



Bedfordshire, Luton & Milton Keynes Guidelines for the prescribing and use of specialist infant formula in primary care. September 2024

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BLMK Infant Formula Prescribing Guidelines 2024

Introduction:

Whilst these guidelines advise on appropriate prescribing of specialist infant formulae, breast milk remains the optimal milk for infants. Breastfeeding should always be promoted and encouraged.

This guideline aims to provide information for healthcare professionals on the use of prescribable infant formulae and specialist infant formulae available over the counter that is to be used under medical supervision. It provides guidance on initial and on-going prescribing, when to discontinue prescribing and other considerations for use of specialist formulae.

The guideline covers five specific conditions where infant formulae is often used. Some conditions are able to be effectively managed in primary care and prescribers will be able to oversee the management of these formulae with some input from specialist care where appropriate. Some formulae will need specialist input before commencing use and guidance is provided on when these formulae should be discontinued.

The formulary contained within this guidance is not complete with regard to all specialist infant formulae. Specialist nutritional products or infant formulae prescribed to patients that fall outside this guidance should be overseen by a specialist clinician in acute or community, who will provide clear rationale for use, timescale for prescribing and review criteria.

Specific exceptions:

If all nutrition is received by a feeding tube e.g. Nasogastric/Nasojejunal/Gastrostomy tube for clinical reasons (such as unsafe swallow), a dietitian will recommend a prescription for the appropriate monthly amount and type of formula. A dietitian may calculate a different volume or suggest the use of a formula outside these guidelines based on individual need. The specific need and clinical rationale will be included with the feed prescription request.

Volumes of feed to prescribe infants:

Please use the guide below to estimate quantity of powdered infant formula to prescribe. Volumes stated are the maximum that are required for an average child (on the 50th percentile for weight); however those under the care of a dietitian may require more or less formula. Over prescribing can occur if infants are being overfed. If you suspect an infant is being overfed or a parent requires support on responsive feeding refer to the 0-19 team for assessment.

Initially prescribe a 1-week trial of 2 x 400g or 1 x 800g tin of powdered infant formula to see if the infant will tolerate the formula.		
Age of infant	Number of tins for 28 days	
Under 7 months	10 x 400g OR 5 x 800g tins	
Between 7 – 12 months	7 x 400g tins OR 3 x 800g tins	
Over 1 year	Will be stated on prescription request from paediatric dietitian.	

Diagnosis	Guidance	Age Range	Available Formulae	Volume < 7 months for 28 days	Volume > 7 months for 28 days	Review criteria
Cow's Milk Allergy	First line extensively hydrolysed formula (EHF) For use first line if mild to moderate milk allergy suspected. Whey-based formula contains lactose.	Birth to 1-2 years	First line EHF: SMA Althera (Whey-based) (Nestle) (v) (h) Aptamil Pepti 1 (Whey- based) (Nutricia)	10 x 400g tins	7 x 400g tins	
	infants with <u>severe</u> <u>diarrhoea/severe GI symptoms</u> who would benefit from a lactose free formula		Mutramigen 1 LGG (Casein- based) (Mead Johnson)			Prescribe up to 1 year of age or until advised by dietitian. Infants who are at significant
	Second line amino acid-based formula (AAF) For use with treatment of severe symptoms of cow's milk allergy.	Birth to 1-2 years	First line AAF: Puramino (Mead Johnson) (h)	10 x 400g tins	7 x 400g tins	nutritional risk i.e. multiple food allergies, may require prescribed specialist infant formula beyond 1 year of age. This should only be under
	Only recommended for use in primary care if symptoms have not improved after use of an EHF following a 2-4 week trial.		Alternative AAF: Neocate LCP (Nutricia) (v) (h) SMA Alfamino (SMA Nutrition) (v)	Should only be of stock unavail AAF	used in the event ability of first line	the direction of a paediatric dietitian.
Faltering Growth	High energy formula To be started in secondary or specialist care if an infant is at risk	Birth to 18 months or > 8kg of body weight	SMA High Energy (SMA Nutrition) (v) (h) Similac High Energy (Abbott Nutrition) Infatrini	Quantity to be advised following assessment	Quantity to be advised following assessment	Should be stopped once an infant has achieved catch-up growth or > 8kg of body weight. Refer to most recent report from paediatric dietitian
	faltering growth.		(Nutricia)			for information.
Preterm	faltering growth. Post discharge formula.	Birth to 3-6	(Nutricia) SMA Gold Prem 2 powder	10 x 400g tins	N/A	for informa

