NHS Forth Valley
Local Enhanced Service Specification
Provision of near patient testing

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Consultation and Change Record – for ALL documents

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Consultation Process:			
Distribution:		Area Drug and Therapeutics Committee	
Change Record			
Date	**Author**	**Change**	**Version**
01/04/2014	SR	• Sulfasalazine has additional check 2 weeks after initatiation. • Mesalazine, olsalazine and balsalzide do not require monitoring. • Denosumab does not require monitoring • Recommended CXR as baseline for Methotrexate monitoring. • Clearer and consistent advice on when to discuss monitoring abnormalities for all medications.	1.2
31/05/2016	SR	See note regarding use of small symptomatic doses of AAs Monitoring of renal patients is done in the Renal Clinic	1.3
01/04/2017	SR	• Clearer guidance on basic monitoring as per BSR guidance 2017- shown below in normal font and in bold additional drug specific monitoring requirements • more frequent monitoring is appropriate in patients at higher risk of toxicity; conversely less frequent monitoring might be appropriate in certain circumstances.Thes decisions are the responsibility of the initiating clinician (	2.0

		specialist) • baseline CXR removed for MTX (lung function assessment might be considered by specialist as indicated) • more intensive monitoring (monthly) when Leflunomide and Methotrexate co-prescribed for the first year • addition of Sacubitril/Valsartan	

Date	**Author**	**Change**	**Version**
04/2017	SR	4.1 Addition of Sacubitril / Valsartan for first year only	3.0
		4.11 responsibility of education at initiation by specialist (and clear communication of this)	
		4.13 responsibility of annual review by specialist	
		8. one off additional payment for participating practices for 2017/18- TBC	
		8 clarification on when duplicate claims are appropriate	

1. Introduction

This enhanced service specification outlines the more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

2. Background

The treatment of several diseases within the field of medicine is increasingly reliant on drugs that, while clinically effective, need regular blood monitoring. This is due to the potentially serious side effects that these drugs can occasionally cause. It has been shown that the incidence of side effects can be reduced significantly if this monitoring is carried out in a well-organised way, close to the patient's home. Although initiation of these drugs is usually the remit of the specialist, increasingly, the monitoring of these drugs is being managed in primary care. Approximately 6% of hospital admissions are due to adverse drug reactions (ADRs)[i] and 3.7% are drug related and preventable[ii]. Cytotoxic drugs, like methotrexate, leflunomide and azathioprine, do not cause emergency hospital admission on the same scale as for example, warfarin, as its indications and therefore its use are more limited. However, their inherent toxicity means that they do regularly cause severe harm, including death (although this is rare), and have been the subject of regular National Patient Safety Agency (NPSA) alerts as a consequence[iii]. Practices need to ensure that prescriptions for community cytotoxic drugs are appropriate and carefully monitored to minimise risk. Recent data, drawing on work in progress, indicates that the prescribing and monitoring of community cytotoxics is suboptimal and potentially unsafe. Whilst we have seen great improvements, both nationally and locally in the management of these drugs (for example in the number of patients co-prescribed methotrexate 2.5 mg and 10 mg tablets) We need to be able to show that we continue to prescribe and monitor these medications in a reliably safe way.

This enhanced service provides clear guidance to help practices deliver safe, reliable care and provides a framework for measuring care to drive improvement.

Note from renal clinic regarding monitoring of Renal patients on Tacrolimus, Ciclosporin, Mycophenolate Cyclophosphamide and Azathioprine

"*The FV monitoring protocol for LES NPT drugs was set up for monitoring of mainly rheumatology and gastroenterology patients receiving immunosuppression. It does not apply to renal transplant recipients or patients attending the renal clinic where immunosuppression has been initiated for treatment of vasculitis or glomerulonephritis. Renal patients on immunosuppression will have all routine monitoring of their bloods performed at the renal clinic. Very occasionally there may be a specific follow up request to primary care for bloods between clinic visits but the relevant GP would be informed directly about this.*"

3. Aims

The near patient testing service is designed to be one in which:

- The service to the patient is safe, reliable and convenient.
- Therapy should only be started for recognised indications for specified lengths of time.
- The drugs are appropriately prescribed according to current guidance.
- Patients on these drugs are regularly monitored in accordance with guidance to prevent avoidable harm from these drugs monitored regularly.
- Patients are informed about these drugs, their side effects and the need for and process for being monitored.

