HEREFORDSHIRE & WORCESTERSHIRE MEDICINES & PRESCRIBING COMMITTEE

TREATMENT GUIDELINES FOR HEART FAILURE WITH REDUCED EJECTION FRACTION - HFrEF

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and/or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

These guidelines are designed to be used to guide in the management of patients with heart failure with reduced ejection fraction (HFrEF) in both primary and secondary care.

This guideline is for use by the following staff groups:

All staff responsible for the management of patients with heart failure

Lead Clinician(s)

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Dr D Wilson	Consultant Cardiologist

Approved by Specialist Medicine Divisional Governance Meeting on:	8th February 2022
Review Date:	8th February 2025

This is the most current document and is to be used until a revised version is available

Key amendments to this guideline

Date	Amendment	By:
April 2009	Guideline approved by Worcestershire Area Prescribing Committee	
June 2011	Addition of BNP added to guideline	D Abban
June 2011	Amendment approved at Cardiology Meeting June 2011	D Abban
Feb 2013	Update, NICE guidance 2010/ESC guidelines 2012	K Smith/Dr Abban
06/05/2014	Telephone numbers on appendix 1 updated for south office	Jamie-Rae Tanner
06/08/2015	Document extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
August 2016	Document extended for 12 months as per TMC paper approved on 22nd July 2016	TMC
August 2017	Further Extension as per TMC paper approved on 22nd July 2015	TMC
July 2016	Major re write/update and addition of ARNIs, Guidelines specified to relate only to patients with at least moderate LVSD	Dr Taylor/K Ridout
December 2017	Sentence added in at the request of the Coroner	
August 2020	Document extended for 6 months during COVID period	QGC/Gold Meeting
September 2021	Inclusion of SGLT2i and potassium binders, updated drug sequencing and recognition of updated NICE guidance 2018/ESC guidelines 2021,	L Moore / R Taylor
February 2022	Document approved for 3 years	Dr R Taylor/ Specialist medicine meeting

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Medical Therapy Guidelines to treat Heart Failure with reduced ejection fraction (HFrEF) for use in Primary Care

Introduction

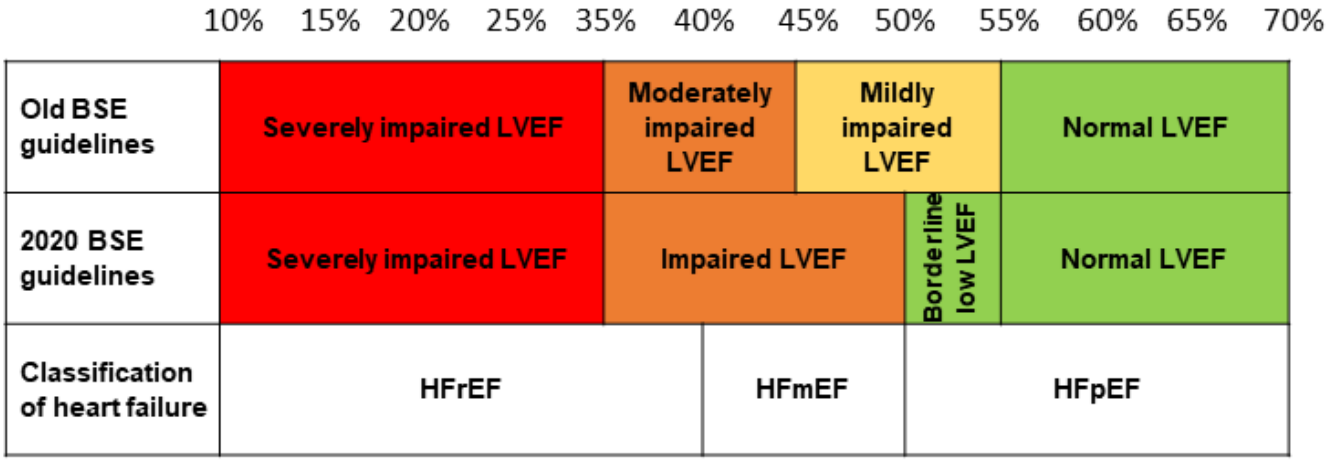
These guidelines are primarily designed to be used as a protocol for the nurses in the heart failure service to use in the management of patients with heart failure with reduced ejection fraction (HFrEF) primary care. However as they also represent best practice for the management of heart failure (and are in accordance with the latest NICE and ESC guidance) they will provide a useful guide to all individuals in primary and secondary care who are responsible for the care of an individual with heart failure.

Competencies Required

Experienced nurses working within the Heart Failure Service who have either undergone or are working towards specific training in the management of patients with chronic heart failure, with a recognized non-medical independent prescribing qualification.

This document only covers patients with a diagnosis of heart failure syndrome and an LVEF <40%.

In 2020 the British Society of Echocardiography (BSE) changed the recommendations for reporting of LV function, and this is followed in Worcestershire. The image below shows this change in classification of LV function, and how different LVEFs relate to the classification of disease in patients with heart failure syndrome.



The definition of HFrEF is the presence of heart failure syndrome and an LVEF <40%. Nonetheless, the various therapies covered in this guidance necessitate different LVEFs, and these should still be followed for the allocation of specific treatments.

Although not covered by this document, patients with heart failure and more preserved LVEF are prone to fluid overload and require diuretic therapy and the principles herein remain a useful guide for the management of diuretic therapy. Similarly, ACEI and beta blockers may have a role in preventing adverse remodeling post myocardial infarction and again the principles herein will be a useful practical guide.

LIST OF ABBREVIATIONS

ACEI	angiotensin converting enzyme inhibitor
ARB	angiotensin receptor blockers
ARNI	Angiotensin receptor neprilysin inhibitor
BB	Beta-Blockers
If	Funny channel Inhibitor
HFrEF	Heart failure with reduced ejection fraction
MRA	mineralocorticoid receptor antagonist
NSAIDs	Non-steroidal anti-inflammatory drugs
NHYA	New York heart association
RAASI	Renin angiotensin aldosterone system inhibitors
SGLT2i	Sodium-Glucose Co-transporter 2 inhibitors

The Sequencing of therapies for patients with HFrEF

There are four main classes of drugs (ACEI/ARNI, BB, MRA, SGLT2i) which both reduce the risk of HF hospitalisation and death and thus form the cornerstone of treatment for patients with HFrEF. Previous iterations of this document included a flowchart dictating which order these prognostic therapies should be used, but this has been removed from the current version. This is a widely debated and challenged topic in heart failure at present. The sequencing of drugs should be patient specific and the following factors should be considered:

- The most serious and unexpected complication of HFrEF is sudden cardiac death, and the most effective and rapidly-acting means of preventing this is with BBs. Accordingly, BBs are a good first choice therapy in many patients. However, BBs should not be commenced until a patient is euvolaemic, otherwise they are likely to exacerbate heart failure.

- Low starting doses of each of these classes of drug have meaningful benefits, and achievement of low doses of all 4 classes should take priority over up-titration.

- Many patients will already be receiving one or more of the drug classes, either for conditions that preceded the development of heart failure or following prescription in primary care.

- Minimising steps in the addition and up-titration of heart failure therapies has benefits for both the patient and a 'time-stretched' health care service. When appropriate making 2 changes at once will facilitate this

- A broad approach of starting an ARNI as first line in preference to ACEI was not recommended by NICE in the 2018 guidance and has a Class IIb recommendation in the ESC 2021 guidelines. The ESC includes two studies which have examined the use of ARNI in hospitalized patients, some of whom had not been previously treated with ACE-I and states initiation in this setting appears safe and reduces subsequent CV death or HF hospitalisations by 42% compared to enalapril

- In patients where no reversibility in LV dysfunction is anticipated consider starting an ARNI without prior use of an ACEI/ARB which would save a significant amount of resource by cutting down the number of patient contacts. These patients would need to be selected by a cardiology consultant.

- When switching a patient with HFrEF and LVEF <35% from an ACEi to an ARNI repeat echocardiographic assessment is not required when improvement in LV function is not anticipated.

- The latest version of treatment the NICE 2018 (Appendix 1) and ESC 2021 (Appendix 2) recommended flow charts are included within the appendix as they are particularly useful in identifying patients who benefit from device therapy.

The Use Of Loop Diuretic Therapy In Heart Failure

Introduction

Diuretics should be used routinely for the relief of symptoms and fluid retention in patients with heart failure, and titrated (up and down) according to need following the initiation of subsequent heart failure therapies.

(NICE Guidelines 2018)

Thiazide diuretics or metolazone can be considered in addition to a loop when the clinical response to a loop in isolation is insufficient.

Contraindications

- Known allergic reaction (drug specific)

Cautions (seek specialist advice)

- K+ ≤3.5 mmol/L – may be made worse by diuretic.
- Significant renal dysfunction Cr ≥ 221 umol/L or eGFR <30. It is important to appreciate that a further deterioration in renal function is likely and patient will need close biochemical monitoring. Patient may not respond to usual doses of loop diuretic (and do not use thiazide diuretic).
- Symptomatic or severe asymptomatic hypotension (SBP <90 mmHg) – may be made worse by diuretic-induced hypovolaemia.
- Drug interactions to look out for:
  - NSAID – may attenuate effects of diuretic.
  - Combination with ACE inhibitors or ARB or renin inhibitors – risk of hypotension (usually not a problem).
  - Combination with other diuretics (e.g. loop plus thiazide) – risk of hypovolaemia, hypotension, hypokalaemia, and renal impairment.
- Diabetes: Loop diuretics may exacerbate diabetes (but hyperglycaemia less likely than with thiazides)
- Hepatic impairment - hypokalemia induced by loop diuretics can precipitate hepatic encephalopathy)

Common Side Effects (see current BNF for full list)

- Electrolyte imbalance
- Metabolic alkalosis
- Postural hypotension
- Pancreatitis
- Acute urinary retention
- Blood disorders (including bone-marrow depression, thrombocytopenia and leucopenia)
- Tinnitus and deafness (usually with high parenteral doses)
- Hyperuricaemia
- Worsening renal impairment, especially in the elderly
- Temporary increase in serum cholesterol and triglyceride levels

Section A - Patient Selection Criteria

- All patients with clinical evidence of congestion (irrespective of LVEF)
- Patient has none of the documented contraindications

