Standards of Excellence in Practice
Davis Family Care 2019
Objectives:

In order to continue to provide an excellent standard of care in our facilities, Davis Health System is working together with our physicians to provide acceptable standards based on the most recent literature and practice standards.

Standardization of acceptable practices is beneficial to both the provider and the patient as it will provide continuity of excellence that can be expected from any of Davis Health Care’s facilities.

We realize that this is merely an outline, and will not take away from the provider’s ability to make decisions. Rather, this should be a guideline to follow for best practices. If, at any point in time, an accepted standard should change, it will be reflected in this handbook.
Preventative care for patients over 65 YOA

This discussion took place on May 20\textsuperscript{th} 2016 at the monthly Population health meeting.

- **Breast Cancer**
  - Begin annual mammograms at age 40, and repeat yearly no longer than 24 months apart
  - In individuals over the age of 75, annual mammograms will depend on comorbidities
  - No mammogram if life expectancy is less than 10 years.

- **Prostate Cancer**
  - Discussion with patient should begin at 50 for men who are at average risk and expected to live at least 10 more years
  - Screening should not be performed in men who are 70 years and older or who have a life expectancy of less than 10 years
  - Digital Rectal Exam SHOULD NOT be performed unless the man requests it
  - PSA should be completed if family history of prostate cancer and symptomatic

- **Cervical Cancer**
  - Screening should be stopped after age 65 in patients that have had at least three consecutive negative HPV results within the previous 10 years- the most recent in the last 5 years.
  - Women who have had a total hysterectomy and do not have a history of grade 2 or higher cervical intraepithelial neoplasia should not be screened
- **Lung Cancer**
  - Annual screening using low dose CT in patients 55-80 with a 30 pack history and currently smoke or have quit in the last 15 years
  - Discontinue screening once the patient has been tobacco free for 15 years, or health changes that would limit life expectancy or the willingness/ability to have curative lung surgery

- **AAA Screening**
  - One time screening for men aged 65-75 who have smoked more than 100 cigarettes in their lifetime
  - One time screening for men aged 65-75 who have never smoked, but who have risk factors for AAA
  - AAA screening should NOT be performed in women regardless of smoking history they have significant risk factors.
  - Patients with AAA 3.0-3.9 cm should be monitored with US every 2-3 years (C)
  - Patients with AAA 4-5.4 cm should be monitored with US or CT every 12 mos (C)

- **Cognitive Screening**
  - CMS requires mini COG as part of the yearly AWV
  - The USPTF and the AAFP recommend against routine cognitive screening. The USPSTF found inadequate direct evidence on the benefits of screening for cognitive impairment. The USPSTF found no published evidence on the effect of screening on decision making or planning by patients, clinicians, or caregivers.

- **Vaccinations**
  - For patients over 65 who have not received either pneumonia vaccine, the recommendation is to give the 13 valent vaccine followed by the 23 valent vaccine 1 year later. If the patient has already received the 23 valent vaccine, they can receive the 13 valent any time as long as a year has passed since the previous injection.
  - TdAP is NOT routinely recommended for patients over age 65, and is NOT covered by medicare part B.
Zoster is recommended for patients over age 60 to decrease the rate of post herpetic neuralgia, but is NOT covered at this time by Medicare part B.

Influenza vaccination is recommended yearly for all patients over age 65.

- **Dental Screening**
  - Yearly dental screening is recommended for all patients regardless of whether or not they are edentulous.

- **Vision Screening**
  - Yearly vision screening is recommended, and yearly dilated eye exams are recommended for patients with underlying diabetes, hypertension, and hyperlipidemia.

- **Depression Screening**
  - Yearly depression screening is recommended and should be documented clearly in the chart.

- **BMI**
  - BMI should be assessed at every visit.

- **Statin therapy for CVD**
  
  Use regardless of cholesterol level for patients with ASCVD risk of 7.5-10% or greater

- **Tobacco Use**
  - Tobacco use should be addressed at every visit, and assistance with cessation should be offered.

- **Hypertension Screening**
  - Screen annually
- **Osteoporosis Screening**
  - See section on osteoporosis

- **Colon Cancer Screening (updated 7/18)**
  - Begin at age 50 and continue through age 75.
  - Individualize discussion for patients aged 76-85.
  - Screening not recommended for patients over age 85 or with a 10 year or less life expectancy.
  - Screen with FIT yearly, flexible sigmoidoscopy q 5 years, or colonoscopy q 10 years.
  - DO NOT repeat screen within 10 years if good quality colonoscopy was obtained.

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**TABLE 3**

<table>
<thead>
<tr>
<th>TEST AND INTERVAL</th>
<th>YEARS OF LIFE GAINED PER LUMI PERSONS SCREENED</th>
<th>COLON CANCER-DETECTIVE PREVENTION PER LUMI PERSONS SCREENED</th>
<th>COMPLICATIONS PER LUMI PERSONS SCREENED</th>
<th>LIFETIME COLONOSCOPIES PER PERSON SCREENED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colonoscopy every 10 years</td>
<td>279</td>
<td>24</td>
<td>15</td>
<td>4.0</td>
</tr>
<tr>
<td>Colonoscopy every 5 years</td>
<td>348</td>
<td>22</td>
<td>10</td>
<td>1.7</td>
</tr>
<tr>
<td>FIT every year</td>
<td>244</td>
<td>22</td>
<td>10</td>
<td>1.0</td>
</tr>
<tr>
<td>FIT-DNA every year</td>
<td>251</td>
<td>20</td>
<td>12</td>
<td>1.7</td>
</tr>
<tr>
<td>FIT-DNA every three years</td>
<td>228</td>
<td>20</td>
<td>12</td>
<td>1.0</td>
</tr>
<tr>
<td>Faecal occult blood every year</td>
<td>221</td>
<td>20</td>
<td>10</td>
<td>1.0</td>
</tr>
<tr>
<td>Faecal occult blood every two years</td>
<td>255</td>
<td>23</td>
<td>12</td>
<td>2.5</td>
</tr>
<tr>
<td>Stool-based faecal immunochemical test (FIT) every year</td>
<td>247</td>
<td>23</td>
<td>11</td>
<td>3.3</td>
</tr>
</tbody>
</table>

FIT = fecal immunochemical test; FIT-DNA = multigenerated stool DNA test
Information from reference 2.
*This is a recommendation, and should be discussed in detail with your patients. The studies show lack of utility in cancer screenings in patients with less than 10 years to live, but this should be a personal discussion.

<table>
<thead>
<tr>
<th>TABLE 2: Advantages, Disadvantages, and Costs of Colorectal Screening Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DESCRIPTION</strong></td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Colonoscopy</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Computed tomographic colonography</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>FIT</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Flexible sigmoidoscopy</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Guaiac-based</td>
</tr>
</tbody>
</table>
TOOLS TO AID IN CANCER SCREENING DECISIONS

Lee Index:  http://eprognosis.ucsf.edu/lee.php

Palliative Performance Scale:

Schonberg Index:  http://eprognosis.ucsf.edu/schonberg.php

Clinical Frailty Scale:
http://geriatricresearch.medicine.dal.ca/pdf/Clinical%20Frailty%20Scale.pdf

Eprognosis iphone or ipad applications for breast and colon cancer screening:

Eprognosis website for breast and colon cancer screening:
http://cancerscreening.eprognosis.org

USPTF services selector tool:
http://epss.ahrq.gov/PDA/index.jsp
DECISION AIDS FOR PATIENTS

Should I continue having mammograms?

Should I continue getting mammograms after age 75?
http://archinte.jamanetwork.com/data/Journals/INTEMED/929788/IOI120136sup\n  p1_prod.pdf

Should I get a mammogram? Ages 75+
http://www.wvmedical.com/Site/Content/Departments/Womens_Imaging_Center/CH_Mammography_Ages_75_Pamphlet_2_015_WEB.pdf


Clinical Practice Guidelines for the Management of Hypertension in the Community. A Statement by the American Society of Hypertension and the International Society of Hypertension. 17 December 2013


WWW.USPREVENTIVESERVICETASKFORCE.ORG
Corresponding Values of Systolic BP/Diastolic BP for Clinic, Home (HBPM), Daytime, Nighttime, and 24-Hour Ambulatory (ABPM) Measurements.

<table>
<thead>
<tr>
<th>Clinic</th>
<th>HBPM</th>
<th>Daytime ABPM</th>
<th>Nighttime ABPM</th>
<th>24-Hour ABPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>120/80</td>
<td>120/80</td>
<td>120/80</td>
<td>100/65</td>
<td>115/75</td>
</tr>
<tr>
<td>130/80</td>
<td>130/80</td>
<td>130/80</td>
<td>110/65</td>
<td>125/75</td>
</tr>
<tr>
<td>140/90</td>
<td>135/85</td>
<td>135/85</td>
<td>120/70</td>
<td>130/80</td>
</tr>
<tr>
<td>160/100</td>
<td>145/90</td>
<td>145/90</td>
<td>140/85</td>
<td>145/90</td>
</tr>
</tbody>
</table>

Table 11
Detection of White Coat Hypertension or Masked Hypertension in Patients Not on Drug Therapy

Office BP: 
≥130/80 mm Hg but <160/100 mm Hg after 3 mo trial of lifestyle modification and suspect white coat hypertension

Daytime ABPM or HBPM
BP <130/80 mm Hg

Yes

White Coat Hypertension
- Lifestyle modification
- Annual ABPM or HBPM to detect progression (Class IIA)

No

Hypertension
- Continue lifestyle modification and start antihypertensive drug therapy (Class IIA)

Office BP: 
120-129/<80 mm Hg after 3 mo trial of lifestyle modification and suspect masked hypertension

Daytime ABPM or HBPM
BP ≥ 130/80 mm Hg

Yes

Masked Hypertension
- Continue lifestyle modification and start antihypertensive drug therapy (Class IIB)

No

Elevated BP
- Lifestyle modification
- Annual ABPM or HBPM to detect MH or progression (Class IIB)
Detection of White Coat Hypertension or Masked Hypertension in Patients on Drug Therapy

Detection of White Coat Effect or Masked Uncontrolled Hypertension in Patients on Drug Therapy

- Office BP at goal
  - Yes
    - Increased CVD risk or target organ damage
      - Yes: Screen for masked uncontrolled hypertension with HBPM (Class IIb)
        - HBPM BP above goal
          - Yes: Masked Uncontrolled Hypertension: Intensity therapy (Class IIb)
          - No: Continue current therapy (Class IIa)
      - No: Screening not necessary (No Benefit)
    - No: Office BP ≥5-10 mm Hg above goal on ≥3 agirts
      - Yes: Screen for White coat effect with HBPM (Class IIb)
        - HBPM BP at goal
          - Yes: White Coat Effect: Confirm with ABPM (Class IIa)
          - No: Continue titrating therapy
      - No: Screening not necessary (No Benefit)

Figure 2
Screening for Secondary Hypertension

New Onset or Uncontrolled Hypertension in Adults

Conditions
- Drug-resistant/induced hypertension;
- Abrupt onset of hypertension;
- Onset of hypertension at <30 y;
- Exacerbation of previously controlled hypertension;
- Disproportionate TOD for degree of hypertension;
- Accelerated/malignant hypertension
- Onset of diastolic hypertension in older adults (≥ 65 y)
- Unprovoked or excessive hypokalemia

Yes ➔ Screen for secondary hypertension (Class I) (see Table 13)

No ➔ Screening not indicated (No benefit)

Positive screening test

Yes ➔ Refer to clinician with specific expertise (Class IIb)

No ➔ Referral not necessary (No benefit)

Figure 3
<table>
<thead>
<tr>
<th>Common Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prevalence</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Renal parenchymal disease</td>
</tr>
<tr>
<td>Renovascular disease</td>
</tr>
<tr>
<td>Primary aldosteronism</td>
</tr>
<tr>
<td>Obstructive sleep apnea</td>
</tr>
<tr>
<td>Drug or alcohol-induced</td>
</tr>
</tbody>
</table>

*Uncommon Causes will be listed in the next two pages*
### Causes of Secondary Hypertension with Clinical Indications and Diagnostic Screening Tests (3 of 3)

<table>
<thead>
<tr>
<th>Uncommon Causes (continued from previous page)</th>
<th>Prevalence</th>
<th>Clinical Indications</th>
<th>Physical Exam</th>
<th>Screening Tests</th>
<th>Additional/Confirmatory Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Congenital adrenal hyperplasia</td>
<td>Rare</td>
<td>Hypertension and hypokalemia; virilization (11-beta-hydroxylase deficiency [11-beta-OH]) incomplete masculinization in males and primary amenorrhea in females (17-alpha-hydroxylase deficiency [17-alpha-OH])</td>
<td>Signs of virilization (11-beta-OH) or incomplete masculinization (17-alpha-OH)</td>
<td>Hypertension and hypokalemia with low or normal aldosterone and renin</td>
<td>11-beta-OH: elevated deoxycorticosterone (DOC), 11-deoxy cortisol and androgens 17-alpha-OH; decreased androgens and estrogens; elevated deoxycorticosterone and corticosterone</td>
</tr>
<tr>
<td>Microcorticoi...</td>
<td>Rare</td>
<td>Early onset hypertension; resistant hypertension; hypokalemia or hyperkalemia</td>
<td>Arrhythmias (with hypokalemia)</td>
<td>Low aldosterone and renin</td>
<td>Urinary cortisol metabolites; genetic testing</td>
</tr>
<tr>
<td>Acromegaly</td>
<td>Rare</td>
<td>Acral features, enlarging shoe, glove or hat size; headache, visual disturbances; diabetes mellitus</td>
<td>Acral features; large hands and feet; frontal bossing</td>
<td>Serum growth hormone ≥1 ng/mL during oral glucose load</td>
<td>Elevated age- and sex-matched IGF-1 level; MRI scan of the pituitary</td>
</tr>
</tbody>
</table>

* Depending on the clinical situation (hypertension alone, 5%; hypertension starting dialysis, 22%; hypertension and peripheral vascular disease, 28%; hypertension in the elderly with congestive heart failure, 34%).

† 8% in general population with hypertension; up to 20% in patients with resistant hypertension.

‡ Although obstructive sleep apnea is listed as a cause of secondary hypertension, RCTs on the effects of continuous positive airway pressure on lowering BF in patients with hypertension have produced mixed results.

§ May treat patients with resistant hypertension with a MRA whether or not primary aldosteronism is present.

Table 13
# Frequently Used Medications and Other Substances That May Cause Elevated BP*

<table>
<thead>
<tr>
<th>Agent</th>
<th>Possible Management Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>• Limit alcohol to ≤1 drink daily for women and ≤2 drinks for men</td>
</tr>
<tr>
<td>Amphetamines (e.g., amphetamine, methylphenidate, dexamphetamine, dextroamphetamine)</td>
<td>• Discontinue or decrease dose &lt;br&gt; • Consider behavioral therapies for ADHD</td>
</tr>
<tr>
<td>Antidepressants (e.g., MAOIs, SNRIs, TCAs)</td>
<td>• Consider alternative agents (e.g., SSRIs,) depending on indication &lt;br&gt; • Avoid tyramine containing foods with MAOIs</td>
</tr>
<tr>
<td>Atypical antipsychotics (e.g., clozapine, olanzapine)</td>
<td>• Discontinue or limit use when possible &lt;br&gt; • Consider behavior therapy where appropriate &lt;br&gt; • Lifestyle modification (Section 6.2) &lt;br&gt; • Consider alternative agents associated with lower risk of weight gain, diabetes mellitus, and dyslipidemia (e.g., aripiprazole, ziprasidone).</td>
</tr>
<tr>
<td>Caffeine</td>
<td>• Generally limit caffeine intake to &lt;300 mg/d &lt;br&gt; • Avoid use in patients with uncontrolled hypertension &lt;br&gt; • Coffee use in patients with hypertension associated with acute increases in BP; long-term use not associated with increased BP or CVD</td>
</tr>
<tr>
<td>Decongestants (e.g., phenylephrine, pseudoephedrine)</td>
<td>• Use for shortest duration possible and avoid in severe or uncontrolled hypertension &lt;br&gt; • Consider alternative therapies (e.g., nasal saline, intranasal corticosteroids, antihistamines) as appropriate</td>
</tr>
<tr>
<td>Herbal supplements (e.g., Ma Huang [ephedra], St. John’s Wort [with MAO inhibitors, yohimbine])</td>
<td>• Avoid use</td>
</tr>
<tr>
<td>Immunosuppressants (e.g., cyclosporine)</td>
<td>• Consider converting to tacrolimus, which may be associated with less effects on BP</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>• Use low-dose (e.g., 20–30 mcg ethinyl estradiol) agents or a progestin-only form of contraception and/or consider alternative forms of birth control where appropriate (e.g., barrier, abstinence, IUD) &lt;br&gt; • Avoid use in women with uncontrolled hypertension</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>• Avoid systemic NSAIDs when possible &lt;br&gt; • Consider alternative analgesics (e.g., acetaminophen, tramadol, topical NSAIDs,) depending on indication and risk</td>
</tr>
<tr>
<td>Recreational drugs (e.g., “bath salts” [MDPV], cocaine, methamphetamine, etc.)</td>
<td>• Discontinue and/or avoid use</td>
</tr>
<tr>
<td>Systemic corticosteroids (e.g., dexamethasone, fludrocortisone, methylprednisolone, prednisolone, prednisone)</td>
<td>• Avoid or limit use when possible &lt;br&gt; • Consider alternative modes of administration (e.g., inhaled, topical) when feasible</td>
</tr>
<tr>
<td>Angiogenesis inhibitor (e.g., bevacizumab) and tyrosine kinase inhibitors (e.g., sunitinib, sorafenib)</td>
<td>• Initiate or intensify antihypertensive therapy</td>
</tr>
</tbody>
</table>

* List is not all-inclusive.

