

A Guide for West Yorkshire Minuteful Kidney

Hypertension Project

GP Pack / Standard Operating Procedure

V1.6

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1. Purpose of this Pack

The purpose of this GP Pack is to provide participating practices with a detailed/step by step guide to the Minuteful Kidney uACR home testing process, the roles, and responsibilities of each party, and useful resources. This pack contains clear-cut directions and detailed instructions to ensure consistent and efficient implementation, standardised care and support for people at risk of chronic kidney disease (CKD) in West Yorkshire (WY).

2. Introduction

CKD affects over 3.5 million people in the UK, and it is projected that this will increase to over 4 million by 2030. Often general symptoms are not apparent or diagnosed until a later stage. There is a clear need to proactively test for kidney damage within at-risk populations, particularly those with hypertension who will have an increased risk of CKD development. In turn, patients in all stages of CKD are at a higher risk of cardiovascular disease. Routine uACR testing for patients with hypertension will enable detection of CKD in the earlier stages. Currently this stands at less than 30% of individuals with hypertension. Via earlier identification and treatment there will be a decreased risk of progression to cardiovascular disease, in addition to dialysis or kidney transplant avoidance.

In November 2023, WY Integrated Care Board (WYICB) secured funding via the Health Technology Adoption and Acceleration Fund (HTAAF) to improve patient access to Urine ACR (uACR) testing using an ‘at home’ test solution, [Minuteful Kidney](#), provided by Healthy.io.

The Minuteful Kidney solution consists of a uACR home testing kit delivered to a patient’s registered home address by Healthy.io to be used with a patient’s smartphone and a free downloadable application/app. Both the testing kit and the app are CE marked under the UK’s MHRA regulatory framework. Patients with hypertension who would be required to attend a GP clinic for traditional uACR testing will be provided with a quick, easy, safe, and convenient alternative to ‘in clinic’ uACR tests. This in turn will support practices to reduce the number of untested patients with hypertension and support patients who may be disengaged from attending primary care appointments for traditional testing methods.

Healthy.io will provide 1-2-1 support to eligible patients to undertake the test, whilst providing data related to test completion, demographics of those tested/not yet

tested and test results to practices and aggregate anonymised data to the WY Minuteful Kidney oversight team to inform implementation and project evaluation. As the home testing service is fully outsourced to the Minuteful Kidney team within Healthy.io it helps minimise impact on GP practices, saving a practice time on processing urine samples, chasing tests, and encountering missed appointments. The Minuteful Kidney solution has already successfully supported 1,350+ NHS practices across the UK and tested 200,000+ at-risk patients.

There is no cost to practices for the Minuteful Kidney uACR home testing service. Funding via the Health Technology Adoption and Acceleration Fund (HTAAF) has enabled WY ICB to commission 40,000 minuteful kidney kits available for use to improve uACR testing to those with hypertension who have not had a uACR test in the previous 12 months. The number of kits available via funding however will not enable every eligible person to access this uACR testing method. Taking a pragmatic approach, the number of Minuteful Kidney kits allocated to each participating GP practice will be relative to practice list size; however further adjustments will be made according to the practice registered IMD score. Those practices in IMD 1-3 will receive a 20% uplift in the number of kits; those in IMD 4-6 will receive a 10% uplift compared to those in IMD 7-10.

Minuteful Kidney deployment will commence across participating GP practices from 5th March 2024. Deployment will progress until 28th February 2025, following which an evaluation will take place and an understanding of how digital uACR testing may be used sustainably in the [WY CKD Pathway](#) moving forward. The number of kits allocated will be capped per practice for the first round of invitations - which will target those with hypertension and no uACR in previous 12 months living with > 3 long-term conditions. Practices will be given the opportunity to invite further eligible patients based on the number taken up amongst those invited, and the remaining kits for a second round of invitations.

West Yorkshire practices are asked to engage with Healthy.io to 'case find' eligible patients for the 'at home' test via the use of a clinical search file based on [West Yorkshire ICB search criteria](#). Practices should not use previous searches linked to home uACR testing and diabetes. WY data quality specialists will make the search files available to all practices via a WY shared folder within each clinical system. The provided search file can be run on a practice's EPR (SystemOne and EMIS) making it quick and easy to identify untested patients which meet the criteria for the service. A separate short guide will be made available via the [Minuteful Kidney](#) webpage (and from the Healthy.io onboarding team when they contact practices) to support practice teams to identify those eligible and those who should receive prioritised invites to participate. Practice teams may wish to use local knowledge of their practice population to adapt the list of patients to be invited to participate in round one invitations.'

Once a list of eligible patients is obtained with the use of the search file, practices will be required to contact the patients via text (preferred), or letter (if required) to ask if they wish to opt out of the 'at home' test service within 5-7 days. Once opt-out patients have been identified, practices are required to remove them from the list, and send the finalised list securely to Healthy.io.

It is advised that practices stagger the rate at which patients are onboarded to the service by Healthy.io. A realistic plan/pace for patient onboarding over a wider period can be agreed between the Practice and Healthy.io to limit the number of test results that are returned in any one week, enabling practices to reasonable manage the test results. For those eligible patients who are not digitally active and are unable to undertake an 'at home' uACR, practices are encouraged to invite patients to the clinic/practice for a standard lab-based test.

Practices are required to enter the appropriate SNOMED (or Read) codes to the patient's EHR to capture who has been invited and who has declined the offer of the Minuteful Kidney 'at home' test. These codes are available later in this pack.

Following receipt of an eligible patient list with a patient onboarding rate stipulated by the practice, Healthy.io will distribute a uACR test kit to a patient's registered address with instructions to download the 'Minuteful Kidney app on their smartphone. An in-app virtual nurse 'Emily' explains how the patient should complete the test, step-by-step. Healthy.io provide all direct patient care and support to undertake the uACR test at home. Patient support is provided to undertake the uACR test via several channels. For patients yet to undertake the Minuteful Kidney uACR test, Healthy.io provide supportive prompts to patients over a 35-day period.

Following successful completion of the test, a patient can immediately view their results in the Minuteful Kidney app, with a supportive and reassuring video explaining their test result if their result is 'abnormal' or 'high abnormal'.

In addition to patients immediately seeing their uACR test result via the Minuteful Kidney app, the test result is sent to a practice's Electronic Patient Record (EPR) via the secure message exchange for social care and health ("MESH") service; viewable within the named GP's pathology inbox, as is custom for other traditional lab-based pathology results.

There may also be an opportunity to test how the WY Community Pharmacy Pathfinder pilot can support those with newly detected hypertension gain access to timely digital uACR testing as part of this project. Contact Sarah De Biase at sarah.debiase1@nhs.net for more information. Participating Pharmacies include:

ODS Code	Place	Parent ORG code	Registered Business Name	T/A Pharmacy Name	Address
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FEC80	Kirklees	P1XK	HEALTHY CHOICE PHARMA LTD	Dewsbury Pharmacy	Healds road, Dewsbury, WF13 4HT
FF997	Calderdale	P079	JE GOODY	Luddendenfoot Clinic Pharmacy	Kershaw Drive, Luddendenfoot, HX2 6PD
FWF97	BD&C	P4H4	H AND H PHARMA SERVICES LTD	Kirkgate Pharmacy	60 Kirkgate, Bradford, BD1 1TQ
FHX24	BD&C	P3K7	RUMI HEALTH	Daynight Pharmacy	101 Killinghall Road, Bradford, BD3 8AB
FQW63	Leeds	PVAT	MISSIONSTART LIMITED	Pharmacy Plus Health (Alwoodley)	1 Saxon Mount, Saxon Mount, Leeds, LS17 5DT
FWD92	Leeds	P3J4	SA2 LIMITED	Midway Pharmacy (Middleton)	23 Middleton Park Circus, Leeds, LS10 4LX
FCG05	Wakefield	S7M7E	SAXEL LTD	Midway Pharmacy (Horbury)	Cluntergate, Horbury, Wakefield, WF4 5AF
FDV85	Bradford	P3D8	AA PHARM LTD	Sahara Pharmacy	46-48 Duckworth Lane, Bradford, BD9 5HB
FRW36	Halifax	P163	J SWIRE & SON LTD	King Cross Pharmacy	210-212 King Cross Road, Halifax, HX1 3JP

Work is underway to develop a protocol for the pathfinder pharmacies to follow which will include using Minuteful Kidney to test those who have persistent elevated blood pressure following ambulatory BP checks. The pharmacies must work closely with partner GP practices to ensure robust communication systems if Minuteful Kidney kits are to be offered via this pathfinder pilot. This process will be defined in Q2/3 of the Minuteful Kidney scheme. Each participating pharmacy may have a local tailored approach and an overview of these will be shared on the [Minuteful Kidney](#) webpage when finalised.

3. Rationale

In West Yorkshire alone, 72,094 individuals are identified as having CKD (stages 3-5) with a prevalence rate of 3.8% which is lower than the national average of 4.2%. There is significant variation across West Yorkshire. Wakefield has the highest prevalence, and Leeds have the lowest. Bradford and Kirklees Place has some of the highest prevalence, with Kirklees having the highest unplanned admissions in the region. 50% of patients with CKD reside in CORE20PLUS5 practices within West Yorkshire.

There is a clear need to proactively test for kidney damage within at-risk populations, particularly those with hypertension who will have an increased risk of CKD development due to their blood pressure impacting blood vessels, this reducing oxygen and nutrients to their kidneys. In turn, patients in all stages of CKD are at a higher risk of cardiovascular disease. In fact, people with CKD are up to 20 times more likely to die of cardiovascular disease than they are of end-stage renal disease due to their kidney impairment impacting the hormone system which regulates blood pressure. uACR is an independent marker of that increased risk and intervention to reduce this helps reduce not only progression of kidney diseases but reduce cardiovascular diseases. Currently, less than 30% of individuals with hypertension has recommended uACR monitoring thus disadvantaging them the benefit of early intervention.

The early stages of CKD (stages 1-3) are managed within primary care and monitoring of patients with a diagnosis of CKD is an essential component of the NICE (2021) CKD guidance (NG203) to facilitate a patient's on-going optimisation of care.

Potential missed diagnosis is a major problem with CKD with about 1:3 not coded on patient's electronic health records as per national CKD audit. To support their regulatory function the [CQC](#) routinely conduct clinical searches to identify cases with two measurements of eGFR < 60 ml/min in the last 2 years without diagnosis code of CKD. Additionally, CQC looks at adequate monitoring of patients with CKD stage 4 or 5 who have not had a urea and electrolytes (U+E) test in the last 9 months. This project will screen CKD using the Minuteful Kidney home uACR testing solution and

will improve care through appropriate monitoring. Equally, the project will support accurate [QOF CKD registers](#).

With the use of MinuteKidney's 'at home' uACR test the following benefits are anticipated:

Patient Benefits and Outcome:

- A more convenient 'at home' test and service will save patient travel, work, and care time, thus increasing uACR testing adherence.
- Earlier intervention/treatment and prevention of patients exacerbating to End Stage Renal Disease.
- Earlier intervention/treatment and prevention of a patient developing heart disease or stroke.
- Improved patient knowledge and self-management.
- A timelier referral to secondary care and joined up care where required.
- Increased access to uACR testing and treatment for CKD in populations more at risk of health inequalities.

Primary Care Benefits:

- Reduced practice backlog of untested patients with hypertension.
- Minimised workload associated with traditional 'in clinic' uACR testing.
- Accurate CKD registers and CQC compliance
- Minimised effort/workload to target harder-to-reach patients.
- Improved collaboration between members of the healthcare team, and practice guidelines which consider the frequently co-morbid nature of CKD.
- Enhanced collaboration between primary care and nephrology services may support primary care practitioners when diagnosing CKD in primary care.
- Diagnosis and population risk stratification of CKD.
- Change in practice/clinician behaviours relating to CKD detection, diagnosis, and management.

System Wide Benefits:

- System wide financial savings from slowing the growth of complications associated with HTN and CKD, including CVD events and/or progressive CKD/need for dialysis or transplant.