Section B - Patient Advice

- Explain benefits of therapy. Treatment is given to relieve breathlessness and oedema
- Loop diuretics are usually best taken before breakfast and/or between 12:00 and 13:00 hrs on an empty stomach (to ensure a consistent and prompt effect).
- Timing of taking the loop diuretic is not fixed, however it is better to avoid taking after 6pm as this can lead to nocturia.
- Advise patients how to recognize overtreatment (dizziness and/or light-headedness) or under treatment (increased breathlessness, frothy sputum, increasing peripheral oedema) and to report these promptly to specialist nurse or GP
- Advise them to report sudden sustained weight increase or decrease (more than 1kg over 3 days) to specialist nurse or GP
- Gout can occur
- Advise patient to self-weigh daily (after waking and voiding but before breakfast and dressing), educate patient to alter their own diuretic dose according to need and agree an action plan.
- Advise patient to avoid NSAIDS not prescribed by a physician, as these will counteract treatment and risk further deterioration in renal function.
- Ideally avoid soluble analgesia, antacids and any other medications with high sodium content

Section C – Initiation, Titration and Managing Adverse Effects During Titration

In the majority of cases furosemide is the first line diuretic of choice

Name	**Initiation Dose**	**Usual maximum dose***	**Titrate up in steps of****
Loop diuretics			
Furosemide	40mg	120mg b.d.	40mg
Bumetanide	1mg	5mg o.d. (can be split)	1mg
Thiazides			
Bendroflumethiazide	2.5mg	10mg o.d.	2.5mg
Thiazide-like diuretics			
Metolazone	2.5mg	5mg b.d.	2.5mg

*When higher doses are considered this should be discussed with the patient's cardiologist.
**Larger titrations may be required if heart failure continues to worsen. The patient should be monitored closely and discussed with cardiologist.

- Check renal function and electrolytes before use
- Start with a low dose (see initiation dose above)
- Adjust dose according to symptoms and signs of congestion, blood pressure, and renal function.
- In congested patients aim an effective dose for a patient to achieving positive diuresis with a simultaneous reduction of body weight by 0.75-1.0 kg per day.
- Identify the patients ideal 'dry weight' (i.e. to keep the patient free of symptoms and signs off congestion – euvolaemia)
- For maintenance use minimum dose necessary to maintain the patient's 'dry weight'
- Dose may need to be increased or decreased according to the patient's volume status (Remember that excessive diuresis is more dangerous than oedema itself)
- Recheck blood chemistry 1-2 weeks after initiation and after any increase in dose (urea/BUN, creatinine, K+)

If insufficient response/diuretic resistance

- Check compliance and re-assess daily fluid intake
- Increase dose of diuretic
- Consider switching from furosemide to bumetanide which has greater bioavailability
- Add an MRA/increase dose of MRA
- Add a thiazide or metolazone (these work synergistically)
  (NB only consider a thiazide if eGFR >30ML/min/1.73m2)
  Metolazone is no longer licensed for use in the UK but is available as a 'special order' product from community pharmacies. Please be aware that it may take longer to source than previously

  If still congested, consider semi-elective admission for short term I.V. diuretic administration.

PROBLEM SOLVING

- **Asymptomatic low blood pressure:**
  Dose may be reduced, but only if no symptoms or signs of congestion.

- **Symptomatic hypotension (Causing dizziness/light headedness)**
  Reduce dose if no symptoms or signs of congestion.
  Reconsider need for nitrates, calcium channel blockers and other vasodilators.
  If these measures do not solve problem, seek specialist advice.

- **Hypokalaemia/hypomagnaesaemia:**
  Increase ACEI/ARB dose.
  Add MRA, potassium supplements (potassium chloride); magnesium supplements (magnesium aspartate).

- **Hyponatraemia**
  Management depends on assessment of patient's volume status.
  - If volume depleted:
    reduce dose/stop loop diuretics if possible.
    stop any thiazide diuretics
  - If volume overloaded:
    fluid restriction.
    increase dose of loop diuretic.
    discuss with cardiologist appropriateness /need for inpatient treatment, I.V. inotropic support, ultrafiltration

- **Hyperuricaemia/gout:**
  consider allopurinol prophylaxis.
  for symptomatic gout use colchicine for pain relief.
  avoid NSAIDs.

- **Hypovolaemia/dehydration:**
  if volume status suggests hypovolaemia then reduce the diuretic dosage.

- **Renal impairment (rising creatinine/urea):**
  check for hypovolaemia/dehydration.
  exclude use of other nephrotoxic agents, e.g. NSAIDs, trimethoprim.
  withhold MRA.
  if using concomitant loop and thiazide diuretic stop thiazide diuretic.
  consider reducing/temporarily withholding ACEI/ARB.

The Use of ACEI or ARB in Heart Failure

Introduction

Given in adequate doses, ACE inhibition significantly reduces mortality, hospital admissions for heart failure and risk of further acute myocardial infarction. All patients with HFrEF should be considered for an ACEI as 1st line therapy (along with beta-blockers). Clinical judgement should be used to decide which to start first (NICE 2018).

ARBs should be used in treating heart failure only if the patient is intolerant of an ACEI due to persistent intolerable cough or angioedema. ARBs may not be any safer than ACEI in patients with renovascular disease (NICE 2018).

ACEI / ARB therapy should be initiated at the appropriate dose and titrated upwards at short intervals (no less than 2 weekly) until optimum tolerated dose or target dose is achieved (ESC 2021).

Contraindications

Absolute contraindications include:

- Hypersensitivity to ACEI (including angioedema)
- Bilateral renal artery stenosis

(If patient has Angioedema with an ACEI it is reasonable to challenge with an ARB)

Cautions

- Patients with peripheral vascular disease or generalized atherosclerosis are more likely to have clinically silent renovascular disease (in patients with severe bilateral renal artery stenosis ACEI and ARB reduce or abolish glomerular filtration, and are likely to cause severe and progressive failure)
- Use with care in patients with severe or symptomatic aortic stenosis and hypertrophic cardiomyopathy (risk of hypotension) – Do not use if critical aortic stenosis.
- Use cautiously if SBP <90mmHg. However low BP (particularly when asymptomatic) is **not** a contraindication to treatment
- Avoid non-steroidal anti-inflammatory drugs, as these increase the risk of renal damage
- The concurrent use of potassium-sparing diuretics, potassium-containing salt substitutes and trimethoprim increases the risk of hyperkalaemia

Side Effects

The most common side effects include: cough, hypotension, renal insufficiency, hyperkalaemia, angioedema, rash, gastro intestinal disturbance, taste disturbance, hypoglycemia, jaundice or marked elevations of hepatic enzyme (discontinue if jaundice or marked elevations of hepatic enzymes occur during treatment).

Section A - Patient Selection Criteria (ACEI)

- All patients with HFrEF (moderate or severe) on echocardiogram – there is also evidence of benefit in patients with asymptomatic LVSD.
- Creatinine <221 umol/l (in patients with worse baseline function, specialist advice should be sought before commencing)
- Patient has no contraindications to initiation of ACEI therapy (see contraindications)
- Do not start ACEI in patients with possible haemodynamically significant valve disease until assessed by a specialist.

Note: ACEI should be considered in patients with a previous myocardial infarction even if they do not have the LV systolic dysfunction, in order to prevent or delay the onset of HF. However, this is beyond the scope of this guidance document.

Section B – Patient Advice

- Explain benefits of therapy. Treatment is given to
  - Improve symptoms
  - Prevent worsening of HF leading to hospital admission
  - Increase survival
- Symptomatic benefit (when seen) is within a few weeks to a few months after starting treatment.
- Advise patients to report principal adverse effects (i.e dizziness/symptomatic hypotension, cough)
- Warn patients that postural dizziness is common particularly early in therapy. Encourage patient not to discontinue medication without seeking medical advice.
- Explain the need for close blood test monitoring
- Advise patients to avoid purchased over the counter NSAIDS and salt substitutes high in K+

Section C - Managing Adverse Effects During Titration

Ramipril and perindopril are currently the ACE Inhibitor of choice and candesartan is the ARB of choice for the Herefordshire & Worcestershire Medicines and Prescribing Committee.(HW MPC)

Name	**Initiation Dose**	**Target Dose**
ACE inhibitors		
Ramipril	1.25mg bd	5mg bd
Lisinopril*	2.5mg/5mg	35mg od
Perindopril Erbumine	2mg od	4mg od (may be on higher doses if also being used for hypertension or post MI)
ARBs		
Candesartan	4mg od	32mg od
Valsartan	40mg bd	160mg bd
Losartan	25mg od	150mg od (Will need to be prescribed as 100mg & 50mg)

*Beware in patients with renal impairment as relies totally on glomerular filtration for excretion

- Check baseline renal function and electrolytes
- Start with suggested initiation dose (see below for exceptions)
- Double the dose at not less than 2-week intervals in the community (More rapid dose up-titration may be carried out in the hospital in-patient setting)
- Aim for target dose (see above) or, failing that, the highest tolerated dose
- Remember: some ACEI is better than no ACEI
- Re-check renal biochemistry 7-10 after initiation and 7-10 days after each dose titration.
- Once at tolerated maximum dose monitor blood chemistry 6 monthly thereafter
- See Problem Solving for when to stop up-titration, reduce dose or stop treatment
- In the following conditions a lower start dose, and slower up titrations may be warranted at the discretion of the prescribing clinician:
  - Severe heart failure (NYHA class IV)
  - Receiving high dose diuretic therapy (e.g. > 80mg furosemide daily or equivalent)
  - Hypovolaemia.
  - Hyponatraemia (<130mmol/l)
  - Pre –existing symptomatic hypotension (<90mmHg)

- Unstable heart failure
- High-dose vasodilator therapy
- Valve disease as primary cause
- Unknown cause of heart failure

PROBLEM SOLVING

Asymptomatic low blood pressure

- Does not usually require any change in therapy

Symptomatic hypotension

- Dizziness/light headedness is common and often improves with time: offer reassurance
- Reconsider need for nitrates, calcium-channel blockers, other vasodilators and reduce dose/stop if possible
- If no signs or symptoms of congestion, consider reducing diuretic dose
- If these measures do not solve problem then consider splitting dose or reducing dose.
- Patients on ramipril may benefit from a single dose taken just before bed.