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Summary Gu	idelines for Specialist Infant Formulae	TO BE PURC	HASED OVER THE COUNTER	
Diagnosis	Guidance	Age Range	Available Formulae	Considerations for use
Cow's Milk Allergy	Soya Formula: NO LONGER AVAILABLE			
Gastro- oesophageal reflux disease (GORD)	Thickened Formula Parents should prepare thickened formulae as advised by manufacturer	Birth to 1 year	Aptamil Anti-reflux® (Cow & Gate) Cow and Gate Anti- Reflux® (Nutricia) SMA Anti- Reflux® (SMA Nutrition)	 To be used under medical supervision. Review use of thickened formula and thickening agents after 6 months as thickeners can reduce bioavailability of nutrients. Pre-thickened formula should not be used along with other thickening agents i.e. Carobel. If thickened formula is unsuccessful in managing symptoms, consider starting alginate therapy.
Lactose Intolerance	Lactose-free Formula For use in managing symptoms of secondary lactose intolerance. Not suitable for infants with suspected cow's milk allergy.	Birth to 1 year	SMA LF (SMA Nutrition) (h) Aptamil Lactose-Free (Nutricia) (h)	To be used under medical supervision. Should only be used for a maximum of 6-8 weeks after which infant should be challenged with a standard cow's milk based infant formula. After 1 year can use shop bought full fat lactose free milk.
NB: These guid use – including	NB: These guidelines are for use in primary care. Alternative products may be requested by specialist or secondary care if clinically indicated. Rationale and guidelines for use – including guantity and timelines for review will be included in correspondence.			
KEY	Suitable to vegetarians (v) suitable for halal d	iets (h) NB: no	formulae are suitable for vegan diets	
	First line choice – can be initiated in primary of	care		
	Preferably started in secondary or specialist s	services. If start	ed in primary care, refer to secondary	or specialist care for advice & support
	To be started in secondary or specialist care only			
	Over the counter use recommended – do not prescribe			

DIAGNOSIS:

- Cow's milk allergy (CMA) suspected after taking an allergy focused history as per <u>NICE Food</u> <u>allergy in children</u>.
- Refer to local cow's milk allergy pathway or <u>iMAP guideline (2019)</u> for clinical advice on diagnosing and managing cow's milk allergy in primary care.
- <u>NICE Quality Standard QS118</u> recommends a cow's milk exclusion trial MUST be followed by reintroduction of cow's milk, if the diagnosis for <u>non-IgE mediated CMA</u> is to be confirmed or excluded. Provide these <u>guidelines</u> to the family when prescribing specialist formula.
- Lactose free formulas are <u>not suitable</u> for treating CMA as they contain cow's milk protein (see lactose intolerance on page 11)

