

# Mount Sinai Health System Heart Failure Ambulatory Pathway



# Mount Sinai Health System Ambulatory Pathway Heart Failure

# **Background**

- This document is intended to provide guidance to support primary care providers and the collaborative team on heart failure diagnosis and management
- Primary care has a vital role in providing holistic, person-centered care from first symptoms to end of life
- 3 types of heart failure: Heart Failure with Reduced Ejection Fraction (HFrEF), Heart Failure with Preserved Ejection Fraction (HFpEF), and Right Sided Heart Failure (RHF)
- While this pathway's major focus is on HFrEF, the content outlines, in appropriate sections, unique considerations for HFpEF and RHF
- Hypertension control, dietary compliance, reduced salt intake apply to all types of heart failure
- The optimal care of patients with HFrEF involves a commitment to guideline directed medical therapy (GDTM) and a multidisciplinary care team



# **Table of Contents**

This 2022 MSHS Heart Failure Ambulatory Pathway is organized into the following sections:

Prevention, Diagnosis, Categorization and Staging of Heart Failure	Page 4
Medications	Page 6
New Therapies for HFrEF: SGLT-2is	Page 16
Vaccinations	.Page 18
Care Delivery Steps and Clinical Integration Models	.Page 19
Testing and Referrals	.Page 20
Use of BNP in Heart Failure	.Page 20
Palliative Care	Page 27
Disease Management Services including Remote Patient Monitoring	.Page 28
Initial and Subsequent Visit Primary Care Templates	Dago 32

# Prevention, Diagnosis, Categorization, and Staging of Heart Failure

# **Prevention**

To prevent the initial development of heart failure (HF)<sup>1</sup>:

- Effectively manage contributing comorbidities such as diabetes and hypertension
- Regular physical activity (exercising ≥5 d/wk)
- Maintaining a healthy body weight
- Not smoking
- Eating fruits and vegetables (4 servings/day) and moderate alcohol intake (1 drink/day)

# **Diagnosis**

Initial evaluation of patients with symptoms or signs suggestive of HF includes clinical assessment (history and physical exam), electrocardiogram, echocardiogram, blood tests, and chest radiograph.

Early measurement of brain natriuretic peptide (BNP) or N-terminal proBNP levels is suggested in patients with suspected HF in whom the diagnosis is uncertain. BNP levels > 400 ng/L imply a cardiac cause with a sensitivity of 95-97% and a negative predictive value of 90-97%. While BNP levels < 100 ng/L imply a pulmonary cause, BNP levels 100-400 BNP are neither sensitive nor specific for excluding or confirming HF<sup>2,3</sup>.

# Categorization of Heart Failure<sup>4,5</sup>

# **Heart Failure with Reduced Ejection Fraction (HFrEF)**

EF less than or equal to 40%. Mortality benefit proven with Carvedilol, long acting metoprolol (succinate), and bisoprolol, ACE inhibitors/ARBs or Spironolactone.

<sup>&</sup>lt;sup>1</sup> Horwich TB and Fonarow GC. Prevention of Heart Failure. JAMA Cardiol. 2017 Jan 1;2(1):116.

<sup>&</sup>lt;sup>2</sup> Ponikowski P, Voors AA, Anker SD et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. Eur Heart J. 2016 Jul 14;37(27):2129-2200.

<sup>&</sup>lt;sup>3</sup> Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America Circulation. 2017 Aug 8;136(6):e137-e161. Hereafter referred to as the "2017 Heart Failure Pathway."

<sup>&</sup>lt;sup>4</sup> Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: Executive Summary. A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, circulation 2013;128:1810. Hereafter referred to as the "2013 Heart Failure Pathway."

<sup>&</sup>lt;sup>5</sup> Konstam MA, Kiernan MS, Bernstein D et al. Evaluation and Management of Right-Sided Heart Failure A Scientific Statement From the American Heart Association. Circulation. 2018;137:e578–e622



# **Heart Failure with Preserved Ejection Fraction (HFpEF)**

A clinical syndrome in which patients have symptoms and signs of HF, a normal or near normal left ventricular ejection fraction (LVEF ≥50 percent), and evidence of cardiac dysfunction as a cause of symptoms (eg, abnormal left ventricular filling and elevated filling pressures).

- Approximately ~50% of patients with heart failure have an EF> 50%, a proportion that is increasing over time. Dominant form of heart failure in the elderly.
- No therapies with proven mortality benefit, unlike HFrEF.

# Prevention, Diagnosis, Categorization and Staging of Heart Failure

# Right Sided Heart Failure (RHF)

RHF is a clinical syndrome in which symptoms and signs are caused by dysfunction of the right heart structures (predominantly the right ventricle [RV], but also the tricuspid valve apparatus and right atrium) or impaired vena cava flow, resulting in impaired ability of the right heart to perfuse the lungs at normal central venous pressures.

- RHF is commonly seen with HFrEF (48%) and HFpEF (20-40%) and, when present, independently associated with increased morbidity and mortality, thus important to ensure actively managed in conjunction with treatment of left heart failure
- Cardiac MRI more accurate than echocardiogram in assessing RV structure and function
- Cardiac catheterization is definitive test, if non-invasive testing inconclusive

## **Common Classifications of Heart Failure**

New York Heart Association (NYHA) Functional Classification			
Class	Functional Capacity: Heart Failure Related Symptoms According to Activity Level	Associated HF Severity	
Class I	Patients with cardiac disease (low EF, prior history of systolic or diastolic HF symptoms) but no limitation of ordinary physical activity. Ordinary physical activity does not cause symptoms (undue fatigue, SOB, palpitations).  Note: Patient may have mild symptoms on greater-than-ordinary activity, e.g. walking up 4 flights of stairs, carrying heavy objects.	Very mild or no impairment	
Class II	Patients with cardiac disease causing slight limitation of physical activity. Ordinary physical activity causes symptoms.  Note: "Ordinary" activity generally means: walking (not running) up 1-2 flights, walking a few blocks on flat ground, carrying lightweight objects.	Mild	



Class III	Patients with cardiac disease causing marked limitation of physical activity. Comfortable at rest. Less-than-ordinary activity causes symptoms.	Moderate to severe
Class IV	ANY amount of physical activity causes symptoms. Symptoms may be present at rest.	Severe

ACC/AHA Stages of Heart Failure		
Stage A	At high risk for HF but without structural heart disease or symptoms of HF	
Stage B	Structural heart disease but without signs or symptoms of HF	
Stage C	Structural heart disease with prior or current symptoms of HF	
Stage D	Refractory HF requiring specialized interventions.	



# **Medications**

# Guidelines for Initial Medication Selection in Heart Failure with Reduced Ejection Fraction (HFrEF) Based Primarily on Clinical Findings<sup>6,7,8,9</sup>

Table 1: Starting and Target Doses of Select Guideline-Directed Medical Therapy for HFrEF		
	Starting Dose	Target Dose
ARNI		
Sacubitril/valsartan	24/26 mg-49/51 mg twice daily	97/103 mg twice daily
ACEI		
Captopril	6.25 mg 3x daily	50 mg 3x daily
Enalapril	2.5 mg 2x daily	10-20 mg 2x daily
Lisinopril	2.5-5 mg daily	20-40 mg daily
Ramipril	1.25 mg daily	10 mg daily
ARB		
Candesartan	4-8 mg daily	32 mg daily
Losartan	25-50 mg daily	150 mg daily
Valsartan	40 mg 2x daily	160 mg 2x daily
Beta Blockers		
Bisoprolol	1.25 mg once daily	10 mg once daily
Carvedilol	3.125 mg 2x daily	25 mg 2x daily for weight <85 kg 50 mg 2x daily for weight ≥85 kg
Metoprolol succinate	12.5-25 mg/d	200 mg daily

<sup>&</sup>lt;sup>6</sup> Felker GM, Ellison DH, Mullens W, et al. Diuretic Therapy for Patients With Heart Failure: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;75(10):1178-1195.

<sup>&</sup>lt;sup>7</sup> Diuretics, Loop, In Epocrates for apple IOS software. [Mobile Application Software], retrieved June 18, 2020

<sup>&</sup>lt;sup>8</sup> Medication tables and figures adapted from Yancy CW, Januzzi JL Jr, Allen LA, Butler J, Davis LL, Fonarow GC, Ibrahim NE, Jessup M, Lindenfeld J, Maddox TM, Masoudi FA, Motiwala SR, Patterson JH, Walsh MN, Wasserman A. 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Decision Pathways. J Am Coll Cardiol 2018;71:201-30. Hereafter referred to as "2017 ACC HeartFailure Pathway"

<sup>&</sup>lt;sup>9</sup> Medication tables and figures adapted from Maddox TM, Januzzi JL Jr., Allen LA, Breathett K, Butler J, Davis LL, Fonarow GC, Ibrahim NE, Lindenfeld J, Masoudi FA, Motiwala SR, Oliveros E, Patterson JH, Walsh MN, Wasserman A, Yancy CW, Youmans QR. 2021 update to the 2017 ACC expert consensus decision pathway for optimization of heart failure treatment: answers to 10 pivotal issues about heart failure with reduced ejection fraction: a report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol 2021;77:772–810. Hereafter referred to as "2021 ACC Heart Failure Pathway"



# Table 1: Starting and Target Doses of Select Guideline-Directed Medical Therapy for HFrEF (continued)

*Note:* Unlike immediate-release metoprolol and atenolol, metoprolol ER is proven to improve symptoms of heart failure, lower the risk of death from heart failure, and lower the risk of hospitalization due to heart problems. While atenolol is technically another hypertension drug, it doesn't have these additional benefits.