Environmental Benefits:

- With the current growth estimations of the population requiring RRT, it is expected that there will be an increased carbon burden of 1.1-1.5 kilotonnes CO₂e per year by 2032 (using a 3.4 tonne/person/year estimate). Earlier detection and prevention of CKD will reduce carbon emissions resulting from RRT.

4. Minuteful Kidney Governance

Project overall governance is provided by the WY Improving Population Health Function, Long-term Condition and Personalisation steering group.

A Minuteful Kidney – Hypertension Project oversight group is in place and has been operational throughout the implementation stage. This group will continue to provide oversight and monitoring throughout the deployment and evaluation stage.

The oversight group consists of membership from:

- WY digital transformation team
- the supplier (Healthy.io)
- WY ICB LTCP clinical leads and programme managers
- Y&H Renal Network clinical leads and project managers

Meeting fortnightly, this group will provide system oversight and gather feedback from wider stakeholders, including Place leads and local medical committees; and from practice teams and clinicians to inform project evaluation and understand how digital uACR testing may be used sustainably in the WYCKD pathway.

5. Minuteful Kidney Processes and Guidance

This following 'Section 5' provides an overview of the 3 stages and associated process for the West Yorkshire Minuteful Kidney - Hypertension Project:

Process Stage and Process	Overview
Stage 1: Practice Onboarding Process	<ul style="list-style-type: none"> • Initial key tasks for practices are primarily associated with this stage. The key actions consist of: • Booking and attending an 'Initiation Call' with Healthy.io (call takes approximately 35 minutes). • Signing a Data Protection Agreement (DPA) agreement between Healthy.io and the practice. • Booking and attending a 'Practice Onboarding/Site Set Up Call' with Healthy.io (call takes approximately 10-15 minutes). • Updating the practice Privacy Notice with content provided by Healthy.io. • As part of the above 'Practice Onboarding Call', practices will be supported to add Healthy.io as a 'Trading Partner' on their EPR and perform a MESH Test using a test/fictitious patient to ensure that patient uACR tests are received into the named GP's pathology inbox. Practices will also be supported to run the patient search file provided by Healthy.io to generate a list of eligible patients. • Sending patient text (or letter) to eligible patients asking that they contact the practice within 5-7 days if they wish to opt out of the Minuteful Kidney service. • Removing opt-out patients from the eligible patient list. • Sending a finalised eligible patient list to Healthy.io with any requirements to stagger the rate at which patients are onboarded to the service by Healthy.io over a wider-period from the Initiation Call taking place.
Stage 2: Patient Onboarding and Testing Process	<ul style="list-style-type: none"> • Following practice onboarding, patient engagement and support to undertake the uACR test is fully outsourced to the Minuteful Kidney team at Healthy.io to help minimise the impact on GP practices. • Once a patient has successfully undertaken their uACR test at home, GPs are then required to check a patient's uACR test result within their pathology inbox.

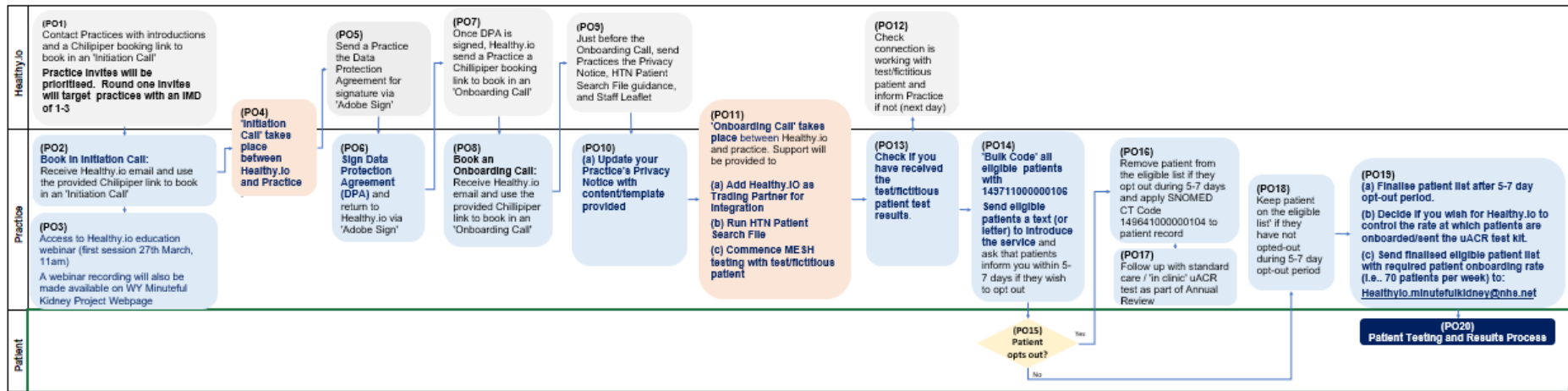
**Stage 3: Post uACR
Test Result Process**

- This final stage requires practices to follow up on a patient's uACR test results using the guidelines detailed in this process.
- Practice education and guidance process with associated roles and responsibilities.

5.1. Practice Onboarding Process

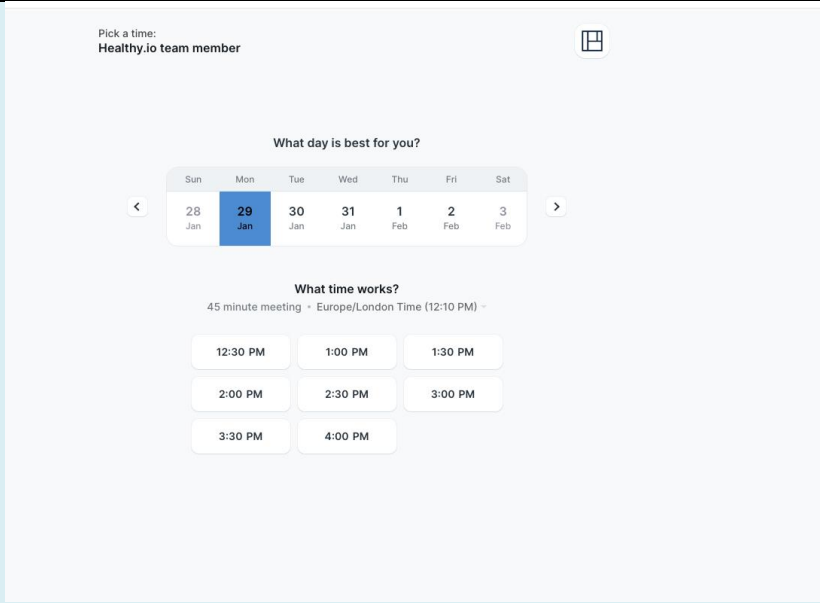
The actions for each party are colour coded as below:

Practice Actions	Joint Practice and Healthy.io Actions
Healthy.io Actions	Patient Actions



Below provides more detail on the actions required from each participating party as per the reference number within the above 'Practice Onboarding Workflow'.

Step Ref.	Responsibility	Process Step Instruction
PO1	Healthy.io	<p>Healthy.io initial Engagement:</p> <p>For Practices not wishing to opt-out of the Minuteful Kidney service, West Yorkshire ICB will send the practice contact details to Healthy.io (Senior Partners and Practice Manager).</p> <p>The onboarding of West Yorkshire Practices will be prioritised. Round one invites will target West Yorkshire practices with an Indices of multiple deprivation (IMD) of 1-3.</p> <p>Based on prioritization, Healthy.io will then send an introductory email to the Practice contacts with a Chilipiper booking link to join an 'Initiation Call'.</p>
PO2	Practice	<p>'Initiation Call' Booking:</p> <p>You will receive an email from Healthy.io's Contract Manger: adam.marshall@Healthy.io with an introduction to the service.</p> <p>The email will contain the following link to book in an 'Initiation Call' at a date and time most convenient for you and any wider practice members who may wish to attend. https://healthy.chilipiper.com/book/p-p-catch-all. You can also book an Initiation call via WestYorks-GP-Practices - Healthy</p> <p>By clicking on the above Chilipiper link, you will be taken to the below screen:</p>



Pick a time:
Healthy.io team member

What day is best for you?

Sun	Mon	Tue	Wed	Thu	Fri	Sat
28 Jan	29 Jan	30 Jan	31 Jan	1 Feb	2 Feb	3 Feb

What time works?

45 minute meeting • Europe/London Time (12:10 PM)


12:30 PM	1:00 PM	1:30 PM
2:00 PM	2:30 PM	3:00 PM
3:30 PM	4:00 PM	

You can select the date and time most convenient for you and wider practice members.

You will then see the following screen where you will be asked for some limited information so that Healthy.io know which practice is making the booking, who the representative is, and whether you use EMIS or SystemOne.

Almost there!

Thursday, Feb 8th 2024 9:30 AM - 10:15 AM Change

First Name * 

First Name is required

Last Name *


Email *

Phone *

Job Title *

Practice Name *

ODS Code *

EMR * 

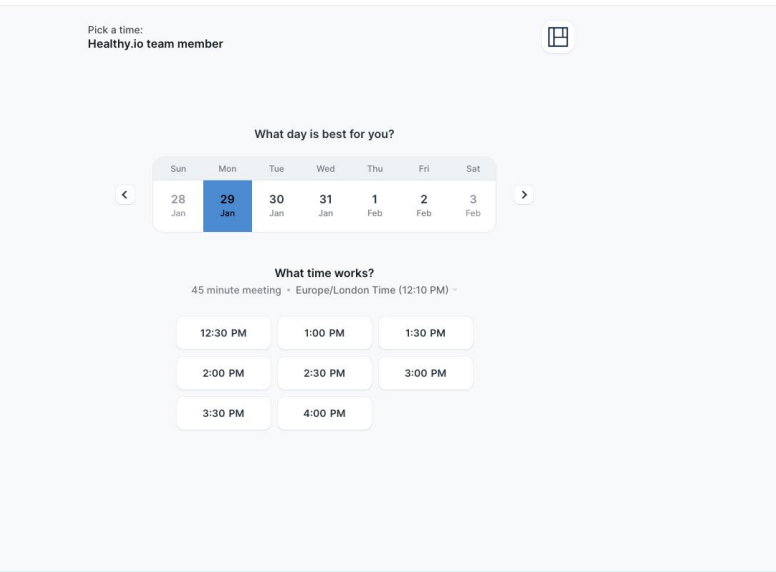
Once the above fields have been completed, click on the “confirm meeting” button.

The staff member who has provided their email above will automatically receive an invitation to their calendar.

Forward the calendar invite to wider staff who may also wish to join the ‘Initiation Call’.