Cough

- Cough is common in patients with HF, many of whom have smoking-related lung disease
- Cough is also a symptom of pulmonary oedema, which should be excluded when a new worsening cough develops
- ACEI-induced cough does not always require treatment discontinuation
- When a troublesome cough does develop (e.g. one stopping the patient from sleeping) and can be proved to be due to ACEI (i.e. recurs after ACEI withdrawal and re-challenge), substitution of an ARB is recommended

Worsening renal function and hyperkalaemia

- Some rise in urea, creatinine, and potassium is to be expected after an ACE inhibitor; if an increase is small and asymptomatic, no action is necessary
- Appendix 3 covers the management of worsening renal function and hyperkalaemia in patients on RAASi
- In some circumstances where the use of ACE inhibitors is not feasible due to hyperkalaemia, potassium binders should be considered as an option for treating hyperkalaemia. This will be infrequent and requires approval of the heart failure MDT.

THE USE OF BETA BLOCKERS IN HEART FAILURE

INTRODUCTION

Beta blockers licensed for use in heart failure should be initiated in patients with HFrEF after diuretic and with ACEI therapy (regardless of whether or not symptoms persist).
Offer beta-blockers licensed for heart failure to all patients with heart failure due to left ventricular systolic dysfunction (regardless of whether or not symptoms persist), including patients who:

- Are older
- have peripheral vascular disease
- have erectile dysfunction
- have diabetes mellitus
- have interstitial pulmonary disease and
- have chronic obstructive pulmonary disease without reversibility

(NICE Guidelines 2018)
Switch stable patients who are already taking a beta-blocker for a comorbidity (for example, angina or hypertension), and who develop heart failure due to left ventricular systolic dysfunction, to a beta-blocker licensed for heart failure. (NICE 2018)

CONTRAINDICATIONS

- 2nd or 3rd degree AV block (in absence of a pacemaker)
- Critical limb ischaemia
- Known allergic reaction /adverse event (drug-specific)

Asthma is a relative contra-indication. A cardio-selective beta-blocker can be trialled under close medical supervision by a consultant (after consideration of the risks for and against their use). Clarify the accuracy of the diagnosis of asthma; COPD is not a contra-indication.
In the following situations appropriate specialist advice should be sought before commencing Beta blockade:

- NHYA Class IV Heart failure – Risk of decompensation
- History of Prinzmetal's angina / vasospastic angina.
- Myasthenia gravis
- Portal hypertension (risk of deterioration in liver function)
- History of hypersensitivity – may increase sensitivity to allergens and result in more serious hypersensitivity response also may reduce response to adrenaline

CAUTIONS

- Symptoms of hypoglycaemia and thyrotoxicosis may be masked
- History of chronic obstructive airways disease (introduce cautiously and monitor lung function)
- If persisting signs of congestion: raised jugular venous pressure, ascites, marked peripheral; try to relieve congestion and achieve 'euvolaemia' before starting a beta-blocker.
- Use cautiously if pre-existing first degree AV block/ sinus node disease or on other rate limiting medication such as verapamil*, diltiazem*, digoxin, amiodarone or ivabradine.

**Non-dihydropyridine calcium channel blockers should be discontinued in heart failure caused by reduced ejection fraction due to their negative inotropic effects.*

SIDE-EFFECTS (see current BNF for full list)
Bradycardia, worsening heart failure, hypotension, conduction disorders, bronchospasm, peripheral vasoconstriction (including exacerbation of intermittent claudication and Raynaud's phenomenon), gastrointestinal disturbances, fatigue, sleep disturbances, headache, exacerbation of psoriasis, alopecia, dizziness

SECTION A - PATIENT SELECTION CRITERIA

- Confirmed left ventricular systolic dysfunction on echocardiogram (moderate or severe) regardless of aetiology.
- Patient has none of the above documented contraindications

Patients with severe (NYHA class IV) symptoms benefit from beta-blockers but treatment can precipitate a decompensation and should be initiated by a specialist with due consideration of need for inpatient initiation.
If Heart rate less than 60bpm prior to treatment then specialist should decide on appropriateness of beta-blockade.

SECTION B - PATIENT ADVICE

- Explain the known benefits of the therapy:
- Treatment is given to improve symptoms,
- To prevent worsening of HF leading to hospital admission
- To increase survival.
- Symptomatic improvement may develop slowly after starting treatment, sometimes taking 3–6 months or longer.
- Temporary symptomatic deterioration may occur during initiation or up-titration phase
- Advise patient to weigh themselves daily (after waking and voiding but before breakfast and dressing) and agree an action plan if they do have sudden weight gain
- Take with food (carvedilol)
- Advise not to drive if they feel faint or dizzy
- Warn patients who wear contact lenses of possible dry eyes
- Encourage patient never to stop beta blockers before seeking advice from GP or Heart Failure Nurse
- Advise patients with COPD to report any increased wheeze.

SECTION C – INITIATION, TITRATION AND MANAGING ADVERSE EFFECTS DURING TITRATION

DO NOT START A BETA- BLOCKER WHILST THE PATIENT IS DECOMPENSATED. WAIT UNTIL THE PATIENT HAS BEEN ADEQATELY OFF-LOADED.

Bisoprolol is currently the beta-blocker of choice for the HW MPC / County Cardiac Network.

- Start with the recommended initiation dose
- The higher initiation doses can be used in stable patients (Minimal symptoms, HR >60bpm, SBP >100mmHg, not congested) with none of the cautions above.
- Increase the dose at not less than 2-week intervals by the recommended incremental dose (slower up-titration may be needed in some patients when cautions apply).
- Aim for target dose, or failing that, the highest tolerated dose (remember: some beta-blocker is better than no beta-blocker).
- Monitor heart rate, blood pressure, and clinical status (symptoms, signs of congestion, body weight).
- When to stop up-titration, reduce dose, stop treatment–see PROBLEM SOLVING.

Name	Initiation Dose	Increment dose	Target Dose
Bisoprolol	1.25-2.5mg od	2.5mg	10mg od
Carvedilol	3.125 -6.25 mg bd	6.25mg	25mg bd*
Nebivolol**	1.25mg-2.5mg od	2.5mg	10mg od

*Target dose of carvedilol is 50mg bd if body weight > 85kg
** Nebivolol is considerably more expensive and should only be used on the directive of consultant cardiologist.

PROBLEM SOLVING

Asymptomatic low blood pressure

- Does not usually require any change in therapy

Worsening symptoms: (increased dyspnoea, fatigue, oedema, weight gain).

- If worsening congestion increase dose of diuretic or halve dose of beta-blocker (if increasing diuretic dose does not work).
- If marked fatigue consider reducing beta-blocker (rarely necessary and if required usually only temporarily)
- Review patient in one week if no improvement discuss with GP/Cardiologist
- If serious deterioration in condition halve or stop dose and seek advice from appropriate physician

Bradycardia: (< 50 bpm)

- If bradycardic with worsening symptoms, halve dose or, if there is severe deterioration in symptoms stop beta blocker
- Review need /appropriateness of any other rate-limiting drugs.
- Consider checking digoxin level if appropriate
- If heart rate < 45 bpm record ECG to document rhythm (?AV block)
- A 12 lead ECG should be recorded in the event of **any** symptomatic bradycardia.
- Asymptomatic sinus bradycardia or 1st degree AV block does not require reduction or cessation of beta blockade

Symptomatic hypotension: (< 90 mmHg associated with dizziness, fainting, confusion)

- Check blood chemistry to exclude other causes for symptoms
- Consider stopping any vasodilatory drugs (e.g.nitrates, calcium channel blockers)
- Consider temporary reduction in ACEI
- If no signs or symptoms of congestion, consider reducing diuretic dose
- If unresolved reduce dose or stop beta blocker after seeking advice

THE USE OF MINERALOCORTOCOID ANTAGONISTS (MRA) IN HEART FAILURE

INTRODUCTION

Patients with heart failure due to left ventricular systolic dysfunction, who remain symptomatic (NHYA Class II-IV) despite treatment with an ACEI (or ARB) and a beta blocker, should be prescribed a MRA.

The RALES mortality trial showed that low dose spironolactone together with ACEI and diuretic therapy markedly and progressively improved survival of patients in advanced heart failure, irrespective of aetiology (RALES 1999). More recently, the EMPHASIS-HF and EPHESUS trials have confirmed this is the case with eplerenone.

CONTRAINDICATIONS

- Known allergic reaction during previous exposure (drug specific)
- Addison's disease

CAUTIONS

- Hyperkalaemia and significant renal dysfunction are relative contraindications:
- Seek specialist advice if K+ > 5.0 mmol/L or Creatinine 221 umol/L or eGFR <30 mL/min/1.73m$_2$
- Avoid NSAIDs, as these increase the risk of renal damage
- The concurrent use of potassium-sparing diuretics, potassium-containing salt substitutes, renin inhibitors and trimethoprim increases the risk of hyperkalemia
- Significant acute porphyria
- Strong Cytochrome P450 3A4 inhibitors (e.g. ketoconazole, clarithromycin, ritonavir, nelfinavir will increase the risk of hyperkalaemia / renal dysfunction (eplerenone only)

SIDE EFFECTS (see current BNF for full list)

Side effects include: Gastro-intestinal disturbances, gynaecomastia (less common with eplerenone), lethargy, headache, confusion, rashes, hyperkalaemia (discontinue), hyponatraemia (especially when used with a loop diuretic), atrial fibrillation (eplerenone), arterial thrombosis (eplerenone) hepato-toxicity, blood disorders.

SECTION A - PATIENT SELECTION CRITERIA

- Patients with heart failure due to left ventricular systolic dysfunction (any aetiology), who remain symptomatic (NHYA Class II-IV) despite treatment with an ACE inhibitor (or ARB) and a beta blocker
- Patient has none of the above contraindications

SECTION B - PATIENT ADVICE

- Explain the known benefits: to improve symptoms, to prevent worsening of HF leading to hospital admission, and to increase survival.
- Symptomatic improvement occurs within a few weeks to a few months of starting treatment.
- Avoid NSAIDs not prescribed by a physician (i.e. purchased over-the-counter) and salt substitutes high in K+.
- Warn of the possible side effects – particularly gynaecomastia (with spironolactone) and signs of sodium and water depletion
- If diarrhoea/vomiting occurs or there is infection with fever leading to intense sweating patients should be aware the risk of dehydration and electrolyte imbalance and contact their nurse / physician.

SECTION C - INITIATION, TITRATION AND MANAGING ADVERSE EFFECTS DURING TITRATION

Spironolactone is currently the MRA of choice for the HWMPC / County Cardiac Network
Eplerenone should be used in patients with previous intolerance of spironolactone because of gynaecomastia, and continued in patients already taking it

Name	**Initiation Dose**	**Target Dose**
Spironolactone	25mg od	25-50mg
Eplerenone	25mg od	50mg od

- Check renal function and electrolytes
- Start with initiation dose.
- Consider dose up-titration after 4–8 weeks.
- If asymptomatic after starting spironolactone 25mg then further increments not required.
- Check blood chemistry at 7-10 days after starting/increasing dose and at 1,2,3, 6, 9, and 12 months; 6-monthly thereafter.