benefits.	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Aldosterone Antagonists			
Eplerenone	25 mg daily	50 mg daily	
Spironolactone	12.5-25 mg daily	25-50 mg daily	
SGLT2 Inhibitors			
Dapagliflozin	10 mg daily	10 mg daily	
Empagliflozin	10 mg daily	10 mg daily	
Vasodilators			
Hydralazine	25 mg 3x daily	75 mg 3x daily	
Isosorbide dinitrate	20 mg 3x daily	40 mg 3x daily	
Fixed-dose combination isosorbide dinitrate/hydralazine	20 mg/37.5 mg (one tab) 3 x daily	2 tabs 3x daily	
Ivabradrine			
Ivabradrine	2.5-5 mg 2x daily	Titrate to heart rate 50-60 bpm.  Maximum dose 7.5 mg 2x daily	
Digoxin			
Digoxin	0.125 mg once	0.25 mg once	
Diuretics—Thiazides			
Chlorthalidne	12.5-25 mg once	100 mg	
Hydrochlorothiazide	25 mg once or twice	200 mg	
Metolazone	2.5 mg once	20 mg	
Diuretics—Loop			
Bumetanide	0.5-1.0 mg once or twice	10 mg	
Furosemide	20-40 mg once or twice	400 mg	
Torsemide	10-20 mg once	200 mg	



# Other HFrEF Medication Notes<sup>4</sup>

- It is recommended that only one of the neurohormonal antagonist (Beta-blocker, ACE, ARB, ARNI, Aldosterone antagonist) be increased at each visit. If the patient is hemodynamically stable, it is generally acceptable to double the dose of these agents when escalating the dose.
- In general, calcium channel blockers should be avoided in HFrEF. However, third generation
  calcium channel blockers such as amlodipine may be used for blood pressure control in HFrEF.
  Other calcium channel blockers such as verapamil, diltiazem, and nifedipine should be avoided in
  patients with HFrEF due to their negative ionotropic effects and studies indicating worse
  outcomes.
- Anticoagulation indicated if atrial fibrillation present. Choice of agent should be individualized. Routine anticoagulation for heart failure without atrial fibrillation is not indicated.
- If possible, avoid non-steroidal anti-inflammatory drugs (NSAIDs) in HFrEF, because they can cause sodium retention and vasoconstriction and can reduce the effectiveness and increase the toxicity of ACE inhibitors and diuretics.

# **HFPEF MEDICATION CONSIDERATIONS**

- Routine use of nitrates associated with adverse outcomes and should be avoided in HFpEF.<sup>3</sup>
- Mineralocorticoid receptor antagonists may be useful adjunctive therapy.

# RHF MEDICATION CONSIDERATIONS<sup>4</sup>

Judicious use of diuretics as RHF patients are volume sensitive.

<sup>&</sup>lt;sup>3</sup> 2017 Heart Failure Pathway

<sup>&</sup>lt;sup>4</sup> 2013 Heart Failure Pathway

<sup>&</sup>lt;sup>4</sup> Konstam MA, Kiernan MS, Bernstein D et al. Evaluation and Management of Right-Sided Heart Failure A Scientific Statement From the American Heart Association. Circulation. 2018;137:e578–e622



**HFrEF Stage C Treatment** ARNI/ACEI/ARB (ARNI preferred; Figures 3A and 3B)\*, AND evidence-based beta-blocker<sup>†</sup> (Figure 3C) with diuretic agent (Figure 3D) as needed For patients with For persistently eGFR ≥ 30 For patients with symptomatic mL/min/1.73m<sup>2</sup> or For patients resting HR ≥ 70, For patients with patients despite creatinine ≤ 2.5 meeting eGFR on maximally persistent ARNI/betamg/dL in males criteria (Figure tolerated betavolume overload, blocker/aldosterone or ≤ 2.0 mg/dL in 3F), NYHA class blocker dose in NYHA class II-IV antagonist/SGLT2 females or K+≤ II-IV sinus rhythm, inhibitor, NYHA 5.0 mEq/L, NYHA class II-III class III-IV NYHA Class II-IV Titrate Add Add Add Add Hydralazine + Aldosterone SGLT2 Diuretic agent isosorbide Ivabradine inhibitor antagonist (Figure 3D) dinitrate (Figure 3H) (Figure 3E) (Figure 3F) (Figure 3G)

Figure 2: Treatment Algorithm for Guideline-Directed Medical Therapy Including Novel Therapies

Blue boxes indicate Class I guideline recommendations, while the pink box indicates a Class II recommendation. ACEI = angiotensinconverting enzyme inhibitors; ARB = angiotensin receptor blockers; ARNI = angiotensin receptor-neprilysin inhibitor; eGFR = estimated glomerular filtration rate; HFrEF = heart failure with reduced ejection fraction; HR = heart rate; NYHA = New York Heart Association; SLGT2 = sodium-glucose contransporter-2

†Carvedilol, metoprolol succinate, or bisoprolol

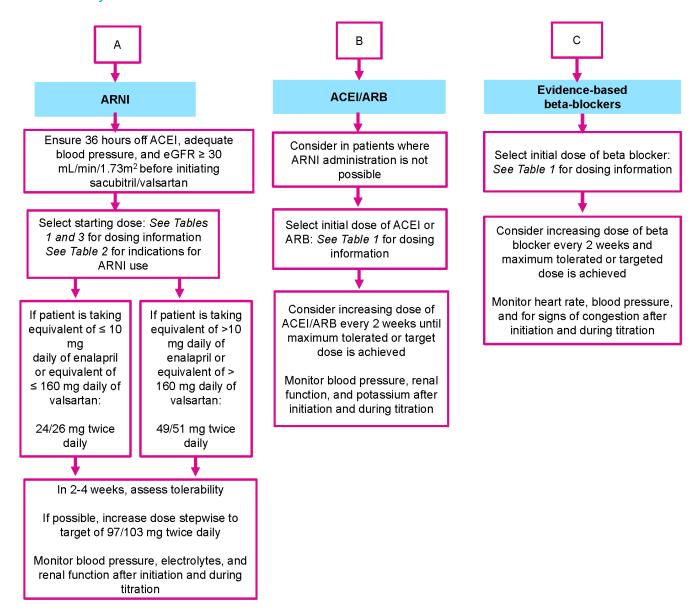
\*ACEI/ARB should only be considered in patients with contraindications, intolerance or inaccessibility to ARNI. In those instances please consult Figure 3 for guidance on initiation.





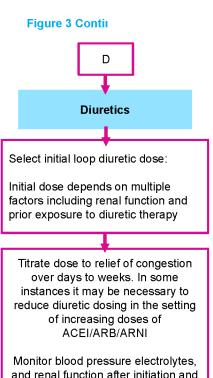
### TITRATION GUIDELINES FOR COMMON HEART FAILURE MEDICATIONS

Figure 3 Guideline-Directed Medical Therapy Including Novel Therapies in the Expert Consensus Decision Pathway for Chronic Heart Failure





### TITRATION GUIDELINES FOR COMMON HEART FAILURE MEDICATIONS

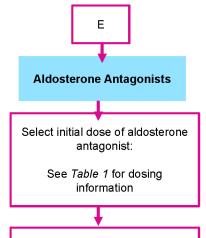


and renal function after initiation and during titration

If reaching high dose of loop diuretic (i.e. equivalent of 80mg of furosemide twice daily) consider

- Changing to a different loop diuretic or
- Adding thiazide diuretic, taken together with loop diuretic

Monitor blood pressure, electrolytes, and renal function after initiation and during titration

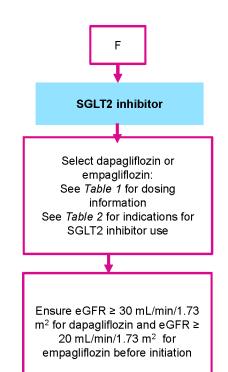


Consider increasing dose of aldosterone antagonist at least every 2 weeks until maximum tolerated or target dose is achieved

Monitor electrolytes (especially potassium) and renal function 2-3 days following initiation, and then 7 days after initiation/titration

Then, check monthly for 3 months and every 3 months afterwards

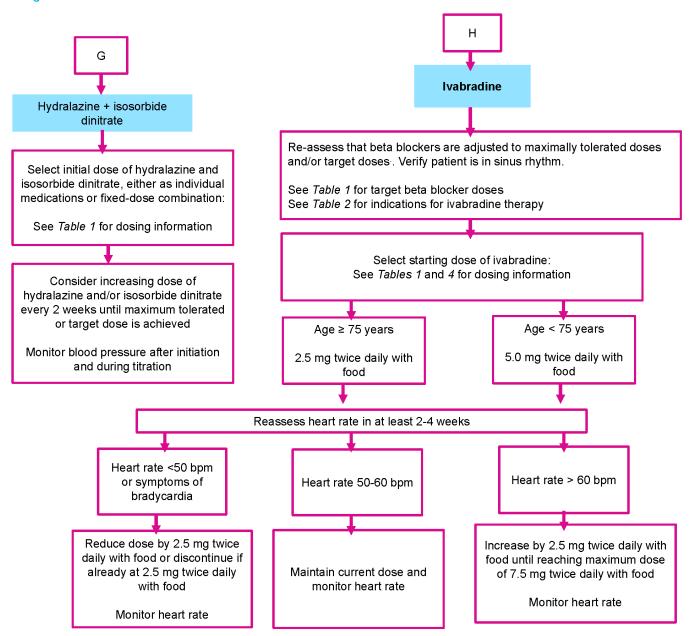
Clinical status may warrant closer monitoring