PO3	Healthy.io Education Sessions	<p>Healthy.io will be host 3 education sessions / webinars led by their Clinical Lead, Professor Raj Thakkar. The first webinar will take place on the 27th of March, 11:00 – 12:00. This session will be recorded and accessed via The West Yorkshire Minuteful Kidney Project webpage to also enable practices to watch at their convenience. The webinar will cover the following:</p> <ul style="list-style-type: none"> • What is CKD? • CKD as a risk factor for CVD • The importance of ACR testing • How to improve outcomes in your patients • About the home ACR testing service • How home ACR testing can work for your practice
PO4	Healthy.io and Practice	<p>‘Initiation Call’</p> <p>The ‘Initiation Call’ will take place between the participating Practice and Healthy.io. In this call, you will be provided with an overview of the Minuteful Kidney solution, and Healthy.io will answer any questions you may have about the service offered, the onboarding, and test process.</p> <p>The ‘Initiation Call’ usually takes approximately 35 minutes.</p>
PO5	Healthy.io	<p>Following the ‘Initiation Call’, Healthy.io will send a participating practice a Data Protection Agreement (DPA) for signature via ‘Adobe sign’.</p>
PO6	Practice	<p>Sign Data Protection Agreement (DPA):</p> <p>Once you are in receipt of the Data Protection Agreement (DPA) from Healthy.io, review and sign via ‘Adobe Sign’.</p> <p>The Data Protection Agreement (DPA) content can also be found in Appendix 1 of this pack.</p>

PO7	Healthy.io	<p>Booking Link for an 'Onboarding Call'.</p> <p>Once the 'Data Protection Agreement' is signed, Healthy.io will send a participating practice a Chilipiper booking link to book in an 'Onboarding Call' with Healthy.io.</p>
PO8	Practice	<p>Book in an 'Onboarding Call'</p> <p>Once you have signed the Data Protection Agreement (DPA), you will receive the below Chilipiper link from Healthy.io to book in an 'Onboarding Call'.</p> <p>https://healthy.chilipiper.com/router/site-setup. You will be required to complete your details in the screen shown below:</p> <div data-bbox="618 639 1420 1315" data-label="Form"> <p>Almost there! Thursday, Feb 8th 2024 9:30 AM - 10:15 AM Change</p> <p>First Name * ⓘ First Name is required</p> <p>Last Name *</p> <p>Email *</p> <p>Phone *</p> <p>Job Title *</p> <p>Practice Name *</p> <p>ODS Code *</p> <p>EMR *</p> </div> <p>Then chose a date/time most convenient for you and any staff that may also wish to attend:</p>

		
PO9	Healthy.io	Just before the Onboarding Call, Healthy.io will send participating practices a Privacy Notice template/content, a Staff Leaflet, and information resources.
PO10	Practice	<p>Update your Practice’s Privacy Notice and Save HTN Patient Search File:</p> <p>Prior to the Onboarding Call with Healthy.io you will be required to complete the following actions:</p> <p>(a) Privacy Notice: use the Privacy Notice template/content to update your Practice’s Privacy Policy/Notice. The Privacy Notice content/template can also be found in Appendix 2 of this pack.</p>

PO11	Healthy.io and Practice	<p>Onboarding Call:</p> <p>The 'Onboarding Call' takes place between Healthy.io and you as the participating Practice, usually lasting approximately 10 - 15 minutes. This video call enables Healthy.io to support you with the following:</p> <ul style="list-style-type: none"> • Adding Healthy.io as a Trading Company to your EPR. • Running the HTN Patient Search File. WY data quality specialists will make the search files available to all practices via a WY shared folder within each clinical system. A separate short guide is available via the MinuteKidney webpage (and from the Healthy.io onboarding team when they contact practices). The provided search file can be run on a practice's EPR (SystemOne and EMIS) making it quick and easy to identify untested patients which meet the criteria for the service. The search file is designed to provide a breakdown of 'Priority Groups' as detailed in the patient search criteria in Appendix 3. • Healthy.io will encourage you to perform a test using a test/fictitious patient within your EPR to check connectivity is working correctly and to ensure that you will receive a patient's uACR test results.
PO12	Healthy.io	<p>Healthy.io MESH Testing Validation:</p> <p>Healthy.io will check to see if the test patient's result has been received within 24hrs. Healthy.io will inform the practice if the test is not successful and provide additional support where required.</p>
PO13	Practice	<p>Practice MESH Testing Validation:</p> <p>Although Healthy.io will check that the test was successful within 24hrs and inform you if not, it is advised that you also check your pathology inbox to see if the test/fictitious patient test result has been received.</p>

PO14	Practice	<p>‘Bulk Code’ Eligible Patients and Contact Patients Via Text (or Letter):</p> <p>Once you have extracted the eligible patient list using the provided HTN Patient Search File, apply the following SNOMED CT code to each eligible patient record: 1149711000000106 Provision of albumin to creatinine ratio semi-quantitative urinalysis home test kit offered (situation).</p> <p>Following coding, contact the eligible patient via text (preferable), or letter (if required) to introduce the MinuteKidney service.</p> <p>You should follow your own internal policies for sending out patient texts and letters, however, please see the suggested wording for the text in Appendix 4 of this pack, and suggested wording for letters in Appendix 5. Within the suggested text and letter narrative, there is also now a reference to the West Yorkshire Health and Care Partnership website providing patient facing information about cholesterol, statins, and chronic kidney disease.</p> <p>Please also ensure to have updated your practice’s Privacy Policy and signpost patients to this within the text or letter.</p> <p>The text or letter should ask patients to inform you if they wish to opt out of the MinuteKidney service within 5 days, or 7 days if you wish to account for non-working days.</p>
PO15	Patient	<p>Following receipt of the practice text (or letter) a patient may wish to opt-out the MinuteKidney service. Patients must inform their practice of this with 5-7 days.</p>
PO16	Practice	<p>Patient Opt-Out / Removal from Eligible Patient List and Patient Decline Coding:</p> <p>Where a patient has opted out of the service within 5-7 working days, remove the patient from the eligible patient list, and apply SNOMED CT Code: 149641000000104 Provision of albumin to creatinine ratio semi-quantitative urinalysis home test kit declined (situation), to the patient record to indicate that the patient has declined the MinuteKidney home uACR test.</p>

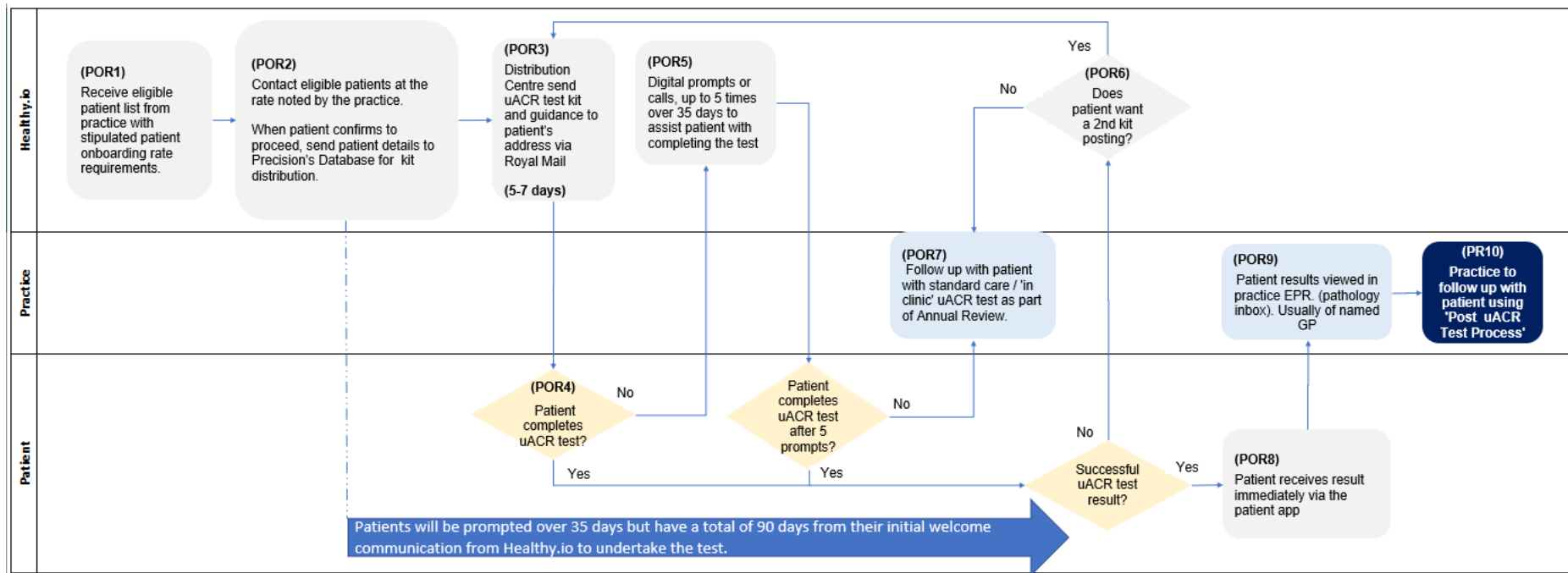
PO17	Practice	<p>Opt-Out Patient Follow Up:</p> <p>For patient’s opting out of the Minuteful Kidney ‘at home’ uACR test, you should follow up with the patient using standard care, i.e., an ‘in clinic’ uACR test as part of the patient’s Annual Review.</p>
PO18	Practice	<p>Eligible Patient List Inclusions:</p> <p>If a patient has not replied to the text or letter stipulating that they wish to opt-out during the 5-7 day opt-out period, the patient should remain on the eligible patient list.</p>
PO19	Practice	<p>Finalise Eligible Patient List and Decide the Required Rate of Patient Onboarding:</p> <p>Following the 5-7day opt-out period, the eligible patient list should be finalised. Ensure to have removed any patients from the list that opted out (as per step PO16).</p> <p>The Patient Search File provided by Healthy.io will also have exported the following patient demographics:</p> <ol style="list-style-type: none"> 1. Registered GP Name 2. NHS Number 3. Gender 4. First Name 5. Last Name 6. Date Of Birth 7. Email Address 8. Landline 9. Mobile number 10. Postal Address (inc post code) <p>You will be able to inform the rate at which eligible patients are onboarded to the Minuteful Kidney uACR testing service. It is recommended that you ask for Healthy.io to stagger patient roll out for those in the eligible cohorts to support your clinical teams to minimise workload, for example.,70 patients from the list per week. Your decision will also be informed by the volume of patients that</p>

		<p>are eligible for the service. The HTN Patient Search File also generates a separate eligible patient list in a prioritised format if practices wish to 'stagger' the rate at which patients are onboarded by priority. The priority criteria can be found in Appendix 3 of this GP Support Pack.</p> <p>Once the list is finalised, email to: Healthyio.minutefulkidney@nhs.net noting any rate at which eligible patients are to be onboarded to the service.</p>
<p>PO20</p>		<p>See Patient Onboarding and Testing Process in Section 5.2</p>

5.2. Patient Onboarding and Testing Process

This stage of the process is fully outsourced to MinuteKidney. No practice activity is required until a patient has successfully undertaken the 'at home' uACR, and the test results received into the named GP's pathology inbox. Actions for all parties are colour coded as below:

- Healthy.io Actions**
- Patient Actions**
- Practice Actions**



Below details the actions required of each participating party as per the reference number within the above 'Patient Onboarding and Testing Process' visual.

POR1	Healthy.io	<p>Minuteful Kidney Receipt of Eligible Patient List for Onboarding:</p> <p>Healthy.io will receive the Practice's eligible patient list with patient onboarding rate requirements.</p>
POR2	Healthy.io	<p>Healthy.io will then contact the patient to welcome them to the service. If the patient wishes to proceed, Healthy.io send the following patients details to the Precision's Database: 1. First Name 2. Last Name 3. Address 4. Telephone Number.</p>
POR3	Healthy.io	<p>Healthy.io's Distribution Centre uses the above information to send the Minuteful Kidney test kits out to patients via post (Royal Mail). A patient will receive their uACR test in the post with 5-7 days of the patient being processed.</p>
POR4	Patient	<p>Patient Completes the uACR Test:</p> <p>Patients are required to undertake the uACR test within 90 days of their initial welcome call by Healthy.io. When the patient receives the Minuteful Kidney uACR test kit and guidance in the post, they are required to download the Minuteful Kidney App onto their Smartphone (the app is supported by both iOS and Android).</p> <p>If the patient does not have a Smartphone, they can use a Smartphone belonging to a friend, neighbour, relative, or carer if they wish to do so. The phone number of the Smartphone being used however must be the same as the one registered with their GP as this will be used to verify the patient on the app (with their date of birth). If the patient wants the number used for testing to be different to the one registered with their GP, this can be changed via live chat, emailing Healthy.io's customer support team, or by calling the Healthy.io team on 020 7183 7939.</p> <p>To help tackle health inequalities across our area, the focus will be on improving access to patients from deprived and ethnic minority communities. Minuteful Kidney offers a digital first approach for uACR testing. If a patient opts for the digital offer but does not have a smartphone and unable to use one</p>