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

Mild to Moderate New Jac modiated	Covers New Jrr mediated	Mild to Mederate Jr. mediated
Mild to Moderate Non-IgE mediated	Severe Non-IgE mediated	Mild to Moderate IgE-mediated
Cow's Milk protein (CMP)	Cow's Milk Protein (CMP).	Cow's Milk Protein (CMP) may be up to 2 hours after.
Usually several of these symptoms will be present, symptoms persisting despite first line measures are likely to be allergy related:	One but usually more of these severe, persisting and treatment resistant symptoms: • Gastrointestinal – Diarrhoea,	One but usually more of these severe , persisting and treatment resistant symptoms:
 Gastrointestinal – persistent irritability 'colic' reflux (GORD), vomiting, food refusal or aversion, diarrhoea like stools, constipation especially soft stools with excessive straining, abdominal discomfort, painful flatus, blood/mucous in stools otherwise well infant. Skin- pruritus (itching) erythema (flushing) non-specific rashes, moderate persistent atopic dermatitis. 	 vomiting, abdominal pain, food refusal or food aversion, significant blood and/or mucus in stools, irregular or uncomfortable stools with/without faltering growth Skin – severe atopic dermatitis with/without faltering growth 	 Gastrointestinal - vomiting, diarrhoea, abdominal pain/colic. Skin- acute pruritus, erythema, urticaria, angioedema or acute "flaring" of persisting atopic dermatitis. Respiratory- rarely in isolation of other symptoms acute rhinitis and/or conjunctivitis Anaphylaxis – immediate reaction with severe respiratory or cordiovaceular signs and
The symptoms above are very common in otherwise well infants so clinical judgement is required. Trial exclusion diets must only be considered if history and examination strongly suggest cow's milk allergy especially in breastfed infants.		symptoms (rarely a severe gastrointestinal presentation) Emergency treatment and admission
TREATMENT SUMMARY:	TREATMENT SUMMARY	TREATMENT SUMMARY
Exclusively breastfeeding mother Trial strict exclusion of all cow's milk from her own diet and advise to take daily calcium and vitamin D for 2-4 weeks. Find guidance <u>here</u> .	Exclusively breastfeeding mother Trial strict exclusion of all cow's milk from her own diet and advise to take daily calcium and vitamin D for 2-4 weeks. Find guidance here.	Exclusively breastfeeding mother Trial strict exclusion of all cow's milk from her own diet and advise to take daily calcium and vitamin D for 2-4 weeks. Find guidance here.
Formula-fed or 'mixed feeding' If mother unable to revert to fully breastfeeding, trial extensively hydrolysed formula for 2-4 weeks.	Formula-fed or 'mixed feeding' If mother unable to revert to fully breastfeeding, trial amino acid formula for 2-4 weeks.	Formula-fed or 'mixed feeding' If mother unable to revert to fully breastfeeding, trial extensively hydrolysed formula for 2-4 weeks
Complete <u>IMAP nome challenge</u> to confirm diagnosis after elimination trial then refer to paediatric dietitian	URGENT REFERRAL TO LOCAL ALLERGY SERVICE (Includes dietitian) Refer to iMAP (2019) for treatment	URGENT REFERRAL TO LOCAL ALLERGY SERVICE (Includes dietitian)
guidelines. <u>Find here</u>	guidelines. Find here	guidelines. <u>Find here</u>
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COW'S MILK ALLERGY – guidance for choice of formula when mother unable to fully breastfeed.

FIRST LINE: Extensively Hydrolysed Formula (EHF)		
Available Formulae	Age range	Clinical guidance/notes
First line EHF: Althera (Whey-based) (SMA Nutrition) Pepti 1 (Whey-based) (Aptamil)	Birth to 1-2 years	Whey-based formula contain lactose.
Nutramigen 1 LGG (Casein-based) (Mead Johnson)		Use casein-based first line in infants with <u>severe</u> <u>diarrhoea/severe GI symptoms</u> who would benefit from a lactose free formula

Second stage or follow-on EHF:

Follow-on formulae are not routinely recommended for infants. The evidence for obtaining any nutritional benefit is limited. It is also not recommended to move an infant settled on a first stage formula onto a second stage formula of another brand. There are currently two brands that provide follow-on formula: Nutramigen 2 LGG (from 6 months) Nutramigen 3 LGG (from 1 year), and Aptamil Pepti 2 (from 6 months).

SECOND LINE: Amino Acid Formula (AAF) – for severe cow's milk allergy		
Available Formulae	Age range	For use with Clinical guidance/notes
First line AAF: Puramino (Mead Johnson)	Birth to 1-2 years	For use with treatment of severe symptoms of cow's milk allergy Only recommended for use in primary care if symptoms have not improved after use of an EHF following a 2-4 week trial
Alternative AAF		

The following products should only be used in the event of stock unavailability of first line AAF: Neocate LCP (Nutricia) & SMA Alfamino (SMA Nutrition)

Infants with **multiple allergies** may require prescribed **specialist infant formula beyond 1 year of age.** There is currently only one brand: Neocate Junior (Nutricia) (From 12 months). **This should only be prescribed on written request from a paediatric dietitian and should not be started in primary care.**

OVER THE COUNTER Soya Formula DISCONTINUED

There is no soya formula available to purchase over the counter. Alternative products will be required for infants who rely on soya-based formula in the long term.