### TITRATION GUIDELINES FOR COMMON HEART FAILURE MEDICATIONS

**Figure 3 Continued** 





# Table 2: Guideline-Recommended Indications for ARNI, Invabradinen and SGLT2 Inhibitor Use<sup>8</sup>

# **Indications for Use of ARNI**

- HFrEF (EF ≤40%)
- NYHA Class II IV HF
- Administered in conjunction with a background of GDMT for HF in place of an ACEI or ARB

# **Indications for Use of Invabradine**

- HFrEF (EF ≤ 35%)
- On maximum tolerated doses of beta blocker
- Sinus rhythm with a resting heart rate ≥70 bpm
- NYHA Class II or III HF

# **Indications for Use and SGLT2 Inhibitor**

- HFrEF (EF ≤40%) with or without diabetes
- NYHA Class II IV HF
- . Administered in conjunction with a background of GDMT for HF

Table 3: Dose Adjustments of Sacubitril/Valsartan for Specific Patier Populations <sup>9</sup>	nt	
Population	INITIAL DOSE	
High-dose ACEI		
> Enalopril 10 mg total daily dose or therapeutically equivalent dose of another ACEI	49/51 mg	
High-dose ARB	twice daily	
> Valsartan 160 mg total daily dose or therapeutically equivalent dose of another ARB		
De novo initiation of ARNI OR Low or medium dose ACEI		
≤ Enalapril 10 mg total daily dose or therapeutically equivalent dose of another ACEI		
Low or medium dose ARB		
≤ Valsartan 160 mg total daily dose or therapeutically equivalent dose of another ARB	24/26 mg	
ACE/ARB naïve		
Severe renal impairment (eGFR <30 mL/min/1.73 m <sup>2</sup> )*		
Moderate hepatic impairment (Child-Pugh Class B)		
Elderly (age ≥75 years)		

<sup>\*</sup>This population was not studied in the PARADIGM-HF trial. The statement is consistent with FDA-approved labeling indications.



# TABLE 4: Contraindications and Cautions for Sacubitril/Valsartan, Ivabradine, and SGLT2 inhibitors<sup>9</sup>

# Contraindications and Cautions for Ivabradine

### **Ivabradine**

# Contraindications - HF with preserved Ejection Fraction (HFpEF)

- Presence of angina with normal EFHypersensitivity
- Severe hepatic impairment (Child-Pugh C)
- Acute decompensated HF
- Blood pressure <90/50 mm Hg
- Sick sinus syndrome without a pacemaker
- Sinoatrial node block
- 2<sup>nd</sup> or 3<sup>rd</sup> degree AV block without a pacemaker
- Resting heart rate <60 bpm
- Persistent atrial fibrillation or flutter
- Atrial pacemaker dependence

## **Cautions**

- Sinus node disease
- Cardiac conduction defects
- Prolonged QT interval

# Contraindications and Cautions for Sacubitril/Valsartan<sup>9</sup>

# Sacubitril/Valsartan

# **Contraindications**

### Within 36 hours of ACEI use

# History of angiodema with or without an ACEI or ARB

# **Pregnancy**

Lactation (no data)

Severe hepatic impairment (Child-Pugh C)

Concomitant aliskiren use in patients with diabetes

Known hypersensitivity to either ARBs or ARNIs

# **Cautions**

Renal impairment:

- Mild-to-moderate (eGFR 30-59 mL/min/1.73  $\,\mathrm{m}^2$ ): No starting dose adjustment required
- Severe eGRF <30mL/min/1.73 m<sup>2</sup>): Reduce starting dose to 24 mg/26 mg twice daily; double the dose every 2-4 weeks to target maintenance dose of 97 mg/103 mg twice daily as tolerated

Hepatic impairment:

- Mild (Child-Pugh A): No starting dose adjustment required
- Moderate (Child-Pugh B): Reduce starting dose to 24 mg/26 mg twice daily; double the dose every 2-4 weeks to target maintenance dose of 97 mg/103 mg twice daily as tolerated

Renal artery stenosis

Systolic blood pressure <100 mmHg

Volume depletion

# Recommended Indications/Contraindications for Vasodilators 3,4

### **Indications**

 In self-described African American patients with persistently symptomatic NYHA Class III-IV HFrEF despite optimal GDMT, hydralazine-isosorbide dinitrate combinations can reduce morbidity and mortality

<sup>&</sup>lt;sup>3</sup> 2017 HF Guideline

<sup>&</sup>lt;sup>4</sup> 2013 HF Guideline

<sup>&</sup>lt;sup>9</sup> 2021 ACC Heart Failure Pathway



# **Contraindications**

- Hypersensitivity to either agent
- Concomitant use of phosphodiesterase-5 inhibitors or riociquat (i.e. pulmonary HTN med)

### **Cautions**

- Volume depletion
- Hypotension

# Recommended Indications for Cardiac Glycoside Use 4

# **Indications for Use of Digoxon**

- Can be useful in HFrEF for persistent NYHA Class III and IV symptoms despite optimal guideline directed therapy to reduce hospitalizations for HF<sup>3</sup>
- May be useful adjunctive therapy to control heart rate in atrial fibrillation
- In HF, the target steady-state, serum concentration is 0.5 ng/ml to 0.8 ng/ml, preferably obtained prior to receipt of next dose
- Has narrow toxic to therapeutic window

# **Contraindications**

- Significant sinus or AV block
- Acute or subacute kidney injury

# **Cautions**

- Dose adjustments warranted based on ideal body weight and renal function
- Presence of hypokalemia, hypomagnesemia, or hypercalcemia
- Use cautiously with other medications that effect sinus or AV nodal function or impact serum digoxin concentration
- Cardiac amyloidosis

<sup>&</sup>lt;sup>3</sup> 2017 HF Guideline

<sup>&</sup>lt;sup>4</sup> 2013 HF Guideline Mount Sinai Health Partners



# New Therapies for HFrEF: SGLT-2i (Sodium Glucose Cotransporter-2 Inhibitors

SGLT-2 Inhibitors, which were originally used for diabetic control, now have an increasing role in HFrEF care.

**Mechanism:** The primary mechanism for glucose regulation of these medications is through inhibition of reabasorption of glucose in the kidney.

**Impact:** Of note, all 3 SGLT-2i show benefit in HF with DM<sup>10,11</sup>. Please note table below.

Effect of SGLT-2i on Select CV Outcomes in Placebo Controlled Trials <sup>10</sup>			
SGLT-2i	3 Point MACE*	HF Hospitalizations	
Canagliflozin (trade: Invokana) Dapagliflozin (trade: Farxiga) Empagliflozin (trade: Jardiance)	Decreased risk: Canagliflozin -14% Dapagliflozin -14% Empagliflozin -17%	Decrease: Canagliflozin -33% Dapagliflozin -27% Empagliflozin -35%	

<sup>\*3</sup> Point MACE (events/100 pt-yrs): Major nonfatal stroke, nonfatal MI, CV death, HF hospitalizations. Mean follow-up periods ranged from 18 -50 months across studies.<sup>10</sup>

# When to consider and how to prescribe

In patients with and without diabetes, with HFrEF or worsening CKD, (Step 4 if still symptomatic on ARNI, B-Blocker, Mineralocorticoid Receptor Antagonist) consider adding a SGLT2 Inhibitor if GFR >30.

\*If the patient's HbA1C is < 8% and are taking agents which can cause hypoglycemia (e.g. insulin, sulfonylureas/metaglitinides), their regimen may need to be modified to avoid hypoglycemia. For those with HbA1C > 10%, attention should be paid towards excessive glucosuria induced diuresis and an increased incidence of GU/mycotic infections.

\*If not able to tolerate or GFR < 30, add a Glucagon-like peptide 1 receptor agonists (GLP-1 RAs), which are more easily tolerated without the risk of DKA or amputations.

<sup>&</sup>lt;sup>10</sup> Seferovic PM, Coats AJS, Ponikowski P, et al. European Society of Cardiology/Heart Failure Association position paper on the role and safety of new glucose-lowering drugs in patients with heart failure. Eur J Heart Fail. 2020;22:196-213.

<sup>&</sup>lt;sup>11</sup> Davies MJ, D'Alessio DA, Fradkin J, et al. Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia. 2018;61:2461–2498.



# **Contraindications and Cautions for SGLT2 Inhibitors** 9,11,15

# **SGLT2** Inhibitors

# **Contraindications**

- Diabetes Type I due to increased risk of diabetic ketoacidosis
- Known hypersensitivity to drug
- Lactation (no data)
- On dialysis
- Symptomatic hypotension or BP <95 mmHg</li>
- Risk for foot amputations (neuropathy, ulcers, PVD, deformity)
- Recurrent UTI's/genital mycotic infections
- GFR <30

### Cautions

- For HF care, dapagliflozin, eGFR <30 mL/min/1.73 m2
- For HF care, empagliflozin, eGFR <20 mL/min/1.73 m2
- Pregnancy
- Increased risk of mycotic genital infections
- May contribute to volume depletion. Consider altering diuretic dose if applicable
- Ketoacidosis in patients with diabetes:
  - Temporary discontinuation before scheduled surgery is recommended to avoid potential risk for ketoacidosis
  - Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis, regardless of blood glucose level
- Acute kidney injury and impairment in renal function: consider temporarily discontinuing in settings of reduced oral intake or fluid losses
- Urosepsis and pyelonephritis: evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated
- Necrotizing fasciitis of the perineum (Fournier's gangrene): rare, serious, life-threatening cases have occurred in both female and male patients; assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise
- Osteopenia



Of note, a SGLT-2i diabetic medication, **Dapagliflozin (Trade: Farxiga)**, was FDA approved <sup>12</sup> in May 2020 for adults with NYHA Class II-IV HFrEF with and **without DM** to reduce the risk of cardiovascular death and heart failure hospitalizations. In 2019, in the Dapagliflozin And Prevention of Adverse-Outcomes in Heart Failure (DAPA-HF) trial <sup>1313</sup>, a randomized, double-blind, placebo-controlled study of nearly 5,000 HFrEFpatients who received 10 mg daily of dapagliflozin in addition to standard care exhibited fewer cardiovascular deaths, hospitalizations for heart failure, and urgent heart failure visits compared to controls receiving the placebo after 18 months.