Table 14
### Basic and Optional Laboratory Tests for Primary Hypertension

<table>
<thead>
<tr>
<th>Basic Testing</th>
<th>Optional Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting blood glucose*</td>
<td>Echocardiogram</td>
</tr>
<tr>
<td>Complete blood count</td>
<td>Uric acid</td>
</tr>
<tr>
<td>Lipid profile</td>
<td>Urinary albumin to creatinine ratio</td>
</tr>
<tr>
<td>Serum creatinine with eGFR*</td>
<td></td>
</tr>
<tr>
<td>Serum sodium, potassium, calcium*</td>
<td></td>
</tr>
<tr>
<td>Thyroid-stimulating hormone</td>
<td></td>
</tr>
<tr>
<td>Urinalysis</td>
<td></td>
</tr>
<tr>
<td>Electrocardiogram</td>
<td></td>
</tr>
</tbody>
</table>

*May be included in a comprehensive metabolic panel

Table 17
# Best Proven Nonpharmacologic Interventions for Prevention and Treatment of Hypertension*

<table>
<thead>
<tr>
<th>Nonpharmacologic Intervention</th>
<th>Dose</th>
<th>Approximate Impact on SBP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Hypertension</td>
</tr>
<tr>
<td>Weight loss</td>
<td>Ideal body weight is best goal but at least 1 kg reduction in body weight for most adults who are overweight. Expect about 1 mm Hg for every 1 kg reduction in body weight.</td>
<td>-5 mm Hg</td>
</tr>
<tr>
<td>Healthy diet</td>
<td>Diet rich in fruits, vegetables, whole grains, and low-fat dairy products with reduced content of saturated and trans fat.</td>
<td>-11 mm Hg</td>
</tr>
<tr>
<td>Reduced intake of dietary sodium</td>
<td>&lt;1,500 mg/d is optimal goal but at least 1,000 mg/d reduction in most adults</td>
<td>-5/6 mm Hg</td>
</tr>
<tr>
<td>Enhanced intake of dietary potassium</td>
<td>Dietary potassium 3,500-5,000 mg/d, preferably by consumption of a diet rich in potassium</td>
<td>-4/5 mm Hg</td>
</tr>
<tr>
<td>Physical activity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aerobic</td>
<td>• 120-150 min/wk</td>
<td>-5/8 mm Hg</td>
</tr>
<tr>
<td></td>
<td>• 65%-75% heart rate reserve</td>
<td></td>
</tr>
<tr>
<td>Dynamic Resistance</td>
<td>• 90-150 min/wk</td>
<td>-4 mm Hg</td>
</tr>
<tr>
<td></td>
<td>• 50%-80% 1 rep maximum</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 6 exercises, 3 sets/exercise, 10 repetitions/set</td>
<td></td>
</tr>
<tr>
<td>Isometric Resistance</td>
<td>• 4 x 2 min (hand grip), 1 min rest between exercises, 30%-40% maximum voluntary contraction, 3 sessions/wk</td>
<td>-5 mm Hg</td>
</tr>
<tr>
<td></td>
<td>• 8-10 wk</td>
<td></td>
</tr>
<tr>
<td>Moderation in alcohol intake</td>
<td>Alcohol consumption</td>
<td>-4 mm Hg</td>
</tr>
<tr>
<td></td>
<td>In individuals who drink alcohol, reduce alcohol† to:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Men: ≤2 drinks daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Women: ≤1 drink daily</td>
<td></td>
</tr>
</tbody>
</table>

* Type, dose, and expected impact on BP in adults with a normal BP and with hypertension.
† In the United States, one “standard” drink contains roughly 14 grams of pure alcohol, which is typically found in 12 ounces of regular beer (usually about 5% alcohol), 5 ounces of wine (usually about 12% alcohol) and 1.5 ounces of distilled spirits (usually about 40% alcohol).

Table 15
The American College of Physicians and the American Academy of Family Physicians (AAFP) offer thoughtful and balanced guidance that incorporates the results of these trials for adults 60 years and older.\textsuperscript{10,11} (Table 2\textsuperscript{11}). The AAFP has declined to endorse the ACC/AHA guideline and continues to endorse the 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults.\textsuperscript{12,13}

### TABLE 2.
Comparison of Guidelines for Pharmacologic Treatment of Hypertension in Older Adults

<table>
<thead>
<tr>
<th>AMERICAN COLLEGE OF PHYSICIANS/AMERICAN ACADEMY OF FAMILY PHYSICIANS GUIDELINE</th>
<th>AMERICAN COLLEGE OF CARDIOLOGY/AMERICAN HEART ASSOCIATION GUIDELINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment is recommended for adults 60 years and older with systolic BP persistently at or above 150 mm Hg to achieve a target systolic BP of less than 150 mm Hg to reduce the risk of stroke, cardiac events, and possibly mortality. (Strong recommendation based on high-quality evidence.)</td>
<td>Treatment is recommended for noninstitutionalized, ambulatory, community-dwelling adults 65 years and older with an average systolic BP of 130 mm Hg or above to achieve a target systolic BP of less than 130 mm Hg. (Strong recommendation based on high-quality evidence.)</td>
</tr>
<tr>
<td>Initiating or intensifying pharmacologic treatment should be considered for certain adults 60 years and older with high cardiovascular risk, based on individualized assessment, to achieve a target systolic BP of less than 140 mm Hg. (Weak recommendation based on low-quality evidence.)</td>
<td>Decisions regarding the intensity of pharmacologic therapy and choice of drugs can reasonably be made based on clinical judgment, patient preferences, and a team-based approach to assess risks and benefits for adults 65 years and older with hypertension, a high burden of comorbidities, and limited life expectancy. (Moderate recommendation based on consensus opinion.)</td>
</tr>
</tbody>
</table>

BP = blood pressure.

\textit{Information from references 2 and 11.}

In treating hypertension, we are treating a risk factor in asymptomatic patients to prevent disease, not treating a disease to relieve suffering. Most persons who receive preventive medication will not benefit, and many will be harmed. Choosing a threshold and target for treatment should be based on the science supporting CVD risk reduction, while considering the benefits and harms in individual patient circumstances and respecting patient choice.
The discussion on the topic of Hypertension took place on 4/11/18. The group was presented with standards from the AAFP, the JNC8, the ACC, the American Society of hypertension, and the AHA. The decision was made to follow the recommendations of the AAFP as these recommendations fit well with our practices. The recommendations are as follows:

- Treatment of hypertension should begin when BP is 150/90 or higher in adults greater than 60, and 140/90 or higher in adults less than 60
- If a patient over 60 has CAD or DM, treatment should be initiated at 140/90
- Treatment begins with education and lifestyle management as well as an initial medication — ABR, CCB, or thiazide diuretic in white/non black population or thiazide or CCB in the black population. If CKD, ARB as initial therapy then add on
- Due to recent literature, the ACE class should be avoided if possible, and ARB should be used instead
- If target is not reached with ONE MONTH, increase the dose of the medication or add medication
- Risk of adverse outcomes is lowest at BP of 115/75
- All patients with hypertension need to be seen in the clinic at least three times a year.
- indapamide and chlorthalidone preferred thiazides.
<table>
<thead>
<tr>
<th>Patient Type</th>
<th>1st drug</th>
<th>Add 2nd</th>
<th>Add 3rd</th>
</tr>
</thead>
<tbody>
<tr>
<td>When hypertension is the only or main condition</td>
<td>Black of All Ages</td>
<td>CCB or thiazide</td>
<td>ARB</td>
</tr>
<tr>
<td>White and non black &lt;60 yoa</td>
<td>ARB</td>
<td>CCB or thiazide</td>
<td>CCB +ARB+thiazide</td>
</tr>
<tr>
<td>White and non black &gt;60 yoa</td>
<td>CCB, thiazide, ACE or ARB</td>
<td>Add another</td>
<td>Add another</td>
</tr>
<tr>
<td>Other conditions</td>
<td>Diabetes</td>
<td>ARB (or CCB/thiazide in black patient)</td>
<td>CCB/thiazide</td>
</tr>
<tr>
<td>CKD</td>
<td>ARB (ACE only in black patient)</td>
<td>CCB/thiazide (loop if GFR &lt;30) BP target is &lt;130/80 if albumiuria</td>
<td>CCB/thiazide</td>
</tr>
<tr>
<td>CAD</td>
<td>B-blocker PLUS ACE/ARB</td>
<td>CCB/thiazide</td>
<td>CCB/thiazide</td>
</tr>
<tr>
<td>CHF</td>
<td>ARB PLUS B-blocker PLUS spironolactone+ other diuretic</td>
<td>Regardless of BP, cand add dihydropyridine CCB</td>
<td>AVOID non-dihydropyridine CCBs</td>
</tr>
</tbody>
</table>
Blood Pressure (BP) Thresholds and Recommendations for Treatment and Follow-Up

BP Thresholds and Recommendations for Treatment and Follow-up

- Normal BP (BP <120/80 mm Hg)
  - Promote optimal lifestyle habits
  - Reassess in 1 y (Class IIa)

- Elevated BP (BP 120-129/<80 mm Hg)
  - Nonpharmacologic therapy (Class I)
  - Reassess in 3–6 mo (Class I)

- Stage 1 Hypertension (BP 130–139/80–89 mm Hg)
  - Nonpharmacologic therapy (Class I)
  - Reassess in 3–6 mo (Class I)

- Stage 2 Hypertension (BP ≥ 140/90 mm Hg)
  - Clinical ASCVD or estimated 10-y CVD risk ≥10%*
    - Yes: Nonpharmacologic therapy and BP-lowering medication (Class I)
    - No: Reassess in 1 mo (Class I)

* Using the ACC/AHA Pooled Cohort Equations. Note that patients with DM or CKD are automatically placed in the high-risk category. For initiation of RAS inhibitor or diuretic therapy, assess blood tests for electrolytes and renal function 2 to 4 weeks after initiating therapy.

† Consider initiation of pharmacological therapy for stage 2 hypertension with 2 antihypertensive agents of different classes. Patients with stage 2 hypertension and BP ≥160/100 mm Hg should be promptly treated, carefully monitored, and subject to upward medication dose adjustment as necessary to control BP. Reassessment includes BP measurement, detection of orthostatic hypotension in selected patients (e.g., older or with postural symptoms), identification of white coat hypertension or a white coat effect, documentation of adherence, monitoring of the response to therapy, reinforcement of the importance of adherence, reinforcement of the importance of treatment, and assistance with treatment to achieve BP target.
**Heart Failure with Reduced Ejection Fraction (HFrEF)**

**Recommendations for Treatment of Hypertension**
**In Patients with Heart Failure with Reduced Ejection Fraction (HFrEF)**
Referenced studies that support recommendations are summarized in online Data Supplement 34

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>C-E0</td>
<td>1. Adults with HFrEF and hypertension should be prescribed GDMT* titrated to attain a BP less than 130/80 mm Hg.</td>
</tr>
<tr>
<td>III: No Benefit</td>
<td>B-R</td>
<td>2. Nondihydropyridine CCBs are not recommended in the treatment of hypertension in adults with HFrEF.</td>
</tr>
</tbody>
</table>

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

**Recommendations for Treatment of Hypertension**
**In Patients with Heart Failure with Preserved Ejection Fraction (HFpEF)**
Referenced studies that support recommendations are summarized in online Data Supplement 35, 36

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>C-E0</td>
<td>1. In adults with HFpEF who present with symptoms of volume overload, diuretics should be prescribed to control hypertension.</td>
</tr>
<tr>
<td>I</td>
<td>C-LD</td>
<td>2. Adults with HFpEF and persistent hypertension after management of volume overload should be prescribed ACE inhibitors or ARB and beta blockers titrated to attain systolic BP less than 130 mm Hg.</td>
</tr>
</tbody>
</table>
Management of Hypertension in Patients with Stable Ischemic Heart Disease (SIHD)

Hypertension With SIHD

Reduce BP to <130/80 mm Hg with GDMT beta blockers*, ACE inhibitor, or ARB† (Class I)

BP goal not met

Angina pectoris

Yes

Add dihydropyridine CCBs if needed (Class I)

No

Add dihydropyridine CCBs, thiazide-type diuretics, and/or MRAs as needed (Class I)

* GDMT beta blockers for BP control or relief of angina include carvedilol, metoprolol tartrate, metoprolol succinate, nadolol, bisoprolol, propranolol, and timolol. Avoid beta blockers with intrinsic sympathomimetic activity. The beta blocker atenolol should not be used because it is less effective than placebo in reducing cardiovascular events.

† If needed for BP control.

Figure 5
Management of Hypertension in Patients with Chronic Kidney Disease

**Treatment of Hypertension in Patients with CKD**

BP goal <130/80 mm Hg
*Class I*

**Albuminuria**
≥300 mg/d or ≥300 mg/g creatinine

- **Yes**
  - **ACE inhibitor** *(Class IIa)*
  - **Usual “first line” medication choices*

- **No**
  - **ACE inhibitor intolerant**
    - **Yes**
      - ARB* *(Class IIb)*
    - **No**
      - **ACE inhibitor** *(Class IIa)*

*CKD stage 3 or higher or stage 1 or 2 with albuminuria ≥300 mg/d or ≥300 mg/g creatinine.

