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PCCS CKD QI Programme

Chronic Kidney Disease Treatment and Management

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Dr Jim Moore Disclosures



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- Amgen
- AstraZeneca
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- Cuviva
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- VIFOR

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Chronic Kidney Disease Treatment and Management



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- Primary care management of chronic kidney disease
- Guidance and data for use of dapagliflozin, empagliflozin and finerenone for chronic kidney disease and diabetic kidney disease
- Patient engagement
- Virtual chronic kidney disease clinics and specialist advice

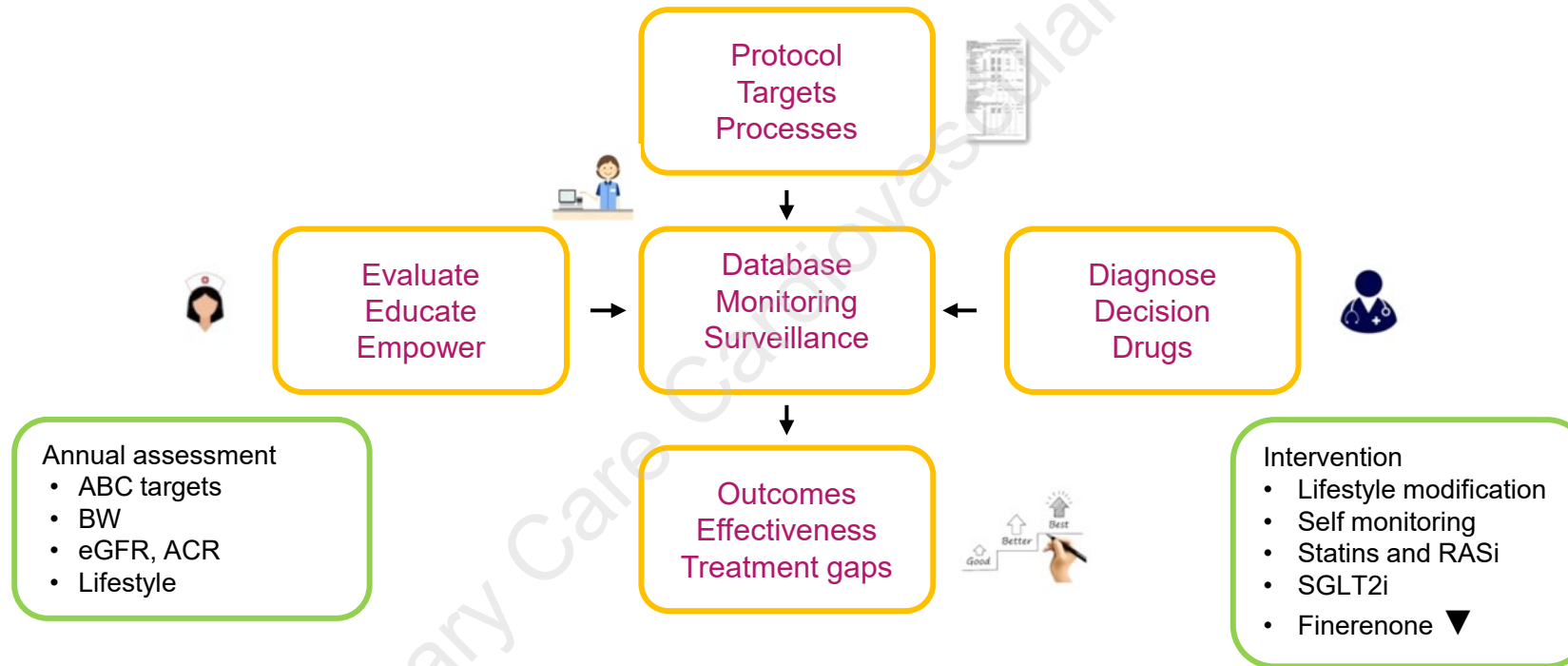


How would the management of CKD look like in an ideal world from a Primary Care perspective?



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ABC, atrial fibrillation, blood pressure and cholesterol; ACR, albumin:creatinine ratio; BW, body weight; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; RASi, renin-angiotensin system inhibitors; SGLT2i, sodium-glucose co-transporter-2 inhibitors.

Speaker's experience.



Identification and management in primary care



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Identification

- CKD coding
- Case finding for unidentified CKD using eGFR and ACR
- Inequalities
- Frailty and EOL

Management

- Education – cardiovascular health / lifestyle / modifiable risk-factors

Medical optimisation

- Blood pressure optimisation
- Lipid lowering therapy
- Maximum renin angiotensinogen aldosterone inhibition
- Sodium glucose transporter-2 inhibitor (SGLT2i) and or finerenone



CVD risk management in patients with CKD should be initiated early



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- Code patient's CKD status on medical record
- Full cardiovascular risk assessment including relevant history: smoking status, physical examination (including weight), labs and QRISK etc
- Discuss/offer lifestyle measures for control of modifiable risk factors e.g. referral to local weight loss pathway, smoking cessation etc
- Uptitrate to maximum tolerated dose of ACEi or ARB. Consider addition of dapagliflozin, empagliflozin or finerenone in line with national guidance and local pathways
- Avoid NSAIDs and other nephrotoxic medications
- Aim for BP <140/90 unless ACR>70 mg/mmol, whereby aim for BP<130/80
- Consider antiplatelet and lipid lowering therapy as indicated by cardiovascular risk
- Consider referral to secondary care as per NICE guidance and local pathways
- Optimise secondary prevention e.g. HF



