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#### REFERENCES

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## SPECIALIST INFANT FORMULA: THE ESSENTIAL NEED FOR PRESCRIPTIONS TO BE MAINTAINED

**It is well established that breastfeeding is the best way to feed a baby, being important for both the mother and the infant. The World Health Organisation (WHO) recommends that babies are exclusively breastfed until six months of age, after which breastfeeding should be complemented with the introduction of solid foods until the age of two.<sup>1</sup>**

When a mother cannot, or chooses not to, breastfeed, and there are no medical concerns, then a standard infant formula may be used. Some infants are unable to receive adequate nutrition from breastmilk, or standard formula alone, because of a disease, disorder or medical condition. For these infants, the only alternative source of nutrition which is suitable and safe, is a scientifically formulated infant formula. These specialist milks are known as Foods for Special Medical Purposes (FSMPs) intended for infants.

Correct nutrition during infancy is essential to ensure adequate growth, health and development.<sup>2</sup> An underlying illness or condition can lead to malnutrition, with nutritional deficiencies, stunting and/or wasting presenting. This can be detrimental for an infant and have long-lasting implications for the health of the child.<sup>1</sup>

Infant foods for special medical purposes (iFSMPs) are medical products, specifically formulated and produced for a medical need and intended for the exclusive or partial feeding of infants and young children, allowing infants to receive adequate nutrition when breastmilk or standard infant formula alone cannot provide it.

There is a diverse range of iFSMPs available to address a number of conditions which infants can suffer from; it is essential that infants receive the appropriate formula for their individual requirements so that they are able to achieve optimal growth and development. The conditions for which iFSMPs may be used can vary greatly

in terms of their permanence, severity and impact on day-to-day life. The age at which they should be introduced also varies, with some medical conditions being detected at birth by newborn screening (e.g. PKU), and others having a later onset or diagnosis, e.g. between six to 12 months, such as cows' milk protein allergy (CMPA).

#### CONDITIONS WHERE AN IFSMP MAY BE REQUIRED

##### Cows' Milk Protein Allergy

CMPA is the most common highly complex food allergy in infants and young children, affecting 1.9% to 4.9% of infants and children worldwide.<sup>3</sup> It is an allergic reaction to one or both of the proteins, casein and whey, found in milk. CMPA can be categorised as immediate (IgE-mediated) or delayed (non IgE-mediated).

Exposure can occur either through breastfeeding (via cows' milk protein in the maternal diet), through standard infant formula, or when weaning occurs and solids are introduced.

Symptoms include skin problems such as eczema, hives and swelling, respiratory symptoms and gastrointestinal issues. In worst case scenarios, CMPA can lead to admission to A&E and/or paediatric intensive care units due to anaphylaxis and can potentially lead to death. It is important that those affected by CMPA are diagnosed and managed appropriately. For confirmed CMPA, strict avoidance of cows' milk protein is currently the safest strategy

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for management, i.e. elimination of cows' milk protein for the breastfeeding mother, via an elimination diet, managed by a qualified professional.

If this is not possible, or an infant is formula-fed, a specific iFSMP can be prescribed, such as an extensively hydrolysed formula (eHF) or an amino-acid based formula (AAF), as stated by NICE and MAP guidelines.<sup>4,5</sup>

In an eHF, the protein has been hydrolysed into smaller peptides which the immune system does not recognise as cows' milk protein and, therefore, no reaction occurs.<sup>6</sup> These are tolerated by the majority of infants and children (90%) with CMPA. An AAF, which is made-up of free amino acids, is an alternative for those infants and young children who cannot tolerate an eHF, or those with severe symptoms.<sup>7</sup>

### **Lactose Intolerance**

Infants with lactose intolerance have the inability to digest the carbohydrate lactose because they lack the enzyme lactase. Typically, lactose intolerance in infants only lasts from a few days up to a few weeks. The common symptoms of lactose intolerance are gastrointestinal with loose stools, abdominal pain, flatulence, bloating and discomfort commonly presenting. It is during this time that an iFSMP containing an alternative carbohydrate source to the lactose present in standard formula plays a vital role in managing the condition and ensuring the continued nourishment, development and health of the child.

Although lactose intolerance can cause similar symptoms, it should not be confused with CMPA. Formulae for lactose intolerance are not suitable for infants with CMPA as they still contain cows' milk protein.