- 26% relative risk reduction and 5% absolute risk reduction for composite outcome of CV death or the worsening of HF (triggering hospitalization or urgent visit requiring IV diuretics)
- NNT was 21 for death or hospitalization for HF or urgent visit.
- Findings were similar in those with and without diabetes.
- Contraindications and cautions in below table below
   Dapagliflozin is covered through a majority of payers. Of note, costs \$589 per month (\$7,068 annually), without discount<sup>14</sup>.

# **HFpEF Consideration**

Consider use of SGLT-2i (GFR >30) or GLP-1 Agonists if SGLT-2i contraindicated.
 However, trials ongoing to evaluate impact of SGLT-2i in HFpEF

Vaccinations <sup>16</sup>	
Influenza vaccine	Recommended for all patients with HF
Pneumococcal vaccination	The PPSV23 is recommended for all adult patients with heart failure.  Administration of PCV13 should also be considered for patients <u>&gt;</u> 65 years old

<sup>&</sup>lt;sup>9</sup> 2021 HF Guidelines

<sup>&</sup>lt;sup>12</sup> FDA approves new treatment for a type of heart failure. FDA. 5 May 2020. Updated 22 May 2020. https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-type-heart-failure

<sup>&</sup>lt;sup>13</sup> McMurray JV, Solomon SD, Inzucchi SE, et al. Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction. N Engl J Med. 2019;381(21):1995-2008.

<sup>&</sup>lt;sup>15</sup> Colucci WS. Secondary pharmacologic therapy in heart failure with reduced ejection fraction (HFrEF) in adults. UpToDate. 14 April 2020. Accessed 17 June 2020. https://www.uptodate.com/contents/secondary-pharmacologic-therapy-in-heart-failure-with-reduced-ejection-fraction-hfref-in-adults

<sup>&</sup>lt;sup>14</sup> www.goodRx.com. Accessed 2 June 2020.

<sup>&</sup>lt;sup>16</sup> Matanock A, Lee G, Gierke R, et al. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Updated Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep 2019;68:1069–1075.

# **CARE DELIVERY STEPS & CLINICAL INTEGRATION MODELS**

- A wide-variety of team members can be involved in the diagnosis, severity classification and care of heart failure. Please see table 5 below for care delivery steps.
- Below are **potential team members and options** to integrate primary and advanced care for heart failure patients.

Table 5: Care Delivery Step	Possible Team Member(s)
Diagnosis and Severity Classification	Specialist, PCP, APN
Initial Treatment (Medications, Nutrition, Vaccines)	Specialist, PCP, APN, Pharmacy
Maintenance Treatment (Medication Adjust/Adherence, Nutrition, Vaccines)	Specialist, PCP, APN, Pharmacy
Self-Management (Weight monitoring/ Symptom response, Motivational Interviewing)	Pharmacy, Care Management (RN), Health Coaches, Certified Diabetic Educators
Coordinate Specialty Treatment or Testing / Advanced Care	Care Management (SW, RN)
Behavioral Health- Screen and Refer/ Initiate Treatment	PCP, APN, Pharmacy, LCSW (If available)
Care Management / Home Care Services	CM (RN, SW), Home Health Aide, Community Paramedicine
Tele-monitoring / Home Care Services	Specialist, Care Management (RN), Home Health Aide
Palliative Care- Screening	Specialist (Cardiologist, Pulmonologist, or Palliative Care), PCP, APN, Pharmacy, Care Management (RN)

Team Member Acronym Legend		
Acronym	Full Name	
PCP	Primary Care Provider	
APN	Advanced Practice Nurse	
RN	Registered Nurse	
LCSW	Licensed Clinical Social Worker	
SW	Social Worker	

# **TESTING & REFERRAL**

# USE OF BNP IN HEART FAILURE<sup>3</sup>

B-type natriuretic peptide (BNP) and N-terminal pro-B type natriuretic peptide (NT-proBNP) are the most studied biomarkers in Heart Failure:

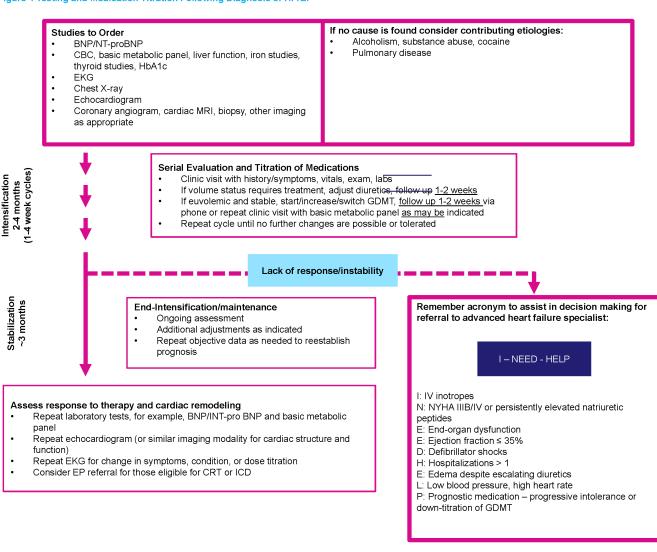
- BNP is released in direct relationship to myocardial wall stress.
- It plays a role in diagnosis and prognostication.
- Higher concentrations of BNP or NT-proBNP in an ambulatory patient with HFrEF informs high risk, particularly when the concentrations are rising.
- Current clinical practice guidelines give a Class I recommendation to measure NTproBNP or BNP to support a clinical diagnosis of HF, to assess disease severity, or to establish prognosis.
- More recently, biomarkers have been examined for their role as a marker of clinical responsiveness to GDMT for HFrEF. Patients whose natriuretic peptide concentrations do not fall with GDMT ("nonresponders") have a worse prognosis.
- Measurement can support clinical judgment with respect to prescription of GDMT, and to provide helpful objective data regarding decision-making for referral to advanced HF therapies.
- In the setting of worsening symptoms, the reassessment of BNP or NT-proBNP may be informative.
- However, serial assessment of BNP or NT-proBNP to guide aggressive titration of GDMT is not indicated and not warranted.
- Several factors may interfere with the interpretation of natriuretic peptide concentrations:
  - Severe renal dysfunction
  - o Sacubitril/valsartan (Entresto) will increase BNP levels due to neprilysin inhibition, and concentrations tend not to return to baseline despite chronic therapy. BNP concentrations will increase (while NT-proBNP will most often fall) with ARNI therapy, and thus it may be more prudent to check only NT-proBNP in patients on ARNI.
  - o Also, transient increases in natriuretic peptide levels have been documented in the initial phases of beta-blocker initiation; such changes should not preclude uptitration of beta-blocker therapy, which should be guided by patient tolerance instead of asymptomatic change in natriuretic peptide levels.

**HFpEF BNP considerations:** Absolute values are lower than in HFpEF, with up to 30% of HFpEF patients having normal levels<sup>17</sup>.

<sup>&</sup>lt;sup>3</sup> 2017 Heart Failure Pathway

<sup>&</sup>lt;sup>17</sup> Henning RJ. Diagnosis and treatment of heart failure with preserved left ventricular ejection fraction World J Cardiol 2020 January 26; 12(1): 7-25

Figure 4 Testing and Medication Titration Following Diagnosis of HFrEF



BNP = B-type natriuretic peptide; CBC = complete blood count; CRT = cardiac resynchronization therapy; EKG = electrocardiogram; EP = electrophysiology; GDMT = guideline-directed medical therapy; HbA1c = hemoglobin A1c; HFrEF = heart failure with reduced ejection fraction; ICD = implantable cardioverter defibrillator; IV = intravenous; MRI = magnetic resonance imaging; NT-proBNP = N-terminal pro-B-type natriuretic peptide; NYHA = New York Heart Association

# HFpEF Evaluation and Testing Considerations 17,18

- Consider Amyloidosis (Red Flag Sxs- Carpal Tunnel, Spinal Stenosis, Neuropathy).
   Note: High baseline BNP levels and serum troponin concentrations are highly suggestive of cardiac amyloidosis, allowing differentiation from other etiologies of cardiac hypertrophy. In cardiac amyloid, the electrocardiogram may show low voltages despite the presence of ventricular hypertrophy on the echocardiogram.
- If etiology of HFpEF remains unclear consider Rheumatologic causes (Scleroderma, Sarcoidosis, Connective Tissue Disease).
- Cardiac imaging plays an important role in diagnosis:
  - Echocardiogram: EF>50%, LVH, pulmonary hypertension, and evidence of significant diastolic dysfunction are common findings.
  - Cardiac MRI: useful in evaluating myocardial extracellular volume, detecting infiltrative processes, and assessing scar burden (2013 guideline).
  - Technetium pyrophosphate scanning can be useful in the evaluation of patients with suspected cardiac amyloidosis.
- Cardiac catheterization: invasive hemodynamic assessment of LV, RV, and pulmonary artery pressures, at rest and with exercise, and endomyocardial biopsy are helpful when noninvasive evaluation is inconclusive.

