaning give: 'BDA Milk Allergy sheet' **and** Allergy UK Cow's Milk Free diet information

Review: 2 - 4 weeks
Symptoms significantly improved?

Yes → *Unless symptoms severe,* do early home reintroduction of cow's milk to test diagnosis & monitor

No → Expedite dietetic opinion if not already involved

Symptoms worsen?

Yes → Continue CM elimination diet & **refer to Dietitian**

No → Resume normal diet **Not CMPA**

No

Formula-fed infant

Trial of hydrolysed formula (EHF):
Prescribe as ACUTE 2 - 3 tins initially *to assess tolerance*
See page 9

If weaning give: 'BDA Milk Allergy sheet' **and** Allergy UK Cow's Milk Free diet information

Mixed feeding: If symptoms only with introduction of top up feeds replace with breastfeeding or EHF top-ups.

Review: 2 - 4 weeks
Symptoms significantly improved?

Yes → *Unless symptoms severe,* do early home reintroduction of cow's milk to test diagnosis & monitor

Symptoms worsen?

Yes → Restart EHF **CMPA confirmed**

No → Resume normal diet **Not CMPA**

No → Trial lactose-free alternative EHF if appropriate (see page 9)

NB if severe systemic reaction to EHF then AA trial required + refer to dietitian

Review: 2-4 weeks
Symptoms significantly improved?

Yes

No → **Refer to specialist clinician and prescribe AA formula if CMPA still suspected**

Simple mild/moderate non-IgE CMPA can be managed in primary care, please ensure:

- Parents/carers are given the correct resources and information (see page 10 for appropriate literature)
- Parents/carers are aware that 80% infants grow out of CMPA by the time they're 2 so it's important to reintroduce milk gradually with the milk ladder once the baby is 9-12 months old (or 6 months from diagnosis)
- Milk prescription is reviewed regularly to ensure age-appropriate amounts
- GP/primary care clinician to review at 1 year to advise on weaning off formula and onto alternative plant-based milk if the milk allergy is still present. See page 15 for suitable milks. Ensure a plan for reviewing and stopping formula
- Ensure dietetic support is available if needed when weaning

Cow's Milk Protein Allergy (CMPA)

Norfolk and Waveney Integrated Care Board

Presentation: see iMAP Presentation of suspected CMPA in 1st year of life on page 11

- There are 2 types of CMPA: Non-IgE-mediated and IgE-mediated. Mild/moderate non-IgE-mediated allergy can be managed in primary care
- If CMPA suspected complete allergy focused clinical history **(Resource 1 page 10)**

Treatment- see flow chart on page 7

- Provide advice to parent/carer about CMPA and the treatment process. **Provide Resource 2 (page 10)** information sheet if possible
- **Breast fed babies** can react to milk proteins that are transferred in breast milk from the mother's diet (though not always). If it is suspected that a breastfed baby is reacting to cow's milk protein via breast milk, the mother should be advised to avoid cow's milk and dairy products in their diet while breastfeeding. This involves a cow's milk elimination trial of up to six weeks. Support and information should be provided to the mother. Please note mild-to-moderate non-IgE mediated cow's milk allergy in exclusively breastfed babies is rare and is not a reason to stop breastfeeding. **Provide Resource 3 to carers (page 10)**
- **Formula fed infants** should be trialled on Extensively Hydrolysed Formulae (EHF), see table below for products. EHFs are suitable for 90% of infants with CMPA. The taste and smell of hydrolysed formulae can be unpleasant. Compliance can be improved by using a bottle, closed cup, or a straw. Younger infants may take them more readily than older infants
- Lactose-containing EHFs are now first line as evidence suggests lactose is an important prebiotic for infants, leading to colonisation of the gut by beneficial bacteria. This is thought to improve the gut microbiome and have positive effects on the immune system. If the infant does not tolerate lactose-containing EHF after a reasonable trial, then a lactose-free EHF should be trialled before stepping up to an amino acid formula (AAF). NB infants who have a systemic reaction to EHF are unlikely to tolerate alternative EHF and will need an AAF
- Introduction of a new formula to babies **who do not have a severe reaction** is best done by mixing it with their current formula and gradually changing over
- Only prescribe 3 or 4 tins initially to ensure acceptance of the product
- **In order to confirm the diagnosis it is essential to advise a planned home reintroduction during weeks 2-4 of the cow's milk elimination diet for both breast- and formula-fed infants** (only in suspected non-IgE mild-moderate allergy). This is now a NICE Food Allergy Quality Standard. Provide **Resource 5 (page 10)** to carers to support this
- The child/infant should follow a cow's milk free diet until 9-12 months of age and for at least 6 months after diagnosis
- Early introduction of some allergenic foods in infants at high risk of allergies may be advised by the dietitian/paediatrician, there is evidence that this may help to prevent other food allergies
- Beyond 1 year calcium enriched plant-based milks can be purchased/used as an alternative source of milk (see page 13 for a list of suitable milks)
- Ongoing prescription of specialist formulas beyond 1 year may be required in those with severe or multiple allergies (e.g. soya). This should be led by the Paediatrician or allergy Dietitian