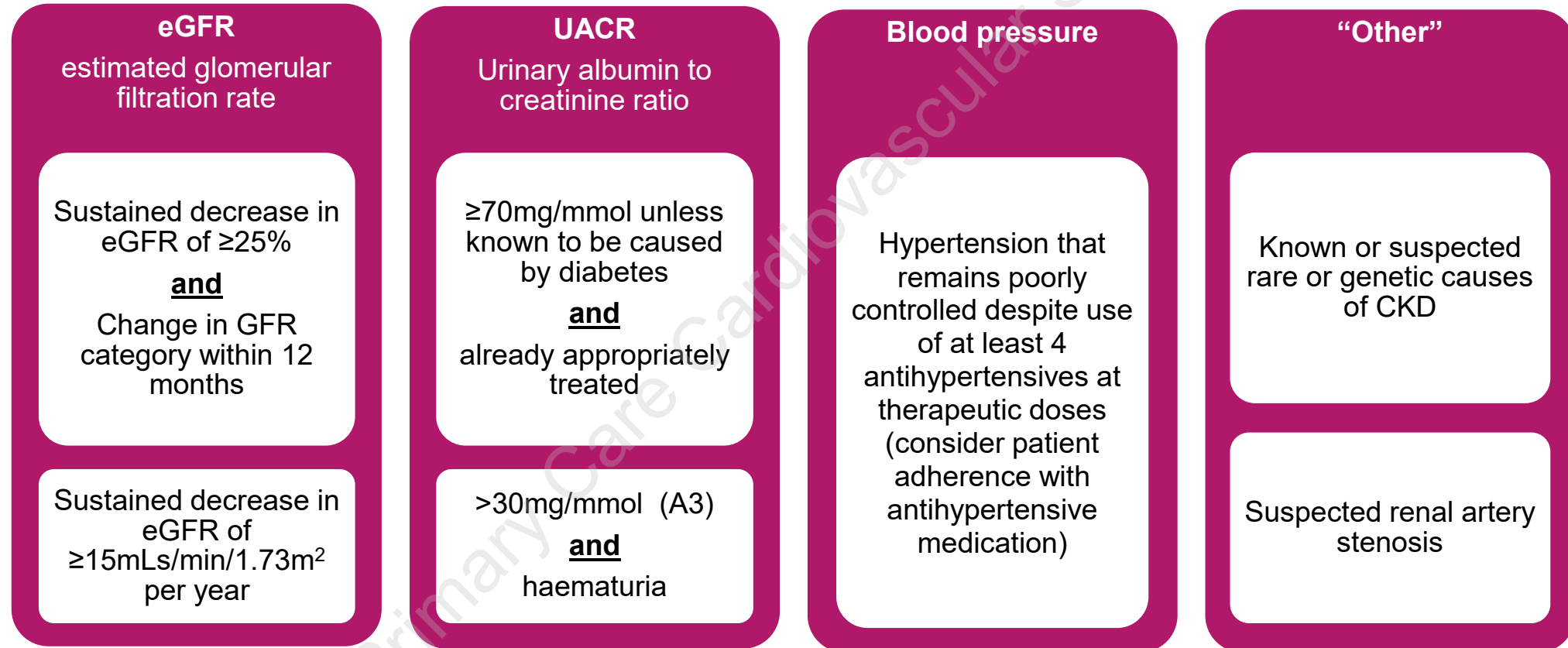
Referral of adults with CKD for specialist assessment



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Refer patients (taking into account their wishes and comorbidities) if they have any of the following:





Primary care management: CKD/BP/Diabetes



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BP

CKD and ACR
< 70mg/mmol

Aim for BP
below 140/90 mmHg

CKD and ACR
≥ 70 mg/mmol

Aim for BP
below 130/80 mmHg

CKD, hypertension and ACR ≤
30 mg/mmol

Follow NICE guidelines for
recommendations on
treating hypertension

CKD, hypertension and ACR >
30 mg/mmol

offer ARB or ACE inhibitor*

Diabetes

For CKD and diabetes*, offer an
ARB or an ACE inhibitor† if ACR ≥
3mg/mmol

No diabetes

Refer for nephrology assessment
and offer ARB or ACE inhibitor† if
ACR ≥ 70 mg/mmol.

If ACR > 30 but < 70 mg/mmol
agree frequency of CKD
monitoring. Consider discussing
with nephrologist if eGFR ↓ or ACR ↑

- Check serum potassium and eGFR prior to starting RAS antagonists (repeat checks 1 and 2 weeks after initiation and after dose increase)
- If eGFR decreases by ≥ 25% or serum creatinine increases by ≥ 30% investigate other causes of renal deterioration. If no other cause found stop RAS antagonist or reduce dose to a previously tolerated lower dose and add an alternative antihypertensive medication if needed

*Type 1 or type 2. †titrated to highest licensed dose that the person can tolerate. ACR, albumin:creatinine ratio; ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; BP, blood pressure; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; RAS, renin-angiotensin system.
NICE Guideline (NG203). <https://www.nice.org.uk/guidance/ng203>. Accessed January 2023.



Statin therapy for CKD¹



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Offer atorvastatin 20 mg for primary or secondary prevention of CVD in patients with CKD

- Increase dose if lipid target for primary or secondary prevention of CVD is not achieved and eGFR $\geq 30\text{ml/min/1.73m}^2$
 - Primary prevention target: $> 40\%$ reduction in non-HDL cholesterol
 - Secondary prevention target: LDL cholesterol $\leq 2.0\text{ mmol/L}$ or non-HDL cholesterol $\leq 2.6\text{ mmol/L}$
- If eGFR $< 30\text{ml/min/1.73m}^2$ agree use of higher doses with renal specialist

Follow up:

- Measure liver transaminase and full lipid profile at 2 to 3 months after starting or changing lipid-lowering treatment
- If lipid targets are not met:
 - Discuss adherence and dose timing
 - Encourage patients to continue improvements to diet and lifestyle, and to make further changes if appropriate
 - Consider increasing the statin intensity/dose if the person is not currently taking a high-intensity statin at the maximum tolerated dose

Do not offer any of the following to patients with CKD for prevention of CVD:

- Plant stanols and sterols
- Fibrates
- Nicotinic acid
- Bile acid sequestrant
- Omega-3 fatty acid compounds (icosapent ethyl is an exception if used as per NICE TA805)²

! In patients intolerant
to 3 different statins
seek specialist
advice on treatment
options

People on RRT are out of the scope of NICE guidance NG238 on use of statin therapy in patients with CKD.
CKD, chronic kidney disease; CVD, cardiovascular disease; eGFR, estimated glomerular filtration rate; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NICE, National Institute for Health and Care Excellence; RRT, renal replacement therapy.

1. NICE Guideline (NG238). <https://www.nice.org.uk/guidance/ng238>. Accessed June 2024; 2. NICE Guideline (TA805). <https://www.nice.org.uk/guidance/ta805>. Accessed June 2024.



