NHS
Norfolk and Waveney
Integrated Care Board

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Norfolk and Waveney Integrated Care System

NHS Norfolk and Waveney
Policy Statement and Formulary: Infant Formula Milk Products

Guide 4: Infant Formula milks NOT for prescribing

- **Gastro-oesophageal reflux**
- **Secondary lactose intolerance**

If you have any queries about prescribing specialist infant formulae related to this guidance, please contact the Medicines Optimisation Dietetic team at N&WICB:
nwicb.dieteticqueries@nhs.net

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).
- It should be noted that at least 40% of infants have some degree of reflux at some time.
- GOR usually begins before the infant is 8 weeks old and resolves in 90% of affected infants before they are 1 year old.
- A specific infant formula or medical management is not always necessary.

See NICE guideline NG1 Gastro-oesophageal reflux disease in children and young people and CKS Management of gastro-oesophageal reflux disease (GORD) in children for further information.

Treatment

- If the infant is thriving and not distressed reassure the parents and monitor.
- **Follow the treatment flow chart on page 4 for stepped approach of intervention.**
- Advice should start with ruling out red flags and reviewing the feeding history. Advice on avoiding overfeeding, positioning during and after feeding, and activity after feeding may be helpful as a first step.
- If the infant is formula fed OTC formulae (pre-thickened) for reflux are available if parents/carers wish to try these (prior to commencing alginate therapy).
- Pre-thickened formulas should not be used along with other thickening agents, e.g., Infant Gaviscon®, Carobel® to avoid over thickening of the stomach contents. Over the counter pre-thickened formulae contain carob gum, or starches. These formulae will require use of a large hole (fast flow) teat.
- If a breastfed infant is showing signs of overt regurgitation with marked distress then advice should be sought from a specialist breastfeeding advisor.
- A trial of a prescribed alginate should be offered if the above interventions have not been successful after a 1-2 week trial. 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 Carobel® can be purchased and used to thicken standard formulae 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)
HiPP Anti-reflux milk® (HiPP)	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 (approx. every 2 weeks).

Flowchart: Treatment of Infants with GOR/GORD

Infant with **overt regurgitation** AND at least one of the following: *unexplained feeding difficulties, distressed behaviour, faltering growth, chronic cough, hoarseness, an episode of pneumonia*

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

- Frequent, forceful (projectile) vomiting
- Blood-stained (green/yellow) vomiting
- Haematemesis (excluding swallowed blood e.g. following nosebleed or ingested blood from a cracked nipple)
- Onset of regurgitation and/or vomiting after 6 months old or persisting after 1 year old
- Blood in stool or chronic diarrhoea
- Abdominal distension, tenderness or palpable mass
- Appearing unwell / Fever
- Dysuria
- Bulging fontanelle
- Rapidly increasing head circumference or persistent headache
- Altered responsiveness, for example lethargy or irritability
- Infants or children with/or at high risk of atopy (consider possibility of CMPA- see guide 1)

Yes → **Further investigation /Urgent referral**

No

STEP 1

Breastfed: Advise assessment with appropriately trained person

Formula fed: Use the 'stepped care approach'- Review the feeding history, then:

1) Reduce the feed volumes only if excessive for the infant's weight
2) Suggest a trial of smaller, more frequent feeds (while maintaining an appropriate total daily amount of milk) unless the feeds are already small and frequent
3) Suggest a trial of OTC thickened formula* (see page 3). Advise the need for large hole (fast flow) or variable flow (split) teat

Review after 1-2 weeks

If symptoms have improved continue but advise to trial stopping every 2 weeks to see if still needed. If symptoms not improved move to step 2

STEP 2

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*

Formula fed infant: Advise parent/carer to:

- Discontinue the **pre-thickened formula**
- Offer a trial of 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 to trial stopping 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/

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 7

- 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 lactose 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/carers should be advised to purchase it as it is a similar cost to cow's milk formula.**
- 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
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.

Flowchart: Treatment of Secondary Lactose Intolerance in Primary Care

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Symptoms of Lactose Intolerance > 2 weeks
(Often after infectious gastroenteritis):

- Loose watery green stools
- Abdominal pain
- Bloating and increased wind

Always consider the possibility of Cow's Milk Protein Allergy (CMPA). See guide 1

Breastfed infant

- **There is no need to stop breastfeeding.** Breast milk remains the optimal milk and will assist with gut healing in secondary lactose intolerance
- Lactase drops such as Colief® can be added to expressed milk to make digesting the lactose easier. Using lactase drops for more than a week if symptoms do not improve is not recommended
- **Refer to breast feeding advisor**

Formula fed infant

0 – 12 months

Advise parent/carer to buy lactose free formula- see page 6
***Healthy start vouchers can be used if eligible**

>12 months

Advise parent/carer to buy lactose free whole or semi-skimmed milk products

If weaning/weaned, advise lactose free diet
Useful link: -
https://www.nhs.uk/conditions/lactose-intolerance/treatment/

Review after 2 weeks
Have symptoms resolved? Did diarrhoea stop 48 hrs after lactose free diet?

NO

- Ensure dietary compliance
- **Consider CMPA (guide 1)**
- Consider referral

YES

- Advise to continue **lactose free diet** for up to 8 weeks
- **After 6 - 8 weeks** *gradually reintroduce* lactose containing formula / milk / foods

Follow up
Have symptoms reoccurred?

NO

Continue to follow normal diet

YES

- Advise lactose free formula / milk / foods
- **Investigate cause** (consider CMPA and coeliac disease)
- **Refer if still needs lactose free diet after 6 months**