Review and discontinuation

- Review prescriptions regularly to check that the formula prescribed is appropriate for the child's age
- Quantities of formula required will change with age. Avoid adding to the repeat template for these reasons unless a review process is established
- Challenging with cow's milk: Milk tolerance should be evaluated by using the (mild/mod non-IgE allergy only) with the published recipes **(See Resources 6 & 7 on page 10)**, or a supervised challenge (by specialists for severe non-IgE or IgE-mediated allergy)
- Review the need for the prescription if you can answer 'yes' to any of the following questions:
  - Is the patient over one year of age?
  - Has the formula been prescribed for more than one 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/drink cow's milk containing foods? (E.g., cheese, yoghurt, ice-cream, custard, chocolate, cakes, cream, butter, margarine)

Extensively hydrolysed Formula (EHF)			
Product	**Pack size**	**Cost per 100kcals**	**Indicated Age Range**
First Line (lactose-containing)			
SMA Althera® (Contains lactose) SMA Nutrition/Nestle	400g	£0.49	Birth until infant has grown out of allergy (up to 12m as per policy)
Aptamil-Pepti 1® (Contains lactose) Nutricia	400g or 800g	£0.51	Birth to 6 months
Aptamil-Pepti 2® (Contains lactose) Nutricia	400g or 800g	£0.50	6 months until infant has grown out of allergy (up to 12m as per policy)
Second line (lactose-free)			
*Alimentum® (Clinically lactose free) Abbott Nutrition	400g	£0.48	Birth until infant has grown out of allergy (up to 12m as per policy)
Nutramigen 1 LGG® (Clinically lactose-free) Mead-Johnson	400g	£0.56	Birth to 6 months
Nutramigen 2 LGG® (Clinically lactose-free) Mead-Johnson	400g	£0.56	6 months until 1 year (Nutramigen 3 LGG available for >1 year in exceptional clinical need)
Amino Acid Formula –GPs may only initiate if EHF not tolerated after reasonable trial and if they have made a formal referral to a paediatrician or paediatric allergy dietitian, and it is not clinically appropriate to wait for a specialist recommendation			
Elecare® Abbott Nutrition	400g	£1.11	Birth until infant has grown out of allergy (up to 12m as per policy)

Nutramigen Puramino® Mead Johnson	400g	£1.13	Birth until infant has grown out of allergy (up to 12m as per policy)
SMA Alfamino SMA Nutrition/Nestle	400g	£1.15	Birth until infant has grown out of allergy (up to 12m as per policy)
Neocate LCP® Nutricia	400g	£1.16	Birth until infant has grown out of allergy (up to 12m as per policy)