Figure 6
Management of Hypertension in Patients with a Previous History of Stroke (Secondary Stroke Prevention)

Stroke ≥72 h from symptom onset and stable neurological status or TIA

Previous diagnosed or treated hypertension

Yes

Restart antihypertensive treatment (Class I)

Aim for SBP <140/90 mm Hg (Class IIb)

No

Established SBP ≥140 mm Hg or DBP ≥90 mm Hg

Initiate antihypertensive treatment (Class I)

Aim for SBP <130/80 mm Hg (Class IIb)

Established SBP ≥140 mm Hg or DBP ≥90 mm Hg

Usefulness of starting antihypertensive treatment is not well established (Class IIb)

Figure 9
Resistant Hypertension: Diagnosis, Evaluation, and Treatment

Confirm Treatment Resistance
- Office SBP/DBP ≥130/80 mm Hg
- Patient prescribed ≥3 antihypertensive medications at optimal doses, including a diuretic, if possible
- Office SBP/DBP <130/80 mm Hg but patient requires ≥4 antihypertensive medications

Exclude Pseudo-Resistance
- Ensure accurate office BP measurements
- Assess for nonadherence with prescribed regimen
- Obtain home, work, or ambulatory BP readings to exclude white coat effect

Identify and Reverse Contributing Lifestyle Factors
- Obesity
- Physical inactivity
- Excessive alcohol ingestion
- High salt, low-fiber diet

Discontinue or Minimize Interfering Substances
- NSAIDs
- Sympathomimetic (e.g., amphetamines, decongestants)
- Stimulants
- Oral contraceptives
- Licorice
- Ephedra

Screen for Secondary Causes of Hypertension
- Primary aldosteronism (elevated aldosterone/renin ratio)
- CKD (eGFR <60 mL/min/1.73 m²)
- Renal artery stenosis (young female, known atherosclerotic disease, worsening kidney function)
- Pheochromocytoma (episodic hypertension, palpitations, diaphoresis, headache)
- Obstructive sleep apnea (snoring, witnessed apnea, excessive daytime sleepiness)

Pharmacologic Treatment
- Maximize diuretic therapy
- Add a mineralocorticoid receptor antagonist
- Add other agents with different mechanisms of actions
- Use loop diuretics in patients with CKD and/or patients receiving potent vasodilators (e.g., minoxidil)

Refer to Specialist
- Refer to appropriate specialist for known or suspected secondary cause(s) of hypertension
- Refer to hypertension specialist if BP remains uncontrolled after 6 mo of treatment


Figure 10


Diabetes Mellitus

NEW INFORMATION AS OF APRIL 2018

1. Screening
   a. Providers should assess social context, including potential food insecurity, housing stability, and financial barriers, and apply that information to treatment decisions.”
   b. Patients with prediabetes (A1C >= 5.7) should be tested yearly
   c. Patients with h/o of GDM should have lifelong testing at least every three years.
   d. For all other patients with no risk factors, testing should begin at age 45 and continue q 3 years.
   e. Asymtomatic children and adolescents
      a. Screen if BMI over the 85th percentile or weight >120% of IBW and have one or more risk factors.
         i. Maternal history of diabetes or GDM during the child’s gestation
         ii. FH of T2D in first or second degree relative
         iii. Native American, African American, latino, Asian American, pacific Islander
         iv. Signs of insulin resistance

2. Comorbidities
   a. Screen type one diabetics for autimmune thyroid disease and celiac disease soon after diagnosis
   b. diabetes is a/w increased risk of cancers of the liver, pancreas, endometrium, colon, rectum, breast and blader – maintain screenings
   c. diabetes distress – evaluate for burnout or distress due to the disease.
   d. metformin is a/w decrease in B12. Monitor in patients with anemia or neuropathy.

3. Prevention
   a. patients with prediabetes should be referred to intensive behavioral lifestyle intervention. They should aim to achieve and maintain 7% loss of body weight and increase moderate intensity physical activity
   b. metformin therapy for revention should be considered for prediabetics whose BMI is greater than or equal to 35 or who are under 60 as well as women with prior GDM.

4. Monitoring
   a. Efficacy of self monitoring of blood glucose has been called into question unless patient is treated with insulin.
   b. A1C two time a year in patients who are meeting treatment goals
   c. A1C quarterly in patients whose therapy has changed or who are not meeting glycemic goals.

5. Pharmacotherapy
   a. NEW – metformin remains first line, and insulin initiation remains the same, however, if patient has established ASCVD, addition of one of the agents shown to improve risk of cardiovascular events and cardiovascular mortality should be immediately considered. These are Invokana, Jardiance, and Victoza.
b. NEW – ACE/ARB are NOT recommended for prevention of DKD in patients with normal BP, UACR, and eGFR. They are still recommended first line for treatment of the diabetic patient with hypertension. Assess for DKD at least yearly.
c. If office BP is >160/100, dual therapy with ACE/ARB, thiazide diuretic, or dihydropyridine CCB recommended.
d. ASA recommended for all diabetics with ASCVD 75-162mg/day. If ASA allergy, Plavix should be used. Dual therapy is recommended for a year after ACS and may have benefits beyond this period.
e. COMBINATION (statin/fibrate or statin/niacin) therapy has not been shown to improve ASCVD and are not recommended. Only treat with fibrates if TGs >500 to decrease risk of pancreatitis.
f. screen for retinopathy within 5 years of diagnosis of type 1 and at diagnosis of type 2, then yearly. RETINAL PHOTOGRAPHY is a screening, but not a substitute for comprehensive eye exam.
g. screen for peripheral neuropathy within 5 years of diagnosis of type one and at diagnosis of type 2 and yearly thereafter. Pregabalin and duloxetine are recommended as initial pharmacologic treatments in diabetes.

6. Children
   a. in metabolically stable patients, A1C<8.5, metformin is initial therapy. If marked hyperglycemia (FBG >250, A1C >8.5 without DKA) and symptomatic, treat initially with basal insulin while metformin is initiated and titrated to max tolerated dose. Basal insulin can then be weaned if A1C target is met and remains in target.
Screening:

Screen asymptomatic patients every 3 years, and annually for any patients with two or more risk factors. Risk factors are as follows:

Acanthosis nigricans, Age >45 years, antipsychotic therapy, CV diagnosis or FH of type 2 diabetes, glucocorticoid exposure, HDL<35, TG>250, History of gestational diabetes or delivery of a baby >9lbs, HTN >140/90, on medication for HTN, impaired fasting glucose, metabolic syndrome, NASH, overweight, obese, PCOS, sedentary lifestyle, sleep disorders in the presence of glucose tolerance, African American, native American/Alaskan native, Hispanic/latino, Asian American, native Hawaiian, pacific islander, physical inactivity, PCOS.

Screening should be done with a fasting glucose or A1C.

Interpretation of Tests

<table>
<thead>
<tr>
<th>Test</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prediabetes or increased risk of diabetes</td>
<td>Impaired FPG 100-125 or impaired 2 hour gt1 140-199 Risk is continuous extending below the lower limit of the range and becoming disproportionately greater at higher ends of the range</td>
</tr>
<tr>
<td></td>
<td>Or... A1C 5.7-6.4</td>
</tr>
<tr>
<td>Diabetes</td>
<td>A1c &gt;/= 6.5. In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing</td>
</tr>
<tr>
<td></td>
<td>FBG &gt;/= 126 – no caloric intake for at least 3 hours</td>
</tr>
<tr>
<td></td>
<td>Two hour GTT &gt;/= 200mg/dl using 75g anhydrous glucose load dissolved in water</td>
</tr>
<tr>
<td></td>
<td>Random plasma glucose &gt;/= 200 with classic symptoms of hyperglycemia</td>
</tr>
</tbody>
</table>
Recommendations for treatment:

Patients with prediabetes or new onset diabetes should undertake extensive lifestyle changes to slow the progression of T2D. This could include, but is not limited to, intensive nutritional training, diabetes education, individual and group counseling from dietitians and exercise physiologists, caloric restriction, and regular exercise.

If A1C is greater than or equal to 6.5 or FBG greater than or equal to 126, metformin should be used as a first line therapy to reduce microvascular complications, assist in weight management, reduce the risk of CV events, and reduce the risk of mortality. After a 3 month trial with metformin, if A1c is not at goal, then add a sulfonylurea, TZD, DDP-4, GLP-1 agent, or insulin. (See 2018 recommendations for patients with ASCVD) If after another three months, if A1C is not at goal, add a third agent. If still not at goal at this point, more complex insulin strategies must be attempted.

Other Considerations:

A1C goal should be 6.5-7, depending on the patient, but, patients with existing CV disease, two or more CV disease risk factors, or duration of diabetes of 10 years or longer should have higher A1C goals because of lack of benefit and the potential for increased risk of mortality compared with lower A1C goals.

If A1C initially is greater than 9, begin with dual therapy

If A1C is greater than 10 initially, begin with metformin and basal insulin

Add a statin drug if the patient has at least a 7.5% risk of CVD per the Framingham risk model

Add ASA if Framingham risk is greater than 10%

All patients with normal renal function should be on an ACE/ARB

Choice of agents used should take into account cost to the patient as well as risk of side effects. As a group, Davis Family Care physicians have chosen to use the SU group of medications only as a last resort due to the significant risk of profound hypoglycemia in the elderly patient. All patients with diabetes need to be seen in the clinic AT LEAST three times a year.
At diagnosis, initiate lifestyle management, set A1C target, and initiate pharmacologic therapy based on A1C:

- **A1C is less than 9%, consider Monotherapy.**
- **A1C is greater than or equal to 9%, consider Dual Therapy.**
- **A1C is greater than or equal to 10%, blood glucose is greater than or equal to 300 mg/dL, or patient is markedly symptomatic, consider Combination Injectable Therapy (See Figure 3).**

**Monotherapy**

Lifestyle Management + Metformin

Initiate metformin therapy if no contraindications (See Table 7)

- **A1C at target after 3 months of monotherapy?**
  - **Yes:** - Monitor A1C every 3–6 months
  - **No:** - Assess medication-taking behavior
    - Consider Dual Therapy

**Dual Therapy**

Lifestyle Management + Metformin + Additional Agent

- **ASCVD?**
  - **Yes:** - Add agent proven to reduce major adverse cardiovascular events and/or cardiovascular mortality (see recommendations with " on p. 24 and Table 7)
  - **No:** - Add second agent after consideration of drug-specific effects and patient factors (See Table 7)

- **A1C at target after 3 months of dual therapy?**
  - **Yes:** - Monitor A1C every 3–6 months
  - **No:** - Assess medication-taking behavior
    - Consider Triple Therapy

**Triple Therapy**

Lifestyle Management + Metformin + Two Additional Agents

Add third agent based on drug-specific effects and patient factors (See Table 7)

- **A1C at target after 3 months of triple therapy?**
  - **Yes:** - Monitor A1C every 3–6 months
  - **No:** - Assess medication-taking behavior
    - Consider Combination Injectable Therapy (See Figure 3).
Initiate Basal Insulin
Usually with metformin +/- other noninsulin agent

Start: 10 U/day or 0.1–0.2 U/kg/day
Adjust: 10–15% or 2–4 units once or twice weekly to reach FBG target
For hypo: Determine & address cause; if no clear reason for hypo,↓ dose by 4 units or 10–20%

If A1C not controlled, consider combination injectable therapy

Add 1 rapid-acting insulin injection before largest meal
Start: 4 units, 0.1 U/kg, or 10% basal dose. If A1C <8%, consider ↑ basal by same amount
Adjust: ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached
For hypo: Determine and address cause; if no clear reason for hypo, ↑ corresponding dose by 2–4 units or 10–20%
If A1C not controlled, advance to basal-bolus

Add GLP-1 RA
If not tolerated or A1C target not reached, change to 2 injection insulin regimen
If goals not met, consider changing to alternative insulin regimen

Change to premixed insulin twice daily (before breakfast and supper)
Start: Divide current basal dose into ½ AM, ½ PM or ¼ AM, ¾ PM
Adjust: ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached
For hypo: Determine and address cause; if no clear reason for hypo, ↑ corresponding dose by 2–4 units or 10–20%
If A1C not controlled, advance to 3rd injection

Add ≥2 rapid-acting insulin injections before meals (‘basal-bolus’)
Start: 4 units, 0.1 U/kg, or 10% basal dose/meal. If A1C <8%, consider ↑ basal by same amount
Adjust: ↑ dose(s) by 1–2 units or 10–15% once or twice weekly to achieve SMBG target
For hypo: Determine and address cause; if no clear reason for hypo, ↑ corresponding dose by 2–4 units or 10–20%

If goals not met, consider changing to alternative insulin regimen

Change to premixed analog insulin 3 times daily (breakfast, lunch, supper)
Start: Add additional injection before lunch
Adjust: ↑ doses by 1–2 units or 10–15% once or twice weekly to achieve SMBG target
For hypo: Determine and address cause; if no clear reason for hypo, ↑ corresponding dose by 2–4 units or 10–20%
<table>
<thead>
<tr>
<th>TABLE 4. Components of the Comprehensive Diabetes Medical Evaluation at Initial and Follow-Up Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PAST MEDICAL AND FAMILY HISTORY</strong></td>
</tr>
<tr>
<td>Diabetes history</td>
</tr>
<tr>
<td>• Characteristics at onset (e.g., age, symptoms)</td>
</tr>
<tr>
<td>• Review of previous treatment regimens and response</td>
</tr>
<tr>
<td>• Assess frequency/cause/severity of past hospitalizations</td>
</tr>
<tr>
<td>Family history</td>
</tr>
<tr>
<td>• Family history of diabetes in a first-degree relative</td>
</tr>
<tr>
<td>• Family history of autoimmune disorder</td>
</tr>
<tr>
<td>Personal history of complications and common comorbidities</td>
</tr>
<tr>
<td>• Macrovascular and microvascular</td>
</tr>
<tr>
<td>• Common comorbidities</td>
</tr>
<tr>
<td>• Presence of hemoglobinopathies or anemias</td>
</tr>
<tr>
<td>• High blood pressure or abnormal lipids</td>
</tr>
<tr>
<td>• Last dental visit</td>
</tr>
<tr>
<td>• Last dilated eye exam</td>
</tr>
<tr>
<td>• Visits to specialists</td>
</tr>
<tr>
<td>Interval history</td>
</tr>
<tr>
<td>• Changes in medical/family history since last visit</td>
</tr>
</tbody>
</table>

| **SOCIAL HISTORY**                                                                               |
| Assess lifestyle and behavior patterns                                                           |
| • Eating patterns and weight history                                                             |
| • Sleep behaviors and physical activity                                                          |
| • Familiarity with carbohydrate counting in type 1 diabetes                                       |
| • Tobacco, alcohol, and substance use                                                             |
| • Identify existing social supports                                                               |
| Interval history                                                                                 |
| • Changes in social history since last visit                                                       |

| **MEDICATIONS AND VACCINATIONS**                                                                  |
| • Medication-taking behavior                                                                     |
| • Medication intolerance or side effects                                                          |
| • Complementary and alternative medicine use                                                      |
| • Vaccination history and needs                                                                   |

| **TECHNOLOGY USE**                                                                               |
| • Assess use of health apps, online education, patient portals, etc.                              |
| • Glucose monitoring (meter/CGM): results and data use                                            |
| • Review insulin pump settings                                                                    |

| **SCREENING**                                     |
| Psychosocial conditions                           |
| • Screen for depression, anxiety, and disordered eating; refer for further assessment or intervention if warranted |
| • Consider assessment for cognitive impairment*                                                   |
| Diabetes self-management education and support    |
| • History of dietitian/diabetes educator visits                                               |
| • Screen for barriers to diabetes self-management                                              |
| • Refer or offer local resources and support as needed                                        |
| Hypoglycemia                                      |
| • Timing of episodes, awareness, frequency and causes                                           |
| Pregnancy planning                               |
| • For women with childbearing capacity, review contraceptive needs and preconception planning |

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TABLE CONTINUED ON P. 19 →
### TABLE 4. Components of the Comprehensive Diabetes Medical Evaluation at Initial and Follow-Up Visits, continued from p. 18

<table>
<thead>
<tr>
<th>PHYSICAL EXAMINATION</th>
<th>INITIAL VISIT</th>
<th>EVERY FOLLOW-UP VISIT</th>
<th>ANNUAL VISIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Height, weight, and BMI: growth/pubertal development in children and adolescents</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Blood pressure determination</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Orthostatic blood pressure measures (when indicated)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Fundoscopic examination (refer to eye specialist)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Thyroid palpation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Skin examination (e.g., acanthosis nigricans, insulin injection or insertion sites, lipodystrophy)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Comprehensive foot examination</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Visual inspection (e.g., skin integrity, callous formation, foot deformity or ulcer, toenails)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Screen for PAD (pedal pulses; refer for ABI if diminished)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Determination of temperature, vibration or pinprick sensation, and 10-g monofilament exam</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LABORATORY EVALUATION</th>
<th>INITIAL VISIT</th>
<th>EVERY FOLLOW-UP VISIT</th>
<th>ANNUAL VISIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• A1C, if the results are not available within the past 3 months</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• If not performed/available within the past year</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Lipid profile, including total, LDL, and HDL cholesterol and triglycerides‡</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Liver function tests‡</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Spot urinary albumin-to-creatinine ratio</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Serum creatinine and estimated glomerular filtration rate‡</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Thyroid-stimulating hormone in patients with type 1 diabetes‡</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Vitamin B12 if on metformin (when indicated)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Serum potassium levels in patients on ACE inhibitors, ARBs, or diuretics‡</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSESSMENT AND PLAN</th>
<th>INITIAL VISIT</th>
<th>EVERY FOLLOW-UP VISIT</th>
<th>ANNUAL VISIT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goal setting</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Set A1C/blood glucose target and monitoring frequency</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• If hypertension diagnosed, establish blood pressure goal</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Incorporate new members to the care team as needed</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Diabetes education and self-management support needs</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cardiovascular risk assessment and staging of CKD</th>
<th>INITIAL VISIT</th>
<th>EVERY FOLLOW-UP VISIT</th>
<th>ANNUAL VISIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• History of ASCVD</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Presence of ASCVD risk factors (see Table 9.2)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Staging of CKD (see Table 10.1)†</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Therapeutic treatment plan</th>
<th>INITIAL VISIT</th>
<th>EVERY FOLLOW-UP VISIT</th>
<th>ANNUAL VISIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Lifestyle management</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Pharmacologic therapy</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Referrals to specialists (including dietitian and diabetes educator) as needed</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Use of glucose monitoring and insulin delivery devices</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

---

Tables 9.2 and 10.1 are in the full 2018 Standards of Care. *≥265 years. †May be needed more frequently in patients with known CKD or with changes in medications that affect kidney function and serum potassium (see Table 10.2 in the full Standards of Care). #May also need to be checked after initiation or dose changes of medications that affect these laboratory values (i.e., diabetes, blood pressure, cholesterol, or thyroid medications). ‡On people without dyslipidemia and not on cholesterol-lowering therapy, testing may be less frequent. ABI, ankle-brachial pressure index.
<table>
<thead>
<tr>
<th>Table 7. Drug-Specific and Patient Factors to Consider When Selecting Antihyperglycemic Treatment in Adults With Type 2 Diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy</strong></td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td><strong>Metformin</strong></td>
</tr>
<tr>
<td><strong>SGLT2 Inhibitors</strong></td>
</tr>
<tr>
<td><strong>GLP-1 RAs</strong></td>
</tr>
<tr>
<td><strong>Thiazolidinediones</strong></td>
</tr>
<tr>
<td><strong>Dipeptidyl Peptidase-4 (DPP-4) Inhibitors</strong></td>
</tr>
</tbody>
</table>

References


KARLY PIPPITT, MD, and MARLANA LI, MD, University of Utah School of Medicine, Salt Lake City, Utah, HOLLY E. GURGLE, PharmD, University of Utah College of Pharmacy, Salt Lake City, Utah, *Am Fam Physician*. 2016 Jan 15;93(2):103-109.