PROBLEM SOLVING

Renal Dysfunction and hyperkalaemia:

- Appendix 3 covers the management of worsening renal function and hyperkalaemia in patients on RAASi
- When wishing to half the reduce the dose of spirololactone or eplerenone 12.5 mg OD or 25mg alternate days are reasonable options.
- In some circumstances where the use of MRAs is not feasible due to hyperkalaemia, potassium binders should be considered as an option for treating hyperkalaemia. This will be infrequent and requires approval of the heart failure MDT.

Gynaecomastia (10% in the RALES study)

Male patients may need to be discontinue spironolactone if they experience breast discomfort or significant breast tissue increase. These patients should be switched to eplerenone.

THE USE OF ANGIOTENSIN RECEPTOR NEPRILYSIN INHIBITORS (ARNI) IN HEART FAILURE

INTRODUCTION

Sacubitril/valsartan is the first in class for this agent and consists of an angiotensin receptor blocker (ARB) combined with a neprilysin inhibitor as a single molecule.

These drugs MUST NOT be co-prescribed with an ACEI or ARB.

Sacubitril valsartan should always be prescribed using the generic name to avoid concomitant prescribing of ACEI or additional ARB therapy.

When compared to an ACE inhibitor, this combination drug was shown to reduce the risk of CV death or first hospitalisation for heart failure (ARR 4.7%) and reduce the risk of all-cause mortality (ARR 2.8%) in selected populations.

CONTRAINDICATIONS

- Systolic Blood pressure < 100mmHg
- Hypersensitivity to the active substances or to any of the excipients listed.
- Concomitant use with ACE inhibitors.
- Sacubitril valsartan must not be administered until 36 hours after discontinuing ACEI therapy.
- Known history of angioedema related to previous ACEI or ARB therapy.
- Hereditary or idiopathic angioedema.
- Concomitant use with aliskiren (a direct renin inhibitor) in patients with either diabetes mellitus or renal impairment (eGFR <60 ml/min/1.73 m2).
- Severe hepatic impairment, biliary cirrhosis and cholestasis.
- Second and third trimester of pregnancy.
- Treatment should not be initiated if the serum potassium level is >5.4 mmol/l.

CAUTIONS

- Avoid abrupt withdrawal (especially if concurrent ischaemic heart disease)
- Hypotension (symptomatic hypotension more likely if age >65yrs, renal disease, SBP<112)
- This drug can cause deteriorating renal function. Down-titration should be considered in patients who develop a clinically significant decrease in renal function.
- Use may be associated with an increased risk of hyperkalaemia. Monitoring of serum potassium is recommended and if clinically significant hyperkalaemia adjustment of concomitant medicinal products, or temporary down–titration or discontinuation is recommended. If serum potassium level is >5.4 mmol/l discontinuation should be considered.
- Angioedema: 0.4% risk but likely higher in black patients. If angioedema occurs discontinue drug and do not re-administer.
- Renal artery stenosis: close monitoring of renal function recommended
- BNP is not a suitable biomarker of heart failure in patients treated with this drug as its breakdown is reduced.
- Patients with moderate hepatic impairment (Child Hugh B or ALT/AST >2x ULN) are likely to have greater exposure and safety is not established.

SIDE EFFECTS

The most clinically significant side effects are symptomatic hypotension, deteriorating renal function, cough, angioedema. See the BNF for a full list of possible adverse effects.

SECTION A - PATIENT SELECTION CRITERIA

In accordance with NICE 2018 and the HW MPC patients must meet all of the following criteria for licensed use of sacubitril valsartan:

- New York Heart Association (NYHA) class II to IV symptoms
- Left ventricular ejection fraction ≤ 35%
- Taking a stable dose of an ACEI or an ARB, **which has been stopped**
- Systolic blood pressure >100mmHg
- No contra-indications to treatment

In patients where no reversibility in LV dysfunction is anticipated consider starting an ARNI without prior use of an ACEI/ARB which would save a significant amount of resource by cutting down the number of patient contacts. Patients should be selected by a cardiology consultant.

SECTION B – PATIENT ADVICE

- Explain benefits of therapy, and drugs place in treating patients with heart failure.
- Warn of possible side effects, particularly – hypotension, dizziness, cough.
- Advise of the risk and warning symptoms of angioedema - swelling of your face, lips, tongue, and throat, and inform patient to get emergency medical help if they have these symptoms or trouble breathing.
- Explain the need for close blood test monitoring.
- Encourage patient not to discontinue medication without seeking medical advice.
- Warn patients of the danger of taking concomitantly with an ACEI or ARB and encourage patient to carry alert card

SECTION C – INITIATION AND TITRATION

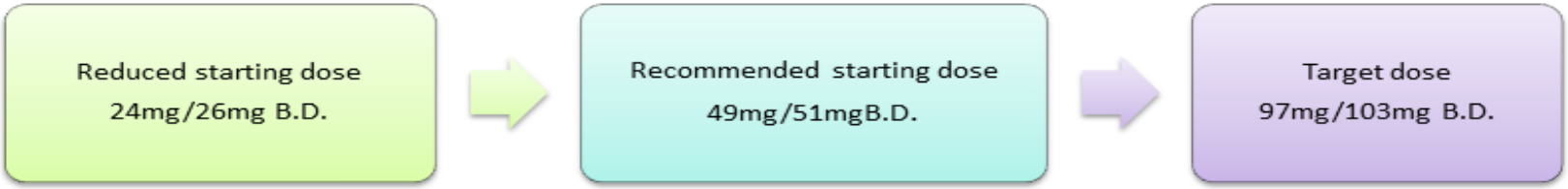
Treatment with sacubitril valsartan should be started on the recommendation of a heart failure specialist. In Worcestershire this can be any Consultant Cardiologist, heart failure specialist nurse or GPwER who has access to the heart failure MDT. The drug can then be initiated and up-titrated under the guidance of a heart failure nurse or any general practitioner who feels competent to do so. For patients in whom the drug is implemented by the heart failure team, monitoring can continue in primary care once the patient has been stable on the maximum tolerated dose for 1 month.

The flowchart overleaf guides dose initiation and up-titration.

Practical Guide to Sacubitril / Valsartan initiation and dose titration

Sacubitril valsartan should always be prescribed using the generic name to avoid concomitant prescribing of ACE-I or additional ARB therapy

The first dose of Sacubitril Valsartan must not be used until at least 36hours post the final dose of ACEi therapy



Start at the **reduced starting dose** if:
- Previously only on a low dose of an ACEi / ARB
- Baseline SBP 100-110mmHg
- Moderate renal impairment (eGFR 30-60)
- Moderate liver impairment (AST/ALT >2x ULN)

These patients should move to the next steps at 3-4 week intervals (if clinically tolerated).

Start at the **recommended starting dose**
If previously stable on at least:

Lisinopril	10mg	Candesartan	16mg
Perindopril	4mg	Irbesartan	150mg
Ramipril	5mg	Losartan	50mg
		Valsartan	160mg

These patients should move to the next step at 2-4 week intervals (if clinically tolerated).

Patients should move to the next stepped dose up (at the appropriate time point) providing they do not experience:
- hyperkalaemia (K+>5.4 mmol/L)
- significant deterioration in renal function
- symptomatic hypotension

THE USE OF SODIUM-GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITORS IN HFrEF

INTRODUCTION

Dapaglifozin is the first SGLT2 Inhibitor to be licenced and receive NICE approval for the treatment of HFrEF. In The DAPA-HF study, in patients with HFrEF and persisting symptoms, the addition of dapaglifozin to optimised standard care, was shown to lower the risk of dying from cardiovascular causes, and reduce the likelihood of hospitalisation or an urgent outpatient visit because of heart failure (composite ARR 4.9%).

Empaglifozin has received licence as a treatment for HFrEF and NICE guidance is expected in early 2022. As this is likely a class effect. If the patient is diabetic and already on an alternative SLGT2 inhibitor for diabetes this should be continued and there is no requirement to switch.

CONTRAINDICATIONS

- Current decompensated heart failure.
- Type 1 diabetes mellitus
- eGFR <15ml/min/1.73m2 (dapaglifozin) or eGFR <20ml/min/1.73m2 (empaglifozin)
- Previous unacceptable side effects associated with an SGLT2 inhibitor.

CAUTIONS

- Symptomatic hypotension or systolic blood pressure < 95 mmHg
- Elderly patients may be at greater risk for volume depletion, and are more likely to be treated with higher doses of diuretics.

SIDE EFFECTS

- Hypoglycaemia in Diabetic patients: especially when treated with Insulin and/or sulfonylurea (see initiation and patient advice)
- Vulvo-vaginitis, balanitis and related genital infections Urinary tract infection.
- Volume depletion / hypovolaemia
- Diabetes ketoacidosis (when used in T2D)
- Necrotising fasciitis of the perineum (Fournier's gangrene): Extremely rare but often fatal

SECTION A - PATIENT SELECTION CRITERIA

SGLT2 inhibitors can be initiated in secondary or primary care following the advice of a Heart failure Specialist. In accordance with NICE TA679 and the HWMPC patients must meet all of the following criteria

• New York Heart Association (NYHA) class II to IV symptoms
• Left ventricular ejection fraction ≤ 40%
• Patient already on optimally tolerated standard care consisting of ACE or ARBs or ARNI, with BB and if tolerated MRA.
• Systolic blood pressure >95mmHg

SECTION B – PATIENT ADVICE

- Explain benefits of therapy, and drugs place in treating patients with heart failure (see introduction).
- Patient should understand the indication for this medication is heart failure and not diabetes. This will help avoid someone making subsequent changes in medication regime if renal function deteriorates.
- May experience increased urine output in the first few days of therapy. Report signs of dizziness, thirst, low blood pressure and excessive urine output beyond a few days.
- Increased risk of genital/urinary tract Infection,
    - discuss importance of good personal hygiene
    - Advise to seek medical attention if they experience a combination of pain, tenderness, erythema, or swelling in the genital or perineal area, with fever or malaise. Either uro-genital infection or perineal abscess may precede necrotising fasciitis.