*Please note at the time of writing Alimentum® is currently unavailable

Resources list- please provide suitable information to parents/carers

1) Allergy Focused Clinical History (iMAP) imap-allergy-focused_history_original.pdf (wordpress.com)
2) Initial Fact Sheet for Parents (iMAP) [suitable for breastfeeding and formula feeding] https://gpifn.files.wordpress.com/2019/10/imap_patient_factsheet_original.pdf
3) Initial fact sheet for infants with symptoms of mild to moderate non-IgE mediated allergy whilst being exclusively or partly breastfed (iMAP) https://gpifn.files.wordpress.com/2019/10/imap-supporting-breastfeeding-factsheet.pdf
4) The Early Home Reintroduction to Confirm the Diagnosis of Cow's Milk Allergy (iMAP) https://gpifn.files.wordpress.com/2019/10/home_reintroduction_protocol_to_confirm_or_exclude_diagnosis_original.pdf
5) The iMAP Milk Ladder imap_final_ladder-may_2017_original.pdf (wordpress.com)
6) iMAP Milk Ladder recipes imap-recipes_final_original.pdf (wordpress.com)
7) Cow's Milk free diet for breastfeeding mums Norfolk and Norwich University Hospitals NHS Foundation Trust » Cows-Milk Free Diet for Breast Feeding Mums 10.1.4 – V3 (nnuh.nhs.uk)
8) Milk free weaning Milk allergy | British Dietetic Association (BDA) and/or Cows-Milk-Free-Diet-Information-For-Babies-and-Children.pdf (allergyuk.org)
9) British Dietetic Association Calcium information sheet (for breastfeeding mothers avoiding cow's milk) Calcium Food Fact Sheet, British Dietetic Association (bda.uk.com)

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

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

Having taken an Allergy-focused Clinical History and Physically Examined

Apr 2019

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

Mild to Moderate Non-IgE-mediated CMA

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

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

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

Gastrointestinal

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

Skin

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

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

↓

Cow's Milk Free Diet
Exclusively breast feeding mother*
Trial exclusion of all Cow's Milk Protein from her own diet and to take daily Calcium and Vit D

Formula fed or 'Mixed Feeding'*
If mother unable to revert to fully breastfeeding, trial of Extensively Hydrolysed Formula - eHF

See Management Algorithm

Severe Non-IgE-mediated CMA

Mostly 2-72 hrs. after ingestion of Cow's Milk Protein (CMP)
Usually formula fed, at onset of mixed feeding.
Rarely in exclusively breast fed infants

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

Gastrointestinal

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

Skin

Severe atopic dermatitis +/- Faltering Growth

↓

Cow's Milk Free Diet
Exclusively breast feeding mother*
If symptomatic, trial exclusion of all Cow's Milk Protein from her own diet and to take daily Calcium & Vit D

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

Ensure:
Urgent referral to local paediatric allergy service
Urgent dietetic referral

Severe IgE CMA

ANAPHYLAXIS

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

Emergency Treatment and Admission

Mild to Moderate IgE-mediated CMA

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

One or more of these symptoms:

Skin – one or more usually present

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

Gastrointestinal

Vomiting, diarrhoea, abdominal pain/colic

Respiratory – rarely in isolation of other symptoms

Acute rhinitis and/or conjunctivitis

↓

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

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

If diagnosis confirmed (by IgE testing or a Supervised Challenge in a minority of cases) :
Follow-up with serial IgE testing and later Planned Challenge to test for acquired tolerance

Dietetic referral required

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

*** Actively support continued breastfeeding (see over)**

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

Frequently asked questions about CMPA

Q. Can goat's milk formula be used as a treatment for CMPA?

- No: Goat's milk and sheep's milk are not advised due to the cross reactivity with cow's milk

Q. What happens when an infant reaches 1 year of age and is still allergic to cow's milk?

- Children over 1 year can use **unsweetened** and **fortified soya-based or pea-based** milk alternative which have suitable amounts of micronutrients, energy and protein and are widely available in supermarkets (see page 13 or LinkClick.aspx (knowledgeanglia.nhs.uk))
- In multiple/complex allergy continue prescription of specialist formula as recommended by allergy/paediatric dietitian

Q. What happens when an infant reaches 2 years of age and still has multiple allergies and is prescribed specialist formula?

- The formula milk should no longer be required and the child can go onto an **unsweetened** and **fortified plant-based** milk alternative which has suitable amounts of micronutrients, energy and protein (see page 13 or LinkClick.aspx (knowledgeanglia.nhs.uk))
- **Rice milk is not suitable for children under the age of 4½ years**

Q. Are vitamin and mineral supplements required?

- Department of Health recommends that all children aged 6 months to 5 years are given vitamin supplements containing vitamins A, C and D every day
- All infants from birth to 1 year of age who are being exclusively or partially breastfed should be given a daily supplement containing 8.5 to 10µg of vitamin D (340-400 IU/d)
- The government recommends that children from the age of 6 months to 5 years are given a daily supplement of vitamin A (233µg) unless they are consuming over 500ml of infant formula a day.
- Babies who are having more than 500ml (about a pint) of infant formula a day shouldn't be given vitamin supplements. This is because formula is fortified with vitamins
- Vitamin supplements can be obtained through the Healthy Start voucher scheme if eligible (see page 24)
- Children on a cow's milk free diet may require a calcium supplement. This will be advised by the Paediatric Dietitian