		<p>belonging to a friend, neighbour, relative or carer, support to join the programme may be available. Please see the digital access pages on the Healthier Together website to find the nearest services that offer digital devices, or refer to your local social prescriber service who can find local support. https://wyhealthiertogether.nhs.uk/parents/carers/worried-about-daily-life/digital-poverty.</p> <p>The Minuteful Kidney Smartphone App contains "chat-like" instructions, which incorporates video, audio, and textual directions, and guides the patient on how to perform the test. The in-app virtual nurse 'Emily' explains how to complete the test, step-by-step. The test is recommended for the first urine of the day, and this is further highlighted in the patient leaflet.</p> <p>A cup is included in the kit and the patient fills it with a urine sample. The patient dips the reagent strip into the urine sample for 1 second, blots it on the absorbing pad to remove excess liquid, and then places it on the Colour-Board in the designated location. The App instructs the patient to wait for 75 seconds to allow for chemical reactions to occur and the reagent colours to form. The app blocks the patient from scanning the Colour Board before a 75-second timer has ended, to assure proper chemical reaction. Following the incubation period, the App instructs the patient to photograph the Colour-Board, making sure that all four black and white hexagons are in the frame. The scanned images are then further analysed by the algorithm.</p> <p>Patients have several additional options for further support. They can contact Healthy.io's helpline on 020 7183 7939 or via email: support-uk@minuteful-kidney.com. They can also use the in-app chat function should they need any additional support with the test kit.</p>
POR5	Healthy.io	<p>Patient Prompts:</p> <p>Healthy.io's Engagement Centre will contact patients who have not completed the tests to prompt them to complete them and offer further support where needed. Healthy.io will prompt the patient 5 times over a period of 35 days if they have not completed the test. After this time, there will be no further prompts, however the patient will have a full 90 days to complete the test from their initial welcome communication from Healthy.io.</p>

POR6	Healthy.io	<p>Unsuccessful Test/Posting of 2nd Kit:</p> <p>If for whatever reason the patient has completed the uACR test, but the test is unsuccessful, Healthy.io's Engagement Team will contact the patient and check if they would like a 2nd kit posting to them.</p>
POR7	Practice	<p>Non-Completion of Patient uACR Test - Follow Up:</p> <p>If a patient has not completed the Minuteful Kidney uACR test following 90 days or has been unable to successfully take the test on 2 occasions, practices should follow up with a patient as deemed clinically appropriate.</p> <p>It is advised that Practices revert to requesting that a patient take the standard 'in clinic' uACR test as part of their Annual Review.</p>
POR8	Patient	<p>Patient Gains Test Results:</p> <p>Where a patient completes the test successfully, they can see their test results immediately within the App. The result will be either Normal, Abnormal, or High Abnormal.</p> <p>In addition to a message within the mobile app, patients with a test result of Abnormal or High Abnormal are also provided with a video explaining their test result (see below). The video is reassuring, asking them not to worry. Patients are informed that their GP will contact them to follow up as appropriate.</p> <p>Normal A1:</p> <p>Abnormal A2: The app provides a reassuring video explain their test result: MK Results Raj Abnormal 06.mp4 - Google Drive</p> <p>High abnormal A3: The app provides a reassuring video explain their test result: MK Results Raj Highly Abnormal 06.mp4 - Google Drive</p>

<p>POR9</p>	<p>Practice</p>	<p>Practice Receives Test Results in Pathology Inbox, and Automatic Coding in Patient Record:</p> <p>A patient's test results will automatically be transmitted back to the Electronic Medical Record (EMR) via the NHS Digital Message Exchange for Social and Health Care (MESH) API, for the GP to review. As the named GP you will receive the results into your pathology inbox for review in the same manner you would receive them for any traditional laboratory-based urine ACR test.</p> <p>EMIS Based Practices: When the patient's results are sent via MESH API to EMIS, read code - 46TC is automatically applied, which is converted to the below SNOMED code in EMIS.</p> <p>Urine albumin:creatinine ratio (observable entity) 1023491000000104</p> <p>SystemOne Based Practices: When the patient's results are sent via MESH API to SystemOne, read code - XE2n3 is automatically applied, which is converted to the below SNOMED code in SystemOne:</p> <p>Urine albumin:creatinine ratio (observable entity) 1023491000000104</p> <p>Please note that the Minuteful Kidney home testing solution is a semi-quantitative test, and therefore you will be provided with a category of the uACR result (A1 Normal, A2 Abnormal, A3 High Abnormal) based on the range below. Due to the semi-quantitative nature of the home test, you will not be provided with the specific number / (mmol) within that range.</p>
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		Parameter Name (Abbreviation)	Conventional Units	International System of Units (SI)
		Albumin (ALB)	10 mg/L 30 mg/L 80 mg/L 150 mg/L	10 mg/L 30 mg/L 80 mg/L 150 mg/L
		Creatinine (CRE)	10 mg/dL 50 mg/dL 100 mg/dL 200 mg/dL 300 mg/dL	0.9 mmol/L 4.4 mmol/L 8.8 mmol/L 17.7 mmol/L 26.5 mmol/L
		Albumin-Creatinine Ratio (ACR)	Normal (< 30 mg/g) Abnormal (30-300 mg/g) High Abnormal (> 300 mg/g)	Normal A1 (< 3.4 mg/mmol) Abnormal A2 (3.4-33.9 mg/mmol) High Abnormal A3 (> 33.9 mg/mmol)
POR10	Practice	GPs are asked to follow up with the patient using the Post uACR test process in Section 5.3 of this GP Pack.		

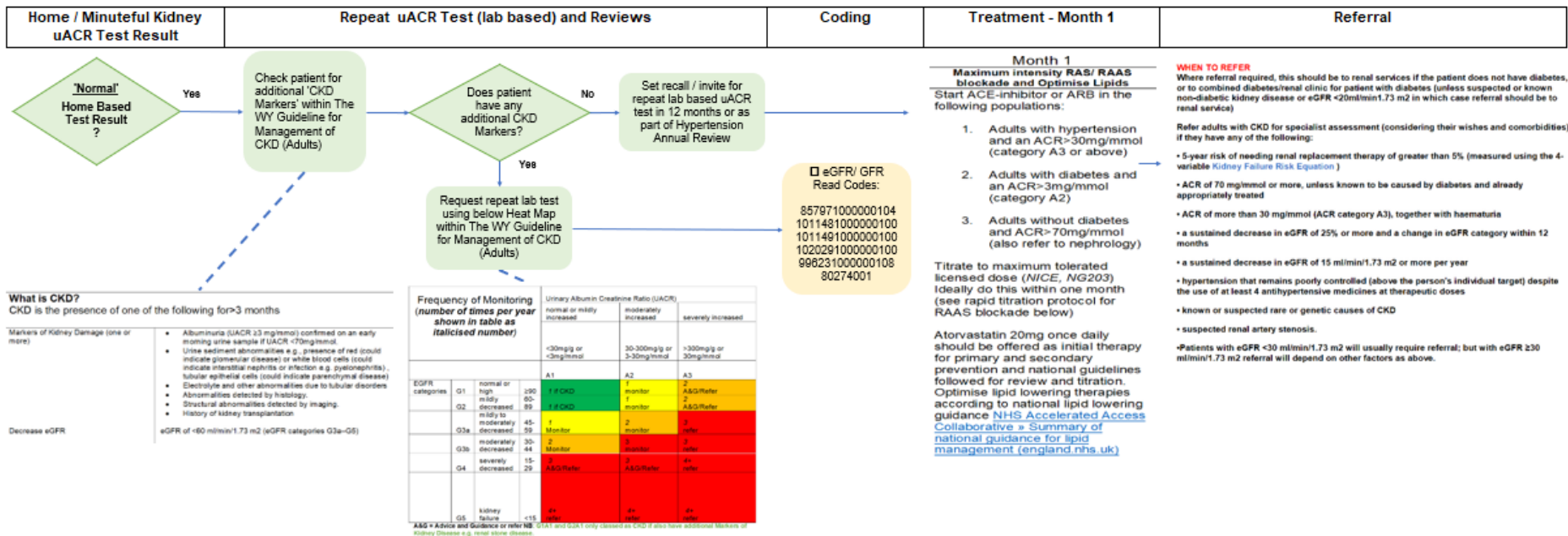
5.3. Post 'At Home' uACR Test Follow Up Process

The key activity required from primary care is to follow up on a patient's uACR test result using the below 'Post uACR Test Process'. Please note that the MinuteKidney home testing solution is a semi-quantitative test, and therefore provides participating practices with a category of the uACR result (A1 Normal, A2 Abnormal, A3 High Abnormal). A GP will not be provided with the specific number (mmol) within the range.

Based on the category provided by the 'at home' uACR test, practices are advised to account for any additional markers of CKD detailed in the ['WY Guideline for Management of CKD in Adults'](#), also available in [Appendix 6](#) of this GP Pack which provides a 'Heat Map' to stipulate the frequency and urgency of a repeat traditional / lab based uACR test, and the referral criteria.

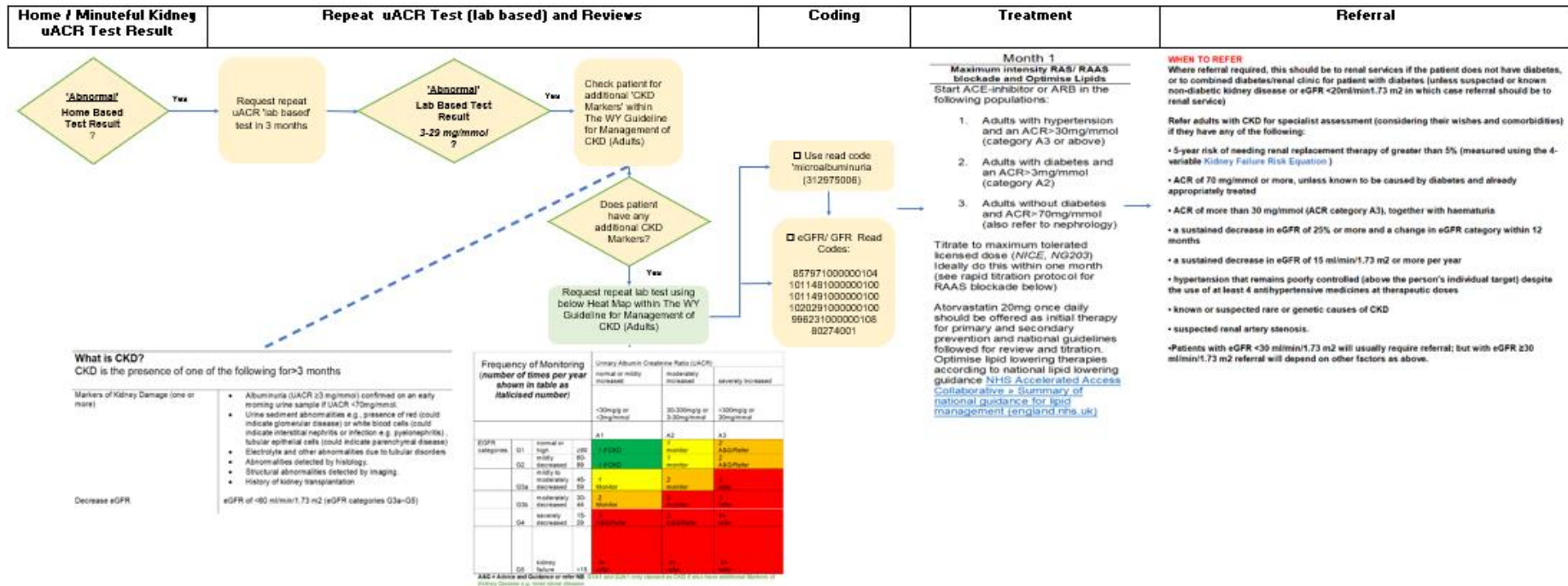
5.3.1. Normal Test Result (A1) Follow Up Process

If a patient's uACR test has returned a 'A1 Normal' result, they may not be required to repeat a traditional / lab based uACR test until a further 12 months or at their next Annual Review. Practices are however advised that uACR levels are not the only early marker of CKD, and other markers should be considered when deciding the frequency and urgency of a repeat test and review. The below process references sections of the ['WY Guideline for Management of CKD in Adults'](#).