### **Preterm**

Thanks to advances in antenatal care, an increasing number of preterm babies are surviving. These babies are vulnerable and specialist paediatric dietitians have a critical role to play in making sure that the diet of these infants is effectively managed. Expressed breastmilk supplemented by a breastmilk fortifier is the preferred method of feeding. However, mothers of preterm infants may be under particular stress, which may affect their milk supply. If so, a specialist ready-to-feed preterm formula may be required,<sup>8</sup> which typically contains higher levels of energy, a higher protein:energy ratio and higher levels of key micronutrients, such as iron and vitamin D, when compared with standard formula. These formulae are designed to support the increased metabolic requirements of preterm infants.

### **Faltering growth**

Faltering growth is a term used to describe an infant who is not gaining weight or length, as expected, over a period of time. Causes of faltering growth can include: higher nutritional requirements, or an inability to consume enough nutrients to meet requirements, e.g. through muscular disorders or respiratory disease; poor swallowing; vomiting and diarrhoea; or poor absorption of nutrients, such as digestive disorders including cystic fibrosis and chronic kidney disease.

Faltering growth may be managed with a specialist high energy infant formula, which provides more calories and protein than a standard infant formula, to help achieve catch-up growth. Turn to page 15 for more on the NICE guideline on faltering growth.

### **Gastro-oesophageal reflux**

Reflux, or gastro-oesophageal reflux, is when the stomach acid moves up into the oesophagus

or even into the mouth. It is common for this to happen in infants during or immediately after feeding. However, when the volumes of returned feed are significant and the infant has additional symptoms, such as excessive crying, poor growth and regular vomiting, then either an anti-reflux formula, which is pre-thickened or thickens in the stomach, or a feed thickener added to standard formula, may be required to manage this condition.

### THE ROLE OF THE HEALTHCARE PROFESSIONAL

All iFSMPs should be used under the guidance of a healthcare professional.

If an infant shows signs or symptoms which indicate that a specialist product may be required, it is essential that the infant is diagnosed and managed appropriately. Paediatric dietitians have the specialist expertise to collaborate with a GP to diagnose, advise and prescribe the appropriate product for an infant, ensuring that sufficient nutrients are provided to safeguard growth and development.

As infants have relatively high nutritional needs and growth trajectories, their nutritional support should be constantly monitored. One size does not fit all; as children grow and develop, their nutritional needs change, therefore they may need different nutritional inputs at different stages. Moreover, some conditions are characterised by periods of relapse and remission, e.g. Crohn's disease, which makes ongoing monitoring even more important. The value of good paediatric dietetic advice in these situations cannot be underestimated.

Not only is a medical condition stressful for the infant, it can be very upsetting for parents or carers. Conditions, such as gastro-oesophageal reflux, lactose intolerance and CMPA, can be significantly distressing and frightening for the parents of infants who suffer from them.<sup>9</sup> Therefore, any concerned parent should be encouraged to see their GP and subsequently referred to a paediatric dietitian to ensure the appropriate formula is recommended when their child is unwell and the condition professionally managed. This eliminates the risk of the parent or guardian receiving inappropriate advice about the dietary management of their child, which could put the health of the infant at risk.

### PRESCRIPTIONS ARE AT RISK

All iFSMPs go through a strict application process, which the Advisory Committee on Borderline Substances (ACBS) - the committee responsible for what is available on prescription - assesses and approves, taking into consideration the cost and efficacy of all these formulae for the dietary management of clinical conditions. These products are also highly regulated by EU legislation<sup>10</sup> and supported by robust evidence, allowing healthcare professionals and patients to trust in the efficacy and quality of the products available.

Even though these products are ACBS approved, highly regulated and the NHS Constitution<sup>11</sup> states that, 'Access to NHS services is based on clinical need, not an individual's ability to pay', prescriptions of iFSMPs are at risk. Proposals by some Clinical Commissioning Groups (CCGs) have included restrictions to soya-based infant formula, thickened infant formula and formula for lactose intolerance, for example. These specialist products play a vital role in safeguarding the health and development of vulnerable infants and young children, no matter the severity of the condition, in both the hospital and the community.

### PUTTING NUTRITION AT THE HEART OF PATIENT CARE

The role of a paediatric dietitian in diagnosis, treatment and review is fundamental. Prescribing the appropriate iFSMP provides optimal nourishment for all infants with a disease, disorder or medical condition. BSNA supports the following:

- iFSMPs to be recognised as an integral part of the management of diseases, disorders and medical conditions which require nutritional support.
- iFSMPs to be accessible to all patients who need them. All care pathways should clearly identify how and when iFSMPs should be used to help manage a patient's condition.
- iFSMPs to be prescribed and used appropriately when needed, and for patients to be regularly reviewed and monitored by a healthcare professional.