U.S. Preventive Services Task Force


**Management of Blood Glucose with Noninsulin Therapies in Type 2**

Diabetes
CHRISTA M. GEORGE, PharmD, and LUCY L. BRUIJN, MD, MPH, University of Tennessee Health Science Center, Memphis, Tennessee, KAYLEY WILL, PharmD, Texas Tech University Health Sciences Center, Abilene, Texas, AMANDA HOWARD-THOMPSON, PharmD, University of Tennessee Health Science Center, Memphis, Tennessee, *Am Fam Physician*. 2015 Jul 1;92(1):27-34.

INITIAL EVALUATION: MAY INCLUDE A BNP IF CHF IS A POSSIBILITY, CBC TO TEST FOR ANEMIA, CMP TO ASSESS RENAL FUNCTION AND BICARB STATUS (POSSIBLE CHRONIC HYPERCAPNIA, AND SPIROMETRY

ADDRESS RISK FACTORS: Risk factors include history of exposure to cigarette smoke or heating fuels; occupational exposure to toxins, dusts, or industrial chemicals; exposure to environmental pollution, such as wood smoke and traffic pollutants; history of asthma or childhood respiratory tract infections; and α-antitrypsin deficiency

SPIROMETRY RESULTS

If reduced FVC on spirometry, obtain lung volumes to determine concomitant restriction. DLCO if hypoxemia by pulse oximetry (eg, PaO₂ < 92 mmHg) and evaluation for lung resection or lung volume reduction surgery

REVERSIBLE DEFECT

IRREVERSIBLE OR PARTIALLY REVERSIBLE DEFECT

CHRONIC BRONCHITIS if pt has a chronic productive cough for three months in each of two successive years in a patient in whom other causes of chronic cough (eg, bronchiectasis) have been excluded.

EMPHYSEMA if patient doesn’t meet other criteria

ASTHMA
COPD TREATMENT ALGORITHM

ASTHMA

CHRONIC BRONCHITIS

EMPHYSEMA

DETERMINE SEVERITY USING NIH GUIDELINES

DETERMINE STAGE USING GOLD CRITERIA

If intermittent, LABA PRN

If persistent...stepwise approach

1. Low dose ICS
2. Either add LABA or increase ICS dose
3. Medium dose ICS with LABA
4. High dose ICS, LABA, and consider Xolair
5. High dose ICS, LABA, oral steroid, and consider xolair

AVOIDANCE OF RISK FACTORS
ICS – Inhaled corticosteroid
LABA – Long acting beta agonist
SABA – short acting beta agonist
SAAC – short acting anticholinergic agent
LAAC – long acting anticholinergic agent
PDE4I – phosphodiesterase 4 inhibitor

<table>
<thead>
<tr>
<th>Components of Severity</th>
<th>Intermittent</th>
<th>Persistent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ages 0-4 years</td>
<td>Ages 5-11 years</td>
</tr>
<tr>
<td>Symptoms</td>
<td>&lt;2 days/week</td>
<td>2-4 days/week but not daily</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>0</td>
<td>&lt;2/4/month</td>
</tr>
<tr>
<td>SABA use for symptom control (not to prevent BDP)</td>
<td>&lt;2 days/week</td>
<td>&gt;2 days/week but not daily</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>None</td>
<td>Minor limitation</td>
</tr>
<tr>
<td>Lung function</td>
<td>Normal FEV, between exacerbations</td>
<td>Normal FEV, between exacerbations</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>FEV/FVC</td>
<td>&gt;65%</td>
<td>Normal+</td>
</tr>
<tr>
<td></td>
<td>Not applicable</td>
<td>Normal+</td>
</tr>
</tbody>
</table>

| Risk factors          | Generally, more frequent and intense events indicate greater severity. |
|                       | Generally, more frequent and intense events indicate greater severity. |

Consider severity and interval since last asthma exacerbation. Frequency and severity may fluctuate over time for patients in any severity category. Relative annual risk of exacerbations may be related to FEV1.

Recommended Step for Initiating Therapy

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step B</th>
<th>Step 3</th>
<th>Step 3</th>
<th>Step 3</th>
<th>Step 4 or 5</th>
</tr>
</thead>
</table>
| In 2-6 weeks, depending on severity, assess level of asthma control achieved and adjust therapy as needed. For children 0-4 years old, if no clear benefit is observed in 4-6 weeks, consider adjusting therapy or alternate diagnosis. | Consider short course of oral/systemic corticosteroids. | See "Stepwise Approach for Managing Asthma Long Term," page 7. The stepwise approach is meant to help, not replace, the referral decision-making needed to meet individual patient needs.
GOLD CRITERIA:

<table>
<thead>
<tr>
<th>GOLD CRITERIA</th>
<th>DIAGNOSIS</th>
<th>FEV1/FVC</th>
<th>FEV1</th>
<th>CHRONIC SYMPTOMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild COPD</td>
<td>FEV1/FVC &lt; 70%</td>
<td>FEV1 &gt; or equal to 80% predicted</td>
<td>With or without chronic symptoms (cough, sputum production)</td>
<td></td>
</tr>
<tr>
<td>Moderate COPD</td>
<td>FEV1/FVC &lt; 70%</td>
<td>FEV1 between 50 and 80% predicted</td>
<td>With or without chronic symptoms (cough, sputum production)</td>
<td></td>
</tr>
<tr>
<td>Severe COPD</td>
<td>FEV1/FVC &lt; 70%</td>
<td>FEV1 between 30 and 50% predicted</td>
<td>With or without chronic symptoms (cough, sputum production)</td>
<td></td>
</tr>
<tr>
<td>Very Severe COPD</td>
<td>FEV1/FVC &lt; 70%</td>
<td>FEV1 &lt; or equal to 30% predicted or FEV1 &lt; 50% predicted plus chronic respiratory failure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GOLD class</th>
<th>mMRC 0-1</th>
<th>mMRC &gt;1</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>CAT &lt;10</td>
<td>CAT &gt;9</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>patient group</td>
<td>first choice treatment</td>
<td>alternative treatment</td>
</tr>
<tr>
<td>---------------</td>
<td>------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>A</td>
<td>when necessary: SAAC or SABA</td>
<td>LAAC or LABA or SAAC + SABA</td>
</tr>
<tr>
<td>B</td>
<td>LAAC or LABA</td>
<td>LAAC + LABA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>ICS + LAAC or LABA</td>
<td>LAAC + LABA or LAAC + PDE4I or LABA + PDE4I</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>ICS + LAAC and/or LABA</td>
<td>ICS + LABA + LAAC or ICS + LABA + PDE4I or LAAC + LABA or LAAC + PDE4I</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REFERENCES

http://www.spirometry.guru/goldcopd.html
http://www.aafp.org/afp/2001/0815/p603.html
SYSTOLIC CONGESTIVE HEART FAILURE

DEFINITION:

- Heart failure is a complex clinical syndrome that results from structural or functional impairment of ventricular filling or ejection of blood. It may result from disorders of the pericardium, myocardium, endocardium, heart valves, or great vessels, or from metabolic abnormalities, but most patients have symptoms resulting from impaired left ventricular myocardial function. Manifestations include dyspnea and fatigue, which may limit exercise tolerance, and fluid retention, which may lead to pulmonary congestion and peripheral edema.

PRE DISPOSING FACTORS:

- Coronary heart disease – relative risk 8.1; overall PAR 62 percent, 68 percent in men and 56 percent in women.
- Cigarette smoking – relative risk 1.6, PAR 17 percent.
- Hypertension – relative risk 1.4, PAR 10 percent.
- Obesity – relative risk 1.3, PAR 8 percent; the importance of obesity was also demonstrated in a long-term follow-up from the Framingham Heart Study that estimated that approximately 11 percent of cases of HF in men and 14 percent in women are attributable to obesity.
- Diabetes – relative risk 1.9, PAR 3 percent.
- Valvular heart disease – relative risk 1.5, PAR 2 percent; however, valve disease is an increasingly common cause of HF at older ages, with calcific aortic stenosis being the most common disorder requiring surgery.

Ischemic cardiomyopathy is the most common cause of SYSTOLIC cardiomyopathy in this country.
The classification system that is most commonly used to quantify the degree of functional limitation imposed by HF is one first developed by the NYHA. This system assigns patients to one of four functional classes, depending on the degree of effort needed to elicit symptoms:

- **Class I** – Patients with heart disease without resulting limitation of physical activity. Ordinary physical activity does not cause HF symptoms such as fatigue or dyspnea.

- **Class II** – Patients with heart disease resulting in slight limitation of physical activity. Symptoms of HF develop with ordinary activity but there are no symptoms at rest.
● Class III – Patients with heart disease resulting in marked limitation of physical activity. Symptoms of HF develop with less than ordinary physical activity but there are no symptoms at rest.

● Class IV – Patients with heart disease resulting in inability to carry on any physical activity without discomfort. Symptoms of HF may occur even at rest.

**DIAGNOSIS**

- Because heart failure is largely a clinical diagnosis based on findings from the history and physical examination, there is no single diagnostic test. The initial laboratory evaluation should include a complete blood count, urinalysis, fasting lipid profile, liver function testing, and measurement of serum electrolytes (including calcium and magnesium), blood urea nitrogen, serum creatinine, glucose, and thyroid-stimulating hormone. When indicated, serial monitoring should include renal function testing and measurement of serum electrolytes. For all patients with heart failure, 12-lead electrocardiography should be obtained. In select patients, screening for hemochromatosis or human immunodeficiency virus infection may be considered. Diagnostic testing for rheumatologic diseases, amyloidosis, or pheochromocytoma is reasonable in patients with heart failure in whom there is clinical suspicion for these diseases.

- Chest radiography should be performed in patients with suspected or new-onset heart failure and in those with acutely decompensated heart failure to evaluate heart size and pulmonary congestion, and to detect any cardiac, pulmonary, or other disease that may cause or contribute to the patient’s symptoms.

- Two-dimensional echocardiography with Doppler should be performed during the initial evaluation to assess ventricular function, size, wall thickness, wall motion, and valve function. Repeat measurement of ejection fraction and measurement of the severity of structural remodeling are useful in patients who have had a significant change in clinical status, experienced or recovered from a clinical event, undergone treatment that may have had a significant effect on cardiac function, or who may be candidates for device therapy.
TREATMENT

STAGE A (1)

• CONTROL RISK FACTORS – HYPERTENSION AND HYPERLIPIDEMIA
• DIURETICS HAVE BEEN SHOWN TO DECREASE THE RISK OF HEART FAILURE IN PATIENTS
• ACE-I, ARB AND BETA BLOCKERS ARE ALSO EFFECTIVE
• STATIN DRUGS FOR HYPERLIPIDEMIA
• IN WOMEN, DM2 HAS BEEN SHOWN TO INCREASE THE RISK OF HEART FAILURE 300%
• OBESITY, DYSGLYCEMIA, AND TOBACCO USE ARE ALSO RISK FACTORS AND NEED TO BE ADDRESSED.

STAGE B (II)

• ALL MODALITIES FOR STAGE A (I) PLUS :
• ACE/ARB HAVE BEEN SHOWN TO DECREASED MORTALITY AND SYMPTOMS IN PATIENTS WITH H/O MI OR ACS AND A DECREASED EF
• BETA BLOCKER THERAPY HAS BEEN SHOWN TO DECREASE MORTALITY AT THIS STAGE
• STATIN THERAPY DECREASES RISK OF SYMPTOMATIC HF AS WELL AS CV EVENTS
• ACE PLUS BETA BLOCKER IN ALL PATIENTS WITH DECREASED EF

STAGE C (III)

• CONTINUE WITH STAGE A AND B TREATMENT
• SYMPTOM MANAGEMENT
• DIURETICS IF FLUID RETENTION (MONITOR ELECTROLYTES AND DEHYDRATION)
• ALDOSTERONE RECEPTOR ANTAGONISTS IN CLASS II-IV CASES WITH EF 35% OR LESS (MONITOR HYPERKALEMIA AND RENAL INSUFFICIENCY)
• SODIUM RESTRICTION
• SLEEP STUDIES
• EXERCISE
STAGE D (IV)

- CONTINUE TREATMENT FOR STAGE A-C
- MAY AT THIS POINT ADD NITRATES, HYDRALAZINE, DIGOXIN, ANTICOAGULATION, AND OMEGA 3 FATTY ACIDS IF NOT ON FOR OTHER REASONS
- Referral of patients with refractory HFrEF to a program with expertise in the management of refractory HF and advanced treatment strategies is suggested. Hospitalization rates for patients with HF may be reduced by approximately 20 to 30 percent through the implementation of comprehensive outpatient and inpatient support programs. However, less intensive strategies have been found to be ineffective in improving patient outcomes.
- BASICALLY, THIS SECTION IS MOSTLY INPATIENT AND PALLIATIVE INFORMATION.

OTHER CONSIDERATIONS

<table>
<thead>
<tr>
<th>Table 3. Pharmacologic Therapy for Heart Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>THERAPY</td>
</tr>
<tr>
<td>STARTING DOSAGE</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Aldosterone antagonists†</td>
</tr>
<tr>
<td>Eplerenone (Inspra)</td>
</tr>
<tr>
<td>Spironolactone (Aldactone)</td>
</tr>
<tr>
<td>Angiotensin-converting enzyme inhibitors†</td>
</tr>
<tr>
<td>Captopril</td>
</tr>
<tr>
<td>Enalapril (Vasotec)</td>
</tr>
<tr>
<td>Fosinopril</td>
</tr>
<tr>
<td>Lisinopril (Prinivil)</td>
</tr>
</tbody>
</table>
REFERENCES


• Up To Date. Epidemiology and causes of heart failure. Authors:Ramachandran S Vasan, MD, DM, FACC, Peter WF Wilson, MD Section Editor:Wilson S Colucci, MD Deputy Editor:Susan B Yeon, MD, JD, FACC. Literature review current through: Dec 2016. | This topic last updated: Nov 30, 2016.
Diastolic Congestive Heart Failure

Definition and Epidemiology

Heart failure with preserved ejection fraction causes almost one-half of the 5 million cases of heart failure in the United States. It is more common among older patients and women, and results from abnormalities of active ventricular relaxation and passive ventricular compliance, leading to a decline in stroke volume and cardiac output.

Patients with typical symptoms (e.g., fatigue, weakness, dyspnea, orthopnea, paroxysmal nocturnal dyspnea, edema) and signs (S3 heart sound, displaced apical pulse, and jugular venous distension) of chronic heart failure should be considered.

Echocardiographic findings of normal ejection fraction with impaired diastolic function confirm the diagnosis.

