High risk drug monitoring requirements for Primary care for adults

Updated: July 2020

This guideline is for patients that have been transferred to primary care once doses of medications are stable.
Refer to Summary of product characteristics, NICE guidance and shared care protocols for full information

Drug	Indication	BHRUT Shared care guideline	Monitoring until the patient is stabilised	Monitoring required in Primary care once patient is stable on dose									Other
				FBC	LFTs	U&Es. Renal Function	TFTs	Glucose / HbA1C	CRP or ESR	Lipid Profile	Blood Pressure	Weight/BMI	
ACE, ARB	CVD		**Prior to starting treatment:** U&Es, Renal function, BP **Treatment initiation:** Monitor U&Es & Renal function after 2 weeks of commencing treatment & after each dose change. Monitor BP after 4 weeks after each dose change.			12 monthly (inc creatinine & potassium)					12 monthly		Refer to the SPC for the medication regarding the suitability of dose to select.
Amiodarone	CVD		**Prior to starting treatment:** U&Es, serum potassium, TFTs, LFTs, Renal function ECG & chest X-ray. In patients co-administering warfain - more frequent INR monitoring is required, ideally weekly for the first 7 weeks.		6 monthly	6 monthly	6 monthly						ECG - 12 monthly TFTs up to 12 months after cessation
Antipsychotic Agents (amisulpride, aripiprazole, clozapine, lurasidone,olanzapine, paliperidone, quetiapine, risperidone, chlorpromazine, flupentixol, haloperidol, levomepromazine, pericyazine, perphenazine, pimozide, prochlorperazine, promazine, sulpiride, trifluperazine, zuclopenthixol)	Mental Health		**Prior to starting treatment:** HbA1c, U&Es, blood lipid profile, LFTs,BP, Pulse, Weight (inc waist circumference), BMI, smoking status & lifestyle details. **After Treatment initiation**: Pulse & BP: In Schizophrenia - at 12 weeks after 1st dose & after every dose change in Bipolar disorder. FPG & HbA1c: 12 weeks after 1st dose. Weight: In Schizophrenia - weekly for the first 6 weeks, then at 12 weeks & 1 year. Lipids: In Schizophrenia - at 12 weeks. ECG (for patients on Haloperidol, Pimozide & Sertindol & have a previous ECG abnormality): If clinically indicated. Prolactin: At 6 months or clinically indicated. Smoking history: at 3 months	12 monthly	12 monthly	12 monthly		12 monthly		12 monthly	12 monthly	12 monthly	Waist Circum, Prolactin & Pulse - 12 monthly. UKMI also recommends ALT, creatinine, haemoglobin. As part of Annual physical monitoring for patients with bipolar disorder NICE additionally recommend: CV status (incl pulse and BP), metabolic status (incl fasting blood glucose, HbA1c, and blood lipid profile.
Azathioprine	Gastroenterology / Hepatology	**Pre-treatment**: FBC, U&Es Renal function, LFTs, TPMT phenotype, Varicella Zoster, **Treatment initiation**: FBC, LFT every week for 4 weeks (after any increase in dose). Thereafter at least every 3 months. U&E's - Annually	**Prior to starting treatment:** FBC, U&Es, renal funtion, TPMT Assay & LFTs. **After treatment initiation**: FBC every 2 -4 weeks for 2 months. LFT every week for 6 weeks. Then 2 weekly until dose is stable for 6 week. (This applies to changes in dose)	3 monthly	3 monthly (inc albumin)	3 monthly			3 monthly				