See First Steps Nutrition Trust for further support and information

REVIEW CRITERIA

- Most children will tolerate a plant-based milk alternative over 1 year of age and their prescription for formula can be stopped. The dietitian will only recommend ongoing prescribing of specialist infant formula in cases where a child is at significant nutritional risk due to multiple food allergies or faltering growth. Refer to the latest written correspondence from the paediatric dietitian for guidance.
- All patients using these formulas require assessment from a paediatric dietitian for advice on calcium intake, challenging with cow's milk using the milk ladder and other feeding issues relating to a restricted diet

Faltering growth

DIAGNOSIS:

The term 'faltering growth' (previously called 'failure to thrive') is widely used to refer to a slower rate of weight gain in childhood than expected for age and sex. Guidance on diagnosing faltering growth is outlined in <u>NICE guidelines NG75: Faltering growth: recognition and management of faltering growth in children (2017)</u>. Please consult this guidance in order to follow best practice one when it is appropriate to consider prescribing a high calorie formula for infants.

HIGH ENERGY FORMULA – do not initiate in primary care		
Available Formulae	Age range	Clinical guidance/notes
SMA High Energy (SMA Nutrition)	Birth to 18 months or	To be started in secondary or specialist care if an infant is at risk of or has been diagnosed with faltering growth.
Similac High Energy (Abbott Nutrition)	8kg in body weight	NB: Infatrini Peptisorb is a partially hydrolysed high calorie feed that is used in specific circumstances to
Infatrini (Nutricia)		manage infants with faltering growth.

REVIEW CRITERIA:

- Infants with faltering growth should be referred to a paediatric dietitian for advice on a high energy, high protein diet and the consideration of the use of a specialist high energy infant formula.
- Clinical effectiveness of the supplements should be assessed by regular growth monitoring and assessment.
- Once catch-up growth has been achieved, the high energy formula should be discontinued to prevent excessive weight gain.
- If consuming the full therapeutic dose (as advised by the dietitian) and failing to gain weight or achieve expected growth, consider a referral to a paediatrician for further investigation.

Pre-term infants

DIAGNOSIS:

Infants born before 34 weeks gestation and weighing less than 2kg at birth are considered pre-term and may be discharged from hospital on a pre-term nutrient enriched formula.

Pre-term formulas and feeding products have been specifically designed to meet the raised nutritional needs for babies born prematurely.

TREATMENT SUMMARY:

The feed of choice for all infants, including pre-term infants, is breast milk. Every effort will be made to support mum to breastfeed. However, in some circumstances it may not be possible to solely breastfeed or breastfeeding may not be possible at all. In these circumstances a pre-term nutrient enriched post discharge formula will be necessary.

- Infants will have had their prescribed formula commenced on discharge from the Neonatal unit. It should not be initiated by primary care.
- Specific prescribing instructions will be sent to GP practices on discharge from the Neonatal Unit.
- Use of preterm formula liquid formulations in the community should be discouraged due to the high-cost implications.
 There are no nutritional differences between liquid or powder formulations. Pre-term infants who have been discharged on a liquid formulation should be encouraged to transition to a powdered preterm formula shortly after discharge.
- Pre-term formulas should not be used in primary care to promote weight gain in patients other than infants born prematurely.