SECTION B2 – SPECIFIC ADVICE FOR DIABETIC PATIENTS

- The risk of hypoglycaemia is low when used alongside metformin, Dipeptidyl peptidase-4 (DPP-4) inhibitors: 'Gliptins' or Glucagon-like peptide-1 (GLP-1) receptor agonists
- There is increased risk of hypoglycaemia if patient taking insulin or a sulphonyurea (commonly gliclazide)
    - If patient self-monitors blood glucose advise that they need to be vigilant and may need to reduce their insulin dose if blood glucose low
    - If patient does not self-monitor then these mediations may need to be reduced, and advise that review by clinician/nurse who usually manages their diabetes is required
- Discuss the small increased risk of diabetic keto-acidosis including
    - Avoidance: Discuss sick day rules with the patient and provide leaflet used by diabetes specialist nurse (appendix). Omit SGLT2i and RAAS inhibitors if acute illness with poor oral intake, vomiting, diarrhoea
    - Recognition: several of: excessive thirst, increased urination, breathlessness or laboured breathing, abdominal or leg pains, nausea and vomiting, confusion or drowsiness, sweet smelling breath.

SECTION C – INITIATION

Name	**Initiation Dose**	**Target Dose for Heart failure**
Dapaglifozin	10mg od	10mg od
Empaglifozin	10mg od	10mg od

Licenced dose of dapaglifozin and empaglifozin for heart failure is 10mg once daily (further increments only required if being advised for glycaemic control).
Ensure HbA1c within last 3 months for all patients:

- In non-diabetic patients HbA1c should be checked prior to initiation to ensure the patient does not have undiagnosed Diabetes. If pre-diabetes (Hba1c between 42 – 47 mmol/mol) or diabetes (HbA1c ≥48 mmol/mol) ensure that this is communicated to patient and GP.

- In type II diabetic patients with an HbA1c <53mmol/mol and an eGFR >45, it is likely that other glycaemic medication will need to be reduced first, particularly if they are taking a sulphonyurea or insulin.

In type II diabetic patients there may be a need to adjust current diabetes regime. Providing the patient is not on insulin or a sulphonyurea the risk of hypoglycaemia is low. If the patient is on one of these recommend close monitoring of blood glucose in a patient who undertakes home monitoring. For patients on either Insulin or a sulphonyurea, who do not perform home glucose monitoring, a SLGT2i should only be commenced by (or following discussion with) the diabetes nurse or clinician who manages the patients diabetes (either GP or diabetologist). Where adjustment to the patient's diabetic regime is not necessary it is still important that the decision to commence an SLGT2i is communicated to the patient's diabetes team.

Clinical review should be planned 7 -10 days post initiation to assess patient's fluid status. Encourage early reporting of symptoms associated with hypotension/volume depletion with a view to adjusting diuretic therapy if required.

Renal impairment: No dosage adjustment required

Severe hepatic impairment: starting dose of 5 mg is recommended. If well tolerated, the dose may be increased to 10 mg.

(To support the heart failure specialist nurse team in the use of this new class of agent for heart failure, there is an consensus that when initiating in a person with diabetes they should liaise with the healthcare provider responsible for that persons diabetes care)

SECTION D - PROBLEM SOLVING

- Asymptomatic hypotension
  Can continue current therapy and counsel regarding recognition of symptoms such as dizziness/lightheaded, extreme lethargy. Asymptomatic low blood pressure (systolic <95mmHg) in itself is not an indication to stop a SGLT2i.

- Symptomatic hypotension
  Reduce/stop hypotensive agents which do not confer benefit in heart failure.
  If required, down-titrate either the SLGT2i or an alternative heart failure therapy.

- Volume depletion
  If clinical signs of volume depletion, reduce diuretic therapy and temporarily withhold SLGT2 inhibitor for 48 hours (or longer if concerns that volume depletion may not be corrected).
  If not on any loop diuretic then down-titrate SLGT2i.

- Renal function decline
  There is often a dip in renal function noted after initiation of SGLT2i, this will usually return to baseline within 1-3 months.

- Diabetic ketoacidosis (DKA)
  This is the most serious side effect that is not infrequent. Regardless of blood glucose level, assess for ketoacidosis immediately if the symptoms documented above occur.

  Restarting a SGLT2i is not recommended in patients who have suffered DKA without specialist advice from a Diabetologist.

SGLT2i initiation for HFrEF

Indications

NYHA II –IV, LV EJ <40%,

optimally tolerated standard care (ACE/ARB or ARNI, BB, MRA)

Systolic BP >95

Dapagliflozin eGFR >15 Empagliflozin eGFR >20

Contraindications

Current decompensation of heart failure symptoms

Type I diabetes

Previous unacceptable side effects of SGLT2 inhibition

Caution—Previous DKA, discuss with Diabetic specialist

Known Diabetic

HbA1c - update if last result more than 3 months old

Baseline renal function

Non Diabetic—Check HbA1c and U + E

<42– No action

42-47—pre diabetes } Ensure GP services aware for ongoing monitoring/ therapy

>48 - diabetes

Liase with person responsible for management of Diabetes (GP, Practice Nurse, Diabetes specialist Team) to agree any adjustments in therapy and appropriate Diabetes review.

- HbA1c <53 - any therapy may need to be adjusted to reduce risk of hypoglycaemia
- Insulin +/- sulphonylurea (glibenclamide, Gliclazide, glimepiride, glipizide, tolbutamide) increase risk of hypoglycaemia, dose adjustment likely
- Therapy with metformin alone is less likely to cause hypoglycaemia, dose adjustment may not be required

Patient counselling

General

Genital fungal infections are common. Discuss symptoms and encourage personal hygiene regime.

Make aware of increased urine output on initiation. Encourage early reporting of dizziness, thirst, low blood pressure, excessive weight loss.

Diabetes specific

Hypoglycaemia is common ensure awareness of signs/symptoms and monitoring requirements

Sick day rules

Make aware of DKA signs and symptoms

Dappagliflozin/Empagliflozin - 10mg once daily

Consider reduction in severe hepatic Impairment (5mg once daily and increase if tolerated)

A reduction in blood pressure/volume depletion is more common in those treated with anti-hypertensive and diuretic agents, the elderly and those with a history of hypotension. However routine reduction of therapies at initiation is not recommended. Consider at clinical review in 7-10 days, or before if patients report adverse effects.

Clinical review 7-10 days—Problem Solving

Update U+E to check for electrolyte disturbance.

Asymptomatic hypotension—counsel regarding adverse symptoms—continue therapy

Symptomatic hypotension—medication review, consider stopping therapies which do not provide long term benefit

Volume depletion—consider diuretic dose reduction or temporary withholding therapy for 24/48 hours with early review.

Ongoing monitoring

Renal function—dip in eGFR, rise in creatinine is expected but this often returns to baseline in 1-3 months. Persistent eGFR <45 may require diabetic therapy adjustment due to reduced efficacy. Renal function recommended four to six monthly.

LM Draft three 1.10.2021

THE USE OF IVABRADINE IN HFrEF

Ivabradine is indicated in patients with HFrEF with NYHA II-IV symptoms, in patients in sinus rhythm and whose heart rate is **≥75bpm**, in combination with standard therapy including beta-blockers, or when beta- blocker therapy is contraindicated or not tolerated, and who have an ejection fraction of 35% or less. (Based on results of the SHIFT study).

➢ **Ivabradine should be initiated only by a heart failure specialist after 4 weeks of stable optimal standard therapy; (NICE 2018).**

CONTRAINDICATIONS

- Severe bradycardia
- Cardiogenic shock
- Acute myocardial infarction
- Immediately after cerebrovascular accident
- Sick-sinus syndrome, sino-atrial block, 2nd and 3rd degree heart block
- Patients with pace-maker
- Congenital QT syndrome

CAUTIONS

- Monitor for atrial fibrillation or other arrhythmias
- Hypotension (avoid if severe)
- Retinitis pigmentosa
- No safety data available for the drug's use if eGFR <15

SIDE-EFFECTS (see current BNF for full list)

Main side-effects include: bradycardia, first-degree heart block, ventricular extrasystoles; headache, dizziness; visual disturbances including phosphenes and blurred vision; *less commonly* nausea, constipation, diarrhoea, palpitations, supraventricular extrasystoles, dyspnoea, vertigo, muscle cramps, eosinophilia, hyperuricaemia, and raised plasma-creatinine concentration.

SECTION A - PATIENT SELECTION CRITERIA

- Patients with HFrEF (any aetiology), who remain symptomatic (NHYA Class II-IV) despite 4 weeks of stable optimum tolerated treatment with an ACE inhibitor (or ARB), a beta blocker and an MRA.
- LVEF ≤35%,
- Patients must be in sinus rhythm with a heart rate of ≥75bpm
- Patient has none of the above contraindications

SECTION B - PATIENT ADVICE

- Explain the known benefits: to prevent worsening of heart failure, reduce hospital admissions and improve survival.
- Warn of possible side effects – especially bradycardia and advise to report any symptoms of bradycardia (syncope, dizziness, fatigue etc).

SECTION C - INITIATION, TITRATION AND MANAGING ADVERSE EFFECTS DURING TITRATION

The usual recommended starting dose of ivabradine is 5 mg twice daily (2.5mg bd in those over 75 years old). After two weeks of treatment, the dose can be increased to 7.5 mg twice daily if resting heart rate is persistently above 60 bpm (beats per minute) or decreased to 2.5 mg twice

daily if resting heart rate is persistently below 50 bpm, or in case of symptoms related to bradycardia such as dizziness, fatigue or hypotension. If heart rate is between 50 and 60 bpm, the dose of 5 mg twice daily should be maintained.