Q. Why is soya formula not advised?

- Soya formula is no longer recommended for infants with CMPA as there is concern that phytoestrogens contained in these formulae could affect babies' reproductive development.
- Some infants with CMPA will also react to soya protein.
- Soya formula contains added sugars instead of the milk sugar lactose which are more likely to harm babies' teeth. Parents wishing to feed their infant on a soya-based formula should be advised of the risks and advised to purchase the formula over the counter. It is not advised for infants below 6 months

Q. Can lactose free products be used in cow's milk protein allergy?

- No. These products contain cow's milk protein and are therefore not suitable

Norfolk and Waveney Integrated Care Board

Suitable plant-based milk alternatives for age 1+ with Cow's Milk Protein Allergy (CMPA)

Plant-based milks

- Global and UK dietary guidelines recommend that children who are not being breastfed after the age of 1 year drink animal milk as the main milk drink; normally cows' milk
- Animal milks contain high quality protein, all essential amino acids, and are a good source of vitamins and minerals including calcium, vitamin A, B vitamins, zinc and iodine
- Plant-based milk alternatives are variable, and many have limited nutritional equivalence to animal milks- some are low in energy and nutrients
- It is important to try to reintroduce animal/ cow's milk products (if following an omnivorous diet) when clinically appropriate to ensure 'tolerance' of cow's milk in foods and drinks (discuss this process with your healthcare professional)
- In the UK, public health guidance suggests that unsweetened, fortified milk alternatives can be included as the main milk drinks from the age of 1 (with the exception of rice-based milks which are high in arsenic)

Types of plant-based milk alternatives that are suitable

- **Unsweetened** and **fortified soya-based** and **pea-based** products should be first choice as they contain suitable amounts of micronutrients, energy, and protein
- **Oat based** milk alternatives are second choice as they have a lower protein content and contain free sugars from the processing of oats
- Choose full fat/whole versions to improve the energy content
- Choose milks which are fortified with **calcium** and **iodine**, as well as **Vitamin D** and **B vitamins**
- Nut-based and coconut-based products are very low in energy and protein
- Please note: Unsweetened, full-fat plant-based alternative milks can be used in cooking and in weaning foods from 6 months

Examples of some widely available suitable milks to be used as a drink for infants 1+ (this list is not exhaustive): Correct at the time of writing June 2022

Soya-based	• Tesco Soya Unsweetened • Chilled Alpro Soya No sugars • Alpro Soya Growing up 1-3+ years • M&S Plant Kitchen Unsweetened Soya Drink	£1.00/L £1.60 £1.70/L £1.00/L
Pea-based	• Unsweetened Mighty Pea M.LK • Qwrkee Plant-based Pea Ml'k Unsweetened	£2.00/L £2.50/L
Oat-based (ensure protein content is approx. 1g/100ml or more)	• Oatly Barista/whole • Asda Oat Barista • MOMA Oat Drink Whole • Mighty Milkology Whole Dairy Free Oat Milk Alternative	£1.90/L £1.20/L £1.85/L £2.10/L

Sources:
Plant-based milk alternatives in the diets of 1–4-year-olds. First Steps Nutrition Trust [accessed June 2022]
Cow's Milk Free Diet Information For Babies and Children. Allergy UK [accessed June 2022]

Managing Preterm Infants

Indications

- These children will have had their formula commenced in hospital. It should not be started in primary care
- It is started for babies born before 34 weeks gestation, weighing less than 2kg at birth.
- For advice on vitamin supplementation please see East of England Perinatal Network guidance (https://www.eoeneonatalpccsicnetwork.nhs.uk/wp-content/uploads/2022/02/EOE-vitamin-guidance-final-Dec_2018.pdf December 2018).
- These formulas should not be used in primary care to promote weight gain in patients other than those born prematurely

Specialised Formula – Pre-term infants		
Product	Number of tins per month	Indicated Age Range
SMA Gold Prem 2 (powder) 800g SMA	As advised by hospital	<6 months corrected age
Nutriprem 2 (powder) 800g Cow and Gate	As advised by hospital	<6 months corrected age

Review and discontinuation of treatment

- The Health Visitor or other suitable healthcare professional should monitor growth (weight, length and head circumference) while the baby is on these formulae.
- These products should be discontinued by six 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 six months corrected age the formula should be reviewed. Change to a standard formula if no concerns with growth (can be purchased over the counter)

Faltering growth

The NICE clinical guideline entitled 'Faltering Growth – recognition and management of faltering growth in children' was published in September 2017, with an updated Quality Standard in 2020. See NICE guidance Faltering growth for more information.