Recommended Formulae	Age range	Clinical guidance/notes
SMA Gold Prem 2 powder (SMA Nutrition)	Birth to 3-6 months corrected age	Dietary management of low birthweight or pre- term infants post discharge.
Cow & Gate Nutriprem 2 powder (Nutricia)		
Corrected age: is the actual age of th	e infant minus the numbe	er of weeks premature.

corrected age. Is the actual age of the infant minus the number of weeks pre

PRE-TERM post discharge formula – DO NOT initiate in primary care

REVIEW CRITERIA:

- Infants should have their growth (weight, length and head circumference) monitored by their Health Visitor and/or community neonatal nurses whilst on these formulae.
- All pre-term formulas should be stopped by 6 months corrected age and parents advised to start a standard infant formula.
- Pre-term formula can be stopped before 6 months corrected age if there is excessive or rapid weight gain. If stopped under 6 months of age, <u>vitamin</u> & <u>iron</u> supplementation will be required in line with local guidelines.
- For advice on pre-term infant weaning refer to the <u>Bliss website.</u>

ONWARD REFERRAL:

- If there are concerns regarding growth whilst the infant is on specialist preterm formula, please refer the infant to the paediatric dietitian.
- If there are concerns regarding growth at six months corrected age or following return to a standard infant formula, please refer the infant to the Paediatric Dietitian.

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Gastro-oesophageal reflux

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).

Refer to NICE for full guidance: <u>NICE guideline [NG1] Gastro-oesophageal reflux disease in children and</u> young people: diagnosis and management (2015)

DIAGNOSIS:

Recognise regurgitation of feeds as a common and normal occurrence in infants that:

- is due to gastro-oesophageal reflux (GOR) a normal physiological process in infancy
- does not usually need any investigation or treatment
- is managed by advising and reassuring parents and carers.

If parents would like more information signpost to the reflux in babies summary on the NHS website.

Be aware that in a small proportion of infants, GOR may be associated with signs of distress or may lead to certain recognised complications that need clinical management. This is known as gastro-oesophageal reflux disease (GORD).

When reassuring parents and carers about regurgitation, advise them that they should return for review if any of the following occur:

- the regurgitation becomes persistently projectile
- there is bile-stained (green or yellow-green) vomiting or haematemesis (blood in vomit)
- there are new concerns, such as signs of marked distress, feeding difficulties or faltering growth
- there is persistent, frequent regurgitation beyond the first year of life.

If GORD is suspected assess for presence of red flags which may indicate disorders other than <u>GOR/GORD. NICE Quality standard [QS112] Gastro-oesophageal reflux in children and young people</u> (2016) and any <u>risk factors</u> or <u>complications</u> that increase the likeliness of GORD. Onward referral to paediatric services will be required.

Be aware that some symptoms of a non-IgE-mediated cows' milk protein allergy can be similar to the symptoms of GORD, especially in infants with atopic symptoms, signs and/or a family history. If a non-IgE-mediated cows' milk protein allergy is suspected, follow section on milk allergy management.

TREATMENT SUMMARY:				
Breastfed infant	Formula fed infant			
Take a feeding history	Take a feeding history.			
 Advice should be given to the mother with regards to breastfeeding technique, positioning and attachment (Refer to the 0-19 team). 	 Ask about the type of formula used, how it is prepared, the frequency of feeding and the volume consumed, positioning during and after feeding and any resistance or refusal to feed. 			
 If symptoms persist consider prescribing 1-2 week trial of alginate therapy e.g <u>Gaviscon infant</u>® offered on a spoon 	 Reduce the feed volume only if excessive for infant's weight (a total feed volume of 150mls/kg/day over 24 hours as 6-8 feeds is usually recommended). Offer a 1.2 weak trial of amount for the second s			
DETORE REEDS.	3. Offer a 1-2 week trial of smaller more frequent feeds (whilst maintaining an appropriate total feed volume)			
treatment and advise parents to stop at regular intervals e.g every 2 weeks in order to see if the symptoms have	 4. Offer a 1-2 week trial of a purchased thickened formula (see below) or a thickener that can be added to the usual infant formula e.g Instant carobel®. 			
improved and treatment can be stopped.	 If unsuccessful <u>STOP</u> the thickened formula or feed thickener and offer alginate therapy e.g <u>Gaviscon infant</u>® added to formula for a period of 1-2 weeks. 			
Pharmacological treatment of GORD is outlined in <u>NICE guideline</u> .	 If symptoms improve continue with treatment and advise parents to stop at regular intervals e.g every 2 weeks in order to see if the symptoms have improved and treatment can be stopped. 			
	Pharmacological treatment of GORD is outlined in <u>NICE</u> guideline.			