Measurement of natriuretic peptides is useful in the evaluation of patients with suspected heart failure with preserved ejection fraction in the ambulatory setting.
### WHAT IS NEW ON THIS TOPIC: HEART FAILURE WITH PRESERVED EJECTION FRACTION

A systematic review found that jugular venous distention, an S3 heart sound, and displaced apical impulse significantly increased the likelihood of heart failure.

In the absence of hypertension, evidence does not support treating heart failure with preserved ejection fraction with any medication except diuretics. Additionally, trials of angiotensin receptor blockers, digoxin, nitrates, and spironolactone raised concerns about adverse effects.

### SORT: KEY RECOMMENDATIONS FOR PRACTICE

<table>
<thead>
<tr>
<th>CLINICAL RECOMMENDATION</th>
<th>EVIDENCE RATING</th>
<th>REFERENCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians should obtain a brain natriuretic peptide or N-terminal pro–brain natriuretic peptide level for patients with possible heart failure if the diagnosis is uncertain.</td>
<td>C</td>
<td>3, 5–7, 9, 13</td>
</tr>
<tr>
<td>Patients with suspected heart failure should be referred for two-dimensional transthoracic echocardiography to confirm the diagnosis and identify preserved or reduced ejection fraction. This includes those with elevated brain natriuretic peptide levels or physical examination findings suggestive of heart failure, and those who meet the Framingham, MICE (Male, Infarction, Crepitations, Edema), or Netherlands criteria for heart failure.</td>
<td>C</td>
<td>3, 5, 10, 11, 13</td>
</tr>
<tr>
<td>Patients with HFrEF who have signs and symptoms of fluid overload should be treated with diuretics.</td>
<td>B</td>
<td>3, 5, 31</td>
</tr>
<tr>
<td>Patients with HFrEF should be referred for endurance and resistance training.</td>
<td>B</td>
<td>3, 5, 29</td>
</tr>
<tr>
<td>Patients with HFrEF and coronary artery disease who have indications should be offered revascularization.</td>
<td>C</td>
<td>3, 5, 30</td>
</tr>
<tr>
<td>Hypertension in patients with HFrEF should be treated according to evidence-based hypertension treatment guidelines.</td>
<td>C</td>
<td>3</td>
</tr>
<tr>
<td>The use of nitrates, spironolactone, and angiotensin receptor blockers should be avoided in patients with HFrEF. Digoxin should also be avoided in patients 65 years and older who have HFrEF.</td>
<td>B</td>
<td>18, 23, 25, 27</td>
</tr>
</tbody>
</table>

HFrEF = heart failure with preserved ejection fraction.

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to https://www.aafp.org/afhsort
ANTICOAGULATION

Coumadin management in outpatient setting:

<table>
<thead>
<tr>
<th>INR</th>
<th>Adjustment in total mg of warfarin per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1.5</td>
<td>Increase 15 percent per week</td>
</tr>
<tr>
<td>1.51 to 1.99</td>
<td>Increase 10 percent per week**</td>
</tr>
<tr>
<td>2 to 3</td>
<td>No change</td>
</tr>
<tr>
<td>3.01 to 4</td>
<td>Decrease 10 percent per week</td>
</tr>
<tr>
<td>4.01 to 4.99</td>
<td>Hold one dose; restart with dose decreased by 10 percent per week</td>
</tr>
<tr>
<td>5 to 8.99</td>
<td>Hold until INR is 2 to 3; restart with dose decreased by 15 percent per week</td>
</tr>
</tbody>
</table>

The table provides an algorithm for monitoring and adjustment of maintenance warfarin dosing with a goal of maintaining the INR between 2 and 3. The maintenance dose algorithm requires that INR measurements are made at a maximum interval of every four weeks, with at least weekly monitoring for out of range INRs (<2 or >3). All percent changes in warfarin dosage are adjusted based on the current INR value and calculated based upon the sum of the previous seven days of warfarin doses (also known as mg of warfarin per week). The increase or decrease in warfarin dose per week is distributed over the following week, preferably as evenly as possible to avoid large fluctuations. This algorithm is not applicable to selecting a warfarin starting dose or for adjusting the starting dose during the first week of treatment. Refer to UpToDate content on the use of warfarin for details.


**As an example, a patient taking 30 mg of warfarin per week with an INR of 1.8 would increase the dose by 10 percent (increase by 3 mg to 33 mg per week). The new weekly dose (33 mg) could be distributed as 5 mg daily on six days of the week and 3 mg on the remaining day. Several alternate means of distributing the dose could also be used (eg, 5 mg daily on five days of the week and 4 mg daily on the remaining two days).
<table>
<thead>
<tr>
<th>Rule Number</th>
<th>Current INR</th>
<th>Previous INR</th>
<th>Suggestion</th>
<th>Severity</th>
<th>Method of Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>INR $\geq 0$ and $&lt; 1.6$</td>
<td>If no previous INR after enrollment or previous INR was $\geq 1.8$.</td>
<td><em>Action Point Low.</em> Message if dosage of coumadin was changed in the past 25 days. Inquire about a/s of clotting, and if necessary, refer to an appropriate facility for care. Consider extra dose of coumadin. Increase weekly dose by 5-15%. Retest in 7-14 days. Previous INR zone: XXXXX (if available)</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
<tr>
<td>2</td>
<td>If previous INR is $&lt; 1.8$</td>
<td></td>
<td><em>Action Point Low.</em> Message if dosage of coumadin was changed in the past 25 days. Consult the medical director, pharmacist or nurse practitioner for advice. Retest in 7-14 days. Previous INR zone: XXXXX</td>
<td>High (2)</td>
<td>Message Log</td>
</tr>
<tr>
<td>3</td>
<td>INR $\geq 1.6$ and $&lt; 1.8$</td>
<td>If no previous INR after enrollment or previous INR was $\geq 1.8$.</td>
<td><em>Red Zone Low.</em> Message if dosage of coumadin was changed. Consider an extra half to whole dose of coumadin. Increase weekly dose by 210%. Retest in 10-14 days. Previous INR zone: XXXXX (if available)</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
<tr>
<td>4</td>
<td>If previous INR is $&lt; 1.8$</td>
<td></td>
<td><em>Red Zone Low.</em> Message if dosage of coumadin was changed in the past 25 days. Consult the medical director, pharmacist or nurse practitioner for advice. Retest in 10-14 days. Previous INR zone: XXXXX</td>
<td>High (2)</td>
<td>Message Log</td>
</tr>
<tr>
<td>5</td>
<td>INR $\geq 1.8$ and $&lt; 2.0$</td>
<td>If no previous INR after enrollment or previous INR was Green Zone ($\geq 2.0$ and $\leq 3.0$)</td>
<td><em>First Yellow Zone Low.</em> Message if dosage of coumadin was changed in the past 25 days. Retest in 10-14 days. Previous INR zone: XXXXX (if available)</td>
<td>Low (4)</td>
<td>Message Log</td>
</tr>
<tr>
<td>6</td>
<td>If previous INR was $&lt; 1.8$</td>
<td></td>
<td><em>First Yellow Zone Low.</em> Message if dosage of coumadin was changed in the past 25 days. INR is changing in desired direction. Retest in 7-10 days. Previous INR zone: XXXXX</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
<tr>
<td>7</td>
<td>If previous INR was $\geq 1.8$ and $&lt; 2.0$</td>
<td></td>
<td><em>Repeated Yellow Zone Low.</em> Message if dosage of coumadin was changed in the past 25 days. Increase coumadin weekly dose by 3-10%. Retest in 14 days. Previous INR zone: XXXXX</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
<tr>
<td>8</td>
<td>If previous INR was $\geq 4.5$ (action point high or critical)</td>
<td></td>
<td><em>Possible sliding Yellow Zone Low.</em> Message if dosage of coumadin was changed in the past 25 days. Consult the medical director, pharmacist or nurse practitioner for advice. Retest in 7-10 days. Previous INR zone: XXXXX</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
<tr>
<td>9</td>
<td>If previous INR was anything else</td>
<td></td>
<td><em>First Yellow Zone Low.</em> Message if dosage of coumadin was changed in the past 25 days. Consult the medical director, pharmacist or nurse practitioner for advice. Retest in 14 days. Previous INR zone: XXXXX</td>
<td>Medium (3)</td>
<td>Message Log</td>
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</tr>
<tr>
<td>10</td>
<td>INR ≥ 2.0 and ≤ 3.0</td>
<td>If no previous INR after enrollment or previous INR</td>
<td>Green Zone. Message if dosage of coumadin was changed in the past 25 days. Retest in 30 days. Previous INR zone: XXXX (if available)</td>
<td>Low (4)</td>
<td>Message Log</td>
</tr>
<tr>
<td></td>
<td></td>
<td>was (≥ 1.8 and &lt; 3.4), and (was not a repeated yellow zone, or lastINR ≤ 3.0 and ≥ 2.0))</td>
<td></td>
<td></td>
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<tr>
<td>11</td>
<td></td>
<td>If previous INR was (≥ 1.8 and &lt; 3.4), and (was a repeated yellow zone, or (previous INR &gt; 3.0 and &lt; 3.4, or previous INR ≥ 1.8 and &lt; 2.0))</td>
<td>Possible sliding green zone. Message if dosage of coumadin was changed in the past 25 days. Retest in 14-21 days. Previous INR zone: XXXX (if available)</td>
<td>Low (4)</td>
<td>Message Log</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>If previous INR was &lt; 1.8 or ≥ 3.4, and the change is &lt; 30%</td>
<td>Possible sliding green zone. Message if dosage of coumadin was changed in the past 25 days. Retest in 14 days. Previous INR zone: XXXX (if available)</td>
<td>Low (4)</td>
<td>Message Log</td>
</tr>
<tr>
<td>13</td>
<td></td>
<td>If previous INR was &lt; 1.8 or ≥ 3.4, and the change is &gt; 30%</td>
<td>Possible sliding green zone. Message if dosage of coumadin was changed in the past 25 days. INR change greater than 30%. Consult the medical director, pharmacist or nurse practitioner for advice. Retest in 14 days. Previous INR zone: XXXX (if available)</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
<tr>
<td>14</td>
<td>INR &gt; 3.0 and &lt; 3.4</td>
<td>If no previous INR after enrollment or previous INR was a Green Zone (≥ 2.0 and ≤ 3.0)</td>
<td>First Yellow Zone High. Message if dosage of coumadin was changed in the past 25 days. Retest in 10-14 days. Previous INR zone: XXXXXX (if available)</td>
<td>Low (4)</td>
<td>Message Log</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>If previous INR was Yellow Zone High (≥3.0 and &lt;3.4)</td>
<td>Repeated Yellow Zone High. Message if dosage of coumadin was changed in the past 25 days. Decrease coumadin weekly dose by 5-10%. Retest in 14 days. Previous INR zone: XXXXXX (if available)</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
<tr>
<td>16</td>
<td></td>
<td>If previous INR was ≥3.4 and &lt; 4.5</td>
<td>First Yellow Zone High. Message if dosage of coumadin was changed in the past 25 days. INR is changing in desired direction. Retest in 7-10 days. Previous INR zone: XXXXXX (if available)</td>
<td>Medium (3)</td>
<td>Message Log</td>
</tr>
</tbody>
</table>
PERIPROCEDURAL MANAGEMENT

**FIGURE 1** PMAC Pathway Decision Algorithm Summary

**WHETHER TO INTERRUPT**
- **CONSIDERATIONS**: Consider VKA vs. DOAC, evaluate patient bleed risk, evaluate procedural bleed risk (no clinically relevant, low, intermediate, high or uncertain), consider additional information and use clinical judgment.
- **GUIDANCE**: Do not interrupt or Interrupt.

**WHEN TO INTERRUPT**
- **CONSIDERATIONS**: Consider VKA, FXa Inhibitor or DTI, and either INR or CrCl.
- **GUIDANCE**: When to interrupt.

**WHETHER TO BRIDGE**
- **CONSIDERATIONS**: Consider VKA vs. DOAC, evaluate thrombotic risk balanced by patient bleed risk, consider additional information, and use clinical judgment.
- **GUIDANCE**: Do not bridge or Bridge.

**HOW TO BRIDGE**
- **CONSIDERATIONS**: Evaluate CrCl and patient allergies.
- **GUIDANCE**: How to bridge.

**PERFORM THE PROCEDURE**

**HOW TO RESTART ANTICOAGULATION**
- **CONSIDERATIONS**: Consider post-procedure bridging plan, VKA vs. DOAC, procedure type (cardiac valve, intraspinal, intracranial); and evaluate post-procedure bleed risk, bleeding complications, hemostasis, and tolerance of oral medications.
- **GUIDANCE**: How to restart.

CrCl = creatinine clearance; DOAC = direct oral anticoagulant; DTI = direct thrombin inhibitor; FXa = factor Xa; INR = international normalized ratio; VKA = vitamin K antagonist
**WHETHER TO INTERRUPT VKA THERAPY**

**CONSIDERATIONS**

- Procedural bleed risk?
  - Not clinically important or low
  - Intermediate or high
  - Uncertain

**GUIDANCE**

- Perform the procedure uninterrupted. Exit the pathway.
- Insufficient data on best practices; likely interrupt but consult with proceduralists.
- Use clinical judgment: Persistent concern for bleeding?
  - No
  - Yes

- **INTERRUPT**
- **INTERRUPT**

**WHEN TO INTERRUPT**

**CONSIDERATIONS**

- INR measurement 5-7 days prior to procedure?
  - Supratherapeutic
  - Goal level (2.0 to 2.5 or 2.0 to 3.0)
  - Subtherapeutic

**GUIDANCE**

- Discontinue ≥5 days before procedure depending on current INR, time to procedure, and desired INR for procedure; recheck INR 24 hours before procedure.
- Discontinue 5 days before procedure depending on current INR, time to procedure and desired INR for procedure; recheck INR 24 hours before procedure.
- Discontinue 3-4 days before procedure; recheck INR 24 hours before procedure if a normal INR is desired.

**DOAC** — direct oral anticoagulant

**ICH** — intracranial hemorrhage

**INR** — international normalized ratio

**VKA** — vitamin K antagonist

**CONTINUE TO WHETHER TO BRIDGE**
**FIGURE 3** Detailed Algorithm: Whether to Interrupt, and How to Interrupt for DOACs

**WHETHER TO INTERRUPT DOAC THERAPY**

- Increased patient bleed risk? Yes
  - Procedural bleed risk?
    - No clinically important risk
    - Low
    - Uncertain, intermediate, or high

  - Perform the procedure uninterrupted, but time it at DOAC interval trough.

**INTERRUPT**

**WHEN TO INTERRUPT**

- Type of DOAC
  - DTI: FXa inhibitor
  - DTI: FXa inhibitor

- Measure CrCl

<table>
<thead>
<tr>
<th>CrCl</th>
<th>Discontinue</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;15</td>
<td>No data; consider dTT and/or ≥48 hrs. ≥72 hrs</td>
<td>Discontinue</td>
</tr>
<tr>
<td>15-29</td>
<td>No data; consider anti Xa level and/or ≥48 hrs. ≥36 hrs</td>
<td>Discontinue</td>
</tr>
<tr>
<td>30-49</td>
<td>≥24 hrs</td>
<td>Discontinue</td>
</tr>
<tr>
<td>50-79</td>
<td>≥36 hrs</td>
<td>Discontinue</td>
</tr>
<tr>
<td>≥80</td>
<td>≥24 hrs</td>
<td>Discontinue</td>
</tr>
</tbody>
</table>

- CrCl <15
  - No data; consider dTT and/or ≥48 hrs. ≥72 hrs
  - ≥36 hrs
  - ≥24 hrs

- CrCl <15
  - No data; consider anti Xa level and/or ≥48 hrs. ≥36 hrs
  - ≥24 hrs

- CrCl <30
  - No data; consider dTT. ≥120
  - ≥72 hrs
  - ≥48 hrs
  - ≥24 hrs

- Parenteral bridging not indicated for DOACs.
  - Perform the procedure and continue to "How to Restart."
WHETHER TO BRIDGE

CONSIDERATIONS

Thrombotic risk?

Low

Moderate

High

Recent TE < 3 months?

Yes

No

Increased patient bleed risk?

Yes

No

Prior stroke or TIA?

Yes

No

Use of parenteral agent not indicated.

Likely do not bridge

Likely bridge

Likely bridge

Likely do not bridge

Consider delaying procedure; strongly consider parenteral agent.