Anaemia in CKD



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Consider investigating anaemia in patients with CKD if:

- Hb levels ≤ 110 g/litre
- Symptomatic of anaemia (tiredness/SOB/lethargy/palpitations)

Following anaemia assessment:

- If no alternative cause found, refer to specialist secondary care services for further advice, as it is likely that anaemia is attributed to CKD
- In this case, the patient may be considered for ESA treatment by secondary care



NICE recommendations for adults with type 2 diabetes and CKD¹



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Offer an ARB or an ACE inhibitor* if ACR is ≥ 3 mg/mmol

In addition, offer an SGLT2 inhibitor for:

- ACR > 30 mg/mmol and
- They meet the criteria in the MA (including relevant eGFR thresholds)

In addition, consider an SGLT2 inhibitor if:

- ACR 3 – 30 mg/mmol and
- They meet the criteria in the MA (including relevant eGFR thresholds)

Dapagliflozin[†] and empagliflozin[‡] are recommended as add-on to optimised standard care to treat CKD.^{2,3}

Finerenone is recommended as add-on to optimised standard care^{4§}

*titrated to the highest licensed dose that the person can tolerate. [†]only if people have an eGFR 25–75 ml/min/1.73m² at treatment initiation and have type 2 diabetes or a urinary ACR of ≥ 22.6 mg/mmol. [‡]in people with an eGFR 20–44 ml/min/1.73m² or 45–90ml/min/1.73m² and either a urinary ACR of ≥ 22.6 mg/mmol or type 2 diabetes. [§]in patients with stage 3 and 4 CKD with albuminuria associated with type 2 diabetes and who have an eGFR ≥ 25 ml/min/1.73m². ACR, albumin:creatinine ratio; ACE, angiotension-converting enzyme; ARB, angiotensin receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; MA, marketing authorisation.

1. NICE Guideline (NG28). <https://www.nice.org.uk/guidance/ng28>. Accessed April 2024; 2. NICE Guideline (TA775). <https://www.nice.org.uk/guidance/ta775>. Accessed April 2024; 3. NICE Guideline (TA942). <https://www.nice.org.uk/guidance/ta942>. Accessed April 2024; 4. NICE Guideline (TA877). <https://www.nice.org.uk/guidance/ta877>. Accessed April 2024.



NICE TA for dapagliflozin for treating CKD



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Recommendations

Dapagliflozin is recommended as an option for treating CKD in adults, only if:

- It is an add-on to optimised standard care including highest tolerated licensed doses of ACE inhibitors or ARBs, unless these are contraindicated and
- People have an eGFR of 25 ml/min/1.73m² to 75 ml/min/1.73m² at the start of treatment and:
 - Have type 2 diabetes or
 - Have a uACR \geq 22.6 mg/mmol

This recommendation is not intended to affect treatment with dapagliflozin that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.



NICE TA for empagliflozin for treating CKD



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Recommendations

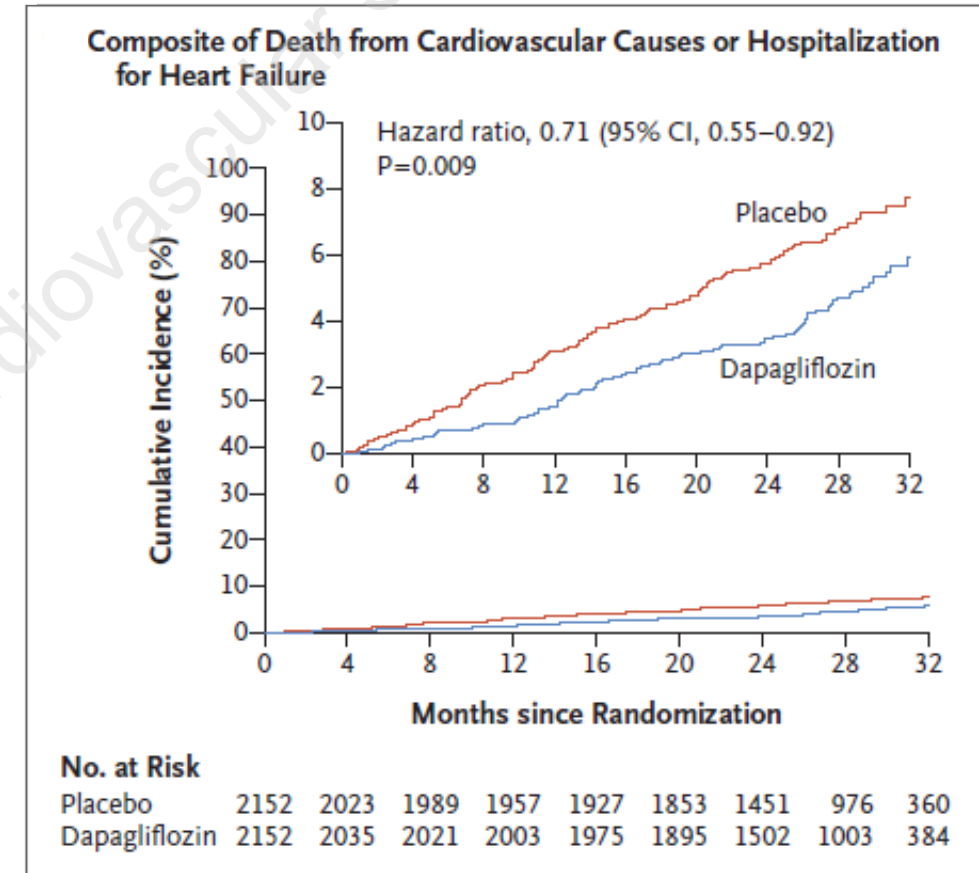
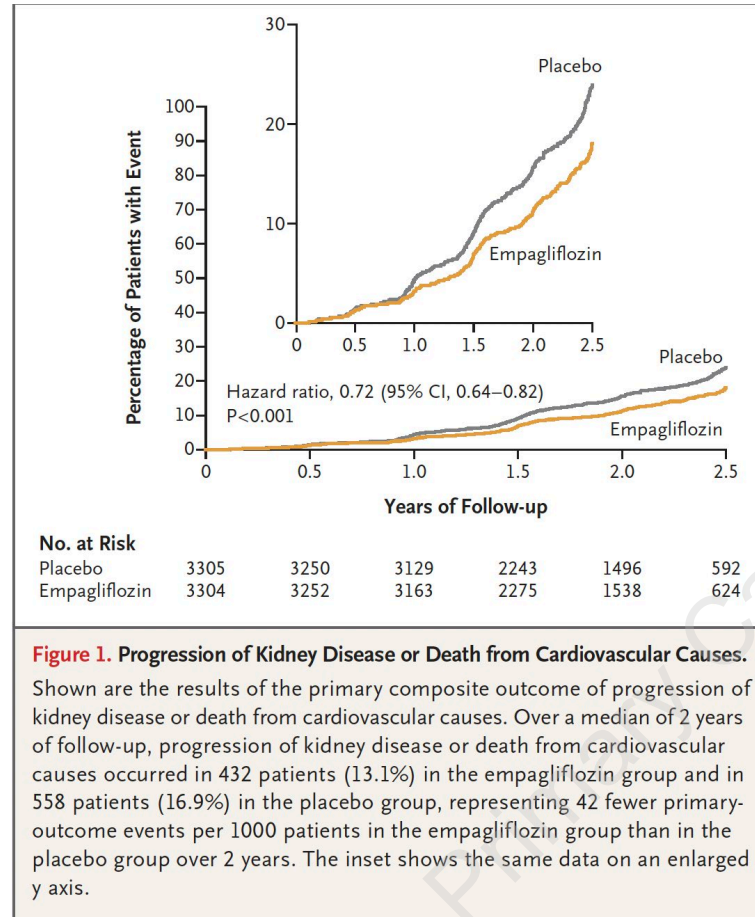
Empagliflozin is recommended as an option for treating CKD in adults, only if:

- It is an add-on to optimised standard care including highest tolerated licensed doses of ACE inhibitors or ARBs, unless these are contraindicated and
- People have an eGFR of:
 - 20 ml/min/1.73m² to less than 45 ml/min/1.73m² or
 - 45 ml/min/1.73m² to 90 ml/min/1.73m² and either:
 - A uACR \geq 22.6 mg/mmol or
 - Type 2 diabetes

- If people with the condition and their clinicians consider empagliflozin to be 1 of a range of suitable treatments (including dapagliflozin), after discussing the advantages and disadvantages of all the options, use the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.
- This recommendation is not intended to affect treatment with empagliflozin that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.



Evidence for SGLT2i on CVD and renal outcomes in patients with and without diabetic kidney disease^{1,2}



CI, confidence interval; SGT2i, sodium glucose transporter-2 inhibitor.

1. The EMPA-KIDNEY Collaborative Group. N Engl J Med 2023;388:117–127; 2. Heerspink HJL, et al. N Engl J Med 2020;383:1436–1446.



Use of SGLT2 inhibitors



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	Empagliflozin ¹	Dapagliflozin ²
Dose	10 mg OD with or without food	
Can be initiated down to an eGFR of:	20 mL/min/1.73m ²	15 mL/min/1.73m ²
Age	No dose adjustment recommended on basis of age	
Cautions	In patients for whom a drop in BP could pose a risk	
Not recommended / avoid in:	<ul style="list-style-type: none">BreastfeedingType 1 diabetesPregnancy	<ul style="list-style-type: none">BreastfeedingType 1 diabetesPregnancy
Contraindicated if:	Hypersensitivity to active ingredient or excipients	
Liver	Severe hepatic impairment <ul style="list-style-type: none">Not recommended	Severe hepatic impairment: <ul style="list-style-type: none">Start with 5 mg, increase to 10 mg if well tolerated

5

Figure 2: SGLT2i Initiation in CKD			
		uACR (mg/mmol)	
		<20	≥20
eGFR (mL/min/1.73 m ²)	≥60	Suggested in T2DM	Recommended
	45–60	Suggested in T2DM	Recommended
	20–45	Recommended	Recommended
	<20	Suggested ^[D]	Suggested ^[D]
	Dialysis	Not recommended ^[D]	

Please note, NICE recommends SGLT2 inhibitors if uACR is ≥ 22.6 mg/mmol.^{3,4}

BP, blood pressure; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; NICE, National Institute for Health and Care Excellence; OD, once daily; SGLT2i, sodium-glucose co-transporter-2 inhibitors; T2DM, type 2 diabetes mellitus; uACR, urinary albumin:creatinine ratio.

1. Empagliflozin SmPC; 2. Dapagliflozin SmPC; 3. NICE Guideline (TA775). <https://www.nice.org.uk/guidance/ta775>. Accessed April 2024; 4. NICE Guideline (TA942). <https://www.nice.org.uk/guidance/ta942>. Accessed April 2024; 5. Medscape. CKD Interventions in Primary Care. March 2024. Available at: https://www.kidneyresearchuk.org/wp-content/uploads/2023/03/CKD-Hack-v6_3_Interventions.pdf?_gl=1*d63x9u*_up*MQ..*_ga*NzA1MTM1MDY5LjE3MTc0MTYzMjE.*_ga_737HY1XF35*MTcxNzQxNjMxOS4xLjAuMTcxNzQxNjMxOS4wLjAuMA..

Accessed May 2024.



Considerations when prescribing SGLT2 inhibitors



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Risk of urinary tract infection/genital infection^{1,2}



Risk of DKA

- Counsel patients on signs and symptoms of DKA⁴
- Patients at increased risk of DKA include those:⁵
 - With a previous episode of DKA
 - Unwell with intercurrent illness
 - Following a very low carbohydrate or ketogenic diet



Counsel patients
on sick day
guidance.³



Fournier's gangrene⁴

- Rare but serious and potentially life-threatening
- Advise patients to seek urgent medical attention if they experience pain, tenderness, erythema or swelling in the genital or perineal area, with fever or malaise

DKA, diabetic ketoacidosis; SGLT2, sodium-glucose co-transporter-2. 1. Empagliflozin SmPC; 2. Dapagliflozin SmPC; 3. Imperial College Healthcare NHS Trust. Getting the most from your Sodium Glucose Co-transporter-2 Inhibitors (SGLT2i). Available at: https://www.imperial.nhs.uk/-/media/website/patient-information-leaflets/pharmacy/getting-the-most-from-your-sodium-glucose-cotransporter2-inhibitors.pdf?rev=c7c50dafb8bc4760aacc51a2d6c139fe&sc_lang=en#:~:text=It%20is%20best%20practice%20to,fasting%20e.g.%20before%20an%20operation. Accessed May 2024; 4. BNF. Empagliflozin. Available at: <https://bnf.nice.org.uk/drugs/empagliflozin/>. Accessed April 2024; 5. NICE. Type 2 diabetes in adults: management [NG28]. Available at: <https://www.nice.org.uk/guidance/ng28>. Accessed April 2024.