PROBLEM SOLVING
Bradycardia:

- Review other medications that may be causing bradycardia
- Check ECG to exclude arrhythmia

Treatment must be discontinued if heart rate remains below 50 bpm or symptoms of bradycardia persist. (Procoralan SPC, Servier).
AF or any other arrhythmia:

- Treatment with ivabradine must be discontinued if persistent AF or any other arrhythmia develops during treatment

Visual changes:

- Usually transient, and gradually disappear after a few months of treatment
- If persistent or causing discomfort consider discontinuation

THE USE OF DIGOXIN IN HEART FAILURE

INTRODUCTION

Cardiac glycosides are indicated in atrial fibrillation in order to control ventricular rate and thereby improve ventricular rate, function and any degree of symptomatic heart failure.
In sinus rhythm, digoxin is recommended to improve the clinical status of patients with HFrEF despite first and second line treatment. The starting dose for patients in heart failure (in sinus rhythm) is 62.5micrograms to 125micrograms once daily.
The primary benefit and indication for digoxin in heart failure is to reduce symptoms.
(DIG trial/NICE 2018, ESC 2021)

CONTRAINDICATIONS

- Intermittent complete heart block and second degree AV block
- Myocarditis, constrictive pericarditis
- Supraventricular arrhythmias associated with accessory conducting pathways e.g. Wolff-Parkinson White syndrome
- Ventricular tachycardia or fibrillation
- Hypertrophic obstructive cardiomyopathy (unless concomitant atrial fibrillation and heart failure (but use with caution)

CAUTIONS

- Sick sinus syndrome
- Recent myocardial infarction
- Thyroid disease
- Reduce dose in the elderly and in renal impairment
- Avoid hypokalaemia, hypomagnesaemia, hypercalcaemia
- Pregnancy
- Amiodarone, erythromycin, verapamil and poor renal function commonly increase plasma digoxin levels and the maintenance dose of digoxin should be reduced.

SIDE EFFECTS (see current BNF for complete list)

Main side effects (most are associated with excessive dosage): anorexia, nausea, vomiting, diarrhoea, abdominal pain, visual disturbances, headache, fatigue, drowsiness, confusion, delirium, hallucinations, depression, arrhythmias, AV block, rash, intestinal ischaemia, gynaecomastia, thrombocytopenia.

SECTION A - PATIENT SELECTION CRITERIA

- Worsening or severe (symptomatic) heart failure (NYHA class III –IV) due to left ventricular systolic dysfunction despite all other appropriate first and second line therapies and device therapy (when appropriate).
- Patients with atrial fibrillation requiring rate control.
- Patient has none of the documented contraindications.

If the patient does not fit into the above criteria, consider discussion with appropriate physician.

SECTION B - PATIENT ADVICE

- Explain the known benefits of digoxin therapy.
- Warn of possible side effects.
- Encourage the patient not to discontinue medication without seeking medical advice.

SECTION C - MANAGING ADVERSE EVENTS DURING TITRATION

Digoxin toxicity – Can arise with any dose of digoxin but is more common when the 'therapeutic' concentration is exceeded. However measurement of digoxin concentration is not a reliable guide therefore routine serum levels are not required. Watch for the following symptoms and STOP the drug, at least temporarily if any of these occur. An urgent serum digoxin concentration should be measured and advice from appropriate physician sought.

- Anorexia
- Nausea and vomiting
- Xanthopsia (yellow tint to vision)
- Symptomatic bradycardia
- Ventricular arrhythmias

In elderly patients the symptoms and signs may be less specific but may include:

- Confusion (new onset or increasing)
- Deteriorating mobility and falls

Raised Plasma digoxin levels – Commonly increase because of deteriorating renal function and drug interactions (see BNF for full list of interactions).

- **Amiodarone** – will cause a gradual increase in digoxin levels. Halve digoxin dose when starting amiodarone
- **Erythromycin** – will cause a rapid increase in digoxin levels and an alternative should be used whenever possible.
- **Poor renal function** (including diarrhoea/vomiting and any other cause) - Monitor renal function closely. Omit or reduce digoxin doses until clinically stable again.
- **Digoxin induced arrhythmias** – common in hypokalaemic patients.
- **Changes to drug therapy** – particularly important when changes to diuretic and ACEI therapy are made.

Blood sample for digoxin levels should be taken at least 8 hours after the last dose

Palliative Care Treatment for Heart Failure

Palliative Care is extremely important in failure. It is most applicable for those patients with NYHA class 3 and 4 Heart Failure. Heart failure management can be considered in three stages:

Stage 1. Chronic disease management (NHYA I-III)
The therapies discussed so far in this document represent those required in this phase. The goals of care include active monitoring, effective therapy to prolong survival, symptom control, patient and carer education and supported self-management.

Stage 2. Supportive and palliative care (NHYA III-IV)
Patients entering this stage of their disease should be considered for advanced heart failure therapies such as transplant / LVAD if appropriate*
After this relatively stable primary phase needing routine chronic disease management; patients enter a secondary phase of decline requiring increased utilization of medical and hospital care. At this point the goals of care should shift to maintaining optimal symptom control and quality of life. Prognostic therapies are no longer as important.
Identification of when to concentrate on palliative treatment is difficult. Prognostic scores which may help to identify those with reduced survival include:
HF Survival Score: http://www.heartfailurerisk.org/
Seattle HF Score: https://depts.washington.edu/shfm/
However these only consider some parameters and practically the following are probably more useful indications that the focus of care should shift.
- recurrent episodes of decompensation within 6 months despite optimal tolerated therapy
- progressive renal dysfunction
- Persisting hyponatraemia
- a greater than 5% non-fluid-related weight loss (cachexia)
- escalating diuretic dose requirements
- the occurrence of malignant arrhythmias
- chronic poor quality of life or intractable NYHA class IV symptoms,

Shared care with close liaison between specialist palliative care services, the HF team and/or the primary care physician is likely to lead to optimally managed and coordinate patient's care.
Care might shift to a palliative focus over time rather than a focus on disease modification. Good communication is a paramount aspect of care delivery with the patient and family understanding the rationale for a change in focus of care.
Key aspects of treatment include:

Symptom assessment and control.

- Morphine (with an antiemetic when high doses are needed) can be used to reduce breathlessness, pain and anxiety
- Diuretic management: increased to relieve severe congestion or down titrated due to excessive thirst.
- Reducing HF drugs that reduce blood pressure to maintain sufficient oxygenation and reduce the risk of falls.
- Stopping non-essential therapies e.g. cholesterol lowering drugs, osteoporosis treatments.

Common Medication Contraindicated for use in Heart Failure

Consider stopping or reducing down to the lowest effective dose any of the following medication in patients with heart failure, following consideration of past medical history and concomitant medical conditions and if necessary after discussion with an appropriate medical professional:

- NSAIDs (diclofenac, ibuprofen, indomethacin, ketorolac, naproxen, and piroxicam) and COX2 inhibitors (etoricoxib and rofecoxib) – can cause fluid retention and are associated with an increased risk of hospital admission due to heart failure. (Note – the same applies to aspirin when used as an analgesic)
- Steroids (prednisolone and dexamethasone) – can cause hypertension in a dose related manner due to increased peripheral resistance and sodium and water retention. Although usually only used in cases of important likely benefit, because of their well-known adverse effects.
- Diltiazem and verapamil – have negative ionotropic effects which may further worsen cardiac function.
- Nifedipine and nicardipine - have a negative safety profile in heart failure (Note - amlodipine and felodipine, may be used to treat hypertension but may compromise attaining optimal dosage of ACEIs/ARBs, beta-blockers and aldosterone antagonists.)
- Pioglitazone - May cause fluid retention and heart failure by increasing renal sodium reabsorption.
- Flecainide and dronedarone (anti-arrhythmics) –may increase the risk of ventricular arrhythmias, worsen heart failure and increase risk of mortality and hospital admissions.
- Moxonidine – increases risk of heart failure mortality.

Common Medication to be used with Caution in Heart Failure

- Tricyclic Antidepressants (e.g amitriptyline) - can prolong QT interval and cause arrhythmias as well as risk of hypotension.
- Theophylline – tachycardia and atrial arrhythmia can occur even when used at therapeutic levels in heart failure. Close monitoring is required if this is to continue.
- PDE-5 inhbitiors (sildenafil, vardenafil, tadalafil) – are vasodilators so can precipitate hypotension (especially if used alongside GTN/nitrates). Note – sildenafil is sometimes used in pulmonary hypertension.
- Over the counter medicines including: Those with high salt content which may cause fluid retention, e.g. effervescent preparations and some antacids. Decongestants for coughs and colds such as pseudoephedrine may increase workload on the heart. Laxatives taken with a large amount of water such as bulk-forming agents.
- Caution with some herbal/homeopathic remedies – seek advice if unsure.

Management of Heart Failure in Pregnancy and Breastfeeding

Some of the commonly used medication used in heart failure is contraindicated for use in pregnancy and/or breastfeeding, and some may be used with caution. There is limited data for the use of drugs in pregnancy and breastfeeding and the consensus is that medication should only be used where the perceived benefits outweigh the risks. Due to limited data it is often difficult to determine if the risk is associated with maternal clinical condition alone or medication. Use and choice of heart failure medication in pregnancy and breastfeeding will depend upon maternal clinical condition, gestation, maternal co-morbidities and other potential risks to the baby or mother. All women of child bearing age with heart failure should be reviewed by a heart failure specialist ideally prior to conception for optimization of medical therapies and to discuss risks. Discussing management of pregnancy in all women of child-bearing age with heart failure. Below list the potential risks associated with the main classes of heart failure drugs:

Loop diuretics – Furosemide and bumetanide are generally contraindicated in pregnancy as are associated with maternal hypovolaemia and reduced placental perfusion. However there are no reports of teratogenicity with either, and they have been used for pulmonary congestion when essential. Both are considered to be safe in breastfeeding as excretion into breast milk is likely to be too small to be harmful. Furosemide is the preferred option due to most experience, short half life and high protein binding. Note - loop diuretics may theoretically inhibit lactation.

ACE inhibitors – All are relatively contraindicated in pregnancy and only used if essential. Use in the 1st trimester has been associated with neonatal cardiac malformation, CNS malformation, including neural tube defects and renal defects. Use in the 2nd or 3rd trimesters has been associated with oligohydramnios, renal tubular dysgenesis, intrauterine growth restriction including under-development of neonatal cranial and leg bones, poor lung and bladder maturation, patent ductus arteriosis and compression of the umbilical cord, which may result in reduced neonatal blood flow. There is limited evidence for the safe use of ACEI in breastfeeding with premature and newborn infants theoretically at risk from profound hypotension and renal toxicity when exposed via breast milk. Captopril and enalapril are the preferred choices in breastfeeding.

ARBs – All are contraindicated in pregnancy unless essential. The risks associated with ARB use in pregnancy is similar to ACE inhibitors. Information on the use in breastfeeding is very limited, therefore are not recommended as ACE inhibitors are considered safer.