# RHF Evaluation and Testing Considerations<sup>5</sup>

- RHF impairs LV filling leading to decreased Stroke Volume and Cardiac Output, neurohormonal activation, salt and water retention, increased central venous pressure, systemic venous hypertension, congestive hepatopathy and cardiorenal syndrome.
  - Cardiorenal syndrome- Increased CVP and renal vein pressure and decreased cardiac output lead to renal dysfunction.
  - Cardiohepatic syndrome- Due to hepatic congestion and decreased perfusion.
     May lead to cirrhosis.

<sup>&</sup>lt;sup>5</sup> Konstam MA, Kiernan MS, Bernstein D et al. Evaluation and Management of Right-Sided Heart Failure A Scientific Statement From the American Heart Association. Circulation. 2018;137:e578–e622

<sup>&</sup>lt;sup>17</sup> Henning RJ. Diagnosis and treatment of heart failure with preserved left ventricular ejection fraction World J Cardiol 2020 January 26; 12(1): 7-25

<sup>&</sup>lt;sup>18</sup> Wolfson AM, Shah KS, Patel JK. Amyloid and the Heart. Current Cardiology Reports (2019) 21: 164.

# When to Refer to a HF Specialist

# Triggers for HF Patient Referral to a Specialist/Advanced Heart Failure Program<sup>3, 9, 19</sup>

New-onset HF (regardless of EF): Refer for evaluation of etiology, guideline-directed evaluation and management of recommended therapies, and assistance in disease management, including consideration of advanced imaging, endomyocardial biopsy, or genetic testing for primary evaluation of new-onset HF

Chronic HF with high-risk features, such as development of 1 or more of the following risk factors:

- Need for chronic IV inotropes
- Persistent NYHA functional class III-IV symptoms of congestion or profound fatigue
- Systolic blood pressure ≤90 mm Hg or symptomatic hypotension
- Creatinine ≥1.8 mg/dl or BUN ≥43 mg/dl
- Onset of atrial fibrillation or ventricular arrhythmias or repetitive ICD shocks
- 2 or more emergency department visits or hospitalizations for HF in prior 12 months
- Inability to tolerate optimally dosed beta-blockers and/or ACI/ARB/ARNU and/or aldosterone antagonists
- Clinical deterioration, as indicated by worsening edema, rising biomarkers (BNP, NTproBNP, others), worsened exercise testing, decompensated hemodynamics, or evidence of progressive re-modeling on imaging
- High mortality risk using a validated risk model for further assessment and consideration of advanced therapies, such as Seattle Heart Failure Model

To assist with management of GDMT, including replacement of ACEI or ARB therapy with ARNI for eligible patients or to address comorbid conditions such as chronic renal disease or hyperkalemia, which may complicate treatment.

Persistent reduced LVEF ≤35% despite GDMT for ≥3 months for consideration of device therapy in those patients without prior placement of ICD or CRT, unless decided therapy is contraindicated or inconsistent with overall goals of care.

# Second opinion needed regarding etiology of HF; for example:

- Coronary ischemia and the possible value of revascularization
- Suspected myocarditis
- Established or suspected specific cardiomyopathies, e.g., hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasis, Chagas disease, restrictive cardiomyopathy, cardiac sarcoidosis, amyloidosis, aortic stenosis.
- Valvular heart disease and the possible value of valve repair

Annual review of patients with established advanced HF in which patients/caregivers and clinicians discuss current and potential therapies for both anticipated and unanticipated events, possible HF disease trajectory and prognosis, patient preferences, and advanced care planning.

Assessment of patient for possible participation in a clinical trial.

<sup>&</sup>lt;sup>3</sup> 2017 Heart failure Pathway

<sup>&</sup>lt;sup>9</sup> 2021 HF Guidelines

<sup>&</sup>lt;sup>19</sup> Department of Cardiology, Mount Sinai Health System Mount Sinai Health Partners February 2022

# When to Refer for Device Therapy

- Consider EP referral for primary ICD or CRT in patients with:
  - o EF ≤ 35% for at least 90 days (or 40 days post MI) on chronic GDMT.

# When to Refer to Cardiac Rehab<sup>20</sup>

People of all ages with heart conditions, including HF, can benefit from a cardiac rehab program.

- Medicare and most other insurers provide reimbursement for cardiac rehab for HFrEF.
  - Exceptions include cardiac rehab in the wake of procedures to implant a pacemaker or implantable cardioverter defibrillator (ICD).
  - Coverage after heart failure is usually limited to patients with compromised EF.
     Specifically, patients with left ventricular ejection fraction of 35% or less and New York Heart Association Class II to IV symptoms with at least 6 weeks of heart failure therapy will be covered. Anyone outside this criteria will not be covered.

# **Mount Sinai Heart's Cardiac Rehabilitation Program**

Cardiac Rehabilitation has substantial benefits in driving outcomes for most patients with Heart Failure. Providers who refer patients can expect a 6-12 weeks (2-3x a week) comprehensive, individualized program, well beyond exercise and diet to include education, counseling, and emotional support, among other services. Program is covered by Medicare, NY State Medicaid, and most commercial plans.

Consider referring patients to Mount Sinai Heart's Cardiac Rehabilitation Program if patient has the following diagnosis or condition:

- Stable, HFrEF, with left ventricular ejection fraction of 35% or less and New York Heart Association class II to IV symptoms with at least 6 weeks of heart failure therapy.
- Stable Angina
- Hx of PCI
- Hx of MI within the preceding 12 months
- Bypass or valve surgery
- Heart Transplant
- Any patients with diabetes who you believe will benefit. (Diabetes alone is not a covered condition/diagnosis but we can encourage them to enroll into our Medical Fitness program).
- Minimal insurance coverage for HFpEF if no other cardiac history.

### Locations and How to Refer

**Mount Sinai Doctors - East 85th Street** 

Address: 234 E 85th Street, Lower Level, New York, NY 10028

Phone: 212-241-8597

# Mount Sinai South Nassau Cardiac Rehabilitation Program

The MSSN Cardiac Rehabilitation Program is a 36 session program where patients commit to coming to the Center every M-W-F for 12 weeks. The program is covered by Medicare and the

<sup>&</sup>lt;sup>20</sup> (American Heart Association: Am I Eligible for Cardiac Rehab: <a href="https://www.heart.org/en/health-topics/cardiac-rehab/am-i-eligible-for-cardiac-rehab">https://www.heart.org/en/health-topics/cardiac-rehab/am-i-eligible-for-cardiac-rehab</a>

program accepts NY Medicaid, and most commercial plans. When a referral is made to the Cardiac Rehabilitation Program insurance is verified, authorizations obtained and patients are called to inform them of any copays and out of pocket expenses they will incur.

MSSN Cardiac Rehabilitation program follows CMS strict admissions guidelines for Outpatient Cardiac Rehabilitation. Listed below are the diagnoses that are accepted:

- An acute myocardial infarction within the preceding 12 months
- A coronary artery bypass surgery
- · Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty or coronary stenting
- A heart or heart-lung transplant
- Heart Failure: Stable, chronic heart failure is defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks

# **Locations and How to Refer**

**Mount Sinai South Nassau** 

Address: 440 Merrick Road, Oceanside, NY 11572

Phone: 516-255-8280

# **Suggested Actions for Managing Comorbities in Heart Failure Patients**

ratients			
Managing Comorbidities of Heart Failure <sup>3, 9, 19</sup>			
Comorbidity	Association with Heart Failure Outcomes	Clinical Trial Evidence for Modulating Comorbidity	Suggested Action
		Cardiova	ascular
Coronary Artery Disease	Strong	Strong	Evaluate and revascularize in appropriate patients
Atrial Fibrillation/Flutter	Strong	Intermediate	Treat according to current ACC/AHA/HRS Guideline for the Management of Patients with A-Fib
Mitral Regurgitation	Strong	Intermediate	Refer to structural heart disease expert & treat according to current AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease. Consider transcatheter intervention in carefully selected patients with symptomatice HF and secondary MR
Aortic Stenosis	Strong	Strong	Refer to structural heart disease expert & treat according to current AHA/ACC Guideline for the Management of Patients with Valvular Heart Disease
Hypertension	Uncertain	Strong for prevention	Treat according to ACC/AHA hypertension guidelines
Dyslipidemia	Uncertain	Strong for prevention	Treat according to ACC/AHA Guidelines on the Managerment of Blood Cholesterol and the ACC

<sup>&</sup>lt;sup>3</sup> 2017 Heart Failure Pathway

<sup>&</sup>lt;sup>9</sup> 2021 HF Guidelines

<sup>&</sup>lt;sup>19</sup> Department of Cardiology, Mount Sinai Health System Mount Sinai Health Partners February 2022