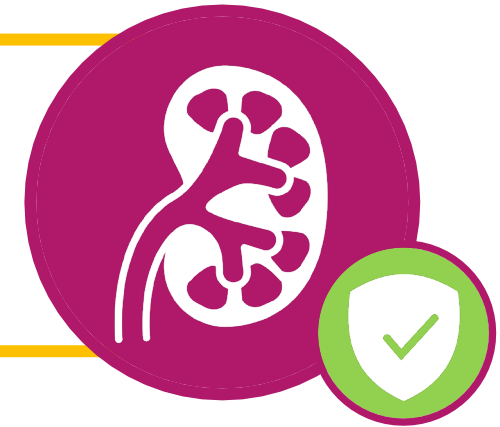
Finerenone licensed Indication



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Finerenone is indicated for the treatment of chronic kidney disease (Stage 3 & 4 with albuminuria) associated with type-2 diabetes in adults¹





NICE TA for finerenone for treating CKD in type 2 diabetes



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Recommendations

Finerenone is recommended as an option for treating stage 3 and 4 CKD (with albuminuria) associated with type 2 diabetes in adults. It is recommended only if:

- It is an add-on to optimised standard care. This should include, unless they are unsuitable, the highest tolerated licensed doses of:
 - ACE inhibitors or ARBs, and
 - SGLT2 inhibitors, and
- People have an eGFR of 25 ml/min/1.73m² or more

This recommendation is not intended to affect treatment with finerenone that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.



FIDELIO-DKD: primary composite endpoints^{1,2}



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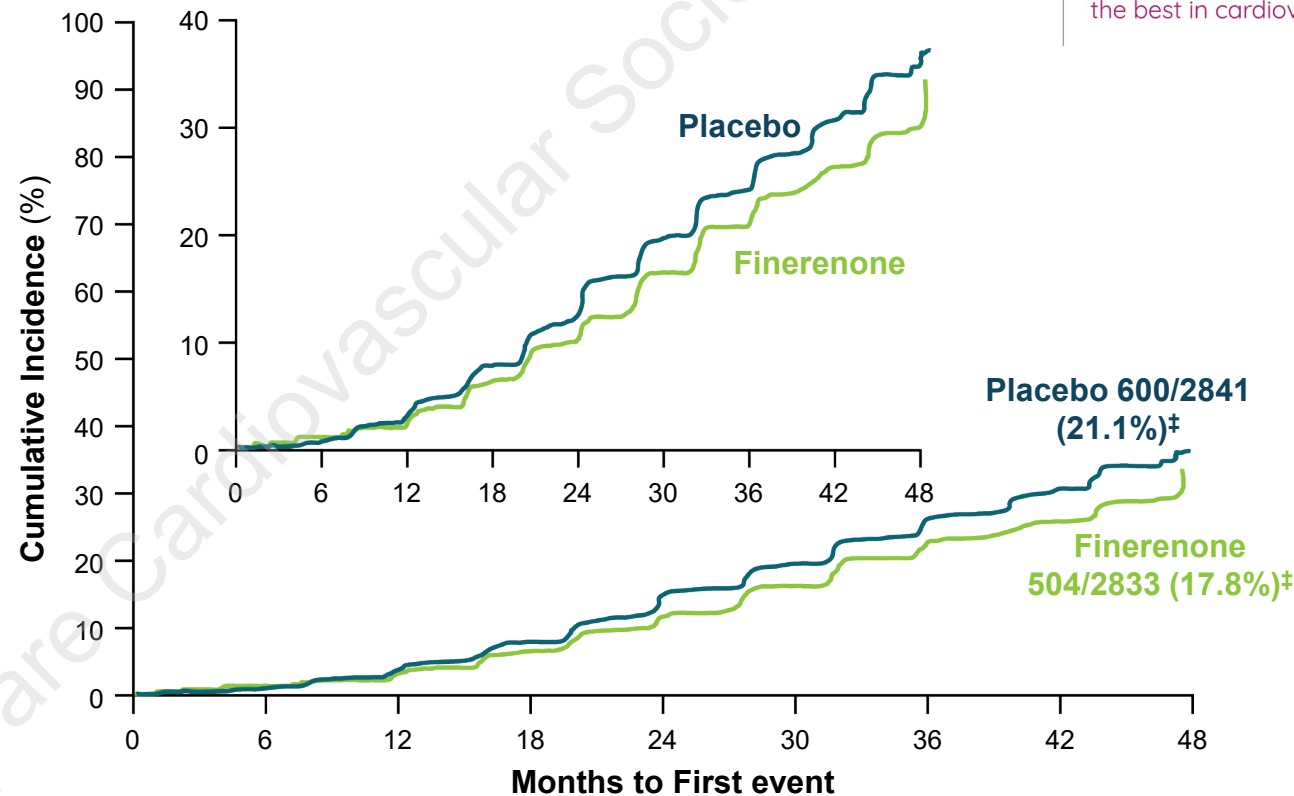
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Primary renal endpoint:

Kidney failure*, sustained $\geq 40\%$ decrease in eGFR from baseline over a period of at least 4 weeks, or death from renal causes[†]

HR 0.82
(95% CI, 0.73–0.93)
p=0.001

After 3 years:
ARR 3.4% (95% CI, 0.62–6.2)
NNT 29 (95% CI, 16–166)



No. at Risk

	0	6	12	18	24	30	36	42	48
Placebo	2841	2724	2586	2379	1758	1248	792	453	82
Finerenone	2833	2705	2607	2397	1808	1274	787	441	83

*ESKD or an eGFR <15 ml/min/1.73 m²; [†]Events were classified as renal death if: (1) the patient died; (2) RRT had not been initiated despite being clinically indicated; & (3) there was no other likely cause of death; [‡]Median follow-up 2.6 years. ARR, absolute risk reduction; CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; HF, heart failure; HR, hazard ratio; MI, myocardial infarction; NNT, number needed to treat; RRT, renal replacement therapy. 1. Adapted from Bakris GL et al., N Engl J Med 2020; 383:2219-2229; 2. Adapted from Bakris GL et al., N Engl J Med 2020; 383:2219-2229 Supplementary appendix.