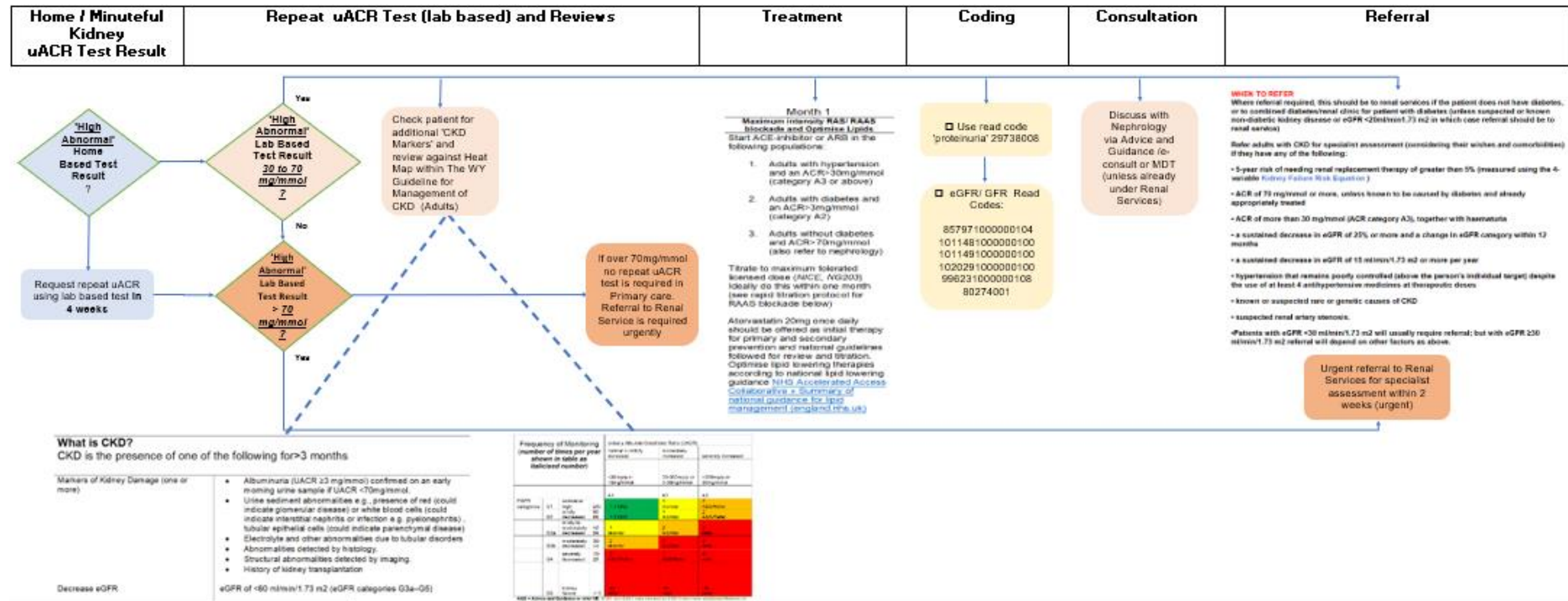
5.3.2. Abnormal Test Result (A2) Follow Up Process

Practices are advised that uACR levels are not the only early marker of CKD, and other markers should be considered when deciding the frequency and urgency of a repeat lab-based test and review. The below process references sections of the [‘WY Guideline for Management of CKD in Adults’](#).



5.3.3. High Abnormal Test Result (A3) Follow Up Process

Practices are advised that uACR levels are not the only early marker of CKD, and other markers should be considered when deciding the frequency and urgency of a repeat lab-based test and review. If a patient's 'home based' uACR test is 'High Abnormal' it is however strongly advised that Practices arrange for a repeat test using the traditional lab-based approach within 4 weeks to ascertain if a patient's results are 30-70mg/mmol or over 70 mg/mmol. The below process references sections of the ['WY Guideline for Management of CKD in Adults'](#).



5.4. Practice Support and Education Overview

There is a strong educational and clinical support component to this project. System Clinical Leadership will be provided by Emily Turner, WYICB CVD Prevention clinical lead, Dr Waqas Tahir, WYICB diabetes clinical lead, in partnership with the Y&H Renal Network Clinical Lead for WY, Dr Sunil Daga, to support more joined up care for those most at risk of CKD.

Furthermore, Place based clinical leadership will be deployed to support practices to access further advice and guidance regarding the management of CKD for adults. This includes peer review and decision-making support relating to atypical presentations and/or access to specialist renal consultancy/shared care with secondary care were required.

Both System and Place based clinical leadership will respond to identified learning needs or requests for peer support/shared care from participating practices; mobilising their collective resource based on need and particularly where there are 'hotspots' of abnormal/high abnormal uACR results across the system. these 'hotspots' will be identified using the aggregate, anonymised data shared by Healthy.io each month.

In addition to the resources accompanying this GP Pack, resources are also made available on:

3 education sessions/webinars will also be available from Healthy.io's Clinical Lead, Professor Raj Thakkar. The first will be held on the 27th of March, 11:00 – 12:00. This first session/webinar will be recorded and made available on the West Yorkshire Minuteful Kidney Project Website to enable practices to view at their convenience. The webinars will cover:

- What is CKD?
- CKD as a risk factor for CVD
- The importance of ACR testing
- How to improve outcomes in your patients
- About the home ACR testing service
- How home ACR testing can work for your practice

5.5. Practice Support and Education Roles and Responsibilities

Role	Responsibilities
Minuteful Kidney – Hypertension Project Team	Notify nominated WYICB system clinical lead where there is evidence of:

	<ul style="list-style-type: none"> • Prioritise practices who provide care for communities with higher levels of socioeconomic deprivation, drawing on CVDPrevent hypertension prevalence data • Larger number of abnormal AND high abnormal test results in a PCN and/or a GP practice (hotspots). • Contact from practice for clinical support e.g. complex patient. • Request for education.
Healthy.io Clinical Lead	<ul style="list-style-type: none"> • Outreach/education sessions for practices.
WYICB System Clinical Leads	<ul style="list-style-type: none"> • Receive updates from Healthy.io as to practices that later opt out. • Receive updates at least fortnightly from Healthy.io as to hotspots • Engage with Place Clinical Lead to co-produce response/agree who will link up with hotspots/site. • Deep dive as to reasons for greater than expected prevalence abnormal/high abnormal results to inform learning and support for PCNs/practices. • Advice for and consult with Place Clinical Leads. • Coordinate with Place Clinical Leads 'virtual drop in' (or another mode) peer support/consultancy sessions re: BP and/or kidney damage optimisation. • Knowledge mobilisation and share learnings to inform WY renal pathway optimisation, responding to learning needs for primary care teams and influence future commissioning decisions relating to ACR home testing. • Share widely the West Yorkshire CKD pathway to support adoption.
Place Clinical Leads	<ul style="list-style-type: none"> • Receive updates at least fortnightly from Healthy.io as to hotspots (as well as System Leads). • Engage with System Clinical Lead(s) to co-produce response/agree who will link up with hotspots/site. • Deep dive as to reasons for greater than expected

	<p>prevalence abnormal/high abnormal results to inform learning and support for PCNs/practices.</p> <ul style="list-style-type: none"> • Peer support primary care colleagues and peer clinical leads. • Coordinate with system clinical leads 'virtual drop in' peer support/consultancy sessions re: BP and/or kidney damage optimization. • Share learning to inform continuous improvement, case studies, inform WY renal pathway optimisation, responding to learning needs for primary care teams and influencing future commissioning decisions relating to ACR home testing.
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6. Minuteful Kidney Evaluation

Using a 'high-risk' cohort of 40,000 patients, Minuteful Kidney will assist West Yorkshire Health and Care Partnership (WY ICB) in addressing health inequalities and deliver on the Core20PLUS5 approach. The outcomes of interest for this evaluation are:

- Improved patient uptake with routine/yearly ACR testing.
- Improved uACR testing uptake among those at more risk of health inequalities.
- Diagnosis and risk stratification - chronic kidney disease.
- Improved optimisation of hypertension and CKD
- Impact on primary and secondary care resource use
- Practice/Clinician behavioural change.
- System benefits of improved screening, detection and management of CKD in populations living with HTN

The evaluation will compare those tested and with abnormal uACR results with a comparator untested population and will aim to understand the differences in primary care utilisation, and secondary care utilisation: admissions (planned and unplanned); the differences in prevalence of CVD events which result in a presentation to secondary care; and if possible, the differences in morbidity and mortality rates (however the length of follow up may be a limiting factor), and healthcare costs.

Evaluation follow up is intended to be at least 12 months; however, if possible 18 months follow up will be aimed for. Sub analysis may include cost consequence

analysis, explore prescribing costs, clinician /admin resource use (primary and secondary care) and any additional costs e.g., estates.

7. Minuteful Kidney Clinical Safety

The deployment of Minuteful Kidney across West Yorkshire has the potential to deliver substantial benefits to patients, practices, and the wider Health System. It must however be recognised that clinical risk management is required to ensure that the solution does not compromise patient safety. Please note that the below risk management standards apply to 'clinical risk' only, meaning that the scope is limited to the management of risks related to patient safety as distinct from other types of risk such as financial.

7.1. Clinical Safety Standards

DCB 0129 Standard:

Healthy.io as the manufacturer of Minuteful Kidney has been required to undertake clinical risk management activities as part of their obligations under the DCB 0129 standard. This includes an assessment of all clinical functionality which has potential for causing harm to patients. Furthermore, it includes operational use and potential misuse of that clinical functionality. There is a requirement that Healthy.io then maintain the associated Hazard log and Clinical Safety Case Report, providing updates, highlighting any newly identified clinical safety risks, and any changes in the level of existing clinical risks.

DCB 0160 Standard:

Deploying organisations are legally required to follow the DCB 0160 clinical risk management standard. This is mandatory under the Health and Social Care Act 2012. A qualified Clinical Safety Officer via DigiSafe Consulting Ltd has completed the initial DCB0160 activities on behalf of participating practices across West Yorkshire, with an internal review and sign off by Dr Jason Broch, Chief Clinical Information & Innovation Officer for Leeds, and CSO.

7.2. DCB 0160 and DCB 0129 Documentation

The responsibility for the clinical safety activities resides with Healthy.io, West Yorkshire ICB, and the deploying GP practices.

WY ICB have ensured that there has been a thorough risk assessment with suggestions for mitigation. Deploying GP practices are independent healthcare organisations and are therefore accountable for deploying the technology in line with this guidance.

Practices are required to review the clinical safety documentation and apply mitigations applicable to the practice.

DCB 0160 Documentation

The DCB160 Clinical Safety Case Report and Hazard log for Minuteful Kidney can be found at:

https://www.wypartnership.co.uk/application/files/3517/0920/7835/WY_Minuteful_Kidney_Clinical_Safety_Guidance.docx

DCB 0129 Documentation:

Due to the commercial sensitivity of the supplier's DCB0129 documentation and supporting evidence, these documents cannot be accessed via the above West Yorkshire Health and Care Partnership website. To obtain these documents, please email dawn.kellett1@nhs.net who will send these documents via SafeDrop due to the large file sizes.

Practices are also required to then create the following 'Clinical Risk Management File' to store the DCB 0160 and DCB0129 documentation.

Clinical Risk Management File

- Supporting Evidence (sub folder)
- DCB0160 Clinical Safety Case Report (sub folder)
- DCB0160 Hazard log (sub folder)
- DCB0129 (sub folder)

Healthy.io as the manufacturer of the Minuteful Kidney solution will act as the key engagement point for eligible patients whilst they undertake the 'at home' uACR tests. As a result, it is highly likely that any occurring clinical incidents and near misses will be reported by the patient to Healthy.io's contact centre, where their registered Clinical Safety Director (Professor Raj Thakkar) will assess and assign a SAC score. Clinical safety issues will be managed according to priority until they have been resolved. The priority will be to remediate any serious issues urgently and, where appropriate, supplement this with a strategic fix as soon as reasonably practicable. Following review by Healthy.io's Clinical Safety Director, all clinical safety incidents or near misses will be communicated to WY ICB in line with the below escalation timelines:

SAC-5 (24hrs)

SAC-4&3 (48hrs)

SAC-2&1 (7 days)

All deploying practices will also be notified of significant incidents, particularly where there may be a requirement to implement operational controls, and the DCB0129 and DCB0160 hazard log will then be updated as required.