			ECDP on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of ASCVD Risk
Peripheral Vascular Disease	Moderate	None	Treat according to current AHA/ACC vascular guidelines
Cerebrovascular Disease	Moderate	Weak	Treat according to current AHA stroke guidelines
		Noncardio	vascular
Obesity	Moderate (inverse association)	Weak	Further data needed
Chronic Lung Disease	Strong	Weak	Optimize therapy, consider pulmonary consultation, Smoking cessation
Diabetes Mellitus	Strong	Strong	Optimize therapy, consider SGLT-2i, consider endocrine consult & follow current American Diabetes Association Standards of Medical Care in Diabetes
Chronic Renal Disease	Strong	Strong	Optimize RAASi therapy, consider nephrology consult, administer SGLT2 inhibitor, use hydralazine/ISDN if ARNI/ACEI/ARB cannot by used
Anemia	Moderate	Weak	Evaluate secondary causes, consider transfusing in severe cases
Iron Deficiency	Strong	Intermediate	Consider intravenous iron replacement for symptom improvement in NYHA Class Iland III and iron deficiency (ferritin <100 mg/mL or 100 to 300 ng/mL if transferrin saturation is <20%), to improve functional status and QoL
Thyroid Disorder-hypo or hyper	Strong	Weak	Consider referral to endocrinologist and/or treatment
Sleep Disordered Breathing	Strong	Intermediate	Consider sleep study and treat severe obstructive sleep apnea to improve sleep quality, consider referring to sleep specialist. Adaptive servoventilation should not be used in HF patients with central sleep apnea
Hyperkalemia	Uncertain, may limit initiation and titration of GDMT	Weak	Recommend dietary modifications, consider treatment with patiromer

# HFpEF Consideration<sup>17</sup>

Management of co-morbid conditions is primary focus of care for HFpEF. Major disease focus areas: Atrial fibrillation, Coronary Artery Disease, Diabetes, Pulmonary Hypertension, Obesity, Cardiac Valvular Disease, Chronic Anemia and Rheumatologic Disease.

<sup>&</sup>lt;sup>17</sup> Henning RJ. Diagnosis and treatment of heart failure with preserved left ventricular ejection fraction World J Cardiol 2020 January 26; 12(1): 7-25.

# **Palliative Care**

# Background<sup>28</sup>

- Palliative care is beneficial at any stage of a serious illness<sup>29</sup>
- Palliative care, and the medical sub-specialty of palliative medicine, is specialized medical care for people living with serious illness
- It focuses on providing relief from the symptoms and stress of a serious illness.
- The goal is to improve quality of life for both the patient and their family

# **Referral Criteria**

Consider a specialty-level palliative care referral for patients who meet any of these criteria:

- NYHA class III/IV symptoms with frequent heart failure readmissions
- Anxiety or depression adversely affecting patient's quality of life or their ability to manage their illness
- Assistance with decision-making regarding advanced therapies (VAD, transplant, home inotropic therapy)

# **Referral Options for Palliative Care Within MSHS**

Patients with Congestive Heart Failure may be referred to one of two practices. The services provided at each location are identical; please choose the location that is most convenient to your patient.

# **Mount Sinai Health System Palliative Care Practices**

- To make a referral to the Martha Stewart Center for Living at 1440 Madison Avenue, please call: 212-241-1446
- To make a referral to the Martha Stewart Center for Living Downtown at Union Square, please call: 212-844-1712

Remote patient monitoring facilitates care. Strongly consider use of pulmonary artery pressure monitoring (CardioMEMS) to reduce heart failure hospitalization rates.

<sup>&</sup>lt;sup>28</sup> Information developed and provided by the Mount Sinai Brookdale Department of Geriatrics and Palliative Medicine

<sup>&</sup>lt;sup>29</sup> Center to Advance Palliative Care; Serious Illness Quality Alignment HUB: State Palliative Care Definitions and Standards. Available at: <a href="https://www.capc.org/documents/133/">https://www.capc.org/documents/133/</a>).

# **Remote Patient Monitoring (RPM)**

Remote patient monitoring is important in heart failure management for select patients using these two approaches:

# CardioMEMS

- Consider use of pulmonary artery pressure monitoring (CardioMEMS) to reduce heart failure hospitalization rates, for both HFrEF and HFpEF<sup>19</sup>
- o Many current Mount Sinai patients (especially HFpEF and RHF) benefit from this monitoring

# Connected Hearts Program

- Using Omron<sup>®</sup> devices for home blood pressure measurement and weight measurement via Bluetooth data hub transmission to Epic EMR flowsheet
- Clinical Pharmacist monitors data and intervenes directly with patients on medications, diet and care coordination

# **Pharmacy**

- Pharmacists are a key part of the care team for chronic disease management including heart failure, diabetes, and COPD
- The team of pharmacists is rapidly expanding in primary and specialty care
- They are credentialed providers that can prescribe and adjust medications through the Collaborative Drug Treatment Model<sup>22</sup>

# Referrals to pharmacists are appropriate for:

- Uncontrolled chronic diseases, such as:
  - o Hypertension, Diabetes, Heart Failure, Asthma, COPD
- Polypharmacy
- Medication Reconciliation
- Medication Adherence

# **Home Health**

- Referrals for Home Health should be handled through the designated Home Health nurse coordinator, a member of the care management team
- The Home Health nurse coordinator will assess the patient's needs and determine appropriateness of Home Health
- **Telephonic education and reinforcement** can be also be delivered by the Nurse Clinical Coordinator. (The Home Health RN will not provide patient interventions, they will refer to the nurse care coordinator, if needed.)
- Providing Home Health nursing and therapy can promote recovery in vulnerable HF patients with post-hospital syndrome and potentially reduce readmissions<sup>23</sup>
- Nursing interventions can include various educational components, including recognition of HF symptoms with an action plan, dietary guidelines, medication management, and weight monitoring.

<sup>&</sup>lt;sup>19</sup> Department of Cardiology, Mount Sinai Health System

<sup>&</sup>lt;sup>22</sup> Academy of Managed Care Pharmacy, Practice Advisory on Collaborative Drug Therapy Management, https://www.amcp.org/sites/default/files/2019-03/Practice%20Advisory%20on%20CDTM%202.2012\_0.pdf, accessed online July 28, 2020

<sup>&</sup>lt;sup>23</sup> Jones CD, Bowles KH, Richard A, Boxer RS, Masoudi FA. High-Value Home Health Care for Patients With Heart Failure: An Opportunity to Optimize Transitions From Hospital to Home. Circulation. 2017;10(5):e003676.

# Care Coordination in Heart Failure at MSHS<sup>24</sup>

- The medical complexity inherent in most patients with HF generally requires the involvement of multiple clinicians across many care settings
- Interdisciplinary, team-based care may be the most effective approach to complex HF care
- Mount Sinai Health Partners Care Management social workers and nurses partner with patients, family caregivers, and providers to identify and address known risk factors that can impact patients' health
- Care Management intervention includes:
  - A comprehensive assessment of the patient's understanding of and ability to manage their illness and the psychosocial issues that impact their care
  - Development of a comprehensive care plan to set goals to optimize health and quality of life

# Referral Criteria may include those with:

- Multiple no-shows
- Unexplained non-adherence to medications, testing or treatment
- Demonstrated difficulty managing symptoms and/or disease processes (including those newly diagnosed)
- Frequent admissions or ED visits that may be preventable with additional support
- Complex family dynamics that deplete the provider
- · Difficulty accessing needed community-based care
- A high "worry score" (patients you as the provider are most worried about from visit to visit)

# How to refer to care management:

- Use the MSHP Care Management Referral in Epic (order #391414)
- Email mshpcmreferral@mountsinai.org or call 212-241-7228
  - o Providers who refer patients can expect:
    - Prompt and efficient processing of your referral
    - Communication about referral processing and assignment through the Epic Inbasket
    - Follow up from clinical staff within one week of assignment

# Behavioral Health<sup>25</sup>

Patients should be screened for depression using the PHQ-2/PHQ-9 and referred to psychiatric services, as indicated, through their current care pathway depending on their clinic.

- Individuals with CHF are 2-5 times more likely to have anxiety and depressive disorders compared with the general population<sup>26</sup>
- Patients with chronic medical illness and a co-morbid psychiatric diagnosis have poorer quality of life, increased functional disability, and increased mortality, to name a few
- Increased recognition of treatment of these comorbid conditions is essential

<sup>&</sup>lt;sup>24</sup> Information developed and provided by the Mount Sinai Care Management Department

<sup>&</sup>lt;sup>25</sup> Information developed and provided by the Mount Sinai Department of Psychiatry.