FIDELIO-DKD: secondary composite endpoints^{1,2}



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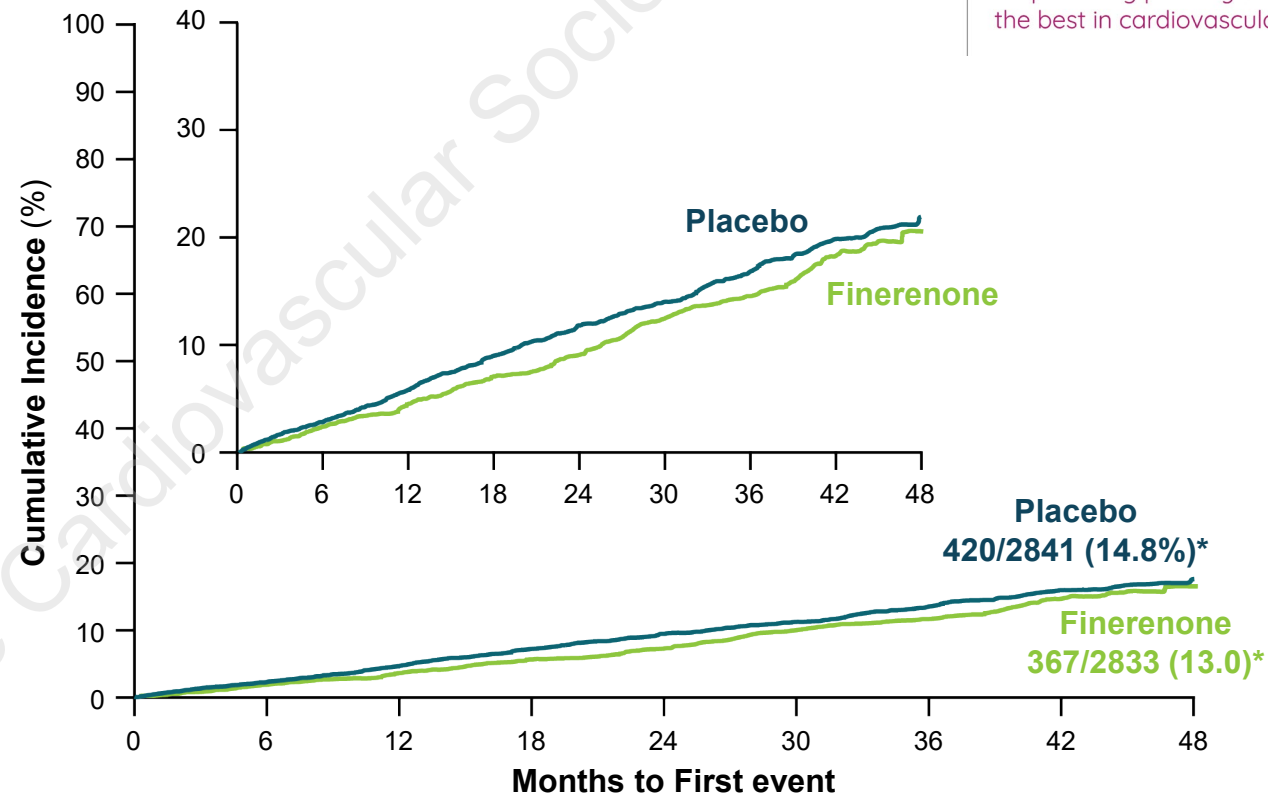
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Secondary cardiovascular endpoint:

Time to death from CV causes, non-fatal MI,
non-fatal stroke or hospitalisation for HF

HR 0.86
(95% CI, 0.75–0.99)
p=0.03

After 3 years:
ARR 2.4% (95% CI, 0.3–4.5)
NNT 42 (95% CI, 22–397)



No. at Risk

Placebo	2841	2753	2653	2549	1969	1475	951	536	115
Finerenone	2833	2760	2688	2582	2017	1488	984	537	111