Symptoms and diagnosis

Healthcare professionals may have concerns about faltering growth in infants if:

- They lose more than 10% of their birthweight in the early days of life
- They do not return to their birthweight by 3 weeks of age
- There is a fall across 1 or more weight centile spaces, if birthweight was below the 9th centile
- There is a fall across 2 or more weight centile spaces, if birthweight was between the 9th and 91st centiles
- There is a fall across 3 or more weight centile spaces, if birthweight was above the 91st centile
- The current weight is below the 2nd centile for age, whatever the birthweight

- If there is concern about faltering growth: weigh the infant or child and measure their length (from birth to 2 years old). Plot the above measurements and available previous measurements on the UK WHO growth charts to assess weight change and linear growth over time. Individual growth pattern, feeding behaviours, parental factors and any indicators of underlying illness should be considered when assessing the need for high energy formulae
- It is essential to rule out possible disease related/medical causes for the faltering growth e.g., iron deficiency anaemia, feeding problems, coeliac disease, constipation, GORD or a child protection issue. If identified appropriate action should be taken

Onward referral

- Infants with faltering growth should be referred to paediatric services without delay.
- Refer any infant who is weaned to a paediatric dietitian for advice on a high energy high protein diet. If the problem appears related to food refusal/fussy eating, consider referral for behavioural intervention

Treatment

- Prescribe an equivalent volume of high energy formula to the child's usual intake of regular formula as per recommendation from paediatrician or paediatric dietitian
- Where all nutrition is provided via nasogastric (NG)/nasojejunal (NJ)/percutaneous endoscopic gastrostomy (PEG) tubes, the paediatric dietitian will advise on appropriate monthly amounts of formula required which may exceed the guideline amounts for other infants
- Do not add formula to repeat templates as ongoing need for formula and amount required will need to be checked with each prescription request

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 a clear aim/goal and guidance given about discontinuation of prescribed formula
- All infants on high energy formula will need growth (weight and height/length) monitored to ensure catch up growth occurs. Once catch-up growth is achieved the formula should be discontinued to minimise excessive weight gain

Faltering growth		
Product	Number of units per month-**guide only**	Indicated Age Range
SMA High Energy Ready to feed SMA Nutrition	84 x 200ml	From birth to 18 months or weight 8kg
Infatrini ready to feed Nutricia	135 x 125ml OR 84 x 200ml	From birth to 18 months or weight 8kg
Similac High Energy Abbott	84 x 200ml	From birth to 18 months or weight 8kg
Metabolic Disorders - follow specialist unit recommendation		
Tertiary Care recommendation – prescribe initially as per recommendation then confirm with paediatrician/dietitian as to possibility of changing to one of above		

The following types of infant formula milks (some examples listed) are not recommended for prescribing on the NHS by the Norfolk and Waveney CCGs, as they may be purchased at a similar price to standard formula milks.

1) Gastro-oesophageal reflux (GOR) and gastro-oesophageal reflux disease (GORD)

Symptoms and diagnosis

- Gastro-oesophageal reflux (GOR) is the passage of gastric contents into the oesophagus. It is a common physiological event that can happen at all ages from infancy to old age and is often asymptomatic. It occurs more frequently after feeds/meals. In many infants, GOR is associated with a tendency to 'overt regurgitation' – the visible regurgitation of feeds
- Gastro-oesophageal reflux disease (GORD) refers to gastro-oesophageal reflux that causes symptoms (for example, discomfort or pain) severe enough to merit medical treatment, or to gastro-oesophageal reflux-associated complications (such as oesophagitis or pulmonary aspiration)
- GORD should be suspected in children who present with regurgitation plus any one of the following: hoarseness, unexplained feeding difficulties, faltering growth, chronic cough, and distressed behaviour. Crying, crying while feeding, and adopting unusual neck postures were judged to indicate that the infant or child was likely to be experiencing some discomfort
- It should be noted that at least 40% of infants have some degree of reflux at some time.
- A specific infant formula is not always necessary, and resolution of symptoms can occur through reducing the quantity of feed and suitable positioning post-feed