Azathioprine	Rheumatology		**Prior to starting treatment**: FBC, U&Es, renal funtion, TPMT Assay & LFTs. **After treatment initiation:** FBC, creatine, CrCl, LFTs (albumin) every 2 weeks until dose stable for at least 6 weeks. Then monthly for 3 months. (This applies to changes in dose)	3 monthly	3 monthly (inc albumin)	6 monthly			3 monthly				
Carbamazepine	Neurology		**Prior to starting treatment:** U&Es, renal funtion, FBC & LFTs **Treatment initiation:** Plasma concentration for optimum response 4–12 mg/litre (20–50 micromol/litre) measured after 1–2 weeks.	12 monthly	12 monthly	12 monthly							Regular blood test monitoring in adults with epilepsy is not recommended as routine, and should be done only if clinically indicated.
Carbimazole	Endocrine		**Prior to starting treatment:** TFTs, FBC & LFTs **Treatment initiation:** Monitor TFTs every 4-6 weeks of commencing treatment. Then 3 monthly once a maintenance dose is achieved.	6 monthly (if evidence of infection)			6 monthly						
Ciclosporin (non -transplant)	Rheumatology		**Prior to starting treatment**: FBC, LFTs (inc albumin), U&Es, Renal function, Lipids, serum potassium & magnesium, glucose level, height and weight. **After treatment initiation:** Serum potassium & magnesium, BP - monitor periodically. Creatinine every 2 weeks until dose stable for at least 12 weeks. Then monthly. Monitor lipids after 4 weeks. FBC, creatine, renal function, LFTs (albumin) every 2 weeks until dose stable for at least 6 weeks. Then monthly for 3 months. (This applies to changes in dose)	3 monthly	3 monthly	1 monthly (inc serum potassium)		Measure at each monitoring visit	3 monthly	12 monthly	1 monthly		Ciclosporin enhances the clearance of magnesium. This can lead to symptomatic hypomagnesaemia, especially in the peri-transplant period. Control of serum magnesium levels is therefore recommended in the peri-transplant period, particularly in the presence of neurological symptom/signs. If considered necessary, magnesium supplementation should be given.
Clozapine	Mental Health		Monitoring is normally undertaken by the specialist service	1 monthly						12 monthly		6 monthly	

Denosumab (60mg s/c injection every 6 months only)	Osteoporosis	**Pre-treatment:** U&Es, Renal function, Calcium levels. Signs & symptoms of cellulitis. **Ongoing treatment:** Calcium levels & CrCl, 2-4 weeks before each injection. **Post 3 years treatment:** DXA scan.	**BNF & SPC:** Correct hypocalcaemia & vitamin D deficiency before starting treatment. Monitor plasma-calcium concentration during therapy. Monitoring of calcium levels is recommended before each dose and, in patients predisposed to hypocalcaemia within two weeks after the initial dose.			CrCl 2-4 weeks prior to each injection							Measure calcium level & vitamin D 2-4 weeks prior to each injection.
Digoxin	CVD		**Initial monitoring requirements before commencing therapy:** U&Es, Renal function, potassium, calcium and Magnesium levels (if patient on long term PPI or other medicines that may cause hypomagnesaemia)			12 monthly (inc potassium level)							Periodic Magnesium levels should be checked in patients on long term PPIs or other medicines that may cause hypomagnesaemia.
Eplenerone	Aldosterone antagonists		**Pre-treatment**: U&Es & RF. **After treatment initiation:** U&Es, Renal function at weeks 1,4,8, & 12 and at weeks 1 & 4 after any dose increase			6 monthly							
Hydroxycarbamide	Psoriasis		**Pre-treatment:** LFTs, Uric acid, U&Es, Renal Function, FBC. **After treatment initiation:** FBC - weekly until dose is stable	3 monthly	3 monthly	3 monthly							Monitor Uric acid levels every 3 months.
Leflunomide	Rheumatology		**Pre-treatment:** Height, Weight & BP. FBC, U&Es, Renal Function, LFTs (inc albumin) **After treatment initiation:** FBC, U&Es, Renal Function, LFT (inc albumin) - every 2 weeks until dose stable for 6 weeks. Then monthly for 3 months. (This applies to changes in dose)	1-2 monthly	1-2 monthly (inc albumin)	3 monthly			3 monthly		1-2 monthly	1-2 monthly	If co-prescribed with another potentially hepatotoxic drug, continue monitoring at least once a month.
Lithium	Management of acute mania or hypomanic episodes, episodes of recurrent depressive disorders where treatment with other antidepressants has been unsuccessful, prophylaxis of bipolar affective disorder & Control of aggressive behaviour or intentional self-harm	U&Es, Renal function, FBC & Calcium, TSH, Weight - 6 monthly (or more frequently if clincally indicated) Lithium level (maintenance dose) 0.4 – 1.0 mmol/l (12 hours post dose): Every 3 months for year 1, then every 6 months. Every 3 months for people in any of the following groups: People aged 65 years and over, people taking drugs that interact with lithium, people who are at risk of impaired renal or thyroid function, raised calcium levels or other complications, people who have poor symptom control, people with poor adherence. People whose last plasma lithium level was 0.8 mmol/ litre or higher.	**Pre-treatment**: Renal function, U&Es, TFTs, Weight, Height, Cardiac function (if suitable) & FBC. **After treatment initiation:** Lithium plasma levels to be monitored weekly after starting and after each dose change. Levels should be taken 12 hours post dose. Level should be maintained between 0.4 - 1.0 mmol/L (lower level may be suitable for the elderly).			6 monthly	6 monthly			12 monthly	12 monthly	12 monthly	*Serum Lithium level - 3 monthly up until first year of treatment then every 6 months if stable. Serum Calcium - 6 monthly **Shared guideline recommendation:** ECG - Every 12 months for patients with significant cardio vascular disease or risk factors for it. The patients lithium monitoring book must be updated at each visit. If the hospital has the monitoring responsibility, the hospital is responsible for contacting the patient if any action is required. If the GP has the monitoring responsibility, the GP is responsible for contacting the patient if any action is required.