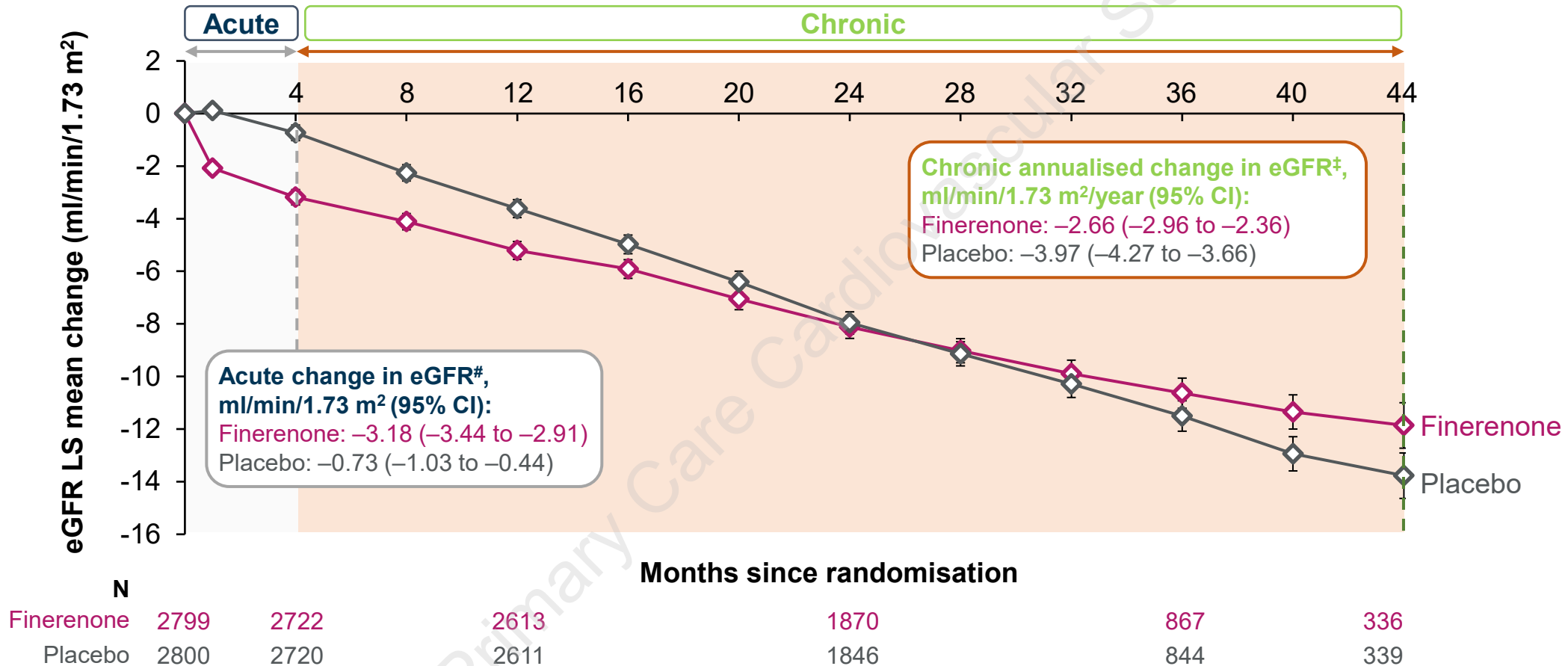
*Median follow-up 2.6 years. ARR, absolute risk reduction; CI, confidence interval; CV, cardiovascular; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; HF, heart failure; HR, hazard ratio; MI, myocardial infarction; NNT, number needed to treat.

1. Adapted from Bakris GL et al., N Engl J Med 2020; 383:2219-2229; 2. Adapted from Bakris GL et al., N Engl J Med 2020; 383:2219-2229 Supplementary appendix.



Change from baseline level in eGFR*

Mean eGFR at baseline (ml/min/1.73 m²): Finerenone = 44.4 ± 12.5, Placebo = 44.3 ± 12.6



*Mixed model analysis of eGFR over time. Full analysis set; [#]LS mean change in eGFR slope from baseline to month 4; [‡]LS mean change in eGFR slope from month 4 to the permanent discontinuation or end-of-study visit.

CI, confidence interval; eGFR, estimated glomerular filtration rate. Adapted from Bakris GL et al., N Engl J Med 2020; 383:2219-2229 Supplementary appendix.



Initiating treatment



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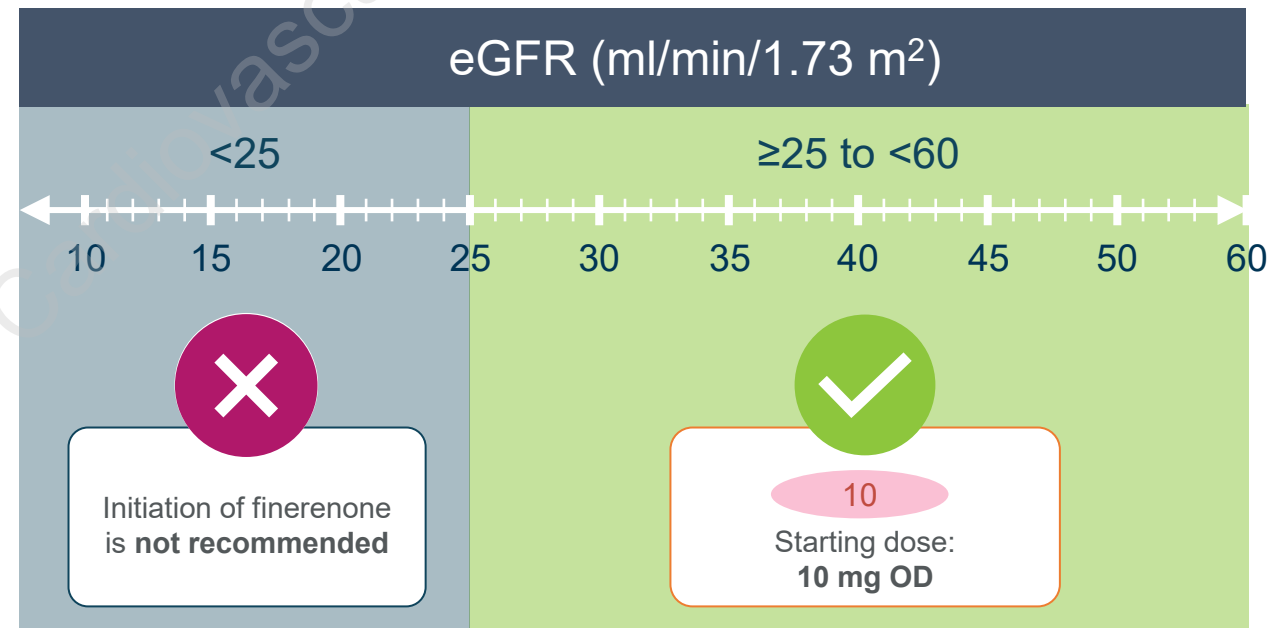
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Measurement of Serum Potassium Level & eGFR

Serum potassium levels & eGFR have to be measured to determine whether patients can initiate finerenone

The recommended starting dose of finerenone is 10mg OD

Serum potassium levels	
mmol/l	Initiation of finerenone
≤4.8	✓ Can be started
>4.8–5.0	✓ May be considered*
>5.0	✗ Not recommended



*Initiation of finerenone may be considered with additional serum potassium monitoring within the first 4 weeks based on patient characteristics & serum potassium levels.
Summary of Product Characteristics Finerenone 10 & 20mg tablets March 2022.