4. Service outline

Under the terms of this local enhanced service, GP practices will be contracted to:

4.1 **Provide a near patient testing drug monitoring service** in respect of the following specified drugs and in accordance with any local shared care protocols (See appendix 2)

a) Atypical antipsychotics*
   - Amisulpride
   - Olanzapine
   - Quetiapine
   - Risperidone/*Paliperidone*
     Aripiprazole

The "Physical Health monitoring Guidelines for people with significant Mental health Problems" (ref 5) states "*in certain circumstances, eg dementia patients with severe behavioural problems, elderly psychotic patients, learning disability patients, may not be able to give consent to agree to the suggested monitoring tests. When an antipsychotic is felt to be clinically the most appropriate intervention, then these medications can be prescribed without baseline or ongoing tests as long as it is documented..*"

b) Immunosuppressant drugs

   - Azathioprine and mercaptopurine
   - Leflunomide
   - Methotrexate
   - Penicillamine
   - Sodium aurothiomalate / *Auranofin*
   - Cyclophosphamide.
   - Hydroxycarbamide
   - *Mycophenolate*
   - *Ciclosporin*
   - Tacrolimus
   - Dapsone

- Acitretin

c) Sulfasalazine **for the first year only** (No payment for mesalazine, balsalazide, -olsalazine) ,

d) Sacubitril /Valsartan **for the first year only**

e) **other drugs that do not appear on this list may be claimed for as a " forced claim". This will be reviewed on a case by case basis, but should require a minimum of 3 monthly assessments done by the practice to qualify**

4.2 **Develop and maintain a register.** Practices should be able to produce an up-to-date register of all patients being monitored under the near patient testing service.

4.3 **Record individual management plans.** Patients on these drugs should have the following information clearly highlighted in their notes:

- their contact telephone number
- diagnosis
- planned duration of treatment, and
- monitoring timetable – see locally agreed guidance in Appendix 2

4.4 **Prescribe appropriately.** Patients should be prescribed the drugs according to the local FV guidelines (see Appendix 2) unless specifically advised by the responsible specialist to do otherwise.

Specifically for patients on methotrexate

- A patient on methotrexate should only be prescribed one strength of tablet, 2.5 mg
- Methotrexate is prescribed to be taken weekly, unless in exceptional circumstances, e.g. for cancer treatment.
- Each prescription details the number of tablets to be taken and the dosage, i.e. 4 x 2.5mg tablets weekly (10 mg).
- The prescription for methotrexate is only issued after review of the patient's blood test (see 4.5 below).

4.5 **Conduct appropriate review of blood test prior to issuing of prescription for Methotrexate and Azathioprine.** Practices require to have systems to ensure that patients' blood tests are reviewed prior to a prescription of high-risk drugs being issued, (as per NPSA guidance).It is suggested that the same systematic approach should apply to all the drugs covered by the NPT LES

4.6 **Offer appropriate vaccination for patients on immunomodifying drugs** It is considered best practice that patients on cytotoxics receive appropriate

pneumococcal vaccine and an annual flu vaccination. Practices are expected to offer pneumococcal vaccine once only and influenza vaccine annually to all eligible patients. Item of service fee is available for pneumococcal vaccination of appropriate patients.

4.7 **Follow current guidance.** Patients' drug dosing and advice on the interval for blood testing given to the patient follows current national and local guidance Note simplifications in monitoring according to BSR guidelines 2017 (ref 6)
NHS Forth Valley Monitoring protocols of all Local Enhanced Service Near Patient Testing drugs can be found at: (Appendix 2 , or **http://www.nhsforthvalley.com/__documents/qi/ce_guideline_prescribing/monitoring-protocol-for-les-npt-drugs.pdf**

4.8 **Initiation.** If commenced in primary care, provide therapy and monitoring which follows specialist advice and is in line with shared care protocols (see Appendix 2).