See NICE guideline NG1 Gastro-oesophageal reflux disease in children and young people for further information.
CKS Scenario management: covering the management of children with gastro-oesophageal reflux disease (GORD) in primary care, can be found at this link:
https://cks.nice.org.uk/gord-in-children#!scenario

Treatment – see flow chart on page 19

- If the infant is thriving and not distressed reassure the 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
- OTC formulae (pre-thickened or those that thicken in the stomach) for reflux are available if carers wish to try these (prior to commencing alginate therapy)
- Pre-thickened formulas should not be used along with other thickening agents, e.g. Gaviscon®, Carobel® to avoid over thickening of the stomach contents. Over the counter pre-thickened formulae contain carob gum, or starches. This produces a thickened formula and will require the use of a large hole (fast flow) teat
- If pre-thickened formulae or OTC feed thickeners are not successful in improving symptoms or in breastfed infants a 1-2 week trial of thickeners such as Infant Gaviscon® can be trialled. Infant Gaviscon® contains sodium and should not be given more than six times in 24 hours or where the infant has diarrhoea or a fever. N.B. Each half of the dual sachet of Infant Gaviscon® is identified as ‘one dose’. To avoid errors, prescribe with directions in terms of ‘dose’. Dispensing pharmacists should advise about appropriate

doses of OTC products. Can be given with bottle feeds or with small volumes of cooled boiled water for breastfed infants as per manufacturer's instructions

Over the counter formulae to be purchased In the first instance, Carobel® can be purchased and used to thicken standard formulae/expressed breastmilk or one of the following can be tried:	
Aptamil® Anti-reflux (Nutricia)	Birth to one year (pre-thickened)
Cow & Gate® Anti-reflux (Cow & Gate)	Birth to one year (pre-thickened)
SMA Anti-Reflux® (SMA)	Birth to one year (pre-thickened)

Review and discontinuation of treatment

- Review as per flow chart below
- 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 (e.g. Infant Gaviscon®) should be trialled periodically

Treatment of Infants with GOR/GORD

Norfolk and Waveney Integrated Care Board

Infant with *overt regurgitation* OR *more than one* of: *unexplained feeding difficulties, distressed behaviour, faltering growth, chronic cough, hoarseness, a single episode of pneumonia*

Are any of the following 'Red Flags' present? See NICE NG 1 for full details

- Frequent projectile vomiting
- Bile-stained vomiting or haematemesis
- Onset of regurgitation after 6 months or persistent, beyond the first year of life
- Chronic diarrhoea or blood in the stool
- Abdominal distension, tenderness or palpable mass
- Altered responsiveness, bulging fontanelle, fever
- persistent back arching or features of Sandifer's syndrome
- Infants with, or at high risk of, atopy
- Signs of distress / complications / symptoms of GORD

Yes → **Further investigations / Referral**

No

STEP 1

Formula fed: Rule out overfeeding. If infant is thriving and not distressed, **give reassurance, practical advice** *e.g., smaller more frequent feeds* **(see** Reflux in babies - NHS Choices**) and monitor**
Breast feeding: advise assessment with appropriately trained person

If infant is not settled / not gaining weight move on to STEP 2

STEP 2

Formula fed infant: Advise parent/carer to: -

- Replace standard formula with **a Pre-thickened formula,** similar price to buy* (See page 18 of Infant Formula Milk Formulary)
- OR advise parent/carer to buy a thickener to add to their usual formula (e.g., Instant Carobel®) Advise the need for large hole (fast flow) or variable flow (split) teat
- Advise the use of cooled, pre-boiled water to make up formula

Breast fed infant: Prescribe an alginate **(Infant Gaviscon®) < *4.5kg -1 sachet*** *(1 dose),* ***>4.5kg -2 sachets*** *(2 doses) make up as per leaflet, offer on a spoon/in feeding bottle part way through each feed*

Review after 1 - 2 weeks
Symptoms have improved?