DO NOT BRIDGE

USE CLINICAL JUDGMENT

BRIDGE

CONSIDERATIONS

No

CrCl < 30?

Heparin allergy or recent HIT?

Yes

No

Administer therapeutic UFH or LMWH.

UFH

LMWH

Follow local protocol for management of HIT and heparin allergy.

Consider individualized strategies such as using prophylactic/low-dose parenteral anticoagulant, or postoperative bridging only.

How to bridge

Start UFH when the INR is < 2 or after omitting 2-3 doses of the OAC if the INR is not measured. Discontinue >4 hours prior to the procedure and if the aPTT is the normal range.

Start LMWH when the INR is < 2 or after omitting 2-3 doses of the OAC if the INR is not measured. Discontinue >12-24 hours prior to the procedure based on renal function and whether you are administering it once daily or q12 hours.

PERFORM THE PROCEDURE

aPTT - activated partial thromboplastin time assay; ASA - acetylsalicylic acid (aspirin); DOAC - direct oral anticoagulant; HIT - heparin-induced thrombocytopenia; ICH - intracranial hemorrhage; INR - international normalized ratio; LMWH - low-molecular-weight heparin; OAC - oral anticoagulation; TE - thromboembolic event; TIA - transient ischemic attack; UFH - unfractionated heparin; VKA - vitamin K antagonist
FIGURE 5  Algorithm: How to Restart Anticoagulation

**PERFORM THE PROCEDURE**

**HOW TO RESTART ANTICOAGULATION**

**CONSIDERATIONS**

- **Original anticoagulant?**
  - No
    - Cardiac valve surgery?
      - Yes
        - DOAC
      - No
        - Recommend anticoagulation therapy using a VKA.
  - Yes
    - Complete hemostasis achieved, with no bleeding complications, no high-risk features of the patient, and absence of a potentially catastrophic bleed location (intracranial, intraspinal)

**GUIDANCE**

- **Use clinical judgment.**
  - Consider parenteral anticoagulation until oral medications are possible. Start parenteral agent 48-72 hrs following the procedure. When tolerating oral medications, convert from parenteral agent to DOAC.

- **Reasonable to reinstate DOAC 48-72 hrs after the procedure.**
  - Consider using reduced dose on the evening after the procedure.

- **Consider delaying reintroduction of anticoagulation; use clinical judgment.**
  - Start VKA within 24 hrs.
  - Start VKA within 24 hrs. Restart parenteral agent if applicable 48-72 hours following the procedure. Discontinue parenteral agent when INR reaches 2.

**DOAC** — direct oral anticoagulant

**INR** — international normalized ratio

**VKA** — vitamin K antagonist

* In cooperation with the managing team and the proceduralist

† At a dose based on postprocedural renal function
## DECISION MAKING TOOLS

### TABLE 1  Patient Bleed Risk Factors

<table>
<thead>
<tr>
<th>HAS-BLED parameters (52)*</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension†</td>
<td></td>
</tr>
<tr>
<td>Abnormal renal function‡</td>
<td></td>
</tr>
<tr>
<td>Abnormal liver function§</td>
<td></td>
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<tr>
<td>Prior stroke</td>
<td></td>
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<tr>
<td>History of or predisposition to (anemia) major bleeding</td>
<td></td>
</tr>
<tr>
<td>Labile INR (VKA)¶</td>
<td></td>
</tr>
<tr>
<td>Elderly (&gt;65 years)</td>
<td></td>
</tr>
<tr>
<td>Concomitant use of an antiplatelet agent or nonsteroidal anti-inflammatory drug</td>
<td></td>
</tr>
<tr>
<td>Alcohol or drug usage history (≥8 drinks/week)¶</td>
<td></td>
</tr>
</tbody>
</table>

**Additional items included in the periprocedural management algorithm**

- Prior bleed event within 3 months (including intracranial hemorrhagic)
- Quantitative or qualitative platelet abnormality
- INR above the therapeutic range at the time of the procedure (VKA)
- Bleed history from previous bridging
- Bleed history with similar procedure

*Each bullet is counted as 1 point. A HAS-BLED score ≥3 was shown to be highly predictive of bleeding events, with 1 point being given for the presence of each individual parameter (54). †Defined in HAS-BLED as systolic blood pressure >160 mm Hg. ‡Defined in HAS-BLED as presence of chronic dialysis, renal transplantation, or serum creatinine ≥200 micromol/L. §Defined in HAS-BLED as chronic hepatic disease (e.g., cirrhosis) or biochemical evidence of significant hepatic derangement (e.g., bilirubin >2x ULN, AST or ALT >3x ULN). ¶Defined in HAS-BLED as time in the therapeutic range <60%. ©Defined in HAS-BLED as >8 U/week.

ALT = alanine transaminase; AST = aspartate transaminase; HAS-BLED = Hypertension, Abnormal renal and liver function, Stroke, Bleeding, Labile INRs, Elderly, Drugs or alcohol; INR = international normalized ratio; ULN = upper limit of normal; and VKA = vitamin K antagonist.

### TABLE 2  Recommended Durations for Withholding DOACs Based on Procedural Bleed Risk and Estimated CrCl When There Are No Increased Patient Bleed Risk Factors

<table>
<thead>
<tr>
<th>CrCl, mL/min</th>
<th>Dalirestat</th>
<th>Apixaban, Edoxaban, or Rivaroxaban</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>50-79</td>
<td></td>
<td></td>
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<tr>
<td>30-49</td>
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<tr>
<td>15-29</td>
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<tr>
<td>&lt;15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥30</td>
<td></td>
<td>Apixaban: 17 Edoxaban: 17 Rivaroxaban: 13</td>
</tr>
<tr>
<td>15-29</td>
<td></td>
<td>Apixaban: 17 (off dialysis) Edoxaban: 10-17 (off dialysis) Rivaroxaban: 13 (off dialysis)</td>
</tr>
<tr>
<td>&lt;15</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Procedural bleed risk**

- Low: ≥34 h, ≥36 h, ≥48 h, ≥72 h
- No data. Consider measuring dTT and/or withholding ≥96 h.
- ≥24 h, ≥36 h, No data. Consider measuring agent-specific anti-Xa level and/or withholding ≥96 h.

**Uncertain, intermediate, or high**

- ≥48 h, ≥72 h, ≥96 h, ≥120 h
- No data. Consider measuring dTT.
- ≥48 h, No data. Consider measuring agent-specific anti-Xa level and/or withholding ≥72 h.

**Notes:** The duration for withholding is based on the estimated DOAC half-life withholding times of 2 to 3 half-lives for low procedural bleeding risk and 4 to 5 drug half-lives for uncertain, intermediate, or high procedural bleeding risk (46, 60, 67).

CrCl = creatinine clearance; DOAC = direct-acting oral anticoagulant; dTT = dilute thrombin time.
REFERENCES

• Up to date
• [http://www.onlinejacc.org/content/early/2017/01/05/j.jacc.2016.11.024/T2](http://www.onlinejacc.org/content/early/2017/01/05/j.jacc.2016.11.024/T2)
• Intermountain Health Care Clinical Care Models
Clinical Decision Making in Pain Management

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are:
- heroin
- lysergic acid diethylamide (LSD)
- marijuana (cannabis)
- 3,4-methylenedioxymethamphetamine (ecstasy)
- methaqualone, and peyote

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are:
- Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin),
- cocaine
- methamphetamine
- methadone
- hydromorphone (Dilaudid)
- meperidine (Demerol)
- oxycodone (OxyContin)
- fentanyl
- Dexedrine, Adderall, and Ritalin

Schedule III

Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV. Some examples of Schedule III drugs are:
- Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine),
- ketamine
- anabolic steroids
- testosterone

Schedule IV

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are:
- Xanax
- Soma
- Darvon
- Darvocet
- Valium
- Ativan
- Talwin
- Ambien
- Tramadol

Schedule V

Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are:
- cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC),
- Lomotil
- Motofen
- Lyrica
- Parepectolin
Licensing Requirements

Physicians and Physician assistants must complete 3 hours of drug diversion training every two years to maintain licensure. This can be done either online or in person.

Nurse practitioners must complete 3 hours of drug diversion training upon receiving their license, then one hour yearly thereafter. There are links to online and face to face courses on the WV board of nursing website.

Legal Issues

Any practitioner who fails to register with the WV Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database shall be subject to an administrative penalty of $1000 by the licensing board of his or her licensure. (per chapter 60A Article 9 of the WV controlled substances act)

A physician is not subject to disciplinary sanctions by a licensing board or criminal punishment by the state for prescribing, administering, or dispensing pain relieving controlled substances for the purpose of alleviating or controlling pain if: a. in the case of a dying patient experiencing pain, the physician practices in accordance with an accepted guideline and works to relieve the dying patient’s pain and promote the dignity and autonomy of the dying patient, or b. the case of a patient who is not dying and is experiencing pain, the physician works to relieve the pain within acceptable guidelines. (per WV management of pain act section 30 article 3A-2)

A provider can be disciplined if he/she a. fails to maintain complete, accurate, and current records documenting the physical exam and medical history of the patient and basis for clinical diagnosis and treatment plan; b. writes a fictitious or false prescription for a controlled substance; c. prescribes, administers, or dispenses a controlled substance in violation of the provisions of the federal Comprehensive Drug Abuse Prevention and Control act of 1970; d. diverts controlled substances prescribed for a patient to the physician’s own personal use. (per the WV management of pain act section 30 article 3A-3)
Chronic Pain

Definition:

Pain that typically lasts greater than three months or past the time of normal tissue healing.

Types of Pain:

Nociceptive: Caused by stimuli that threaten or provoke actual tissue damage

Primarily involves nonnarcotic and opioid analgesia. Tylenol is typically recommended as 1st line for OA and chronic low back pain. However, it is less effective than NSAIDS and has potential for hepatic toxicity at doses more than 3-4 g/day

Alternative 1st line is NSAIDS for mild-moderate chronic low back pain and OA

Opioids only considered for patients who have persistent pain despite conservative therapy with low addiction risk, no contraindications.

Neuropathic: Results from damage or pathology within the nervous system – can be central or peripheral

Establish a diagnosis whenever possible and treat the underlying problem

Initial treatment is antidepressants (tricyclic or dual reuptake SNRIs), gabapentin or Lyrica with adjunctive topical therapy for localized pain

Combination therapy is often required.

Caveats:

The guidelines herein are intended for patients over 18 with chronic pain outside of palliative, cancer, or end of life pain.

Use of opioid pain medication in pre high school graduates is highly discouraged as this is a/w a 33% increase in the risk of later opioid misuse.

Keep in mind that the CDC found that evidence on long-term opioid therapy for chronic pain outside of end-of-life care remains limited, with insufficient evidence to determine long-term benefits versus no opioid therapy though evidence suggests risk for serious harms that appears to be dose dependent.
Evidence suggested that long-term opioid therapy is a/w an increased risk for an opioid abuse or dependence diagnosis.

Factors a/w increased risk for misuse includes h/o substance abuse d/o, younger age, major depression, and use of psychotropic meds.

Recent opioid use was a/w an increased risk for any overdose events and serious overdose events versus nonuse.

Opioid therapy prescribed for acute pain is a/w greater likelihood of long term use.

Patients who received early opioids had an increased likelihood of receiving five or more opioid prescriptions 3—730 days following onset that increased with greater early exposure.

Effectiveness of Nonopioid therapies:

- CBT – small positive effects on disability and catastrophic thinking
- Exercise therapy is evidenced to help reduce pain and improve function in low back pain and OA of the knee and hip, and improve physical function, fibromyalgia symptoms, and well-being in fibromyalgia
- Multimodal therapies can help reduce pain more than singular therapies
- Analgesics, antidepressants, and anticonvulsants have also had evidence of benefit

Guidelines for use:

Initial evaluation

Nonpharmacological therapy and nonopioid therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacological therapy and nonopioid pharmacologic therapy as appropriate.

Nonopioid therapy consists of cognitive behavioral therapy, NSAIDS, PT, acetaminophen, exercise therapy, psychological therapy, arthrocentesis, injections, anticonvulsants, and antidepressants.

Before beginning opioids, clinicians should establish treatment goals including realistic goals for pain and function and should discuss how opioid therapy should be discontinued if benefits no longer outweigh the risks. Therapy should be continued only if there is clinically meaningful improvement in pain and function. Clinicians need to determine how effectiveness will be evaluated and should establish treatment goals with patients. These goals should involve both improvements in pain relief and in
physical, emotional, and social function. Depression scales and PEG scales should be done prior to and during treatment.

**During Therapy**

Before and during therapy, the PR actioner should explain the expected benefits, but that resolution of pain is unlikely; goal should be improved function despite ongoing pain; advise about serious adverse effects and side effects; discuss vehicle operation; discuss risk of respiratory depression and death at higher doses; review risk increases when taken with benzodiazepines; discuss risks to household members; discuss periodic reassessment; discuss and use the PMDP; address cognitive issues.

Methadone accounts for 1/3 of opioid related OD deaths despite representing <2% of opioid prescriptions in the US.

Concurrent use of narcotics and benzodiazepines put patients at greater risk for potentially fatal overdose. Concurrent use has been evidenced in 31-61% of fatal overdoses. This risk is greater for patients with sleep apnea or other causes of sleep disordered breathing, patients with renal or hepatic insufficiency, older adults, pregnant women, patients with depression or other mental health conditions, and patients with alcohol or other substance use disorders.

Patients who do not experience clinically meaningful pain relief early in treatment (within one month) are unlikely to experience pain relief with longer term use.

Initiation of opioids with an ER/LA versus immediate-release opioids for titrating patients was a/w a greater risk for nonfatal overdose with the risk being greater in the first two weeks after initiation of treatment.

No data exists for the rapidity of dose adjustment

Little consistency or reliability to the real world was found with risk assessment instruments.

The indication for switching to LA/ER opioids is for daily management of pain severe enough to require around-the-clock, long-term opioid treatment in patients for whom other treatment options are ineffective, not tolerated, or would otherwise inadequate to provide sufficient management of pain.

Time scheduled opioid use was a/w substantially higher average daily opioid dosage than as needed medications.

Clinicians should carefully assess any patient receiving >= 50 morphine mg equivalents (MME)/day and should avoid increasing dosage to >=90 MME/day. If increasing the dose above 50MME/day, clinicians should assess whether opioid treatment goals are being met. If rx is greater than 50MME, clinicians should implement additional
precautions including increased frequency of follow up and offering naloxone and overdose education to patients and their household members. If increasing >90MME/day, it is suggested that the clinician consult with a pain medicine specialist for guidance.

**Acute Pain**

When using opioids for acute pain, clinicians should use the lowest effective dose and prescribe for only 3-7 days.

Evaluate the benefits and harms with patients within 1-4 weeks of initiation and at least every 3 months thereafter.

**Tapering off of opioids**

Tapers reducing weekly dosage by 10-50% of the original dosing have been recommended as have rapid tapers over 2-3 weeks in the case of a severe adverse event such as an overdose.

The current recommendation is approximately 10% per week with the realization that this can take months.

Working together with mental health is suggested for psychosocial support for anxiety related to the taper.

**Special circumstances**

Over 65- monitor often

Patients with substance use disorder – use PMDP data and drug testing as well as the Drug Abuse Screening Test and the Alcohol use Disorders Test

Prior overdose – discontinue use if possible

**PMDP**

Use when starting opioid therapy and every three months thereafter

Should be reviewed for both prescribed medication as well as other medications, also use to determine the MME the patient is receiving.

Monitor for benzodiazepines – clinicians should avoid prescribing both whenever possible.
Discuss safety concerns with other physicians prescribing for the patient.

**Urine Drug Testing**

Upon start of medication and at least annually to assess for prescribed meds as well as other meds.

A positive opiates assay detects morphine which may denote morphine, codeine, or heroin, but does not detect synthetics such as fentanyl or methadone and may not detect semi synthetics such as oxycodone – the test needs to be specific.

**Abuse**

Clinicians should offer or arrange evidence based treatment for patients that become addicted. This can be done with buprenorphine, methadone, or naloxone combined with psychology intervention.