4.9 **Have systems for call and recall.** The monitoring frequency should be determined by following local guidance. Blood tests should be taken as closely as possible to the planned date. To ensure that systematic call and recall of patients on the register is taking place, practices should clearly inform patients of the advised dose of their drugs and date of follow-up blood test. This information should be recorded in the patient's notes. There should be systems for identifying patients who do not attend for drug monitoring.

4.10 **Ensure compliance with monitoring.** GP practices are required to consider how to work with individual patients who have difficulties complying with monitoring requirements.

4.11 **Provide patient education.** `The decision to start NPT medications will be made in secondary care and initial patient education is the responsibility of the specialist. The completion of this patient education should be clearly documented in communication with the GP. However practices should support patients (and/or their carers and support staff when appropriate) in getting

- appropriate information about the drugs they are being prescribed
- information about the relevant drug's side effects, and
- what they should do if side effects occur.

Patients should be asked about any side effects every time drug monitoring is carried out and record that this has taken place in the notes.

4.12 **Ensure staff are trained.** Each practice must ensure that all staff involved in providing any aspect of care under the LES have the necessary training and skills to do so.

4.13 **Generally work in accordance with good practice.** It is considered good practice to:

- At initiation, and thereafter annually, an appropriate review of the patient's health is carried out by the specialist including checks for potential complications and, as necessary, a review of the patient's own monitoring records.
- Ensure that all clinical information relating to the LES is recorded in the patient's own GP-held lifelong record.
- Refer if monitoring show abnormalities in line with current FV guidance (appendix 2)

5. Data Collection by GP practices-clinical

It is important that practices collect regular data on their prescribing and monitoring of these drugs, both to identify where their care is unreliable and to act as a focus for improvement.

5.1 All practices involved in the LES should provide details **monthly** of the number of patients being prescribed all drugs (see 4.1) covered by the service via ESCRO (or forced claim) for practice remuneration.

5.2 All practices involved in the LES should be able to provide (if required, for example in a practice verification visit), details of the practice system for recognising normal and abnormal monitoring tests, how patients are informed of the results and how they are advised of follow up. BSR guidance recommends that prescriptions for DMARDS should be removed from repeat prescription system, or be dealt with separately to ensure monitoring is ongoing, and the prescriber be empowered to withhold prescriptions if the patient is not attending for monitoring.

5.3 It is recommended that the following data is updated annually,

- the patient's contact phone number
- diagnosis
- current monitoring timetable (see Appendix 1&2)

6.1 Board data

% of oral Methotrexate prescriptions for non 2.5mg tabs will be available at Board level.

7. Significant event analysis (SEA)

Practices should consider continuing to undertake SEAs for internal use where patients have been harmed, or potentially harmed as a result of high risk drug use but these no longer need to be submitted. However SEAs where interface issues relating to these medications has jeopardised patient safety should be submitted as per other interface related SEAs through the Whole System Working system(MOSES)

8. Practice remuneration

Each practice contracted to provide this service will receive:

- DMARDs - £95.90 per patient, per annum

- Atypical antipsychotics - £50.00 per patient, as a one off initiation fee (in recognition of decreased work load as per new guidelines). Practices should only consider claiming this if some or all of the appropriate testing has been performed in Primary care.

- Sulfasalazine, £95.95 fee payable only for first year- in accordance with monitoring guidelines. (*Balsalazide, Mesalazine, Olsalazine do not require ongoing monitoring- no fee)*

- *Sacubitril/Valsartan, £95.95 fee payable for the first year- in according to monitoring guidance in Appendix 2*

- FOR 2017/18 there is an additional one off payment, adjusted according to the practices recorded NPT LES activity over the preceeding year, the amount is to be confirmed and will be communicated to practices in due course.

Practices can claim for the administration of a pneumococcal vaccine in eligible immunocompromised patients (DMARDs, and biologicals processed as a forced claim) as an Item of Service.

Please note that practices may only claim near patient testing fees for patients who are actively being monitored by the practice. As a rule of thumb, monitoring requirements should be at least every 3months to qualify for ES payments. This could be applied to new drugs that practices are asked to monitor that do not appear on the list at 4.1-. Practices should submit a "forced claim" for such drugs

Please also note that practices may elect to sign up to this NPT LES ,as per this specification, with or without care of patients on Atypical Antipsychotics.