Beta-blockers – None have shown any teratogenic risk, but use in pregnancy has been associated with intra-uterine growth restriction, neonatal hypoglycaemia, bradycardia and hypotension. Labetalol is commonly used in pregnancy for maternal hypertension. Consider continuation of chronic beta blocker therapy in stable asymptomatic women, where there are no adverse effects on the neonate. Of the three beta-blockers licensed for use in heart failure; metoprolol is excreted into breast milk though infants have shown very low serum levels so is likely to be safe and no adverse events have been reported. Carvedilol is highly protein bound so presents a low risk in breastfeeding, however experience is lacking so other agents are preferred. Bisoprolol has relatively low protein binding and moderately high renal excretion so presents a higher risk for accumulation in breastfed infants. Again there is little experience of bisoprolol use in breastfeeding, so other agents are preferred. (Note - Propranolol is considered the preferred choice in breastfeeding however is not licensed for use in heart failure).

Mineralocorticoid Receptor Antagonists – Spironolactone and eplerenone are contraindicated in pregnancy unless potential benefits outweigh the risks. Spironolactone has been shown to be teratogenic in animal studies but limited data suggests use in breastfeeding is safe. There is no safety data for the use of Eplerenone in pregnancy or breastfeeding so avoidance is advised.

Ivabradine – Contraindicated in pregnancy and breastfeeding as toxicity shown in animal studies and is present in significant amounts in breast milk.

ARNI – Contraindicated in pregnancy and breastfeeding as toxicity shown in animal studies and is present in significant amounts in breast milk.

NOTE – Although digoxin is no longer a recommended treatment for heart failure it is generally safe in pregnancy and breastfeeding so may be a useful agent. Also isosorbide dinitrate plus hydralazine is the preferred vasodilator therapy during pregnancy if essential. There is a large volume of evidence supporting the safety of hydralazine in pregnancy, but there is limited evidence for the safety of isosorbide dinitrate. There is limited safety data for the use of this combination in breastfeeding, but as ACE inhibitors are considered compatible with breastfeeding, so are generally restarted post-partum.
Useful reference sources for drug use in pregnancy or breastfeeding: Best use of medicines in pregnancy - http://www.medicinesinpregnancy.org/
Specialist Pharmacy Service – Safety in Lactation - https://www.sps.nhs.uk/?s=&cat%5B0%5D=266&cat%5B1%5D=3008
Note these are not an exhaustive lists.

Monitoring Tool

STANDARDS	%	Clinical Exceptions
All patients with confirmed LVSD should be on maximum tolerated Angiotensin Converting Enzyme Inhibitor (ACE I) or Angiotensin Receptor Blocker (ARB) therapy	100	Contraindicated, Intolerant
All patients with confirmed LVSD should be on maximum tolerated beta blocker therapy	100	Contraindicated, Intolerant
All patients with confirmed LVSD still symptomatic on ACE I and Beta-blockers should receive Spironolactone or Eplerenone	100	Contraindicated. Intolerant

How will monitoring be carried out?	paper audit tool
When will monitoring be carried out?	Yearly
Who will monitor compliance with the guideline?	Heart Failure Specialist Nurses

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Name	Committee / group
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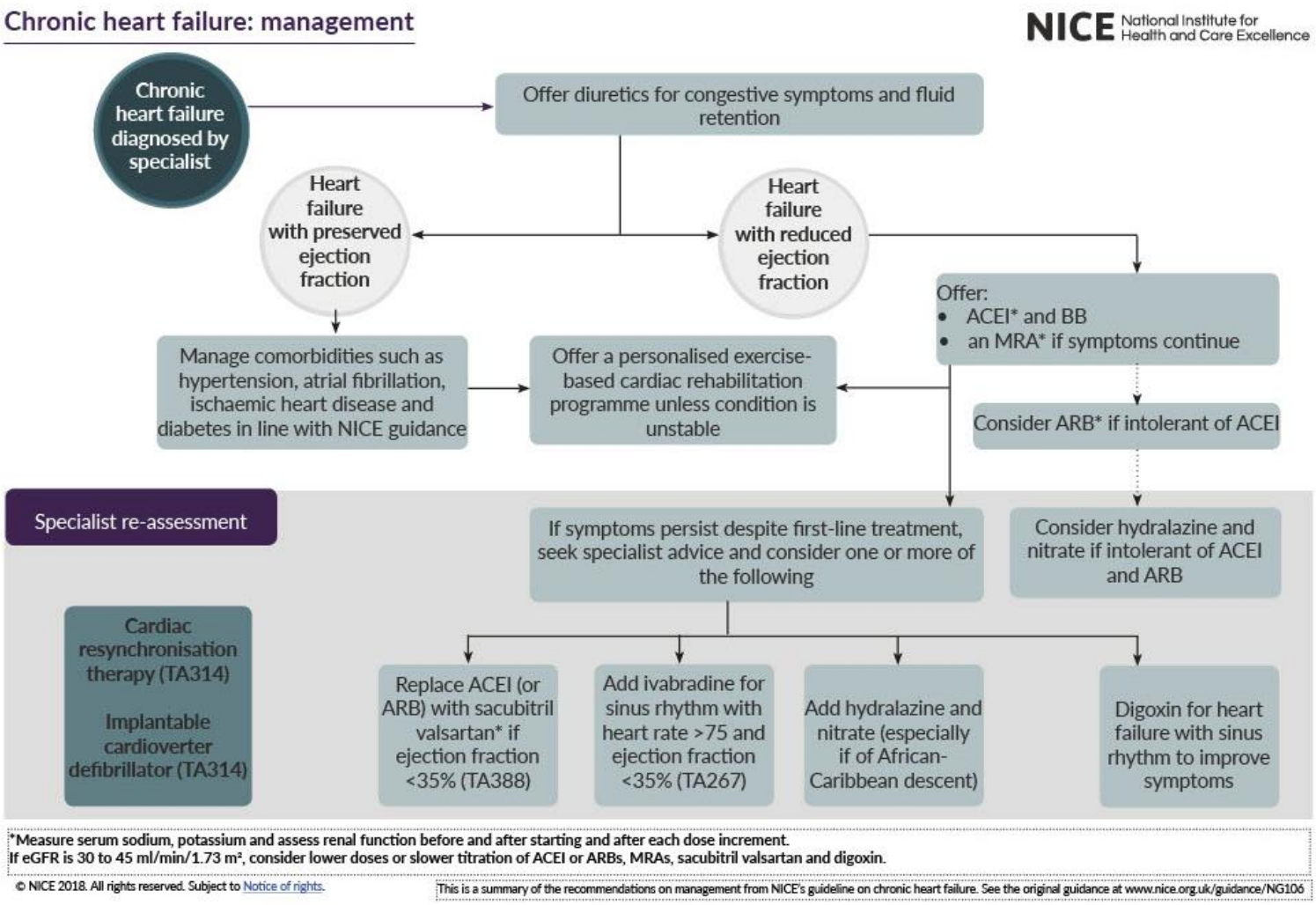
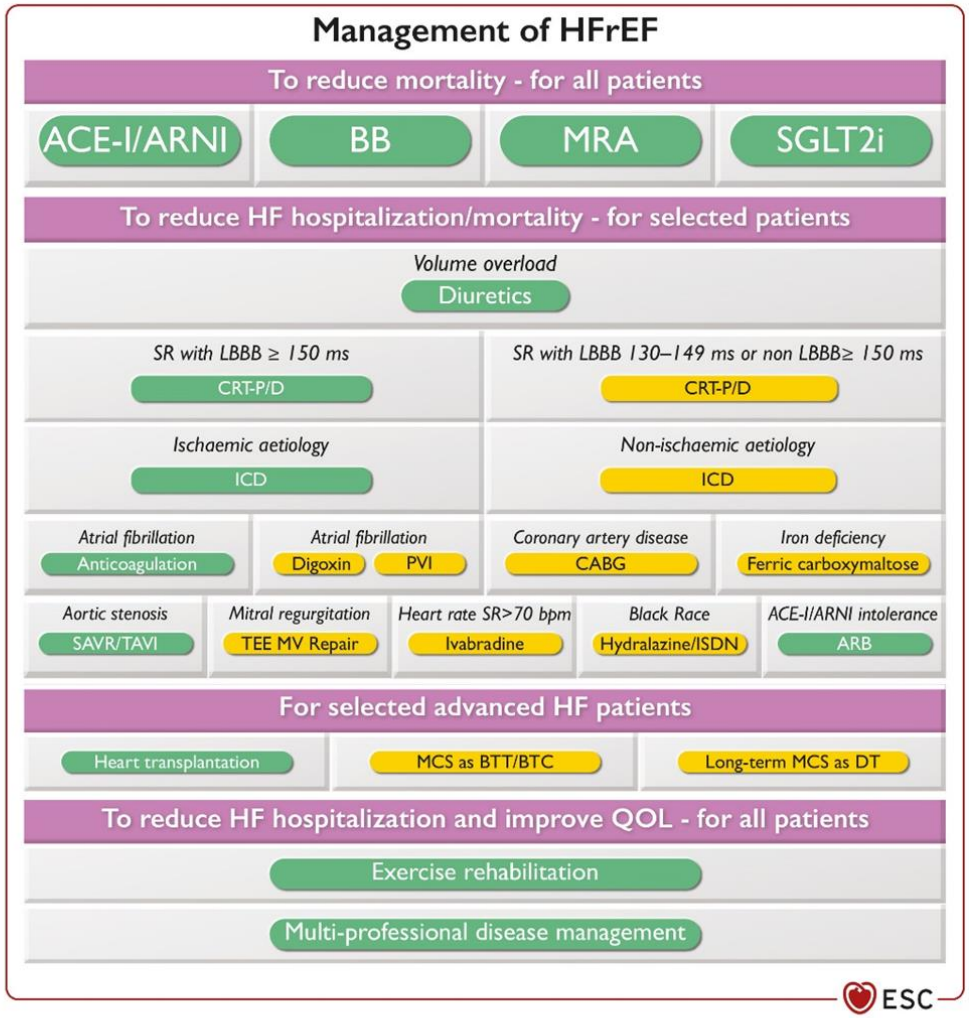
Appendix 1