Mercaptopurine	Gastroenterology / hepatology / Rheumatology	Pre-treatment: FBC, U&Es, Renal function, LFTs, TPMT phenotype, Varicella Zoster, FBC, LFT - At initiation and after any increase in dose - Every week for 4 weeks. Thereafter at least every 3 months. U&E's - Annualy	**Pre-treatment:** FBC, LFTs, U&E (creatine) TPMT assay. **After treatment initiation**: FBC every 2 weeks for 8 weeks. LFTs weekly for 6 weeks, then 2 weekly until dose is stable for at least 6 weeks. Then monthly for 6 months and thereafter, if stable 3 monthly. U&E's every 6 months.	3 monthly	3 monthly	6 monthly			3 monthly				
Mesalazine			**Pre-treatment**: U&Es, renal function & LFTs. **After treatment initiation:** U&Es, renal funtion & LFTs - 3 monthly for 1 year		Every 3 months for the first year, then every 6 months or annually depending on the patients risk factors.	Every 3 months for the first year, then every 6 months or annually depending on the patients risk factors.							
Methotrexate (oral)	Psoriasis, Crohn's Disease, Ulcerative Colitis, Pulmonary Sarcoidosis, Rheumatoid Arthritis, Psoriatic Arthritis	**Treatment initation:** FBC, U&Es & LFTs 7 days post 1st dose, then 2 weekly for 4 weeks, then monitor monthly until dose stable. Then FBC & LFTs: 3 monthly. For Gastroenterology conditions, ESR and/or CRP monthly to assess response to treatment. For Rheumatology Conditions, FBC, U&Es & LFTs: 2 weekly for 6 weeks, then monitor monthly for 3 months. **Ongoing treatment:** FBC & LFTs: 3 monthly + For Gastroenterology conditions, ESR and/or CRP monthly to assess response to treatment. U&E's 6 monthly once stabilised For Dermatology condition, U&E's: 3 monthly For Rheumatology Conditions, U+E, ESR and CRP 3 monthly	**Pre-treatment:** FBC, U&Es, renal function & LFTs (inc albumin). **After treatment initiation:** FBC, U&Es, renal function & LFTs (inc albumin) 2 weekly until Methotrexate dose stable for at least 6 weeks, then monitor monthly for 3 months or until disease stablised. Then FBC, U&E, renal function & LFTs: 3 monthly. For rheumatology: ESR and/or CRP to be monitored every 3 months to assess response to treatment.	2-3 monthly	2-3 monthly	2-3 monthly			3 monthly				**Shared guideline recommendation:** Record all blood results in the methotrexate patient held record book, issued by the hospital
Mycophenolate (non-transplant)	Neurology/Respiratory/Dermatology	**Pre-treatment:** FBC, U&Es, LFTs, TPMT phenotype, Varicella Zoster serology. **Monitoring:** FBC, LFT, U&Es - At initiation and after any dose change. Monitor weekly for 4 weeks. Then at least every 3 months.	**Pre-treatment:** FBC, LFT (inc albumin), U&Es & Renal function. **After treatment initiation:** FBC, LFT (inc albumin), U&Es & Renal function - 2 weekly until dose stable for at least 6 weeks. Then monthly for 3 months or until maintenanance dose achieved. **Ongoing treatment:** FBC, LFT (inc albumin), U&Es & Renal function every 3 months	1 monthly	1 monthly	1 monthly							In females of child bearing age, exclude pregnancy whilst on treatment.