Finally, please be aware that patients on 2 drugs covered by the NPT LES are only eligeable for one claim, on the assumption that blood testing does not need to be done twice.
The exception to this rule is the co-prescription of leflunomide with methotrexate, as this requires monthly monitoring for the first year instead of 3 monthly monitoring for monotherapy. The specialist might advise continuing intensive monitoring beyond 1 year, in which case a forced claim can be submitted
However initiation of the second drug can justify a second claim for the initiation process (eg with AAs)

9. References

1. Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004;329(7456):15-9.

2. Howard RL, Avery A, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. British Journal of Clinical Pharmacology 2007;63(2):136-47.

3. NPSA. Actions that can make anticoagulant therapy safer. Birmingham: National Patient Safety Agency, 2007.

4. SIGN 131 management of schizophrenia

5 physical health guideline & shared care protocol for People with significant mental health problems (FV ADTC 2013)

6. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs Rheumatology 2017

10. Appendices

Please note: Appendix 3 documents are provided as hyperlinks (hover your mouse over the appendix title and follow the pop-up instructions to access them). Remaining appendices are provided as hard copies on the following pages. Should you require electronic copies of any documents please contact Senior Quality Improvement Facilitator: who??

Clinical Material

Appendix 1 has been removed as it has been superceeded by appendix 2

Appendix 2 Monitoring Protocols for all LES NPT drugs. Up to date versions of these guidelines can be found below.

Appendix 2 Monitoring Protocols for all LES NPT drugs – *Updated April 2017*

NHS Forth Valley Local enhanced service: Provision of near-patient testing

Drug Monitoring Protocol – July 2017

Drug	Suggested Monitoring	Additional Information
Musculoskeletal and joint diseases (BNF Chapter 10)		

Drug	Suggested Monitoring	Additional Information
Azathioprine and mercaptopurine (prodrug)	**Baseline:** • FBC, U&Es, and LFTs. • **TPMT genotype** (by specialist) **Initiation** • FBC U&ES and LFTs 2 weekly until dose stable for 6 weeks, **Routine:** • 3 monthly FBC U&Es LFTS thereafter (4 weekly if TPMT heterozygote) • 2 weekly bloods for 6 weeks after any dose increase	If any of the following results are received, treatment should be withheld until discussed with specialist **(ideally by urgent sci gateway advice req)** • White cell count <3.5.x10^9/l • Neutrophils <1.6x x10^9/l • **Unexplained eosinophilia** • **Platelet count <100 x10^9/l and falling (local agreement)** • **MCV>110 f/l (local agreement)** • **Unexplained AST, ALT >100, alb <30** • **New eGFR <60 or Cr inc by >30%/ in 12 mths** *Monitoring of renal Patients is done in the Renal Clinic*
Leflunomide	**Baseline:** • FBC, U&Es, and LFTs. **BP and weight** **Initiation** • FBC U&ES, LFTs and BP/ weight 2 weekly for the until dose stable for 6 weeks, **Routine:** • 3 monthly FBC U&Es LFTS **BP and weight** thereafter • 2 weekly bloods BP/ weight for 6 weeks after any dose increase • **4 weekly testing if co-prescribed with Methotrexate for the first year only**	As above
Methotrexate	**Baseline:** • FBC, LFTs, U&Es • **Lung function tests to be considered** (by specialist) **Initiation:** • FBC U&ES and LFTs 2 weekly for the until dose stable for 6 weeks, **Routine :** • 3 monthly FBC U&Es LFTS thereafter • 2 weekly bloods for 6 weeks after any dose increase • **4 weekly testing if co-prescribed with Leflunomide for first year**	• as above **CXR no longer required**