Continuation of treatment & dose adjustment¹



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- Serum potassium & eGFR have to be re-checked 4 weeks after:
 - Initiation of treatment
 - Restarting treatment (with 10 mg OD)
 - An increase in dose to 20 mg OD
- Thereafter, serum potassium should be re-measured periodically & as needed based on patient characteristics & serum potassium levels
- Due to limited data finerenone should be discontinued if eGFR <15ml/min/1.73m²

The recommended target dose & maximum recommended dose of finerenone is 20 mg OD

Serum potassium (K ⁺)	Current finerenone dose	Action to take
≤4.8 mmol/L	10 mg OD	Increase dose to 20 mg OD*
	20 mg OD	
>4.8–5.5 mmol/L	10 mg OD	Continue on current dose
	20 mg OD	
>5.5 mmol/L	10 mg OD	Withhold treatment Consider restarting at 10 mg OD when serum potassium ≤5.0 mmol/L
	20 mg OD	Withhold treatment Restart at 10 mg OD when serum potassium ≤5.0 mmol/L

*Maintain 10 mg OD if eGFR has decreased by >30% compared with the previous measurement.

1. Finerenone SmPC.



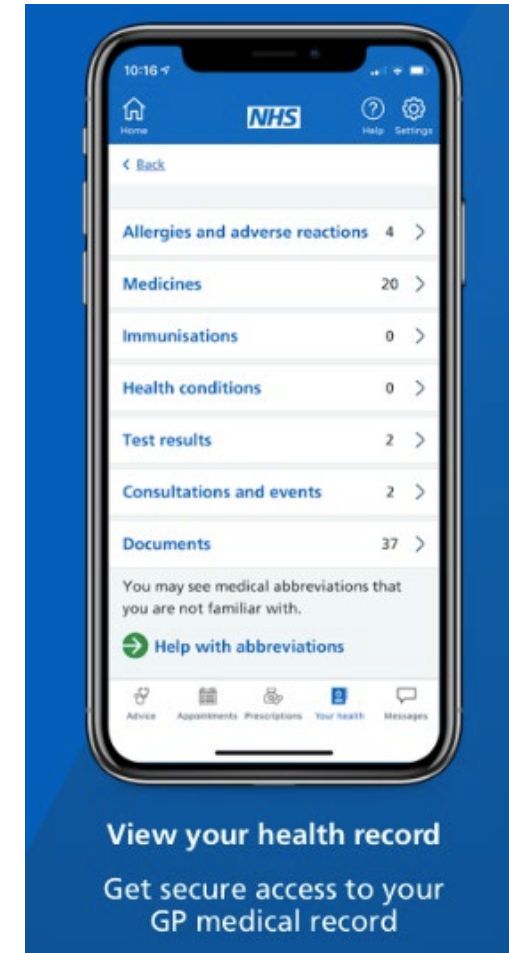
Engage with stakeholders: Patients¹



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- Provide the right information to the right patients
 - Send with clinic appointment letter
 - Posters/leaflets in clinics
 - Patient knows best/patient view apps
- Empower patients to ask about treatments that might benefit them
- Educate patients about drug-specific factors
 - Sick day rules², DKA risk
- Shared decision-making with patients is key



Adapted from NHS APP: GP Health Record.

DKA, diabetic ketoacidosis. 1. Speaker's experience; 2. NHS London Clinical Networks. Sick day rules: how to manage Type 2 diabetes if you become unwell with coronavirus and what to do with your medication. 2020; Available from: <https://www.england.nhs.uk/london/wp-content/uploads/sites/8/2020/04/3.-Covid-19-Type-2-Sick-Day-Rules-Crib-Sheet-06042020.pdf>. Accessed March 2022; 3. NHS APP. GP Health Record. Available from: <https://www.nhs.uk/nhs-app/nhs-app-help-and-support/health-records-in-the-nhs-app/gp-health-record/>. Accessed March 2022.



Major challenges when managing patients with heart failure & CKD



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- Sequencing of drugs for the patient with HFrEF
- Response to deterioration in renal function when initiating/optimising drugs
- Decompensated (congested) patient with heart failure and AKI
- Hyperkalaemia
- Seek specialist advice where appropriate



Virtual CKD – East London Experience



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- A virtual CKD clinic, in which nephrologists can see the entire GP patient record (with consent) and enter management suggestions.
- A suite of IT tools for practices to improve identification and management of CKD. A novel 'trigger tool' alerts GPs to cases of possible CKD progression.

Major impacts include:

- A reduction in wait time for a specialist opinion from 64 to 5-10 days
- Only 20% of patients referred to the virtual clinic require a hospital appointment
- Significant improvements to GP identification and management of CKD.
- Nurse led self-management education for patients
- 96% of GPs were satisfied with the clinical advice they received.

Final report
December 2018

Innovating for Improvement

Development and evaluation of a renal learning health system across inner east London.

Clinical Effectiveness Group (CEG), Queen Mary University of London



CKD, chronic kidney disease; GP, general practitioner; IT, information technology.

Clinical Effectiveness Group, Queen Mary University of London. The Health Foundation. Innovating for Improvement: Development and evaluation of a renal learning health system across inner east London. 2018. Available from: <https://www.health.org.uk/sites/default/files/2019-05/IFI%20R6%20Queen%20Mary%20final%20report.pdf>. Accessed March 2022.



Specialist Advice



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- Specialist Advice is an umbrella term for a range of specialist-led models, that can be provided in Secondary, Community or Primary Care settings, which allow the sharing of relevant clinical information so that:
- **Prior to or instead of referral** the referring clinician is able to seek advice from a specialist through asynchronous methods e.g. e-RS A&G, or synchronous methods g. telephone, virtual specialist reviews
- **Where a referral has been made** the specialist is able to review the clinical information, returning the referral with guidance where appropriate or where it is necessary direct the onward referral to the most appropriate clinician, clinic and/or diagnostic pathway first time e.g. e-RS Referral Assessment Services (RAS), triage services



Summary



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- CVD risk management should be initiated early in patients with CKD¹
- CKD management should include optimisation of BP, anaemia and comorbidities (e.g., diabetes)²
- Management options for type 2 diabetes and CKD include:
 - ACE inhibitors and ARB, dapagliflozin, empagliflozin and finerenone³⁻⁶
- Virtual CKD clinics may help to improve identification and management of CKD⁷
- Management of patients with CKD is ultimately the decision of the individual clinician

ACE, angiotension-converting enzyme; ARB, angiotensin receptor blocker; BP, blood pressure; CKD, chronic kidney disease; CVD, cardiovascular disease.

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