**Naloxone**

WV board of pharmacy has made pharmacists and interns capable of dispensing without a prescription. When dispensing, they are required to counsel to the proper administration of the medication, the importance of contacting EMS and the risk of failing to do so. They are also required to provide educational materials including the 1-844-HELP-4-WV line and a copy of the “I have narcan” trifold available at [www.wvoems.org](http://www.wvoems.org).
<table>
<thead>
<tr>
<th>CLINICAL RECOMMENDATION</th>
<th>EVIDENCE RATING</th>
<th>REFERENCES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consider buprenorphine formulations as an alternative to other opioids to treat chronic pain in patients at increased risk of opioid misuse, opioid use disorder, or overdose.</td>
<td>C</td>
<td>16</td>
</tr>
<tr>
<td>Pain that progresses despite chronic opioid therapy may represent opioid-induced hyperalgesia. Taper the opioid and wait until acute withdrawal resolves before reassessing pain. Inform the patient that opioid withdrawal is associated with physical pain, and does not necessarily represent progression of the underlying disease.</td>
<td>C</td>
<td>24–28</td>
</tr>
<tr>
<td>When opioid misuse is detected, do not terminate the patient from your practice or refuse to prescribe further opioid therapy. Instead, add opioid misuse to your problem list and intervene to change the patient's behavior. If aberrant behavior resolves, reward course correction. If aberrant behavior continues, consider the diagnosis of opioid use disorder and treat (or refer) accordingly.</td>
<td>C</td>
<td>29–34</td>
</tr>
<tr>
<td>Offer naloxone to patients at risk of opioid overdose.</td>
<td>C</td>
<td>35–37</td>
</tr>
<tr>
<td>To mitigate the risk of overdose, do not prescribe benzodiazepines concurrently with chronic opioid therapy. Also, avoid benzodiazepine coprescribing as treatment for opioid withdrawal, especially in patients with opioid misuse or opioid use disorder.</td>
<td>C</td>
<td>10, 15, 35, 36, 38–41</td>
</tr>
<tr>
<td>When discontinuing opioids, decrease the dosage slowly, especially in patients who experience intolerable withdrawal. Standard recommendations to decrease the dosage by 5% to 10% of the starting dosage every one to four weeks may still be too fast for some patients, especially those on long-term high dosages. Some patients may need to decrease by as little as 5% or less every two to three months, with even smaller decrements toward the end of the taper. It is not unreasonable to take many months to wean some patients off chronic opioid therapy.</td>
<td>C</td>
<td>60</td>
</tr>
</tbody>
</table>
# BEST PRACTICES IN PAIN MANAGEMENT: RECOMMENDATIONS FROM THE CHOOSING WISELY CAMPAIGN

<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
<th>SPONSORING ORGANIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not prescribe opioid analgesics as first-line therapy to treat chronic noncancer pain.</td>
<td>American Society of Anesthesiologists</td>
</tr>
<tr>
<td>Do not prescribe opioid analgesics as long-term therapy to treat chronic noncancer pain until the risks are considered and discussed with the patient.</td>
<td>American Society of Anesthesiologists</td>
</tr>
<tr>
<td>Do not prescribe opioids for treatment of chronic or acute pain for workers who perform safety-sensitive jobs, such as operating motor vehicles, forklifts, cranes, or other heavy equipment.</td>
<td>American College of Occupational and Environmental Medicine</td>
</tr>
</tbody>
</table>

*Source: For more information on the Choosing Wisely Campaign, see [http://www.choosingwisely.org.](http://www.choosingwisely.org) For supporting citations and to search Choosing Wisely recommendations relevant to primary care, see [http://www.aafp.org/afp/recommendations/search.htm.](http://www.aafp.org/afp/recommendations/search.htm)*
Information on Non-Narcotic Analgesia

Tylenol:

MOA is uncertain
Liver toxicity can occur even at therapeutic levels
Recommending 3-3.25mg/day max and avoid in heavy drinkers

NSAIDS

Exert synergy when paired with opioids
AGS recommends against use when possible despite this being recommended by several other societies as a first line treatment
Cox-2 has fewer GI side effects than NSAIDS, but doses above 200mg/day are a/w increased cardiac risk
Nephrotoxicity, edema, ATN, interfere with cardio protective effects of ASA, CHF exacerbations, HTN, prothrombotic, hepatic toxicity, inability to concentrate are all potential side effects.

Anticonvulsants

Gabapentin, pregabalin, carbamazepine are only ones approved that have good studies for pain
Gabapentin (up to 3600mg/day div tid) and pregabalin (up to 600mg/day div tid) have proven efficacy for neuropathic pain
Pregabalin also approved and studied in central neuropathic pain and fibromyalgia
Carbamazepine is treatment of choice for trigeminal neuralgia, though not effective for other pain.
Antidepressants – TCAs

Have independent analgesic effects as well as ability to relieve depressive symptoms associated with pain

Potentiate the endogenous opioid system

Can take 6-8 weeks at the highest dose tolerated to see effect, though onset of analgesia can be seen in one week

Amitriptyline has most anticholinergic effect and desipramine has the least. Nortriptyline is also low

Sleep induction occurs 1-3 hours after ingestion

If patient gets a “hangover”, take earlier in the evening

Educate on anticholinergic side effects

Relatively contraindicated in patients with severe cardiac disease – particularly conduction issues – obtain a pre treatment EKG

Desipramine and nortriptyline can be used safely in older patients, but starting dose should be reduced by ½.

Antidepressants SSRI/SNRI

Duloxetine and venlafaxine have been studied in peripheral neuropathy and milnacipran has been studied in fibromyalgia

Venlafaxine is for peripheral neuropathy

Duloxetine is for peripheral neuropathy, fibromyalgia, chronic low back pain, and OA – up to a 30% reduction in pain.

SSRIS only pain relief studies may be related to helping with the depression a/w pain.

Topicals

Lidocaine – topical patch shows efficacy and tolerability in patients with postherpetic pain and allodynia

Capsaicin – 0.025 and 0.075 percent cream. Used in post herpetic neuralgia, HIV, neuropathy, and diabetic neuropathy. Must be applied 3-4 times a day for 6-8 weeks for optimal pain relief. Also comes as a patch, but must be applied under clinical supervision

NSAIDS – weak studies for anything but acute pain.

Botox used in severe post herpetic neuralgia
Benzodiazepines/Cannabis

Use of benzodiazepines was associated with greater pain severity, prescription of higher doses of opioids, substance use, and greater mental health comorbidities.

Several cannabis trials had positive results for chronic pain, but the long term effects are not known and it is not currently legal in this state.

Non pharmacologic therapies

Behavioral medicine – CBT, biofeedback, relaxation, psychotherapy

Aerobic exercise

Acupuncture

PT/OT

Chiropractic/OMT

Ultrasound

Electric neuromodulation – TENS, spinal cord stim

Thermal applications

Interventional – ablative, botox, nerve blocks, trigger points, epidural steroids

Surgical

Summary

In our current environment, we are now pain specialists. Narcotics are not a ‘never’ proposition, and are certainly the only option for some patients, but our prescribing practices must be evidence based. The federal and state boards have established guidelines and it is the goal of our population health team to make sure we are all apprised of these changes as they occur.

References

- Us Department of Health and Human Services/centres for Disease Control and Prevention: MMWR; March 15, 2016, Volume 65.
- West Virginia Board of Pharmacy website
- WV Board of medicine website
- WV Board of Nursing website
- WV Board of Medicine website
ASCVD
RISK
REDUCTION
A CLINICAL APPROACH
Table 1

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Major Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults aged ≥21 years with clinical ASCVD (including history of or current acute coronary syndrome, myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin)</td>
<td>1. For patients age ≥57 years, high-intensity statin (or moderate-intensity statin if not a candidate for high-intensity statin due to safety concerns) 2. For patients age &gt;75 years, moderate-intensity statin</td>
</tr>
<tr>
<td>Adults aged ≥21 years with LDL-C ≥190 mg/dL (not due to modifiable secondary causes)</td>
<td>1. High-intensity statin therapy to achieve ≥50% reduction in LDL-C statin (or moderate-intensity statin if not a candidate for high-intensity statin due to safety concerns) 2. May consider combining statin and non-statin therapy to further reduce LDL-C 3. Gastroscopic screening of close biologic relatives should be performed to identify others with the disease who would benefit from treatment</td>
</tr>
<tr>
<td>Adults aged 40–75 years without ASCVD but with diabetes and with LDL-C ≥70–169 mg/dL</td>
<td>1. Moderate-intensity statin 2. If 10-year ASCVD risk ≥7.5%, consider high-intensity statin</td>
</tr>
<tr>
<td>Adults aged 40–75 years without ASCVD or diabetes, and with LDL-C ≥100–129 mg/dL and an estimated 10-year risk for ASCVD of ≥2.5%</td>
<td>1. Estimate 10-year ASCVD risk using Pooled Cohort Equations (2) 2. In selected individuals with 10-year ASCVD risk ≥5%, or age ≤50 or ≥75 years, individualize decisions based on presence of other high-risk features.</td>
</tr>
</tbody>
</table>
FIGURE 1 Patient Populations Addressed and Factors and Interventions to Consider

PATIENT POPULATIONS ADDRESSED: 4 STATIN BENEFIT GROUPS

- Adults ≥21 years of age with clinical ASCVD, on statin for secondary prevention
- Adults ≥21 years of age with baseline LDL-C ≥190 mg/dL (not due to secondary modifiable causes), on statin for primary prevention
- Adults aged 40-75 years without clinical ASCVD but with diabetes and baseline LDL-C 70-189 mg/dL, on statin for primary prevention
- Adults aged 40-75 years without clinical ASCVD or diabetes, with baseline LDL-C 70-189 mg/dL and an estimated 10-year risk for ASCVD of ≥7.5%, on statin for primary prevention

FACTORs TO CONSIDER
- Adherence and lifestyle
- Statin intolerance
- Control of other risk factors
- Clinician-patient discussion regarding potential benefits, potential harms, and patient preferences regarding addition of non-statin medications
- Percentage LDL-C reduction (may consider absolute LDL-C level achieved)
- Monitoring of response to therapy, adherence, and lifestyle

OPTIONAL INTERVENTIONS TO CONSIDER
- Referral to lipid specialist and registered dietitian nutritionist
- Ezetimibe
- Bile acid sequestrants
- PCSK9 inhibitors
- Mipomersen, lomitapide, LDL apheresis may be considered by lipid specialist for patients with familial hypercholesterolemia

Abbreviations: ASCVD = atherosclerotic cardiovascular disease, LDL = low-density lipoprotein, LDL-C = low-density lipoprotein cholesterol, PCSK9 = proprotein convertase subtilisin/kexin 9.
Patients ≥21 Years of Age with Stable Clinical ASCVD without Comorbidities, on Statin for Secondary Prevention

- Patients with stable clinical ASCVD without comorbidities,* on statin for secondary prevention
  - Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL) on maximally tolerated statin†
    - Yes
    - 1. Address statin adherence.
    - 2. Intensify lifestyle (may consider phytosterols).
    - 3. Increase to high-intensity statin if not already taking.
    - 4. Evaluate for statin intolerance if unable to tolerate moderate-intensity statin.‡ Consider referral to lipid specialist if statin intolerant.
    - 5. Control other risk factors.
    - Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL) on maximally tolerated statin†
      - Yes
        - CLINICIAN-PATIENT DISCUSSION FACTORS TO CONSIDER
          1. Potential for additional ASCVD risk reduction from addition of non-statin therapy to lower LDL-C (see Table 4)
          2. Potential for adverse events or drug-drug interactions from addition of non-statin therapy (see Table 3)
          3. Patient preferences (see Table 4)
      - NO
      - Optional non-statin medications to consider
        - Consider ezetimibe first.§
      - Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL) on maximally tolerated statin/other medications†
        - Yes
          - Continue to monitor adherence to medications and lifestyle, and LDL-C response to therapy.
        - NO
          - Consider adding or replacing with PCSK9 inhibitor second.‖
          - Decision for no additional medication
          - Continue to monitor adherence to medications and lifestyle, and LDL-C response to therapy.

---

*Comorbidities are defined as diabetes, recent (<3 months) acute ASCVD event, ASCVD event while already taking a statin, baseline LDL-C ≥190 mg/dL not due to secondary causes, poorly controlled major ASCVD risk factors, elevated lipoprotein(a), and chronic kidney disease. Patients with ASCVD and baseline LDL-C ≥190 mg/dL are addressed in a separate algorithm. Patients with symptomatic heart failure, those on maintenance hemodialysis, and those with planned or current pregnancy require individualized care.

†The Expert Panel emphasizes that these are not firm triggers for adding medication, but they are factors that may be considered within the broader context of an individual patient’s clinical situation.

‡See section on strategy for assessment and management of statin intolerance.

§May consider BAS if ezetimibe intolerant and triglycerides <300 mg/dL.

‖Consider only if on maximally tolerated statin and either ezetimibe or BAS, with persistent <50% LDL-C reduction or LDL-C ≥100 mg/dL. Strongly consider if fully statin intolerant and attempts to lower LDL-C with ezetimibe and/or BAS result in persistent <50% LDL-C reduction or LDL-C ≥100 mg/dL.
**FIGURE 3** Patients ≥21 Years of Age without Clinical ASCVD and with Baseline LDL-C ≥190 mg/dL Not Due to Secondary Causes, on Statin for Primary Prevention

- Patients without clinical ASCVD and with baseline LDL-C ≥190 mg/dL not due to secondary causes,* on statin for primary prevention

  - Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL) on maximally tolerated statin†
    - YES
      - Address statin adherence.
      - Intensify lifestyle (may consider phytosterols).
      - Increase to high-intensity statin if not already taking.
      - Evaluate for statin intolerance if unable to tolerate moderate-intensity statin; t
        - Referral to lipid specialist recommended if statin intolerant.
      - Control other risk factors.
      - Consider referral to lipid specialist and RDN for all patients, especially if LDL-C ≥250 mg/dL or homozygous FH; §
        - YES
          - Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL) on maximally tolerated statin†
            - NO
              - CLINICIAN-PATIENT DISCUSSION FACTORS TO CONSIDER
                1. Potential for additional ASCVD risk reduction from addition of non-statin therapy to lower LDL-C (see Table 4)
                2. Potential for adverse events or drug-drug interactions from addition of non-statin therapy (see Table 3)
                3. Patient preferences (see Table 4)

                Optional non-statin medications to consider:

                  Consider ezetimibe (or BAS second line).] Consider PCSK9 inhibitor.

                  Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL) on maximally tolerated statin/other medications†
                    - YES
                      - 1. Repeat clinician-patient discussion.
                      - 2. Add other non-statin medication(s) above.
                      - 3. Consider referral to lipid specialist and RDN.
                      - Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL) on maximally tolerated statin/other medications†
                        - YES
                          - Continue to monitor adherence to medications and lifestyle, and LDL-C response to therapy.
                        - NO
                          - Referral to lipid specialist recommended
                            - YES
                              - Decision for no additional medication
                            - NO
                              - Continue to monitor adherence to medications and lifestyle, and LDL-C response to therapy.

Abbreviations: ASCVD = atherosclerotic cardiovascular disease, BAS = bile acid sequestrant, FH = familial hypercholesterolemia, LDL-C = low-density lipoprotein cholesterol, PCSK9 = proprotein convertase subtilisin/kexin 9, RDN = registered dietitian-nutritionist.

*e.g., hyperthyroidism, nephrotic, extreme dietary patterns
†The Expert Panel emphasizes that these are not firm triggers for adding medication, but they are factors that may be considered within the broader context of an individual patient's clinical situation.
‡See section on strategy for assessment and management of statin intolerance.
§May consider mipomersen, lomitapide, or LDL apheresis for appropriate patients.
] Consider BAS if ezetimibe is intolerable and triglycerides <500 mg/dL.
Patients aged 40–75 years without clinical ASCVD and with diabetes and baseline LDL-C 70–189 mg/dL, on statin for primary prevention

Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL or may consider non-HDL-C <130 mg/dL in patients with diabetes) on maximally tolerated statin*  

YES

NO

1. Address statin adherence.
2. Intensify lifestyle (may consider phytosterols).
3. Evaluate for statin intolerance if unable to tolerate moderate-intensity statin.† Consider referral to lipid specialist if statin intolerant.
4. Control other risk factors.