Penicillamine	**Baseline:** • FBC and platelet counts, plus renal function (urinalysis, U&Es, creatinine). **Routine:** • Urinalysis and FBC should be checked fortnightly until on a stable dose.	• As above PLUS • **>++ proteinuria on more than 1 occasion** • **>++ haematuria on more than 1 occasion**
Sodium Aurothiomalate (gold)	**Baseline:** • FBC, LFTs, U&Es **urinalysis** **Initiation:** • FBC U&ES and LFTs **urinalysis** 2 weekly for the until dose stable for 6 weeks, **Routine :** • 3 monthly FBC U&Es LFTS & **urinalysis** thereafter • 2 weekly for 6 weeks after any dose increase	• as above PLUS • **check urinalysis prior to each injection and withhold injection and seek advice if** • **++ proteinuria/ haematuria on more than 1 occasion**
Sulfasalazine ONLY *<u>Not</u> Mesalazine , Olsalazine or Balsalazide)*	**Baseline:** • FBC LFTs, U&Es **Initiation:** • FBC U&ES and LFTs 2 weekly for the until dose stable for 6 weeks, **Routine:** • **up to 1 year** 3 monthly FBC U&Es LFTS • **Beyond 1 year** no requirement for routine monitoring	• As above PLUS **Forth Valley guidelines are that Sulfasalazine should be monitored for 1 year after initiation, and hence eligible for NPT ES claim for 1 year only.**
Cyclophosphamide	**Baseline:** • Full Blood Count • U&Es, LFTs and urinalysis and repeated 4-6 weekly while on drug	*Monitoring of renal Patients is done in the Renal Clinic*
Tacrolimus	**Baseline:** • FBC U&ES and LFTs **glucose BP** **Initiation:** • FBC U&ES and LFTs **BP** 2 weekly for the until dose stable for 6 weeks, **Routine :** • **<u>MONTHLY</u> FBC U&Es LFTS GLU BP AND WEIGHT** thereafter (unless specialist agrees otherwise) • 2 weekly for 6 weeks after any dose increase	*Monitoring of renal Patients is done in the Renal Clinic*
Ciclosporin	**Baseline:**	As above, PLUS-

	• FBC U&ES and LFTs **glucose BP** **Initiation:** • FBC U&ES and LFTs **BP** 2 weekly for the until dose stable for 6 weeks, **Routine :** • **<u>MONTHLY</u> FBC U&Es LFTS GLU BP AND WEIGHT** thereafter (unless specialist agrees otherwise) • 2 weekly for 6 weeks after any dose increase	BNF advises to prescribe as a branded drug name as there is significant variations in bioavailability between different products. Guidelines suggest that persistently **raised BP** best responds to Ca Channel blockers and if BP remains difficult to control, stopping ciclosporin should be considered *Monitoring of renal Patients is done in the Renal Clinic*

Mycophenolate or Mofetil	**Baseline:** • FBC, LFTs, U&Es **Initiation:** • FBC U&ES and LFTs 2 weekly for the until dose stable for 6 weeks, **Routine :** • 3 monthly FBC U&Es LFTS thereafter • 2 weekly for 6 weeks after any dose increase	As above *Monitoring of renal Patients is done in the Renal Clinic*
Mercaptopurine (as for AZA)	**Baseline:** • FBC, U&Es, and LFTs. • **TPMT genotype** (by specialist) **Initiation** • FBC U&ES and LFTs 2 weekly for the until dose stable for 6 weeks, **Routine:** • 3 monthly FBC U&Es LFTS thereafter (4 weekly if TPMT heterozygote) • 2 weekly for 6 weeks after any dose increase	As above
Hydroxycarbomide	**Baseline:** • FBC, U&Es LFTs **uric acid** on initiation • FBC uric acid weekly for 6 weeks **Routine:** • FBC 4 and 6 weeks after dose changes • FBC **uric acid** U&Es LFTs 3 monthly	Discuss with initiating Haematologist if: • **Hb decrease by 25g/l or Hb <105 g/l (stop and discuss)** • **PCV >0.45 (for PRV) (venesection required?)** • **WCC less than 2.5 (or Neut <1.5)(stop and discuss) or more than 20x109/l (discuss)** • **Platelets < 100 (stop and discuss) or > 400x109/l (discuss)** **Ask about oral or skin ulceration/sore throat, abnormal bruising, itching, pregnancy. Raised MCV is normal. should co-prescribe aspirin or Clopidogrel and Allopurinol**
Dapsone	**Baseline:** • FBC, Retic count, U&Es, and LFTs. • **Test for G6PD (by specialist)** **Initiation** • FBC, Retic count and LFTs weekly for 6 weeks, and then fortnightly for 2/12 **Routine:** • 3 monthly tests thereafter	If any of the following results are received, treatment should be withheld until discussed with relevant clinician: • Lymphocytes <0.5.x10^9/l • White cell count <3.5.x10^9/l • Neutrophils <1.5.x10^9/l • >2-fold rise in AST, ALT from baseline AND >100