7.3. Clinical Incident Reporting

Although it is highly likely that a patient will contact Healthy.io as their engagement point, if a patient makes a deploying practice aware that use of the MinuteKidney solution has resulted in an injury or a near miss, practices are required to report this to West Yorkshire ICB by emailing:

wycb-wak.clinicalincidentreporting@nhs.net

When reporting the clinical incident, ensure to include the following details:

- Reporter name
- Date
- Issue description
- Issue severity
- Contact information
- Patient details may be required for investigation, balancing the need for information with privacy considerations.

8. Key Contacts

MinuteKidney – Hypertension Oversight Group and Clinical Leadership:

Dr Sunil Daga	Consultant Nephrologist, Leeds Teaching Hospitals NHS Trust WY ICS Kidney health Clinical Lead, YH Renal Network	sunildaga@nhs.net
Emily Turner	Advanced Pharmacist Leeds ICB,	emily.turner1@nhs.net
Dr Waqas Tahir	GP Partner Affinity Care (Cowgill Surgery, Clayton) GPwER Diabetes and CVRM	waqas.tahir@bradford.nhs.uk

	<p>Diabetes Clinical Lead – Bradford System Programme Board</p> <p>WY ICS Diabetes Clinical Lead</p> <p>Associate Clinical Lead – Diabetes Clinical Networks (Y&H)</p>	
Mark Wright	<p>Consultant Nephrologist Leeds Teaching Hospitals NHS Trust</p> <p>YH Renal Network Lead</p>	mark.wright8@nhs.net

West Yorkshire ICB and NHSe Project Reporting:

Sarah De Biase	<p>Long-term Conditions and Personalisation Senior Programme Manager; West Yorkshire Health and Care Partnership</p>	sarah.debiase1@nhs.net
Dawn Kellett	<p>Digital Project Manager, West Yorkshire Health and Care Partnership</p>	dawn.kellett1@nhs.net
Gillian Dinsey	<p>Yorkshire & Humber Renal ODN Manager, Sheffield Teaching Hospital NHS Foundation Trust</p>	gillian.dinsey@nhs.net

Healthy.io:

Adam Marshall	<p>Account Manager and Programme Manager, Healthy.io</p>	adam.marshall@healthy.io
Roberto Rossini	<p>Head of Kidney Services UK, Healthy.io</p>	roberto.rossini@healthy.io

Damian O'Boyle	Director of Client Services UK, Healthy.io	damian@healthy.io
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Resources / Appendices

1. Data Processing Agreement

A Data Processing Agreement for signage between Healthy.io and participating practices can be found on the [Minuteful Kidney Hypertension Website](#), and via the following direct link: [Healthy.io - West Yorkshire - Data Processing Agreement GP Practices - 29.1.24.docx \(live.com\)](#)

2. Privacy Notice

Healthy.io makes albumin to creatinine ratio (“ACR”) testing easier and more convenient, by allowing patients to test from home using a testing kit, and a smartphone app called Minuteful™ Kidney. The ACR test is one of the 9 NICE recommended annual care processes for patients living with diabetes.

An ACR test is part of a patient’s health care review if the patient has a chronic kidney disease (CKD) or is at risk of CKD (for example diabetes or hypertension). The test looks for particles of protein in urine called albumin. Carrying out a Minuteful™ Kidney ACR test allows the patient’s doctor to identify and monitor the presence of albumin, which may suggest the first signs of CKD.

Before we can use Healthy.io to provide the service, Healthy.io undergoes a review by the NHS national team, then a further review takes place in each local area when Healthy.io works with a GP Surgery. In our area, this involved our Integrated Care Board reviewing Healthy.io's data processing methods through a standardised data processing risk assessment exercise which is defined under UK data protection legislation and NHS regulations; this review is carried out by the local ICB completing and signing off a Data Protection Impact Assessment (DPIA) on the Healthy.io service. Further to this, Healthy.io then goes on to work with GP Surgeries in our area, and prior to any personal data being shared with Healthy.io, we enter into a Data Processing Agreement; it is under the terms of the Data Processing Agreement, supported by the DPIA, that any personal data shared with Healthy.io is regulated.

The minimum amount of personal details is shared with Healthy.io to provide you with the Minuteful Kidney service. The personal data shared with Healthy.io are:

- Registered GP name, NHS number, main spoken language, gender, first name, last name, date of birth, email address, home phone number, mobile

phone number, address, ethnicity, diabetes type, CKD diagnosis and stage, date and value of last - ACR test.

- When you complete the test on your phone the following data is also processed: test date, test result, smartphone information (carrier, operating system, device, model, app version, city), app information (IP address).

The following is a summary of the relationships involved:

- Data Subject: Patient
- Data Controller: GP Surgery
- Data Processor: Healthy.io under a Data Processing Agreement to the GP Surgery.
- Sub Processor: A 'Sub-processor' is a trusted third-party data processor engaged by Healthy.io who has access to personal data. Healthy.io uses third party Sub-processors to provide elements of services (such as data hosting, posting out the test kits to your address and to send out service messages). Healthy.io has contracts in place with Sub-processors which ensures appropriate use of your data.

Healthy.io may store or process limited data about you in countries outside the UK. Most of the data processing is carried out in the UK, EEA or country with a UK Adequacy Regulation (such as Israel). However, in order for Healthy.io to provide you with the service, a limited amount of personal data may be processed in the US. Where data is processed outside of the UK or EEA, such as in the US, we will take the required steps to ensure that your personal data is protected to the standard and data transfer mechanisms required by UK Data Protection Law. Page 29 of 32 The lawful basis for processing is:

- Personal data: UK GDPR Article 6(1)(e): public task
- Special category data: UK GDPR Article 9(2)(h): Health or social care (with a basis in law)
- (The basis in law is the) Data Protection Act 2018: Schedule 1, Part 1: (2) Health or social care purposes
- Common Law Duty of Confidentiality (CLDC) is satisfied as this service is to support the provision of direct care. It should be noted that consent is not used for any part of the data processing for this service as the service supports the provision of direct care which satisfies the CLDC. However, patients have the right to object (commonly referred to as opting out or choosing not to take up the service). If you do not wish to receive a home test kit from Healthy.io we will continue to manage your care within the GP Surgery.

As this service is to support the provision of direct care, the General Practice Data for Planning and Research (previously known as the type 1 opt out) and the National Data Opt-Out (previously known as the type 2 opt out) do not apply to this service.

Individual rights requests (such as Subject Access Request) are the responsibility of the GP Surgery. Any individual rights requests that are made directly to Healthy.io will be reported to the GP Surgery to process and confirm actions required to be taken by Healthy.io.

Healthy.io will store the data we share with them securely for the duration of the contract with us. If required by law, Healthy.io will keep your data for the minimum time required under the applicable law. The personal data that Healthy.io will retain after the end of the contract with us is any personal data related to complaints (complainant name, contact details and nature of complaint, and any other personal data that may be needed to manage the complaint) which Healthy.io are legally required to retain for 10 years under the applicable UK regulations that govern the product as a medical device.

When personal data is no longer required, Healthy.io will delete or anonymise data in line with Data Protection Legislation and appropriate industry guidance.

3. HTN Patient Search File Criteria

The Healthy.io standard Hypertension search will look for:

- those 18+ with Hypertension AND
- if they haven't taken a urine ACR Test within the last 12 months.
- DO NOT EXCLUDE THOSE WITH DIABETES

Exclusion criteria for the West Yorkshire standard Hypertension searches are:

- * Living in a care/residential/nursing home
- * Pregnancy
- * History of a Catheter
- * Are in Palliative Care
- * Have Dementia
- * Have had a Kidney Transplant
- * Severe frailty (which encompasses nursing home /palliative and dementia patients)
- * If the patient has withdrawn consent to record sharing /national opt out in place
- * If patient does not have a registered mobile phone number

Prioritisation within identified cohort

- 1) >3 LTCs - HTN , T2D , CKD , CVD(IHD/Stroke/TIA) , chronic respiratory disease (COPD or Asthma), Heart Failure, Atrial Fibrillation, Obesity/Unhealthy weight (BMI>25) **OR** on NSAIDs
- 2) BP using UCLP priorities:
 - **Priority 1** - BP >180/120
 - **Priority 2a** - BP >160/100
 - **Priority 2b** - BP >140/90 if South Asian/ Black AND CVD risk factors*/ comorbidities
 - **Priority 2c** - No BP reading in last 18 months
 - **Priority 3a** - BP >140/90 if South Asian/ Black **OR** CVD risk factors*
 - **Priority 3b** - BP >140/90 **OR** >150/90 if ≥80
 - **Previous Urine ACR** >30mg/mol **OR** eGFR< 45ml/min (last 24months)

* The definition of the CVD risk factors /comorbidities for prioritisation searches Priority 2b and 3a in email below are:

Priority a:

- Established cardiovascular disease.
- Diabetes
- Obesity BMI >35
- [ckd]* obviously this we won't know as those eligible won't have this coded.

Priority b:

- qrisk > 20%
- and smoking

4. Suggested Patient Text Message

Dear [FIRST NAME]. Your annual kidney health urine test is due soon. [GP Surgery NAME] has partnered with Healthy.io who provide the Minuteful Kidney service allowing you to complete your test from the comfort of your home. Once complete, the results are shared directly with your GP. To find out more visit: [LINK TO DATA CONTROLLERS PRIVACY NOTICE]. To opt out of this service please [GP Surgery OPTION: ENTER GP Surgery PHONE NUMBER OR OTHER OPT OUT METHOD] by <ADD APPLICABLE DATE 5-7 DAYS FROM THE DATE THE TEXT MESSAGE IS BEING SENT>. If no opt-out is received by this date, Healthy.io will be provided with your contact details to engage with you, and if you then wish to proceed, they will send the test kit to your registered address. More information about cholesterol, statins and chronic kidney disease can be found via Public Information Resources on the [West Yorkshire Health and Care Partnership Website](#).

5. Suggested Patient Letter

Dear [Patient name],

Having high blood pressure is associated with increased risk of cardiovascular and kidney disease. With regular checks of your kidney function, you can reduce the risk of developing these complications.

We are therefore excited to inform you of a new service at [Insert practice name] that will allow patients with high blood pressure to test their kidney function from home.

A part of your annual review, you should have a simple urine test. This test looks at your urinary albumin to creatinine ratio (ACR). The ACR test checks your kidney function by looking for particles of protein in your urine called albumin. If there is albumin in your urine, this means you are at increased risk of kidney disease and heart disease. If this is picked up at an early stage, you can be put on medication that will reduce your risk of any complications.

To help you perform this test, we are working with a company called Healthy.io, who provide a MinuteFul Kidney urine test kit and an accompanying free-to-download app that allows people to do the test at home. The test is easy to do and only requires the use of your smartphone, and a test kit that will be sent to your home.

Healthy.io will contact you to arrange your test kit being sent to you. To find out more about kidney disease or the test, see here: <http://minuteFul.com/>. For further information, see our privacy notice: [insert practice/CCG/PCN privacy policy link here].

To opt out of this service please [PRACTICE OPTION: ENTER PRACTICE NUMBER OR OTHER OPT OUT METHOD] by <ADD APPLICABLE DATE 5-7 DAYS FROM THE DATE THE TEXT MESSAGE IS BEING SENT>. If no opt-out is received by this date, Healthy.io will be provided with your contact details to engage with you, and if you then wish to proceed, they will send the test kit to your registered address. More information about cholesterol, statins and chronic kidney disease can be found via Public Information Resources on the [West Yorkshire Health and Care Partnership Website](#).

Best wishes,

[insert practice name]"

6. West Yorkshire Guideline for the Management of CKD

West Yorkshire Guideline for the Management of Chronic kidney Disease (CKD) for Adults

Think
Cardiovascular

Think
Kidneys

Think
Diabetes

What is CKD?