Yes → Continue above treatment but advise trial stop every 2 weeks to see if still needed

No

STEP 3

Breast fed infant: Consider further investigations / GORD / specialist referral

Formula fed infant: STOP thickened formula/thickener
Prescribe an alginate **(Infant Gaviscon®)** dose as above, *can be mixed with feed in the bottle*
Review after 1 - 2 weeks
If symptoms have improved continue, but advise trial stop every 2 weeks to see if still needed. If symptoms not improved consider further investigation/specialist referral

***NOT TO BE PRESCRIBED. Healthy Start vouchers** are available for parents and carers on **low incomes** and can be used towards the cost of formula milk labelled '*suitable from birth' if based on cow's milk* http://www.healthystart.nhs.uk/

2) Secondary Lactose Intolerance

Symptoms and diagnosis

- Lactose is the natural sugar found in cow's milk and the milk of other mammals such as goats and sheep (and humans). Lactose intolerance is when the digestive system can't break down lactose due to reduced action of the enzyme lactase
- Primary lactase deficiency is extremely rare in infants and does not usually present until after two years of age and may not fully manifest until adulthood
- Secondary lactose intolerance is more common and usually occurs following an infectious gastrointestinal illness but may be present alongside newly or undiagnosed coeliac disease, or food allergy (due to the lining of the gut being damaged)
- Symptoms include abdominal bloating, pain, increased (explosive) wind, and loose green stools
- Lactose intolerance should be suspected in infants who have had any of the above symptoms that persist for more than two weeks
- Resolution of symptoms within 48 hours of withdrawal of lactose from the diet confirms diagnosis

Treatment- see flow chart on page 22

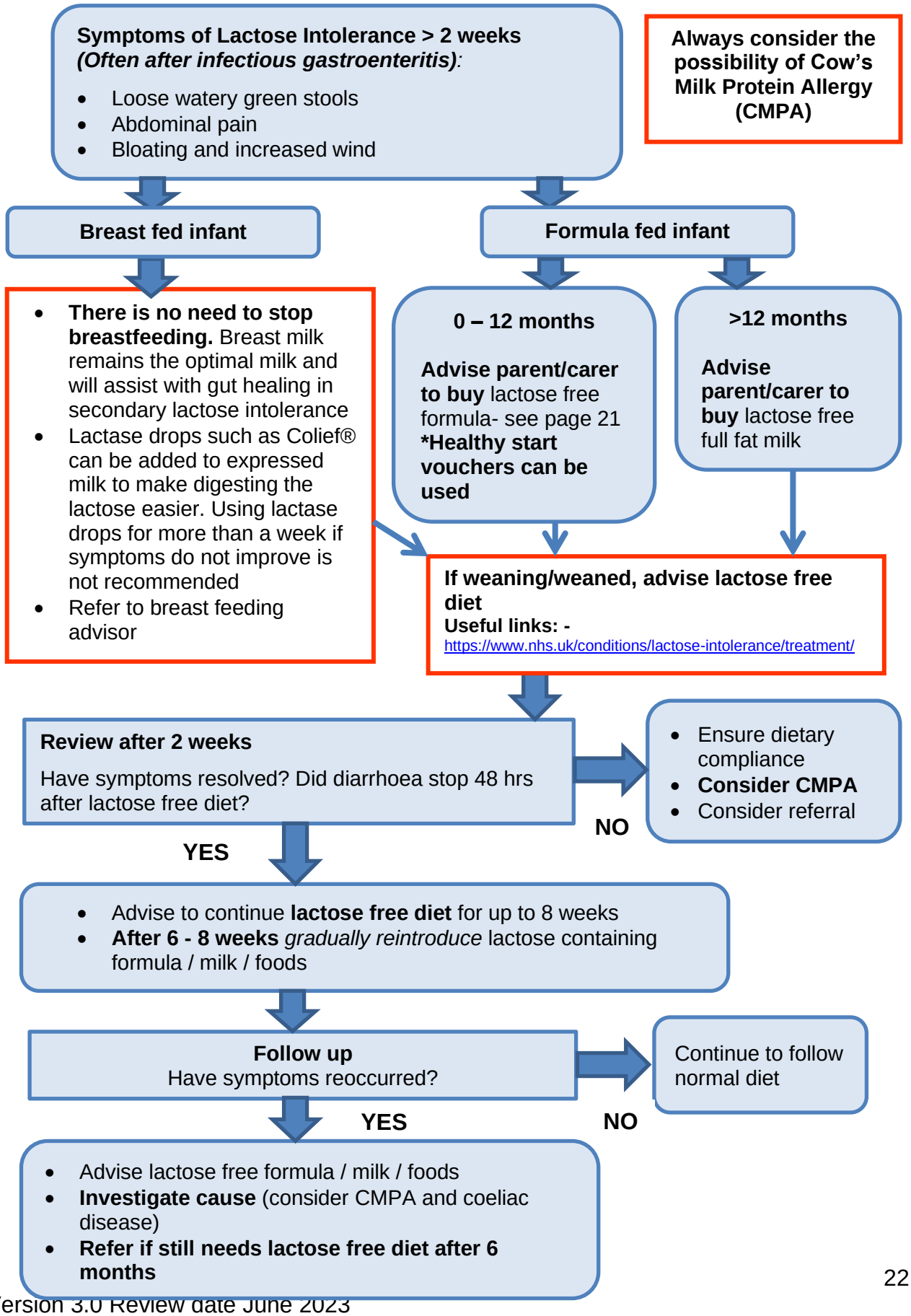
- Secondary lactose intolerance does not always mean an infant needs specialist formula milk, as long as the cause for the gut damage is identified and removed the gut should heal and lactase enzyme activity should normalise
- In exclusively breastfed infants secondary lactose intolerance is not a reason to give up breastfeeding
- In formula fed infants treat secondary lactose intolerance with OTC low lactose/lactose free formula for **six to eight weeks** to allow symptoms to resolve. Standard formula and/or milk products should then be slowly reintroduced to the diet
- Lactose-free formulae should not be used long term; **if an infant continues to react to lactose then the cause of this must be investigated**
- **Lactose free formula can be purchased at a similar price to standard formula, GPs should not prescribe it.** Advise to use lactose free formula with appropriate safety netting (advice on what to do if symptoms do not improve)
- In infants who have been weaned, low or lactose free formula should be used with a milk free diet. In children over one year who previously tolerated cow's milk, suggest using lactose free full fat cow's milk, yoghurt and other dairy products, available from supermarkets (many own brand milks are now available) on a **short-term basis**
- Soya formula should not routinely be used for patients with secondary lactose intolerance. It should not be given at all to those under six months due to high phytoestrogen content. It should only be used in patients over six months who do not tolerate the lactose-free formulae suggested here. **Parents should be advised to purchase it as it is a similar cost to cow's milk formula and readily available**
- Lactose free formulae are more cariogenic than standard lactose-containing formulae due to lactose being replaced with added sugars, they are not suitable for long term use unless there is evidence of primary lactose intolerance (very rare)

