Briefing Note: Choosing Wisely- Changes to prescribing of specialist hypoallergenic infant formulas

**Background**

Cow’s milk protein allergy (CMPA) is one of the most common childhood allergies in the developed world, with a prevalence of 2-7.5% among children under one year old. It is also the most clinically complex allergy to diagnose as ‘most of the presenting symptoms overlap with other conditions that are also common in infants, such as eczema or reflux colic’; ‘it is estimated that, globally, cow’s milk protein allergy is responsible for approximately 40% of gastroesophageal reflux disease (GERD) and 70% of chronic constipation and 11% of deaths from anaphylaxis’.

Data from 2008 estimated that 2.3% of 1-3 years old in the UK suffer from CMPA. A recent health economic analysis on the financial implications of CMPA on the NHS concluded that approximately 18,350 infants in the UK will present to GPs each year with CMPA.

At present, there is no cure for food allergy but there are numerous guidelines for the diagnosis and treatment of CMPA. These include National Institute for Clinical Excellence Guidelines (NICE) CG116, the Milk Allergy in Primary Care (MAP) guidelines and the British Society for Allergy and Immunology Guideline for specialists. All of these advocate milk avoidance and in practice, for those infants who are no longer breast-fed, this will often require special, hypoallergenic infant formula (classified as ‘Food for Special Medical Purposes’), such as Extensively Hydrolysed Infant Formula (EHF) or Amino Acid Formula (AAF). For babies suffering from CMPA, these formulas may be the only source of nutrition and without them they are at risk of a severely impaired quality of life through chronic symptoms or possibly anaphylaxis.

**Scope of the Issue**

Since November 2016, a number of Clinical Commissioning Groups (CCGs) across the England consulted on plans to de-prescribe a number of products and medicines that they provide as a means to reduce NHS spending. For products considered to be widely available from community pharmacies or supermarkets for similar or lower price it was proposed that GPs would no longer prescribe them.

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2 NICE Clinical knowledge summary on cow’s milk allergy in children, 2015.
8 NHS Milk-snatchers are opening the way for more GP cuts. Inside Croydon. https://insidecroydon.com/2017/03/01/nhs-milk-snatchers-are-opening-the-way-for-more-gp-cuts/
Alongside gluten-free products and vitamin D, a small number of CCGs have also taken the decision to consult on the removal of specialist infant formulas from prescription. While some of these products, such as soya, lactose free formula and thickeners are available from supermarkets and over the counter from community pharmacies, the specialist infant formulas to specifically treat CMPA are not readily accessible. They are also prohibitively expensive. It is therefore wholly inappropriate to remove prescribing for such specialist products.

Some of the reasoning behind some CCGs proposing the de-prescribing of hypoallergenic infant formulas relates to confusion between lactose intolerance and CMPA. This has been confirmed through engagement with the CCGs and in the case of Richmond CCG, an acknowledgement of this issue and in response to the consultation a decision not to de-prescribe. However, other consultations suggest that de-prescribing is being considered even where there may not be confusion around this issue. This is of even greater concern.

EHF and AAF are not currently available to be purchased from community pharmacies or supermarkets. If the proposed go ahead, access to these formulas would be severely restricted to only those who have the means to buy them online at, most likely, inflated costs. The most vulnerable members of our communities will be hit the hardest by these changes. A normal tin of formula is roughly £10-12 and will last for around a week. Specialist infant formulas cost up to £48 a tin, and the tin is half the size of a normal formula and last for approximately two and a half days.

Finally, these specialist infant formulas are defined in the UK legislation as ‘Foods for Special Medical Purposes’ and are required to treat a medical condition and as such should be administered under medical supervision. This ensures that babies diagnosed with CMPA are prescribed with the correct formula and health outcomes monitored by healthcare professionals. The use of inappropriate formulas may well lead to increased GP visits, hospital admissions and even infant mortality.

Actions to date
Allergy UK, the British Dietetic Association (BDA) and The British Society for Allergy and Clinical Immunology (BSACI) have actively engaged with some of the CCGs currently conducting consultation processes and have presented their very serious concerns in regards to the high cost of specialist infant formulas, their limited availability and the fact that babies with diagnosed or suspected CMPA need specialist formula in order to receive appropriate nutrition.

As a result of this engagement, Richmond CCG has acknowledged that the text in the document relating to Cow’s Milk Protein Allergy (CMPA) was misleading. CMPA should not have been included in the list of those who might be affected by the proposal and new guidelines will be developed with local dieticians, other healthcare professionals and stakeholders, and Allergy UK outlining a suitable care pathway.

Croydon CCG has now decided to restrict prescription at 12 months of age for CMPA despite hearing our collective concerns. Allergy UK will continue working with this CCG to address our concerns and potentially revert its decision by highlighting the fact that children with CMPA will most likely outgrow it by the age of 3 years old.

Furthermore, Allergy UK have undertaken an exercise using Freedom of Information requests (FOI) to understand how many CCGs have already or are planning to review the provision of infant formulas on prescription. The results are:

http://www.croydonccg.nhs.uk/get-involved/Changes-to-prescribing/Pages/default.aspx
• 118 CCGs will continue to prescribe specialist infant formulas with no planned changes
• 13 have a review planned in the near future
• 11 have a review underway
• 43 did not reply

Eight of those who did not reply are within the North West London Clinical Commissioning Group (CCGs) who have recently launched a consultation with a proposal to de-prescribe using the generic term ‘infant formula’. We wrote to them in June 2017 to ask for clarification whether this proposal includes specialist formulas for CMPA, advising them of our concerns. We have not yet received a reply.

Inquiries made of NHS Clinical Commissioners, the body that represents CCGs across England, indicates that at the moment it has no intention to include infant formulas within its efforts to remove some £400 million of “low value” prescribing. However, we intend to keep this under review and will await the next group of products slated for removal from prescription.

**Recommendations**

Whilst we understand the financial challenges the NHS is currently facing and the need for the CCGs to make efficiency savings, we strongly believe that specialist infant formulas to treat CMPA (EHF and AAF) should remain available on prescription. If removed, there is likely to be a significant impact on the ability of these parents to feed their children. Most worryingly the well-being and life of this babies will be put at risk.

The consultation documents submitted by some of the CCGs evidence a clear lack of knowledge and understanding of CMPA, its diagnosis and management. Investing in education and training in Allergy and improving knowledge of allergic disease among healthcare professionals is therefore a priority and would result in savings itself. Without this, there remains ongoing risk of misdiagnosis, unnecessary prescriptions, mismanagement, and unnecessary morbidity will continue to characterise the way in which CMPA is dealt with in primary care.

We would like for the NHS in England to send a clear message to all the CCGs that are currently undertaking or are planning to undertake consultation processes to re-examine their decision, highlighting the fact that specialist infant formulas for the treatment and management of CMPA are not just ‘baby milks’ and should have never been placed alongside self-care medications in their consultation documents.

This briefing note has been prepared by Allergy UK, British Society for Allergy & Clinical Immunology, the British Dietetic Association, and the Royal College of Paediatrics and Child Health.