Patient has ≥50% LDL-C reduction (may consider LDL-C <100 mg/dL or may consider non-HDL-C <130 mg/dL in patients with diabetes) on maximally tolerated statin*

YES

NO

CLINICIAN-PATIENT DISCUSSION FACTORS TO CONSIDER
1. Potential for additional ASCVD risk reduction from addition of non-statin therapy to lower LDL-C (see Table 4)
2. Potential for adverse events or drug-drug interactions from addition of non-statin therapy (see Table 3)
3. Patient preferences (see Table 4)

Optional non-statin medications to consider

Consider ezetimibe first; BAS second-line.§

For the small proportion of patients in this group with 10-year ASCVD risk <7.5% and no other high-risk features, starting with moderate-intensity statin to achieve 30–49% LDL-C reduction (may consider LDL-C <100 mg/dL or non-HDL-C <130 mg/dL) is acceptable. If this level of LDL-C reduction is not achieved, consider increasing to high-intensity statin

Continue to monitor adherence to medications and lifestyle, and LDL-C response to therapy.

Abbreviations: ASCVD = atherosclerotic cardiovascular disease, BAS = bile acid sequestrant, HDL-C = high-density lipoprotein cholesterol, LDL-C = low-density lipoprotein cholesterol, RDN = registered dietitian nutritionist.

*The Expert Panel emphasizes that these are not firm triggers for adding medication, but they are factors that may be considered within the broader context of an individual patient’s clinical situation. Due to increase in triglycerides often present in diabetes, may also consider combination therapy if non-HDL-C ≥ 130 mg/dL.

†See section on strategy for assessment and management of statin intolerance.

§Consider BAS if ezetimibe intolerant and triglycerides <300 mg/dL. Colesevelam may have modest salutary effects on HbA1c and may worsen hypertriglyceridemia.
### TABLE 1
**Four Statin Benefit Groups and Major Recommendations From the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults (1)**

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Major Recommendations</th>
</tr>
</thead>
</table>
| 1. Adults aged ≥21 years with clinical ASCVD (including history of or current acute coronary syndrome, myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or peripheral arterial disease presumed to be of atherosclerotic origin) | 1. For patients age ≤75 years, high-intensity statin (or moderate-intensity statin if not a candidate for high-intensity statin due to safety concerns)
2. For patients age >75 years, moderate-intensity statin |
| 2. Adults aged ≥21 years with LDL-C ≥190 mg/dL (not due to modifiable secondary causes) | 1. High-intensity statin therapy to achieve ≥50% reduction in LDL-C (or moderate-intensity statin if not a candidate for high-intensity statin due to safety concerns)
2. May consider combining statin and non-statin therapy to further reduce LDL-C
3. Cascade screening of dose biologic relatives should be performed to identify others with the disease who would benefit from treatment. |
| 3. Adults aged 40-75 years without ASCVD but with diabetes and with LDL-C 70-189 mg/dL. | 1. Moderate-intensity statin
2. If 10-year ASCVD risk ≥7.5%, consider high-intensity statin. |
| 4. Adults aged 40-75 years without ASCVD or diabetes, and with LDL-C 70-189 mg/dL and an estimated 10-year risk for ASCVD of ≥7.5% | 1. Estimate 10-year ASCVD risk using Pooled Cohort Equations (2).
   a. If ≥7.5%, moderate- or high-intensity statin;
   b. If ≥5 to <7.5%, consider moderate-intensity statin.
   c. In selected individuals with 10-year ASCVD risk <5%, or age <40 or >75 years, individualized decisions based on presence of other high-risk features. 
3. Before initiation of statin therapy for primary prevention, it is reasonable for clinicians and patients to engage in a discussion that considers the potential for ASCVD risk-reduction benefits and for adverse effects and drug-drug interactions, as well as patient preferences for treatment. |

*The 2013 ACC/AHA guideline recommends consideration of other ASCVD risk factors (LDL-C ≥160 mg/dL, family history of premature ASCVD, hs-CRP ≥2.0 mg/L, CAC score ≥100 Agatston units, ABI <0.9, and high lifetime ASCVD risk).

ABI indicates ankle-brachial index; ACC, American College of Cardiology; AHA, American Heart Association; ASCVD, atherosclerotic cardiovascular disease; CAC, coronary artery calcification; hs-CRP, high-sensitivity C-reactive protein; and LDL-C, low-density lipoprotein cholesterol.

### TABLE 2
**Examples of High-, Moderate-, and Low-Intensity Statin Therapy (Adapted From 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults)**

<table>
<thead>
<tr>
<th>High-Intensity Statin Therapy</th>
<th>Moderate-Intensity Statin Therapy</th>
<th>Low-Intensity Statin Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily dose lowers LDL-C, on average, by approximately ≥50%.</td>
<td>Daily dose lowers LDL-C, on average, by approximately 30% to &lt;50%.</td>
<td>Daily dose lowers LDL-C, on average, by &lt;30%.</td>
</tr>
<tr>
<td>Atorvastatin 40-80 mg</td>
<td>Atorvastatin 10-20 mg</td>
<td>Fluvastatin 20-40 mg</td>
</tr>
<tr>
<td>Rosuvastatin 20-40 mg</td>
<td>Fluvastatin 40 mg twice daily</td>
<td>Lovastatin 20 mg</td>
</tr>
<tr>
<td></td>
<td>Fluvastatin XL 80 mg</td>
<td>Pravastatin 10-20 mg</td>
</tr>
<tr>
<td></td>
<td>Lovastatin 40 mg</td>
<td>Simvastatin 10 mg</td>
</tr>
<tr>
<td></td>
<td>Pitavastatin 2-4 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pravastatin 40-80 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rosuvastatin 5-10 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Simvastatin 20-40 mg</td>
<td></td>
</tr>
</tbody>
</table>

Bold face type indicates statins and doses that were evaluated in RCTs included in the 2013 ACC/AHA guideline.

ACC indicates American College of Cardiology; AHA, American Heart Association; LDL-C, low-density lipoprotein cholesterol; and RCT, randomized controlled trial.
## SORT: KEY RECOMMENDATIONS FOR PRACTICE

<table>
<thead>
<tr>
<th>Clinical recommendation</th>
<th>Evidence rating</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>All women 65 years and older should be screened for osteoporosis with dual energy x-ray absorptionmetry of the hip and lumbar spine.</td>
<td>B</td>
<td>5</td>
</tr>
<tr>
<td>Women younger than 65 years should be screened for osteoporosis if the estimated 10-year fracture risk equals or exceeds that of a 65-year-old white woman with no risk factors.</td>
<td>B</td>
<td>1, 5</td>
</tr>
<tr>
<td>The U.S. Preventive Services Task Force concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis in men.</td>
<td>C</td>
<td>5</td>
</tr>
<tr>
<td>A fall risk assessment should be performed and a multicomponent exercise program and smoking cessation should be recommended to decrease fracture risk in individuals 65 years and older with osteoporosis or a history of vertebral fracture.</td>
<td>C</td>
<td>17, 20, 22</td>
</tr>
<tr>
<td>Bisphosphonates should be used as first-line pharmacologic treatment for osteoporosis.</td>
<td>A</td>
<td>16, 26</td>
</tr>
<tr>
<td>In patients who cannot tolerate or whose symptoms do not improve with bisphosphonate therapy, teriparatide (Forteo) and denosumab (Prolia) are effective alternative medications to prevent osteoporotic fractures.</td>
<td>A</td>
<td>16, 26, 44</td>
</tr>
</tbody>
</table>

*A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to http://www.aafp.org/afpsort.*
<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Sponsoring organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do not use dual energy x-ray absorptiometry (DEXA) to screen for osteoporosis in women younger than 65 years or in men younger than 70 years with no risk factors.*</td>
<td>American Academy of Family Physicians</td>
</tr>
<tr>
<td>Do not routinely repeat dual energy x-ray absorptiometry (DEXA) scans more often than once every two years.</td>
<td>American College of Rheumatology</td>
</tr>
</tbody>
</table>

*Risk factors include, but are not limited to, fractures after 50 years of age, prolonged exposure to corticosteroids, diet deficient in calcium or vitamin D, cigarette smoking, alcoholism, and thin/small build.

Source: For more information on the Choosing Wisely Campaign, see http://www.choosingwisely.org. For supporting citations and to search Choosing Wisely recommendations relevant to primary care, see http://www.aafp.org/afp/recommendations/search.htm.
RISK FACTORS:

Lifestyle

- Alcohol (≥ 3 drinks/day)
- Aluminum (eg antacids)
- Excess vitamin A
- Frequent falls
- High caffeine intake
- High salt intake
- Immobilization (eg bedrest) or inadequate physical activity
- Low BMI
- Low calcium intake
- Tobacco use (active OR passive)
- Vitamin D insufficiency

Genetic Factors

- Cystic Fibrosis
- Ehlers-Danlos syndrome
- Gaucher disease
- Glycogen storage disease
- Hemochromatosis
- Homocysteinuria
- Hypophosphatasia
- Idiopathic hypercalciuria
- Marfan syndrome
- Menkes disease
- Osteogenesis Imperfecta
- Parental h/o hip fracture
- Porphyria
- Riley-Day Syndrome

Medical/Endocrine Issues

- Hypogonadal state
- Androgen insensitivity
- Anorexia nervosa and bulimia
- Athletic amenorrhea
- Hyperprolactinemia
- Panhypopituitarism
- Premature ovarian failure
- Turner and Kleinfelter syndrome
Medical/ Endocrine Issues (continued)

Adrenal insufficiency
Cushing syndrome
Diabetes Mellitus
Hyperparathyroidism
Thyrotoxicosis

GI
Celiac disease
Gastric bypass
Inflammatory bowel disease
Malabsorption
Pancreatic disease
Previous GI surgery
Primary biliary cirrhosis

Hematologic
Hemophilia
Leukemia and lymphoma
Multiple myeloma
Sickle cell disease
Systemic mastocytosis
Thalassemia

Rheumatic/autoimmune
Ankylosing spondylitis
RA
SLE

Miscellaneous
Alcoholism
Amyloidosis
Chronic metabolic acidosis
CHF
Depression
Emphysema
ESRD
Epilepsy
Idiopathic scoliosis
MS
Muscular Dystrophy
Parenteral nutrition
Post transplant bone disease
Prior fracture as an adult
Sarcoidosis
**Medications**

- Anticoagulants
- Anticonvulsants
- Aromatase inhibitors
- Barbiturates
- Chemotherapeutic agents
- Cyclosporine A
- Depo medroxyprogesterone
- Glucocorticoids (>\= 5mg/day of prednisone or equivalent for >3 mos)
- Gonadotropin releasing hormone agonists
- Lithium
- Oral hypoglycemic
- PPIs
- Tacrolimus
- SSRIs

No guidelines have been issued regarding screening intervals or cessation of screening. The USPTF suggests a minimum of 2 years between screenings to reliably measure BMD change because of limitations in test precision.
<table>
<thead>
<tr>
<th>Agent</th>
<th>Benefit</th>
<th>Adverse effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisphosphonate1, 46, 64, 71</td>
<td>Decreases vertebral fracture (45%–70%)</td>
<td>Gastrointestinal tract (nausea, vomiting, abdominal pain, dyspepsia, esophagitis, reflux)</td>
</tr>
<tr>
<td></td>
<td>Decreases spine and hip fracture 50% over 3 years (alendronate)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decreases nonvertebral fracture 36% over 3 years (risedronate)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decreases nonvertebral fracture 25% over 3 years (zoledronic acid)</td>
<td></td>
</tr>
<tr>
<td>Selective estrogen-receptor modulators (raloxifene, tamoxifen)1, 40</td>
<td>Increases BMD, decreases bone turnover, decreases vertebral and nonvertebral fracture (30%–50%)</td>
<td>Increases risk of VTE (deep vein thrombosis, pulmonary embolism, cardiovascular accident), vasomotor symptoms, urogenital symptoms</td>
</tr>
<tr>
<td>Hormone therapy2, 27, 40, 48</td>
<td>No hip fracture prevention</td>
<td>Increases risk of CV events (raloxifene)</td>
</tr>
<tr>
<td></td>
<td>Decreases BMD loss</td>
<td>Increases risk of VTE</td>
</tr>
<tr>
<td></td>
<td>Decreases hip, vertebral, and nonvertebral fracture (23%–60%)</td>
<td>Increases risk of CV disease in older postmenopausal women (probably &gt;10 years after menopause)</td>
</tr>
<tr>
<td>Parathyroid hormone2, 27</td>
<td>Decreases vertebral fracture (65%–69%)</td>
<td>Injection site reactions</td>
</tr>
<tr>
<td></td>
<td>Decreases nonvertebral fracture (35%–40%)</td>
<td>Nausea, dizziness</td>
</tr>
<tr>
<td></td>
<td>No hip fracture prevention</td>
<td>Leg cramps</td>
</tr>
<tr>
<td>Calcitonin2, 49</td>
<td>Stabilizes BMD loss</td>
<td>Rhinitis, epistaxis (intranasally administered)</td>
</tr>
<tr>
<td></td>
<td>Increases BMD (modest) in cervical spine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decreases vertebral fracture (20 IU/day, intranasal)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Decreases fracture-associated pain</td>
<td></td>
</tr>
<tr>
<td>Denosumab50</td>
<td>Reduces risk of vertebral and nonvertebral fractures and risk of hip fracture</td>
<td>Gastrointestinal tract symptoms (diarrhea, nausea, vomiting), dermatitis, rash, arthralgia, limb and back pain, peripheral edema, nasopharyngitis, headache, hypocalcemia, hypercholesterolemia</td>
</tr>
</tbody>
</table>

*Percentages denote relative risk.

1 First-line therapy.

2 Alendronate, risedronate, and zoledronic acid are FDA approved for prevention and treatment of postmenopausal osteoporosis.

4 Alendronate and risedronate are FDA approved for male osteoporosis and glucocorticoid-related osteoporosis.

5 Overall mild but is the reason for discontinuation of therapy for 11%–25% of patients.

6 FDA approved for postmenopausal osteoporosis, men at high fracture risk, men and women at risk due to glucocorticoids.

7 No advantage to higher or lower doses.

CV, cardiovascular; FDA, Food and Drug Administration; VTE, venous thromboembolism.
WHEN TO TREAT OSTEOPOROSIS

- The National Osteoporosis Foundation recommends that postmenopausal women and men 50 years and older should be considered for treatment if they have a hip or vertebral fracture including fragility fracture, a T-score more negative than −2.5 at the femoral neck or spine (with secondary causes excluded), or osteopenia and a FRAX 10-year risk score of at least 3% for hip fracture or at least 20% for major osteoporotic fracture. A fragility fracture is one occurring in the absence of trauma or with minimal trauma such as a fall from a standing height or less.

- An additional, less common adverse effect of bisphosphonates is osteonecrosis of the jaw. It has been seen in cancer patients receiving intravenous bisphosphonates, but a causal relationship has not been established.

- A recent FDA panel voted against continued use of calcitonin for treatment of osteoporosis, citing a possible link to increased cancer risk and a lack of evidence of benefit. The cancer link was not clear but was believed to be plausible after considering the available evidence.

- The decision about whether to stop therapy with bisphosphonate after a finite period of time is subject to debate. Further analysis of the FLEX data revealed that women with a femoral neck BMD T score of −2.5 or below at the 5-year mark had a higher risk of subsequent fractures after discontinuation, so some centers have adopted strategies where bisphosphonate treatment is discontinued, only in patients where t-score is > −2.5.

- Although multiple case series demonstrate a possible association between atypical fractures and bisphosphonate therapy, results have conflicted among several population-based studies. Cumulatively, the current body of evidence is thought to support this association. Although more research is needed to understand causality, the evidence supporting the use of bisphosphonates to reduce overall fracture risk greatly outweighs the risk of an atypical fracture.
WHEN TO TREAT OSTEOPENIA

- Most guidelines for osteopenic patients therefore primarily emphasize lifestyle changes like smoking cessation, nutritional improvements, calcium and vitamin D supplementation, exercise regimens etc. as primary interventions. However, as seen from the NORA data, a significant number of high-risk osteopenic patients will still need pharmacologic intervention in order to reduce their fracture risk significantly.

- Most guidelines for treatment consider the presence of a low energy fracture in an osteopenic patient a clear indication for specific osteoporosis therapy.

- In order to better delineate individuals at high risk of osteoporotic fracture the WHO developed the Fracture Risk Assessment (FRAX) tool (www.shef.ac.uk/FRAX). It is an internet based clinical tool for calculation of fracture risk in the individual patient based on assessment of significant risk factors for osteoporotic fracture. The FRAX algorithm is based on large-scale prospective population-based studies.

- https://www.sheffield.ac.uk/FRAX/

- Generally FRAX based ten year risks of 20% or higher for all osteoporotic fractures and 3% or higher for hip fracture are considered reasonable intervention thresholds.