CKD is the presence of one of the following for >3 months

Markers of Kidney Damage (one or more)

- Albuminuria (UACR ≥ 3 mg/mmol) confirmed on an early morning urine sample if UACR < 70 mg/mmol.
- Urine sediment abnormalities e.g., presence of red (could indicate glomerular disease) or white blood cells (could indicate interstitial nephritis or infection e.g. pyelonephritis), tubular epithelial cells (could indicate parenchymal disease)
- Electrolyte and other abnormalities due to tubular disorders
- Abnormalities detected by histology.
- Structural abnormalities detected by imaging.
- History of kidney transplantation

Decrease eGFR

eGFR of < 60 ml/min/1.73 m² (eGFR categories G3a–G5)

Offer Screening for CKD using eGFR, serum creatinine and Urine Albumin: Creatinine Ratio (UACR) to people with any of the following risk factors:

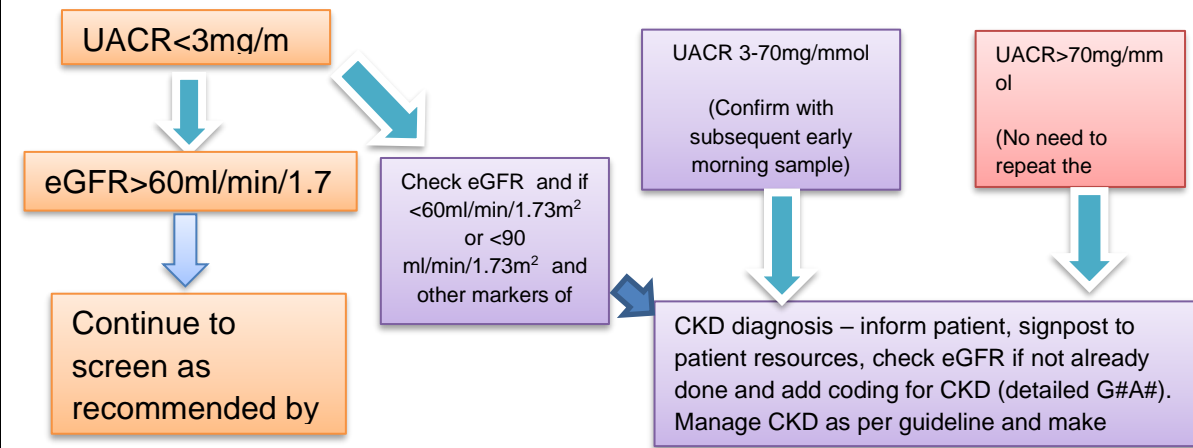
- All people living with diabetes at least annually
- For those with an eGFR < 60 ml/min/1.73m² a UACR should be requested
- Hypertension—annually as part of hypertension reviews
<https://cks.nice.org.uk/topics/hypertension/diagnosis/investigations/>
- Cardiovascular disease (ischaemic heart disease, chronic heart failure, peripheral arterial disease or cerebral vascular disease) annually as part of routine reviews
- History of acute kidney injury (monitor yearly for 3 years even if function back to baseline)
- Structural renal tract disease, recurrent renal calculi or prostatic hypertrophy
- Multi-system disease e.g., Systemic lupus erythematosus, vasculitis, myeloma
- Family history of end-stage kidney disease (GFR category G5) or hereditary kidney disease
- Haematuria /Proteinuria (opportunistic detection)
- Treated with nephron-toxic agents (NSAIDs, Lithium, Calcineurin inhibitors, Aminosalicylates etc)
-

Every patient at the time of a clinician diagnosing CKD should have a urine dipstick because haematuria raises possibility of systemic renal disease or structural renal abnormalities which needs further assessment.

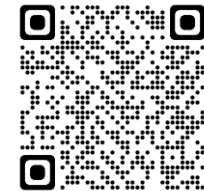
Haematuria

1. Use dipstick reagent strips rather than urine microscopy.
2. Evaluate further if a result of 1+ or more (initially repeat dipstick in 2 weeks)
3. Result is not useful if the person is menstruating if someone has a catheter or has a known infection.

Urine Albumin: Creatinine Ratio (UACR) and CKD Diagnosis
 UACR is a useful marker of renal damage and complication risk. It is the usual method of assessing proteinuria. A confirmed (repeated) UACR>3mg/mmol represents proteinuria which is clinically significant.



KFRE (Kidney Failure Risk Equation)
[The Kidney Failure Risk Equation](#)



Healthcare professionals can use the Kidney failure risk equation to determine 2 and 5 year risk of treated kidney failure (dialysis and transplantation) for a patient with CKD stage 3a-5
 There are also videos available on this website to explain risk to people living with CKD
www.kidneyfailureisk.co.uk
 NB: KFRE must be calculated using eGFR EPI (not MDRD)

How do we categorise CKD, how often should we test and when should we refer/seek advice?

When reviewing results, place the test results in clinical context including consideration of why the blood tests were taken. If history of acute illness, then assess and manage accordingly. Consider acute kidney injury (AKI) and the possibility of obstruction if rapidly declining eGFR. Think Kidneys <https://www.thinkkidneys.nhs.uk/aki/resources/primary-care/>, <https://www.thinkkidneys.nhs.uk/campaign/>

Frequency of Monitoring (<i>number of times per year shown in table as italicised number</i>)				Urinary Albumin Creatinine Ratio (UACR)		
				normal or mildly increased	moderately increased	severely increased
				<30mg/g or <3mg/mmol	30-300mg/g or 3-30mg/mmol	>300mg/g or 30mg/mmol
				A1	A2	A3
EGFR categories	G1	normal or high	≥90	1 if CKD	1 monitor	2 A&G/Refer

WHEN TO REFER
 Where referral required, this should be to renal services if the patient does not have diabetes, or to combined diabetes/renal clinic for patient with diabetes (unless suspected or known non-diabetic kidney disease or eGFR <20ml/min1.73 m2 in which case referral should be to renal service)
 Refer adults with CKD for specialist assessment (considering their wishes and comorbidities) if they have any of the following:
 • 5-year risk of needing renal replacement therapy of greater than 5% (measured using the 4-variable [Kidney Failure Risk Equation](#))

	G2	mildly decreased	60-89	1 if CKD	1 monitor	2 A&G/Refer
	G3a	mildly to moderately decreased	45-59	1 Monitor	2 monitor	3 refer
	G3b	moderately decreased	30-44	2 Monitor	3 monitor	3 refer
	G4	severely decreased	15-29	3 A&G/Refer	3 A&G/Refer	4+ refer
	G5	kidney failure	<15	4+ refer	4+ refer	4+ refer

A&G = Advice and Guidance or refer NB: G1A1 and G2A1 only classed as CKD if also have additional Markers of Kidney Disease e.g. renal stone disease.

- ACR of 70 mg/mmol or more, unless known to be caused by diabetes and already appropriately treated
- ACR of more than 30 mg/mmol (ACR category A3), together with haematuria
- a sustained decrease in eGFR of 25% or more and a change in eGFR category within 12 months
- a sustained decrease in eGFR of 15 ml/min/1.73 m2 or more per year
- hypertension that remains poorly controlled (above the person's individual target) despite the use of at least 4 antihypertensive medicines at therapeutic doses
- known or suspected rare or genetic causes of CKD
- suspected renal artery stenosis.
- Patients with eGFR <30 ml/min/1.73 m2 will usually require referral; but with eGFR ≥30 ml/min/1.73 m2 referral will depend on other factors as above.

Patient Information

How to Look after your kidneys <https://www.kidneycareuk.org/order-or-download-booklets/ckd-health-check-look-after-your-kidneys-and-keep-yourself-well/>

Chronic Kidney Disease <https://www.kidneycareuk.org/order-or-download-booklets/chronic-kidney-disease/>

A healthy diet and lifestyle for kidneys <https://www.kidneycareuk.org/order-or-download-booklets/healthy-diet-and-lifestyle-your-kidneys/>

Medicines for chronic kidney disease <https://www.kidneycareuk.org/order-or-download-booklets/medicines-chronic-kidney-disease/>

Medicines for high blood pressure <https://www.kidneycareuk.org/order-or-download-booklets/medicines-high-blood-pressure/>

Diabetes and kidney disease <https://www.kidneycareuk.org/order-or-download-booklets/diabetes-and-kidney-disease/>

4 Key things in 4 months to Save Lives for Adults with CKD (ideally do in every patient with eGFR<60 or UACR ≥ 3 mg/mmol)

Month 1	Month 2		Month 3	Consider at month 4 onwards
<p>Maximum intensity RAS/ RAAS blockade and Optimise Lipids</p> <p>Start ACE-inhibitor or ARB in the following populations:</p> <ol style="list-style-type: none"> Adults with hypertension and an ACR>30mg/mmol (category A3 or above) Adults with diabetes and an ACR>3mg/mmol (category A2) Adults without diabetes and ACR>70mg/mmol (also refer to nephrology) <p>Titrate to maximum tolerated licensed dose (<i>NICE, NG203</i>) Ideally do this within one month (see rapid titration protocol for RAAS blockade below)</p> <p>Atorvastatin 20mg once daily should be offered as initial therapy for primary and secondary prevention and national guidelines followed for review and titration. Optimise lipid lowering therapies according to national lipid lowering guidance NHS Accelerated Access Collaborative » Summary of national guidance for lipid management (england.nhs.uk)</p>	<p>Start SGLT2i (Referring to 'safe and effective use of SGLT2is' guidance)</p> <p>Person with Type 2 Diabetes</p> <p>Start Dapagliflozin 10mg once daily ensuring the person has an eGFR 25-75 mL/min/1.73m² recognising that glycaemic benefits will be limited at an eGFR <45ml/min/1.73m²</p> <p style="text-align: center;">OR</p> <p>Start Empagliflozin 10mg once daily ensuring the person has an eGFR 20-90ml/min/1.73m² recognising that glycaemic benefits will be limited at an eGFR<45ml/min/1.73m²</p>		<p>Optimise Blood Pressure and Other Cardiovascular Risk Factors</p> <p>Initiate further blood pressure agents to treat to target</p> <ul style="list-style-type: none"> UACR < 70mg/mmol: <130/80mmHg UACR>70mg/mmol: Ideally <120/80mmHg taking into consideration frailty and co-morbidities. <p>Caution in the elderly/frail – consider reviewing the targets</p> <p>Encourage home monitoring of Blood Pressure (NB targets are 5mmHg lower for HBPM)</p> <p>In those who have had a cardiovascular event, ensure offered aspirin with appropriate gastric protection (in some cases a H2 receptor antagonist may be preferred e.g., if having electrolyte abnormalities or in the instance of acute interstitial nephritis (ANI). Famotidine is the H2 receptor antagonist of choice in this situation).</p> <p>Aspirin may be considered for primary prevention in those at high cardiovascular risk. Initiation should be balanced with consideration of the increased bleeding risk, including thrombocytopenia with low eGFR.</p>	<p>Consider referral for Finerenone (see shared care guidance)</p> <p>Only for people living with Type 2 Diabetes and who also has:</p> <ul style="list-style-type: none"> stage 3 or 4 CKD (eGFR ≥25- <60ml/min/1.73m²) with albuminuria (UACR ≥3mg/mmol) been optimised on standard care (RAAS blockade and SGLT2i inhibitors) <p>Finerenone can only be initiated if serum potassium ≤4.8mmol/L or if serum potassium >4.8 to 5 mmol/L then initiation can be considered with additional monitoring in the first 4 weeks based on patient characteristics and potassium levels.</p> <p>Initiate the lower dose of Finerenone 10mg if eGFR 25-59ml/min/1.73m²</p>
	<p>(NB: Agents are listed in alphabetical rather than preferential order)</p> <p>Follow the guidance in the document 'Safe and Effective Use of SGLT2is'</p> <p>*We would not advocate switching SGLT2is so in those already established (including those on Canagliflozin) we would advise they continue and those already established on empagliflozin 25mg once daily</p>			

should continue unless indicated to drop dose.