<sup>&</sup>lt;sup>26</sup> Ratcliff, Chelsea & Fletcher, Terri & Petersen, Nancy & Sansgiry, Shubhada & Kauth, Michael & Kunik, Mark & Stanley, Melinda & Cully, Jeffrey. (2017). Recognition of anxiety, depression, and PTSD in patients with COPD and CHF: Who gets missed?. General Hospital Psychiatry. 2017;47:61-67

# Rapid Follow Up Clinics (RFU Clinics)

- RFUs can provide additional post-discharge support
- Treatment in specialized HF clinics using nurse intervention reduces readmission frequencies and improves quality of care for HF patients<sup>27</sup>
- For referrals contact the individuals listed below

Campus	Failure Rapid Follow Up Clinic Informati Primary Contact	Hours & Location	Uses ReDS Vest (Y/N)
MSH	Jennifer Ullman, NP (212) 241-7300 Jennifer.Ullman@mountsinai.org	<ul> <li>Wednesdays 8:00 am to 5:00 pm, flexible hours upon request</li> <li>1190 Fifth Avenue, GP1C</li> </ul>	Yes
MSBI	Jayitha Janardhanan, NP (646) 400-4889 <u>Jayitha.Janardhanan@mountsinai.org</u>	<ul> <li>Tuesday 9:00 am to 12:00 pm</li> <li>10 Union Square East</li> </ul>	No
MSQ	Dr. Preethi Pirlamarla, MD Preethi.Pirlamarla@mountsinai.org	<ul> <li>Monday 1:00 pm to 5:00 pm, Tuesday 1:00 pm to 5:00 pm, Thursday 1:00pm to 2:00 pm, Friday 9:00am to 12pm</li> <li>MSQ Ambulatory Pavilion 2510 30th St., 5th Floor</li> </ul>	Yes, outpatient only
MSM	Cathleen Varley, NP (212) 523-2700 Cathleen.Varley@mountsinai.org	<ul> <li>Monday thru Thursday 8:00 am to 4:30 pm, Friday 8am- 1pm</li> <li>440 West 114<sup>th</sup> Street, 2<sup>nd</sup> Floor, Cardiovascular Institute</li> </ul>	Yes (inpatient to be available 2022)
MSSN	Jozelle Diaz, NP Jozelle.Diaz@snch.org	<ul> <li>Monday and Wednesday through Friday 11:00 am to 4:00 pm</li> <li>One Healthy Way, Oceanside, NY 11572</li> <li>Telehealth available</li> </ul>	No

# ReDS Vests<sup>27</sup>

MSHS has several vests in use including at Rapid Follow Up clinics

- The ReDS vest measures lung fluid in heart failure patients
- The vest uses radar technology to measure the % of water in the Right Middle Lobe
- It is non-invasive and readings are available within 90 seconds

<sup>&</sup>lt;sup>27</sup> Gustafsson F, Arnold JMO, Heart failure clinics and outpatient management: review of the evidence and call for quality assurance, European Heart Journal, 2004;25(18):1596–1604

# **Certified Diabetes Educators (I.E. Wellness Coaches)**

Certified Diabetes Educators (CDEs) practice at the top of their license. They can help manage patients with both a diagnosis of diabetes and heart failure. CDEs are embedded in primary and specialty care

Patients receive customized education and strategies to achieve optimal quality of life. CDE engagement includes:

- Assessing and educating patients and caregivers on their health condition(s)
- Cohesive collaboration with the medical team to integrate evidenced-based care into patient's plan of care
- Ongoing monitoring, real time support and follow up by the medical team
- Seamless communication amongst the medical team
- Specialty care consultations for high risk patients
- Oversight and training by a Heart Failure Medical Director, and outcomes evaluation

# **Community Paramedicine (CP)**

Community Paramedicine offers rapid evaluation and in-home treatment for patients with acute symptoms with the goal of stabilizing the patient at home and preventing ED visits. The response is provided by a paramedic with ED physician oversight and telemedicine support. There is a <60 min response time to anywhere in New York City, 24/7. We also offer service to Nassau County, Long Island. Relevant diagnostic tools and medications that can be performed/administered in the home setting include:

- EKG
- Vital Signs
- Complete Physical Assessments
- IV Fluids
- IV Medications including Lasix, Zofran and more!
- Pain management

# Learn more about this service:

Email Ari Breslauer, MPH, CCEMT-P, Program Director, Community Paramedicine at Ari.Breslauer@mountsinai.org

# Who can initiate this service at my practice?

Any clinician (including mid-levels and RN's) can trigger this service for their patient who needs
urgent evaluation and treatment at home, with the goal of stabilizing the patient and preventing an ED
visit.

# **Initial and Subsequent Office Visit Templates**

	Initial Visit (confirm diagnosis, etiology, and initiate appropriate therapy)
Provider History	Duration of illness
	NYHA Class (I-IV)
	Weight gain/loss, new or worsening edema, orthopnea, and dyspnea
	Assessment of comorbidities including obesity, prior CAD, atrial fibrillation, DM, HLD, and smoking
	Potential clues suggesting etiology of heart failure if unknown (ischemic vs. non-ischemic).

Assess, if indicated, for any known or suspected anemia, valvular, lung, liver, thyroid, renal, or rheumatologic diseases, pulmonary hypertension, sleep apnea, HIV infection, recent pregnancies, relevant travel, or symptoms of pheochromocytoma Complete medication review, including OTC medications PHQ 2 and if positive, PHQ 9. Current/past alcohol use Prior drug abuse, including IVDA Diet and fluid intake Family history Inquire if Healthcare Proxy form has been completed Previous COVID-19 infection and antibody status Blood pressure, pulse, weight, BMI, possibly 02 sat Assessment of volume status Cardiovascular exam (especially JVD, hepatojugular reflex, and presence of S3) Provider Telemedicine consideration: **Physical** "edema check": ("PLACE YOUR FINGERS WHERE YOU HAVE SWELLING ON YOUR LOWER LEG, PUSH DOWN HARD AND REMOVE, DO YOU SEE AN INDENTATION? IF YES, HOW DEEP IS THAT INDENTATION 1. Lab work CBC with diff BMP, magnesium Lipid profile BNP or NT-proBNP (if no prior documentation) Troponin (risk marker) Digoxin level, if signs or symptoms of toxicity or recent addition of interacting drug PT/INR (Every patient on warfarin should be enrolled in an anticoagulation clinic or have his/her PT/INR followed closely by a designated provider.) 2. Consider the following in appropriate patients if the etiology of HF is unknown TSH LFTs Diagnostic HIV Ab (if not recently documented) **Studies** Anemia panel and Hemochromatosis screen (transferrin sat, ferritin) Rheumatologic evaluation Evaluation for amyloidosis, if red flags present Others as indicated 3. Procedures 12-lead EKG: document QRS duration Echo with Doppler flow studies; document EF Chest X-ray: PA & Lat Ischemic workup in appropriate patients Telemedicine considerations When possible, get blood tests done ~ 1 week prior to virtual visit, either at office, local phlebotomy

center (Labcorp/Quest) or have blood drawn at home (Apex Lab)

Results of home cardiac rhythm (KardiaMobile) monitoring can be transmitted to practice in

When available, staff can outreach to patient in advance of visit to collect needed information

Patient should upload results of home monitoring into Epic or fax to office prior to visit

advance of visit

# For patients with HFrEF

Plan to initiate treatment in stepwise manner. Titrate to target dose as per GDMT.

If the patient is hemodynamically stable, it is generally acceptable to double the dose of the neurohormonal antagonist (Beta-blockers, ACE, ARB, ARNI mineralocorticoid antagonists (i.e. Spironolactone)) when increasing the dose. It is recommended that only one of these agents be increased each visit. Caution is advised if increasing more than one.

# **Document contraindications or intolerance**

- ACEI/ARB: initiate/titrate to target dose, document contraindications/intolerance.
- Use Subcutril/Valsartan (i.e. Entresto) instead of ACE/ARB for patients with NYHA class II-III and LVEF ≤ 35% who are stable an an ACEI/ARB.
- Beta blocker: initiate/titrate using either carvedilol, sustained-release metoprolol succinate, or bisoprolol
- Aldosterone antagonist: initiate/titrate if not contraindicated (GFR>30ml/min,K <5.0 mEg/ml) and NYHA class II-IV HF with LVEF ≤ 35% (NYHA Class II should have hx of prior CV hospitalization or elevated BNP) or post-MI with LVEF ≤ 40% with symptoms of HF or who have DM
- Hydralazine/isosorbide dinitrate: Initiate/titrate in African American patients NYHA class III-IV on standard medical therapy including ACEI/ARB or ARNI, and BB; consider in all patients who cannot tolerate an ACEI/ARB or ARNI unless contraindicated.
- Diuretic: initiate/titrate in patients with fluid retention.
- Ivabradine: if sinus rhythm, HR >70 bpm on maximally tolerated beta blocker, NYHA II-III, and no contraindications
- Digoxin for NYHA III-IV symptoms despite optimal GMT and/or rate control for atrial fib.
- Dapagliflozin (ie SGLT-2i) should be considered as adjunctive therapy, to reduce CV death and worsening HF, even in absence of Type 2 diabetes, unless contraindicated, and after considering potential incremental cost to patient
- Anticoagulation indicated if atrial fibrillation present. Choice of agent should be individualized. Routine anticoagulation for heart failure without atrial fibrillation is not indicated.
- Antiplatelet therapy: as indicated
- Lipid-lowering therapy: as indicated

# For patients with HFpEF.

- Focus on treating volume overload (diuretics, salt restriction) and effectively managing their comorbidities.
- Mineralocorticocoid receptor antagonists may be helpful in HFpEF.
- Consider use of SGLT-2i (GFR >30) or GLP-1 Agonists if SGLT-2i contraindicated.
- Avoid nitrates.

# Consideration s for Patients with Coexisting Type 2 Diabetes

Medical

**Therapy** 

- Metformin remains first line therapy for diabetes (if GFR > 30).
- SGLT-2i (dapaqliflozin, canaglifozin, empaglifozin) are preferred in HFrEF when additional therapy required, unless contraindicated/cautions (Type 1 DM, symptomatic hypotension or SBP <95 mmHg, GFR <30, prior/high risk for DKA, risk of foot amputation (ulcer, PVD, neuropathy, deformity), recurrent UTI's/genital mycotic infections}.
- Thiazolidinendiones (pioglitazone, rosiglitazone) are contraindicated.
- GLP-1 receptor antagonists (exenatide, semaglutide, dulaglutide, liraglutide) can be used if SGLT-2 inhibitors are contraindicated. Contraindications to GLP-1 RA include personal/fam hx of medullary thyroid cancer, MEN Type 2, pancreatitis, gastroparesis, GFR <30. (perhaps remove)
- DPP-4 inhibitors (linagliptin, sitagliptin, alogliptin) should be used cautiously in all patients who have diagnosis. Saxagliptin should not be used. (perhaps remove)

# **Immunizations**

Pneumococcal vaccination (PPSV-23 and possibly PV-13) and annual influenza vaccination in the absence of known contraindications. For telemedicine visits, can be ordered and subsequently administered in office or at local pharmacy.