Lactose Free Formula		
Product	Pack size	Indicated Age Range
SMA LF (SMA)	400g	From birth to one year
Enfamil O-Lac (Mead Johnson)	400g	From birth to one year
Aptamil Lactose Free (Nutricia)	400g	From birth to one year

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
- Refer to the paediatric dietitian if the child is weaned and a lactose free diet is required
- Congenital or primary lactase deficiency requires specialist management

Treatment of Secondary Lactose Intolerance in Primary Care



Healthy Start

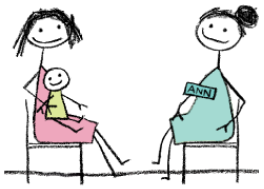
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Healthy Start is a UK-wide government scheme to improve the health of low-income pregnant women and their families.

Women who are more than 10 weeks pregnant or have a child under 4 an apply to get help to buy healthy food and milk.

If eligible, a Healthy Start card will be sent which can be used in some UK shops. Money will be added to the card every 4 weeks.

The card can be used to buy:



- plain liquid cow's milk
- fresh, frozen, and tinned fruit and vegetables
- fresh, dried, and tinned pulses
- infant formula milk based on cow's milk

The card can also be used to collect:

- Healthy Start vitamins – these support during pregnancy and breastfeeding
- Vitamin drops for babies and young children – these are suitable from birth to 4 years old

Applying

Women are eligible if:

1) If they receive Universal credit
   + They're at least 10 weeks pregnant or have at least one child under 4 years old
   + The family's monthly 'take-home pay for this period' is £408 or less from employment

2) If they receive Child Tax Credit
   + They have at least one child under 4 years old
   + The family's annual income is £16,190 or less

How to apply – Get help to buy food and milk (Healthy Start)