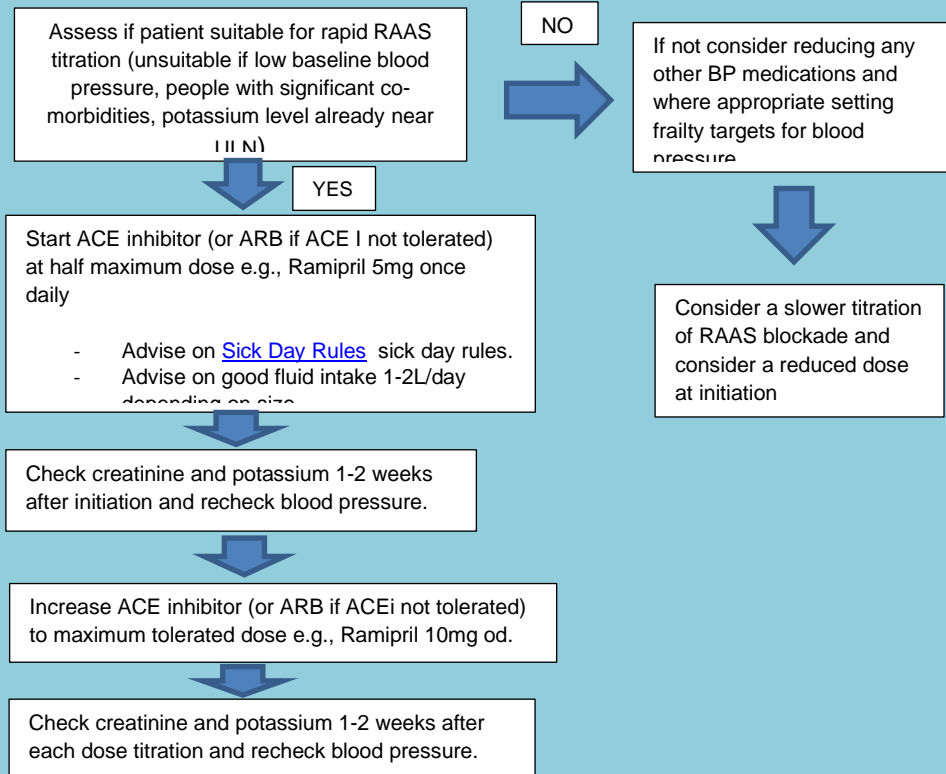
Specialist initiation only if history of: transplantation; on immunological therapy; polycystic kidney disease; haemodialysis.

In those with established CAD or PAD at high risk of ischaemic events ([see NICE](#)) consider 2.5mg bd rivaroxaban alongside aspirin. Only if eGFR>15ml/min.

Lifestyle advice – diet, exercise, weight management, smoking cessation



Rapid Titration Protocol for RAAS Blockade



Blood Results and Monitoring

ACE inhibitor and ARB eGFR and Serum Creatinine

Accept a serum creatinine rise < 30% or eGFR fall of < 25% from baseline: after ACEi/ARB initiation or dose increase.
 If renal function deterioration greater than stated above seek nephrologist advice (to exclude possible renovascular disease)
 STOP ACEi/ARB if changes in creatinine/ eGFR exceed the above and no other causes of deteriorating renal function (e.g., dehydration, use of NSAIDs) is found.

Potassium (K+)

If K⁺ >6.0 mmol/L -would need urgent repeat U&E (please follow local guidance and ideally this would be a same day repeat) and if 6.5 mmol/L or greater or if there are symptoms consistent with hyperkalaemia, you would usually send to A&E for repeat potassium and ECG. If K⁺ >6.0 mmol/L stop ACEi/ARB and start low potassium diet, a recommended patient information can be found: <https://www.kidney.org.uk/potassium>.

If K⁺ remains persistently ≥6.0mmol/L and because of this hyperkalaemia people are unable to take an optimised dose of RAAS inhibitor. consider referral for sodium zirconium cyclosilicate (for CKD stage 3b-5, not on dialysis only)

If K⁺ >5.5mmol/ stop MRAs (including Finerenone)

Aim to restart medications once K⁺ ≤ 5.5 mmol/L (note lower starting doses with Finerenone below)

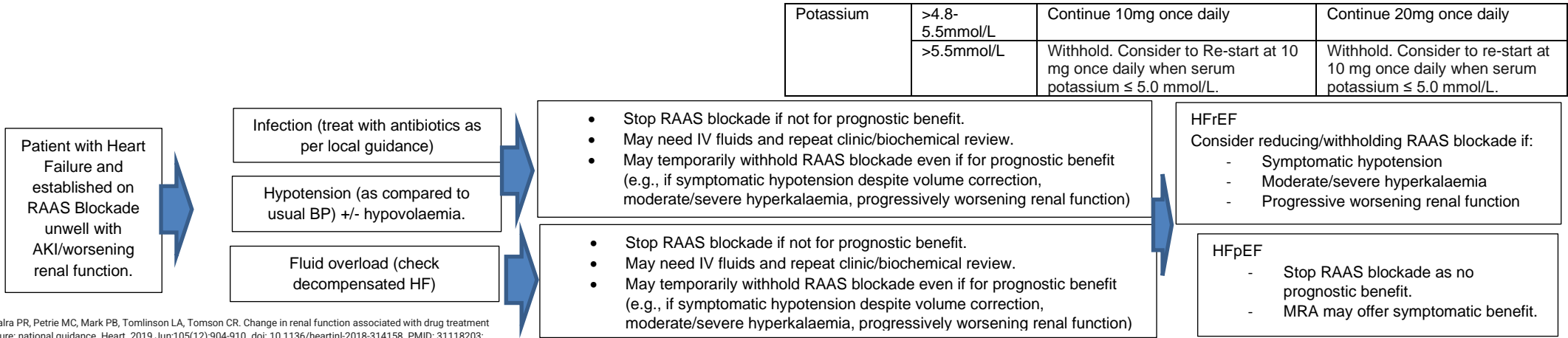
If the patient has proteinuria or heart failure with reduced ejection fraction and would benefit from an ACEi/ARB seek nephrologist advice as introduction of furosemide, potassium binders or bicarbonate to facilitate reintroduction of these agents.

Concomitant use of ACEi/ARB with spironolactone and other potassium sparing diuretics requires close monitoring of potassium. The Think Kidneys campaign has a useful guidance which can be found [2020-statement-on-Changes-in-Kidney-Function-FINAL.pdf \(thinkkidneys.nhs.uk\)](#)

Finerenone

Serum potassium and eGFR must be remeasured 1-2 weeks after initiation or re-start of Finerenone treatment or after an increase in dose (note SPC recommends 4 weeks). Then to check at 4 weeks, if normal to then extend monitoring to 3 months and thereafter the serum potassium is monitored exactly as would be undertaken based on the individual's long-term health conditions or acute health conditions that may arise (a minimum of every 12 months) ([see shared care guidelines](#))

		Current Finerenone dose	
		10mg	20mg
Current Serum	≤4.8mmol/L	Increase to 20mg once daily	Continue 20mg once daily



Clark AL, Kalra PR, Petrie MC, Mark PB, Tomlinson LA, Tomson CR. Change in renal function associated with drug treatment in heart failure: national guidance. Heart. 2019 Jun;105(12):904-910. doi: 10.1136/heartjnl-2018-314158. PMID: 31118203;

7. Minuteful Kidney Patient Searches for SystmOne and EMIS

7.1. Leeds Patient Searches

GP practices locate the Minuteful Kidney searches for S1 and EMIS

Disclaimer

This clinical system tool has been developed to support the launch of the associated initiative. It is the practice's responsibility to ensure the appropriate SNOMED codes recorded are applied to patient records and that the tools within this document are tested and displaying/retrieving information for the correct cohort of patients. Clinical system tools are only as good as the quality of the coded data that is recorded, and it remains the practice's responsibility to ensure that the tools are working as expected and are retrieving the correct patients. Patients who are not correctly coded will NOT be achieved. It is therefore important to ensure that SNOMED codes are recorded appropriately, this also supports you in meeting the accountability principle of your data protection obligations. In the case of searches, protocols and views, practices should review which SNOMED codes the tools are based on and use their clinical judgment to amend according to practice policy, if necessary. Further clarification, and assistance, is available by contacting the DQ team (wycib-leeds.dataqualityteam@nhs.net).

Leeds Summary of the service

Following the scheme introduction letter and go-live of the West Yorkshire ICB programme for Minuteful Kidney programme on the 6th March 2024 the Data Quality team have ensured you have access to the required searches to support. Details of how you access the searches for your clinical systems can be found below.

Leeds TPP SystmOne Searches

The SystmOne searches are available as follows:

S1 TPP > Leeds ICB > Healthy IO HTAAF > Minuteful Kidney

The screenshot shows the Leeds ICB SystmOne interface. On the left is a navigation tree with the following items: 2023 24 | Strep A, 2024 25 | CaRe4Me, 2024 25 | NDPP, 2024 25 | T2 Day, Blood Pressure Monitoring at Home, Cancer Screening Programme Data Quality, Data Quality Toolkit, EARLY Detection, Harm minimisation over 60s, Healthy IO HTAAF (expanded), Minuteful Kidney (10) (expanded), Sub reports (55), and Heart Failure Pilot. The 'Minuteful Kidney' search is selected and expanded to show a list of priority groups:

- 1 - LTC groups >3 conditions (highest priority group)
- 2 - Priority 1 BP >180/120 (excluding higher priority groups)
- 2 - Priority 2a BP >160/100 (excluding higher priority groups)
- 2 - Priority 2b BP >140/90 South Asian/Black ethnicity and CVD factors (excluding higher priority groups)
- 2 - Priority 2c No BP reading in the last 18m (excluding higher priority groups)
- 2 - Priority 3a BP >140/90 South Asian/Black ethnicity OR CVD risk factors (excluding higher priority groups)
- 2 - Priority 3b BP >140/90 or >150/90 if 80+ (excluding higher priority groups)
- 3 - UACR>30 or eGFR <45 (excluding higher priority groups)
- 4 - Not in any priority group

Leeds Emis Web Searches

The Emis searches are available as follows:

Emis Web > Leeds ICB Central 27491 > Leeds Data Quality > Healthy.io Minuteful WY hypertension for ACR HT > Minuteful Kidney

Leeds ICB central 27491

- Leeds Data Quality
 - Healthy.io Minuteful WY hypertension for ACR
 - Minuteful Kidney**
 - zDenominator

Name	Po
Cohort1 LTCs	
Patients without ACR in last 12m Cohort1 LTCs	
Cohort2 BP 1 (BP GT 180/120)	
Patients without ACR in last 12m Cohort2 BP GT 180/120	
Cohort2 BP 2a (BP GT 160/100)	
Patients without ACR in last 12m Cohort2 BP GT 160/100	
Cohort2 BP 2b (BP GT 140/90 + BAME + CVD risk factors)	
Patients without ACR in last 12m Cohort2 BP GT 140/90 + BAME + ...	
Cohort2 BP 2c (No BP reading in last 18m)	
Patients without ACR in last 12m Cohort2 No BP in last 18m	
Cohort2 BP 3a (BP GT 140/90 + BAME or CVD risk factors)	
Patients without ACR in last 12m Cohort2 BP GT 140/90 + BAME or ...	
Cohort2 BP 3b (BP GT 140/90 or GT 150/90 if over 80)	
Patients without ACR in last 12m Cohort2 BP GT 140/90 or 150/90	
Cohort3 Poor renal function	
Patients without ACR in last 12m Cohort3 Poor renal function	
Healthy.io All eligible Hypertension Patients without ACR in last 12m	
Practice - Hypertension (incl. diabetes) with ACR in last 12m	

Leeds Contacts

Please contact wycb-leeds.dataqualityteam@nhs.net to discuss any issues with the clinical searches to support the scheme.

For advice and support with the scheme please contact

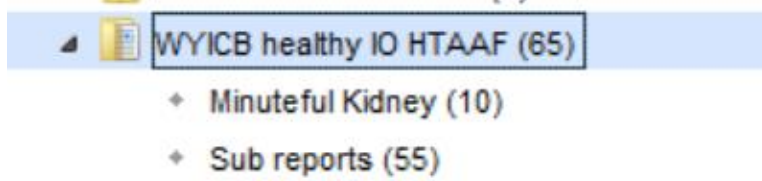
Minuteful Kidney & Hypertension Project Team at wycb-wak.ltccpc.wy@nhs.net.

7.2. Calderdale, Kirklees and Wakefield Patient Searches

CKW searches are located in clinical systems in following locations:

TPP SystemOne

Reporting – Data Quality



Emis Web