	• 2 and 4 weeks after subsequent dose increases	
Acitretin	**Baseline:** • FBC, LFTs, U&Es, **Fasting Lipids including Triglycerides, (Glucose if diabetes**) **Initiation:** • FBC, LFTs, U&Es, **Fasting Lipids including Triglycerides, (Glucose if diabetes)** monthly for 2 months, then 3 monthly **Routine :** • FBC, LFTs, U&Es, **Fasting Lipids including Triglycerides (Glucose if diabetes)** 3 monthly	If Acitretin is used in a woman of childbearing potential **contraception** needs to be discussed and undertaken for 3 years If any of the following results are received, treatment should be withheld until discussed with relevant clinician. • Lymphocyte <0.5x10^9/l • Neutrophils <1.5x10^9/l • >2-fold rise in AST, ALT from baseline AND >100 • Fasting Triglycerides >5mmol/L
Atypical Antipsychotics(AA)	See below, amended as per SIGN 131 (ref 4, 5)	
Amisulpiride **Olanzapine** **Quetiapine** **Risperidone** **Aripiprazole** **Incl Paliperidone**	**Baseline:** • BMI. BP smoking status. Bloods (cholesterol (incl HDL for QOF(MH14) & glucose or HBA1c) **Routine** • **After 1/12** check BMI • **After 3/12** check BMI cholesterol and glucose or HBA1c • **Yearly** check BMI cholesterol (incl HDL) and glucose or HBA1c • **Check ECG and prolactin if clinically indicated**	Review if: • Investigate/review/ treat raised Glu or HBA1c as per diabetic investigations • prolactin <600mU/l continue medication and repeat if clinically indicated. If 600-2500mU/l and no symptoms continue drug but monitor annually. If symptoms or >2500 review medication options. If not able to change meds refer endocrine clinic • ECG- sig change in pulse (tachycardia, arrhythmias) • QT interval> 450ms* • Small doses of AAs do not need to be monitored if this will cause patient distress
***Qt interval advice**	Precalculated QTc interval (already corrected for heart rate) on automated ECG interpretations, should always be less than 450ms. These interpretations are pretty reliable If you are reliant on working out the QT interval yourself- qt interval is start of Q wave to end of t wave qt at a heart rate of 60bpm should be <0.42, then take 0.02 off this for every 10nbp above 60 eg 70bpm, qt<0.40 etc	
Sacubitril/valsartan	**Baseline(2ry care)** • BP U&ES **Initiation: (1ry care)** **STOP current ACE for 48hrs or ARB for 24 hrs**	Baseline SBP>100, U&Es drives choice of dose +/- diuretic rx **Review if** SBP<100- or symptomatic hypotension reduce dose to prev level

	Check U&ES and BP 1-2 weeks after each dose change **Double dose at monthly intervals if tolerated to max 97/103mg** **Routine (1ry care)** • U&ES at 1, 3 and 6 months, then annually	DBP- no guidance U&Es- reduce or stop if >15% drop in eGFR (as per ACE/ARB) K (as per usual ACE/ARB guidance) Na (as per usual ACE/ARB guidance)

[i] Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. BMJ 2004;329(7456): 15-9.
[ii] Howard RL, Avery A, Slavenburg S, Royal S, Pipe G, Lucassen P, et al. Which drugs cause preventable admissions to hospital? A systematic review. British Journal of Clinical Pharmacology 2007;63(2):136-47.
[iii] NPSA. Actions that can make anticoagulant therapy safer. Birmingham: National Patient Safety Agency, 2007.

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