Chronic heart failure: management
NICE National Institute for Health and Care Excellence
Chronic heart failure diagnosed by specialist
Offer diuretics for congestive symptoms and fluid retention
Heart failure with preserved ejection fraction
Heart failure with reduced ejection fraction
Offer:
ACEI* and BB
an MRA* if symptoms continue
Manage comorbidities such as hypertension, atrial fibrillation, ischaemic heart disease and diabetes in line with NICE guidance
Offer a personalised exercise-based cardiac rehabilitation programme unless condition is unstable
Consider ARB* if intolerant of ACEI
Specialist re-assessment
If symptoms persist despite first-line treatment, seek specialist advice and consider one or more of the following
Consider hydralazine and nitrate if intolerant of ACEI and ARB
Cardiac resynchronisation therapy (TA314)
Implantable cardioverter defibrillator (TA314)
Replace ACEI (or ARB) with sacubitril valsartan* if ejection fraction <35% (TA388)
Add ivabradine for sinus rhythm with heart rate >75 and ejection fraction <35% (TA267)
Add hydralazine and nitrate (especially if of African-Caribbean descent)
Digoxin for heart failure with sinus rhythm to improve symptoms
*Measure serum sodium, potassium and assess renal function before and after starting and after each dose increment.
If eGFR is 30 to 45 ml/min/1.73 m², consider lower doses or slower titration of ACEI or ARBs, MRAs, sacubitril valsartan and digoxin.
© NICE 2018. All rights reserved. Subject to Notice of rights.
This is a summary of the recommendations on management from NICE's guideline on chronic heart failure. See the original guidance at www.nice.org.uk/guidance/NG106

NHS Worcestershire Acute Hospitals NHS Trust

Appendix 2



ESC

Strategic phenotypic overview of the management of heart failure with reduced ejection fraction

ACE-I = angiotensin-converting enzyme inhibitor; ARB = angiotensin receptor blocker; ARNI = angiotensin receptor-neprilysin inhibitor; BB = beta-blocker; b.p.m. = beats per minute; BTC = bridge to candidacy; BTT = bridge to transplantation; CABG = coronary artery bypass graft; CRT-D = cardiac resynchronization therapy with defibrillator; CRT-P = cardiac resynchronization therapy with pacemaker; DT = destination therapy; HF = heart failure; HFrEF = heart failure with reduced ejection fraction; ICD = implantable cardioverter-defibrillator; ISDN = isosorbide dinitrate; LBBB = left bundle branch block; MCS = mechanical circulatory support; MRA = mineralocorticoid receptor antagonist; MV = mitral valve; PVI = pulmonary vein isolation; QOL = quality of life; SAVR = surgical aortic valve replacement; SGLT2i = sodium-glucose co-transporter 2 inhibitor; SR = sinus rhythm; TAVI = transcatheter aortic valve replacement; TEE = transcatheter edge to edge. Colour code for classes of recommendation: Green for Class of recommendation I; Yellow for Class of recommendation IIa (see Table 1 for further details on classes of recommendation).
The Figure showsmanagement options with Class I and IIa recommendations. See the specific Tables for those with Class IIb recommendations.

www.escardio.org/guidelines

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure (European Heart Journal 2021 – doi:10.1093/eurheartj/ehab368)

Appendix 3: The management of worsening renal function and hyperkalaemia in patients on RAASi

Some rise in urea, creatinine, and potassium is to be expected with use of RAAS inhibitors (ACE/ARB/MRA/ARNI); if an increase is small and asymptomatic no action is necessary. The following tables provide guidance on how and when to respond to changes in serum creatinine and Potassium.

Table 1 Management of RAAS inhibitors in response to change in renal function

Clinical assessment:

- Compare with baseline renal function (review series of results).
- Assess fluid status: if intravascularly depleted (jugular venous pulse not visible, postural drop in BP and no oedema), consider cautious intravenous fluids.
- Interpret BP in the context of usual values (low BP does not necessarily mean patient needs fluid).
- Reduce/withdraw RAASI if symptomatic hypotension.
- Repeated clinical and biochemical assessment is vital.
- Presence of moderate or severe hyperkalaemia may override recommendations based on change in renal function.
- In severe renal dysfunction assess for symptoms or uraemia.

	Recommendations for RAAS inhibitors	
Change in renal function compared with baseline	**HFpEF (assuming no other prognostic indication).**	**HFREF.**
Increase in serum creatinine by <30%	Consider stop ACEI/ARB/ARNI Review MRA according to fluid status.	Continue unless symptomatic hypotension.
Increase in serum creatinine 30%–50%	Stop RAAS inhibitor.	Consider reducing dose or temporary withdrawal.*
Increase in serum creatinine >50%	Stop RAAS inhibitor.	Temporarily stop RAAS inhibitor.*
Severe renal dysfunction, for example, eGFR <20	Stop RAAS inhibitor.	Stop RAAS inhibitor if symptomatic uraemia irrespective of baseline function.

*Reinitiate and/or retitrate when renal function improved in patients with HFrEF.
ACEI, ACE inhibitor; ARB, angiotensin receptor blocker; BP, blood pressure; eGFR, estimated glomerular filtration rate; HFrEF, heart failure with reduced left ventricular ejection fraction; HFpEF, heart failure with preserved left ventricular ejection fraction; MRA, mineralocorticoid receptor antagonists; RAAS, renin–angiotensin–aldosterone.

Table 2 Considerations when managing a patient with heart failure who develops hyperkalaemia

Serum K^+ >5.4	All patients		
Check for overdiuresis/hypovolaemia. **Non-selective beta-blockers can increase potassium. Review indication (prognostic benefit in HFrEF but not HFpEF) – try to continue in HFrEF.** **Stop K supplements.** **Stop amiloride and triamterene.** **Stop non-steroidal anti-inflammatory drugs.** **Stop trimethoprim.** **Stop sodium substitutes.** **Check for digoxin toxicity.** **Provide low K diet advice.**			
Serum K^+	**Mild hyperkalaemia 5.5–5.9 mmol/L**	**Moderate hyperkalaemia 6.0–6.4 mmol/L**	**Severe hyperkalaemia >6.5 mmol/L**
Patient clinically well, no AKI	Increase frequency of biochemical monitoring but do not stop RAAS inhibitors. Consider reducing dose.	Stop RAAS inhibitor(s), repeat test Re-start at lower dose once K^+<5.5 Re-start one drug at a time, with biochemical monitoring, if the patient was previously on a combination of ACEI/ARB/ARNI plus MRA.	Admit to hospital for immediate K^+-lowering treatment. Stop RAAS inhibitor(s). Repeat blood test 24 hours later. Restart at lower dose once K^+ <5.5 Restart one drug at a time, with biochemical monitoring, if the patient was previously on a combination of ACEI/ARB/ARNI plus MRA.
Patient clinically unwell with sepsis or hypovolaemia and/or AKI.	Withhold RAAS inhibitors until sepsis/hypovolaemia corrected, then restart.	Withhold RAAS inhibitor(s) until sepsis/hypovolaemia corrected, then restart once K^+ <5.5.	Withhold RAAS inhibitor(s) until sepsis/hypovolaemia corrected, then restart once K^+ <5.5. Restart one drug at a time, with biochemical monitoring, if the patient was previously on a combination of ACEI/ARB/ARNI plus MRA.
Patient clinically unwell with decompensated heart failure with/without AKI	Do not withhold RAAS inhibitors. Consider reduce dose. Treat congestion with loop diuretics or combination of loop and thiazide diuretics.	Reduce dose of RAAS inhibitor(s) and monitor frequently. Treat congestion with loop diuretics or combination of loop and thiazide diuretics.	Withhold RAAS inhibitor(s) and restart at lower dose when serum K^+ <6.0. Restart one drug at a time, with biochemical monitoring, if the patient was previously on a combination of ACEI/ARB/ARNI plus MRA.

ACEI, ACE inhibitor; AKI, acute kidney injury; ARB, angiotensin receptor blocker; ARNI angiotensin receptor-neprilysin inhibitor; RAAS, renin–angiotensin–aldosterone; MRA, mineralocorticoid receptor antagonist.

Clark AL, *et al*. *Heart* 2019;**105**:904–910. doi:10.1136/heartjnl-2018-314158

Appendix 4: Community Heart Failure Team Contact/Referral Details

Please use Team e mail for all correspondence as this is checked daily Monday to Friday.

North Team		
Team e mail	Wah-tr.communityheartfailurenursesnorth@nhs.net	
Admin Team	Sue Causer and Julie Rudd	
Phone	Direct Line – 01562 828818 (Answer phone for out of hours)	Ext - 53134
Postal Address	Heart Failure Team Level 4, Block C Kidderminster Treatment Centre, Stourbridge Road, Kidderminster, DY11 6RJ	
Areas Covered		
Redditch	Lynda Moore	07748 147 025
Bromsgrove	Huw Wiseman	07786 391 464
Wyre Forest Stourport & Kidderminster	Jayne Wiseman	07553 367 290
Wyre Forest Bewdley & Kidderminster	Rachel Hunt	07775 915 952

South Team		
Team e mail	Wah-tr.communityheartfailurenursessouth@nhs.net	
Admin Team	Ann Berry	
Phone	Direct Line – 01905 733029 (Answer phone for out of hours)	Ext. - 38776
Postal Address	Heart Failure Nurse Service Kings Court 3 - Ground Floor Worcestershire Royal Hospital Charles Hastings Way, Worcester, WR5 1DD	
Areas Covered		
Worcester City	Cathy Banks	07879 803 775
Droitwich, Great Whitley, Tenbury, Ombersley.	Sally Baker	07747 004 539
Pershore, Evesham, Broadway, Bredon, Inkberrow.	Ricky Hollander	07423 459 674
Malvern, Greater Malvern.	Jacqui Maciejewski	07917 107 769
Upton, Pershore Worcester City (st Johns)	Samantha Hargreaves	07734 228 520

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
Date assessment completed	**Dec 22**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Treatment Guidelines for Heart Failure with Reduced Ejection Fraction - HFrEF			
What is the aim, purpose and/or intended outcomes of this Activity?	See body of document			
Who will be affected by the development & implementation of this activity?	❑ Service User ❑ Patient ❑ Carers ❑ Visitors		❑ Staff ❑ Communities ❑ Other _____	
Is this:	x❑ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	See body of document			

Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	See body of document
Summary of relevant findings	See body of document

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age				See body of document
Disability				See body of document
Gender Reassignment				See body of document
Marriage & Civil Partnerships				See body of document
Pregnancy & Maternity				See body of document
Race including Traveling Communities				See body of document
Religion & Belief				See body of document
Sex				See body of document
Sexual Orientation				See body of document
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)				See body of document
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				See body of document

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
How will you monitor these actions?	**N/A**			
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Completed on behalf of owner
Date signed	Dec 2022
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	N
2.	Does the implementation of this document require additional revenue	N
3.	Does the implementation of this document require additional manpower	N
4.	Does the implementation of this document release any manpower costs through a change in practice	N
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	N
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.