# **Device** Therapy

- Remote monitoring of BP, pulse, weight, possibly 02 sat.
- Consider EP referral for primary ICD or CRT in patients with:

	<ul> <li>EF ≤ 35% for at least 90 days (or 40 days post MI) on chronic GDMT.</li> </ul>
Escalation Pathway	<ul> <li>Primary Care: Every patient should have a primary care physician (Patients should be seen at least quarterly by PCP or Cardiologist.)</li> <li>Cardiology: All new diagnoses of heart failure, assistance desired with GDMT, including replacement of ACEI/ARB w ARNI, and/or other significant co-existing cardiac disorders</li> <li>Advanced Heart Failure: Refer patients if refractory symptoms or end stage heart failure, (acronym "I-NEED_HELP")</li> <li>Cardiac Rehabilitation: If stable HFrEF, EF &lt;35%, NYHA III-IV despite 6 weeks of HF therapy.</li> </ul>
Other Referrals to Consider	<ul> <li>Sleep Medicine Referral if coexisting obstructive sleep apnea.</li> <li>Care Management referral: frequent ED visits and hospitalizations, multiple no shows, non-adherence to treatment plan, complex psychosocial issues impacting care, difficulty accessing community resources</li> <li>Pharmacist referral (if available): uncontrolled HF, non-adherence to medications, polypharmacy, poorly controlled comorbid diseases, med reconciliation</li> <li>Home Health referral: particularly for recently discharged, vulnerable HF patients</li> <li>Behavioral Health referral: active psychiatric disorders adversely impacting heart failure care, not manageable in primary care setting</li> <li>Wellness Coaches (CDE): for patients with co-existing diabetes</li> <li>Remote patient monitoring for select patients: Connected Hearts Program and Cardiomems</li> <li>Palliative Care referral for NYHA III-IV with frequent admissions, significant anxiety and depression, and assistance with decision-making regarding advanced therapies (LVAD, transplant, home ionotropic therapy)</li> </ul>
Patient Education	<ul> <li>Provide patient/family with the heart failure education booklet, "Managing Your Heart Health", and other general information about heart failure.</li> <li>Technique to measure and record blood pressure, pulse, weight, 02 sat at home</li> <li>How to record and transmit cardiac rhythm, for those with afib/flutter. (KardiaMobile)</li> <li>How to access mychart and any desired clinical apps</li> </ul>
Diet/Fluids	<ul> <li>Limit salt intake to &lt; 3 grams/day</li> <li>Other diets as indicated</li> <li>Fluid restriction &lt;2 L/day (6-8 glasses) for patients with moderate hyponatremia (serum sodium &lt;130 mEq/L) and should be considered in other patients to assist in treatment of fluid overload</li> </ul>

	Subsequent Follow-Up Visits		
Provider History	NYHA Class (I-IV)		
	Document etiology of heart failure		
	<ul> <li>Interval history including recent ED visits, hospitalization, weight changes, new/worsening HF symptoms</li> </ul>		
	Reassessment of status of medical comorbidities		
	Complete medication review and assessment of compliance		
	Determine if Healthcare Proxy form has been completed previously		
Provider Physical	BP, pulse,weight, BMI, possibly 02 sat		
	Assessment of volume status		
	Cardiac exam (especially JVD, hepatojugular reflex, and presence of S3)		

 Telemedicine consideration: "edema check": ("PLACE YOUR FINGERS WHERE YOU HAVE SWELLING ON YOUR LOWER LEG, PUSH DOWN HARD AND REMOVE, DO YOU SEE AN INDENTATION? IF YES, HOW DEEP IS THAT INDENTATION

### 1. Lab work as necessary:

- BMP: check 1-2 weeks after dose titration of ACEI/ARB or spironolactone/eplerenone.
- Magnesium: if on diuretic, check at same interval as BMP
- BNP or NT-proBNP if volume status unclear
- Digoxin level, if signs of toxicity or recent addition of interacting drug
- PT/INR (Every patient on warfarin should be enrolled in an anticoagulation clinic or have their PT/INR followed closely by a designated provider)

# Diagnostic Studies

## 2. Procedures:

- Repeat echo if significant change in clinical status, recent clinical event, on GDMT that may significantly affect cardiac function, or may be candidates for device therapy
- Consider cardiac MRI if cause of HFpEF or RHF unclear

# Telemedicine consideration

- When possible, get blood tests done ~ 1 week prior to virtual visit, either at office, local phlebotomy center (Labcorp/Quest) or have blood drawn at home (Apex Lab)
- Results of home cardiac rhythm monitoring (KardiaMobile) can be transmitted to practice in advance of visit
- Patient should upload results of home monitoring into Epic or fax to office prior to visit
- When available, staff can outreach out to patient in advance of visit to collect needed information

# For patients with heart failure with HFrEF:

# Escalate treatment in stepwise manner. Titrate to target dose as per GDMT.

If the patient is hemodynamically stable, it is generally acceptable to double the dose of the neurohormonal antagonist (BB, ACEI/ARB, MRA, ARNI) when increasing the dose. It is recommended that only one neurohormonal antagonist be increased at each visit. Caution is advised if increasing more than one.

By end of Visit #2, each patient should be on both a beta-blocker and either an ACEI or an ARB. Document contraindications or intolerance

- ACEI/ARB: initiate/titrate to target dose, document contraindications/ intolerance.
- Consider Entresto for patients with NYHA class II-III and LVEF ≤ 35% who are stable on an ACEI/ARB.
- Beta blocker: initiate/titrate using either carvedilol, sustained-release metoprolol succinate, or bisoprolol
- Aldosterone antagonist: initiate/titrate if not contraindicated (GFR ≥30ml/min ,K <5.0 mEq/ml) and NYHA class II-IV HF with LVEF ≤ 35% (NYHA Class II should have hx of prior CV hospitalization or elevated BNP) or post-MI with LVEF ≤40% with symptoms of HF or who have DM
- Hydralazine/isosorbide dinitrate: Initiate/titrate in African American patients NYHA class III-IV on standard medical therapy including ACEI or ARNI, and BB; consider in all patients who cannot tolerate an ACEI/ARB or ARNI unless contraindicated.
- Diuretic: initiate/titrate in patients with fluid retention.
- Ivabradine: if sinus rhythm, HR >70 bpm on maximally tolerated beta blocker, NYHA II-III, and no contraindications
- Digoxin for NYHA III-IV symptoms despite optimal GMT and/or rate control for atrial fib.
- Dapagliflozin should be considered as adjunctive theapy, to reduce CV death and worsening HF, even in the absence of diabetes, unless contraindicated and after considering incremental cost to the patient.
- Anticoagulation: For atrial fibrillation the choice of agent should be individualized. Routine anticoagulation for HF without atrial fibrillation is not indicated.

# Medical Therapy

	Antiplatelet therapy: as indicated				
	Lipid-lowering therapy: as indicated				
	For Patients with HFpEF				
	Continue to treat any volume overload (diuretics, salt restriction) and optimize control of comorbid				
	medical disorders				
	Consider the addition of MRA.  Out it is a second of the control of the cont				
	Consider use of SGLT-2i (GFR >30) or GLP-1 Agonists if SGLT-2i contraindicated.				
	Avoid nitrates.  Matterway and a first line the group for disheres (if CER > 20)				
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Considerations	SBP <95 mmHg, GFR <30, prior/high risk for DKA, risk of foot amputation (ulcer, PVD,				
for Patients	neuropathy, deformity), recurrent UTI/genital mycotic infections}.				
with Co-	Thiazolidinendiones (pioglitazone, rosiglitazone) are contraindicated.				
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Diabetes	are contraindicated. Contraindications to GLP-1 RA include personal/fam hx of medullary thyroid				
	cancer, MEN Type 2, pancreatitis, gastroparesis, GFR <30.				
	DPP-4 inhibitors (linagliptin, sitagliptin, alogliptin) should be used cautiously in all patients who have				
	diagnosis. Saxagliptin should not be used.				
	Pneumococcal vaccination (PV23 and possibly, PV 13) and annual influenza vaccination in the				
Immunizations	absence of known contraindications. For telemedicine visits, can be ordered and subsequently				
	administered in office or at local pharmacy.				
	Remote monitoring of BP, pulse, weight, and possibly 02 sat				
<b>Device Therapy</b>	Consider EP referral for primary ICD or CRT in patients with:				
	<ul> <li>EF ≤ 35% for at least 90 days (or 40 days post MI) on chronic GDMT.</li> </ul>				
	Primary Care: Every patient should have a primary care physician (Patients should be seen at least)				
	quarterly by PCP or Cardiologist.)				
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	Palliative Care referral for NYHA III-IV with frequent admissions, significant anxiety and depression,				
	and assistance with decision-making regarding advanced therapies (LVAD, transplant, home,				
	ionotropic therapy)				
Patient Education	Review recommendations, assess knowledge, treatment adherence; identify/address barriers, needs				
	of patient/ family				
	Reinforce technique to measure and record blood pressure, pulse, weight at home, 02 sat as indicated				
Diet/Fluids	Emphasize the importance of daily weights				
	Assess dietary compliance				
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Assess adherence to fluid restriction, as indicated