GASTRO-OESOPHAGEAL REFLUX – guidance for choice of formula				
THICKENED FORMULA– AVAILABLE OVER THE COUNTER – NOT TO BE PRESCRIBED				
Formula	Age range	Clinical guidance/notes		
Aptamil Anti-reflux®	Birth to 1 year	Use a single-hole, fast flow teat		
(Cow & Gate)		Contains carob bean gum		
		Do not use in combination with any other antacids or		
		feed thickeners		
Cow and Gate Anti- Reflux®		Use a single-hole, fast flow teat		
(Nutricia)		Contains carob bean gum		
		Do not use in combination with any other antacids or		
		feed thickeners		
SMA Anti- Reflux®		May require a single hole, fast flow teat		
(SMA Nutrition)		Contains potato starch		
		Do not use in combination with any other antacids or		
		feed thickeners		
FEED THICKENER – TO BE PRE	SCRIBED IF INDIC	ATED		
Instant Carobel®	To be used under	May require a wide or variable flow bottle teat		
(Cow and Gate)	medical	Prepare as per manufacturer instructions		
	supervision			
135g pack		Contains carb bean gum		
1 level scoop = 1.7g	This may be			
	necessary to use if	Do not be used in combination with any other antacids		
	an infant is on a	or thickened formulae		
	specialist infant			
	formula			

REVIEW CRITERIA:

- Review after one month.
- 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 can be trialled from 12
 months.
- Thickeners and thickened formulae should not be used for more than 6 months.

Lactose Intolerance

DISCLAIMER: Lactose intolerance is not the same as cow's milk protein allergy (CMPA). CMPA is caused by an immune response to the protein in cow's milk and causes a variety of symptoms involving the gut, skin and/or respiratory system. Lactose intolerance is not caused by an immune response and does not involve the skin and/or respiratory system.

TREATMENT SUMMARY:

- **Breast fed infants:** continue to be fed as normal. No change to the maternal diet is required as lactose levels cannot be altered by changing the mother's diet.
- Formula fed infants: Replace standard formula with a Lactose free formula for up to 8 weeks, allow symptoms to resolve then reintroduce standard formula/milk products slowly into the diet

OVER THE COUNTER – not to be prescribed			
Available Formulae	Age range	For use with Clinical guidance/notes	
Lactose-free Formula:	Birth to 1 year	Formula to be purchased by family from supermarket, pharmacy or online.	
SMA LF (SMA Nutrition)		For children over 1-year shop bought full-fat lactose free milk can be purchased by parents/carers.	
Aptamil Lactose-Free (Nutricia)			

REVIEW CRITERIA:

Lactose-free formula should not be used for longer than 8 weeks without review with a health care professional. After 8 weeks gradual reintroduction of lactose back into the diet is recommended. For further information please review <u>Managing lactose intolerance: a guide for families.</u>

ONWARD REFERRAL:

If symptoms have not resolved after 8 weeks on lactose free formula/lactose free diet, consider alternative diagnosis e.g. cow's milk allergy or refer to paediatrician for further assessment

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Bedfordshire, Luton & Milton Keynes Integrated Care Board

An assessment framework was used to compile details of infant formulae available at time of review and subsequent recommendations for the prescribing guidelines. This document is available upon request from the BLMK Paediatric Prescribing Support Dietitians.

Useful sources of information

<u>British Dietetic Association (BDA) Food Facts Sheets</u> - dietetic professional organisation where you can download free information sheets on a variety of dietary issues across the life spectrum.

<u>Bliss</u> - website for parents of babies born premature or sick; includes information on weaning your premature infant.

Infant Milk Info: First Steps Nutrition - information about infant milks available on the UK market.

The GP Infant Feeding Network (UK) - website to assist primary care practitioners with best practice in infant feeding.

The Milk Allergy in Primary Care (MAP) guideline 2019 - guidelines for management of cow's milk allergy developed alongside GP infant feeding network and the MAP guideline team

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