Prescribing Specialist Infant Formula in Primary Care

Guidance for use in:

NHS Bradford District and Craven CCG, 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.

This document is for use within the NHS and is not for commercial or marketing purposes

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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 breastfeeding.

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GUIDE TO PRESCRIBING SPECIALIST INFANT FORMULA

COW'S MILK PROTEIN ALLERGY (CMPA)

Take an allergy-focused clinical history: Key Questions

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
Respiratory – rarely in isolation of other symptoms - acute rhinitis and/or conjuctivitis

If SEVERE IgE CMPA 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 of CMPA
Usually several symptoms will be present and persisting
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 MAP (Milk Allergy in Primary Care) Guideline 2019 – 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
- Possible multiple food allergies
- Persisting parental suspicion of food allergy (especially where symptoms are difficult or perplexing) despite a lack of supporting history

Support continued breast feeding where possible. **Lactose Free formula are not appropriate for CMPA.**

Refer all patients with CMPA to a Paediatric Dietitian for milk-free weaning advice

Extensively Hydrolysed Formula (EHF) for Mild to Moderate CMPA	Alphabetical order: **Alimentum** (birth – 2 yrs), **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), **SMA Althera** (birth – 3yrs). **Refer to local CCG formulary if available.**
Amino Acid Formula (AAF) for Severe CMPA	**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. Alphabetical order: **EleCare, Nutramigen Puramino, Neocate LCP, SMA Alfamino. Refer to local CCG formulary if available.**

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 (GOR)

- **Regurgitation of feeds due to GOR is common and normal occurrence in the first 6 months life. In thriving and well infants does not need any investigation or treatment.**
- **First line advice: If no warning signs, give parental reassurance.**
- **If regurgitation is frequent with marked distress treatment should be considered.**
- **Breast-fed infants**: If infant is otherwise well and gaining weight, task the Health Visitor (HV) to complete a breast-feeding assessment, the HV will refer to the Breast-feeding Champion if required. If symptoms persist trial Gaviscon Infant for 1-2 weeks. If successful continue. Try stopping at intervals to see if symptoms have settled.
- **Formula-fed infants – use a stepped approach**:

1. **Avoid overfeeding; reduce volumes only if excessive for the infant's weight (infants up to 6 months recommended volume 150ml/kg/24hrs)**.
2. Check positioning during and after feeds.
3. 2 week trial of an Anti-Reflux (thickened) formula – self purchased, e.g **Aptamil Anti-Reflux, Cow & Gate Anti-Reflux, HiPP Organic Combiotic Anti-Reflux** or **SMA PRO Anti-Reflux are available to buy from supermarkets**. Healthy Start vouchers can be used for these formulas https://www.healthystart.nhs.uk/healthy-start-vouchers/where-to-use-the-vouchers/
   Where Anti-reflux (thickened) formulas are recommended, advice should be given by a HCP to carefully follow manufacturer guidance for making up the Anti-reflux formula as the water temperature required is different to making up standard infant formula.
4. If trial of Anti-reflux formula is not tolerated, prescribe Instant Carobel thickener, to be added to the usual standard infant formula.
5. If unsuccessful, stop thickener and trial Gaviscon Infant for 2 weeks.

Do not prescribe thickeners or antacids for use with Anti-Reflux (thickened) formulas.

Review after 2 weeks, if symptoms not improved consider alternative diagnosis. If any red flags or uncertainly around diagnosis, urgent referral to Paediatrician.

Red flags include Frequent forceful vomiting (i.e. not effortless), Bile stained vomit, Haematemisis, Onset after 6 months age, or symptoms persisting after 1 year old, Blood in stool, Abdominal distension, Chronic diarrhoea, Co-existing atopy, Faltering growth, Systemically unwell.

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

Secondary 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 alphabetical order these are **Infatrini, SMA High Energy, Similac High Energy,** (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 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 such as an immunocompromised infant.

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.

Pre-term infant formula 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.

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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 2019 – Guidance on Managing Cow's Milk Allergy in Primary Care https://www.allergyuk.org/health-professionals/mapguideline

An update to the Milk Allergy in Primary Care guideline 2019, Clinical and Translational Allergy https://ctajournal.biomedcentral.com/articles/10.1186/s13601-019-0281-8#Fig1

The GP infant feeding network (UK) 2019 https://gpifn.org.uk/imap/

Soya Formula

SACN (Scientific Advisory Committee on Nutrition) Feeding in The First Year of Life 2018, page 94, table 10.2

Rice Milk

Food Standard Agency, Arsenic in rice, update September 2018 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) https://journals.lww.com/jpgn/Fulltext/2018/03000/Pediatric_Gastroesophageal_Reflux_Clinical.33.aspx

NICE guideline: Gastro-oesophageal reflux disease in children and young people. Published Jan 2015, last updated Oct 2019 https://www.nice.org.uk/guidance/ng1

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*

Faltering Growth

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

General

infantmilkinfo.org Specialised infant milks in the UK: infants 0-6 months of age, April 2020 **https://infantmilkinfo.org/type-of-infant-milk/specialised-milks/**

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