NOACs - Apixaban, Dabigatran, Edoxaban, Rivaroxaban	Non-valvular Atrial Fibrillation (AF), and for the treatment and secondary prevention of venous thromboembolism	FBC & LFTs monitor yearly (or more frequently if clinically appropriate) Renal function Annually – if CrCl ≥ 60mL/min 6-monthly – if CrCl 30 – 59mL/min 3-monthly – if CrCl 15 – 29mL/min (only applicable for patients on Xa inhibitors)	**Pre-treatment:** U&Es, Renal function (CrCl), LFTs, FBC & BP, baseline clotting screen & body weight Repeat after 3 months. **Ongoing treatment:** LFTs & FBC annually**.** Renal function: Annually – if CrCl ≥ 60mL/min 6-monthly – if CrCl 30 – 59mL/min 3-monthly – if CrCl 15 – 29mL/min	12 monthly	12 monthly	Annually – if CrCl ≥ 60mL/min 6-monthly – if CrCl 30 – 59mL/min 3-monthly – if CrCl 15 – 29mL/min						12 monthly	More frequent U&Es/LFTs advised where intercurrent illness may impact on renal or hepatic function. Note for differences in liscensing between the DOACS refer to SPC.
Long term NSAIDS	Analgesic		**Prior to starting treatment:** U&Es, renal function & BP. Consider features of HF. **Treatment initiation until patient is stable:** Refer to NICE guidance - NSAID prescribing issues.			6- 12 monthly (if patient > 65y)							
Penicillamine	Rheumatology		**Prior to starting treatment:** U&Es, Creatinine, FBC, Urinalysis for proteinuria. **Treatment initiation:** Urinalysis for protein/blood & FBC every 2 weeks for 8 weeks & in the week after each dose increase, then monthly.	1 monthly		1 monthly			3 monthly				Urine tests (protein & blood) monthly
Pioglitazone	Diabetes		**Prior to starting treatment:** U&Es, LFTs, Weight, FBC, HbA1c. **Treatment initiation:** Monitor LFTs regulary & signs of heart failure, weight gain or oedema.		12 monthly	12 monthly		6 monthly					
Spironolactone	Aldosterone antagonists		**Pre-treatment**: U&Es & RF. **After treatment initiation:** U&Es, Renal function at weeks 1,4,8, & 12, then 6, 9 & 12 months. Then 6 monthly. (This would apply to any dose increase).			6 monthly							
Statins	Reduction of hyperlipidaemia		**Prior to starting treatment:** Non-fasting lipid profile - Total cholesterol, Non-HDL-cholesterol & Triglyceride concentrations. TSH, U&Es, renal fuction, LFTs, BP, BMI. Creatinine Kinase level (in patients with unexplained muscle pain). Fasting blood glucose or HbA1c (in diabetics) **3 months after commencing treatment:** Lipid profile, LFTs, Creatinine Kinase (if required) & HbA1c (if required)		12 months (after commencing treatment) & annually					12 monthly			Measure creatinine kinase if patient experiences muscle symptoms (pain. tenderness, weakness).

Sulfasalazine	Rheumatology		Prior to starting treatment: FBC, LFT (inc albumin), U&Es & Renal function, height, weight, BP. Treatment initiation: FBC, LFT (inc albumin), U&Es & Renal function- 2 weekly until dose stable for at least 6 weeks. Then monthly for 3 months. Ongoing treatment: Once maintenance dose achieved & stable for 3 months, FBC, LFT (inc albumin), U&Es & Renal function every 3 months	3 monthly	3 monthly (inc albumin)	3 monthly			3 monthly				
Theophylline/Aminophylline	Respiratory		**Prior to starting treatment:** U&Es, LFTs & smoking status **Treatment initiation:** Monitor plasma Theophylline levels 5 days after starting oral therapy & 3 days after each dose adjustment. Then monitor plasma levels 6-12 monthly once a maintenance dose is achieved.		12 monthly	12 monthly							Monitor plasma Theophylline levels 6-12 monthly or more frequently if clinically indicated once a maintenance dose is achieved
Valproate	Neurology		**Pre-treatment:** LFTs, FBC (inc platelet count, bleeding time and coagulation tests) & BMI/weight LFTs within the first 6 months of treatment. **Ongoing treatment:** LFT, FBC, BMI after 6 months, then annually	12 monthly	12 monthly							12 monthly	MHRA 2015 Guidance: Annual specialist review for women of childbearing potential - Requires annual signed risk assessment form & on the Pregnancy prevention programme (PPP).

References:

1. UKMI - Suggestions for drug monitoring in adults in primary care, revised Oct 2017
2. Joint Formulary Committee (2018). British National Formulary. (76th ed.). London: British Medical Association and Royal Pharmaceutical Society of Great Britain
3. NICE. Do not do. Regular blood test monitoring in adults with epilepsy